

**Reduction of perineal trauma and improved perineal comfort
during and after childbirth: the Perineal Warm Pack Trial**

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**A thesis submitted in accordance with the requirements for admission to
the Degree Doctor of Philosophy**

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Certificate of Authorship/Originality

I certify that the work in this thesis has not previously been submitted for a degree, nor has it been submitted as part of the requirements for a degree, except as fully acknowledged within the text.

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“Don’t wait for the light to appear at the end of the tunnel—stride down there and light the
bloody thing yourself”
(Sara Henderson, 1993)

Dedicated to my partner Malcolm, my rock, and our four beautiful children: Lydia, Luke,
Ethan and Bronte – all of whom were born during the writing of this thesis. It is these
beautiful little souls who have taught me the most important lessons in life:
Live today; love today and laugh today.

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Publications and conference presentations from this research

A number of publications and conference presentations have arisen from this work or have been associated with this work. I have been the first or second author on these papers.

Peer-reviewed publications

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Homer, C., & Dahlen, H. (2007). Obstetric-induced incontinence: A black hole of preventable morbidity? *The Australian and New Zealand Journal of Obstetrics and Gynaecology*, 47, 86–90. (Appendix 2.)

Non-refereed journals

Dahlen, H. (2005). Perfecting the perineum. *Australian Parents*, June/July, 30–32.

Dahlen, H. (2001). A midwife's guide to perineal care and repair: Part Two. *Midwifery Matters*, December.

Dahlen, H. (2001). A midwife's guide to perineal care and repair: Part One. *Midwifery Matters*, September.

Conference presentations

Dahlen, H. G. (2007, July). *Perineal Warm Packs: 'Old Wives' Tales' or evidence-based practice?* Working with risk in midwifery practice. Conference, Sydney, NSW, Australia, (invited speaker).

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Dahlen, H. G. (2005, July). *The Perineal Warm Pack Trial*. Paper (published in proceedings) presented at the 27th Congress of the International Confederation of Midwives, Brisbane, Queensland, Australia.

Dahlen, H. G. (2002, April) (presented by C. Adams and J. Matthews). *Giving third degrees the third degree*. Paper (published in proceedings) presented at the 26th Congress of the International Confederation of Midwives, Vienna, Austria.

Dahlen, H. G. (2001, September). *Giving third degrees the third degree*. Paper (published in proceedings) presented at the Australian College of Midwives Inc. 12th Biennial National Conference, Brisbane, Queensland, Australia

Abbreviations and glossary

Abbreviations

RPA	Royal Prince Alfred Hospital
KGV	King George V Hospital
TCH	The Canterbury Hospital
CALD	Culturally and Linguistically Diverse
NICU	Neonatal Intensive Care Unit
NHMRC	National Health and Medical Research Centre
NSW	New South Wales is the state in Australia in which this study took place

Glossary

Antenatal period	Period of time before birth occurs (the pregnancy)
Antenatal card	A pregnancy record card given to every pregnant woman that she carries with her at all times. Health workers document care given, pathology and ultrasound reports on the card as well as in the antenatal record kept by the hospital.
Area Health Service	A unit of health system administration in NSW. There are eight Area Health Services in NSW and they are each accountable to the NSW Health Department for the management of public hospitals and community health services in the areas.
Asian	China, Vietnam, Hong Kong, Indonesia,

	Japan, Laos, Cambodia, Taiwan, North Korea, South Korea, Thailand, Philippines, Burma and Malaysia.
Birth weight	The first weight of the newborn, obtained as soon as possible after birth.
Elective caesarean	A caesarean section performed before the onset of labour.
Emergency caesarean	A caesarean section performed after the onset of labour.
Epidural anaesthesia	Injection of an anaesthetic agent outside the dura matter, which covers the spinal canal, causing loss of sensation to the lower part of the body.
Episiotomy	A surgical incision of the perineum and vagina to enlarge the vulval orifice.
Ethnic Obstetric Liaison Officers	Usually midwives employed from designated ethnic and cultural backgrounds to provide care, education and support for women from the same background.
Forceps delivery	A hard metal instrument used to grasp the baby's head and deliver the baby vaginally.
Gestation age	The duration of pregnancy in completed weeks from the first day of the last normal menstrual period.

Level Six Maternity Service	In NSW each maternity service has a designated Level (1–6). This thesis included Level Four and Six services. A Level Six maternity service provides a range of services from low risk to the most complex cases. They have 24-hour onsite access to specialist obstetricians and anaesthetists.
Level Four Maternity Service	Level Four maternity service cares for women and babies of low to moderate risk, transferring to a Level Six maternity service all women in preterm labour with pregnancies less than 33 weeks gestation or with complex health problems such as heart disease. They have a 24-hour onsite obstetric registrar and anaesthetic registrar.
Level Three Neonatal Intensive Care	In NSW Levels (1–3) are given to neonatal intensive care units. A Level Three Neonatal Intensive Care unit is the highest level of neonatal care involving 24-hour onsite specialist neonatology support.
Multipara (adjective multiparous)	A woman who has had two or more pregnancies resulting in viable offspring.
NHMRC Clinical Trials Centre	A clinical research organisation that undertakes large multicentre clinical trials and takes part in national and international collaborative trial groups and contributes expertise to trials run by others.
Nullipara (adjective nulliparous)	A woman who has not produced a viable offspring.

Obstetric registrar	Doctor undergoing obstetric training in order to qualify as an obstetrician.
Parity	The total number of live births before the pregnancy or birth under consideration.
Perineal body	A triangular shaped wedge of tissue based on the perineum, separating the lower one third of the posterior vaginal wall from the anal canal.
Postpartum	Occurring after childbirth.
Primigravida	A woman pregnant for the first time.
Primipara (adjective primiparous)	A woman who has had one pregnancy that resulted in viable offspring.
Primiparity	The state of being a Primipara.
Second stage of labour	Time from full dilation of the cervix to the birth of the baby.
Severe perineal trauma	Includes both third and fourth-degree perineal trauma.
Sydney South Western Area Health Service	The Area Health Service in which this research was conducted.
Tertiary referral hospital	Hospital that provides the highest level of care, specialisation and functions as a university teaching hospital. The same as a Level Six Maternity Service.
Vacuum extraction	A form of instrumental delivery in which the baby is delivered vaginally with the aid of a shallow rubber cup fixed to the baby's head, using suction.

Definition of perineal trauma

Degree	Trauma
First	Injury to the skin only.
Second	Injury to the perineum involving perineal muscles but not involving the anal sphincter.
Third	Injury to the perineum involving the anal sphincter complex (classifications of 3a, 3b, 3c not used).
Fourth	Injury to perineum involving the anal sphincter complex and anal epithelium.

RCOG (2004)

Definition of terms used to describe perineal trauma in this thesis

Minor perineal trauma	Minor perineal trauma is defined for the purpose of this thesis as intact, first-degree, vaginal or labial tear
Major perineal trauma	Major perineal trauma is defined for the purpose of this thesis as second, third- and fourth-degree tear and episiotomy
Severe Perineal trauma	Includes both third- and fourth-degree perineal trauma

Abstract

The Perineal Warm Pack Trial investigated the effects of applying warm packs to the perineum during the late second stage of labour on perineal trauma and maternal comfort. A randomised controlled method was used. In the late second stage of labour, primiparous¹ women (n = 717) giving birth were randomly allocated to having warm packs (n = 360) applied to their perineum or standard care (n = 357). Analysis was on an intention-to-treat basis. The primary outcome measure was the requirement for perineal suturing and the secondary outcome measure was maternal comfort.

There was no statistically significant difference in the number of women who required suturing following birth. There were significantly fewer third- and fourth-degree tears in the warm pack group. However, the study was underpowered to assess the uncommon outcome of severe perineal trauma. Women in the warm pack group had significantly lower perineal pain scores when giving birth, on day one and day two following the birth. At twelve weeks, women in the warm pack group were significantly less likely to have urinary incontinence compared to the women in the standard care group.

Warm packs were highly acceptable to both women and midwives as a means to relieve pain during the late second stage of labour. Almost the same number of women (79.7%) and midwives (80.4%) felt that the warm packs reduced perineal pain during the birth. Both women and midwives were positive about using warm packs in the future. The majority of women (85.7%) said they would like to use perineal warm packs again for their next birth and similarly would recommend them to friends (86.1%). Likewise, 91% of midwives were positive about using the warm packs, with 92.6% considering using them in the future as part of care in the second stage of labour.

¹ The term primiparous will be used to refer to first-time mothers who are about to give birth and who have given birth (definition: a woman who has had one pregnancy that resulted in viable offspring) when describing women in the Perineal Warm Pack Trial, to avoid confusion that could occur when moving between the terms nulliparous and primiparous.

Both women and health professionals place a high value on minimising perineal trauma during childbirth and the potential associated morbidity. Perineal warm packs are widely used in the belief that they reduce perineal trauma and increase comfort during the late second stage of labour. This study demonstrated that the application of perineal warm packs in the late second stage does not reduce the likelihood of primiparous women requiring perineal suturing but significantly reduces perineal pain during the birth and on day one and two following the birth. Urinary incontinence also appears reduced at twelve weeks postpartum, though it is unclear as to the reason for this. The practice of applying perineal warm packs in the late second stage was highly acceptable to mothers and midwives in helping to relieve perineal pain and increase comfort and should be incorporated into second-stage pain relief options available to women during childbirth.

Chapter 1: Introduction to the thesis

“Midwives are in a position to set a change in motion: by applying evidence in practice, by modelling it, by teaching and sharing it with other health care professionals, and by pressing the case that all women deserve evidence-based care.

Turning things around happens one birth at a time”

(Albers, 2007, p.182).

1.1 Introduction

Trauma to the genital tract commonly accompanies vaginal birth (Williams, Florey, Mires, & Ogston, 1998) and is known to be more common in primiparous women (Macarthur & Macarthur, 2004a). Numerous factors have been suggested as potential contributors to perineal trauma, as have numerous solutions been suggested for minimisation of that trauma (McCandlish et al., 1998) (Kettle, 2004) (Klein, Janssen, MacWilliam, Kaczorowski, & Johnson, 1997). Some of the contributors, as well as some of the proposed solutions for prevention of perineal trauma², are based on sound evidence – many others are not. There is also evidence that perineal trauma was not always as high as it appears today, leading one to question contemporary second-stage management, both the complex package of care, as well as individual elements in that care (De Wees, 1889) (Ritgen, 1885) (Thacker & Banta, 1983). The Perineal Warm Pack Trial seeks to add to the emerging evidence on methods that may reduce perineal trauma and improve comfort for childbearing women in the second stage.

Countries report wide variations in trauma rates and within countries; further variations exist amongst institutions and health professionals (Renfrew, Hannah, Albers, & Floyd, 1998). In studies where the use of episiotomy is restricted, 55% to 77% of women still sustained trauma significant enough to require suturing (Albers, Garcia, Renfrew, McCandlish, & Elbourne, 1999b) (Mayerhofer et al., 2002) (McCandlish et al., 1998). In

² Perineal trauma is the term used in this thesis instead of genital tract trauma, even though more than trauma to the perineum is considered in actual clinical practice.

Australia, 65.7% of women have some form of perineal trauma and 17.2% have an episiotomy (Laws, Grayson, & Sullivan, 2006b).

Both childbearing women and health professionals place a high value on minimising perineal trauma and reducing potential associated morbidity (Homer & Dahlen, 2007). Many factors contribute to genital tract trauma. There is evidence to support restricting the liberal use of episiotomy (Hartmann et al., 2005) (Carroli & Belizan, 2006); using vacuum extraction rather than forceps for instrumental deliveries (Johanson & Menon, 2004) and the use of antenatal perineal massage to decrease perineal trauma (Beckmann & Garrett, 2006). There is a lack of clear consensus about the effect of perineal guarding (McCandlish et al., 1998) (Mayerhofer et al., 2002); active directed pushing (Bloom, Casey, Schaffer, McIntire, & Leveno, 2006) (Schaffer et al., 2005), maternal position (Gupta, Hofmeyr, & Smyth, 2006) or perineal massage in the second stage of labour (Stamp, Kruzins, & Crowther, 2001). There are also a range of approaches to perineal care that have yet to be fully evaluated to determine their impact on decreasing perineal trauma (Renfrew et al., 1998). It is also important that comfort during the second stage be examined and that strategies to reduce pain during this intense part of the labour be evaluated (Sanders, Peters, & Campbell, 2005). Perineal warm packs in the second stage of labour are one such approach to perineal care that needs further evaluation with regard to the effect on perineal trauma and comfort.

Perineal preservation and perineal comfort during the second stage of labour are important goals in the practice of most midwives, with midwives and obstetricians being aware that perineal trauma is associated with significant short-and long-term morbidity for women (Sleep & Grant, 1987) (Glazener, Adballa, & Stroud, 1995) (McCandlish et al., 1998). Acute postpartum perineal pain is common among women who give birth vaginally and its severity is linked to that of the perineal injury (Kenyon & Ford, 2004) (Albers, Garcia, Renfrew, McCandlish, & Elbourne, 1999a) (Klein et al., 1994). Perineal pain can have long-and short-term negative consequences for women's health and wellbeing (Glazener et al., 1995) (McCandlish et al., 1998) (Sleep & Grant, 1987) (Albers et al., 1999a) (Klein et al., 1994). It can make everyday activities such as sitting, walking, voiding, defecating,

providing self-care and care for the baby, including breastfeeding, difficult. It can also lead to relationship disharmony and sexual disorders that can lead to irritability, resentment, depression and maternal exhaustion (Greenshields & Hulme, 1993) (Steen, Cooper, Marchant, Griffiths-Jones, & Walker, 2000) (Steen & Marchant, 2001) (Barrett et al., 2000) (Sleep & Grant, 1987) (Klein et al., 1994) (Signorello, Harlow, Chekos, & Repke, 2001).

Women who have an intact perineum after the birth of their first baby have stronger pelvic floors (measured by electromyogram) and make a quicker muscle recovery than women experiencing tears or episiotomies (Klein et al., 1994). While perineal trauma has not been clearly associated with urinary incontinence (Woolley, 1995), severe perineal trauma (third- and fourth-degree tears) has been shown to be associated with faecal incontinence (Sultan & Thakar, 2002).

Perineal pain experienced during the second stage of labour can also have an impact on how a woman views her birth experience. Women report that the advancement of the baby's head, and stretching of the perineum in the minutes before giving birth, are accompanied by pain that can be severe (Mander, 1992) (Miller, 1994) (Lowe & Roberts, 1998; Niven & Gijbers, 1984) (Stewart, 1982) and this can lead to women remembering the second stage in a particularly negative light (McKay, Barrows, & Roberts, 1990).

In the developed world there has been a dramatic increase in caesarean section rates in the last decade. Fear of the pain associated with labour as well as perineal injury is reported as a reason why women may request a caesarean section (Kolas, Hofoss, & Daltveit, 2003) (Nerum, Halvorsen, Sorlie, & Oian, 2006). Methods of reducing pain and trauma during the second stage, without having to resort to potentially harmful pharmacological pain relief or major abdominal surgery, would be beneficial to women and indeed to society as a whole. It is curious to observe that much of the research on pain in labour has focused on the first stage, thus largely overlooking the pain associated with the actual birth (Sanders et al., 2005).

Finding ways to prevent or reduce perineal trauma would be of benefit in terms of the physical, emotional and financial costs associated with ongoing morbidity. Likewise finding ways to improve women's comfort during the second stage would also be beneficial. This thesis reports on a study that was designed to determine the efficacy of applying perineal warm packs in the second stage of labour in reducing perineal trauma and improving maternal comfort.

1.2 Background to the study – a personal story

I will never forget the first time I used perineal warm packs. I was a student midwife in the United Kingdom and during my community midwifery placement a very wise midwife, who taught me so much, introduced me to the concept. We were caring for a woman who was in the late second stage. Lisa (not her real name) seemed to be terrified every time a contraction came and the baby's head pushed against her perineum. She kept trying to draw the baby's head back into her body, at one point crossing her legs in desperation. Quietly the midwife left the room, returning minutes later with a bowl of steaming water. All the black and white movies came swirling to mind – the pacing husband below glancing anxiously up the narrow stairway every time his wife screamed and the hot water being boiled in great quantities on the stove, ferried up and down the stairs by surprisingly agile, middle-aged women in bustling skirts.

Now as the midwife placed the warm pack on Lisa's perineum, she crooned softly, "That will help, love." Lisa's eyelids flickered momentarily and her gasping, sucking shrieks eased. She began to push, tentatively at first and then in a focused but amazingly relaxed way. Her distress visibly lifted. Lisa's perineum seemed to glide over the baby's head as all the tension was released and her newborn almost oozed into my waiting hands. Later, when I quizzed the midwife about the effect of the warm pack, she said, "It soothes the ring of fire." There was a clear and sudden realisation that there was something very effective about this simple method. It was later on that I heard that warm packs were supposed to do other amazing things like reduce perineal trauma. To me, what I observed in Lisa was clear; her pain was eased and she was able to give birth to her baby without holding back any

more. Later when I also gave birth, I lived the experience I had seen in Lisa that day and I knew the feeling of comfort produced by this simple, inexpensive and ancient form of care.

I became an avid user of warm packs from then on. I returned to Australia and worked in a maternity unit that was an oasis for midwifery and fostered wonderful woman-centred care. Warm packs became a standard part of our practice. We shared our stories and techniques and I learnt so many wonderful skills during my years there – many of them not scientifically validated but most of them deeply intuitive. Sometimes they worked with one woman and not the other; it was this being in tune with women that helped develop some of my greatest skills as a midwife. Women have always taught me more than the textbooks ever could.

My next job was as the clinical midwifery educator in the Delivery Ward of the biggest tertiary referral hospital in Sydney in New South Wales (NSW), King George V Hospital. Here there were many more women with complications and many more doctors involved in the birth. Births were generally on the bed and in the supine position. Epidurals were quickly resorted to and midwifery knowledge struggled for survival. The first time I walked down the corridor with my bowl of steaming water, the midwives thought I had gone quite mad, let alone the doctors. I went from an environment that embraced warm packs to one that had never heard of them. I did discover later, however, that three floors beneath us, where the Birth Centre was, warm packs were used frequently in second-stage care – more about that story later.

While even midwives who had never used warm packs seemed to understand how they could potentially comfort women, I found my obstetric colleagues particularly disparaging on the subject and this is explored in greater detail in Chapter 3. “Old wives’ tales,” scoffed one obstetrician on seeing me use warm packs. “I thought you girls would have come out of the Ark by now,” he laughed, picking up the episiotomy scissors and putting an end to the argument – well not quite!

The answer became clear to me. This method of second-stage care obviously needed scientific validation. I became determined that this midwifery knowledge not be lost and devalued in the medicalised world in which birth now occurred. Inspired at a midwifery conference in 1997, by another Australian midwife, Heather Musgrove, who presented a paper on a small randomised controlled trial into the effect of perineal warm packs (Musgrove, 1997), I returned to my workplace determined to undertake the Perineal Warm Pack Trial.

1.3 Choice of study design

It was decided during the early days of planning the research, that a randomised controlled trial methodology would be ideal. The randomised controlled trial methodology is widely accepted as the most rigorous way to test for the effect from a treatment. Random allocation to intervention and control groups ensures the groups being compared are on an equivalent footing at the outset of the study, thus eliminating selection and confounding biases (Schultz, 2000). The randomised controlled trial is particularly effective in helping professionals and women choose between different forms of care. Randomised clinical trials were introduced into medicine in the 1950s as a unbiased way to determine the real effects of medical intervention, but the medical profession was slow to recognise their value (Cochrane, 1979) (Enkin, 2006). One could argue that today we have lost perspective on when it is appropriate to use the randomised controlled trial methodology and when it is not. More complex problems, where outcomes depend on a web of interactions between care delivered, individuals concerned, and the context in which they occur, are less suited to a randomised control trial evaluation (Enkin, 2006).

One could argue even more strongly that there are biases evident in the outcomes that researchers choose to evaluate. Midwives and obstetricians often view childbearing women in a different light, making it vital that both are involved in research so that all relevant questions are asked. It was clear when reviewing the literature on warm packs that while much of it was anecdotal, both prevention of trauma and reduction of pain were advocated as 'potential' benefits. In the Perineal Warm Pack Trial it was clear that perineal trauma

was only one aspect of the proposed benefits and so maternal comfort was incorporated as an important consideration. Women and midwives' evaluations of the warm packs were deemed to be as important as clinical outcome measures, so questionnaire evaluation of the warm pack group was also undertaken. When the study commenced there were those in the medical profession who considered our evaluations of women's pain and experience using warm packs as unhelpful, arguing that the only true evaluation of pain would be through blood-testing and other forms of biologically measurable responses. I rejected this argument as the researcher and I opted to use several measures of women's assessment of pain experienced, as well as midwives' evaluations of women's responses. Women's experience is valid and needs to be recognised as such. This proved to be valuable in gaining an understanding of women's experience of pain during the second stage of labour and the contribution warm packs were able to make in reducing that pain. The choice was also made to follow women up until twelve weeks following the birth to determine possible long-term effects of warm packs. While this was time-consuming, it proved to be valuable.

1.4 Characteristics of the population

The multicultural population served by the two hospitals in the study was an important consideration when looking at the evaluation. Australia ranks as one of the most multicultural societies in the world (Rissel, 1997). This is due to the active support given by the Australian Government to immigration through most of the twentieth century. The Australian Bureau of Statistics gives current estimates of one international migrant entering the country every 4 minutes and 47 seconds (Australian Bureau of Statistics, 2007). In 2001, the most common ancestry reported by people living in Australia was: Australian (6.7 million people; 38%); followed by English (6.4 million; 36%); Irish (1.9 million), Italian (800,000); German (742,000); Chinese (557,000) and Scottish (540,000) (Australian Bureau of Statistics, 2003). A further six ancestries, identified with numbers between 15,000 and 500,000 people were: Greek, Dutch, Lebanese, Indian, Vietnamese and Polish. In total, more than 160 ancestries were separately identified. While people from the United Kingdom still make up the majority of migrants, the Vietnam War and the war in Lebanon have resulted in an increase in migrants to Australia from Asia and the Middle East in the

past two decades. Since 1986, the fastest growth among the leading ancestries has been in South and East Asian ancestries, with Chinese, Vietnamese and Indian ancestries more than doubling in number by 2001 (Australian Bureau of Statistics, 2003). When the next census results are released in 2008, this will most likely increase even further.

The latest statistics from the state of NSW, where the Perineal Warm Pack Trial took place, indicate that between 2001–2005 about 72% of women giving birth were born in Australia (NSW Health, 2007). In 2005, mothers born in the United Kingdom, New Zealand, China, Vietnam and Lebanon together accounted for 10.6% of all women giving birth (NSW Health, 2007). Nearly 9% of women giving birth in NSW were from Asian countries—defined for the purpose of this study as being born in the following countries: China, Vietnam, Hong Kong, Indonesia, Japan, Laos, Cambodia, Taiwan, North Korea, South Korea, Thailand, Philippines, Burma and Malaysia. This is discussed further in Chapter 5.

The Perineal Warm Pack Trial was conducted at two maternity hospitals in Sydney, Australia, The Royal Prince Alfred (RPA)³ Hospital and The Canterbury Hospital (TCH). These are public hospitals situated in metropolitan Sydney and located within the Sydney South Western Area Health Service⁴. This area has the largest culturally and linguistically diverse (CALD) childbearing population in the state of NSW. More than 45% of women giving birth at RPA (one of the hospitals involved in the study) are from CALD backgrounds, with 19% being born in an Asian country (RPA, 2006). Almost one quarter (23%) of women at RPA require interpreters to facilitate communication with health-care staff (RPA, 2006). At TCH (one of the hospitals involved in the study), the proportion of CALD childbearing women is higher, with nearly three quarters of women born in countries other than Australia (TCH, 2006). Over 26% were born in an Asian country when using the definition above (TCH, 2006).

³ The King George V (KGV) Hospital was a stand-alone maternity hospital that transferred into a newly built maternity unit in the Royal Prince Alfred Hospital in 2002. The study began in KGV.

⁴ The Sydney South Western Area Health Service is a unit of health system administration in NSW. There are eight Area Health Services in NSW and they are each accountable to the NSW Health Department for the management of public hospitals and community health services in the areas

It was important that the Perineal Warm Pack Trial recruit a sample of women who reflected the cultural and linguistic diversity of the population. There was a particular focus on Asian women, due to the high rate of severe perineal trauma (third-and fourth-degree tears) already noted in the population served by the two hospitals involved in the Perineal Warm Pack Trial (Dahlen, Ryan, Homer, & Cooke, 2007). This is discussed in further detail in Chapter 6.

It is unfortunate that women from different ethnic backgrounds are more likely not to be included in research, due to challenges such as logistical difficulties of arranging interpreters and the cost of translating documents. Including such women is particularly difficult where there is no or minimal funding available for research. While these reasons are valid, it can mean the sample recruited is not representative of the population on which the intervention may be applied and the results may be biased. By including these women we validate their needs as being of equal importance and we can change care to be more culturally appropriate and responsive to the needs of individuals.

Women from CALD populations tend to be under-represented in research (Brown, Lumley, Small, & Astbury, 1994) (Cartwright, 1986). Phoenix (1990) also reported a lack of multicultural and multi-ethnic representation in many studies in maternity care (Phoenix, 1990). It is not always easy to ensure representation, as researchers both in Australia (Brown et al., 1994) and overseas (Summers, McKeown, Lord, & Walton, 1997) have pointed out. Summers et al. (1997) commented that these women are one of several subgroups of the population who may get a relatively poor deal from maternity services and are less likely to respond to blanket survey methodologies (Summers et al., 1997). This is one reason why, in the Perineal Warm Pack Trial, postpartum follow-up at six and twelve weeks was conducted by phone interview and not a written survey. We had previously found a surprisingly high rate of illiteracy in this population of women. Previous research has indicated that people from minority cultural groups do not participate in health research for many reasons, including a lack of understanding as to the relevance of the research; distrust of the research process (Lipson & Meleis, 1989); language barriers; fears about confidentiality (DeSantis, 1990) or cultural requirements for spousal consent (Berg, 1999).

Strategies suggested for improving participation among culturally diverse groups in research are: obtaining community support; using research assistants who are matched in age, gender and culture for recruitment; translating documents; having a systematic approach to sampling and recruitment; flexible and sensitive protocols; ongoing support of bilingual interviewers who collect data; and showing appreciation for the participant's involvement (DeSantis, 1990) (Milburn, Gary, Booth, & Brown, 1992) (Small, Yelland, Lumley, & Rice, 1999). We found that during the Perineal Warm Pack Trial, women from different ethnic backgrounds were eager to participate in the research. The concept of having warm packs applied to the perineum seemed very acceptable to them, particularly for Asian women, many who adhere to strong cultural beliefs about the benefits of heat for childbearing women. As a result, only 34% of the participants in the Perineal Warm Pack Trial had been born in Australia and nearly 33% were born in Asia, which reflects the population served by the hospital in which the study took place (see Chapter 6).

In order to include women from CALD backgrounds in the research, all information forms, consent forms and questionnaires were translated into the main languages spoken (Arabic, Turkish, Mandarin, Vietnamese and Korean). Interpreters and Ethnic Obstetric Liaison Officers (midwives)⁵ were utilised as needed for consent and data collection.

1.5 Aims and research questions

The Perineal Warm Pack Trial was designed to evaluate the effect of applying warm packs to the perineum in the second stage of labour. Specifically, it aimed to identify any differences in women's perineal outcomes and comfort when warm packs are applied to the perineum in the second stage of labour, compared to standard second-stage care that did not involve the use of warm packs.

⁵ Ethnic Obstetric Liaison Officers are midwives employed from designated ethnic and cultural backgrounds to provide care, education and support for women from the same background.

The hypothesis was that applying warmth to the perineum in the second stage of labour would reduce perineal trauma and increase maternal comfort.

The research questions of the Perineal Warm Pack Trial were:

- Will applying warm packs to the perineum in the second stage of labour reduce perineal trauma?
- Will applying warm packs to the perineum in the second stage of labour increase maternal comfort?

The primary outcome measure was the proportion of women who required perineal suturing following birth. Results for this outcome measure are presented in Chapter 6.

The secondary outcome measures were women's perineal pain scores at birth, day one and two following the birth, and their wellbeing at six and twelve weeks following the birth. Results for these outcome measures are presented in Chapters 7 – 9.

1.6 Organisation of the thesis

The thesis is organised into ten chapters, of which this is the first.

Chapter 2 explores historical and anthropological perspectives on perineal care during labour and birth, with a particular focus on perineal care during the second stage. In this chapter, a social-to-surgical model for perineal care is explored, using evidence from historical and anthropological literature. This chapter provides the historical and political context for the Perineal Warm Pack Trial, whereby an ancient art is validated through scientific inquiry, turning what has been considered an 'old wives' tale' into established midwifery knowledge.

Chapter 3 explores contemporary literature that refers to the use of perineal warm packs during the second stage of labour. The physiological effect of heat is also discussed in some detail in this chapter.

Chapter 4 provides a literature review of factors that influence perineal trauma and maternal comfort during the second stage of labour. An in-depth discussion and analysis of the literature is undertaken, thus placing the Perineal Warm Pack Trial in context with the wider body of knowledge regarding perineal care.

Chapter 5 is the methods chapter and describes the setting for the study; the enrolment; randomisation and consent procedures; the outcome measures; and methods of data collection. A general overview of the analysis is also presented.

Chapter 6 is the first of four chapters that present the results of the study. This chapter presents the maternal clinical outcomes from the study. It specifically reports on the primary outcome variable, perineal suturing at birth. Each of the result chapters includes a brief literature review and resembles a journal article

Chapters 7, 8 and 9 present data related to the secondary outcome variable of maternal comfort. Chapter 7 reports on women's evaluations of their pain whilst giving birth, and on day one and two following the birth.

Chapter 8 also presents data related to the second outcome variable of maternal comfort. It specifically examines women and midwives' evaluation of the warm packs through questionnaires conducted soon after the birth, before leaving the Delivery Ward.

Chapter 9 also presents data related to the second outcome variable of maternal comfort and particularly addresses women's postpartum wellbeing. It reports on the results of postpartum follow-up of women in the Perineal Warm Pack Trial, whilst they were in hospital and then later when they were telephoned at home, at six and twelve weeks following the birth.

Chapter 10 presents an overview of the research and returns to the study questions, addressing each in turn. It also discusses the major findings and limitations of the research and implications for second-stage care.

1.7 Summary

This chapter has overviewed some of the factors that influenced the development of the Perineal Warm Pack Trial. It has provided a context for the study by briefly discussing the literature supporting the need for a study and the personal impetus for the study.

The next chapter explores historical and anthropological perspectives on perineal care during labour and birth, with a particular focus on perineal care during the second stage. A social- to-surgical model for perineal care is explored, using evidence from historical and anthropological literature. This chapter provides the historical and political context for the Perineal Warm Pack Trial, whereby an ancient art has been validated through scientific inquiry, turning what has been considered an 'old wives' tale' into established midwifery knowledge.

Chapter 2: From social to surgical: historical perspectives on perineal care during labour and birth

“Nowhere in history do we find a beginning, but always a continuation. How then shall we understand the end, if the beginning remains a mystery?” (Bachofen, 1967, p.2).

2.1 Introduction

This chapter explores historical and anthropological perspectives on perineal care during labour and birth, with a particular focus on perineal care during the second stage. An exploration of the literature describing perineal care is undertaken from the time of Hippocrates (460 – 370 B.C.), through to the modern-day literature. Evidence from anthropology in different societies is examined briefly to further inform the debate.

Much of the written knowledge around childbirth practices is second-hand knowledge. Throughout history men have dominated writings on childbirth, despite the fact that this was predominantly the domain of female midwives. Women’s voices have remained largely silent, giving us little first-hand insight into childbirth practices from their perspective. What knowledge women have articulated has often been dismissed as ‘old wives’ tales’. It is evident that in the past the perineum received great care and attention from midwives, with a strong focus on protection and preservation. With the advent of the man-midwife, the perineum became pathologised and a site for surgical intervention (i.e. episiotomy). In the last 30 years, there has been a re-emergence of care aimed at preserving and protecting the perineum.

2.2 Historical perspectives on perineal care during labour and birth

Perineal warm packs have their origins lost in antiquity, along with many other midwifery practices that aim to support and comfort women during the second stage.

In the book, *The Eternal Eve*, the author (Graham, 1950) writes about childbirth, the oldest miracle, as having many gaps in the story and that there are parts of this story:

Where myths and facts rub shoulders. The myths that surround the birth of mankind are important fragments in the history of the progress that man has made from the Stone Age to the present day. Many of the earliest myths ever recorded are connected with childbirth (Graham, 1950, p.1).

Johann Jakob Bachofen (1815 – 1887) was a Swiss scholar of mythology and Roman law and history. He rightly argued that history, as such, could never be grasped. An event can thus leave us traces, but its inner meaning escapes us, taken away by the current of time, so that it is unknowable to us except to the extent that it has been specified by tradition and myth. Bachofen was the one who first wrote about the gynaecocratic era, in which the feminine principle reigned supreme in history. This will be discussed further in this chapter.

There is little doubt that the birth of the profession of midwifery evolved as naturally as birth itself occurred. As women gave birth they sought and received care from supportive women (Towler & Bramall, 1986). At some unknown point in cultural evolution, certain experienced women became designated as wise women who were called for a birth. Historians have noted that midwifery has been characterised as a social role throughout recorded history, regardless of culture or time (Towler & Bramall, 1986). In their practice, midwives often used herbs and potions, many of these the forerunners of modern-day pharmaceuticals (Chamberlain, 1981). Midwifery was taught via an apprenticeship model, with skills passed from one generation to another. There was no formalised system of education and much of the knowledge and wisdom was not written down but passed on orally (Graham, 1950). Midwives often guarded their knowledge fiercely, so little was recorded. Men have reinterpreted what has been recorded.

2.2.1 The Ancient Greeks

The famous Greek, Hippocrates (460–370 B.C.) – also known as the father of medicine – taught obstetrics and gynaecology. He only occasionally credited his knowledge to

midwives, although he must have owed a great deal of his knowledge to them (Chamberlain, 1981). It is known from history that midwives' knowledge was impressive. Pythagoras' wife, Theono, in the fifth century B.C., famously won a debate with Eurphon, a well-known physician, arguing convincingly that a child was viable before the seventh month (Chamberlain, 1981).

Throughout history, midwives are mentioned but rarely given much attention. The most famous Greek midwife was probably Phaenarete and her fame came not from the practice of her profession but because she gave birth to Socrates (Graham, 1950). It appears that in Greece (800 – 500 B.C.), midwives enjoyed a very high social status. This declined within a few hundred years to the point that Agnodice, known as 'the midwife of Athens' in the fourth century B.C., disguised herself as man in order to learn midwifery from Herophilos, who ran a medical school (O'Dowd & Philipp, 2000). When discovered and put on trial for disguising herself as man and learning with the men, the women of Athens demanded her release, arguing that she had saved their lives (Chamberlain, 1981).

However popular, or famous, some women healers may have been, they operated within a cultural framework that generally denigrated their work (Chamberlain, 1981). If they were famous it was by association to some other person or some notable historical event. They often did not document their knowledge. This was left to the men of the time and was no doubt significantly reinterpreted.

2.2.2 Ancient Ephesus and Salerno

The physician Soranus of Ephesus (98 – 138A.D.) produced one of the most important treatises on obstetrics (Carter & Duriez, 1986). It was called *Gynaecology* and was written specifically for midwives (Temkin, 1956). Soranus was one of the earliest writers to describe the care of the perineum. Born in Ephesus, he studied at Alexandria and practised in Rome in the last few years of the first century (Graham, 1950). Soranus described in detail the equipment a midwife needs for normal labour:

Oil for injection and lubrication; warm water in order that the parts may be cleansed; warm fomentations⁶ for alleviation of the pains; sea sponges for sponging off; pieces of wool in order that the woman's parts be covered (Temkin, 1956, p.70).

Soranus described what one must do during the delivery:

... and one must first soothe the pains by touching with warm hands, and afterwards drench warm pieces of cloth with warm, sweet olive oil and put them over the abdomen as well as the labia and keep them saturated with the warm oil for some time, and one must also place bladders filled with warm oil alongside (Temkin, 1956, p.72).

Soranus also gave instructions that the midwife should support the perineum with a linen pad while the head is advancing and advised an attendant to stand behind the midwife's stool and place a 'pledget' underneath in order to restrain the anus and avoid prolapse and rupture that can accompany straining (Temkin, 1956). Moschion (or Moschio), in the sixth century A.D., made the first translation of Soranus' textbook into Latin (Towler & Bramall, 1986). It was said to be a word-for-word translation and it was this version that was later translated by German, French and English writers in the sixteenth century A.D., under various titles (Towler & Bramall, 1986). The physician Galen, who also significantly influenced writing on childbirth, was born around the time that Soranus died.

During the eleventh century A.D., Trota (or Trocta) became one of the first women to write a text on the subject of obstetrics (*Trotula*), although some historians propose that *Trotula* was in fact written by a man, or several men assuming a woman's name (O'Dowd & Philipp, 2000) (Green, 2002). A series of works known as the *Trotula* were published and they came from the first mediaeval medical school in Salerno (Italy). These works draw heavily on the works of Soranus and again instruct the midwife to support the perineum with a linen pad. They give a full description of the severe perineal trauma that can occur when neglecting this precaution. They also describe how to repair the trauma with silk

⁶ Warm flannels used to apply warmth.

sutures (Trotula, 1940) (Green, 2002) (King & Rabil, 2005). Graham (1950) writes that this is the first time a complete perineal repair is recommended in history.

Afterward we sew the rupture between the anus and the vagina in three or four places with a silk thread (Green, 2002, p. 93).

There is frequent mention of the use of warm water as a therapeutic modality, which is also available in abundance in Salerno with its aqueducts and abundant bathhouses (Green, 2002). In *Trotula*, the care of a woman having a difficult birth is described:

We should prepare a bath and we put [the woman] in it, and after she leaves [the bath] let there be a fumigation of spikienard and similar aromatic substances (Green, 2002, p. 93).

2.2.3 Writings from the sixteenth to eighteenth century in Europe

With the development of printing in the mid fifteenth century, came a number of books on midwifery, many of which continued to perpetuate the ancient traditions passed down by Soranus and Trotula (Carter & Duriez, 1986), who in turn were dependent on the writings of Hippocrates, Aristotle and Galen. The most popular was Eucharius Rosslin's, *A Rosegarden for Pregnant Women and Midwives*, published in 1513 in Germany and reprinted ten times. In 1545, the book was enlarged by Thomas Raynalde and renamed *The Byrth of Mankynde* (Carter & Duriez, 1986). It is even conceivable that a Chinese translation was made, which found its way into Japan and appeared in 1661 titled *Tat Shang Pin* or 'Midwifery Made Easy' (O'Dowd & Philipp, 2000; Towler & Bramall, 1986).

While the aim of these books was to benefit the midwife, who was the principal person involved in the birth, it is unlikely many midwives would have read them, as they were often illiterate. Usually the details given of normal birth are scanty, with a far greater focus on complicated birth and malpresentations (Sharp, 1999). Once again there is little record of midwifery practice and knowledge from the midwives' perspective. It is usually second-hand knowledge written by men who often considered the midwives to be ignorant and careless. What is clear in these texts and from stone engravings of the time is that women

usually gave birth upright on birthing stools and the midwife had plenty of tactile contact with the woman via massage, warm compresses and careful perineal support.

2.2.4 The 'first voice' and the 'other voice'

Elizabeth Gould Davis writes that, "Recorded history starts with a patriarchal revolution" (Gould Davis, 1971, p.18). Much of women's knowledge was written and interpreted through a male viewpoint. The educated men who created Western culture are often considered as the authority or 'first voice' in history. The 'other voice' emerged against a backdrop of a three-thousand-year history of the derogation of women rooted in the civilisations related to Western culture: Hebrew, Greek, Roman and Christian (King & Rabil, 2005). Writers describe how negative attitudes toward women were inherited from these traditions and pervaded the intellectual, medical, legal, religious and social systems that developed in the European Middle Ages. As women's voices began to be heard and they wrote their knowledge down, that 'other voice' began to emerge and challenged the reigning assumptions (King & Rabil, 2005).

2.2.5 Lost literature during the Dark Ages

Very little was written during the Dark Ages in Europe (476 to 1000 A.D.) and the midwife remained a shadowy figure (Towler & Bramall, 1986). During this period of history, great literary works were destroyed by the Church, losing forever much wisdom and knowledge (Gould Davis, 1971). The writings of men like Aristotle were mostly preserved. The Church considered him as 'the wisest of the pagans', partly because of his denial of the truth known by other ancients, that the earth was a sphere revolving around the sun. However, it is thought that less than a third of his work survives today (Dunn, 2006). Likewise, Galen and Hippocrates were permitted as subjects for study during the Dark Ages, as their texts were said to contain little that was overtly pagan. Ehrenreich and English point out that medical students:

Like other scholarly young gentlemen, spent years studying Plato, Aristotle and Christian theology. Their medical theory was largely restricted to the works of

Galen, the ancient Roman physician who stressed the theory of 'complexions' or 'temperaments' of men (Ehrenreich & English, 1976, p.32).

2.2.6 Humeral theory of disease

The works of Aristotle provide some of the oldest written insights into the art and science of midwifery. No doubt they were reinterpreted and are reported by him as second-hand knowledge. Aristotle, like Hippocrates and Galen, subscribed to the humeral theory of disease, holding that there were four primary fundamental qualities in life: hot, cold, wet and dry. These met in binary combination to constitute the four elements: earth, air, fire and water, represented respectively by black bile, yellow bile, blood and phlegm. The body was thought to be composed of these humors, which were responsible for the temperaments: melancholy, choleric, sanguine and phlegmatic (Dunn, 2006). Disorders of the human body were thought to be caused by an upset in the balance of these humors (Dunn, 2006). While it is likely that Aristotle derived his theory of the women being 'cold' and men 'hot' from Hippocratic writings, he imbued the presence of heat in the male with a superiority value compared to the presence of cold in the female. Aristotle believed that the more heat that came into contact with the blood, the more pure it could become and women who were cold were in need of heat. Trotula followed this thinking in her writings, describing women as not to having enough heat to dry up the bad and superfluous humors (Trotula, 1940) and advocating the application of heat as a therapy for women for all sorts of womanly complaints, including childbirth (Trotula, 1940). This belief system stayed in place for 2000 years and derivations of the belief are still adhered to in some cultures, such as is seen today in China. There are no doubts that rituals around birth involving the use of heat and water were influenced by this dominant belief system.

2.2.7 The works of Aristotle?

The author or authors of the popular book, *The works of Aristotle*, which first appeared in England in 1684, remain unknown, but it is generally thought that Aristotle did not write it (Fissell, 2003). The book was enormously popular in Europe and was reprinted many

times, each version reflecting the time⁷. The details about normal labour and birth management at a time when birth was the domain of midwives make it highly likely that (Aristotle, date unknown) a midwife was involved. In *The works of Aristotle*, the author refers to caution describing birth procedures and practices intimately, a caution that no doubt prevented much knowledge regarding childbirth from being written:

If it were not for the public benefit, especially for that of the professors and practitioners of the art of midwifery, I would refrain from treating the secrets of Nature, because they may be turned to ridicule by lascivious and lewd people. (Aristotle, date unknown, p.77).

The book, *The works of Aristotle*, describes in great detail the months of pregnancy and what a pregnant woman should do. He describes very elaborate concoctions for the last months of pregnancy of “Baths of sweet water, with emollient herbs” and instructions for the woman to sit in them “not higher than her navel” (Aristotle, date unknown, pp.223-225). After the baths the woman anoints her belly “with oil of sweet roses and of violets; but for her privy parts, it is better to anoint them with the fat of hens, geese or ducks, or with oil of lilies and the decoction of linseed and marshmallows” (Aristotle, date unknown, p.224). In the last two weeks the woman is instructed to do this every morning and evening and “her privy parts must be gently stroked down with this fomentation” (Aristotle, date unknown, p.224).

The works of Aristotle describe, in great detail, care of the perineum before, during and after childbirth. There are descriptions of “tansey broiled and applied to the privates; or an oil of it made and used” or “the stone aetites⁸ held to the privies, is of extraordinary virtue, and instantly draws away both the child and the afterburthen⁹”, or “take peony seeds and beat them into a powder, and mix the powder with oil, with which oil anoint the privies of

⁷ Many of these original texts, *The works of Aristotle*, are still available for purchase but they are mostly undated, making it difficult to determine when they were published.

⁸ ‘Aetites’ or ‘Eagle-stones’ were hollow stones containing loose matter, a smaller stone or sand which rattles when shaken, thought to have special medical properties (Barb, 1950).

⁹ ‘Afterburthen’ is the after-birth or placenta and membranes.

the woman and child; it will give her deliverance speedily, and with less pain than can be imagined” (Aristotle, date unknown, p.248).

A clear description of intrapartum perineal massage is given:

Let the midwife also, having no rings on her fingers anoint them with oil of fresh butter, and therewith dilate gently the inward orifice of the womb putting her finger ends into the entry thereof, and then stretch them one from the other, when her pains take her; by this means endeavouring to help forward the child, and thrusting by little and little, the sides of the orifice towards the hinder part of the child’s head, anointing it with fresh butter if be necessary (Aristotle, date unknown, p.253).

The description in *The works of Aristotle*, of crowning and perineal sensations in the second stage is detailed:

When the head of the infant is a little advanced into the inward orifice, the midwife’s phrase is: – “it is crowned;” because it girds and surrounds it just as a crown; but when it is so far that the extremities begin to appear without the privy parts, then they say, “The infant is in the passage;” and at this time the woman feels herself as if it were scratched or pricked with pins (Aristotle, date unknown, pp.253-254).

Byzantine midwifery was also described in some detail, especially regarding difficult labours (Graham, 1950):

We must apply cataplasms to the pubes, abdomen and loins, of linseed or honied water, or of oil and water; and use similar hip-baths (Graham, 1950, p. 98).

Persian scholar, Avicenna (980 to 1037 A.D.), wrote that, during a long labour, women should take warm baths to “relax the parts” (Graham, 1950). His medical system was based on Galen, which he mixed with Aristotelian metaphysics as well as traditional Persian and Arab lore. Avicenna was a strong advocate of warm water for curing a multitude of diseases (Trall, 1872).

All these historical writings advocate care and support of the woman and her perineum. These contrast strongly to later writings by doctors on perineal care during labour and birth. It is evident in these that there is a strong surgical focus.

2.3 The writings of midwives

The management of childbirth in early-modern Britain was almost entirely in the hands of women; midwifery manuals, by contrast, were almost all written by men (Sharp, 1999). Thus, when midwives began to write, there was an expected change of tone and obvious clinical experience behind their words. German midwife, Justine Siegemund (1636 – 1706 A.D.) published the book, *The Court midwife* in 1690 (Siegemund, 2005). She authored one of the first books on midwifery along with French midwife Louise Bourgeois (1563 – 1636 A.D.) and Frisian midwife Catharina Schrader (1693 – 1740 A.D.). When Siegemund died she was said to have delivered 6,199 infants; among them were twenty royal births (Siegemund, 2005). Her knowledge was immense.

The Court Midwife is unique because it does not reproduce the medical lore and humoral medicine that fills Jane Sharp's 1617 book, *The Midwives Book or the Whole Art of Midwifery Discovered* (Sharp, 1999). *The Court Midwife* is full of practical midwifery advice. Its publication was historical in that it went through seven subsequent editions and generated several protracted public battles over her right as a woman and midwife to write a book – this came mainly from doctors. While most of the book, like that of English midwives Sarah Stone and Elizabeth Nihell, is filled with advice on manipulations for difficult births, her instructions for perineal care are notable, as they advocate protection rather than intervention. She warns that meddling can lead to severe perineal trauma.

You certainly should not stretch or dilate anything with your fingers. This is a common mistake. This sharp stretching injures the woman's belly and causes swelling before the child gets that far and comes forth. Thus the pain of the child's passing through is all the greater because of the swelling and the injured belly. I have observed that it hurts more than it helps ... it is more necessary to protect the belly than to stretch it if the birth passage is not to tear, as often happens with the

rectum as well, when the rectum is injured so it can no longer close up. This is a grave misfortune for the woman, for she cannot control her bowels at will thereafter (Siegemund, 2005, p.74).

French midwife Madame du Coudray, known as the 'King's Midwife,' was famous for developing the first obstetric mannequin and for her tours around the French country side educating midwives with the King's blessing, between 1760 to 1783 (Gelbart, 1998). Like Siegemund, she warns against "too much vaginal meddling. The best thing is to wait patiently, alert to all cues" (Gelbart, 1998, p.33). Madame du Coudray, using her mannequin, spent many days teaching her students about 'natural delivery' and providing the students with techniques for facilitating the baby's 'slippery exit':

Although great science is not necessary in natural delivery there are still plenty of precautions to take during labour to ensure that favorable beginnings do not end badly (Gelbart, 1998, pp.68-69).

In 1671 Jane Sharp published her book, *The Midwives Book: Or the Whole Art of Midwifery Discovered* (Sharp, 1999). There is a dramatic change in the way the mother's body is portrayed. Her comments contrast with those made by her male counterparts, such as by Hugh Chamberlen who, in *The Accomplisht Midwife* (1673), describes the womb "as a Dungeon, wherein he [the baby] hath been a long time inclosed" (Mauriceau, 1673, p.353). This is in strong contrast to the description in *Trotula* of the foetus being "expelled from its bed" by the force of nature (Green, 2002, p.79). The pleasure of copulation is also described as a necessity, "without which it would be impossible for a Man (so divine an Animal) born for the contemplation of heavenly things, to joyn himself to a Woman in regard of the uncleanness of the parts and of the act" (Mauriceau, 1673, p.26). In contrast, Jane Sharp insists that "we women have no more cause to be angry or ashamed of what Nature hath given us than men have" (Sharp, 1999, p.32). Hobby (2001) says Jane Sharp's book provides a compendium of current beliefs concerning reproduction and childbirth, but also indicates the author's ironic perception of the misogyny that underpinned accepted ideas about the female reproductive body (Hobby, 2001). One can see how, when obstetricians came to dominate birth, this pathological view of a woman's sexual organs

would lead to a surgical response. Green (2002), when explaining why *Trotula* described the body and disease differently from contemporary medicine, states:

These societies saw a different body than we do, not necessarily because the physical body itself differed significantly, but because their intellectual structures of explanation and their social objectives in controlling the body differed (Green, 2002, p.1).

Jane Sharp advises that using “the Eagle-stone held near the privy parts will draw forth the Child” (Sharp, 1999, p. 152). Jane Sharp also warns against “violent drawing forth the child” and the fact that the “privy parts and Genitals of the mother be so torn that her Urine and excrements come out against her will” (Sharp, 1999, p.150). She also advocates a bath for a woman great with child that contains bags of herbs boiled well in water and held against her navel and private parts. After this she is to anoint “her back, her belly and secrets¹⁰” (Sharp, 1999, p.141).

Other midwives, such as Elizabeth Nihell and Sarah Stone, wrote about their practice in direct response to the rise of the Man-Midwife. The political motivation is evident in their work. English midwife, Elizabeth Nihell, wrote a vitriolic treatise on the subject in 1760, titled: *A treatise on the Art of Midwifery; Setting Forth Various Abuses Therein, Especially as to the Practice with Instruments* (Nihell, 1760). Sarah Stone wrote a similar treatise in 1773, titled: *A Complete Practice of Midwifery* (Stone, 1773). Both midwives spend almost no time on descriptions of care for women experiencing normal childbirth, concentrating instead on describing care for the most complex of cases such as, “The delivery of a Woman in a violent Flooding (haemorrhage) and her Child dead” (Stone, 1773, p.3).

Sarah Stone describes her reasons for writing a book on midwifery:

Wherefore is my intention (with God’s assistance) to instruct my sisters of the profession; that it may be in their power to deliver all manner of Births, with more ease and safety, than has hitherto been practiced by Many of them, and without

¹⁰ ‘Secrets’ are the genitals (Sharp, 1999).

exposing the lives of their young Women and Children to every boyish pretender (Stone, 1773, p.14).

Elizabeth Nihell is also equally frank with her reasons for writing her book:

The truth is, that my very natural and strong attachment to the profession, which I have long exercised and actually do exercise, created in me an unsuppressible indignation at the errors and pernicious innovations introduced into it, and every day gaining ground, under the protection of Fashion, fostering a preference of men to women in the practice of midwifery: a preference first admitted by credulous Fear, and admitted without examination, upon the so suspicious recommendation of those interested to make that Fear subservient to their selfish ends (Nihell, 1760, p.ii).

It is a sad reality that very few midwives could or would write about their everyday practices. Siegemund, we are told, was the daughter of a Lutheran pastor to whom she owed her ability to read and write (Siegemund, 2005). Other midwives, who did write, like eighteenth century midwife Martha Ballard, were more caught up with the social detail, the biological events fading into the background (Ulrich, 1990):

A description of childbirth taken from Martha Ballard's Diary could not include anything so precise as the dilation of the cervix or the extraction of the afterbirth. Nor would it focus on the three stages of labour easily recognizable to twentieth century women in the eighteenth century distinction between "grinding or preparing pains," "forcing pains," and "grumbling pains." The diary description would have three stages, but they would be defined in social rather than biological terms, each marked by the arrival of attendants-first the midwife, then the neighbourhood circle of women, finally the afternurse (Ulrich, 1990, p.183).

Willis describes the decline of midwifery from the seventeenth century onwards and says it had in part to do with the fact that the status of medicine was rising as the process of professionalisation got underway:

Midwives by contrast had no society and no journals, and most midwives had to work very long hours to make even an adequate living and few could have the education or leisure necessary to organize themselves for the improvement of the general body. The status of the occupation had thus declined; indeed in the Victorian age with opposition to employment for middle class women, a stigma became attached to the name 'midwife', a term which scarcely be mentioned in polite company as it alluded to matters associated with sexuality and reproduction which were taboo (Willis, 1989, p.97).

The lack of written knowledge by midwives meant that many of their practices disappeared with them. Midwives leave us with descriptions of the management of highly complex births in the seventeenth and eighteenth century, for political reasons. The prudishness associated with female sexuality and reproduction meant that even those who did write about their practice, such as Martha Ballard, did not provide intimate detail lest it offend the sensibilities of those of her time.

2.4 The writings of Man-Midwives

In 1760 John Harvie, one of the famous, English Man-Midwives, published his *Practical Directions shewing a method of Preserving the Perineum in Birth and delivering the Placenta without Violence* (Harvie, 1967). Once again his directions for preserving the perineum date back to the time of Trotula and even Soranus (Graham, 1950). His instructions are, however, more explicit than any earlier author, and actually mention warmth being applied to the perineum:

So, soon as the vertex of the child's head begins to push into the os externum (vulva) it must be allowed to advance in a slow and gradual manner by the action of the labour pains. To do this properly, the accoucheur having directed his patient to lie down upon the bed in the usual position, every pain must be attended to; and as soon as the pain has acted long enough to render the perineum tight, the further action of that pain must be totally prevented by the palm of the left hand applied

over a warm clean cloth against the perineum with a proper force (Harvie, 1967, p.294).

Meanwhile, Sir Fielding Ould altered care of the perineum dramatically in 1742 when he gave the first description of the episiotomy. Whilst no doubt this practice was used only occasionally at first, eventually it became the most common form of obstetric surgery (Kitzinger & Simkin, 1984). Perineal care now moved clearly away from prevention of perineal trauma into deliberate surgical intervention:

It sometimes happens, though the Labour has succeeded so well, that the head of the Child has made its Way through the Bones of the Pelvis, that it cannot however come forward, by Reason of the extraordinary Constriction of the external orifice of the Vagina; so that the Head after it has passed the Bones, thrusts the Flesh and Integuments before it, as if were contained in a Purse; in which condition if it continues long, the Labour will become dangerous, by the Orifice of the womb contracting about the Child's Neck; wherefore it must be dilated if possible by the fingers, and forced over the Child's Head; if this cannot be accomplished, there must be an Incision made towards the Aus with a Pair of crooked Probe-Scissors. The Business is done at one Pinch, by which the whole Body will easily come Forth (Ould, 1742, pp145-6).

2.5 Upright birth to supine birth

It is interesting to note that the move from women giving birth in upright positions, to giving birth in a supine position, meant the perineum also became more visible and readily a site of surgical intervention. The private perineum now becomes public property. In the ancient texts, such as *Soranus' Gynecology* the midwife is explicitly instructed to:

... beware of fixing her gaze steadfastly on the genitals of the labouring woman, lest being ashamed, her body become contracted (Temkin, 1956, p.75).

When Soranus describes the preparation for the birth on the birth stool, he says:

Furthermore it is proper that the face of the gravida should be visible to the midwife who shall allay her anxiety, assuring her that there is nothing to fear and that delivery will be easy (Temkin, 1956, p.74).

With the advent of the man-midwife and the increasing pressure women received to give birth in a supine position, we see the now very visible perineum becomes a focus of fear and intervention. Sir Fielding Ould's description of the head bulging against the perineum as, "if contained in a purse" is consistent, argues Murphy-Lawless, with a woman giving birth in a supine position (Murphy-Lawless, 1998).

Charles White, in 1772, published, *A Treatise on the Management of Pregnancy and Lying-In-Women, and the Means of Curing, but, more especially of Preventing the Principle Disorders to which they are Liable*. He advocated the use of upright positions for labour but strongly discouraged their use for birth. Here we see the steady move away from active birth to medicalised birth:

I would by no means advise that the child should in any case whatever be borne or the placenta extracted in any of these positions. Very easy deliveries, especially in such positions, are often of dangerous consequence, frequently occasioning lacerations of perineum and sphincter ani, prolapsus of the vagina and anus, inversion of the uterus, retention of secundines, flooding, after pains, syncope, faintings and death itself (Graham, 1950, p.379).

In 1900, the popular *King's Eclectic Obstetrics*, widely used in America, was still strongly discouraging of alternative birthing positions, even the commonly used left lateral position –the real reason being the doctor's comfort.

Females, generally, will assume the position recommended by the physician, but where they obstinately prefer a certain position, and it is immaterial, so far as the delivery is concerned, it is better to allow them their own way. Lying upon the left side, with the knees flexed, and a pillow placed between them, is the position most generally recommended in this country and England; but I do not think that the delivery proceeds with so much ease and rapidity, nor is it so convenient for the

practitioner in every respect, as when the female is placed upon the back (Wintermute, 1900, p.301).

By the end of the nineteenth century all sorts of metal contraptions were being invented for restraining or moving the mother into convenient positions for the obstetrician to deliver the baby. The twentieth century saw the introduction of delivery tables with lithotomy stirrups, handcuffs and shoulder restrainers to immobilise the woman on her back and sterile drapes, which isolated the upper part of the woman's body from the obstetrician's working end so that the baby could be born through a hole in the sheet (Kitzinger, 1997, p.213). These artefacts of the industrial revolution reduced further the woman's ability to move about and also reduced the need, or indeed the ability, for carers to touch the labouring woman (Kitzinger, 1997).

In *King's Eclectic Obstetrics* (Wintermute, 1900) the compress is present but has an entirely different function from that previously described. It moves from a means to care for and protect the woman to a means of protecting the accoucheur's sterile hand. Here we see the clear transition from a social model of care to a surgical one.

It is frequently the case, that an evacuation of the rectum occurs with the expulsion of the head, but the compress at the perineum serves to protect the hand of the accoucheur from being soiled by it (Wintermute, 1900, p.303).

The pathological perineum is now established, and social support and care are being rapidly lost. It will only be a short time before surgical intervention becomes the mainstay of birth management.

2.6 The pathological perineum

In the much-read book *Episiotomy and the second stage of labour* (Kitzinger & Simkin, 1984), the authors point out that the basic management of the second stage of labour, was established during the 1920s and has remained virtually unchanged and largely

unquestioned since. Today, thankfully, it is being questioned and many practices, such as routine episiotomy, are no longer routine in many countries.

Perhaps the most concerning development in the management of the birth was the combination of all the technologies of the past 200 years, episiotomy, forceps and anaesthetic. Joseph DeLee was a prominent Chicago obstetrician in the early twentieth century and laid the groundwork for modern-day obstetrics in America. He proposed eliminating the second stage by routinely using episiotomy and forceps under general anaesthesia (Simkin, 1984). DeLee referred to the foetal brain as suffering prolonged pounding and congestion (DeLee, 1920).

Labour has been called, and is believed by many to be, a normal function... and yet it is a decidedly pathologic process. If a woman falls on a pitchfork, and drives it through her perineum, we call that pathologic-abnormal, but if a large baby is driven through the pelvic floor, we say that it is natural, and therefore normal. If a baby were to have its head caught in a door very lightly, but enough to cause cerebral haemorrhage, we would say that is decidedly pathologic, but when a baby's head is crushed against a tight pelvic floor, and the haemorrhage in the brain kills it, we call this normal... In both cases, the cause of the damage, the fall on the pitchfork and the crushing of the door, is pathogenic, that is disease producing, and in the same sense labor is pathogenic, disease producing, and anything pathogenic is pathologic or abnormal (DeLee, 1904, p.34).

Another prominent American obstetrician R.H. Pomeroy referred to the child's head as, 'a battering ram wherewith to shatter a resisting outlet. Why not open the gates and close them after the procession has passed' (Pomeroy, 1918, p.4).

William's Obstetrics resurrected the description of a child's head as a battering ram in 1950 and continued to use it for the next six editions. Shortening the second stage seems to have arisen because of fears over what impact this would have on the baby (Fisher, 1984). It seems this concern about the impact of birth on the baby added to the alarming rise in episiotomy.

It has been observed that the rise in episiotomy in the USA mirrored the move from birth at home to birth in hospital (Thacker & Banta, 1983). In the USA in 1930, approximately 25% of women gave birth in hospital, compared with 70% in 1945. The rate of episiotomy reflects this move. From 1940 to 1980 episiotomy came to be considered as routine and necessary and “too minor an issue for serious medical attention” (Klein et al., 1992).

An exception to this thinking was a remarkable female obstetrician, who in 1957 published a paper called, *The Normal Second Stage of Labour: A Plea for Reform in Its Conduct* (Beynon, 1957). Using the principles of a quality seamstress, and the analogy of an arm being pushed hurriedly through a sleeve, thereby causing it to tear, she advised not forcing the foetal head hurriedly through the vagina. She took one hundred consecutive cases under her care and had the midwives give them no advice to push, but to follow their natural urges. She compared the outcomes with another 393 primigravid women having normal vaginal births occurring over the same period. The rate of episiotomy in her study fell to 39% in the non-pushing group, while it was 63% in the controls. Her calls for reform were ignored for another 25 years, perhaps because she used domestic, female analogies that would have been considered unscientific by the medical fraternity of the time. It was not until the 1980s that women’s voices were heard again in research, when Kitzinger undertook a study with the National Childbirth Trust into women’s experiences of episiotomy (Kitzinger & Walters, 1981). At this time the popular USA textbook *William’s Obstetrics* devoted no space to a consideration of the indications for episiotomy or its risks, or to methods of protecting the perineum and avoiding episiotomies or tears. The authors unquestioningly endorse the current approach to second-stage care with the statement:

It can be said with certainty that, since the era of in-hospital deliveries with episiotomy, there has been an appreciable decrease in the number of women subsequently hospitalized for treatment for symptomatic cystocele, rectocele, uterine prolapse and stress incontinence (Pritchard & MacDonald, 1980, p.430).

Today, fears evident in the 1980s over the impact of the second stage on the pelvic floor morbidity are consistently raised in the literature (Thornton & Lubowski, 2006). While

midwives try to balance the argument as best they can (Homer & Dahlen, 2007) (Appendix 2), the dominant authority of medicine seems to be powerfully persuasive. We have moved from the woman's perineum as potentially harmful to her baby to being potentially harmful to herself. Both belief systems have pathologised the perineum and the process of giving birth and led to extraordinary surgical interventions such as episiotomies, elective forceps and now elective caesareans, all without evidence to support their routine use. The term 'perineal bypass' (caesarean), which has been coined this century, illustrates this. Comments by prominent UK obstetricians, such as Nicholas Fisk, that "if you drink-drive or you ride a bike without a helmet the risk is much lower than with a vaginal delivery" (Kerin, 2001, p.3), add to this distrust of the birth process. Phillip Steer, another prominent obstetrician, sees birth as a battle between the mother and the baby:

The scene is set for a competition between the fetus and the mother ... It is inappropriate to see human labour as a harmonious process which, because 'natural,' should always go well unless there is disturbance by some external agency. Mother and fetus do have a mutual stake in a successful outcome, but sometimes one will win an advantage to the detriment of the other. Labour should instead be seen as an imperfect solution to a complex problem, and one which is still evolving (Steer, 1998, p.1053).

Modern medicine is interventionist by nature. It seeks to cure rather than prevent, to engineer rather than heal (Chamberlain, 1981). The mother's body always has, and potentially always will be, a battleground where those with different ideologies wage war. Evidence seems secondary in this Herculean battle, and even worse, women's voices often seem irrelevant. The surgical model soon dominated the social one, when it came to perineal care.

2.7 The perineum as a surgical site

With the advent of asepsis in the twentieth century, one could argue that the perineum came to be considered a surgical site, with the warm compresses and traditional massages replaced with green drapes, chlorhexadine swabs and the episiotomy scissors, such as are

described in the book *A Midwife's Story* (Armstrong & Feldman, 1986). This book details midwifery training in Scotland in the 1970s.

Her private parts are scrubbed. Her unscrubbed parts are covered with sterile draping. The midwives scrub too: hot water, a soft brush, and iodine for fifteen minutes. We hold our hands up the entire time to keep the soiled water from dripping back onto them. Assistants help with the gowns and we dive our hands upward into sterile gloves. Then we set up the sterile trolley: Forty instruments in order: And if we fail to do that just so, then, yes, everything comes apart again, never mind the woman having a baby. No one asks what one is to do if it is a choice between the sterile trolley and the life of the baby. The idea is not to deliver babies but to become a perfect mechanism in the delivery room (Armstrong & Feldman, 1986, p.22).

With the advent of asepsis, Shorter estimates that the risk of death from puerperal fever after a hospital birth fell by six times between 1870 and 1939, after which time the risk of infection in hospital evened out to the same level as a homebirth setting, if sepsis from abortions was excluded (Shorter, 1991). The final dramatic downturn in maternal death from puerperal fever came following general improvements in women's health, the standard of living and the introduction of sulphonamides into hospital practice by 1936 (Murphy-Lawless, 1998).

The advent of asepsis into childbirth was no doubt one of the greatest discoveries in history. Its contribution to women's health and wellbeing must not be forgotten and never underestimated. However, the elaborate aseptic procedures around birth that resulted, and are still adhered to in many developed countries, should be questioned, as they limit women's freedom to move about and adopt different positions for labour, as well as unnecessarily turning birth into a surgical procedure (Dahlen & Ryan, 2001). Joseph DeLee, the father of modern obstetrics in the United States, devoted six pages of his book, *Obstetrics for Nurses*, to asepsis during labour and one paragraph on care of the labouring woman (DeLee, 1904). Human touch became something to be wary of and he established firm boundaries around the woman that no one should cross.

If the patient, as is often the case, wishes to hold a human hand, have the husband prepare his hands and put on a sterile gown. He may thus help in the labor close up (DeLee, 1904, p.107).

This attitude contrasts strongly with the writings of earlier midwifery texts in which women such as Catharina Schrader (1693 – 1740) show the important role of neighbours and friends in the birthing chamber. “Come let us fetch friends and neighbours. I must help you immediately,” Schrader ordered to one of her patients in 1698 (Schrader, 1987, p.282). In mediaeval times a woman called her ‘god-sibs’ – literally, sisters in God – to nurture her during labour and to care for both her and the baby afterward (Kitzinger, 1997). “These women held and supported her physically, cradled her in their arms, caressed, kissed and stroked her, and used massage to help her through the birth” (Kitzinger, 1997, p.211). This set up strong connections in the community and fostered support for the new mother in the postpartum period. Birth as a social event where one actually had a “duty to one’s neighbours” (Schrader, 1987, p.17) was replaced with birth as a surgical event during which the obstetrician decided who came and went and how they acted in the birth room. The woman remained at an arm’s length from everyone and if she held a human hand it had to be prepared as if for surgery, as described above by DeLee. Increasingly, during the nineteenth century, women in childbirth were isolated from friends and neighbours. With hospital birth that isolation became complete (Kitzinger, 1997)

The ultimate transformation of the perineum into a surgical site came with the advent of perineal shaving. This ritual ridding of pubic hair followed by ritual swabbing and surgical draping of the perineum made the next scene in this surgical drama, the ritual cutting of the perineum, almost expected rather than exceptional. The stage was set and the drama unfolds in accordance. Feminist writers allege that men rewrote the obstetric drama to make them the stars instead of women (Ruzek, 1978).

Kitzinger talks about how women will often reach down to their own perineum to feel their baby’s head or touch themselves. When the sterile area is guarded fiercely, the woman’s

hand has been reportedly slapped, as she reaches down and contaminates the obstetrician's sterile area (Kitzinger, 2000). She writes:

When an obstetrician isolates and exposes a woman's vulva it becomes ritually separated from that part of her body, which she herself is allowed to control.

Transformed into a sterile field it is out of bounds to her own touch. The sterile field – not, in fact, sterile because of juxtaposition of vagina and anus – is an obstetric fiction by which the woman's genital area is depersonalized and de-sexed (Kitzinger, 2000, p.4).

The move to asepsis at birth had the effect of changing the way women were touched, cared for and interacted with during birth. For example:

In the process of creating a sterile field, the medical model separated the woman from her perineum. Doctors treated a sterile vaginal area on a level devoid of the human element and inherent emotions (Harper, 1994, p.70).

Kitzinger (2000) argues that doctors added to the risk of maternal death, due to the way they practised using instruments such as forceps. This added to the risk of puerperal sepsis due to maternal tissue trauma (Murphy-Lawless, 1998). When midwives assisted with birth they generally relied on encouragement and emotional support, helping the mother change position and move about, applying cold and hot compresses and giving herbal medications and massage. They rarely put their hands inside to turn the baby's head and when they did it usually did not involve instruments.

During the Perineal Warm Pack Trial, which was undertaken for this thesis, the issue of asepsis was raised by midwives who began to question the ritualistic swabbing, draping and gowning procedures they undertook for birth. A quality improvement activity was undertaken at the hospital over six months in 2000, and swabbing draping and gowning was abandoned for normal vaginal birth with no adverse outcomes in terms of infection rates and a cost saving of A\$25, 211 per year resulted (Dahlen & Ryan, 2001). This change in practice returned the focus of the midwives to the woman in the second-stage rather than on the sterile procedure. It is interesting to note that in environments supportive of natural

birth, such as birth centres and home birth, that rituals around sterile set-up for normal birth are almost absent and the use of warm packs more common. In Royal Prince Alfred, one of the two hospitals in which the Perineal Warm Pack Trial took place, there was no swabbing, draping and gowning in the Birth Centre and warm packs were used as part of second-stage care. Three floors above the Birth Centre, in the Delivery Ward, swabbing, draping and gowning was a complex ritual and warm packs were not used as part of second-stage care. Some of the midwives in the Delivery Ward had not even heard about perineal warm packs, despite the fact they were used by their own colleagues three floors beneath them in the same maternity unit. Rituals such as these serve to redefine care and alter relationships and practices in ways of which clinicians are so often unaware.

Asepsis was not, however, the final influence in changing the social model of perineal care to a surgical one. Pain relief for childbirth was an influencing factor that needs to be taken into consideration.

2.8 Pain relief and perineal care

The easing of pain had been a dream of mankind since the beginning of time (Graham, 1950). Some anthropologists maintain that the first primitive societies were matriarchal and the first great healer was the Great Mother (Gould Davis, 1971). This woman was priestess, sorceress, healer and midwife and was called upon to relieve those pains that did not disappear under the influence of the simplest remedies. Cold water from the lake eased some pains, while others responded to sunlight or to heat (Graham, 1950). The Greeks and later the Romans used all kinds of local anaesthesia. The stone of Memphis was applied to a painful part and then covered with vinegar. The stone was said to make flesh numb and insensible to pain (Graham, 1950). Mediaeval midwives used the lode stone to draw the baby and placenta out and speed the labour up and ease pain (Chamberlain, 1981). A heated stone is still used in many societies, applied to areas that are painful in order to draw out the pain.

Christianity reinterpreted the pain of labour as part of the wages of sin, for which the woman always paid. By 1847, James Young Simpson was writing about using chloroform on women in labour. It became increasingly popular after Queen Victoria used it for the birth of Prince Leopold in 1853, thereby overcoming the argument that a woman should suffer in childbirth as recompense for Eve's sin (Graham, 1950). Obstetricians took up the use of chloroform one after the other, even observing, as Isaac Baker Brown did, that a ten-minute administration of chloroform would allow the most rigid perineum to relax and dilate so a child's head could be born without tearing the mother's perineum (Graham, 1950). In 1889, De Wees wrote an article about the relaxing effect of chloroform on the perineum (De Wees, 1889). Twilight sleep¹¹ followed in the early 1900s, but the disadvantages eventually made this a practice of the past. Nitrous oxide, pethidine and epidural anaesthesia became other options women would use over the next century.

Midwifery writers have argued that control over the provision and use of pain-relieving drugs was one of the ways in which the medical profession effectively colonised birth within the precincts of the hospital (Hunt & Symonds, 1995). The medical profession in the UK, through the Royal College of Obstetricians and Gynaecologists (RCOG), resisted any moves to allow midwives to administer chloroform, whilst at the same time officially endorsing the extension of pain relief to all women in 1945 (Hunt & Symonds, 1995). The surgical drama was now complete. Women were hospitalised, put into supine positions, and anaesthetised, often unable to push their babies out. Their perineums were shaved, swabbed and draped ready for the surgery that inevitably followed. Perineal care had moved from a social response to a surgical one.

By the end of the nineteenth century, the natural methods of pain relief were all but forgotten. They resurfaced again through the writings of anthropologists and eventually practices, such as perineal warm packs, made their way back into the alternative birth practice and literature in the late 1970s (see Chapter 3).

¹¹ Twilight sleep was a combination of morphine and scopolamine that was intended to produce pain relief and loss of memory. This often completely incapacitated women, causing them to lose control and many were strapped to their beds so they didn't injure themselves.

2.9 Epidural anaesthesia and the perineum

I read in a Readers Digest some months ago of a painless childbirth, which had been successfully introduced in America. An injection in the spine I believe. Why can't something of this kind be brought into this country and within the scope of all mothers? (Mass Observation, 1945).

Today epidural anaesthesia has a significant impact on the care provided to women during the second stage. In Australia no national data are available on the numbers of women who have an epidural, as this is not uniformly collected or reported. The latest data from one State (New South Wales) indicates 21.6% of women have epidural analgesia (range 0% to 54%) (NSW Health, 2007).

The evidence related to epidural anaesthesia is compelling. Evidence from eleven trials involving 3,580 women shows the association between epidural use and longer second stages (Anim-Somuah, Smyth, & Howell, 2005). Seventeen trials involving 6,162 women showed the risk of an instrumental delivery was also increased with epidurals (Anim-Somuah et al., 2005). It has been established that instrumental birth leads to overall increased pelvic floor morbidity. The incidence of severe perineal trauma is increased with instrumental birth (Dahlen et al., 2007) particularly where a midline episiotomy is used (Kudish et al., 2006). In a systematic review of the unintended effects of epidural anaesthesia (Lieberman & O'Donoghue, 2002) the authors say that because existing data indicates an increase in instrumental birth when epidural is used, and severe perineal trauma is increased with instrumental birth, it is likely that increased epidural rates will be associated with increased perineal trauma. Their review identified six studies, which examined severe perineal trauma. Five of the six studies showed a twofold increase in perineal laceration associated with epidural use. Robinson studied 1,942 full-term, primiparous women and found that the association between epidural and severe perineal trauma remained significant in a logistic regression analysis controlling for potential confounding factors (OR¹², 1.4; 95% CI¹³ 1.0 to 2.0) (Robinson, Norwitz, Cohen,

¹² OR is Odds Ratio

McElrath, & Lieberman, 1999). They also classified women into four categories by method of delivery (spontaneous or instrumental) and use of episiotomy (yes/no). Both episiotomy and instrumental delivery were more frequent in women receiving an epidural and when these two practices were taken into account there was no association. Thus epidural use is associated with an increase in severe perineal trauma, but it is mainly due to the increase in instrumental births and thus episiotomy (Lieberman & O'Donoghue, 2002). This is a demonstration of the cascade effect associated with epidural anaesthesia. Potentially harmful practices in labour, such as directed pushing in the second-stage and non-upright birth positions, are more likely to occur when a woman has epidural anaesthesia. This is discussed further in Chapter 4.

The widespread use of epidural anaesthesia has meant the move from a social to a surgical model of perineal care was increasingly rationalised, as intervention in the second stage became more necessary.

2.10 Anthropology

Anthropological writings provide us with some useful glimpses into the use of warm packs as part of the birthing practices in other countries. These insights help inform our own practice as midwives. Midwives have gained knowledge from reading about and working with women from other cultures and countries. Ina May Gaskin developed the Gaskin manoeuvre (hands and knees position) for shoulder dystocia after spending time with Guatemalan midwives who advocated the method (Bruner, Drummond, Meenan, & Gaskin, 1999). This, incidentally, is the first manoeuvre in history to be named after a midwife. It is often in looking at so-called 'primitive societies' that we glimpse the past, a past in which birth was the domain of women and midwives, and a social model prevailed.

Kitzinger describes the use of massage and warm compresses during the second stage amongst Jamaican women.

¹³ CI is Confidence Interval

Nanas advise their clients to walk around during labour and the two women together light the stove, fetch water and set it to boil, make the bed up with newspapers, tear up rags in which to wrap the baby ... During contractions in the late first stage the nana massages the mother's lower abdomen and sometimes in the second stage massages the perineum, with olive oil or castor oil or the oil from toona leaves. Hot compresses are also used (Kitzinger, 1982, p.192).

A comparison of practices and beliefs of traditional birth attendants in Africa, Asia and Latin America revealed a large variation among the different cultures of the three continents, yet surprisingly, in spite of cultural differences there were some common practices and beliefs which appeared to occur in all three continents (Lefebber & Voorhoever, 1997). Common practices observed in the second stage included lubricating the perineum with oil and a compress pressed against it for support during the expulsion of the child (Lefebber & Voorhoever, 1997).

The Mansi, an endangered indigenous people living in Khantia-Mansia (in Russia), are known to hold a clod of earth firmly against the perineum during the birth (Dunham et al., 1991). In central Africa, a woman might give birth outdoors sitting on a skin placed over a mound of sand, which moulds itself to her body and supports her perineum (Kitzinger, 2000). Other African women rock on all fours over a trench filled with smoking herbs under their perineum (Kitzinger, 2000). In South Africa a woman may kneel with her legs wide apart, with her heels supporting her perineum (Kitzinger, 2000).

In East and West Africa, the midwife often uses a foot to provide firm pressure, while in Sierra Leone and among the Kaguru of East Africa the midwife sits facing the mother and supports her perineum with her big toe as the baby's head descends (McCormack, 1982). In India, the midwife may use her foot to guard the perineum (McCormack, 1982).

The Tiwi of northern Australia press heated leaves in the small of the woman's back, between her legs and over her lower abdomen (Goodale, 1971).

Where water is available, midwives often use it to ease pain in the form of hot compresses, but water birth, or immersion in a birth pool, is a modern invention. The desire for warmth continues after the birth in many cultures with fires lit, hot compresses and heated stones applied to the uterus and smoke used to help the perineum heal (Kitzinger, 2000).

It is evident from anthropological and ethnographic writings that the social model of perineal care, involving comfort and support, was and is dominant in much of the developing world where traditional models of birth still dominate. This gives us a glimpse into the past when birth occurred at home and midwives presided, prior to the medicalisation of childbirth.

2.10.1 Birth rituals

Birth is one of those life events, which is surrounded by rituals and practices, characterised by the term 'rite of passage' (Lomas, 1978). Critics such as Bolande, who argued that the external genitalia are a special target of ritual surgery, whose aim is to produce benefits separate from physical health (Bolande, 1969), have interpreted surgery within this context. Rituals often develop in different cultures around critical transitions in life, such as during pregnancy and birth, and they may well be a socially acceptable means of dealing with deep-seated, primitive fears and impulses that might otherwise induce great conflict and anxiety (Bolande, 1969).

Social rituals that supported and comforted the mother during birth were replaced during the last century with surgical rituals stemming from a view that the perineum was a pathological entity in need of expert surgical intervention, firstly to protect the baby and then the mother. With the advent of the active birth movement in the late 1970s and 1980s we see an attempt at reclamation of the perineum from the surgical rituals that surrounded it. The re-emergence of methods of perineal protection and comfort once more appear in the literature and this is discussed in the following chapter. One could argue a dichotomy now exists between two models for perineal care during labour and birth; one a social model mainly promoted by midwives in which preservation and comfort are the aim and

the other a surgical model, mainly promoted by obstetricians, in which pathology is anticipated and surgery is seen as a necessary response in order to protect the mother. Perhaps most concerning is the recent trend of masking the surgical model with a social one, found most obviously in the so called 'natural caesarean' advocated by Professor Nicholas Fisk and described in an article in the UK paper *The Guardian*:

The scent of lavender fills the air and classical music is playing quietly. On the bed, Jax Martin-Betts, 42, is calm focused and in control. With the birth of her second child just minutes away, the midwife Jenny Smith is giving her a massage. Her husband, Teady McErlean, is whispering words of encouragement: just a tiny bit longer, and our baby will be in our arms. It could be a natural birth at any maternity unit in Britain, be we are in an operating theatre at Queen Charlotte's and Chelsea hospital in west London, and the birth we are about to witness sounds like a contradiction in terms: a 'natural' caesarean section (Moorhead, 2005).

Perhaps this is the ultimate example of men rewriting the obstetric drama to make them the stars instead of women (Ruzek, 1978) but it involves disguising the surgical model with an illusion of the social model.

2.11 'Old wives' tales' and midwifery knowledge

The essence of the human being is to take two concepts which are themselves abstract, then put them together to form a new abstract concept which is unlike the two original concepts (Thomas Aquinas).

As discussed in the introductory chapter, an obstetric colleague on seeing me apply perineal warm packs one day, mockingly scoffed, 'old wives' tales.' His comment, "I thought you girls would have come out of the Ark by now," as he laughed and picked up the episiotomy scissors, offended me and made me reflect for a long time afterwards. Why were my attempts to minimise perineal pain and trauma dismissed as so inferior in comparison to his decision to surgically inflict pain and trauma? Despite the evidence already available questioning the use of episiotomy, he still felt his knowledge and technical expertise gave

him superiority over my knowledge and lack of technology. While I felt insulted by the comment, as was his intention, I also rationalised that I should not feel insulted, for this was women's knowledge, so often dismissed or reinterpreted by men. The term 'old wives' tale' has been used several times in discussions and interactions regarding perineal warm packs during this study. What does it mean and where do 'old wives' tales' sit in popular thought?

An 'old wives' tale' is wisdom, like an urban legend, supposedly passed down by old wives to a younger generation. Also known as folklore and mythology, they often originated due to detection of actual associations between seemingly unrelated events. They then became perpetuated through oral traditions (Chamberlain, 1981). Folklore and mythology were often used to interpret processes in human life that seemed mysterious. The term 'old wives' tale' alleges the lack of sophistication of old wives. It ridicules what is often women's knowledge. Just as the word 'crone' was once used to describe a woman who had passed menopause, it has now become a disparaging term like 'old wives' tale.'

'Old wives' tales' often concern pregnancy and birth and are generally ridiculed by the scientific community. Those who hold them through personal experience often validate these beliefs and/or testimony and they are perpetuated by oral traditions, often through the telling and retelling of stories by older women to younger women (Newman, 1969). As already discussed, midwives have a strong oral tradition as a profession, handing down stories through the generations from midwife to midwife.

The history of obstetrics is a record of men's struggle to construct a system of scientific certainties on which the management of labour can be based, and to eliminate women's inconvenient emotions, their 'old wives' tales', and the passion of birth giving (Kitzinger, 1988).

Pregnancy has many 'old wives' tales' associated with it. These have been perpetuated across the centuries and remain in use today (Costigan, Sipsma, & DiPietro, 2006) (Goldfarb, 1988) (Mazzoni, 2002). It has been argued recently that particularly persistent folklore warrants careful study (Costigan et al., 2006). Studies examining the 'old wives' tales' around predicting foetal sex, such as whether a woman is carrying her foetus in front

or across the hips, have been shown not to be predictive (Perry, DiPietro, & Costigan, 1999). On the other hand, a recent study carried out by some of these same authors demonstrated that heartburn severity was associated with babies with average to above average amounts of hair compared to women not experiencing heartburn. They concluded that there was a shared biologic mechanism involving a dual role of pregnancy hormones in both the relaxation of the lower oesophageal sphincter and the modulation of foetal hair growth (Costigan et al., 2006). This seemingly implausible explanation has been the source of ridicule. In the 1950s women were admonished to, “listen to your doctor instead of sewing circle fantasy” (Dorson, 1955). This attitude persists today.

2.11.1 Lessons from Freud

In Freud’s *Introductory Lectures* he tells of how he came to theorise that the act of being born is the source of anxiety (Freud, 1999). Freud says that speculation had a small part to play in his discovery and that he borrowed from the naïve popular mind. What he did, in fact, was take midwifery folklore and turn it into medical knowledge. He tells the story of when he was a medical student and was at lunch one day and overheard the ‘comic’ story of a pupil midwife taking an examination, who was asked what it meant if meconium was present when the membranes ruptured. She replied that it meant the child was frightened. This provoked much laughter and she failed her examination. Freud sat and listened to this story and later he wrote:

But silently I took her side and began to suspect that this poor woman from the humbler classes had laid an unerring finger on an important correlation (Freud, 1999, p.445).

Murphy-Lawless, in her book *Reading Birth and Death: A History of Obstetric Thinking*, comments on this story and says:

Note that the young midwife’s knowledge is considered naïve, that is scientifically unproven and therefore unacceptable and that is derided by the those medics who hear it, with the exception of Freud, who at least has the grace to admit from where he takes the observation, which in his hands then becomes authoritative. The

concepts then passes on into obstetrics also ... Meconium becomes an important indicator of foetal distress, it gets broken down into categories and grades of viscosity and colour as a fine-grained measure of distress (Murphy-Lawless, 1998, pp.230-231).

In the hands of obstetrics the management of babies born following the appearance of meconium stained liquor has gone through many invasive practices, such as squeezing the chest of the baby at birth to stop breathing, suctioning all babies on the perineum and viewing all babies' vocal cords for evidence of meconium 'below the cords'. Modern obstetric practice includes induction of labour for meconium seen on the ultrasound, which in itself is so unreliable to be almost laughable (private communication). In 2004, a large randomised trial demonstrated that there were no benefits to routine suctioning of infants before the delivery of the shoulders (Vain et al., 2004). International guidelines on neonatal resuscitation have now changed to reflect this evidence. Between Freud's realisation and the 2004 Argentinean trial, much unnecessary and potentially harmful intervention took place.

The student midwife in Freud's story would in all reality have had this pregnancy folklore passed down to her from midwives with whom she worked. These women had watched and noticed that babies born following the sighting of green liquor were more likely to be distressed after birth. These women probably took the appearance of meconium as a sign they should be more vigilant during the labour and birth. This is in fact the safest way to respond to the appearance of meconium stained liquor. Murphy-Lawless says:

The grounding of the masculine vision and the excluding of the 'feminine' critically forecloses our subjectivity (Murphy-Lawless, 1998, p.231).

2.11.2 Authoritative Knowledge

When more than one knowledge system exists, one kind of knowledge gains ascendance (Jordan, 1978). The legitimising of one way of knowing as authoritative often leads to the devaluation of all other ways of knowing (Sargent & Bascope, 1996). This way one system

of authoritative knowledge comes to appear natural, reasonable, and shared (Jordan & Irwin, 1989). People actively engage in the production and reproduction of authoritative knowledge, thus continually reinforcing its validity. While Jordan argues that authoritative knowledge is possessed by those who control the artefacts necessary to accomplish the work, other writers (Sargent & Bascope, 1996) argue that it is also contingent on shared experience and social position. Authority entails some status or position that compels trust or obedience (Starr, 1982).

2.11.3 Reclaiming women's knowledge

Throughout history, old wives have for the most part been middle-aged or elderly women (Chamberlain, 1981). But their age and sex were once virtues and they were consulted for their wisdom, experience, acquired skills and knowledge. Their local reputation came from their success in the area of health care (Chamberlain, 1981). This knowledge was shared in the community and passed on through the generations. In the developed world, 'old wives' tales' have now been largely suppressed under the monopoly achieved by the medical profession and its intellectual hegemony over scientific ideas. Obtaining sources on 'old wives' tales' is difficult because they were often common people, illiterate and not of interest to the intellectual establishment. There are few oral and even fewer written histories that document this amazing wealth of knowledge. Thus putting together this ancient knowledge involves the study of history, literature, art, anthropology, ethnography and scientific evidence in order to capture our rich past. Adrienne Rich sums this up:

With a painful consciousness of my own Western cultural perspective and that of most of the sources available to me; painful because it says so much about how female culture is fragmented by male cultures, boundaries, groupings in which women live. However, at this point any broad study of female culture can at best be partial, and what any writer hopes – and knows – is that others like her, with different training, background and tools, are putting together other parts of this immense half-buried mosaic in the shape of a woman's face (Rich, 1977, p.17).

Old wives played a central role in this female culture described by Rich, but the disparity between the official record and actual experience is enormous (Chamberlain, 1981). Galen (129 – 201AD) may have been the man who coined the term ‘old wives’ tales’ referring thus to traditional medicine as ‘old wives’ tales’, (Chamberlain, 1981). Praise for the work of these wise women was rare in historical records, though no doubt much authoritative knowledge is borrowed from wise women and reinterpreted.

In a popular book published in 1975, an obstetrician wrote that everything women said about birth was a “cartload of rubbish” and warned his readers not to listen “to wicked women and their malicious lying tongues” (Bourne, 1975).

Chamberlain argues that:

Medicine, like war, is an extension of politics. The story of old wives is not a story of inferior practice losing ground with the advancements of medical science and technology; rather, it is a story which concerns the politics of medicine—a story of control and access (Chamberlain, 1981, p.139).

Pliny, better known as Pliny the Elder, lived in Rome in the first century A.D. and thought women healers should be quiet and as inconspicuous as possible, so that after they were dead no one would know they had lived (Chamberlain, 1981). This fits well with his belief that the glory consists of doing what deserves to be written, and writing what deserves to be read.

The origins of ‘old wives’ tales’ are as varied as the tales themselves, for medical ideas and drugs have been exchanged and traded across and within cultures for thousands of years. Medicine is an interplay of pagan ritual, herbalism and outmoded medical orthodoxies, making it hard at times to distinguish between them and ‘old wives’ tales’ (Chamberlain (Chamberlain, 1981). Trotula, whose work in the eleventh century A.D. became the basis for subsequent writings on the matter until at least the seventeenth century, believed babies’ eyes should not be exposed to bright lights (Trotula, 1940). This was incorporated into orthodox medicine in the last century, through the Leboyer method of giving birth with the

lights dimmed in birth rooms. Our knowledge today is a mosaic of many ways of knowing, melded together and presented as best knowledge because of its contemporary nature and because we often cannot envisage anything sound coming from previous generations. Women's knowledge, however, is particularly vulnerable to this sort of judgment. Fundamentally childbirth as a social event was primarily the domain of women and women themselves did not record practices – they passed them down orally through the generations until the seventeenth century. Perineal warm packs are one example of this kind of ancient knowledge almost lost under a dominant medical paradigm.

2.11.4 The politics of knowledge

Midwifery knowledge is often seen as 'old wives' tales' or folklore. This could be partly because much of their knowledge has not been scientifically validated, but it is also because historically women's knowledge has often been seen as less important than men's reality. Yet all knowledge begins with observation and an idea emerges from this observation. Not all knowledge has been scientifically validated in order for it to be accepted as important.

Martin argues that, "it is clear that an idea alone without experiment can change the world in a way that has practical consequences, resulting from the idea itself without any experimental science intervening" (Martin, 2000, p.934). Martin goes on to give examples such as a stirrup designed by a horseman somewhere in central Asia who thought that to put a ring on the end of a rope would help him stay on a horse.

Murphy-Lawless (1998) argues that:

Obstetrics is an utterly social body of knowledge, that is a human activity built on strong feelings, intuitions, prejudice, entrenched positions, considerations of institutional power and high passion, all of which have been an intrinsic part of its reasoning and careful observations as it has lumbered along constructing its theories (Murphy-Lawless, 1998, p.229).

Evelyn Fox Keller (Keller, 1992) argues that neither theories of sciences nor the instrumental outcomes of these theories are without aim or purpose. Therefore, if science chooses to move in certain directions it does so with agendas, which foreclose other agendas and the asking of other questions. Thus the experience of male scientific empiricism counts, while women's experimental empiricism is excluded. Hence the story of the obstetrician laughing while I applied warm packs and producing the episiotomy scissors, clearly superior in his eyes.

2.11.5 Women's knowledge of the second stage

Anderson (2000) argues that very little is known about women's experience of the second stage of labour and what aspects of midwifery care help or hinder them in the process of giving birth. Others argue that the experts mute the voices of women, although only women experience birth (Kirkham & Perkins, 1997). The increasingly technological aspects and professionalisation of childbirth mean that women's experiences are too often neglected (Anderson, 2000b). The second stage in particular is associated with the onset of new and frightening sensations, which appear to follow a predictable pattern. Anderson says women describe sensations such as bulging, cracking, splitting, opening and breaking (Anderson, 2000b). On feeling these overwhelming sensations, women have to overcome a barrier of fear that initially prevents them pushing wholeheartedly. Women describe a sensation of holding back:

For fear of opening their bowels, for fear of their backs cracking in half or their pelvis splitting open, for fear of nobody being there ready to catch the baby, for fear of losing control or for fear of simply more, never ending and worsening pain (Anderson, 2000b, p.93).

The Perineal Warm Pack Trial is one addition to this knowledge. It comes from the ancient knowledge of women, much which has been lost in the past, some of which has survived to the present. By validating the art of midwifery with the science of midwifery and the science of midwifery with the art of midwifery, hopefully this ancient knowledge will be established, incorporated into practice and not lost to future generations of women and

midwives. Page and McCandlish (2006) describe this vital blending of the art and science of midwifery:

In her everyday and intimate connection with birth, a midwife is the guardian of one of life's most important events, for each individual and for society as a whole. Being a midwife, being with woman,' is a privileged role; one which a wealth of art and science, knowledge and expertise, humanity and spirit surround and which combine to bring a unique and irreplaceable approach to care (Page & McCandlish, 2006, p. xiii).

This chapter began with the words, "Nowhere in history do we find a beginning, but always a continuation. How then shall we understand the end, if the beginning remains a mystery?" (Bachofen, 1967). This research has become part of that 'continuation' and has shone a dim but determined light at the past, accepting that the 'beginning remains a mystery' but determined that the future not be constrained by this fact.

2.12 Summary

This chapter has traced the history of perineal care during labour and birth with a particular focus on perineal warm packs. It has also draws on anthropological studies that record perineal care in different cultures to support these historical observations. It has followed the at times vague trails in history to show how the care of the perineum was influenced by ancient beliefs, following a social model of care that generally aimed to protect and preserve perineal integrity. The advent of the man-midwife, asepsis and pharmacological pain relief pathologised the perineum, turning it into a surgical site. The concept of midwifery knowledge as old wives' tales has also been explored. The Perineal Warm Pack Trial is about the validation of an ancient art through science, turning what has been considered an 'old wives' tale' into established midwifery knowledge.

The following chapter will explore the reclamation of the perineum in the late 1970s and re-emergence of protection and preservation of the perineum as a central tenet. This next

chapter also examines the modern-day birthing literature and evidence available on the efficacy of warm packs. The physiological effects of heat are also explored in Chapter 3.

Chapter 3: Contemporary literature on perineal warm packs and the physiological effects of heat

“Although the concept of heat has its roots in our basic sensory awareness and is probably among the most primordial concepts of humankind, its subtlety is such that it has only recently been understood and successfully described in a quantitative manner” (Sekins & Emery, 1990, p.65).

3.1 Introduction

The previous chapter produced an historical perspective on perineal care during labour and birth, with a particular focus on perineal warm packs. It also drew on anthropological studies that record perineal care in different cultures to support these historical observations. A social-to-surgical model of perineal care was proposed. The concept of midwifery knowledge as ‘old wives tales’ was explored; and the way midwifery knowledge is often dismissed as not valid by the dominant medical model was also argued.

In this chapter, the reclamation of the perineum in the late 1970s is explored by reviewing contemporary literature advocating the use of perineal warm packs in the second stage of labour. A review of relevant literature on the physiological effects of heat is also discussed in this chapter.

3.2 Perineal warm packs in contemporary midwifery literature

The principles of physiological management of the second stage began to emerge in the late 1970s, due to an interest in ‘out-of-hospital’ births, midwife-attended births and the increasing numbers of birth centres (Simkin, 1984). Champions such as Frederic Leboyer, Michel Odent, Sheila Kitzinger, Janet Balaskas and many others helped to motivate change

in birthing practices. With a focus on supporting a physiological second stage, ancient practices such as hot compresses and perineal massage re-emerged in writings on childbirth (Epstein, 1977) (Schrag, 1979) (Balaskas, 1983) (Priver, 1984) (Flint, 1986). As described at the end of Chapter 2, a dichotomy exists now with alternative birth models or social model standing in sharp contrast with the traditional medical/surgical model. This becomes very apparent when reading birth preparation books written from the different perspectives of midwives, active birth educators and obstetricians. This is discussed more in this section.

In the late 1970s, the use of hot packs to reduce perineal trauma and improve maternal comfort during the second stage of labour started to be discussed in the literature (Balaskas, 1983; Flint, 1986; Priver, 1984; Robertson, 1997; Schrag, 1979; Simkin & Ancheta, 2003). In 1979, Schrag wrote in the *Journal of Nurse Midwifery* that some attendants advocated massaging the perineum with oil to loosen and relax the tissue while others used warm compresses to relax the perineum (Schrag, 1979). Schrag cited the 1760 writings on perineal care by John Harvie (1967)(Harvie, 1967) and homebirth literature of the time (Epstein, 1977). This appears to be the first time warm packs are mentioned in a professional midwifery journal. Childbirth educators like Janet Balaskas wrote on how to avoid perineal tears:

... if the tissues seem very tight it is very helpful to apply hot towels. A small towel (a good way to break in the new nappies) can be used. Take several and pour boiling water over them in a basin. As soon as they are touchable, wring them out, fold and place over the perineum. This is very soothing and will help to bring blood to the area and relax tissues (Balaskas, 1983, pp.132-133).

Practices such as perineal massage were often advocated in the literature to both women and midwives along with the use of warm packs. It was much later before these two practices were studied separately.

Along with massage, the use of hot, moist compresses held gently against the vulva and perineum provides for excellent comfort and relaxation. In general, the patients prefer as much heat as reasonably possible; none has ever complained about the compresses being too hot! During the final few contractions, the woman will

commonly complain of much burning in the periurethral and clitoral areas.

Applying compresses in these locations is usually quite helpful and well received (Priver, 1984, p.75).

Flint (1986) was a strong and influential advocate of perineal warm packs. She describes the application of warm packs to the perineum as helping to prevent tearing, increase stretching and enhance women's comfort. Flint (1986) wrote:

Another thing which appears to help stretching and to prevent tearing is a hot pad applied to the perineum when it is stretched by the baby's head. The easiest thing to use is a sanitary towel soaked in very hot water. Women seem to find this very comforting even though I use it quite hot (Flint, 1986, p.102).

Simkin (2003), another respected, active birth advocate, recommended as a non-pharmacological physical comfort measure, to "apply a hot moist towel, heating pad, heated silica gel pack, heated rice pack or hot water bottle to lower abdomen, groin, thighs, lower back, shoulders or perineum" (Simkin & Ancheta, 2003, p.167). The authors described how "in the second stage, hot compresses on the perineum enhance relaxation of the pelvic floor and reduce pain" (Simkin & Ancheta, 2003, p. 168).

Avery and Burket (1986) noted in their research into antenatal perineal massage that some midwives used warm packs, which could affect their perineal trauma rates (Avery & Burket, 1986). In this small (n = 20), prospective, randomised controlled trial into perineal massage, the authors found that women who practiced perineal massage at least four times a week had a lower incidence of episiotomy and lacerations than those who did not. The authors describe possible variables in the study as, "some [midwives] will massage the perineum during second stage, some use warm compresses to the perineum, and some use warm oil, to name a few" (Avery & Burket, 1986, p. 131).

Cochrane (1992) stated, "A hot pad applied to the perineum will increase blood flow and tissue elasticity" (Cochrane, 1992, p. 64). Fleming (1993) said many midwives used warm packs to help prevent perineal trauma but agreed that there were no scientific studies had

validated this (Fleming, 1993). Other authors advocate the use of warm packs soaked in ginger root and other concoctions (Tritten, 1995) (Stein, 1995).

Some midwifery texts that are now in the public domain also give very specific instructions for the use of warm packs and whilst advocating the addition of other substances. For example, Davis (1993) states:

One of the most helpful and appreciated techniques is the application of hot compresses to the perineum. These stimulate good circulation, promote relaxation and provide relief from burning, tingling sensations. Use a sterile gauze pad, sanitary napkin, or clean washcloth soaked in a solution of hot water with a squeeze of Betadine or other antiseptic. Hot compresses are especially crucial if the perineum blanches with distension. They are also helpful for mothers who involuntarily contract their outlet muscles (Davis, 1993, p.103).

In a number of popular birthing support books for both women and midwives in Australia, advice is given about using warm compresses in the second stage. One book states:

Warm compresses made from a folded washcloth wrung out in warm water and held against the perineum can be soothing if the stinging is very frightening for the woman and she is holding back (Robertson, 1997, 104).

Women also began to make their wishes known, with consumer groups growing in numbers and influence. However, midwives like Anderson (2000) argued that very little is still known about women's experience of the second stage of labour and what aspects of midwifery care help or hinder them in the process of giving birth (Anderson, 2000b). Midwifery research is now focusing on this neglected area, asking women about their experiences of giving birth. This means their stories are heard and their experiences validated. Here is an example of a woman talking about perineal warm packs:

The stinging feeling and the intense pressure were so overwhelming that I was scared I would tear and I felt as though the baby was coming out of my bowels. I needed reassurance from my midwife that I was pushing properly. She presses a warm nappy against my bottom and then I felt a bit more secure. I am still amazed

that I can go through that and not have a single tear (Bennett, Etherington, & Hewson, 1993, p.236).

Perineal warm packs are also mentioned in contemporary literature on women's health literature and sexuality. This literature is in the public domain and available to both childbearing women and health professionals. Women's health books recommend warm packs as a 'non-surgical' option during childbirth (Crowe, 2002). In *Perspectives on Human Sexuality*, the authors describe the common anthropologic evidence from developing countries supporting widespread use of perineal warm compresses during birth (Bolin & Wheleban, 1999).

As described in Chapter 2, and earlier in this chapter, one could argue that a dichotomy now exists, with alternative birth models or a social model of birth standing in sharp contrast to the traditional medical/surgical model. This becomes very apparent when reading birth preparation books written from the different perspectives of midwives, active birth educators and the more traditional obstetric perspective. For example, popular pregnancy advice books for women, such as the American book, *What You Didn't Think to Ask Your Obstetrician*, assert that, "There is no absolute way to avoid an episiotomy, short of having a caesarean section, but there are some methods to decrease your chances" (Poliakin, 1994, p.227). The authors go on to advocate pelvic floor exercises, perineal massage and warm compresses during the birth as possibly having some benefit (Poliakin, 1994). In the book *Childbirth Doesn't Have to Hurt*, warm compresses are suggested as a way to give comfort during the second stage of labour (Bradford & Chamberlain, 2002).

The more medically influenced birth preparation books do not mention warm packs at all. The surgical model is very evident. When the author (an American doctor) describes what the health professional will do at the birth, the following comment is made:

Sooner or later, either your bed will be converted to a delivery table or you will go to a delivery room. Then awake or asleep, your legs are put into stirrups and, with as much dignity as possible, your bottom is washed with sterile fluids and covered with drapes (Gillespie, 1998, p.230).

There is a dichotomy evident between the 'alternative birth' philosophy and the traditional medicalised approach to birth. Here the social and surgical models of perineal care sit in stark contrast to each other.

3.3 Information on perineal warm packs/compresses on the internet

A search of the internet using the Google search engine and the terms: perineal warm pack and perineal warm compress was undertaken to determine what information the general public could obtain about warm packs. This search revealed an overwhelming number of hits on perineal warm packs as well as the advertisement of many products capable of applying heat to all parts of the body, including the perineum (13,400 results using Google search). An example is given below of the sort of advice given on American websites like *MoonDragon Birthing Services* (Services, 2007), which then gets voted the best answer by those who visit the website, and is posted on a Yahoo! Answers website (Yahoo!, 2007):

A wet washcloth can be folded and placed in warm-hot water and used for sore areas that are small in size. During childbirth, we often use wet cloth compresses soaked in warm-hot water or warm-hot comfrey leaf tea on the perineal area during the pushing stage of labour. This reduces painful, stretching-burning sensations, relaxes the perineum and vaginal opening allowing tissue to stretch as the baby's head is crowning. It also keeps the blood circulation in the tissues, preventing tearing while it is stretching open and gives the mother a focal point on where to concentrate her labour efforts when we tell her to "push into the warm cloth." (Services, 2007).

The majority of websites advocating the use of perineal warm packs are alterative birth sites with names as diverse as the *gentlebirth* or *notjustskin* website. The instruction found on these websites, around the use and benefit of warm packs, is varied:

Castor oil packs for the perineum can help relieve prenatal pain around the perineal region as well as make your tissues supple and prevent tearing when you give birth. Castor oil has healing and restorative properties so the relief builds up over time and

the heat increases the blood flow to the area, relieves pain, improves circulation and relieves venous congestion (Silber, 2007).

There are many websites selling products such as *Rapid Aid*, advertised as instant hot perineal compresses with a self-adhesive strip designed to “provide immediate heat, to help encourage relaxation of tissues and increase blood flow circulation in the perineal area prior to childbirth” (Rapidaid, 2007). This product was not advertised to be used during labour, but during pregnancy and following the birth. Likewise, numerous patents have been lodged for warming products that will be available in the future. Some of these are for perineal warm packs.

While this is not evidence to support the use of perineal warm packs, it demonstrates the widely accessible information and products available to the layperson on perineal warm packs.

3.4 Evidence-based practice

As the importance of evidence in underpinning midwifery practice became more widely recognised, descriptions of the use of warm packs and perineal massage were increasingly accompanied by discussions about the evidence or lack of evidence. Often, however, warm packs were often rolled into one concept along with perineal massage. For example, this description of perineal care by Sleep in a book titled *Intrapartum Care: A Research Based Approach*:

Warm compresses or emollients such as olive oil, walnut or almond oils may be used, as well as herbal preparations, for example, calendula cream containing extract of marigold. The woman, her partner or attendant midwife may carry out these therapies. Such practices have enthusiastic advocates (Flint 1986); others are more sceptical suggesting that touch may prove a distraction, creating tension as well as increasing vascularity and oedema in tissues already at risk from trauma (Nobel 1983). Neither of these polarised opinions can be supported by research (Sleep, 1990, p.127).

In the late 1990s, in a systematic review of the evidence regarding practices that minimise trauma to the genital tract, the authors concluded that:

Warm compresses to the perineum in the second stage of labour are associated with lower rates of trauma, and perineal massage with lubricants with higher rates (Renfrew et al., 1998, p.15).

In the widely read *A Guide to Effective Care in Pregnancy and Childbirth*, the authors describe various methods advocated for reducing perineal trauma:

Ironing out (massaging) the perineum as the second stage of labour advances, sometimes with an emollient such as olive oil or the application of a hot pad, is designed to stretch the tissues and reduce the risk of trauma. These techniques have enthusiastic advocates as well as detractors (Enkin et al., 2000, p.294).

Perineal warm packs were frequently advocated and written about from the late 1970s onwards, despite a relative lack of scientific evidence of their efficacy. It is obvious that midwives observed the positive responses and feedback from women when they used the warm packs and were reassured that they were effective. In the early 1990s, as midwifery recognised the need to underpin practice with evidence, a new tone of caution and acknowledgement of the lack of scientific evidence entered the professional literature. In the following chapter, a review of the literature regarding practices thought to influence perineal trauma and maternal comfort during the late second stage of labour is undertaken and the available evidence for the efficacy of perineal warm packs is explored in greater detail.

3.5 The physiological effects of heat

In 1822, the French mathematician J. B. J. Fourier published the mathematical theory that describes heat transfer by conduction, and twenty or more years later, the notion of heat as a weightless, invisible fluid was discounted and heat was universally accepted to be a form of energy (Sekins & Emery, 1990). As described in the previous chapter, heat has been

used as a form of therapy in many societies long before it was understood or fully described. The discussion on the effects of heat in the following section will be divided up into: 1) the mechanical effects of heat on body tissue and 2) the effects of heat on pain.

3.5.1 Mechanical effects of heat

Lehmann's (1990) widely acclaimed, *Therapeutic Heat and Cold* (Lehmann, 1990) was first published in 1958 and remains a widely cited and studied treatise on the subject. This text described that it is generally accepted that heat produces the following desirable therapeutic effects:

1. It increases the extensibility of collagen tissues
2. It decreases joint stiffness
3. It produces pain relief
4. It relieves muscle spasms
5. It assists in resolution of inflammatory infiltrates, oedema and exudates
6. It increases blood flow (Lehmann & De Lateur, 1990, p.417).

Much of the literature associated with the application of heat to human tissue is found in the rehabilitation, physiotherapy, sports injury and biomechanical literature, as the following discussion will show. The efficacy and effect of heat are contradictory. Both warming and cooling are the most common therapeutic modalities used in physical therapy (Lehmann, 1990). In studies where heat has been applied, the increase in temperature has been reported to be effective in increasing tendon extensibility (Warren, Lehmann, & Koblanski, 1976) and reducing joint stiffness (O'Dell, 1975). Increasing skin temperature also increases blood flow to the tissue (Greenburg, 1972), thereby aiding in the healing process by, for example, reducing muscle soreness (Weber, Servedio, & Woodall, 1994). The assumption is that hot packs can effectively change tissue temperature and that changing skin and tissue temperature has a positive therapeutic effect. Other evidence in the literature disputes the ability of warmth to have any significant physiological effect on intramuscular temperature

one centimetre or more below the skin and subcutaneous tissue (Myrer, Draper, & Durrant, 1994) (Myrer, Measom, Durrant, & Fellingham, 1997).

Connective tissue is a visco-elastic structure capable of plastic and elastic changes (Sapega, Quedenfeld, Moyer, & Butler, 1981). Connective tissue is classified into four groups: loose (for example, subcutaneous), dense (for example, fascia and muscle sheaths), organized (for example, ligaments and tendons) and specialized (for example, cartilage and bone) (Knight, Rutledge, Cox, Acosta, & Hall, 2001). As early as 1955, Gersten found increased tendon extensibility following ultrasound exposure, which he attributed to the rise in temperature of the tendon during treatment (Gersten, 1955). It has been shown that collagen shrinks and melts at temperatures above 50°C, but when subjected to temperatures within the therapeutic temperature range (40 – 45°C) it shows different behaviour and is essentially elastic, especially when tension is applied (Lehmann, Masock, Warren, & Koblanski, 1970). The viscous properties of connective tissue allow it to go through permanent change in structure, while the elastic properties enable it to regain its original length (Knight et al., 2001) (Hecox, Mehreteab, & Weisberg, 1994; Lehmann et al., 1970). When an applied stretch to connective tissue is removed, the elastic components recover their original length and the viscous components remain deformed (Knight et al., 2001) (Lehmann et al., 1970) (Hecox et al., 1994). The amount of elastic and viscous deformation can vary considerably depending on the force applied, the duration of the force and temperature of the tissue (Sapega et al., 1981). Thermal agents play a role in determining the amount of elongation obtained from a static stretch (Lehmann et al., 1970). Ultrasound is another method of applying deep heat to connective tissue (Hecox et al., 1994). An elevation of greater than 3 to 4°C is needed to obtain increases in the visco-elastic properties of collagen (Draper & Ricard, 1995) (Draper, Castel, & Castel, 1995).

Two early studies examined heat and its ability to enhance stretch. These studies used a rat tail tendon as a tissue model (Lehmann et al., 1970) (Warren et al., 1976). The studies examined various methods of applying force to collagenous tissue at various temperatures to produce permanent elongation. The effect of heating the tissue prior to applying force was evaluated, and the impact of using a prolonged application of low force was

demonstrated. Elevating tissue temperature prior to applying force resulted in significantly less damage being caused. Lower loads applied at elevated temperatures for prolonged periods were found to produce significantly greater residual elongation (Warren et al., 1976).

A study was also conducted to determine whether heat application could improve the flexibility of the hamstring in humans, and whether the risk of hamstring injury in athletes could be reduced. This study compared 30 seconds of static stretching with 20 minutes of moist heat application. Fifteen of the 30 undergraduate student athletes from a football team were given heat followed by stretching and the other 15 had stretching followed by heat. The study demonstrated that significant benefits could be gained by using moist heat packs in comparison with static stretching (Funk, Swank, Adams, & Treolo, 2001). Another article in the same journal two years later found the application of a moist heat pack took 20 – 25 minutes to increase intramuscular temperatures by 0.4^oC (Sawyer, Uhi, Mattacola, Johnson, & Yates, 2003). In this study, both legs of the same subject were used and the person's legs were randomly assigned to moist heat application or being a control. There was no significant difference obtained in muscle flexibility between the legs that received the moist heat pack and those that did not. This study was particularly invasive, as a 23-gauge indwelling thermistor was inserted to a depth of 2.54 cm to measure hamstring temperature.

Another study compared stretching of the human hamstring with ice, heat, and with stretching alone and concluded that supine hamstring flexibility after stretching with ice was greater than both stretching with heat and stretching alone (Brodowicz, Welsh, & Wallis, 1996). Three groups with eight college baseball players in each group were included. These results are further contradicted by a study showing no advantage in using complete hot or cold immersion to increase hamstring length in healthy subjects (Myrer et al., 1994).

Research has been undertaken on the effects of heat on the biomechanical properties of the intervertebral disc in a porcine (pig) model (Wang, Kabo, Tsou, Halevi, & Shamie, 2005).

The hamstring tendon was also tested. The study was conducted by uniformly heating the specimens in a water bath (60, 65, 70 or 75°C) for ten minutes. The tissue was then measured for shrinkage, stiffness, and 'load to failure' strength. As the heat increased, there was progressive loss of individual collagen outline. Stiffness in the tendon was reduced after heating but for the disc core samples there was no significant difference in either stiffness or load to failure strength after heating (Wang et al., 2005).

It is evident that both cooling and heating have been shown to affect the contractile properties of muscles. However, the reasons remain unclear. A number of these will be outlined in the next section. A study into the effect of cold and hot water immersion on the mechanical properties of human muscle and tendon *in vivo* demonstrated no significant changes in the elongation of muscle fascicle, tendon and aponeurosis during passive stretch of the ankle (Kubo, Kanehisa, & Fukunaga, 2005). The authors concluded that the application of ice and heat packs did not change the mechanical properties of muscle and tendon (Kubo et al., 2005).

Other researchers, studying the effect of thermal agents and prolonged static stretching on shoulder flexibility, found that stretching alone, stretching with heat, stretching with ice, and stretching with combined heat-ice, demonstrated improved shoulder flexibility compared with no intervention at all (Lentell, Hetherington, Eagan, & Morgan, 1992). Others have found that subjects in the heat group demonstrated significantly greater flexibility scores than those in the cold group or those only stretching (Taylor, Waring, & Brashear, 1995), while others have shown that cold application over the muscle before and during stretching was significantly more productive in increasing flexibility than stretching alone (Cornelius & Jackson, 1984).

Further studies into the temperature changes observed in subcutaneous and intramuscular tissue demonstrated minimal effect on deep muscle temperature (Myrer et al., 1997). These authors argued that if most of the physiologic effects attributed to hot and cold contrast therapy depend on substantial fluctuations in tissue temperature, then contrast therapy needs to be reconsidered as a viable therapeutic modality (Myrer et al., 1997).

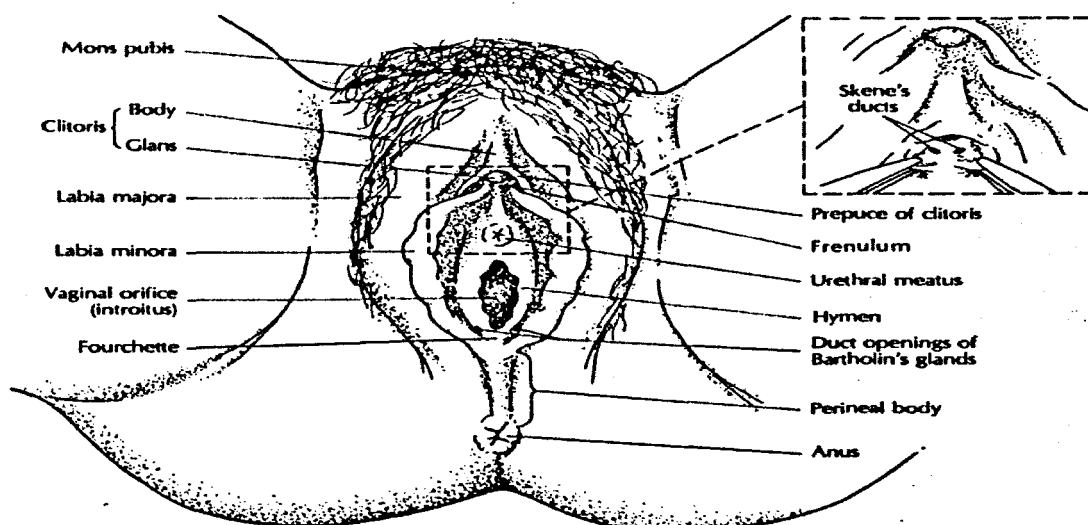
A study into the effects of ice and heat packs applied to the thigh showed that local heat and cold stimuli influenced cerebral haemodynamics and cerebral metabolism (Doering, Brix, Schneider, & Rimpler, 1996). Cerebral haemodynamics, in comparison with cerebral metabolism, demonstrated opposing reactions under thermo-stress. The authors suggest that the effects seen may open up new thermotherapeutic treatments in central nervous system disease (Doering et al., 1996). It is evident that the pleasurable sensations, particularly of warmth, have a more complex effect on the sense of wellbeing than comes from a purely physical response.

There are no direct physiological studies on the perineum in labour and this is a unique body of tissue that cannot be compared with hamstrings, rats' tails, shoulders and knee joints. What can be gleaned from the research is that actual observable physiologic effects of heat application are controversial. There is evidence that heat can alter the temperature and thus properties of skin and subcutaneous tissue, but it is less likely that warm packs would be able to penetrate lower than one centimetre to affect deep muscle temperature. There is a difference between seeing the effects of heat directly on a rat-tail tendon in a laboratory situation and then applying heat externally to a body part covered by skin, fat and muscle and influenced by pregnancy hormones. The depths to which heat can actually penetrate tissue at bearable temperatures over a reasonable time period are more questionable. It is not that heat cannot alter connective tissue, as it clearly can, but the question is how much is this physically possible and to what depth? More questions need to be asked about the psychological effects of warmth. It is known that it can change cerebral blood flow, thus potentially influencing a sense of wellbeing but more research is needed into this area. As already described in Chapter 2, hydrotherapy is an ancient and well-recognised therapeutic modality, evidence in itself that there is some beneficial effect (Graham, 1950; Trall, 1872).

The perineal body, where the warm packs are applied (Figure 3.1), is an approximately three-to-four centimetre body made up of skin, superficial fascia and fat, nerve, lymph and blood supply, superficial muscles, and deep muscles (Nisbet & Rouse, 1992). The precise structures involved in the perineal body are skin; vaginal wall; superficial transverse

perinei; bulbocavernosus muscle; deep transverse perineal muscle; puborectalis muscle; pubococcygeus muscle; rectovaginal septum; internal anal sphincter; external anal sphincter and anus (Frye, 1995; Nisbet & Rouse, 1992). During childbirth, the perineal body thins and stretches considerably to allow the passage of the baby's head through the vaginal opening. It is unknown to what depth heat would penetrate when heat is applied to the perineum and the length of time and amount of heat required to cause physiological changes. It is also possible that different tissues, such as perineal muscle or sphincter fibres, would respond differently to heat.

Figure 3.1: Diagram depicting the female genitalia and perineal body where the warm packs are applied



(Frye, 1995)

3.5.2 Effect of heat on the anal sphincter

Another emerging area of research found in the colorectal literature is into the effect of heat on the anal sphincter. In one study, researchers examined the physiologic effects of hot and cold sitz baths in normal subjects and in a group of patients with anorectal disorders. A significant decrease in anal pressure was noted in both groups during a hot sitz bath (Dodi et al., 1986). In another study, researchers performed anorectal manometry in normal subjects before and after the hot sitz bath of either three or ten minutes duration, with no significant changes noted between pressure measurements at rest or with voluntary

contraction (Pinho, Correa, Furtado, & Ramos, 1993). This could have been due to the short time frame in which the participants were in contact with the warm water.

Shafik tried to elucidate the physiologic mechanism and beneficial effect of the warm sitz by measuring the internal and external sphincter temperature, rectal pressure, and electromyograph (EMG) activity of the anal sphincter in 18 healthy volunteers and 28 patients with chronic anal fissures or thrombosed haemorrhoids (Shafik, 1993a). Measurements were collected before and after the sitz baths performed at different water temperatures (40, 45, 50°C), with each bath lasting 15 minutes. The author noted that there was a decrease in internal sphincter pressure during the sitz bath. Warmer water led to a greater duration of low internal sphincter pressure. Pain relief was also more evident and lasted longer at higher bath temperatures. Shafik (1993) proposed the thermosphincteric reflex and theorised that the relaxation of the internal sphincter muscle is mediated through sensory peri-anal skin receptors stimulated by warm water. He attributed the resulting decrease in spasm and pain relief to the thermosphincteric reflex (Shafik, 1993a). Other researchers also observed that local thermal stimulation evokes relaxation of the hypertonic internal anal sphincter but argued the mechanism was through a somatoanal reflex (Jiang, Chiu, & Lin, 1999).

Shafik also looked at the mechanism of postoperative urinary retention after haemorrhoidectomy by measuring rectal temperature, vesicle and urethral pressures, and EMG activity in both healthy subjects and subjects with post haemorrhoidectomy urinary retention. He attributed urinary retention to a reflex spasm of the internal urethral sphincter. A reduction in urethral pressure was noted with the warm sitz bath, leading to relaxation of the internal urethral sphincter, thereby causing vesicle contraction and urination (Shafik, 1993b).

The potential effects on anal sphincter relaxation will be discussed further in Chapter 6 when the Perineal Warm Pack Trial findings on severe perineal trauma are reported.

3.6 Effects of heat on pain

There is more substantial evidence to support the beneficial effect that heat has on the experience of pain.

Porth (1990), a physiologist, describes the physiological effect of heat on somatic pain as follows:

Heat dilates blood vessels and increases blood flow, it can influence the transmission of pain impulses and increase collagen extensibility: Overall an increase in local circulation can reduce the level of nociceptive stimulation by reducing local ischaemia caused by muscle spasm or tension, it can increase the removal of metabolites and inflammatory mediators that act as nociceptive stimuli and it can help to reduce swelling and relieve pressure on local nociceptive endings. It may also produce the release of endogenous opiates through placebo-type mechanisms (Porth, 1990, p.864).

Midwifery texts also describe the effects of heat in detail when recommending its use as a non-pharmacological physical comfort measure (Simkin & Ancheta, 2003):

Heat increases local skin temperature, circulation, and tissue metabolism. It reduces muscle spasm and raises the pain threshold. Heat also reduces the fight or flight response (as evidenced by trembling and 'goose pimples'). Local heat to a warm blanket calms the woman, and also may increase her receptivity to a stroking type of massage which she cannot tolerate when her skin is sensitive or sore due to the fight or flight response (Simkin & Ancheta, 2003, p. 167).

There is widespread empirical evidence that heat can be used to relieve pain in a large variety of musculoskeletal conditions (Bengston & Warfield, 1984) (Dodi et al., 1986). Heat appears to have an effect on muscle spasms, however, the physiological underpinnings of these observations are extremely limited (Lehmann & De Lateur, 1990). In some cases, reducing the secondary muscle spasms (Lehmann & De Lateur, 1990) may relieve pain. In tension syndromes pain is supposedly due to ischaemia, which in turn can be improved by

the hyperaemia¹⁴ that heat application produces (Lehmann & De Lateur, 1990). This would seem to apply to the distended tense perineum during childbirth.

Heat has also been applied as a counterirritant; that is, the thermal stimulus may affect the pain sensation, as explained by the gate theory of Melzack and Wall (Melzack & Wall, 1965). This theory is that you can 'gate out' or partially block pain with competing sensations such as warmth or massage. When a warm pack is applied, touch and temperature fibres are stimulated, creating a background of pleasurable sensations. The pain now has to compete for access to the spinal cord, thus leading to a reduced sensation of pain. The pain relief experienced with heat application can also be explained through the action of endorphins, which are released.

In pain produced artificially, such as by an injection of sodium chloride, there is evidence that heat, when applied to the free nerve endings in the tissues or to the peripheral nerve, reduces the pain sensation (Hardy, Wolff, & Goodwell, 1940). Research measuring the pain threshold showed this was elevated after heat was applied (Hardy et al., 1940). Kramer (1985) found that ultrasound application increased nerve conduction velocities (Kramer, 1985). Studies by Ahlquist et al. (1986) found that repeated heat applications finally led to abolishment of the whole nerve response (Ahlquist, FFrannzens, Edwall, Fors, & Haegerstam, 1986). However, Lehmann (1990) asserted that, in contrast to the almost universal empirical application of heat for the relief of pain, the physiological data as a basis for this therapeutic indication were limited (Lehmann & De Lateur, 1990).

Heat application is known to influence blood flow to the tissue. It is this mechanism that is probably one of the main effects in reducing muscle spasm or sustained contractions as they occur in tension states. In such conditions, ischaemia may contribute to the pain and perpetuate the abnormal muscle contractions (Lehmann & De Lateur, 1990). A rise in local temperature produces vasodilation and an increase in blood flow by various mechanisms. The elevated temperature appears to have a direct effect on the state of dilation of the capillaries, arterioles, and venules (Lehmann & De Lateur, 1990). In addition, denaturing

¹⁴ Hyperaemia is an excess of blood in a body part.

protein heating may produce an inflammatory reaction resulting from release of histamine-like substances and bradykinin, which produce vasodilation. Lehmann (1990) summates that when vigorous responses are desired, local heating is best. The temperature should be 40 to 45^o C and be applied for a duration of 5 to 30 minutes (Lehmann & De Lateur, 1990). The higher the temperature the more effective the response, and when heat is applied in a wet form, as it is in the case of perineal warm packs, it is conducted rapidly to the tissues.

During the Perineal Warm Pack Trial concerns were raised about the potential for warm packs to be detrimental in the presence of oedema by increasing blood flow to the area. In situations such as this, cold packs may be more advantageous. This is discussed further in Chapter 10.

The evidence on the physiological effects of heat is conflicting. While there is little doubt that heat has a real and observable effect on body tissue, there is doubt about the depth it can penetrate in a reasonable time at a bearable temperature. The evidence supporting the effect of heat on pain is more compelling even if the physiology is once again not fully understood. The newly emerging evidence on the impact of warmth on the anal sphincter will be discussed again in Chapter 6.

3.7 Summary

In this chapter the reclamation of the perineum in the late 1970s has been explored by reviewing contemporary literature advocating the use of perineal warm packs in the second stage of labour. The revival of a social model of care that now competes with the dominant surgical model came with the advent of the active birth movement and re-emergence of the belief that protection and preservation of the perineum, along with the comfort of childbearing woman in the second stage, was deemed as important. Practices aimed at preventing perineal trauma and pain re-emerged in the literature and perineal warm packs became an important factor in this. A review of relevant literature on the physiological effects of heat has also been discussed in this chapter. Chapter 4 contains a literature review

of factors that influence perineal trauma rates and maternal comfort during the late second stage of labour.

Chapter 4: Literature review of factors that influence perineal trauma and maternal comfort during the late second stage of labour

“These pages have not been written for those who lay them aside saying or thinking, ‘much ado about a perineal tear!’ They will have to come to terms with their own consciences” (Ritgen, 1885, p.321).

4.1 Introduction

The previous chapter explored the reclamation of the perineum in the late 1970s by reviewing contemporary literature advocating the use of perineal warm packs in the second stage of labour. A review of relevant literature on the physiological effects of heat was also presented in Chapter 3.

Chapter 4 contains a literature review of factors that influence perineal trauma rates and maternal comfort during the late second stage of labour. The topics reviewed are: perineal massage (antenatal and intrapartum), pelvic floor exercises (antenatal), warm and cold packs, immersion in water (intrapartum), local anaesthetic spray, position in the second stage of labour, coached and uncoached pushing, hand manoeuvres, episiotomy, vacuum versus forceps delivery, epidural, support during labour, place of birth and midwife versus obstetric care during birth.

4.2 Background

Perineal trauma commonly accompanies vaginal birth, and can result from intentional trauma (episiotomy), non-intentional trauma (tears and grazes) or both (Renfrew et al., 1998). Trauma to the genital tract is more common in primiparous women (Williams et al., 1998) and with operative vaginal deliveries (Macarthur & Macarthur, 2004a). Countries

report wide variations in trauma rates. Within countries, further variations exist amongst institutions and health professionals (Renfrew et al., 1998). Complicating this even further is the fact that definitions of perineal trauma differ and reporting is often incomplete (Renfrew et al., 1998).

In studies where the use of episiotomy is restricted¹⁵, 55% to 77% of women still sustained trauma significant enough to require suturing (Albers et al., 1999b) (Mayerhofer et al., 2002) (McCandlish et al., 1998). In Australia, 65.7% of women have some form of perineal trauma, including 17.2% having an episiotomy (Laws et al., 2006b). Perineal trauma is reported as being lower for women who give birth at home (Murphy & Feinland, 1998) and higher for women who are attended by obstetricians (Shorten, Donsante, & Shorten) (Roberts, Tracey, & Peat, 2000), with rates even varying within professional groups and between individual clinicians (Klein et al., 1992; Logue, 1991; Wilkerson, 1984).

As described in Chapter 2, there is evidence that perineal trauma was not always as high as it appears today, leading to questions around contemporary second-stage management. De Wees, in 1889, for example, reported only 51 lacerations in 1,000 consecutive births (5.1%) (De Wees, 1889), while Ritgen, in 1,885, described the exact length of 190 tears (3.9%) occurring during the births of 4,875 women (Ritgen, 1885).

It has been observed that the rise in episiotomy in the USA was directly proportional to the move from birth at home to birth in hospital (Thacker & Banta, 1983). In the USA in 1930, approximately 25% of women gave birth in hospital compared to 70% in 1945. The rate of episiotomy is thought to reflect this shift in the environment of birth (Thacker & Banta, 1983).

¹⁵ Episiotomy is restricted when it is performed for specific indications such as foetal distress and not routinely or because it is believed to reduce perineal trauma.

4.3 Morbidity associated with perineal trauma

Perineal trauma is associated with significant short-and long-term morbidity (Sleep & Grant, 1987) (Glazener et al., 1995) (McCandlish et al., 1998). Acute postpartum perineal pain is common among all women who give birth vaginally and its severity is linked with perineal injury (Kenyon & Ford, 2004) (Albers et al., 1999a) (Klein et al., 1994). Many women fear having perineal sutures and experiencing the pain associated with perineal trauma (Steen & Marchant, 2007). Perineal pain can have long-and short-term negative consequences for women's health and wellbeing. Of the women who sustain perineal trauma, 40% report pain in the first two weeks postpartum, up to 20% still have pain at eight weeks (Glazener et al., 1995) and 7% to 9% report pain at three months (McCandlish et al., 1998; Sleep & Grant, 1987). Women who have an intact perineum following vaginal birth report pain less frequently at 1, 2, 10, and 90 days postpartum (Albers et al., 1999a) (Klein et al., 1994).

Perineal pain can inhibit a woman from mobilising fully and make sitting uncomfortable. This may have a negative effect on her desire or ability to breastfeed or continue breastfeeding (Greenshields & Hulme, 1993). Perineal trauma can make it distressing to void or defecate and pain can impair a woman's ability and willingness to care for her newborn baby. Both pain and perineal trauma can lead to relationship disharmony that can lead to irritability, resentment, depression and maternal exhaustion (Steen et al., 2000) (Steen & Marchant, 2001).

Perineal pain can impair normal sexual functioning, with dyspareunia following vaginal delivery reported by 60% of women at three months and 30% at six months (Barrett et al., 2000). Fifteen per cent of women still report painful sex up to three years later (Sleep & Grant, 1987). Women who have an intact perineum, compared with those who experience perineal trauma, are more likely to resume intercourse earlier; report less pain with the first sexual intercourse; greater satisfaction with sexual experience (Klein et al., 1994); and greater sexual sensation and likelihood of orgasm at six months postpartum (Signorello et al., 2001).

Women who have an intact perineum with their first baby have stronger pelvic floor muscles (measured by electromyogram) and their pelvic floor muscles make a quicker recovery than women experiencing tears or episiotomies (Klein et al., 1994). While perineal trauma has not been clearly associated with urinary incontinence (Woolley, 1995), severe perineal trauma (third-and fourth-degree tear) has been shown to be associated with faecal incontinence (Sultan & Thakar, 2002).

Perineal pain experienced during the second stage of labour can also have an impact on how a woman views her birth experience. Much of the research on pain in labour has focused on the first stage, thus largely overlooking the pain associated with the actual birth (Sanders et al., 2005). The advancement of the foetal head, and stretching of the perineum in the minutes before giving birth, are accompanied by pain that can be severe (Mander, 1992) (Miller, 1994) (Lowe & Roberts, 1998; Niven & Gijbers, 1984) (Stewart, 1982). In an observational study of women in the second stage, seven of the twenty women interviewed following the birth described the second stage of labour purely in negative terms, such as painful, miserable or horrible (McKay et al., 1990). It is also apparent that multiple factors are involved in influencing a woman's perception of pain, including most importantly the attitudes and behaviours of health-care providers during childbirth (Green & Baston, 2003).

4.4 Factors that contribute to perineal trauma

Numerous factors have been suggested as potential contributors to perineal trauma. These include: maternal nutritional status; body mass; history of prior trauma; ethnicity; older age; abnormal collagen synthesis; place of birth; accoucheur preference; epidural usage; infant birth weight; foetal malposition and malpresentation; second-stage management (continuous support, maternal position, style of pushing, techniques to relax the perineum, episiotomy, hand manoeuvres, vacuum versus forceps delivery, immersion in water) and the actual birth of the baby (McCandlish et al., 1998) (Kettle, 2004; Klein et al., 1997). This literature review will focus particularly on second-stage management, as these are factors

more likely to be under the control of health professionals and more directly related to perineal trauma and discomfort experienced during the birth.

A comprehensive review of the literature was undertaken to assess factors that impact on perineal trauma and maternal comfort during the second stage of childbirth. The aim of the review was to ascertain the current knowledge on this topic and make recommendations for future research. The review focused particularly on the second stage, although practices such as antenatal perineal massage are included. The evidence from the trials is summarised descriptively.

4.5 Review methods

The following data sources were used to identify relevant research papers that addressed one or more aspects of trauma reduction: Medline, CINAHL, MIDIRS and the Cochrane Database of Systematic Reviews.

Search terms used to obtain the evidence, included combinations of key words (childbirth, second stage, labour, birth, management, plus perineum/perineal/injury/trauma). All possible combinations of these terms were used. In order to double-check that all key literature had been retrieved, key areas for review, such as warm packs; warm compress; cold packs; perineal massage; pelvic floor exercises; labour support; birth position; pushing/coached/uncoached; episiotomy; vacuum; forceps; Epi-No; epidural, water birth; immersion; midwife; obstetrician; hand manoeuvres; anaesthetic, were combined with perineum, perineal, trauma and injury. Unrestricted and restricted searches were initially made. Restricted searches were made for systematic reviews and randomised controlled trials. Hand-searching of key articles and their reference lists was also undertaken and electronic links to related articles were also accessed.

Three previous systematic reviews of the evidence that focused on prevention of perineal trauma during childbirth were found (Renfrew et al., 1998) (Eason, Labrecque, Wells, & Feldman) (Kettle, 2004). The reference lists of these articles were examined for any studies

that might have been missed in the literature search. This review aims to build on these previous reviews with a broader scope.

The literature found in the review was grouped into several categories: systematic reviews, randomised controlled trials (RCT) or quasi-randomised, prospective cohort studies (non-randomised) and other studies. Where a systematic review is available, this will be discussed along with any relevant, recent studies not included in the review. Where no systematic review is available, RCTs of interventions affecting perineal trauma were reviewed or other papers of specific relevance. Where no RCTs are available, non-randomised research designs such as cohort studies were included. Studies were selected by reviewing the abstracts of articles and then by reviewing the methods section of studies that appeared to be systematic reviews or RCTs.

Using these methods, over 1,900 papers were identified. Literature excluded from the review was either not randomised trials, systematic reviews or relevant cohort studies. In total, 194 papers were incorporated into the literature review. This included 20 systematic reviews, 132 randomised trials and quasi-randomised trials, 27 prospective cohorts and 15 other studies.

4.6 Perineal massage

Perineal massage can be conducted in three main ways: as antenatal digital perineal massage carried out by the woman and/or her partner; as antenatal perineal massage using a massaging device versus control; or as intrapartum digital massage carried out by the midwife. These different methods will be considered separately.

4.6.1 Antenatal digital perineal massage

Antenatal perineal massage has been proposed as one method of decreasing the incidence of perineal trauma. It is suggested that perineal massage may increase the flexibility of the perineal muscles and therefore reduce muscular resistance, which would enable the perineum to stretch without tearing or needing an episiotomy. It is also possible that the

stinging sensation that women experience with perineal massage prepares them for similar sensations they will experience with the crowning of the baby's head.

A systematic review of antenatal perineal massage was identified in the Cochrane Database of Systematic Reviews (Beckmann & Garrett, 2006). The last substantive amendment to this systematic review was in October 2005. The systematic review included randomised and quasi-randomised controlled trials evaluating any described method of antenatal perineal massage undertaken for at least four weeks of pregnancy. Three trials (2,434 women) comparing digital massage with a control group were included (Labrecque, Marcoux, Pinault, Laroche, & Martin, 1994) (Labrecque, Eason, & Marcoux, 1999) (Shipman, Boniface, Tefft, & McCloghry, 1997). All studies except one (Labrecque et al., 1999) included only primiparous women. Perineal massage was associated with an overall 9% reduction in the incidence of perineal trauma requiring suturing (RR 0.91; 95% CI 0.86 to 0.96). Sixteen women would need to do perineal massage in order for one woman not to require perineal suturing (Beckmann & Garrett, 2006). This reduction was only statistically significant for women who had not had a previous vaginal birth. Women who practised perineal massage were less likely to have an episiotomy (three trials, n = 2,417) (RR¹⁶ 0.85; 95% CI 0.75 to 0.97) (NNT¹⁷ 23) (Beckmann & Garrett, 2006). Again this reduction was only statistically significant for women who had not had a previous birth. No statistically significant differences were seen in the incidence of first-second-third-and fourth-degree tears.

Only women who had previously given birth vaginally reported a 32% reduction in the incidence of pain at three months postpartum (one trial, n = 376) (RR 0.68; 95% CI 0.50 to 0.91) (NNT 13) (Beckmann & Garrett, 2006). There was no significant difference between groups in the rate of instrumental birth, sexual satisfaction or incontinence of urine, faeces and flatus. Women generally found antenatal perineal massage quite acceptable (Labrecque, Eason, & Marcoux, 2001).

¹⁶ RR means Relative Risk.

¹⁷ NNT means Numbers Needed to Treat

Two other small, randomised studies examining perineal massage were found that had been excluded from the Cochrane review due to sample size and flawed methodology. One had 20 women participating (Avery & Burket, 1986) and the other had 55 women participating (Avery & Van Arsdale, 1987). In both studies, there was a higher rate of intact perineum in the group who attended the massage. However, both studies were flawed. In the first study, large numbers of women were excluded from the analysis (Avery & Burket, 1986) and in the second (Avery & Van Arsdale, 1987), women were allowed to choose their own study group. The sample size in both studies was also small.

4.6.2 Antenatal perineal massage using a massaging device

Four studies were identified that examined outcomes for women using a perineal massaging device called Epi-No. There were no RCTs available for review. One study was a case-controlled study (Cohain, 2004) and the other three were retrospective cohort studies (Hillebrenner, Wagenpfeil, Schuchardt, Schelling, & Schneider, 2001; Kok et al., 2004) (Kovacs, Heath, & Heather, 2004).

The case-controlled study, undertaken in Israel, sought to describe outcomes for women (n = 290) who had used a perineal dilator (Epi-No) in the weeks before they gave birth (Cohain, 2004). The outcomes from this group were compared to outcomes in the published literature at the same time of the study. The women in the Epi-No group had a lower episiotomy rate and greater reported confidence in giving birth.

A retrospective cohort study conducted in Germany (Hillebrenner et al., 2001) suggested the Epi-No significantly shortened the second stage of labour and reduced the incidence of episiotomy. The study also suggested the one- and five-minute Apgar scores were superior in babies born to women who had used the Epi-No device. Again the sample size was small, with only 50 women participating.

Another of the case-control-studies was undertaken in Singapore and studied 31 primiparous women who used the Epi-No from July to December 2002 (Kok et al., 2004).

The perineal outcomes were compared retrospectively to 60, consecutive obstetrician-booked primiparous women who did not use the Epi-No. The authors concluded that the Epi-No reduced the episiotomy rate (50% vs 93.3%; $p < 0.0001$) but not the rate of perineal trauma (90% vs 96.6%; $p = 0.24$). There was a very high rate of episiotomy and perineal trauma in this study.

Finally, an Australian cohort study compared the outcomes of 48 primiparous women who had used the Epi-No to all other primiparous women ($n = 248$) who gave birth in the same hospital over the same period (Kovacs et al., 2004). Nine women had a caesarean section, leaving 39 women in the study. A significantly higher perineal intact rate (46% vs 17%; $p = 0.0001$) and lower rate of perineal tears (28% vs 49%; $p = 0.01$) were reported in the Epi-No group.

None of these studies randomly selected participants and there was no blinding to the treatment, leaving them vulnerable to bias. The small sample sizes and possibly non-comparable groups were another major limitation.

4.6.3 Perineal massage in the second stage by a midwife

Perineal massage in the second stage of labour has been proposed as a means of relaxing the perineum and possibly preventing tears and the need for an episiotomy (Renfrew et al., 1998) (Enkin et al., 2001). No systematic reviews of perineal massage in the second stage are available. Two randomised controlled trials were reviewed.

The first trial was conducted in Australia across three sites. Women ($n = 1,340$) were randomised in established labour to having their perineum massaged and stretched during second stage, or not (Stamp et al., 2001). An attempt at single blinding of the midwives assessing the trauma was described, but no data is available to describe compliance. Rates of intact perineum, first- and second-degree tears and episiotomies were similar in the massage and the control group. There were fewer third-degree tears in the massage group (12 (1.7%) vs 23 (3.6%); RR 0.45; 95% CI 0.23 to 0.93, $p = 0.04$), although the trial was

underpowered to measure this rare outcome (Stamp et al., 2001). The groups did not differ in any of the secondary outcomes of: pain at three days, ten days or three months; dyspareunia; intercourse not resumed and urinary and bowel control.

A second randomised controlled trial conducted in the USA involved 1,211 women. They were randomised into one of three care measures in the second stage of labour: 1) warm compresses to the perineal area; 2) massage with lubricant; or 3) no touching of the perineum until crowning of the baby's head, known as hands poised (Albers, Sedler, & Bedrick, 2005). The main outcome measure was the incidence of intact perineum. Four hundred and eighty women having their first birth and 731 women having a subsequent birth participated. Perineal massage with lubricant (403 women) provided no apparent advantage in reducing perineal trauma compared with keeping 'hands poised' (404 women) in the late second stage of labour. However, there was no standard care control group. It is interesting to note in this study that of the 5.8% of women who requested the allocated technique be stopped, three quarters were from the massage with lubricants group (54 women). This suggests that this technique may not be as acceptable to women as warm compresses or no hands poised. Follow-up data was not obtained in this study.

4.6.4 Summary of the section

Antenatal digital perineal massage reduces the likelihood of perineal trauma for women (mainly episiotomies) and the reporting of ongoing perineal pain. For every 16 women who practice perineal massage antenatally, one fewer will receive perineal suturing following the birth. It is generally accepted well by women and they should be informed of the likely benefits.

No conclusion can be drawn about the effectiveness of antenatal perineal massage using a massaging device (Epi-No), due to the limited studies available with small sample sizes, lack of randomisation and blinding. More high-quality research in the form of an RCT is required.

There is no benefit from the practice of perineal massage in labour. There is some evidence that this practice is not acceptable to some women and so should be avoided.

4.7 Pelvic floor muscle training

Pelvic floor muscle training during pregnancy can prevent urinary incontinence (Morkved & Bo, 2000; Reilly et al., 2002; Wilson, Herbison, & Herbison, 1996) but a myth appears to prevail amongst health workers that strong pelvic floor muscles (such as obtained through horse-riding) may obstruct labour and increase perineal trauma (Salvesen & Morkved, 2004). Alternatively, training pelvic floor muscles before the labour and birth could produce strong and well-controlled muscles, reducing incontinence and even potentially reducing malpositions and malpresentations (Salvesen & Morkved, 2004). Salvesen and Morkved (2004) randomised 301 primiparous women to having training with pelvic floor exercises (n = 148) for 60 minutes once a week for a period of twelve weeks before the end of pregnancy. Women also expected to perform eight to twelve intensive contractions of the pelvic floor muscles at home twice a day (81% adherence). Another group (n = 153) were not discouraged from doing pelvic floor muscle exercises on their own. Women randomised to the pelvic floor exercises had a lower rate of prolonged second stage of labour (greater than 60 minutes) than women allocated to no training (24% vs 38%, p = 0.03). Overall the duration of the second stage of labour was not significantly shorter (40 minutes v 45 minutes, p = 0.6). Fewer women had breech presentations in the pelvic floor muscle training group (1 vs 9; p = 0.01) and episiotomies (51% vs 64% OR 0.59; CI 95% 0.35 to 1.00). There was no difference between the rates of operative delivery. The authors concluded that pelvic floor muscle training appeared to facilitate rather than obstruct labour.

4.7.1 Summary of the section

There is evidence that pelvic floor exercises can prevent urinary incontinence in about one in six women during pregnancy and one in eight women after pregnancy (Morkved & Bo, 2000; Reilly et al., 2002; Wilson et al., 1996). Pelvic floor exercises could also potentially prevent a prolonged second stage of labour in one in eight women and may reduce the rate

of episiotomy in one in seven women (Salvesen & Morkved, 2004). The role of pelvic floor exercises in influencing foetal malpositions and malpresentations should also be investigated. The pelvic floor is important in enabling foetal rotation and positioning and this could be optimised with better tone. Pelvic floor exercises should be advocated to women during pregnancy and more research is required.

4.8 Warm packs

Four studies examining the effect of warm packs on perineal trauma were found during the literature review and two of these studies examined pain scores following the birth and women's satisfaction with perineal warm packs. There were two randomised controlled trials, one retrospective cohort and two prospective cohort studies. As perineal warm packs are central to this thesis, a full description of each of the studies is provided in chronological order.

The earliest published research into the use of perineal warm packs in the second stage of labour appears to be in 1995 (Lydon-Rochelle, 1995). This was a retrospective, non-randomised cohort study of 1,211 women, comparing birth positions and management of the perineum (including hot compresses, water-based lubricants, perineal support or massage) with perineal lacerations or midline episiotomy. The researchers found that perineal hot compresses and lubricant increased lacerations, while support and massage had no effect. Both primiparous and multiparous women were included in the study (Lydon-Rochelle, 1995).

In 1996, an observational cohort study involving 3,049 women was published (Albers et al., 1996). This study aimed to identify characteristics and care measures related to perineal trauma at birth. Statistical analysis was performed on a sub-set of women who all had spontaneous vaginal term births ($n = 2,595$). All the women in the study received care from nurse midwives in three hospitals during a 12-month period. Warm compresses, flexion of the foetal head, and lateral birth position were associated with a decrease in

perineal trauma, while oils, lubricants, lithotomy position and epidural anaesthesia were associated with increased perineal trauma (Albers et al., 1996).

The next study was published in 1998. This was a prospective cohort study involving 1,404 women who intended to have homebirths in nurse midwifery practices in the USA (Murphy & Feinland, 1998). The analysis focused on 1,068 women in 28 midwifery practices who gave birth at home with a midwife. Associations between perineal trauma and study variables were examined. Both primiparous and multiparous women were included, although data was also analysed separately for these women. In multiparous women the use of warm compresses appeared to increase the trauma (RR 1.8; 95% CI 1.5 to 2.3), while in primiparous women they had no effect (RR 1.1; 95% CI 0.9 to 1.5). Several other practices were examined in this study, such as perineal massage, manual support of the perineum, oils and lubricants and guided pushing.

The limitation of observational studies is that there is a possibility that warm compresses and other interventions also described in these studies are used when the midwife anticipates a higher likelihood of perineal trauma. For example, a primiparous woman with a large baby and a tight perineum may prompt the midwife to intervene where she may not have otherwise. As pointed out by Murphy and Feinland (1998), these associations could be a reflection of the inevitable perineal trauma, despite the preventative measures. Albers, Anderson and Cragin et al. (1996) argue, however, that these measures may cause local irritation and oedema, therefore increasing the chance of trauma. Where treatment methods are mixed, such as massage and warm compresses, it is hard to distinguish which is having the effect on perineal trauma.

In 1997, an Australian midwife conducted the first randomised controlled trial into the use of warm packs on the perineum (Musgrove, 1999). The study was small, involving 71 women having their second normal vaginal delivery. In the experimental group, 70% of women did not require suturing compared to 54% in the control group, which was statistically significant. Pain was also reduced and 80% of the women reported gaining

comfort from the warm packs. The sample size in this study was small and restricted to multigravid women, limiting generalisability.

The largest randomised trial to date was conducted by Albers et al. (2005) and involved 1,211 women who were randomised to one of three care measures in the second stage of labour: 1) warm compresses to the perineal area; 2) massage with lubricant; or 3) no touching of the perineum until crowning of the infant's head (Albers et al., 2005). This study was published after the Perineal Warm Pack Trial had commenced. The main outcome measure was the incidence of intact perineum. Four hundred and eighty women having their first birth and 731 women having a subsequent birth participated. Warm compresses (n = 404) or massage with lubricant (n = 403) provided no apparent advantage in reducing perineal trauma compared with keeping 'hands poised' over the perineum (n = 404) in the late second stage of labour. There was no standard-care control group. In the warm compresses group, 40.4% of women had epidural anaesthesia. Analysis accounted for the four confounding variables of parity, epidural usage, birth weight, or first year versus later years of the study. No difference was seen in the incidence of intact perineum. There was a very low rate of severe perineal trauma (third- and fourth-degree tears) in this study compared to that found in the Perineal Warm Pack Trial. This is discussed further in subsequent chapters. Long-term follow up and pain scores were not collected during this study which is a limitation, but it remains the most rigorous and informative study to date into the effects of warm packs on perineal outcome at birth.

4.8.1 Summary of the section

While warm packs do not appear to reduce perineal trauma and the need for suturing, they appear to improve comfort whilst giving birth. More research is needed into the benefits of warm packs in terms of improving maternal comfort during birth.

4.9 Cold packs

While some care-providers use cold packs during the second stage of labour, there are no studies into the effect on perineal outcomes or maternal comfort during the second stage. A

recent survey of 210 maternity units in the UK found midwives reported using cold packs to control pain at the end of second stage in 21% of the maternity units (Sanders et al., 2005). There is substantial high-quality evidence about the benefits of cold therapy for perineal trauma after the birth (Steen & Marchant, 2007) (Steen, Briggs, & King, 2006; Steen et al., 2000) but none regarding benefits or harms in the second stage.

4.10 Immersion in water

As discussed in Chapter 2, the use of water immersion during pregnancy, labour and birth for relaxation and pain relief has a long history (Garland, 2000). There are suggestions in the literature that giving birth in water may increase the elasticity of the perineum, reducing the incidence and severity of perineal trauma (Alderdice et al., 1995) (Burns, 2001). A systematic review of immersion in water included eight trials (2,939 women). The most recent substantive amendment was undertaken in January 2002. Of the eight trials, six related to the first stage of labour, one to early versus late immersion in the first stage of labour, and one was carried out amongst women in the second stage of labour (Cluett, Nikodem, McCandlish, & Burns, 2002). The four trials that provided information on epidural/spinal anaesthetic found a significant reduction in use amongst women allocated to immersion in water during the first stage of labour, compared to those not allocated (471/1,196 vs 521/1,210; OR 0.84, 95% CI 0.71 to 0.99). One trial reported maternal pain as being less for women using water than those not using water (40/59 vs 55/61; OR 0.23 95% CI 0.08 to 0.63). There were no significant differences in the numbers of instrumental births, episiotomies, second-degree tears and severe perineal trauma. The one trial that reported immersion in water in the second stage versus no immersion demonstrated a significant difference in the pushing experience of women, with fewer women in the immersion group feeling they did not cope satisfactorily with their pushing efforts (3/60 vs 12/57). There were no differences in episiotomy or second-degree tears, but the numbers were very small.

Following this systematic review, Cluett and colleagues conducted an RCT (n = 99 primiparous women) to compare labouring in water with standard methods of labour

augmentation for the management of dystocia in second stage (Cluett, Pickering, Getliffe, & Saunders, 2004). Women randomised to immersion in water had a lower rate of epidural anaesthesia than women allocated to standard augmentation (47% vs 66% RR 0.71, 95% CI 0.49 to 1.01; NNT 5) and significantly less augmentation (71% vs 96%, RR 0.74; 95% CI 0.59 to 0.88; NNT 4) and less obstetric intervention overall (amniotomy, oxytocin, epidural or operative delivery) (80% vs 98%; RR 0.81; 95% CI 0.67 to 0.97). Perineal outcomes were not given.

4.10.1 Summary of the section

Immersion in water in the first stage of labour appears to reduce the need for epidural anaesthesia and reported maternal pain. It also appears to be an effective option for women experiencing labour dystocia, as it reduces the overall need for obstetric interventions and is thus potentially likely to be beneficial for perineal outcome.

4.11 Local anaesthetic spray

While there are numerous studies on methods to reduce perineal trauma, there are fewer studies into techniques to reduce pain, particularly in the second stage of labour. Sanders et al.'s (2005) national survey of UK midwifery practice found that midwives used a variety of techniques aimed at reducing pain in the late second stage of labour, including the use of lidocaine in a few cases (Sanders et al., 2005). Following on from this survey, a randomised controlled trial evaluating the effectiveness and acceptability of lidocaine spray in reducing perineal pain during spontaneous vaginal birth was undertaken (Sanders, Campbell, & Peters, 2006). Women were randomised to receive either an application (five sprays) of lidocaine spray to the perineum and inside aspect of the labia when birth was thought to be imminent (n = 93), or application of a placebo spray (n = 92). No difference was found between the groups for the main outcome of pain during birth (mean (SD): lidocaine 76.9 (21.6) vs placebo 72.1 (22.2), difference between means 4.8 (-1.7 to 11.2; p = 0.14). Most secondary outcomes were similar between the groups. There was a significantly lower incidence of second-degree perineal trauma in the lidocaine group (28% vs 44%; RR 0.63; CI 0.42 to 0.93). The women in the lidocaine group were also less likely to report

dyspareunia on resumption of sexual intercourse (27.1% vs 52.7%; RR, 0.52; 95% CI 0.35 to 0.76). The authors caution that the large number of secondary analyses undertaken means these differences could be chance findings.

4.11.1 Summary of the section

There is no evidence that lidocaine spray reduces perineal pain during the second stage and birth. More research is needed to determine whether or not it reduces perineal trauma.

4.12 Maternal position in the second stage of labour

The supine position is the most commonly used position for the second stage of labour, including the birth, in western cultures (Atwood, 1976) (Deakin, 2001). Studies have shown that women use a variety of positions during labour and birth if they are allowed to (Carlson et al., 1986) (Hanson, 1998). Controversy surrounds whether being upright (sitting, birth stools, chairs, squatting) or lying down has advantages for women giving birth. There is evidence that an upright position could improve the alignment of the foetus as it passes through the pelvis (“drive angle”) (Gold, 1950). There is also radiological evidence of a larger anterior–posterior (Borell & Femstrom, 1957) and transverse pelvic outlet (Russell, 1969), resulting in an increase in the total area in the squatting position (Gupta, Glanville, Lilford, Dunham, & Watters, 1991) (Russell, 1982) (Lilford, Glanville, Gupta, Shrestha, & Johnson, 1989) and kneeling position (Russell, 1982).

Two systematic reviews of position in the second stage of labour were found for this review. The Cochrane review will be the one addressed here (Gupta et al., 2006). The second systematic review arrived at similar conclusions to the Cochrane review and reviewed similar papers (De Jong, Teunissen, & Largro-Janssen, 2004). The most recent substantive amendment to the Cochrane systematic review was undertaken in April 2003, with a new search conducted in September 2005. Several RCTs have been published since this systematic review and will be considered, as well as a large observational cohort.

The Cochrane review examined outcomes for women without epidural anaesthesia using 20 (35 publications) randomised and quasi-randomised trials (n = 6135 women) (Gupta et al., 2006). The authors advise caution in interpreting the findings, as the quality of the trials is variable. Sources of potential bias include three trials where there is non-random allocation and seven trials where the allocation is on admission to the labour ward rather than in the late first stage of labour. In some of the trials subjects are excluded following randomisation and data from some of the trials were not normally distributed. It is important to point out that there are problems with using an RCT methodology for birth positions, as the freedom to instinctively make choices during labour are seen to be equally as important in outcomes and experiences during labour and birth as the position itself. This needs to be taken into consideration when discussing this research.

Upright positions included sitting (including birth stool/chair); semi-recumbent (trunk tilted backward 30° to the vertical); squatting (unaided or using bars) and squatting (using birth cushion). In the review, upright positions were combined with the lateral position for comparison with supine or lithotomy positions. Use of an upright or lateral position compared with supine or lithotomy positions is associated with a reduced duration of second stage of labour (nine trials: mean 4.28 minutes; 95% CI 2.93 to 5.63); a small reduction in assisted deliveries (19 trials: RR 0.80; 95% CI 0.69 to 0.92); a reduction in episiotomies (12 trials: RR 0.83; 95% CI 0.75–0.92) which was partly offset by an increase in second-degree perineal tears (11 trials: RR 1.23; 95% CI 1.09 to 1.39); an increase in estimated blood loss greater than 500 mL (11 trials; RR 1.63; 95% CI 1.29 to 2.05), fewer women reporting severe pain during the second stage of labour (1 trial: RR 0.73; 95% CI 0.60 to 0.90); and fewer abnormal foetal heart-rate patterns (1 trial: RR 0.31; 95% CI 0.08 to 0.98). No significant differences were demonstrated for anaesthesia overall or anaesthesia use during the second stage (seven trials); duration of the second stage for multigravid women (three trials); caesarean section (13 trials); severe perineal trauma (four trials); blood transfusion (two trials); uterine contraction frequency (one trial); manual removal of placenta (three trials); unpleasant birth experience (one trial); feeling out of control (one trial); admission to neonatal intensive care unit (two trials); birth injuries (one trial); perinatal death (three trials) (Gupta et al., 2006).

Three additional randomised controlled trials were identified as published after the Cochrane systematic review (Gupta et al., 2006) and will be considered in the next section.

A multicentred randomised trial investigated the effect of a hands-and-knees position during the second stage of labour for primiparous women ($n = 147$) women with a baby in an occipitoposterior position in labour (Stremmer et al., 2005). The position was confirmed by ultrasound. The primary outcome was that the baby was in an occipitoposterior position (determined by ultrasound) following the one-hour study period. The women allocated to the hands and knees position ($n = 70$) assumed this position for at least 30 minutes over a one-hour study period during labour. The control group ($n = 77$) were actively discouraged from adopting this position during the one-hour study period and could adopt any other position they wished. Women randomised to the hands-and-knees position had significantly less backache. Sixteen per cent of women allocated to using the hands-and-knees position had their baby rotate to an anterior position following the one-hour study period, compared to 7% in the control group (RR 2.4; 95% CI 0.88 to 6.62; NNT 11). There were trends towards benefit for the intervention group for several other outcomes, including operative delivery and foetal head position at delivery (Stremmer et al., 2005).

A recent study, which was a secondary analysis of data from a large trial involving 1,646 low-risk women, has shed light on the association between upright position and increased blood loss. This showed that blood loss was only significantly increased in women in sitting (OR 2.25; 95% CI 1.37 to 3.71) and semi-sitting positions (OR 1.30; 95% CI 1.00 to 1.69) compared to women in a recumbent position, when perineal damage occurred (De Jong, Scheepers, van der Pal-de Bruin, & Largo-Janssen, 2007). In this study, blood was measured rather than estimated, increasing its accuracy. The authors conclude that increased perineal oedema associated with upright positions is the most likely cause of the increased blood loss observed in other trials (De Jong et al., 2007).

Most studies focus on comparing upright positions to supine positions. A recent RCT undertaken in Sweden investigated the effects of a kneeling position ($n = 138$) compared to

a sitting position (n = 133) for primiparous women (Ragnar, Altman, Tyden, & Olsson, 2006) in the second stage. The assigned position was adopted once the second stage commenced and was maintained until the baby's head crowned. The primary outcome was the length of the second stage. There was no difference in the length of second stage between the kneeling and sitting group (kneeling 48.5 min. (SD 27.6 min.); sitting 41 min. (SD 23.4 mins.)). The sitting position was associated with: a higher level of delivery pain (OR 1.3; 95% CI 1.1 to 1.9; $p < 0.01$) a more frequent perception of the second stage as being long (OR 1.4; 95% CI 0.8 to 0.9; $p = 0.002$), less comfort for giving birth (OR 0.5; 95% CI 0.1 to 0.9; $p = 0.03$) and more frequent feelings of vulnerability (OR 2.1; 95% CI 0.9 to 4.6; $p = 0.05$) and exposure (OR 1.7; 95% CI 1.5 to 1.9; $p = 0.02$). Greater postnatal perineal pain was also reported in the first three days in the sitting group (OR 1.9; 95% CI 1.3 to 2.9). De Jong et al (1997) compared an upright delivery position with a supine delivery position using an RCT and concluded that the upright position was associated with less intrapartum pain (De Jong et al., 1997). Ragnar (2006) suggests that previous studies (De Jong et al., 1997; Waldenstrom & Gottvall, 1991) reporting a lower level of pain in upright positions compared with supine positions may not be generalised to include all upright positions (Ragnar et al., 2006). In the Ragnar (2006) study, there were no significant differences in the frequency of anal sphincter ruptures but the number of women was very small. No information is given regarding episiotomy or other forms of perineal trauma. There was a proportionately higher incidence of instrumental deliveries in the sitting group compared with the kneeling, but this did not reach statistical significance.

A randomised trial into the effect of birth position in the second stage of labour on birth outcome in 107 primiparous women using epidural anaesthesia found that the lateral position was associated with lower rates of instrumental birth (16 vs 30; $p = 0.05$) and episiotomy (22 vs 32; $p = 0.05$) compared to supine (Downe, Gerrett, & Renfrew, 2004).

A large prospective cohort study undertaken in the USA collected data for women cared for at three nurse-midwifery services during a 12-month period (n = 3,049) (Albers et al., 1996). Data collection was carried out using a standardised, validated tool. Multivariate analysis by logistic regression was used to identify predictors of episiotomy and

spontaneous perineal tears. Forty-four per cent of women were having their first baby. Giving birth in the lateral position was associated with a lower incidence of spontaneous perineal tears amongst primiparous women ($n = 919$) (OR 0.6; 95% CI 0.2 to 1.0) but not multiparous women (Albers et al., 1996). This is supported by the retrospective, descriptive Australian study by Shorten et al. (2002) that examined data from 2,891 normal vaginal births and found that giving birth in a lateral position was associated with the highest rate of intact perineum (66.6% vs 55% baseline rate) and squatting with the lowest intact rate (44% vs 55% baseline rate) (Shorten, Donsante, & Shorten, 2002). Song and Barnes (2005), also from Australia, analysed data from 3,756 women who had spontaneous vaginal births and found women who gave birth on all fours were the least likely to experience any genital tract trauma that required suturing; this was particularly so with the first vaginal birth and where infant birth weight was over 3,500gms (Soong & Barnes, 2005). When epidural anaesthesia was used, the lateral position was associated with a reduced need for suturing compared to the semi-recumbent (Soong & Barnes, 2005).

4.12.1 Summary of the section

Women who gave birth in a supine position compared with those who gave birth upright, found it more painful, had a higher incidence of foetal distress, more episiotomies, fewer second-degree tears, more instrumental deliveries but lost less blood. There was no difference in the proportion of women who gave birth with an intact perineum in relation to birth position. The reduced reported discomfort experienced was particularly observed in women giving birth in kneeling positions. There is evidence that using a hands-and-knees position in the second stage for women with a baby in an occipito-posterior position reduces backache and shows trends towards rotating babies into an occipito-anterior position and providing other benefits that could lessen perineal trauma. Lower level evidence indicates that giving birth in a lateral position compared to a supine position appears to lead to lower perineal trauma, amongst primiparous women in particular, as does the all-fours position. Recent evidence provides some explanation for the increased blood loss and seems to be the only disadvantage associated with upright birthing positions. This

review indicated that women should be encouraged to give birth in the position they feel to be most comfortable.

4.13 Coached vs uncoached pushing

The benefits and harms of coached versus uncoached pushing in the second stage of labour are vigorously debated in the literature (Roberts, 2002) (Petrou, Coyle, & Fraser, 2000). As discussed in the previous chapter, Beynon (1957) was a pioneer in this area when she compared the outcomes for 100 primigravid women assigned to push as desired with 393 other primigravid women who were instructed to push. The women who actively pushed had an increased need for suturing of their perineal trauma (Beynon, 1957). Caldeyro-Barcia et al. (1959; 1979; 1981) demonstrated that pushing with a closed glottis interferes with placental circulation and leads to a decrease in heart rate (Caldeyro-Barcia, 1979; Caldeyro-Barcia, Pose, & Sica-Blanco, 1959) (Caldeyro-Barcia et al., 1981). Those who support the open glottis method of pushing maintain that the pelvic floor and the foetus are protected (Roberts, 2002).

A protocol for a systematic review of the literature is available in the Cochrane Database of Systematic Reviews but it is not yet complete (Roost & Nickodem, 2002). Six randomised trials were found comparing coached with uncoached pushing (Bloom et al., 2006; Kanauth & Haloburdo, 1986; Parnell, Langhoff-Roos, & Damgaard, 1993; Schaffer et al., 2005; Simpson & James, 2005; Thomson, 1993).

Bloom et al. (2006) randomly assigned primiparous women without epidurals to coached (n = 163) versus uncoached (n = 157) pushing during the second stage of labour (Bloom et al., 2006). Primiparous women allocated to the coached pushing group received standardised closed glottis coached pushing instructions during contractions and were encouraged to breathe normally between contractions. The same group of midwives who gave no instruction on pushing attended the uncoached group; women were encouraged to do what came naturally. The second stage was abbreviated by approximately 13 minutes in coached women (46 minutes vs 59 minutes, $p = 0.01$) and there were no other clinically significant

immediate outcomes for women or their babies. The incidence of meconium stained liquor was increased in the coached group, though most was diagnosed before the second stage. Recruitment for the study was difficult, with only 350 of the 1,413 women eligible to participate. The group was extremely low risk and 94–96% of participants were of Hispanic origin. The episiotomy rate was high for this low-risk population (26% in the coached group vs 20% in the uncoached group). The severe perineal trauma rate (third- and fourth-degree tears) (11% in coached vs 10% in uncoached) was surprisingly high, as was the use of oxytocin for augmentation of labour. Critiques have argued that the population and second-stage practices are such that it makes the applicability of this study's results to other populations limited (Klein, 2006b).

Schaffer et al. (2005) (Schaffer et al., 2005) conducted a randomised controlled trial in the USA into the effects of coached ($n = 67$) versus uncoached ($n = 61$) pushing on pelvic floor structure and function at three months. Women were randomised when fully dilated to either coached or uncoached pushing. Nurses blinded to the treatment carried out pelvic floor assessment at three months postpartum. There were no significant differences between the two groups in demographics, or birth outcomes. Urodynamic testing revealed decreased bladder capacity ($p = 0.05$) and decreased first urge to void ($p = 0.03$) in the coached group. These two studies are the most rigorous of the studies reviewed but again have generalisability issues.

Other studies were not included in the Cochrane review protocol. Parnell et al. (1993) randomised 350 primiparous women to spontaneous pushing or prolonged Valsalva manoeuvres, once the foetal head could be seen (Parnell et al., 1993). Perineal trauma was no different between the two groups, though surprisingly high (95%).

Thompson's (1993) study only had 32 women in it and therefore insufficient power to show a significant difference in perineal trauma. Once again the second stage was longer in the spontaneous pushing group (means (SD): 121.4 minutes (58.4) vs 58 minutes (42), $p = 0.002$). This may have been contributed to by differences, which led to a significant longer first stage as well in this group, rather than being attributed to the type of pushing.

Another small RCT compared women using a breath-holding pushing technique (n = 10) with those encouraged to use an exhalation pushing technique (n = 17) (Kanauth & Haloburdo, 1986). The women in this study all gave birth sitting on a birth chair. This study is very small, with significant methodological problems. They found no significant differences except for an increase in variable foetal heart rate decelerations (30% vs 17.6% no p value given) in the coached group.

Simpson and James (2005) randomised 45 primiparous women with epidurals to coached pushing at full dilation of the cervix, or to a two-hour rest period followed by uncoached pushing. Immediate pushing was associated with lower foetal oxygen saturation and 13 out of 22 women had perineal tears in this group compared to five out of the 23 women with delayed pushing (p = 0.01) (Simpson & James, 2005). However, the sample size in this study was very small.

4.13.1 Birth of baby's head between contractions

Another style of pushing debated in the literature is that of delivering the baby's head in between contractions. Albers (2006) used data from a large randomised clinical trial (n = 1176) of perineal management techniques (perineal massage, warm packs, 'hands poised' the head) to examine other relationships. Twenty per cent of all women in the study experienced sufficient trauma to warrant suturing (34% in primiparous women vs 10% in multiparous women). A regression model was used for first and subsequent vaginal births. In women having their first vaginal birth (n = 452), Valsalva pushing (p = 0.001) and higher infant birth weight (p = 0.05) increased the need for perineal repair whilst delivery of the infant's head between contractions (p = 0.05) was protective. In multiparous women, statistically significant predictors for sutured trauma were prior sutured trauma (p = 0.0001), higher infant birth weight (p = 0.001) and again delivery of the infant's head in between contractions (p = 0.05) was protective.

4.13.2 Summary of the section

Women should be advised to follow their own urges to push during the second stage. While the second stage may be shortened with coached pushing, there is no evidence of benefit from this and some evidence that foetal wellbeing can be compromised. There is some evidence that coached pushing is associated with increased perineal trauma at birth and adverse outcomes for the pelvic floor at three months.

Delivering the baby's head between contractions appears to have some advantages in reducing the requirement for suturing, but further research is needed.

4.14 Hand manoeuvres

Different hand techniques for the accoucheur have been proposed for reducing perineal trauma during birth. These generally involve comparisons between putting pressure on the baby's head to flex the head and support the perineum and not touching the baby's head or the woman's perineum. No recent systematic review has been undertaken.

Four randomised trials evaluating the effect of hand manoeuvres on perineal outcomes were found (McCandlish et al., 1998) (Albers et al., 2005) (da Costa & Riesco, 2006); one of these was a quasi-randomised study (Mayerhofer et al., 2002). The study conducted by Albers et al. (2005) did not have a 'hands on' comparison group and the hands poised group was defined as no touching of the perineum until the baby's head crowned (Albers et al., 2005).

The UK RCT, known as the HOOP trial, is the largest (n = 5,471) and most rigorous study to date (McCandlish et al., 1998). In this study, two methods of perineal management used during spontaneous vaginal birth were compared: a 'hands on' (flex the head and guard the perineum) and 'hands poised' ('hands poised' above the head and perineum). The compliance with the allocated method in the 'hands on' group was very good (95.3%). Compliance was somewhat lower in the 'hands poised' group (70.1%), reflecting midwife preference for the 'hands on' method. The main outcome measure for the trial, perineal

pain in the previous 24 hours reported by women at 10 days postpartum, was lower for women in the 'hands on' group (910/2669 vs 823/2647; RR 1.10; 95% CI 1.01 to 1.18). The difference was mainly in the category of mild pain. The episiotomy rate was higher in the 'hands on' group (10.2% vs 12.9%; RR 0.79 99% CI; 1.02 to 2.78), but all other perineal trauma was similar. An unusual finding was that the rate of manual removal of placenta was higher for women in the 'hands poised' group (2.6% vs 1.5%; RR 1.69; 99% CI 1.02 to 2.78). A large number of other outcomes, including three-month follow-up, showed no differences between the groups.

A RCT conducted by Albers et al. (2005) in the USA has already been described earlier in this chapter. It involved 1,211 women randomised into one of three care measures in the second stage of labour: 1) warm compresses to the perineal area; 2) massage with lubricant; or 3) no touching of the perineum until crowning of the baby's head (Albers et al., 2005). The main outcome measure was a significant difference in the incidence of intact perineum. No significant difference was seen between the three groups but there was no 'hands on' group for comparison in this study.

Another small, randomised trial included 70 primiparous women in two groups ('hands on' n = 35 vs 'hands poised' n = 35) (da Costa & Riesco, 2006). There was no difference in perineal trauma (82.7% vs 82.2% first-degree tear and 17.3% vs 17.8% second-degree tear) or neonatal outcomes between the two groups.

A quasi-randomised, multicentred trial (n = 1,161) was conducted in Austria to investigate the influence of the traditional 'hands on' versus 'hands poised' method on perineal trauma and neonatal outcomes (Mayerhofer et al., 2002). Only midwives who agreed with the aims of the study participated and, as a result, compliance in both groups was high (92% and 94%). Quasi-randomisation was carried out by alternating 'hands on' and 'hands poised' policies according to the date the woman entered the second stage of labour. There was a similar rate of first- and second-degree perineal trauma with 29.8% in the 'hands on' group requiring suturing and 33.7% in the 'hands poised' group requiring suturing. Women in the 'hands on' group were more likely to have an episiotomy performed (17.9% vs 10.1%; p =

0.01). Although there was a higher rate of severe perineal trauma in the 'hands on' group ($n = 16$ (2.7%) vs $n = 5$ (0.9%) $p = 0.5$) the study was underpowered to detect statistical difference in this rare outcome. There were no differences in other outcomes.

4.14.1 Summary of the section

There is evidence from one randomised trial that women in the 'hands on' group reported milder pain at 10 days compared to those allocated to the 'hands poised' group. There is also evidence that episiotomy may be reduced in the 'hands poised' group although perineal trauma remains the same. Either 'hands on' or 'hands poised' can be used to facilitate spontaneous birth.

4.15 Episiotomy

Episiotomy is amongst the most common surgical procedures experienced by women in the USA, occurring in 35% of vaginal births (Hartmann et al., 2005) (Weber & Meyn, 2002) (Kozak, Owings, & Hall, 2004) (Declerqu, Sakala, Corry, Applebaum, & Risher, 2002). In Australia, the episiotomy rate is currently 17.2% (Laws et al., 2006b) but this ranges from as low as 0% to over 30% in many private hospitals where babies are delivered by obstetricians (NSW Health, 2007). In reviewing the literature on episiotomy, over 1,000 articles were identified. There have been several systematic reviews of the evidence on episiotomy (Carroli, Belizan, & Stamp) (Eason et al.) (Kettle, 2004) (Hartmann et al., 2005). The review by Hartmann et al (2005) is the most recent and will be discussed here.

Hartmann et al. (2005) conducted a systematic review of maternal outcomes following routine, compared with restricted use of episiotomy. It included seven randomised trials with a total of 5,001 participants and eight cohort studies involving 6,463 women. (Hartmann et al., 2005). Six of the trials studied mediolateral episiotomy, with only one using midline episiotomy. Three of the trials only included women having their first baby. The evidence is summarised descriptively rather than meta-analysed. All the trials achieved a wide difference in episiotomy use, ranging from 7.6% in the restricted group to 93.7% in the routine group. In the most rigorous trial, with 1,000 participants (Sleep et al.,

1984), women in the restricted use group were more likely to have an intact perineum (33.9% vs 24.3%) with the largest difference in the requirement for suturing seen in primiparous women (74% vs 89%). In the largest study, a multisite Argentine study (n = 2606) (Argentine Episiotomy Trial Collaborative Group, 1993), the need for surgical repair was 63% in the restricted group, compared with 88% in the routine group, with less pain and healing complications in the restricted use group. In the remaining five randomised trials, the intact perineum was lower in the routine episiotomy group compared to the restricted group (RR 0.46; 95% CI 0.30 to 0.70) (Klein et al., 1992) (Sleep et al., 1984) (House, Cario, & Jones, 1986) (Eltorkey, Al Nuaim, Kurdi, Sabagh, & Clarke, 1994) (Dannecker et al., 2004). The need for suturing was 26% higher in the routine groups (three trials) (RR 1.26; 95% CI 1.08 to 1.48). With the exception of two trials (Sleep et al., 1984) (Klein et al., 1992), all the studies reported more severe perineal trauma in the routine use group, but all the trials were underpowered to detect any difference, with an overall incidence of 105/5,001 (seven trials) in the incidence of severe perineal trauma.

Women's experiences of pain were considered in five of the trials. In the Sleep et al. (1984) trial, midwives masked to the allocated group were used to assess pain at 10 days postpartum. The severity of pain was almost identical for restricted and non-restricted groups, as was use of oral analgesia and pain ratings at three months (Sleep et al., 1984). Three other trials reported pain as higher in the routine episiotomy group, but each trial used different pain outcome measures. Where activity was assessed (Dannecker et al., 2004), the restricted group had less associated pain. None of the five studies found that routine episiotomy lessened pain (Hartmann et al., 2005). Two of the studies examined urinary incontinence at three months and there was no difference in the incidence between routine and restrictive use of episiotomy (RR 1.02; 95% CI 0.83 to 1.26) (Hartmann et al., 2005). This finding was supported by the five cohort studies examined. Pooling data from two cohort studies with comparable outcome measures showed an increase in rectal incontinence (RR 1.91; 95% CI 1.03 to 3.56).

Two trials reported on sexual function. In the Sleep et al. (Sleep et al., 1984) trial, 37% of the restricted use group and 27% of the routine use group had resumed sexual intercourse

by one month after birth ($p = 0.01$). No differences were found in sexual function between women who had an episiotomy compared, with women who had a tear at three months. At the third year of follow-up, the likelihood of ever suffering painful intercourse remained comparable between the two groups (Sleep & Grant, 1987). Klein et al. (1994) reported that women in the restricted use group, resumed sexual intercourse on average a week earlier than those in the routine use group. Women who had had an episiotomy had the slowest return to sexual intercourse ($p = 0.02$) and pain with the first postpartum sexual intercourse was also most common and severe ($p = 0.001$) (Klein et al., 1994). By three months, all measures of sexual function were equivalent.

One trial compared midline and mediolateral episiotomy and found more complications occurring in the midline group ($p = 0.001$) (Coats, Chan, Wilkins, & Beard, 1980). Twenty four per cent of the midline group had an extension of the episiotomy into or through the anal sphincter, compared with 9% of the mediolateral group. On the other hand, the midline group had less bruising of the perineum ($p = 0.001$). There were no differences in pain or sexual satisfaction between the two groups, although women in the midline group resumed sexual intercourse earlier ($p = 0.01$).

The authors of the UK NICE Intrapartum Care Guideline (NIHCE, 2006) pooled some of the findings from a single RCT (Dannecker et al., 2004) and a 1999 systematic review (Carroli & Belizan, 2006) and performed a meta-analysis. They found:

- no difference in severe perineal trauma (RR 0.74 95% CI 0.42 to 1.28) (six trials)
- less posterior perineal trauma in the episiotomy group (RR 0.84; 95% CI 0.73 to 0.96) (five trials)
- no difference in anterior trauma (RR 1.33; 95% CI 0.89 to 1.98) (five trials)
- no difference in Apgar scores <7 at 1 minute (RR 1.05 (0.76 to 1.45))

4.15.1 Summary of the section

The evidence does not support maternal benefits traditionally ascribed to routine episiotomy. Outcomes with episiotomy could be considered worse, since a proportion of

women who would have had a lesser injury instead have a surgical incision. Routine use of episiotomy may lead to higher levels of pain in women and a greater incidence in faecal incontinence. A mediolateral episiotomy should be carried out when an episiotomy is required

4.16 Vacuum versus forceps delivery

There is ongoing debate about the benefits of vacuum extraction over forceps delivery when an instrumental birth is required. Proponents of vacuum extraction believe it should be chosen first because it is less likely to cause perineal injury for the mother. A systematic review of vacuum versus forceps was obtained from the Cochrane Database of Systematic Reviews (Johanson & Menon, 1999). The last substantive amendment to this review was in December 1998. Ten trials were included and were judged to be of reasonable quality. The use of a vacuum extractor for assisted vaginal delivery compared with forceps was associated with significantly less maternal trauma (OR 0.41, 95% CI 0.33 to 0.50) and less regional anaesthesia. Fewer caesarean sections were carried out in the vacuum extractor group. There was an increase in neonatal cephalhaematoma and retinal haemorrhages in the vacuum extractor group, but serious neonatal injury was unlikely with either instrument.

4.16.1 Summary of the section

A vacuum extractor should be used where possible rather than forceps, as it leads to less maternal trauma.

4.17 Epidural anaesthesia and perineal trauma

Epidural anaesthesia has been researched extensively and yet there is still limited consensus about what unintended effects it causes (Klein, 2006a; Lieberman & O'Donoghue, 2002). Choosing an epidural for labour pain relief is almost always a choice that the woman makes in consultation with her caregivers. It is critical that both are aware of the potential risks as well as benefits. A recent systematic review is available from the Cochrane Database of Systematic Reviews (Anim-Somuah et al., 2005). This review was last updated in August

2005. Twenty-one studies involving 6,664 women were included and all but one study compared epidural anaesthesia with opiates. Women's perception of pain relief was only obtained from one study (n = 105) which found epidural anaesthesia offered better pain relief than non-epidural analgesia (weighted mean difference (WMD) -2.60, 95% CI -3.82 to -3.8) but there was no difference in maternal satisfaction with pain relief in five trials (n = 1,940) (RR 1.18; 95% CI 0.92 to 1.50) Epidural anaesthesia was associated with an increased risk of instrumental vaginal birth in 17 trials (n = 6,162) (RR 1.38; 95% CI 1.24 to 1.53). Klein (2006) demonstrated the limitations with meta-analysis in a recent editorial pleading for researchers to be "vigilant about which studies get into the meta-analysis and ask ourselves if they make clinical sense" (Klein, 2006a).

In a systematic review of the unintended effects of epidural anaesthesia (Lieberman & O'Donoghue, 2002), the authors state that because existing data support an increase in instrumental birth when epidural anaesthesia is used and severe perineal trauma is increased with instrumental birth, it is likely that this association occurs. In their review of studies that examined severe perineal trauma they found six studies, five of which showed a twofold increase in perineal laceration associated with epidural anaesthesia use. Robinson et al. (1999) studied 1,942 term primiparous women and found that the association between epidural anaesthesia and severe perineal trauma remained significant in a logistic regression analysis controlling for potential confounding factors (OR, 1.4; 95% CI 1.0 to 2.0) (Robinson et al., 1999). They also classified women into four categories by method of delivery (spontaneous or instrumental) and use of episiotomy (yes/no). Both episiotomy and instrumental delivery were more frequent in women receiving an epidural, and when these two practices were taken into account there was no association. Thus epidural use is associated with an increase in severe perineal trauma but it is mainly due to the increase in instrumentals and thus episiotomy (Lieberman & O'Donoghue, 2002). This is a demonstration of the 'cascade of intervention' associated with epidural anaesthesia.

A systematic review of nine studies (n = 2953) assessing the effect of immediate versus delayed pushing in women using epidurals showed a significant reduction in rotational or mid-pelvic instrumental deliveries (31% reduction) (RR 0.59; 95% CI 0.36 to 0.98)

(Roberts, Trovaldesen, Cameron, & Olive, 2004). There were no statistically significant differences noted in episiotomies or perineal tears. However, only four studies reported on episiotomy as a key outcome and only five reported on perineal tears, and both are common covariates in instrumental birth. Any reduction in instrumental deliveries would be beneficial in reducing perineal trauma.

4.17.1 Summary of the section

Women should be informed that whilst epidural anaesthetic is an effective pain relief, it does lead to an increase in instrumental birth. Women need to know of the implications of the higher rate of instrumental birth, specifically the increase in episiotomy and severe perineal trauma. Women should be advised that delayed pushing in the second stage may have advantages of reducing rotational instrumental births and as a result could be beneficial for reducing perineal trauma.

4.18 Support during labour

Historically women have been attended and supported by other women during labour. Researchers have hypothesised that labour support enhances labour physiology and mothers' feelings of control and competence, reducing reliance on medical interventions. It may also limit the 'cascade of intervention'. For example, continuous support may lead to a reduced use of epidural anaesthesia, leading to a reduced use of electronic foetal monitoring, intravenous drips, artificial oxytocin drugs, drugs to combat hypotension, catheterisation, instrumental birth, episiotomy and severe perineal trauma.

A systematic review of continuous support for women during childbirth (Hodnett, Gates, Hofmeyr, & Sakala, 2003) was undertaken to determine the effect of this support on mothers and babies. The most recent substantive amendment was in May 2003. Fifteen trials were identified from eleven different countries, involving 12,791 women. Women who had continuous, one-to-one support during labour were less likely to have regional anaesthesia (six trials, $n = 10,048$; RR 0.90; 95% CI 0.81 to 0.99), have any analgesia/anaesthesia (11 trials, $n = 11,051$; RR 0.87; 95% CI 0.79 to 0.96), have an

instrumental vaginal birth (14 trials, $n = 12,757$; RR 0.89, 95% CI 0.83 to 0.96). There were no significant differences in the rate of episiotomy (one RCT) and perineal trauma (two RCTs). There remains relatively little information about the effects of continuous intrapartum support on mothers' and babies' health and wellbeing in the postpartum period (Hodnett et al., 2003).

4.18.1 Summary of the section

Based on this review it is concluded that all women should have support throughout the labour and birth. The rates of epidural anaesthesia and instrumental births are reduced, suggesting that support is likely to be beneficial rather than harmful for preservation of the perineum. Only three studies, however, examined this outcome and it was found not to be statistically significant.

4.19 Place of birth and perineal trauma

Debate continues over the relationship of the place of birth and its impact on maternal and neonatal outcomes (NIHCE, 2006). Perineal trauma is one such outcome that is addressed in studies.

4.19.1 Home-like environment versus conventional institutional setting

A systematic review of home-like versus conventional institutional settings for birth (Hodnett, Downe, Edwards, & Walsh, 2005) was found. The last substantive update was November 2004. Six trials were included in the review ($n = 8,677$). A recent meta-analysis conducted by the National Collaborating Centre for Women's and Children's Health (draft) (NIHCE, 2006) was also found and will be considered.

In the Cochrane systematic review, allocation to a home-like setting significantly decreased the likelihood of episiotomy (five trials $n = 8,529$) (RR 0.85; 95% CI 0.74 to 0.99) and epidural anaesthesia (six trials, $n = 8,645$) (RR 0.83; 95% CI 0.75 to 0.92). There was an increased likelihood of vaginal/perineal tears (four trials, $n = 8,415$) (RR 1.08; 95% CI 1.03 to 1.13); having a spontaneous vaginal birth (five trials, $n = 8,529$) (RR 1.03; 95% CI 1.01

to 1.06) with high satisfaction with intrapartum care (one trial, n = 2,844) (RR 1.14; 95% CI 1.07 to 1.21).

The meta-analysis performed by the UK National Collaborating Centre for Women's and Children's Health (NIHCE, 2006) found, in the midwife-led units, a significant reduction in the use of epidural anaesthesia and women using any pain relief at all; a reduction in episiotomy; a reduction in overall perineal trauma; and an increase in intact perineum rates and spontaneous vaginal birth (NIHCE, 2006).

4.19.2 Home birth versus hospital birth

Since the mid-1900s, the majority of births have taken place in hospital settings. Three systematic reviews of homebirth versus hospital birth have been undertaken (Olsen, 1997) (Olsen & Jewell, 1998) (NIHCE, 2006). The Cochrane systematic review contained only one study involving 11 women and was too small to draw any conclusions (Olsen & Jewell, 1998). The meta-analysis Olsen undertook in 1997 included controlled observational studies (six). This analysis reported fewer medical interventions in the home birth group, including episiotomy, operative vaginal birth and severe perineal trauma.

The National Collaborating Centre for Women's and Children's Health in the UK undertook a new systematic review for the NICE Intrapartum care guidelines, which are currently in draft form (NIHCE, 2006). They included the two systematic reviews, twelve comparative observational studies and two case-series studies. Five other studies were included just to obtain transfer rates. The main focus of the NICE review was on transfer rates and perinatal mortality, therefore not of great use to this specific review. A brief summary of findings relevant to perineal trauma and comfort in the second stage is provided.

In 2005, a large prospective cohort study was published examining all home births (n = 5,418) involving certified professional midwives across the USA and Canada, of women who were expecting to give birth in 2000 and planned to deliver at home when labour

began (Johnson & Daviss, 2005). The rates of medical intervention; including epidural (4.7%), episiotomy (2.1%), forceps (1.0%) and vacuum extraction (0.6%) were all substantially lower for women having home births compared to low-risk women having hospital births in the USA. Most contrasting was the very low episiotomy rate (2.1%) amongst women giving birth at home compared to 33% for low-risk women giving birth in hospital. These findings are similar to a Canadian prospective cohort study comparing the outcomes of all homebirths (n = 862) attended by midwives over two years (1998 and 1999) with those of planned hospital births attended by either midwives (n = 571) or physicians (n = 743) (Janssen et al., 2002). The participants were matched for obstetric risk status. Women who gave birth at home had less epidural anaesthesia (p = 0.001), fewer episiotomies (p = 0.001) and less surgical intervention in birth (instrumental births and caesarean sections) (p = 0.001) than women who gave birth in hospital with midwives and doctors (Janssen et al., 2002).

A less recent cohort study in Switzerland between 1989 and 1992 of 489 women with a planned home birth and 285 women with a planned hospital birth found women in the homebirth group had less analgesia (p < 0.001), fewer episiotomies (p < 0.001) fewer perineal tears (p < 0.001) and more intact perineum (p < 0.001) (Ackermann-Leibrich et al., 1996). These findings are similar for most of the studies available on home birth versus hospital birth.

Another prospective cohort study that looked specifically at perineal outcomes in a USA homebirth setting (n= 1,068) found 69.9% of women had an intact perineum, 1.4% had an episiotomy, 28.9% had first- or second-degree tears and seven women (0.7%) had severe perineal trauma (Murphy & Fullerton, 1998). Again these perineal outcomes were low compared to those of women experiencing standard hospital care in the USA.

4.19.3 Stand-alone midwifery-led unit versus consultant-led unit

There are no RCTs identified for stand-alone units. There was one structured literature review that evaluated the evidence for midwifery-led units including stand-alone

midwifery-led units (Stewart, McCandlish, Henderson, & Brocklehurst, 2004). Women in stand-alone units were less likely to use any type of analgesia (two retrospective cohorts), perineal trauma was significantly less likely (four cohort studies) and women were more likely to have a normal vaginal birth (four studies) in stand-alone midwifery-led units (Stewart et al., 2004).

4.19.4 Summary of the section

Giving birth in a home-like environment (birth centre) compared to a hospital leads to a lower use of episiotomy and epidural anaesthesia and a higher rate of normal birth. This is protective for perineal damage.

Giving birth at home leads to the lowest levels of perineal trauma, epidural anaesthesia, instrumental birth rate and other obstetric interventions, compared to birth in hospital, regardless of the care provider.

Giving birth in a midwife-led stand-alone unit leads to a lower rate of perineal trauma and higher normal birth rate, with women using less analgesia.

4.20 Midwives and obstetricians' impact on perineal outcomes

As discussed previously, there is some evidence that different care-providers can have an impact on women's perineal outcomes, as can different models of care in which those providers practise.

There is a systematic review including two trials, (n = 1,815) (Flint, Poulengeris, & Grant, 1989) (Rowley, 1998) comparing continuity of care by midwives with non-continuity of care by a combination of doctors and midwives (Hodnett, 2000). The last substantive amendment was in October 1999. Women who received continuity of care were less likely to have an epidural (OR 0.67; 95% CI 0.53 to 0.84); an episiotomy (OR 0.75; 95% CI 0.60 to 0.94); not feel in control during labour (OR 0.48; 95% CI 0.34 to 0.68) and fail to enjoy

labour (OR 0.65; 95% CI 0.47 to 0.90). Women who received continuity of care were more likely to have a vaginal or perineal tear (OR 1.28; 95% CI 1.05 to 1.56).

Other studies have examined perineal outcomes for women under midwifery care or obstetric care. Retrospective analysis of medical record data, using logistic regression models, examined factors that influenced episiotomy rates and outcomes for babies in a sample of women ($n = 2,028$) who delivered vaginally during a 12-month period (1996 – 1997) in NSW, Australia (Shorten & Shorten, 2000). After controlling for clinical factors, privately insured women attended by obstetricians were estimated to be twice as likely to experience episiotomy as publicly insured women ($p < 0.01$) attended by midwives. They were more likely to experience a vacuum extraction ($p < 0.01$). Severe perineal trauma was found to be positively associated with episiotomy. Likewise the numbers of perineal tears requiring suturing were also substantially higher amongst privately insured women ($p < 0.001$) and they had a lower chance of achieving an intact perineum. This supported findings of a previous study showing women who were privately insured experienced higher episiotomy rates (35.7%) than women who were publicly insured (25%) (Shorten & Shorten, 1999).

Another population-based descriptive study in NSW, Australia examined all 171,157 women giving birth to a live baby during 1996 and 1997 (Roberts et al., 2000). When only low-risk women were compared, the rates of obstetric intervention including epidural anaesthesia, episiotomy, and instrumental birth were highest in privately insured women attended by obstetricians in private hospitals in comparison to publicly insured women attended in public hospitals and usually attended by midwives.

Klein and colleagues (Klein et al., 1995) conducted a post-hoc cohort analysis of doctors and women involved in an RCT of episiotomy (Klein et al., 1994; Klein et al., 1992). They found that women attended by doctors who viewed episiotomy very unfavourably were more likely than women attended by other doctors to have an intact perineum (23% vs 11% to 13%, $p < 0.05$). Those who viewed episiotomies favourably were more likely to use the

technique and their patients were more likely to have perineal trauma and to be less satisfied with the birth experience (Klein et al., 1995).

4.20.1 Summary of the section

It appears that midwifery care is associated with a reduced use of episiotomy and when women are cared for in continuity-of-care midwifery models, they are less likely to have an epidural or episiotomy and more likely to feel positive about their birth experience.

Midwifery care is protective for perineal trauma. This is mostly due to the reduced use of episiotomy. The personal belief of the accoucheur has an impact on episiotomy usage.

4.21 Key findings

The key findings from the review are presented in Table 4.1. Each practice reviewed is placed in a category that best describes its effectiveness in reducing perineal trauma and/or improving maternal comfort during the second stage of labour.

Table 4.1: Summary of practices thought to influence perineal trauma and/or maternal comfort during the second stage of labour

<p>Care that reduces perineal trauma and/or improves maternal second-stage comfort</p> <p><i>Recommendations</i></p> <ul style="list-style-type: none"> ○ Teach digital antenatal perineal massage in the last six weeks of pregnancy ○ Giving birth in an upright (especially kneeling/all fours) or lateral position leads to increased maternal comfort during the second stage and lower rates of episiotomy ○ Women should be advised to follow their own urges to push during the second stage ○ Some control of the baby's head during birth is likely to be beneficial ○ Vacuum extractor should be used in preference to forceps, as it leads to less maternal trauma ○ Women should have support throughout labour and birth ○ Giving birth in a home-like environment, such as a birth centre, is protective for perineal damage ○ Giving birth at home leads to the lowest rates of perineal damage ○ Giving birth in a midwife-led stand-alone unit leads to lower rates of perineal trauma ○ Giving birth with midwives compared to obstetricians is associated with a reduced use of episiotomy.
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Care that appears promising but needs further research in order to determine effect on perineal trauma and/or maternal second-stage comfort

Recommendations

- Pelvic floor muscle training may be beneficial in reducing prolonged second stage and episiotomies but more research is needed
- Warm packs do not reduce perineal trauma but may improve maternal comfort
- Immersion in water during labour reduces the need for epidurals and maternal pain and therefore is potentially beneficial for perineal trauma and comfort
- Giving birth to the baby's head in between contractions may lead to lower perineal trauma, but more research is needed.

Care with unknown effects on perineal trauma and/or maternal second stage comfort

Recommendations

- No conclusion can be drawn about the effectiveness of antenatal perineal massage using a massaging device (Epi-No)
- No conclusion can be drawn about benefits or harms of perineal ice packs in the second stage.

Care that should be abandoned in light of the evidence that it does not reduce perineal trauma and/or improve maternal second stage comfort

Recommendations

- Avoid intrapartum perineal massage
- There is no evidence that lidocaine spray reduces perineal pain during the second stage of labour.
- Episiotomy should be avoided unless there are compelling reasons, such as severe foetal distress
- Women should be informed of the greater risk of instrumental birth associated with epidural usage and the associated perineal trauma risk.

4.22 The 'virtual' birth

This section combines the evidence to design the perfect 'virtual' birth. If it were possible to create a 'virtual' birth that would best protect the woman's perineum and provide optimal second-stage-comfort one would suggest a woman book in for care with a midwife and be advised to have her baby at home or in a home-like, midwife-led unit. She should be advised of the importance of having good support during her labour and birth. She should be advised of the benefits of practising antenatal perineal massage and pelvic floor exercises in the weeks before the birth. She should also be advised to avoid epidural anaesthesia if possible, and be mobile as long as possible and maintain an upright birth position. The use of a birth pool or bath during labour will help her facilitate this active birth. Warm perineal packs to the perineum in the late second stage may improve her comfort. She should try to give birth in an upright position, with kneeling and left lateral being the most desirable options for pain and perineal integrity. She should be encouraged to push according to her own instincts and not be instructed unless necessary. Some control of the baby's advancing head may be beneficial, but the perineum should not be massaged during the birth. If she needs an instrumental delivery, then a vacuum extractor should be used in preference to forceps. Episiotomy should be avoided unless there is concerning foetal distress and the baby needs to be born immediately.

4.23 Summary

In this chapter, the evidence around factors that influence perineal trauma rates and maternal comfort during the late second stage of labour has been reviewed. The areas reviewed were perineal massage (antenatal and intrapartum), pelvic floor exercises (antenatal), warm and cold packs, immersion in water (intrapartum), local anaesthetic spray, position in the second stage of labour, coached and uncoached pushing, hand manoeuvres, episiotomy, vacuum vs forceps delivery, epidural, support during labour, place of birth and midwife vs obstetric care during birth. A summary of the key conclusions for each practice reviewed has been presented, along with recommendations for future research. Further research is still required into the potential beneficial effects of antenatal perineal massage using a massaging device; pelvic floor exercises; cold packs during the

second stage, particularly where there is perineal oedema; immersion in water and birth of the baby's head in between contractions. Lastly, more research is needed into perineal warm packs and their effects on perineal trauma and maternal comfort. This is the focus of this thesis.

Chapter 5 will describe the methods that were used in the Perineal Warm Pack Trial, including the setting; sample; system of random allocation; recruitment and consent process; outcome measures and data-collection methods.

Chapter 5: Methods

“Asking questions that arise from practice and being able to find, evaluate and implement the findings of research are crucial to ensuring that care is likely to be beneficial and to avoiding harm” (Page, 2000, p.69).

5.1 Introduction

In the previous chapter, the evidence around factors that influence perineal trauma rates and maternal comfort during the late second stage of labour was reviewed. A summary of the key conclusions for each practice reviewed was presented along with recommendations for future research.

Chapter 5 describes the setting for the study; the enrolment; randomisation and consent procedures; the outcome measures; and methods of data collection. A general overview of the analysis is presented, with more detailed and specific descriptions presented in the subsequent chapters (6 – 9), where the results of the study are described.

5.2 Study Design

A randomised controlled trial method was used. Two randomised groups were compared. The main outcome variables were perineal suturing (yes/no) and pain scores at birth, on day one and two, six and twelve weeks following the birth.

5.3 Ethics approval

Ethics approval was obtained from the University of Technology Sydney Research Ethics Committee and Central Sydney Human Research Ethics Committee (protocol number X97-0191).

5.4 The setting

The Warm Pack Trial was conducted at two maternity hospitals in Sydney, Australia, the Royal Prince Alfred (RPA) Hospital and the Canterbury Hospital (TCH). These are public hospitals situated in metropolitan Sydney and located within the Sydney South Western Area Health Service¹⁸.

5.4.1 Site One: The RPA Hospital

The RPA Hospital is a large tertiary referral hospital¹⁹. It is the principal teaching hospital for the University of Sydney. The specialties in the hospital include cardiac; obstetrics and gynaecology; cancer; respiratory medicine; neurology; and liver and kidney transplants. RPA Women and Children's, which is a division of the main hospital, currently has the highest per annum birth rate (4,926) of any hospital in NSW (1). It is classified as a Level Six maternity service²⁰ co-located with a Level Three Neonatal Intensive Care Unit (NICU)²¹, and provides care for the highest risk women and babies. In the years during which the Perineal Warm Pack Trial was conducted, the birth rate at RPA fluctuated between 4,833 (1997) (RPA, 1997), down to 3,424 (2001) (RPA, 2001), and back to 4,026 (2004) (RPA, 2004). This variation in birth numbers was due to centralisation of two services on one site for a period of time (1997 to 1998) and rebuilding of services at the Canterbury Hospital during the period.

When the Perineal Warm Pack Trial commenced in November 1997, maternity services were provided as a stand-alone service in close proximity to the RPA Hospital, in the King George V Memorial (KGV) Hospital for Mothers and Babies. In 2002, KGV ceased operation as a clinical, stand-alone maternity service, was relocated to the newly built RPA

¹⁸ Sydney South Western Area Health Service is a unit of health system administration in NSW. There are eight Area Health Services in NSW and they are each accountable to the NSW Health Department for the management of public hospitals and community health services in the areas.

¹⁹ Tertiary referral hospitals provide the highest level of care and specialisation and function as university teaching hospitals.

²⁰ Level Six maternity services provide a range of services from low risk to the most complex cases. They have 24-hour onsite access to specialist obstetricians and anaesthetists.

²¹ Level Three Neonatal Intensive Care is the highest level of neonatal care available involving 24-hour onsite specialist neonatology support.

Women and Children's and incorporated into the main hospital site. The staff all relocated with the unit, and the service continued uninterrupted.

5.4.2 Site Two: The Canterbury Hospital

The Canterbury Hospital (TCH) is a metropolitan hospital closely linked to RPA Hospital. Obstetric registrars²² and student midwives²³ rotate during their training from RPA to TCH. It offers a wide range of services. It is classified as a Level Four maternity service²⁴, transferring very high-risk women and babies to RPA or other tertiary referral hospitals. It has an annual birth rate of 1,643 (TCH, 2006). The maternity unit was rebuilt in 1997 and during this period the midwives and women were relocated to RPA. It was here that they became familiar with the Perineal Warm Pack Trial protocols. When the midwives returned to their newly built maternity unit in June 1998, the study continued at TCH. The birth rate at TCH fluctuated for reasons already described from 403 in 1998 (TCH, 1998) to 1,760 in 2004 (TCH, 2004).

5.4.3 Non-inclusion of Birth Centre

The Perineal Warm Pack Trial was conducted in the delivery wards of the two hospitals. Originally the Birth Centre²⁵ at RPA agreed to be involved, but no one was recruited in the first year of the study. Birth Centre midwives were reluctant to be involved in the study because they already used warm packs as part of their care and thought some women would be disadvantaged due to the randomisation process. The midwives in the delivery wards almost never used warm packs in their care of women giving birth. This is discussed further later in this chapter.

²² Qualified medical practitioners undertaking their training in obstetrics in order to become qualified obstetricians.

²³ Registered nurses undertaking a Graduate Diploma in Midwifery or Bachelor of Midwifery students undertaking a degree in midwifery.

²⁴ A Level Four maternity service cares for women and babies of low to moderate risk, transferring to a Level Six maternity service all women in preterm labour less than 33 weeks gestation or women with complex health problems, such as heart disease. They have a 24-hour onsite obstetric registrar and anaesthetic registrar.

²⁵ The RPA Birth Centre is separate from the Delivery ward with its own staff and manager and provides antenatal, intrapartum and early postnatal care for low to moderate risk women. It promotes a philosophy of active birth and is midwife run.

5.5 Study population

5.5.1 *A culturally diverse area*

The area where the study was conducted has the largest culturally and linguistically diverse (CALD) childbearing population in the state of NSW. More than 45% of women giving birth at RPA are from CALD backgrounds, with 19% being born in an Asian country (NSW Health Department, 1998). 'Asian' was defined for the purpose of this study as being born in the following countries: China, Vietnam, Hong Kong, Indonesia, Japan, Laos, Cambodia, Taiwan, North Korea, South Korea, Thailand, Philippines, Burma and Malaysia. Almost one quarter (23%) of women at RPA require interpreters to facilitate communication with health-care staff (RPA, 2006). At TCH the proportion of CALD childbearing women is higher, with nearly three quarters of women born in countries other than Australia (TCH, 2006). Over 26% are born in an Asian country, using the definition above (TCH, 2006). In order to include women from CALD backgrounds in the research, all information forms, consent forms and questionnaires were translated into the main languages spoken (Arabic, Turkish, Mandarin, Vietnamese and Korean). Interpreters and ethnic obstetric liaison midwives²⁶ were used as needed for consent and data collection.

5.5.2 *Definition of ethnicity*

Race, ethnicity and culture are all terms that are the source of ongoing debate in the literature. Culture is difficult to describe and measure, as there are many intervening variables such as language, religion and diet. While self-identity has been used in some studies (Hickey, Trompf, & Reid, 1991) the NSW Department of Health uses questions about country of birth to establish cultural identity (NSW Health, 2007). Epidemiological studies have used categories such as 'white,' 'African – Caribbean' and 'Asian groups' (Douglas, 1998). Culture varies depending upon the process through which migrants and

²⁶ Ethnic obstetric midwives are midwives employed from designated ethnic and cultural backgrounds to provide care, education and support for women from the same background.

their children acquire the values, behaviours and attitudes of their new country- known as acculturation (Rissel, 1997).

The country of birth was used to classify ethnicity. The study focused particularly on Asian women, due to the high rates of severe perineal trauma that was identified in this group during a previous study (Dahlen et al., 2007). This is discussed further in Chapter 6.

5.6 Time frame of the study

The Perineal Warm Pack Trial was conducted from November 1997 through to July 2004. The reasons for this lengthy period of recruitment are multiple and are covered in greater detail later in this chapter.

5.7 Funding

The study received a small amount of funding (A\$2,000), from Johnson and Johnson Medical, to translate information forms, consent forms and questionnaires into the main languages spoken (Arabic, Turkish, Mandarin, Vietnamese and Korean).

5.8 Study participants

The participants were non-insured²⁷, primiparous women, booked into RPA Women and Children's Hospital and TCH Hospital.

5.8.1 Eligibility criteria

Non-insured, primiparous women were eligible to join the study from 36 weeks gestation onwards if:

- they had a singleton pregnancy with a cephalic presentation

²⁷ Non-insured women do not have private health insurance so have their care through a public hospital and usually receive their antenatal care from midwives or general practitioners and have midwives as birth attendants with access to obstetric registrars and consultant obstetricians if complications develop.

- anticipated a normal birth
- they had not performed perineal massage, and did not intend to perform perineal massage antenatally
- they were over 16 years of age for consent reasons.

5.8.2 Decision not to include privately insured women

A decision was made not to include privately insured women²⁸ who had private obstetricians attending the birth. Obtaining consent and cooperation from the private obstetricians was deemed too difficult. Also, there was variation in their practice, with some having high episiotomy rates. Private obstetricians also had different methods of perineal repair that they were unlikely to change for the purpose of the study. Australian research has shown that women with private health insurance, who are mostly cared for and delivered by obstetricians, are twice as likely to experience an episiotomy compared to publicly insured²⁹ women, the majority of whom are cared for by midwives (Shorten & Shorten, 2000). The incidence of severe perineal trauma was also positively associated with this increase in episiotomy (Shorten & Shorten, 2000). Another Australian study demonstrated that even in a matched, low-risk population, episiotomy rates were more than twice as high for women with private health insurance under obstetric care (Roberts et al., 2000) Physicians who believe strongly in episiotomy employ it liberally, as well as other procedures like epidural anaesthesia and caesarean, with no resulting improvement in maternal and neonatal outcome (Klein et al., 1995). For these reasons we limited the study to non-insured women attended by midwives.

5.8.3 Decision to only include primiparous women

A decision was made to only include primiparous women in the study in order primarily to reduce the variables associated with previous births. Rates of perineal trauma are also

²⁸ Privately insured women pay for private health insurance and can select an obstetrician to provide their antenatal care, attend the birth and provide limited postnatal care.

²⁹ Publicly insured women obtain their care through the public health system and use Medicare, which provides national health service funding. This means they are not charged for their care in hospital. They are also cared for by public hospital midwives and doctors assigned to them.

especially high in women having their first baby (Albers et al., 1999a) indicating that this is the population in most need of preventative methods to reduce perineal trauma. More than two thirds of primiparous women require a surgical repair of lower genital tract trauma in Australia. The rate of intact perineum is now a maternity indicator used in Australia to compare hospitals outcomes (Laws, Grayson, & Sullivan, 2006a).

The pain felt during the advancement of the foetal head, and stretching of the perineum in the minutes before giving birth has been reported to be severe, especially in first-time mothers (Miller, 1994). It has been reported that primiparous women especially worry about pain, and this significantly influences feelings of control and resulting satisfaction with the birth experience (Green & Baston, 2003). Perineal outcomes in the first birth can influence subsequent births in terms of birth choices made and outcomes experienced. In the developed world there has been a dramatic increase in caesarean sections. Fear of the pain associated with labour is reported as a reason why women may request elective caesarean section (Kolas et al., 2003) (Nerum et al., 2006). Ways to reduce perineal trauma and improve comfort during and following birth, for primiparous women especially, is desirable and was the focus of this study.

5.9 Recruitment

Midwives in the antenatal clinic approached non-insured primigravid women who were eligible to enter the study when they were around 36 weeks pregnant. Due to the difficulty in recruiting women in the antenatal clinics resulting from staff workload and staff shortages, women were also recruited in the Delivery Ward when in early labour or if admitted for reasons other than labour.

A midwife explained the study to women and they were given the information sheet to read and allowed the opportunity to ask questions about the study (Appendix 3). At the following antenatal visit, or if they were admitted to the Delivery Ward, they were then asked for their consent. When the women consented to participate in the study they signed two consent forms. The women kept one consent form and the other was filed in their notes

(Appendix 4). Women were assured of their right to withdraw from the study at any point without prejudice to their care or their relationship with their health-care providers.

During the study several attempts were made to increase recruitment and randomisation. I began a competition to see who would recruit or randomise the most women. Some women who consented to participate in the study were not being randomised in the Delivery Ward. 'WPT' (Warm Pack Trial) in highlighter pen was written at the top of the antenatal card to alert midwives. Towards the end of the study, the consent forms were stapled to the antenatal card to increase awareness. Women were also asked to remind the midwives they were in the study. The most effective factor influencing recruitment proved to be several key midwives in both sites who encouraged and supported others to participate in the study.

5.10 Exclusion criteria

Eligibility and consent to participate were rechecked once the woman was in established labour. Women who were booked for an elective caesarean section, or found not to have a singleton pregnancy or a cephalic presentation, were excluded at this point. Also women who had experienced an intrauterine foetal death were excluded, due to the large number of potentially upsetting research questions that would follow.

5.11 Power and sample size projection

The primary outcome variable was perineal suturing following birth. Secondary outcomes were perineal pain at birth and following the birth, on day one and day two. A detailed description of the outcome measures is presented later in this chapter.

Using delivery records over the previous seven years it was estimated that 25% of all women required no perineal suturing. In order to detect a reduction of 10% in suturing with a power of 80% ($\alpha = 0.05$, two-sided test), 694 women needed to be randomised. This was considered to be clinically significant. In total, 1,047 primigravid women were

approached to participate in the research and 717 were randomised. More information on the sample is provided in section 5.26.

5.12 Randomisation process

5.12.1 Randomly generated group assignment

The National Health and Medical Research (NHMRC) Clinical Trials Centre attended the randomisation. This clinical research organisation runs large multicentre clinical trials and takes part in national and international collaborative trial groups and contributes expertise to trials run by others. All data regarding the randomisation was kept by the NHMRC Clinical Trials Centre. Group assignment was randomly generated by computer and then sealed in opaque envelopes.

5.12.2 Stratification

Stratified block randomisation was used to restrict chance imbalances and ensure the treatment groups were as like as possible (Beller, Gebski, & Keech, 2002). Stratification occurred according to age and ethnicity in six subgroups of Asian (< 25; 25 to 34 and > 34 years) and non-Asian (< 25; 25 to 34 and > 34 years). As described previously, women were defined as 'Asian' if they were born in China, Vietnam, Hong Kong, Indonesia, Japan, Laos, Cambodia, Taiwan, North Korea, South Korea, Thailand, Philippines, Burma and Malaysia. This particular focus on Asian women was due to the high rates of severe perineal trauma already identified in the population being studied (Dahlen et al., 2007). Age and Asian ethnicity are both factors that have been shown to lead to variations in perineal trauma (Goldberg, Hyslop, Tolosa, & Sultana, 2003). There is a strong association between Asian ethnicity and severe perineal trauma, supporting anecdotal experiences and recent research (Dahlen et al., 2007) (Goldberg et al., 2003). While this may be an issue related to anatomy of the perineum, such as having shorter perineal bodies (Rizk & Thomas, 2000) (Shad et al., 2004), an inability to communicate effectively during the second stage of labour was also identified by midwives in the research hospitals as a contributing factor

(Dahlen et al., 2007). With a large number of women from Asia giving birth in the hospitals involved in the study, stratification was seen as optimal, allowing for easy interpretation of outcomes without adjustment (Beller et al., 2002). This is discussed further in Chapter 6. Stratification for age occurred, as research indicates an association between increased maternal age and perineal trauma.

It was decided not to stratify randomisation by treatment centre, as both groups of midwives had been on one hospital site at the beginning of the study and their practice was very similar. There were also only two hospital sites involved.

5.12.3 Remote allocation concealment

It is important that those responsible for recruiting people into a study are unaware of the group to which a participant will be allocated, should they agree to be in the study (Beller et al., 2002). This helps avoid conscious or unconscious selection of patients into the study. Central randomisation was used, as there were two hospital sites to consider. The randomisation envelopes were stored in a box, which was kept in the Neonatal Intensive Care Unit (NICU) at RPA, to ensure remote allocation concealment. Randomisation occurred in the latter part of the first, or early second stage of labour, to ensure that women who may not be eligible to participate in the study (for example, those having a caesarean section) were not randomised and included in the intention to treat analysis. This is why the rate of caesarean section in this study is so low (2.8%). Randomisation occurred when the midwife in the Delivery Ward phoned the NICU. She stated the age and ethnicity of the woman and a nurse or doctor working in the NICU opened the next available randomisation envelope. The randomised group was then noted by the nurse/doctor and the admitting midwife and documented in two separate places. This was invaluable later when double-checking data or when data was missing. This also meant the allocation was only known after the information on the woman was recorded.

5.13 Protocols

Clear protocols were written for the use of the warm pack treatment and were available in the delivery wards. Perineal warm packs had not previously been used by most of the midwives participating in the study. All midwives involved in the study were trained in the technique and had regular updates. Regular checking of the procedure by myself assured protocol compliance.

5.14 Training midwives in the Perineal Warm Pack Trial procedure

Perineal warm packs were not a standard part of midwives' second-stage care in the hospitals participating in the study. Prior to the commencement of the study, several education sessions were held, explaining the technique and giving the midwives the opportunity to practise on mannequins. A detailed protocol was written for the midwives so they could follow the study procedure easily. These protocols were placed on all the wards participating in the study. Initially there was some resistance to the trial and midwives worried that they could not visualise the perineum when it was covered with the warm pack. Early in the study the midwives began to believe that the warm packs were causing severe perineal trauma, due to their inability to visualise the perineum and respond appropriately. In order to monitor this, a subsequent study was set up examining every severe perineal tear that occurred in the delivery wards over a two-year period (Dahlen et al., 2007). This is explained more fully in Chapter 6. An interim analysis of data from 302 participants also indicated there was no increase in severe perineal trauma amongst women who had warm packs applied. Once midwives became familiar with the study protocol and saw the effect the warm packs had on women's experience of pain, they became more enthusiastic. As new staff commenced in the Delivery Ward they were supported in learning how to apply warm packs. I was also the RPA Delivery Ward Clinical Midwife Educator until 2002, enabling careful, ongoing monitoring of the research. From 2002, I was appointed as the Clinical Midwifery Consultant for both RPA and TCH, which enabled closer monitoring of the study on both sites.

5.15 Study protocol

The study protocol was based on previous research into perineal warm packs and then adapted locally (Musgrove, 1997). Women assigned to the intervention, that is, the warm pack group, received usual care during labour until the second stage of labour, when the vertex of the baby began to distend the perineum and the woman was aware of a stretching sensation. A sterile metal jug was filled with 300 ml of cold tap water (temperature range 18.3°C – 20.2°C) and 300ml of hot water from a boiled kettle (temperature range 96°C – 100.6°C). An industrial thermometer was placed in the jug with a minimum and maximum temperature range marked clearly (45°C – 59°C). A standard, sterile perineal pad was soaked in the water and rung out before being placed gently on the perineum during the woman's contraction. The temperature range of the perineal pad over fifteen minutes was 38°C to 44°C. This meant the perineal pad applied to the perineum was in what is considered to be the therapeutic temperature ranges (Lehmann & De Lateur, 1990). The temperature range of the water over 15 minutes was 45.4°C – 59.7°C. Between contractions, the pad was re-soaked in the water to maintain warmth. The water in the jug was replaced every 15 minutes until delivery (Musgrove, 1997) or if the temperature dropped below 45°C (see Table 5.1). All temperatures were obtained by using the RPA Hospitals Engineering Department's digital, industrial thermometer. Several readings were taken to ensure accuracy. Once the baseline readings had been established, a thermometer was placed in every jug of water being used to ensure the temperature was maintained between the minimum and maximum ranges.

Women assigned to the standard care group did not have warm packs applied to their perineum in the second stage. Standard care was defined as any second-stage practice carried out by midwives, occurring in the two delivery wards at the time that did not include the application of warm packs to the perineum. These included use of various birth positions, and birth stools. One woman in the study had a waterbirth, as this became available to women in the new RPA facility. There were no other restrictions given and women were free to adopt any birth position they liked.

Table 5.1: Temperature ranges used in the Perineal Warm Pack Trial, as determined by repeated electronic thermometer readings

Cold tap water	Temperature range 18.3 ⁰ C – 20.2 ⁰ C
Hot water	Temperature range 96 ⁰ C – 100.6 ⁰ C
300 ml tap water and 300 ml hot water mixed over 15 minutes	Temperature range 45.4 ⁰ C – 59.7 ⁰ C
Industrial thermometer marked with minimum and maximum	Minimum and maximum markings on thermometer 45 ⁰ C – 59 ⁰ C
Warm perineal pad after re-soaking over 15 minutes	Temperature range 38 ⁰ C – 44 ⁰ C
Water in jug replaced	Temperature 45 ⁰ C

5.16 Defining perineal trauma

Perineal trauma that required suturing was defined as greater than a first-degree tear; any tear that was bleeding; and, any tear that did not fall into anatomical apposition. Perineal trauma was defined using categories from the Royal College of Obstetricians and Gynaecologists (RCOG, 2004) (Table 5.2). Classifications of third-degree tears into 3a, 3b and 3c were not used. Separate analysis was done by grouping the perineal outcomes into intact or minor perineal trauma (< 2nd degree tear), defined as intact, first-degree, vaginal or labial tear; and major perineal trauma (\geq 2nd degree tear)³⁰.

³⁰ Intact or minor perineal trauma (< 2nd degree tear) was defined as intact, first-degree, vaginal or labial tear and major perineal trauma (\geq 2nd degree tear) was defined as second, third or fourth-degree tear and episiotomy.

Table 5.2: Degrees of perineal trauma

Degree	Trauma
First	Injury to the skin only
Second	Injury to the perineum involving perineal muscles but not involving the anal sphincter
Third	Injury to the perineum involving the anal sphincter complex (classifications of 3a, 3b, 3c not used)
Fourth	Injury to perineum involving the anal sphincter complex and anal epithelium

RCOG (2004)

5.17 Repairing perineal trauma

Standardisation of perineal repair was implemented for the study to reduce extraneous variables associated with various techniques and materials.

Perineal trauma was repaired using a continuous interlocking technique to the vagina, interrupted sutures to the muscle and a subcuticular technique to the skin. At the time the study commenced this was seen to be best practice in perineal repair (RCOG, 2004). Perineal trauma was sutured with Vicryl 2/0. Marcaine with adrenaline was used as local anaesthetic, except on labial and clitoral trauma, to avoid necrosis due to interruption of microcirculation. In these cases, lignocaine 1% was used. All the midwives and medical staff who sutured had been trained in this technique and it was also the standard approach taken at both hospitals to help ensure compliance. A previous randomised trial undertaken in the RPA Delivery Ward had used the same suturing protocol, so it was familiar (Upton et al., 2002). Random audits of the women's clinical notes during the study showed compliance of over 90% with the suturing protocol and this did not differ between groups.

5.18 Blinding

Where possible, it is ideal to have blinding in randomised controlled trials. Blinding prevents study personnel and participants from determining the group to which the participants have been assigned (which leads to ascertainment bias), safeguards the sequence after allocation, and cannot always be implemented (Schultz, 2000). Group allocation could not be concealed from the midwives who attended the women, or from the women themselves. The only way to introduce some level of blinding into the study was during the assessment of perineal trauma following the birth. This was important, as it was the primary outcome measure for the study.

An independent, senior midwife, unaware of the allocated group, was asked to give an independent assessment of the degree of perineal trauma following each birth and determine whether or not suturing was required. Midwives were instructed not to let other midwives know about the allocation. To ensure the senior midwife was unaware of the allocation, the equipment needed for the application of a warm pack (jug, thermometer, kettle) was set up in the delivery room for every woman in the study, regardless of allocated group. The allocation was not recorded on the postnatal data collection forms and the midwives involved in the follow-up were unlikely to have been present at the birth or when the woman was randomised.

5.19 Intention to treat

Primary analyses were performed on an intention-to-treat basis. This meant that all women in the final sample were included and the data was analysed according to the group to which the women were randomly allocated, irrespective of whether they received the intervention or not. This is generally interpreted as including all patients, regardless of whether they actually satisfied the entry criteria, the treatment received and subsequent withdrawal or deviation from the protocol (Hollis & Campbell, 1999). This approach maintains treatment groups that are similar, apart from random variation. If the analysis is not performed on the groups produced by the randomisation process, this important feature of randomisation may be lost (Hollis & Campbell, 1999). Clinical effectiveness may also

be overestimated if an intention-to-treat analysis is not conducted. An intention-to-treat analysis is most suitable for pragmatic trials of effectiveness rather than for explanatory investigations of efficacy (Hollis & Campbell, 1999) (Roland & Torgerson, 1998).

Five of the participants had practised perineal massage, despite this being a reason for exclusion ($n = 2$ in experimental group and $n = 3$ in control group) and they were retained in the analysis. Reasons for not complying with the assigned treatment during the second stage of labour are detailed in Figure 5.1, but most were due to surgical intervention (warm pack = 55 and standard care = 56). Some women who had forceps or vacuum delivery had the warm packs applied but most did not, especially those having a forceps delivery. In the warm pack group one woman gave birth too quickly for the pack to be applied and two refused to have the warm pack on when it was applied. In the standard care group, three women had warm packs applied (due to strong request or partners applying a warm pack) and one had a waterbirth. When the study commenced at the KGV Hospital, there were no facilities for waterbirth in the Delivery Ward – this was only accessible in the Birth Centre. The Birth Centre midwives withdrew from the study with no women being randomised. After transferring to the new RPA facility, waterbirth became an option for women in Delivery Ward. As a result, one woman had a waterbirth in the standard care group and was kept in this group in the final analysis (Figure 5.1).

5.20 Statistical analysis

All data were analysed with Statistical Package for Social Sciences (SPSS) version 12 (SPSS, 2003). The researcher undertook the analysis along with her supervisors, who are both experienced in statistical analysis. Assumptions for all statistical tests were examined.

Analysis of the primary and secondary measures of outcome was based on the groups as randomly allocated in an intention to treat comparison. Odds ratios (OR), percentage differences and confidence intervals (CI) were shown for primary outcome. Chi square and Student's t-tests were used to examine group differences in the main outcome variables. A logistic regression model was fitted to account for potential confounders on the primary

outcome of requirement for perineal suturing. Women who had a caesarean section were excluded from this analysis. Potential confounders were identified from the literature. These initially were: mode of birth (normal vs instrumental); age (16 – 24 yrs, 25 – 34 yrs, greater than 34 yrs); ethnicity (non-Asian vs Asian); birth weight ($\leq 3,500$ gms vs $> 3,500$ gms); and, birth position (semi-seated, upright, flat, lateral). A screen of $p < 0.25$ was used to justify retaining the variables in the model, except for the group that was retained regardless. Birth position was the only variable that did not consistently meet the $p < 0.25$ screen and thus was removed from the final model. Simple descriptive statistics were used for analysis of the questionnaire results. More detailed explanation of the other analyses will be presented in Chapters 6 to 9.

5.21 Monitoring and adverse events

It was decided that the study would be terminated if there were evidence of a detrimental effect of the warm packs, such as a marked increase in severe perineal trauma in the experimental group or a pattern of adverse events that were not resolved with re-education of the midwives. An interim analysis of the data, once 302 women had been randomised, revealed no reason to terminate the study

There was constant vigilance by myself as the principal researcher regarding adverse events occurring in the study. This involved monitoring the rate of severe perineal trauma occurring in each group. The filling out of an incident form and reporting the event to the appropriate manager managed any adverse incident, such as a burn to the perineum. Identification of the possible cause of the event and possible lapses in protocol were sought. A memo was then issued to all staff involved in the study and the protocol was revisited with the staff.

In the warm pack group there was one adverse event when a woman sustained a superficial burn on her perineum. This was a result of not following the protocol for preparation of the warm packs. Instead of changing the water when it dropped below 45°C , as is described in the protocol, boiling water was added to the water already in the jug. The perineal pad in

the jug appeared to have absorbed the hot water. This very hot pad was then applied to the woman's perineum. Soon after it was removed, a reddened area on the perineum could be seen. Cold packs were immediately applied to the area. A critical incident form³¹ was completed, follow-up for the woman was organised and the staff were informed once again about the protocol. When the woman involved in the incident filled out the maternal questionnaire, she reported feeling the warm packs helped her a lot and she liked them.

Due to concerns over this incident, a policy has been developed regarding the use of perineal warm packs for all hospitals in the Area. The possibility of any form of burning has now been removed with the stipulation that fixed temperature kettles are used for heating all water for perineal warm packs. This means the temperature cannot increase above (45⁰C) and the need for boiling water is eliminated altogether.

5.22 Data storage

Midwives collected data on birth outcomes, perineal trauma and demographics from medical records. Data were also collected on pain scores, perineal outcomes, and satisfaction with warm packs from self-report questionnaires. Each day, a midwife was assigned to collect follow-up pain scores on the postnatal ward as part of other duties, such as checking the emergency and neonatal resuscitation trolleys.

5.23 Ethical considerations

Participants under 16 years of age were not approached to participate in the study due to issues of consent. Interpreters and translated information sheets and questionnaires were used for women who had a poor command and understanding of English.

³¹ A critical incident form is filled out when an adverse event or near miss is encountered in clinical practice. It is given to the manager of the area where it took place and systems are reviewed to minimise the chance of it occurring again.

Hospital unit numbers were used to identify participants. Hospital unit numbers were deleted once data collection and data entry were complete, and participants were only identified by a research code.

Written data were stored in a locked cupboard, which was only accessible to the principal researcher involved in the study. After the completion of the study, the data will be held for a period of five years before being destroyed. The findings were described and summarised by sample or by group. If individual outcomes are described (for example, in the case of negative outcomes or incidences associated with the treatment), the hospital is not identifiable.

There was a midwife–woman relationship³² with some of the midwives and women in the study. This was taken into consideration. While midwives working permanently in the antenatal clinic recruited most of the women, the midwives recruiting women in the delivery ward often had a midwife – woman relationship. All midwives participating in the recruitment of the women were trained in the research protocols and ethical issues such as the importance of providing informed consent, not to coerce the patient to participate, informing the patient that she was under no obligation to participate in the research, indicating there will be no negative repercussion should she decide not to participate and informing the patient that she can withdraw at any time without negative consequence. Women recruited in the Delivery Ward were those who were not in established labour in order not to put them under pressure and ensure the consent was fully informed.

5.24 Issues in recruitment and consent

The midwives recruiting participants were conscious of the dilemmas in the process of seeking informed consent. They were also mindful of the importance of respecting a woman's choice and allowing her to make a non-pressured decision. However, because

³² A midwife–woman relationship refers to an ongoing relationship of care other than just information and consent. For example, many of the midwives in the antenatal clinic would have been providing care for the women during pregnancy and in Delivery Ward the midwife consenting may have cared for them during labour and birth.

there were many midwives involved in the process, rather than a couple of research midwives, the approach may not have been as consistent as it could have been.

Some women may have consented because they believed that this is what the hospital (or midwife) would have wanted them to do. The midwives obtaining consent all wore hospital uniforms and some would care for the woman in labour. This was not ideal, as they may have felt they could not decline to participate in case their care was compromised. It has been reported that participants feel powerless to participate in studies if they are in dependent positions, or if they feel they should please those responsible for their care (Wilson, 1989). Several strategies to reduce this concern were put in place. Both the information and consent form emphasised that participation in the study was voluntary and that women were free to withdraw at any stage without it affecting their treatment or relationship with their caregiver.

Once randomisation had occurred, only two women refused to have the warm pack applied. Unfortunately, the data collected on women who did not participate is not reliable enough to determine how many withdrew and how many were missed due to the workload of the midwives. Anecdotally there appeared to be very few women who were not interested in participating in the study or who withdrew after consent. The consent and information forms were all translated into the main languages spoken (Arabic, Turkish, Mandarin, Vietnamese and Korean) and interpreters were used as needed for consent and data collection. As already described earlier in this chapter, the women took home the information sheet and had time to read it and discuss participation in the study at their next antenatal visit, giving them time to make a considered decision before they gave consent. Information posters were put up in the antenatal classes and antenatal waiting rooms to increase awareness and information about the study.

5.25 Issues in obtaining consent

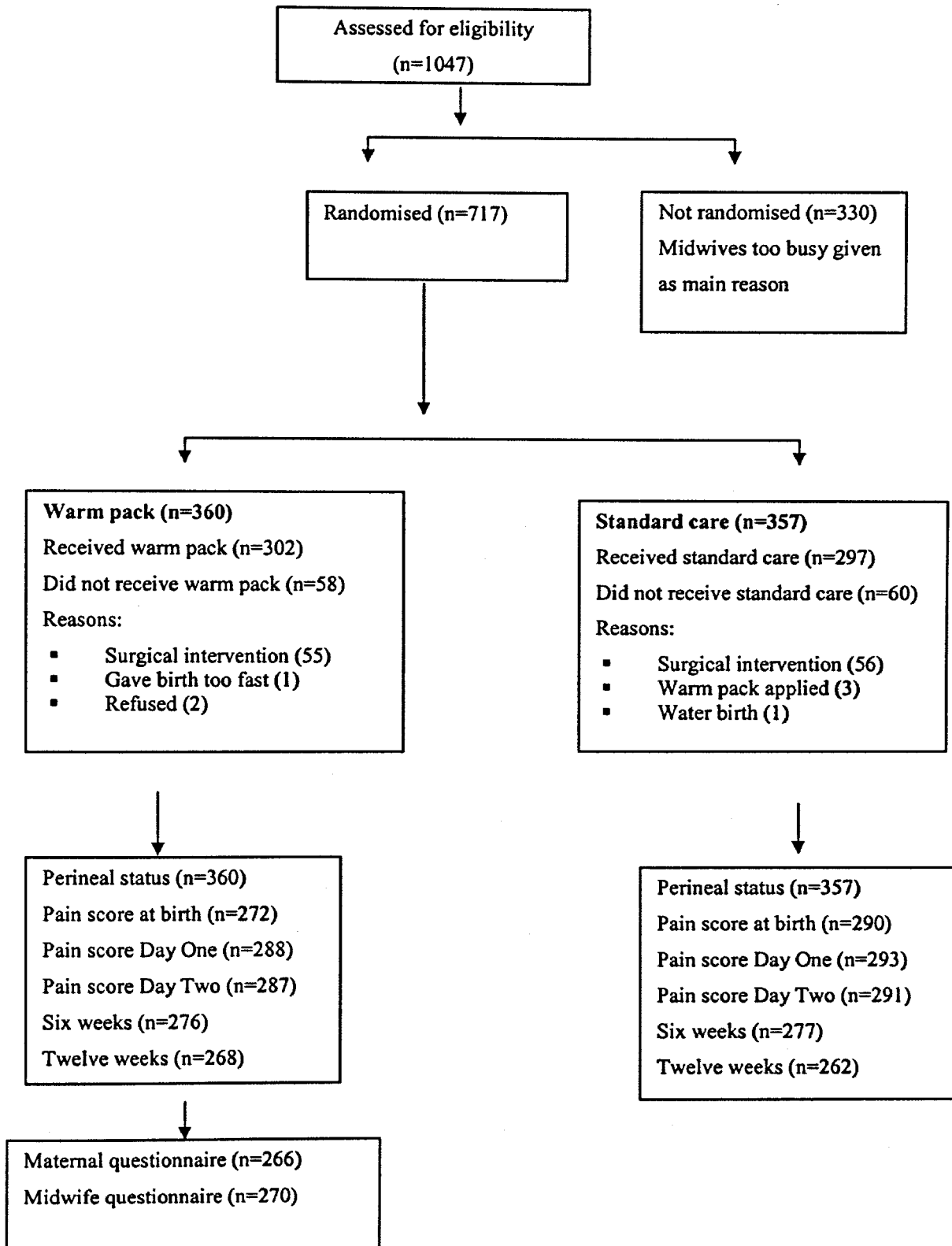
Gaining consent for the study was relatively easy. Women seemed to be very interested in the study and keen to participate. The greatest problem faced was midwives having the time to go through the information and consent process. Because the study took over six years to complete, women involved in the study did return to have subsequent babies and asked for the warm packs. Women also told their friends about the warm packs, so some women who could have potentially have been in the study were unwilling to be randomised in case they were assigned to the control group. In order to resolve this dilemma, these women were informed that the study had not yet concluded, so benefits or harms were unknown. These women were able to have warm packs as long as the protocol was followed and they were not included in the study. The protocol remained the same over the six-year period, with the same equipment and process being used.

5.26 Sample

Between November 1997 and June 2004, 1,047 women were approached and consented to participate in the study and 717 were randomised; 360 to the warm pack group and 357 to the standard care group. Three hundred and thirty women consented but were not randomised, because either staff were either too busy to undertake randomisation, a caesarean section occurred prior to the second stage or women refused to participate after consent was obtained. Due to inconsistent reporting, numbers and reasons why these women were not consented cannot be given. Very few women refused to participate.

In total, 599 women completed the study protocol as randomised, 302 in the warm pack group and 297 in the standard care group. Reasons for not complying with the assigned treatment during the second stage of labour are detailed in Figure 5.1, but most were due to surgical intervention (warm pack = 55; standard care = 56). In the warm pack group, one woman gave birth too quickly for the pack to be applied and two refused to have the warm pack kept on when it was applied. In the standard care group, three women had warm packs applied (due to strong request or partners applying a warm pack) and one had a waterbirth.

Figure 5.1: Flow chart describing progress of women in the study



Primary outcome data were collected for all women who participated in the study. For secondary outcome measures, pain scores at birth were obtained for 76% of women in the warm pack group and 81% of women in the standard care group (Figure 5.1). On days one and two following the birth, 80% of women in the warm pack group and 82% of women in the standard care group completed pain scores. Follow-up interviews at six- and twelve-weeks postnatal were completed with three quarters of the women who participated.

5.27 Baseline maternal characteristics

The women who participate in the study were all primiparous and the two groups were similar in age and ethnicity (Table 5.3).

Table 5.3: Baseline maternal characteristics of women, by allocated group.

	Warm pack group n=360 n (%)	Standard care group n=357 n (%)
Mean Age in years [SD]	27.0 [5.5]	27.2 [4.9]
Age group:		
▪ 16–24 years	128 (35.6)	116 (32.5)
▪ 25–34 years	199 (55.3)	213 (59.7)
▪ >35 years	33 (9.2)	28 (7.8)
Country of Birth		
▪ Non-Asian [#]	244 (67.8)	238 (66.7%)
▪ Asian [#]	116 (32.2%)	119 (33.3%)

Values given as n (%) mean [SD]

[#]Asian: women born in, or identified as being from, China, Vietnam, Hong Kong, Indonesia, Japan, Laos, Cambodia, Taiwan, North Korea, South Korea, Thailand, Philippines, Burma and Malaysia.

5.27.1 Ethnicity

The country of birth was used to establish ethnicity. The warm pack and standard care group did not differ in their country of birth (see Table 5.4). Only four women were recorded as being of Aboriginal descent during the study.

Table 5.4: Ethnicity of women, by allocated group.

	Warm pack group n=360 n (%)	Standard care group n=357 n (%)
Australian born	120 (33.3)	124 (34.7)
Middle Eastern	43 (11.9)	38 (10.6)
Central America	2 (0.6)	6 (1.7)
North America	1 (0.3)	0 (0)
Africa	5 (1.4)	3 (0.8)
UK and Ireland	16 (4.4)	11 (3.1)
New Zealand and Oceania	27 (7.5)	31 (8.7)
European	30 (8.3)	25 (7.0)
Asian	116 (32.2)	119 (33.3)

A chi-squared test was performed to examine differences between allocated groups: $p=0.7$

5.28 Data-collection instruments

Data-collection instruments were modified from a previous study (Musgrove, 1997). Midwives collected intrapartum and postpartum data. Some of the information was obtained from medical records after discharge.

5.28.1 Intrapartum data collection

After women had given birth, the intrapartum section of the Data Collection Form was completed by the midwife (Appendix 5). Information was collected on age, country of birth, Aboriginality, perineal status, perineal suturing (yes/no), length of second stage, use of analgesia, weight of the baby, birth position adopted and mode of birth. These results are presented in Chapter 6.

Pain scores were collected immediately after the birth before the woman left the delivery ward. Women who participated in the study were asked to circle the comment on a scale that represented the perineal pain they experienced when giving birth, with one being 'no pain,' two being 'some pain,' three being 'moderate pain,' four being 'bad pain,' and five being 'the worst pain in my life.' A pain scale with descriptions of pain was chosen to reflect comments women made when giving birth (Appendices 9 and 10). Pain scores experienced when giving birth were collected on 272 women in the warm pack group (75%) and 290 in the standard care group (81%) (Figure 5.1). Reasons for not completing the pain scores were usually the midwives were too busy, there was a change of shift and it was forgotten or the form was lost. Fewer pain scores were obtained from women who had forceps and vacuum extraction births and this may have been due to confusion over whether these women should have been followed-up as they did not have the treatment. No women refused to complete the pain score.

Follow-up pain scores on day one and two were based on the 0 – 10 visual analogue scale (VAS). These results are presented in Chapter 7.

5.28.2 Questionnaires

Questionnaires from a previous study into the effect of warm packs were adapted for use in this study (Musgrove, 1997). They used a multiple-choice format. The questionnaires were piloted on ten women and midwives prior to commencement of the study. No changes were made, as they seemed easy to understand by those who completed them. All questionnaires

were translated into the main languages of women attending the hospitals in the study (Arabic, Turkish, Mandarin, Vietnamese and Korean).

Maternal questionnaires were completed by women who received warm packs before they left the Delivery Ward (usually within four hours of the birth) (Appendix 10). If the questionnaire was not completed, it was taken to the woman in the postnatal ward the following day. This questionnaire collected information on pain scores and satisfaction with the warm packs. Women in the standard care group were only asked about their pain scores (Appendix 10).

The midwives who attended women in the warm pack group were also asked to complete questionnaires following the birth on their perception of the effect of the warm packs on the woman (Appendix 11). If the questionnaire was not completed, the midwife was asked once to complete the form and then it was marked incomplete if it was still unattended. These results are presented in Chapter 8.

5.28.3 Immediate postnatal data collection

Postnatal data collection involved perineal pain scores on day one and two and data on breastfeeding on discharge, early discharge, length of hospital stay and pain relief used during hospital stay (Appendix 6). Unfortunately, the only data that were reliably gathered and able to be analysed related to breastfeeding on discharge and pain scores. It was not the practice in the hospitals where the study was undertaken to use methods of postnatal pain relief, other than analgesia and ice packs (for example, sitz baths, foams, and sprays, gels, ultrasound, heat lamps or hot packs). The analgesia use was poorly recorded and therefore not used due to concerns with its reliability.

On day one and day two following the birth, a pain analogue scale (0 – 10) was used and women were asked to report the level of perineal pain experienced. Pain scores were obtained from 288 (80%) women in the warm pack group and 293 (82%) women in the standard care group on day one following the birth. Day two pain scores were obtained

from 278 (77%) women in the warm pack group and 291 (82%) in the standard care group. The reasons why some women did not complete pain scores on days one and two were that they went home on early discharge, the midwives forgot to go to the postnatal ward or were too busy to go, or the women had visitors when they went to see them. No women refused to complete the pain scores on days one or two.

Data collection was based on two other studies examining similar outcomes (Musgrove, 1997) (Upton et al., 2002). One of the studies (Upton et al., 2002) had recently been completed in the RPA Delivery Ward so the data-collection questions and instruments were kept similar to make the process familiar to the midwives and improve validity and reliability.

5.28.4 Six-weeks and three-months data collection

The final collection of the data occurred at six and twelve weeks postpartum via a telephone interview. This interview was conducted over the phone by the researcher or midwives in the Delivery Ward. The questions on the questionnaire form were read out to the woman and further explanation was given if requested. Interpreters were used as required and followed the same procedure. All midwives received training in completing the questionnaires. Data was collected on pain and symptoms indicating the presence of ongoing perineal trauma and morbidity (Appendices 7 and 8). Questions about resumption of sexual intercourse and associated pain were also asked. Women were asked questions about postpartum urinary incontinence. It would have been ideal to have trialled these data collection forms prior to commencement of the study but this was not done. Unfortunately, a question asked on the history of urinary incontinence prior to or during pregnancy was poorly filled out and could not be used. The data from this question would have been very useful in gaining a better understanding of why urinary incontinence was significantly reduced in the warm pack group (see Chapter 6). There is good evidence that stress incontinence is more likely related to hereditary factors and pregnancy rather than birth (Iosif, 1981) (Beck & Hsu, 1965). There is also evidence that many women have urinary incontinence prior to childbirth, and that this is a significant contributing factor to

postpartum urinary incontinence (Stainton, Strahle, & Fethney, 2005). Other studies show around 62% of primiparous women with incontinence said it started in pregnancy, (Beck & Hsu, 1965) (Wilson et al., 1996) (Viktrup, Lose, Rolf, & Barfoed, 1992) and other studies have found that incontinence rarely starts after childbirth (Sultan, Monga, & Stanton, 1996). This is good reason for trialling data-collection forms and ensuring the questions are well laid out and easy to follow.

Women were also asked whether they were still breastfeeding both at six and twelve weeks following the birth. These results are presented in Chapter 9.

5.29 Choice of outcome measure

The study sought to answer questions relating to a range of clinical outcomes and experiences of women. Outcome measures were chosen for their ability to reflect perineal trauma and maternal comfort. This study was designed to determine the efficacy of the application of warm packs to the perineum in the late second stage of labour. The primary objective was the rate of perineal trauma, as identified by the requirement for perineal suturing. Secondary objectives included women's perception of pain at birth, on days one and two following birth and morbidity at six and twelve weeks following the birth.

5.29.1 Primary outcome measure

Both childbearing women and health professionals place a high value on minimising perineal trauma and reducing potential associated morbidity (Albers et al., 1999a). The primary outcome measure, requirement for perineal suturing, was selected, as it often reflects the severity of the perineal trauma more accurately than descriptions. A second-degree tear can be extensive or very small and whether it is sutured or not will often be a better indicator of the degree of trauma. Midwives are more likely to not suture trauma that is considered minor. The disparity between perineal trauma and suturing is shown in Table 5.5.

Table 5.5: Perineal trauma and suturing, by allocated group.

	Warm pack group n=360 n (%)	Standard care group n=357 n (%)
No perineal trauma	13 (3.6)	17 (4.8)
Not sutured	65(18.7)	65 (18.6)

Perineal trauma that required suturing following childbirth was chosen as the primary outcome measure as it can be associated with significant short- and long-term morbidity for women (Sleep & Grant, 1987) (Glazener et al., 1995) (McCandlish et al., 1998). Rates of perineal trauma are especially high in women having their first baby (Macarthur & Macarthur, 2004a). Studies indicate that, where episiotomy is restricted, 51% to 77% of women giving birth vaginally will sustain some degree of perineal trauma that requires suturing (Albers et al., 1999b) (Mayerhofer et al., 2002) (McCandlish et al., 1998). Almost one third (28.8%) of primiparous women in Australia did not require a surgical repair of lower genital tract trauma.

Other clinical outcome data related to the birth, for example, perineal trauma; length of second stage; and mode of birth, were also collected. Postpartum outcomes such as breastfeeding, resumption of sexual intercourse, and incontinence were also collected.

5.29.2 Secondary outcome measure

Perineal pain experienced during the birth and days one and two following the birth was chosen as a secondary outcome measure. The pain associated with the advancement of the foetal head and stretching of the perineal tissues can be severe (Mander, 1992) (Miller, 1994) (Lowe & Roberts, 1998; Niven & Gijbers, 1984) (Stewart, 1982). Perineal pain experienced during the first couple of days and weeks following the birth can impact on the mother's sense of wellbeing. Fear of the pain associated with labour is reported as a reason

why women may request a caesarean section (Kolas et al., 2003) (Nerum et al., 2006). Effective methods of reducing pain experienced in the late second stage of labour are important in enhancing women's comfort during birth.

5.30 Data entry

Data entry commenced in June 2004 and was completed by December 2004. All data were entered into a Statistical Package for Social Sciences (SPSS) database by the principal researcher. Missing data were obtained from the Obstetric Information System (OIS)³³. Clinical notes were pulled to gain any additional data not in the OIS.

Random checks of the data collection forms were carried out monthly during the study by the principal researcher, looking for incorrect data and outliers. Medical records were compared to these data collection forms for reliability. The main outcome variable (sutured yes/no) was randomly double-checked on every tenth woman. If there was a discrepancy, the clinical notes were reviewed to see if there was any written information on a perineal repair being carried out. If the data were considered incorrect they were rechecked with the original data sheet and the woman's medical or computer records. There was no way of checking the secondary outcome variable (pain scores at birth and day one and two), as this was not collected anywhere else besides the data sheets.

Separate lists of participants and the group to which they were randomised were kept in the Delivery Wards and the NICU. They were checked against each other and three missing cases were identified, where the data sheets had gone missing. The primary outcome measure was able to be obtained from the OIS.

³³ The Obstetric Information System (OIS) is a computerised data-base used by RPA and TCH Maternity Units. Clinical data is recorded here for each woman booked into the service and used for annual reports and research.

5.31 Summary

This chapter has described the methods that were used in the Perineal Warm Pack trial, including the setting; sample; system of random allocation; recruitment and consent process; outcome measures and data-collection methods. A commitment was made to recruit women from CALD populations. A particular focus on Asian women builds on previous work undertaken in this setting (Dahlen et al., 2007). In order to facilitate the inclusion of women from CALD backgrounds, a number of strategies were used, including translation of written material and questionnaires, use of health-care interpreters and ethnic obstetric liaison midwives.

The following chapters (6 – 9) present the results of the study. Chapter 6 presents the clinical outcomes for women in the study.

Chapter 6: Clinical outcomes of labour and birth

“Another thing which appears to help stretching and to prevent tearing is a hot pad applied to the perineum when it is stretched by the baby’s head. The easiest thing to use is a sanitary towel soaked in very hot water. Women seem to find this very comforting even though I use it quite hot” (Flint, 1986, p.102).

6.1 Introduction

The previous chapter described the methods that were used in the study, including the setting; sample; system of random allocation; recruitment and consent process; outcome measures and data-collection methods.

Chapter 6 presents the maternal clinical outcomes from the study. It specifically reports on the primary outcome variable, perineal suturing at birth. This chapter begins with a brief literature review and ends with a discussion of the major findings.

The following chapters (Chapters 7 – 9) present the remainder of the outcomes from the study, including women’s evaluations of perineal pain at birth, days one and two following the birth (Chapter 7); women’s and midwives’ evaluation of the warm packs through questionnaires (Chapter 8); and, postnatal follow-up of women following the birth before discharge from hospital, as well as the results of telephone interviews conducted at six and twelve weeks following the birth (Chapter 9).

6.2 Perineal trauma

As has already been discussed in Chapter 4, trauma to the genital tract commonly accompanies vaginal birth (Williams et al., 1998) and occurs more commonly in primiparous women. It is associated more with operative vaginal deliveries, and

episiotomies (Macarthur & Macarthur, 2004a). Countries report wide variations in trauma rates and within countries further variations exist amongst institutions and health professionals (Renfrew et al., 1998). In Australia, 65.7% of women have some form of perineal trauma, with 17.2% having an episiotomy (Laws et al., 2006b). Almost one third (28.8%) of primiparous women do not require a surgical repair of lower genital tract trauma.

Perineal trauma is associated with significant short- and long-term morbidity (Sleep & Grant, 1987) (Glazener et al., 1995) (McCandlish et al., 1998). Acute postpartum perineal pain is common among women who give birth vaginally and its severity is linked to that of the perineal injury (Kenyon & Ford, 2004) (Albers et al., 1999a) (Klein et al., 1994).

Women who have an intact perineum with their first baby have stronger pelvic floors (measured by electromyogram) and make a quicker muscle recovery than women who experience tears or episiotomies (Klein et al., 1994). While perineal trauma has not been clearly associated with urinary incontinence (Woolley, 1995), severe perineal trauma (third- and fourth-degree tears) has been shown to be associated with faecal incontinence (Sultan & Thakar, 2002).

Numerous factors have been suggested as potential contributors to perineal trauma, such as maternal nutritional status; body mass; history of prior trauma; ethnicity; older age; abnormal collagen synthesis; place of birth; accoucheur preference; epidural usage; infant birth weight; foetal malposition and malpresentation; second-stage management (continuous support, maternal position, style of pushing, techniques to relax the perineum, episiotomy, hand manoeuvres, vacuum versus forceps delivery, immersion in water) and the actual birth of the baby (McCandlish et al., 1998) (Kettle, 2004; Klein et al., 1997).

Both childbearing women and health professionals place a high value on minimising perineal trauma and reducing potential associated morbidity (Homer & Dahlen, 2007). Many factors contribute to genital tract trauma. There is evidence to support: restricting the liberal use of episiotomy (Hartmann et al., 2005) (Carroli & Belizan, 2006); using vacuum

extraction rather than forceps for instrumental deliveries (Johanson & Menon, 2004) and the use of antenatal perineal massage to decrease perineal trauma (Beckmann & Garrett, 2006). There is no clear consensus about the effect of: perineal guarding (McCandlish et al., 1998) (Mayerhofer et al., 2002); active directed pushing (Bloom et al., 2006) (Schaffer et al., 2005), maternal position (Gupta et al., 2006) or perineal massage in the second stage of labour (Stamp et al., 2001). There are also ranges of approaches to perineal care that have yet to be evaluated to determine their impact on decreasing perineal trauma (Renfrew et al., 1998).

Finding ways to prevent or reduce genital trauma would be of benefit in terms of the physical, emotional and financial costs associated with ongoing morbidity. This study was designed to determine the efficacy of one strategy, that is, the application of warm packs to the perineum in the late second stage of labour.

6.3 Research questions of the study

The research questions for the Perineal Warm Pack Trial were:

- Will applying warm packs to the perineum in the second stage of labour reduce perineal trauma?
- Will applying warm packs to the perineum in the second stage of labour increase maternal comfort?

The primary outcome measure was the proportion of women who required perineal suturing following birth. The secondary outcome measures were women's perineal pain scores at birth, days one and two following the birth, and wellbeing at six and twelve weeks following the birth.

The findings relating to the primary outcome are presented in this chapter, as well as baseline characteristics; events during labour; mode of birth; birth position; perineal outcome and birth weight.

The primary outcome measure, 'requirement for perineal suturing', was selected, as it often reflects the severity of the perineal trauma more accurately than descriptions alone. A second-degree tear, for example, can be extensive or very small, and whether it is sutured or not will often be a better indicator of the degree of trauma than whether it is described as deep or superficial. Midwives are more likely not to suture trauma that is considered minor (Fleming, Hagen, & Niven, 2003). The disparity between perineal trauma and suturing has already been discussed in Chapter 5 (Table 5.5).

6.4 Method

The study design, sample size calculation, method of random allocation, outcome measures and data-collection methods were described in Chapter 5. Perineal outcomes and information on requirement for suturing were obtained for all 717 women randomised in the study.

6.5 Results

6.5.1 Baseline maternal characteristics

Both groups were similar in demographic characteristics. The women were all primiparous and similar in age and ethnicity (Table 6.1).

Table 6.1: Baseline maternal characteristics of women, by allocated group.

	Warm pack group n=360 n (%)*	Standard care group n=357 n (%)
Mean age in years [SD]	27.0 [5.5]	27.2 [4.9]
Age group:		
▪ 16 – 24 years	128 (35.6)	116 (32.5)
▪ 25 – 34 years	199 (55.3)	213 (59.7)
▪ > 34 years	33 (9.2)	28 (7.8)
Country/Region of Birth		
Australia	120 (33.3)	124 (34.7)
Middle East	43 (11.9)	38 (10.6)
Central America	2 (0.6)	6 (1.7)
North America	1 (0.3)	0 (0)
Africa	5 (1.4)	3 (0.8)
UK and Ireland	16 (4.4)	11 (3.1)
New Zealand and Oceania	27 (7.5)	31 (8.7)
Europe	30 (8.3)	25 (7.0)
Asian#	116 (32.2)	119 (33.3)
Non-Asian/Asian		
▪ Non-Asian	244 (67.8)	238 (66.7)
▪ Asian	116 (32.2)	119 (33.3)

* Values given as n (%) mean [SD]

Asian: women born in, or identified as being from, China, Vietnam, Hong Kong, Indonesia, Japan, Laos, Cambodia, Taiwan, North Korea, South Korea, Thailand, Philippines, Burma and Malaysia.
A chi-squared test was performed to examine differences between allocated groups: p=0.7.

The country of birth was used to establish ethnicity, particularly Asian/non-Asian, as increase in severe perineal trauma had already been identified in Asian women in this population (Dahlen et al., 2007). The warm pack and standard care group did not differ in their country of birth. There were only four women who identified as being Aboriginal. As discussed previously, there is a high percentage of women from CALD backgrounds in the two hospitals participating in the study.

6.6 Outcomes of labour and birth

There was no significant difference in the duration of second stage, analgesia use, birth position, mode of birth or birth weight between the groups (Table 6.2).

Table 6.2: Distribution of clinical outcomes during labour and birth for women and babies

	Warm Pack n=360 n (%)	Standard Care n=357 n (%)	P
Duration of second stage in minutes (mean [SD])	82.09 [61.1]	86.64 [67.6]	0.35
Analgesia during labour*			0.36
▪ Nil	57 (16.4)	52 (14.9)	
▪ Nitrous oxide	139 (39.9)	124 (35.3)	
▪ Pethidine	91 (26.1)	93 (26.6)	
▪ Epidural	59 (17.0)	79 (22.6)	
▪ Other	2 (0.6)	1 (0.3)	
Position for birth*			0.45
▪ Semi-seated	246 (68.3%)	263 (73.7%)	
▪ Upright (all fours, standing, birth stool, kneeling, squatting)	48 (13.3%)	45 (12.6%)	
▪ Lateral	33 (9.2%)	27 (7.6%)	
▪ Supine (lithotomy) #	21 (5.8%)	14 (3.9%)	
Mode of birth			0.64
▪ Spontaneous vaginal birth	305 (84.7%)	301 (84.3%)	
▪ Forceps	11 (3.1%)	9 (2.5%)	
▪ Vacuum	32 (8.9%)	39 (10.9%)	
▪ Caesarean section	12 (3.3%)	8 (2.2%)	
Birth weight in grams (mean [SD])	3,365 [447]	3,346 [450]	0.32

Includes caesarean section.

*Not all categories add up to correct number due to missing data. Pain relief category determined by highest form of pain relief women received.

6.7 Perineal outcomes

6.7.1 Perineal suturing

There were no statistically significant differences in the proportion of women requiring perineal suturing between the warm pack group (78.6%) and the standard care group (79.9%) (Table 6.3). Differences between major or minor perineal trauma, episiotomy and severe perineal trauma were also examined in order to determine whether there were other differences that had not been detected due to the definition of the outcome variable. There were no statistically significant differences in the rates of intact perineum, or minor perineal trauma³⁴ (<2nd degree tear); or major³⁵ perineal trauma (\geq 2nd degree). There was also no significant difference in the numbers of episiotomies. There was a statistically significant difference in the number of third- and fourth-degree perineal tears, with women in the standard care group more than twice as likely (31/357 vs 15/360) to sustain a severe perineal tear than women in the warm pack group (OR 2.16; 95% CI 1.1 to 4.3 $p = 0.02$) (Table 6.3).

³⁴ Intact or minor perineal trauma was defined as intact, first-degree, vaginal or labial tear.

³⁵ Major perineal trauma was defined as second, third- and fourth-degree tear and episiotomy.

Table 6.3: Perineal tract trauma, by allocated group

	Warm Pack n=360 n (%)	Standard Care n=357 n (%)	OR (95% CI)
Perineal suturing required[#]	283 (78.6)	284 (79.9)	1.0 (0.69-1.47)
Degree of trauma			
▪ Intact or minor trauma (intact, 1 st degree, vaginal, labial tear)	144 (41.4)	141 (40.4)	1.04 (0.78-1.41)
▪ Major trauma (2 nd , 3 rd , 4 th , degree tear, episiotomy)	204 (58.6)	208 (59.6)	
Episiotomy	39 (10.8)	41 (11.5)	0.94 (0.59-1.5)
Severe perineal trauma (3rd and 4th degree)	15 (4.2)	31 (8.7)	2.16 (1.15-4.10)

[#]Women who had a caesarean section were removed from this analysis (12 in warm pack group and 8 in standard care group)

6.7.2 Logistic regression model

The logistic regression model included the three significant predictors for the primary outcome of perineal suturing. These were instrumental birth, birth weight and Asian ethnicity. Age did not significantly contribute to the requirement for perineal suturing (Table 6.4). Warm packs did not have an effect in reducing perineal suturing.

Table 6.4: Logistic regression model for primary outcome of requirement for perineal suturing and influencing variables

		Unadjusted OR (95% CI)	Adjusted OR (95% CI)
Group	Warm pack	1.0	1.0
	Standard care	1.0 (0.7-1.5)	1.0 (0.7-1.5)
Age	16 – 24 yrs	1.0	1.0
	25 – 34 yrs	2.1 (0.9-4.7)	1.7 (0.7-3.8)
	≥ 35 yrs	1.1 (0.5-2.5)	1.1 (0.5-2.5)
Ethnicity [#]	Non-Asian	1.0	1.0
	Asian	2.7 (1.7-4.3)	2.6 (1.6-4.4)
Mode of birth	Normal vaginal	1.0	1.0
	Instrumental vaginal	4.5 (1.8-11.2)	3.7 (1.4-9.3)
Birth weight	≤ 3,500gms	1.0	1.0
	> 3,500gms	1.7 (1.1-2.6)	1.8 (1.2-2.9)

[#] Women were defined as 'Asian' if they were born in, or identified as being from, China, Vietnam, Hong Kong, Indonesia, Japan, Laos, Cambodia, Taiwan, North Korea, South Korea, Thailand, Philippines, Burma and Malaysia.

6.7.3 Episiotomy

Twenty women had a forceps delivery and 41 women had a vacuum extraction. Most of the episiotomies were associated with instrumental deliveries, particularly forceps deliveries (Table 6.5).

Table 6.5: Episiotomy and mode of birth, excluding caesarean section.

	Episiotomy n=80	No episiotomy n=637
	n (%)#	n (%)#
Normal vaginal birth	42 (6.9)	564 (93.1)
Forceps delivery	11 (55)	9 (45)
Vacuum delivery	27 (38)	44 (62)

Percentage within birth type.

A chi-squared test was performed to examine differences between allocated groups: $p=0.0001$.

Only 6.9% of women having normal vaginal births received an episiotomy compared to 55% of those having a forceps birth and 38% of those having a vacuum delivery.

6.7.4 Severe perineal trauma and mode of birth

There was a significant difference between the incidence of severe perineal trauma and mode of birth (Table 6.6).

Table 6.6: Severe perineal trauma and mode of birth, excluding caesarean section.

	Severe perineal trauma =46	No severe perineal trauma n=651
	n (%)#	n (%)#
Normal vaginal birth	32 (5.3)	574 (94.7)
Forceps delivery	5 (25)	15 (75)
Vacuum delivery	9 (12.7)	62 (87.3)

#Percentage within delivery type.

A chi-squared test was performed to examine differences between allocated groups: $p=0.0001$.

6.7.5 Severe perineal trauma and ethnicity

There was a statistically significant difference in third- and fourth-degree perineal tears, with women in the standard care group more than twice as likely (31/357 vs 15/360) to

sustain a severe perineal tear than women in the warm pack group (OR 2.16; 95% CI 1.1 to 4.3, $p = 0.02$) (Table 6.3).

The incidence of severe perineal trauma was significantly higher in Asian women, compared with non-Asian women (Table 6.7).

Table 6.7: Severe perineal trauma and ethnicity.

	Severe perineal trauma =46 n (%)#	No severe perineal trauma n=651 n (%)#
Non-Asian	21 (4.5)	446 (95.5)
Asian	25 (10.9)	205 (89.1)

Percentage within delivery type.

A chi-squared test was performed to examine differences between allocated groups: $p=0.001$.

6.8 Discussion of clinical outcomes of labour and birth

The maternal clinical outcomes from the study have been presented in this chapter and the main outcome variable, perineal suturing at birth, has specifically been described. Several findings need further discussion and clarification.

The high rate of spontaneous vaginal birth found in the participants in this study (85%) and low rate of surgical birth (15%),³⁶ including caesarean section (<3%), is not reflective of the mode of birth in the primiparous population at these two hospitals. Rather it is reflective of the fact that randomisation occurred in the latter part of the first, or early second stage, to ensure that women who may not be eligible to participate in the study (for example, those having a caesarean section) were not randomised and included in the intention to treat analysis. The high use of analgesia for labour and low use of upright birthing positions is reflective of the culture of the delivery wards where these births occurred. The inclusion of

³⁶ Surgical birth is defined as vacuum, forceps or caesarean section.

the Birth Centre would have altered this data and been more reflective of a cross-section of the birthing population. Reasons for the withdrawal of the Birth Centre from the study have already been described in Chapter 5.

The power analysis estimated that 694 participants were needed to show a 10% difference in suturing. Due to time factors, recruitment ceased at 717, despite only 599 women actually having the allocated treatment. It is highly unlikely a further 95 women would have led to a statistically significant difference in the primary outcome measure.

Prior to the study it was considered that covering the perineum with a warm pack in the late second stage might possibly lead to a lower episiotomy rate. However, no significant difference in the proportion of episiotomies between the groups was seen. This may also be due to the fact that the episiotomy rate in the two participating hospitals was reasonably low and most of the episiotomies occurred with instrumental births. The rate of 11% for primiparous women was lower than the Australian average for all women of 17.2% (Laws et al., 2006a). The hospitals had embarked on a quality improvement activity in the years prior to the Perineal Warm Pack Trial to reduce the episiotomy rate. This proved to be very successful (Dahlen, 1999). There is evidence to support restricting the liberal use of episiotomy (Hartmann et al., 2005) (Carroli & Belizan, 2006) and using vacuum rather than forceps for instrumental births to protect the perineum during the birth (Johanson & Menon, 2004).

6.8.1 Severe perineal trauma

The incidence of severe perineal trauma in this study was significantly higher in the standard care group compared with the warm pack group. However, this finding needs to be treated with caution.

A sample size of 694 was selected for the study following calculations based on a 10% reduction in suturing with a power of 80% ($\alpha = 0.05$, two-sided test). In total, 1,047 primigravid women were approached to participate in the research and 717 were

randomised. In order to show a 50% reduction in severe perineal trauma, as was demonstrated in the study, a sample size of 996 would have been required to reduce the severe trauma rate from 8.7 to 4.2%. The large difference in the rate of severe perineal trauma is clinically significant and warrants further investigation. The sample size, however, was not large enough to demonstrate a statistical difference in the relatively rare outcome of severe perineal trauma. The confidence intervals almost cross one (95%; CI 1.1 to 4.3 $p = 0.02$) if there had been a larger sample size this may well have no longer been significant. On the other hand, a larger sample size might have been associated with an even more statistically significant outcome. However, the difference in severe perineal trauma was not the primary outcome for this study. Further investigation of episiotomy, major and minor perineal trauma and severe perineal trauma mean the likelihood of Type 1 error is increased. It is unclear why the incidence of severe perineal trauma was reduced in the warm pack group when other forms of perineal trauma or the need for suturing were not.

As already discussed in Chapter 3, there is some evidence from the colorectal surgery literature that the application of moist heat may have a real physiological effect on the anal sphincter. This needs to be taken into consideration when considering further research in this area. Researchers have such as Shafik (1993) have tried to elucidate the physiologic mechanism and beneficial effect of the warm sitz bath by measuring the internal and external sphincter temperature, rectal pressure, and electromyograph (EMG) activity of the anal sphincter in healthy volunteers and patients with chronic anal fissures or thrombosed haemorrhoids (Shafik, 1993a). Measurements collected before and after the sitz baths, performed at different water temperatures (40, 45, 50⁰ C), with each bath lasting 15 minutes, demonstrated a decrease in internal sphincter pressure during the sitz bath. Warmer water led to a greater duration of low internal sphincter pressure. Pain relief was also more evident and lasted longer at higher bath temperatures. Shafik (1993) proposed the thermosphincteric reflex and theorised that the relaxation of the internal sphincter muscle is mediated through sensory peri-anal skin receptors stimulated by warm water. The resulting decrease in spasm and pain relief was attributed to the thermosphincteric reflex (Shafik, 1993a). Shafik (1993) also noted a reduction in urethral pressure associated with the warm

sitz bath that led to relaxation of the internal urethral sphincter, thereby causing vesicle contraction and urination (Shafik, 1993b). Other researchers such as Jiang et al. (1999) also observed that local thermal stimulation evokes relaxation of the hypertonic internal anal sphincter but argued the mechanism was through a somatoanal reflex (Jiang et al., 1999).

It is possible a similar mechanism is present when perineal warm packs are applied. The warm pack often covers the anal area. Midwives reported during the study, that they often had to use fresh perineal warm pads due to faecal contamination. It is possible that the warmth had an effect on the anal sphincter, relaxing it and making it more elastic and thus less likely to be torn. This might explain why the perineal trauma was only reduced when it came to severe perineal trauma and not in other more minor degrees of trauma. A much larger sample size would be needed to confirm the effect of warm packs on reducing severe perineal trauma.

6.8.2 Severe perineal trauma in Asian women

Severe perineal trauma constitutes a serious morbidity with a high incidence of faecal incontinence for women who experience it (Sultan & Thakar, 2002) and any possible reduction in the incidence should be pursued with further research.

The high rate of severe perineal trauma seen in the Perineal Warm Pack Trial is most likely due to the fact that all the women were primiparous and there were such a high number of Asian women in the study (33%). Compared to an earlier RCT by Albers et al. (2005), participants in the study had a high rate of severe perineal trauma. This may have been to do with the late second-stage randomisation, low number of primiparous women and different ethnic mix in the previous study (Albers et al., 2005).

Our previous study in this population, demonstrated that both primiparous women (OR 4.6; 95% CI 2.9 to 7.2) and Asian-born women (OR 1.9; 95% CI 1.3 to 2.8) were more likely to experience perineal trauma and they experienced it to a greater degree than non-

Asian women (Dahlen et al., 2007)³⁷. Our earlier study examined the risk factors for the occurrence of severe perineal trauma (third- and fourth-degree perineal tears) during childbirth (Dahlen et al., 2007). It was a prospective cohort study and examined data on all women having vaginal births (n = 6,595) in a two-year period between April 1, 1998 and March 31, 2000 in both the birth centre and the labour ward at RPA. Two per cent of women in this sample (n = 134) experienced severe perineal trauma. Primiparity, instrumental delivery, Asian ethnicity and heavier babies were associated with an elevated risk of severe perineal trauma. Midwives identified several factors in this study that they believed contributed to severe perineal trauma. These were lack of good communication with the woman during the birth, different birth positions, delivery technique, ethnicity and obstetric influences (Dahlen et al., 2007).

The conclusions of the previous study were that further identification and validation of the concerns expressed by midwives to reduce severe perineal trauma were warranted, so that preventative strategies can be employed and researched (Dahlen et al., 2007). The Perineal Warm Pack Trial attempted to add to this knowledge. Once again, a strong association was shown between severe perineal trauma and Asian ethnicity. Warm packs also appeared to be equally effective in reducing severe perineal trauma in both the Asian and non-Asian groups, but the sample size was too small to show a difference in this outcome. Asian women were not, however, less likely to be sutured in the warm pack group compared to non-Asian women.

Asian women have been reported in the literature as having a higher rate of perineal trauma, in particular, severe perineal trauma (Combs, Robertson, & Laros, 1990) (Goldberg et al., 2003; Green & Soohoo, 1989) (Hopkins, Caughey, Glidden, & Laros, 2004). The definition of Asian varies in these studies, as some include Indian and Filipino women and some do not. This needs to be taken into consideration. Although the mechanism behind laceration is likely to be multifactorial, having a clearer insight into each potential factor is important if we are to understand the overall issue. Proposed mechanisms to explain this difference between women of different races include variation in tissue type and anatomy

³⁷ A copy of the paper is available in Appendix 1.

(Green & Soohoo, 1989). Histological tissue differences have been seen in studies on skin due to ethnicity (Lee & Hwang, 2002) (Shirakabe, Suzuki, & Lam, 2003). Another way to look at these ethnic variations is to examine research on other gynaecological problems. There is a link between urinary incontinence, for example, and white ethnicity. It is unclear whether a difference in risk of pelvic organ prolapse based on ethnicity exists (Graham & Mallet, 2001) (Bump, 1993) (Sze, Sherard, & Dolzezal, 2002). Observations of anatomic differences between different races have been made (Dahlen et al., 2007) and the relationship between a shorter perineal body and increased rates of severe perineal trauma has been demonstrated (Deering, Carlson, Stitely, Allaire, & Satin, 2004). Previous research has shown that a perineal length less than or equal to 2.5 cm puts women at greater risk of a third or fourth degree tear (40% vs 5.6% $p = 0.04$) (Deering et al., 2004). In the previous study (Dahlen et al., 2007) the most common risk factor for severe perineal trauma as observed by midwives at the birth was 'short perineum' and this was associated predominantly with women of Asian ethnicity.

While the increased incidence of severe perineal trauma in Asian women may be an issue related to the anatomy of the perineum, such as having a shorter perineal body, an inability to communicate effectively has also been identified by midwives as a contributing factor (Dahlen et al., 2007). This lack of communication was related to CALD women being unable to understand the midwives' requests, but was also associated with women who were frightened and out of control. A systematic review of practices to minimise trauma to the genital tract in childbirth found that motivation; confidence; control and pain tolerance had not been specifically addressed by research (Renfrew et al., 1998). The impact of fear and lack of communication on perineal outcome warrants further study. It also is a reminder to midwives of the importance of using health care interpreters to reduce confusion and fear. Unfortunately, it is not always practical or possible to have an interpreter present for the labour and birth. For some women it is also unacceptable, particularly when the interpreter is male.

Higher infant birth weight was also found to be a significant predictor of severe perineal trauma in our previous study (Dahlen et al., 2007). It has been hypothesised that Asian

women are having bigger babies in Australia than they would have in their own countries, due to the dietary changes. Some studies support this hypothesis (Dhawan, 1995), while others have demonstrated that lower birth weight persists in second-generation Asian babies (Margettes, Mohd Yusof, Al Dallal, & Jackson, 2002). It is challenging to obtain data regarding the incidence of severe perineal trauma amongst Asian women in their own countries. A comparative study of birth weights and perineal outcomes in Asian women giving birth in their country of origin and in Australia is needed to address this issue.

6.9 Summary

This chapter has reported on the clinical outcomes of labour and birth. No benefit was found from the application of warm packs in terms of a reduction in perineal suturing at birth. While the study was underpowered to assess the uncommon outcome of severe perineal trauma (third- and fourth-degree tears), and a possible protective effect from the warm packs may be a chance finding, there is enough clinical difference in the rates between the two groups (OR 2.16; CI 1.1 to 4.3) to warrant further investigation. There is also physiological evidence that this effect is possible. The high rate of severe perineal trauma (6.4%) amongst women in this study is partly explained by the fact that they were all primiparous and a large number (33%) were Asian. Both have been shown to be strongly associated with severe perineal trauma in a previous study of women giving birth in these same two hospitals (Dahlen et al., 2007). Severe perineal trauma constitutes a serious morbidity, with a high incidence of faecal incontinence for women who experience it, and any possible reduction in the incidence should be pursued with further research. One of the limitations of this study was that we did not examine the incidence of faecal incontinence. This is discussed further in Chapter 9.

The next chapter reports on the secondary outcome measure, women's evaluations of perineal pain at birth and on days one and two.

Chapter 7: Women's evaluations of perineal pain during and after birth

"I feel that when nature asks us women to push a baby out it is probably the bravest thing we ever have to do. The feeling that trauma must ensue is so strong; in a way, a woman has to abandon her own comfort and safety in order for her child to emerge" (Flint, 1997, p.186).

7.1 Introduction

As discussed in the previous chapter, there was no evidence that warm packs reduced the requirement for suturing following birth. Data related to the secondary outcome variable of maternal comfort is reported on in this chapter. This specifically includes the evaluations of women's pain whilst giving birth, and on days one and two following the birth. This chapter begins with a brief review of the evidence.

Subsequent chapters (8 and 9) report on the evaluation of warm packs from the perspective of women and midwives, using questionnaires as well as following up women after the birth and through telephone interviews at six and twelve weeks following the birth.

7.2 Perineal comfort during and following birth

As shown in Chapter 6, warm packs do not appear to reduce the incidence of suturing, so it is important to ascertain whether they improve maternal comfort.

The second stage in particular, is associated with the onset of new and frightening sensations, which women describe using words such as bulging; cracking; splitting; opening and breaking (Anderson, 2000b). These sensations can make women reluctant to push and frightened of giving birth.

There is evidence that women, particularly primiparous women, are increasingly worried about the pain associated with the labour and birth. The Greater Expectations study conducted in the United Kingdom in the year 2000 showed there had been a big change in pregnant women's attitudes to labour pain and anticipation of ways of coping with that pain from a similar survey in 1987 (Green, Coupland, & Easton, 2003). More pregnant women felt 'very worried' about labour pain, with a marked increase in primiparous women, up from 9% in 1987 to 26% in 2000. Fewer women in 2000 said they were not worried at all compared to 1987 responses. While fewer women said they would put up with a lot of pain in order to have a completely drug-free labour, it was still the case in 2000 as it had been in 1987 that four in five women wanted no drugs or minimum drugs to keep the pain manageable. However, many more women actually had drugs for pain relief than wanted to have them, especially when it came to epidural analgesia.

Perineal pain, such as that experienced with the birth of the baby's head, can be severe and unlike any other pain experienced during labour. Despite this, much of the research on pain in labour has focused on analgesia in the first stage. The pain associated with the actual birth has been largely overlooked (Sanders et al., 2005). For example, of the 68 randomised trials examining epidural anaesthesia in labour, only one included information on the effectiveness of perineal analgesia during birth (Hill, 1995). In a Cochrane Review on birth position in the second stage of labour, only five of 19 trials included maternal pain during the birth as an outcome (Gupta et al., 2006).

Studies that have examined the degree of pain experienced in the different stages of labour show that the most severe pain was experienced in the second stage of labour (Lowe & Roberts, 1998) (Niven & Gijbsbers, 1984). The pain reported was significantly higher than pain scores given by patients suffering from cancer and arthritis (Melzack, 1975), even though arguably women experience this pain for much shorter periods. In an observational study of women in the second stage (McKay et al., 1990), seven of the 20 women interviewed used negative terms such as, painful, miserable or horrible. The authors suggest that strategies to help alleviate some of the intense sensations of the second stage are needed.

The degree to which pain during birth influences maternal satisfaction is controversial. It has become increasingly apparent that adequate analgesia is not the central factor in maximising maternal satisfaction with care. There are multiple factors involved, such as attitudes and behaviours of health care providers during childbirth (Green & Baston, 2003). A Cochrane Review on epidural anaesthesia showed that, while epidurals offered better pain relief than non-epidural anaesthesia, maternal satisfaction with pain relief was not significantly different (Anim-Somuah et al., 2005). Descriptive studies have also demonstrated that a woman's expectations and confidence in her ability to cope with pain are keys to explaining the individual variation in pain experienced during labour and birth (Lowe, 1991).

Midwives and other accoucheurs use a variety of techniques in the second stage of labour to reduce genital tract trauma and pain (Renfrew et al., 1998). A postal survey of 210 maternity units in the UK (Sanders et al., 2005) found that midwives used a variety of non-pharmacological analgesic methods to control pain at the end of the second stage of labour, including hot packs (33%); cold packs (21%); perineal massage (52%); and injectable local anaesthetics (62%). Perineal warm packs are used in the belief that they reduce perineal trauma but equally importantly that they increase comfort during the second stage (Albers et al., 1996) (Balaskas, 1983) (Kitzinger & Simkin, 1984) (Schrag, 1979) (Hobbs, 2001) (Sanders et al., 2005).

The potential physiological beneficial effects of warm packs, as already discussed in Chapter 3, include the dilation of blood vessels and increase of blood flow, both of which influence the transmission of pain (Fritz, 1995) (Hayes, 2000) (Porth, 1990) (Lehmann, 1990). Randomised trials into the efficacy of perineal warm packs have limited generalisability because of their small sample sizes, mixed methods or lack of data about the effects on women's pain (Musgrove, 1999) (Albers et al., 2005). Other approaches have also been tested. A recent randomised controlled trial into the effect of lidocaine spray to the perineum during the birth found no effect on perineal pain (Sanders et al., 2006). A randomised trial into the effect of intrapartum perineal massage on perineal outcomes showed no significant reduction in perineal trauma, although there was no evaluation of

perineal pain associated with the actual procedure (Stamp et al., 2001). A large UK trial compared a 'hands on' technique with a 'hands poised' technique for birth and found greater perineal pain reported by women in the 'hands poised' group at 10 days (McCandlish et al., 1998). The study did not, however, evaluate pain felt during the actual birth.

As already discussed, perineal trauma following childbirth can be associated with significant short and long-term morbidity for women (Sleep & Grant, 1987) (Glazener et al., 1995) (McCandlish et al., 1998). Acute postpartum perineal pain is common among all women who give birth vaginally and its severity is linked to that of the perineal injury (Kenyon & Ford, 2004) (Albers et al., 1999a) (Klein et al., 1994). Many women fear having perineal sutures and experiencing the pain associated with perineal trauma (Steen & Marchant, 2007). Perineal pain can have long- and short-term negative consequences for women's health and wellbeing. Of the women who sustain perineal trauma, 40% report pain in the first two weeks postpartum, up to 20% still have pain at eight weeks (Glazener et al., 1995) and 7% to 9% report pain at three months (McCandlish et al., 1998; Sleep & Grant, 1987). Women who have an intact perineum following birth report pain less frequently at one, two, ten, and ninety days postpartum (Albers et al., 1999a) (Klein et al., 1994).

Perineal pain experienced during the second stage of labour can also have an impact on how a woman views her birth experience. However, it is apparent that multiple factors are involved in influencing a woman's perception of pain, including, most importantly, the attitudes and behaviours of health care providers during childbirth (Green & Baston, 2003). Much of the research on pain in labour has focused on the first stage, thus largely overlooking the pain associated with the actual birth (Sanders et al., 2005).

7.3 Research questions of the study

The research questions have already been presented in Chapter 6. The secondary outcome measure of maternal comfort, which includes women's perineal pain scores at birth and days one and two following the birth, are presented in this chapter.

7.4 Method

The study design, sample size calculation, method of random allocation, outcome measures and data-collection methods have been described in Chapter 5. In this section, the data-collection instruments are fully described.

Data-collection instruments for pain scores were modified from a couple of previous studies, one into the effects of warm packs on perineal trauma (Musgrove, 1997) and the other into the effect of using polyglycolic suture material compared to catgut (Upton et al., 2002). Midwives collected the data.

Pain scores were collected immediately after the birth before the woman left the Delivery Ward. All women in the trial were asked to circle the comment on a scale that represented the pain they experienced when giving birth, with one being 'no pain,' two being 'some pain,' three being 'moderate pain,' four being 'bad pain,' and five being 'the worst pain in my life.' On day one and day two, a pain analogue scale (0 – 10) was used and women were asked to report the level of perineal pain experienced from 0 being 'no pain' to 10 being the 'worst pain ever' (Appendix 6).

7.5 Perineal pain scores at birth

Pain scores were collected, usually within three to four hours of the birth. As already described, all women were asked to circle the comment on a scale that represented the perineal pain they experienced when giving birth.

Reasons for not completing the pain scores were: the midwives were too busy; there was a change of shift; and midwives forgot; or the form was lost. There were fewer pain scores obtained from women who had forceps and vacuum extraction births and this may have been due to confusion over whether these women should have been followed up, as they did not have the treatment. No women who were asked refused to complete the pain score.

There were significant differences between the groups in reporting of pain at birth, on days one and two following the birth. Women in the warm pack group were significantly less likely to report the pain they experienced at birth as 'bad' (n = 69 vs 89; 25% vs 31%) or 'the worst in my life' (n = 92 vs 148; 34% vs 51%), compared to women in the standard care group (Table 7.1). Women in the warm pack group were more likely to say they experienced pain that was mild to moderate (n = 111; 40.8%) when giving birth, compared to women in the standard care group (n = 53; 18.3%) (Figure 7.1).

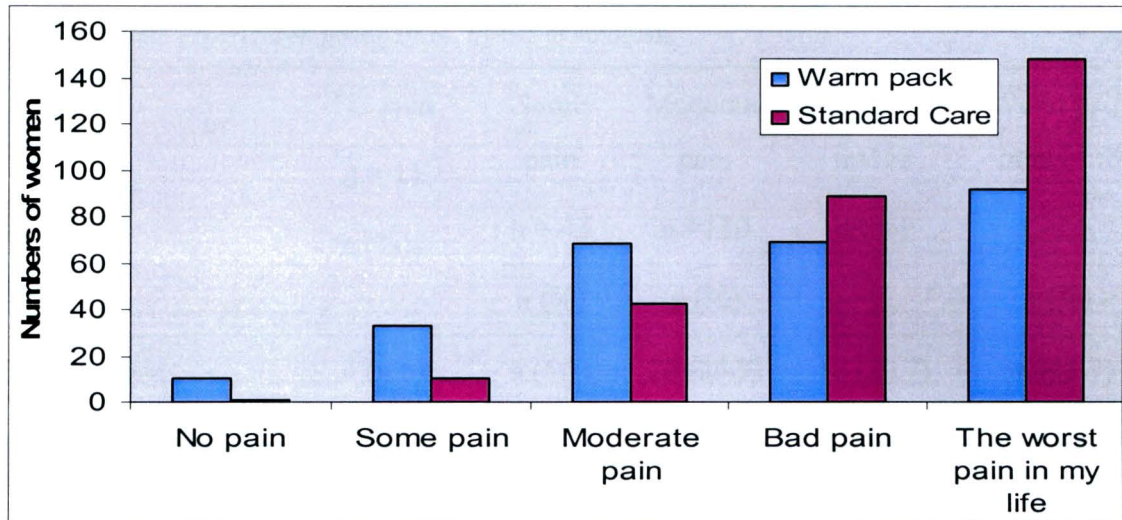
Table 7.1: Pain experienced when giving birth, by group

	No pain n = 11 n (%)#	Some pain n = 43 n (%)	Moderate pain n = 110 n (%)	Bad pain n = 158 n (%)	Worst pain in my life n = 240 n (%)
Warm pack group	10 (3.7)	33 (12.1)	68 (25)	69 (25.4)	92 (33.8)
Standard care group	1 (0.3)	10 (3.4)	42 (14.5)	89 (30.7)	148 (51)

Percentage within group.

A chi-squared test was performed to examine differences between groups: p=0.0001.

Figure. 7.1: Pain reported by women when giving birth, by group



A chi-squared test was performed to examine differences between allocated groups: $p=0.0001$

7.5.1 Analgesia use and pain scores while giving birth

Further analysis indicated that there was no difference in pain experienced by all women in the study whilst giving birth whether they had analgesia or not (Table 7.2). A significant difference was found in the pain experienced whilst giving birth between women who had an epidural and those who did not have analgesia or had other forms of analgesia, such as nitrous oxide and pethidine. Women who had an epidural were less likely to describe the pain of giving birth as 'the worst pain in my life' (Table 7.3). Seventy-six women (13.5%) had an epidural for pain relief during the study. While slightly more women had an epidural in the standard care group ($n = 86$) compared with the warm pack group ($n = 68$), this was not statistically different. Interestingly, women who used nitrous oxide and pethidine seemed to produce similar pain scores to women who used no analgesia at all.

Table 7.2: Pain experienced giving birth, by use of analgesia

	No pain n = 11 n (%)#	Some pain n = 43 n (%)	Moderate pain n = 110 n (%)	Bad pain n=158 n (%)	Worst pain in my life n =240 n (%)
No analgesia	4 (4.6)	5 (5.7)	22 (25.3)	18 (20.7)	38 (43.7)
Analgesia	7 (1.5)	38 (8)	88 (18.5)	140 (29.5)	202 (42.5)

Percentage within analgesia type.

A chi-squared test was performed to examine differences between allocated groups: $p=0.10$.

Table 7.3: Pain experienced giving birth, by use and type of analgesia/anaesthesia

	No pain n = 11 n (%)#	Some pain n = 43 n (%)	Moderate pain n = 110 n (%)	Bad pain n=158 n (%)	Worst pain in my life n = 240 n (%)
No analgesia	4 (4.6)	5 (5.7)	22 (25.3)	18 (20.7)	38 (43.7)
Nitrous Oxide	2 (0.8)	14 (5.8)	49 (20.3)	69 (28.6)	107 (44.4)
Pethidine	1 (0.6)	17 (10.8)	21 (13.3)	50 (31.6)	69 (43.7)
Epidural	4 (5.3)	7 (9.2)	18 (23.7)	21 (27.6)	26 (34.2)

Percentage within analgesia type.

A chi-squared test was performed to examine differences between allocated groups: $p=0.03$.

7.5.2 Pain and perineal trauma

There was no statistically significant difference between pain experienced during birth and severity of perineal trauma (Table 7.4). This indicates that the women do not appear to experience increased pain with more severe perineal trauma when they are actually giving birth.

Table 7.4: Pain scores experienced during birth, by perineal trauma severity

	No pain n = 11 n (%)#	Some pain n = 43 n (%)	Moderate pain n = 110 n (%)	Bad pain n=158 n (%)	Worst pain in my life n =240 n (%)
Perineal trauma intact or minor (< 2 nd degree)	6 (2.4)	23 (9.3)	44 (17.7)	77 (31)	98 (39.5)
Perineal trauma major (≥ 2 nd degree)	5 (1.6)	20 (6.4)	66 (21)	81 (25.8)	142 (45.2)

#Percentage within trauma type.

A chi-squared test was performed to examine differences between allocated groups: p=0.27.

Likewise, pain scores during birth were not increased for women experiencing severe perineal trauma, compared to those not experiencing severe perineal trauma (Table 7.5).

Table 7.5: Pain scores experienced during birth, by severe vs other perineal trauma

	No pain n = 11 n (%)#	Some pain n = 43 n (%)	Moderate pain n = 110 n (%)	Bad pain n=158 n (%)	Worst pain in my life n =240 n (%)
No severe perineal trauma	10 (1.9)	43 (8.1)	103 (19.4)	151 (28.5)	223 (42.1)
Severe perineal trauma	1 (3.1)	0 (0)	7 (21.9)	7 (21.9)	17 (53.1)

Percentage within trauma type.

A chi-squared test was performed to examine differences between allocated groups: p=0.35.

7.5.3 Pain scores at birth and Asian ethnicity

There was no statistically significant difference between Asian and non-Asian women's pain scores at birth (Table 7.6). There was also no difference in pain scores at birth in any of the other major ethnic groups.

Table 7.6: Pain scores at birth, by Asian vs non-Asian women

	No pain n = 11 n (%)#	Some pain n = 43 n (%)	Moderate pain n = 110 n (%)	Bad pain n=158 n (%)	Worst pain in my life n =240 n (%)
Asian	3 (1.7)	19 (10.6)	40 (22.2)	47 (26.1)	71 (39.4)
Non-Asian	8 (2.1)	24 (6.3)	70 (18.3)	111 (29.1)	169 (44.2)

Percentage within ethnicity type.

A chi-squared test was performed to examine differences between allocated groups: $p=0.29$.

7.5.4 Birth position and pain experienced whilst giving birth

Reported pain scores at birth did not differ significantly between the different birth positions when grouped into semi-seated, upright, (all fours, kneeling, standing, birth stool, squatting), flat (lithotomy and flat) and lateral (Table 7.7). When all the birth positions were compared individually there was a significant difference, but some of the cell sizes were very small, making one cautious about findings. However, it was interesting to note that the highest pain scores were associated with the birth stool and lithotomy position and the lowest with kneeling and standing. The high pain scores with the birth stool may well be due to the fact that midwives in the hospitals where the study took place often use the birth stool to facilitate the birth when the second stage is protracted and an instrumental delivery is a possibility. Thus use of a birth stool may indicate a more difficult labour and hence higher pain scores.

Table 7.7: Pain experienced giving birth, by birth position

	No pain n = 11 n (%)#	Some pain n = 43 n (%)	Moderate pain n = 110 n (%)	Bad pain n=158 n (%)	Worst pain in my life n =240 n (%)
Semi-seated	7 (1.7)	31 (7.5)	91 (22.1)	108 (26.3)	174 (42.3)
Upright (all fours, kneeling, standing, birth stool, squatting)	4 (4.5)	4 (4.5)	9 (10.1)	27 (30.3)	45 (50.6)
Flat (lithotomy & flat on back)	0 (0)	1 (14.3)	0 (0)	2 (28.6)	4 (57.1)
Lateral	0 (0)	7 (12.7)	10 (18.2)	21 (38.2)	17 (30.9)

Percentage within birth position type.

A chi-squared test was performed to examine differences between allocated groups: $p=0.06$.

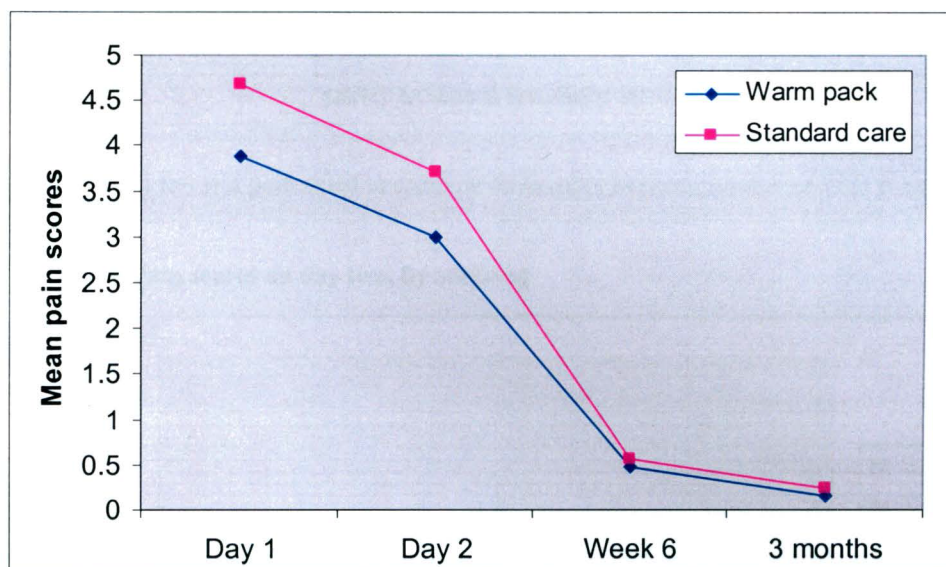
7.6 Perineal pain scores on day one and two

Pain scores were obtained from 288 (80%) women in the warm pack group and 293 (82%) women in the standard care group on day one following the birth. Pain scores collected on day two following the birth were obtained from 278 (77%) women in the warm pack group and 291 (82%) in the standard care group. The reasons why some women did not complete pain scores on day one and two were: women went home on early discharge; midwives forgot to go to the postnatal ward; midwives were too busy; or, the women had visitors when they went to see them. No woman who was asked refused to complete the pain scores on day one and two.

On day one, women in the warm pack group had statistically significantly lower mean pain scores than the standard care group on the 0 – 10 visual analogue scale (mean 3.86 [SD 2.3] vs. mean 4.67 [SD 2.3]). Again, on day two, women in the warm pack group had statistically significantly lower mean pain scores than in the standard care group (mean 3.00

[SD 2.1] vs mean 3.71 [SD 2.2] (Figure 7.2.). While the difference may not seem great, when one considers that the mean pain scores on both day one and day two were quite low, the difference between the groups becomes more clinically important. At six and twelve weeks there was no longer a difference in pain scores. This is discussed further in Chapter 9. Pain scores collected on days one and two were more likely to be from women who had a vaginal birth than from women who had an instrumental birth.

Figure 7.2: Mean perineal pain scores by allocated group, reported by women at day one, day two, six and twelve weeks, using a visual analogue scale (0 – 10)

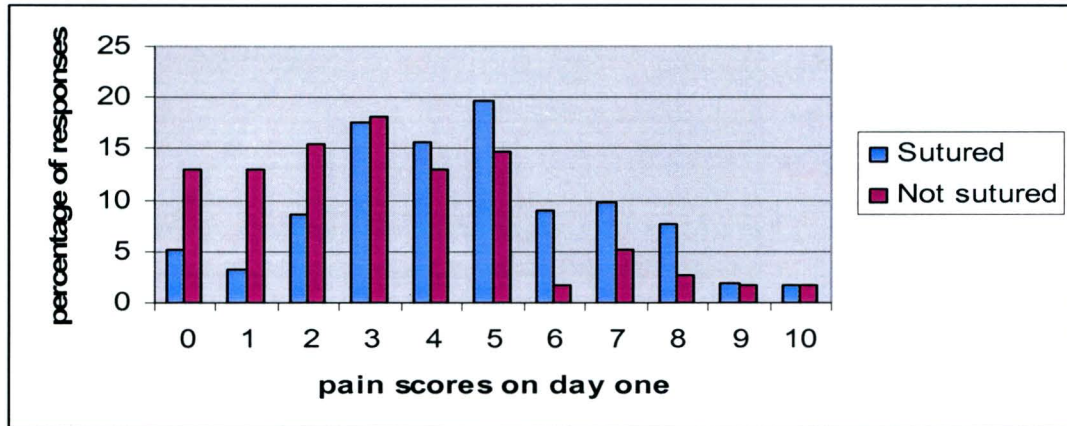


The y – axis is re-coded to be 0 – 5 as there were no pain scores greater than 5 on the visual analogue scale $p < 0.001$.

7.6.1 Pain scores and suturing

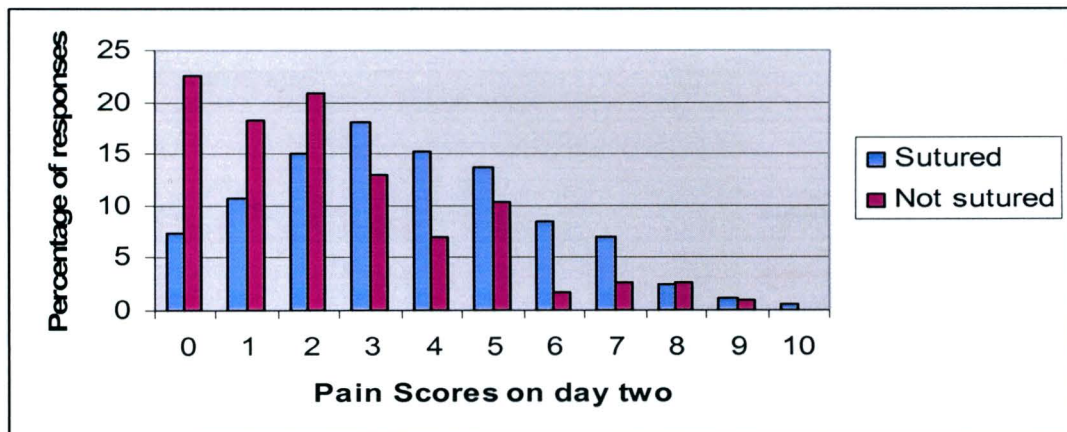
Women in the study who were sutured reported higher pain scores on day one than women who were not sutured (Figure 7.3). This also remained significant on day two (Figure 7.4).

Figure 7.3: Pain scores on day one, by suturing



A chi-squared test was performed to examine differences between sutured and not sutured groups: $p=0.0001$.

Figure 7.4: Pain scores on day two, by suturing

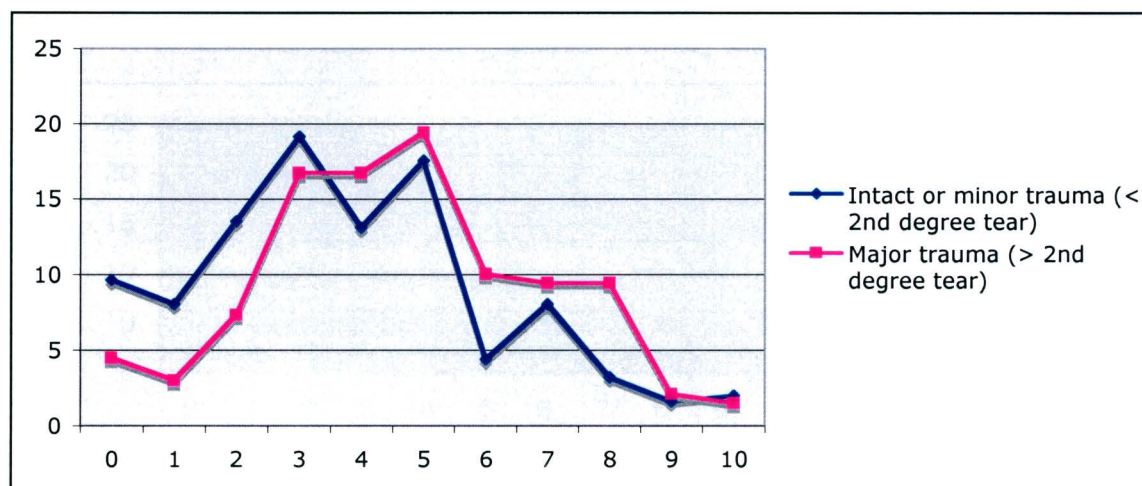


A chi-squared test was performed to examine differences between sutured and not sutured groups: $p=0.0001$.

7.6.2 Pain scores and degree of perineal trauma

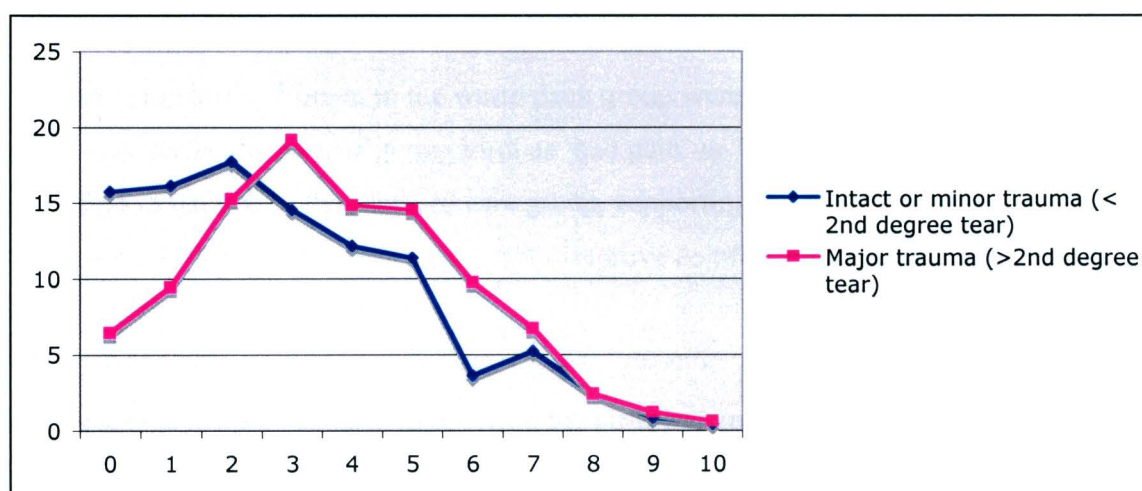
Women who were intact or experienced minor perineal trauma had lower pain scores on day one (Figure 7.5). This also remained significant on day two (Figure 7.6).

Figure 7.5: Pain scores on day one, by intact or minor trauma vs major trauma



A chi-squared test was performed to examine differences between intact or minor perineal trauma and major perineal trauma groups: $p=0.0001$.

Figure 7.6: Pain scores on day two, by intact or minor trauma vs major trauma

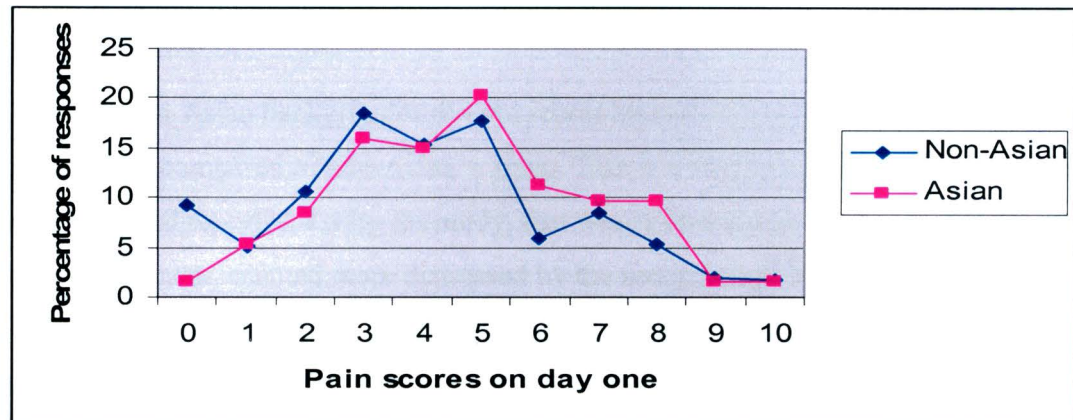


A chi-squared test was performed to examine differences between intact or minor perineal trauma and major perineal trauma groups: $p=0.001$

7.6.3 Pain scores and Asian ethnicity

Non-Asian women reported lower pain scores on day one (Figure 7.7) but this was no longer statistically significant by day two. This is most likely due to the fact that Asian women suffered greater perineal trauma overall and to a greater extent.

Figure 7.7: Non-Asian and Asian women, by pain scores on day one



A chi-squared test was performed to examine differences between non-Asian and Asian groups: $p=0.02$.

7.7 Discussion

There was significant reduction in pain reported at birth and pain reported at days one and two following birth. Women in the warm pack group were statistically significantly less likely to describe the pain of giving birth as ‘bad pain’ or ‘the worst pain in my life’ compared to women in the standard care group, supporting the observations of midwives over the centuries that perineal warm packs improve comfort for women in the second stage.

Higher scores for pain experienced during the birth were not associated with women having, or not having, analgesia in general but were associated with not having an epidural when separate analysis was undertaken. This supports other research that indicates epidural anaesthesia leads to significantly reduced pain during labour (Anim-Somuah et al., 2005).

Women who had major or severe perineal trauma were not more likely to report higher pain scores during the actual birth. This indicates that women do not report increased pain with greater trauma experienced during the birth. This may, however, be also related to the fact that severe perineal trauma is more likely to occur with instrumental births and these women are more likely to have an epidural, thus reducing their sensation Women were,

however, more likely to report increased pain following the birth, when trauma is more severe, supporting previous research (Glazener et al., 1995) (McCandlish et al., 1998) (Sleep & Grant, 1987) (Albers et al., 1999a) (Klein et al., 1994).

Women from Asian backgrounds did not report higher or lower pain scores associated with giving birth compared to non-Asian women. This is contrary to what many of the midwives perceived and reported during the study, that women from some ethnic backgrounds, such as Asian women, seemed more distressed by the second stage of labour. It is highly possible, as other important factors like control and fear were not assessed. Asian women were more likely to have higher pain scores overall in study on day one when compared to the non-Asian women, probably due to higher perineal trauma rates.

It has been rightly argued that the level of perineal pain women experience when actually giving birth and methods that might ease this pain whilst maximising the physiology of normal birth have not been widely studied (Sanders et al., 2005). A focus on reducing perineal trauma is certainly worthwhile, as is research into non-pharmacological methods for reducing pain during birth, yet the latter is often neglected. While pain-free births do occur, they are uncommon. It is more common that the advancement of the foetal head, and stretching of the perineum in the minutes before giving birth, is accompanied by pain and this pain is sometimes severe (Lowe & Roberts, 1998) (Niven & Gijsbers, 1984).

Researchers (Sanders et al., 2005) have argued that whilst thousands of studies have addressed the issue of analgesia provided to women in labour much of this work has overlooked the pain associated with the actual birth. Studies that have examined the degree of pain experienced in the different stages of labour, show that the most severe pain is experienced in the second stage of labour (Lowe & Roberts, 1998) (Niven & Gijsbers, 1984) (McKay et al., 1990). In the Perineal Warm Pack Trial, a large proportion of women described the pain of giving birth as 'bad pain' or 'the worst pain in my life' (55.5%). This supports findings from an observational study of women in the second stage, in which nearly half of the twenty women interviewed described the second stage of labour purely in negative terms (McKay et al., 1990). Warm packs were able to significantly reduce the number of women who reported the pain of giving birth as severe. As already discussed,

strategies to help alleviate some of the intense sensations of the second stage are needed and perineal warm packs can contribute significantly to this.

The fact that perineal pain scores remained statistically significantly lower in the warm pack group at days one and two following the birth, despite no difference in the incidence of suturing between the groups, is intriguing. There are a couple of possible explanations for this. Firstly, this may have occurred because the treatment could not be blinded and women who received the warm packs expected their pain to be lower. Women who did not receive the warm packs may have been disappointed and assumed they suffered additional trauma because they did not receive the treatment. Another possibility is that the warm packs somehow altered connective tissue on a superficial level, leading to fewer small splits and grazes, all of which may contribute to overall levels of pain. It is also possible that the presence of the warm pack on the perineum made midwives touch the perineum less and this led to less bruising. Secondly, as it was impossible to conceal the allocated treatment from the midwives, potential exists for reporting bias in the data collection. However, this is unlikely, as the midwives involved in the study had never used warm packs before and were generally not convinced of their value. A large number of midwives contributed to the data collection, making systematic distortion unlikely.

Being unable to blind women to the group to which they were allocated could have led to bias in the perceptions of pain reported at birth and days one and two following the birth, as they may have expected their pain to be less, as a result of the treatment. Women who did not receive the warm packs may have been disappointed and had a more negative perception of the birth. As analgesia use was poorly recorded and therefore not analysed it is possible that use of analgesia was uneven in the two groups. There is a possibility that women who did not complete pain score assessments may have had different responses. However, the fact that no women refused to complete the pain scores makes this less likely. The fact the midwives were less likely to obtain pain scores from women who had instrumental births is of more concern and shows a lack of understanding with intention to treat protocols. As these women were less likely to receive the treatment and did not receive standard second-stage care, it is unlikely to affect the final results.

7.8 Summary

Women in the warm pack group had significantly lower perineal pain scores when giving birth, on day one and on day two following the birth. The application of perineal warm packs in the late second stage does not reduce the likelihood of primiparous women requiring perineal suturing but significantly reduces pain during the birth and on day one and two. The application of perineal warm packs in the late second stage of labour significantly reduces pain during the birth and on days one and two. This simple, inexpensive practice should be incorporated into second-stage labour care.

Chapter 8 reports on women and midwives' evaluation of the warm packs through questionnaires. Chapter 9 reports on the postnatal follow-up of women following the birth and through telephone interviews at six and twelve weeks after the birth.

Chapter 8: “Soothing the ring of fire:” women and midwives evaluate perineal warm packs used in the second stage of labour

“Warm compresses made from a folded washcloth wrung out in warm water and held against the perineum can be soothing if the stinging is very frightening for the woman and she is holding back” (Robertson, 1997, 104).

8.1 Introduction

In Chapter 7, women’s pain scores when giving birth and on days one and two following the birth were reported. Women in the warm pack group had significantly lower perineal pain scores when giving birth, as well as on days one and two following the birth. While the application of perineal warm packs in the late second stage did not reduce the likelihood of primiparous women requiring perineal suturing, it significantly reduced pain during the birth and on days one and two.

This chapter begins with a brief review of the literature and then specifically examines women and midwives’ evaluation of the warm packs through questionnaires conducted soon after the birth, before leaving the Delivery Ward.

8.2 Women’s experiences of the second stage

As already discussed in Chapter 7, perineal pain, such as that experienced with the birth of the baby’s head, can be severe and unlike any other pain experienced during labour.

Women’s expression of this pain when giving birth has motivated midwives since ancient times to seek out methods that may comfort and ease this pain. In *The Works of Aristotle*, the ‘ring of fire’ that women often experience when giving birth, is described as, “if it

[perineum] were scratched or pricked with pins” (Aristotle, date unknown, pp.253-254)³⁸. Soranus of Ephesus (98 – 138 AD), in his book *Gynaecology*, was one of the earliest writers to describe the care of the perineum. He gave instructions that one should, “drench warm pieces of cloth with warm, sweet olive oil and put them over the abdomen as well as the labia and keep them saturated with the warm oil for some time, and one must also place bladders filled with warm oil alongside” (Temkin, 1956). A more comprehensive description of historical care of the perineum in the second stage of labour was provided in Chapter 2.

Authors have argued that very little is known about women’s experience of the second stage and what aspects of midwifery care help or hinder them in the process of giving birth (Anderson, 2000b). Others have argued that the experts mute women’s voices, and while it is women who experience birth, their experiences are often deemed as unimportant (Kirkham & Perkins, 1997). Researchers who have recorded women’s experiences of the second stage of labour and their perceptions of midwifery care during this crucial time, report that this stage of labour is associated with the onset of new and frightening physical sensations (Anderson, 2000a). Women describe sensations such as bulging, cracking, splitting, opening and breaking as the baby is born (Anderson, 2000a). On feeling these sensations, women have to overcome a barrier of fear that initially prevents them pushing wholeheartedly. Other authors talk about the body image and how it is constructed of boundaries – a perception of where one’s body ends and the outside world begins (Price, 1993). Any change in the body image can be traumatic. This is especially the case during the process of birth when the mother’s body literally opens up, breaching the boundaries of the body (Price, 1993).

As described more fully in Chapter 3, women and midwives describe in the contemporary literature the comfort gained when warm packs are applied, as though the pressure and warmth re-establish the boundaries they feel are being breached. See, for example, these comments made by a woman after receiving warm packs:

³⁸ The author or authors of the popular book, *The works of Aristotle*, which first appeared in England in 1684, remain unknown, but it is generally thought that Aristotle did not write it. Many of these copies remain undated.

The stinging feeling and the intense pressure were so overwhelming that I was scared I would tear and I felt as though the baby was coming out of my bowels. I needed reassurance from my midwife that I was pushing properly. She presses a warm nappy against my bottom and then I felt a bit more secure (Bennett et al., 1993, p.236).

Kitzinger (2000) claims that the vital element in both the art and science of midwifery is the comforts midwives provide by being in contact with a woman. She says, "Much of the touch involved in birth is comfort touch. It aims to ease pain and convey a message of sympathy and understanding" (Kitzinger, 2000, p.209).

While we know that perineal trauma following childbirth is associated with significant short- and long-term morbidity for women (Albers et al., 1999a) (Barrett et al., 2000) (Glazener et al., 1995) (McCandlish et al., 1998) (Sleep & Grant, 1987) (Sultan & Thakar, 2002), the level of pain that women experience when actually giving birth and methods that might ease this pain are less well understood. As discussed in Chapter 7, the pain felt during the advancement of the foetal head, and stretching of the perineum in the minutes before giving birth has been reported to be severe (Miller, 1994). Any method that can reduce this pain would be valuable.

8.3 Research questions of the study

The research questions have already been presented in Chapter 6. The secondary outcome measure of maternal comfort continues to be reported in this chapter.

8.4 Methods

The method has been fully described in Chapter 5. Questionnaires from a previous smaller study into the effect of warm packs in the late second stage were adapted for use in this study (Musgrove, 1997).

Of the three hundred and sixty women randomised to receive warm packs, 302 (84%) received the treatment. Of these, 266 (88%) women completed questionnaires. Two hundred and seventy questionnaires (89%) were completed by midwives following 270 separate births. Some midwives completed several questionnaires and were asked to respond in each questionnaire to questions in relation to the particular woman they had just cared for. The most common reasons for women ($n = 36$) not completing the questionnaires were staff too busy; questionnaire lost; and the woman went home on early discharge before the questionnaire was completed. The most common reasons for midwives ($n = 32$) not completing the questionnaire were: midwife too busy; midwife went to another ward/holidays; or days off or the questionnaire was lost.

8.5 Women's experiences of perineal warm packs

The majority (79.7%) of women who completed the questionnaires felt that the warm pack reduced the pain in their perineum (Table 8.1). Most women (89.1%) reported receiving comfort from the warm pack. Just over half (56%) reported that the warm pack helped them to feel more in control in the second stage. A similar proportion (56%) felt the warm pack numbed the perineum. A small proportion (1.9%) disliked the warm packs 'a lot' and 6.8% women disliked the warm packs 'a little.' Fourteen women (5.3%) were unsure if they disliked the warm packs. Most women (91%) reported 'liking' the warm packs. Equally, the majority of women (85.7%) would like warm packs applied to their perineum during their next birth and would recommend warm packs to their friends (86%) (Table 8.1).

Table 8.1: Maternal questionnaire: warm pack group only.

Questions asked	Maternal Questionnaires n= 266	Percentage %
1. Did you find the warm pack <u>reduced the pain</u> in your perineum?		
a) A lot	124	46.6
b) A little	88	33.1
c) Not sure	44	16.5
d) Not at all	10	3.8
2. Did you get any <u>comfort</u> from the warm pack on your perineum?		
a) A lot	154	57.9
b) A little	83	31.2
c) Not sure	19	7.1
d) Not at all	10	3.8
3. Did the warm pack on your perineum help you to feel more <u>in control</u> during the second stage?		
a) A lot	80	30.1
b) A little	69	25.9
c) Not sure	71	26.7
d) Not at all	46	17.3
4. Do you think the warm pack <u>numbed</u> your perineum?		
a) A lot	52	19.5
b) A little	97	36.5
c) Not sure	65	24.4
d) Not at all	52	19.5
5. Did you <u>dislike</u> the warm pack on your perineum?		
a) A lot	5	1.9
b) A little	18	6.8
c) Not sure	14	5.3
d) Not at all	229	86.1

6. Did you <u>like</u> the warm pack on your perineum?		
a) A lot	187	70.3
b) A little	56	21.1
c) Not Sure	18	6.8
d) Not at all	5	1.9
7. Would you like warm packs applied to your perineum during your <u>next delivery</u> ?		
a) Yes	228	85.7
b) No	7	2.6
c) Not sure	31	11.7
8. Would you <u>recommend</u> warm packs to your friends?		
a) Yes	229	86.1
b) No	4	1.5
c) Not sure	33	12.4

8.6 Midwives' experiences

Most midwives' responses (80.4%) indicated that they felt the warm packs reduced women's perineal pain (Table 8.2). Just over half of the responses (55.9%) indicated that midwives believed warm packs reduced perineal damage. Two thirds (67.8%) indicated warm packs increased women's control in the second stage. Around two thirds (63.3%) indicated that the warm packs increased the stretching of the perineum. Midwives were asked if they thought the warm packs had any effect at all on the woman's second stage. Overall the response was positive, with 77% of midwives completing the surveys reporting an effect. A large majority (91.1%) were positive about using the warm packs as part of their management of the second stage. Only a small number (3.7%) did not like using the warm packs. Most midwives (93%) reported that they would consider using warm packs in the future.

Table 8.2: Midwives' questionnaire: warm pack group only.

Questions asked	Completed Maternal Questionnaires n= 270	Percentage %
<p>1. Do you think the perineal warm pack reduced the woman's <u>perineal pain</u> in the second stage?</p> <p>a) Yes</p> <p>b) Somewhat</p> <p>c) No</p> <p>d) Not sure</p>	<p>145</p> <p>72</p> <p>26</p> <p>27</p>	<p>53.7</p> <p>26.7</p> <p>9.6</p> <p>10</p>
<p>2. Do you think the perineal warm pack reduced <u>perineal damage</u>?</p> <p>a) Yes</p> <p>b) Somewhat</p> <p>c) No</p> <p>d) Not sure</p>	<p>85</p> <p>66</p> <p>66</p> <p>53</p>	<p>31.5</p> <p>24.4</p> <p>24.4</p> <p>19.6</p>
<p>3. Do you think the perineal warm pack increased the woman's <u>control</u> in the second stage?</p> <p>a) Yes</p> <p>b) Somewhat</p> <p>c) No</p> <p>d) Not sure</p>	<p>93</p> <p>90</p> <p>53</p> <p>34</p>	<p>34.4</p> <p>33.3</p> <p>19.6</p> <p>12.6</p>

4. Do you think the perineal warm pack increased the <u>stretching</u> of the perineum?		
a) Yes	81	30.0
b) Somewhat	90	33.3
c) No	43	15.9
d) Not sure	56	20.7
5. Do you think the perineal warm pack had any effect at all on the woman's <u>second stage</u> ?		
a) Yes	128	47.4
b) Somewhat	80	29.6
c) No	40	14.8
d) Not sure	22	8.2
6. Did you <u>like</u> using the perineal warm pack as part of your management of the second stage?		
a) Yes	209	77.4
b) Some what	37	13.7
c) No	10	3.7
d) Not sure	14	5.2
7. Would you consider using perineal warm packs in the <u>future</u> ?		
a) Yes	250	92.6
b) No	4	1.5
c) Not sure	16	5.9

8.7 Discussion

The application of perineal warm packs is widely advocated by midwives (Sanders et al., 2005) to reduce perineal trauma and improve comfort during the birth. This is the largest randomised controlled trial to evaluate the use of warm packs during the late second stage and examine both women's and midwives' experiences.

There are several limitations to this study. Some of the 36 women who did not complete the questionnaires may well have been less positive about the effect of the warm packs and therefore avoided completing the questionnaire. Likewise the 32 responses not received from midwives applying warm packs may have been less positive. It is possible that the impressions of women receiving the warm packs were influenced by the fact they were getting additional attention from the midwife and therefore viewed the pain less negatively. The very act of applying the warm compress to the perineum may be seen as caring and therefore lead women to view the pain in a positive light. Viewing midwives as 'considerate' is associated with feeling in control during the birth and thus viewing the experience more positively (Green & Baston, 2003).

Women and midwives indicated that perineal warm packs were highly acceptable to both childbearing women and midwives as a method to relieve pain. A majority of the women and midwives felt the warm packs reduced perineal pain during the birth. This is similar to the results of the pain scores at birth and days one and two following the birth. Similar proportions of women and midwives felt that the warm packs had some effect in relieving perineal pain. These very similar results from independently completed questionnaires show midwives are sensitive to women's experiences of pain and can make accurate judgments about relief of pain. It seems likely that the intimate relationship between woman and midwife over several hours of labour facilitates this process.

The advancement of the foetal head, and stretching of the perineum in the minutes before giving birth, is accompanied by pain that has been reported to be severe (Anderson, 2000a) (Miller, 1994). This was demonstrated in the Perineal Warm Pack Trial by the large numbers (70.8%) of women reporting the pain of giving birth as severe ('bad pain' or 'the

worst pain in my life'). Amongst the women who received the warm packs, 59.2% reported their pain as severe, whilst in the group of women not receiving warm packs, 81.7% reported their pain as severe. The results of this part of the study support these clinical data, with only ten (4%) women saying they received no reduction in perineal pain from the warm packs. The majority felt they had an effect, with almost one half saying the warm packs reduced the perineal pain 'a lot' and one third saying they reduced the pain 'a little.' Midwives also concurred with women, observing some reduction in pain in over 80% of women who used perineal warm packs. As was discussed in Chapter 4, an Australian midwife previously reported that 80% of women who had used warm packs in a small, randomised controlled trial had gained comfort from them (Musgrove, 1997).

The concepts of comfort and pain were examined in this study. Slightly more women reported gaining comfort from the warm packs than helping with reduction of pain and fewer women reported that the warm packs helped numb the perineum. It seems that the warm packs helped women deal with the stinging sensation experienced in the perineum at the end of the second stage, often described by midwives as the 'ring of fire.' Being able to get comfortable is a significant predictor of feeling in control during the labour and birth (Green & Baston, 2003). Research indicates the memory of pain can be more damaging than its initial experience (Song & Carr, 1999), affecting postnatal and sexual adjustment (Stewart, 1982).

Just more than half of the women felt the warm packs helped them feel more in control in second stage. A greater proportion of midwives felt that the warm packs increased women's control in the second stage, which may stem from the fact midwives see many women in labour and women generally only have their own experience as a reference. A sense of control is a major factor contributing to a woman's birth experience and wellbeing (Green & Baston, 2003). Whilst the word 'control' is often used to refer to external control (control over what is done to you), it can also mean internal control (control over your body and behaviour) (Green & Baston, 2003). Other studies have highlighted control as the ability to control panic (Slade, MacPherson, Hume, & Maresh, 1993) and that two major threats to a woman's sense of internal control are pain and the side-effects of pain relief (Mander,

1992). Importantly, warm packs helped reduce the pain women experienced when giving birth but did not have side-effects, such as are experienced with pharmacological analgesia.

Both midwives and women were positive about using warm packs in the future. A majority of women said they would like to use the warm packs again for their next birth and would recommend them to friends. The majority of midwives were positive about using the warm packs and would consider using them in the future as part of second-stage care. This was surprising, considering they were not part of midwifery practice in the maternity units where the research was undertaken – except in the Birth Centre, and the midwives chose not to be a part of the study.

Whilst no questions were asked to directly elicit maternal satisfaction with the birth in relation to the warm packs, the fact that 85.7% of women would like the warm packs applied during their next birth was positive. For primiparous women especially, worry about pain significantly influences feelings of control and the resulting satisfaction with the birth experience (Green & Baston, 2003). Being able to use warm packs appears to have had a significant impact on women and they are seen as a positive option for future birth experiences. Anecdotally, many of the women in the study have given birth subsequently and have requested warm packs for these births.

Fear of the pain associated with labour is reported as a reason why women may request a caesarean section (Kolas et al., 2003) (Nerum et al., 2006). Ways to reduce the alarming rates of this major surgery need to be investigated urgently. Perineal warm packs are an effective method of reducing pain experienced in the late second stage of labour without women having to resort to potentially harmful pharmacological pain relief. Being able to 'soothe the ring of fire' using perineal warm packs is highly acceptable to women. It is also a very accessible and cost-effective method of pain relief.

8.8 Summary

In this chapter, women and midwives' evaluation of the warm packs through questionnaire has been reported on. The practice of applying perineal warm packs in the late second stage was highly acceptable to mothers and midwives in helping to relieve perineal pain and increase comfort and should be incorporated into pain relief options available to women during childbirth. The women and midwives' reported experiences of using perineal warm packs were similar – especially the associated reduction in pain. Women's pain scores when giving birth supported this. Any practice that reduces pain and improves comfort during second stage should be encouraged and made widely available, especially when it is so accessible and involves minimal financial cost. Clinicians can reassure women that they can 'soothe the ring of fire' without needing to resort to potentially harmful pharmacological methods.

Chapter 9 reports on the postpartum follow-up of women whilst in hospital and also on the results of telephone interviews conducted at six and twelve weeks following the birth.

Chapter 9: Postpartum follow-up of women

“Do not laugh at the princess changed to a frog splayed glass-bellied on the window to your kingdom – she is your mother” (E. A. Horne).

9.1 Introduction

The previous chapter examined women and midwives' evaluation of the warm packs through questionnaires conducted soon after the birth, before leaving the Delivery Ward. The practice of applying perineal warm packs in the late second stage was highly acceptable to mothers and midwives in helping to relieve perineal pain and increase comfort during childbirth.

In this chapter the literature on postpartum maternal health is briefly examined. The results of postpartum follow-up of women in the study, whilst they were in hospital and then later when they were telephoned at home, at six weeks and twelve weeks following the birth, is reported.

9.2 Postpartum maternal health

Postpartum maternal health has been the subject of several major studies to date (MacArthur, Lewis, & Knox, 1991) (Bick & MacArthur, 1995) (Blomquist & Soderman, 1991; Brown & Lumley, 1998) (Thompson, Roberts, Currie, & Ellwood, 2000). What is evident is that childbirth is a major life event and the time taken for physical recovery can be much longer than thought and impact on more women than health professionals may have previously anticipated. Brown and Lumby (1998) surveyed 1,336 women in Victoria, Australia, to ascertain the prevalence of maternal health problems six months after birth (Brown & Lumley, 1998). They found one or more health problems were reported by 94% of women. Of all the problems reported, painful perineum (21%) and sexual problems (26.3%) were two of the most commonly cited problems. These problems were especially relevant to primiparous women and to women who had had an episiotomy and/or

instrumental birth. Compared with spontaneous vaginal births, women having forceps or vacuum extraction had an increased rate of perineal pain (OR 4.69; 95% CI 3.2 to 6.8), sexual problems (OR 2.06; 95% CI 1.4 to 3.0), and urinary incontinence (OR 1.81; 95% CI 1.1 to 2.9).

A population-based cohort study conducted in the Australian Capital Territory used questionnaires at four days postpartum, and at eight, 16 and 24 weeks postpartum to ascertain maternal health following birth (Thompson et al., 2000). A total of 1,295 women participated and 92% completed the study. The researchers found some health problems showed resolution between eight weeks and 24 weeks postpartum, such as: exhaustion (60 – 49%); backache (53 – 45%); bowel problems (37 – 17%); haemorrhoids (30 – 13%); perineal pain (22 – 4%); urinary incontinence (19 – 11%). No significant changes occurred in the incidence of other factors such as sexual problems or depression over the six months. Primiparous women were more likely to report perineal pain and sexual problems than multiparous women. Women with instrumental births reported more perineal pain and sexual problems compared to those with unassisted births (Thompson et al., 2000).

Other studies have examined specific factors in maternal postpartum health such as perineal trauma and pain (MacArthur & MacArthur, 2004b). A prospective cohort study of women (n = 444) on day one, day seven and at six weeks postpartum, found perineal trauma was more common amongst primiparous women, those with operative vaginal delivery and epidural anaesthesia in the second stage of labour. The incidence of perineal pain among the groups during the first week with intact perineum was 75% (day 1) and 38% (day 7). With first- and second-degree tears, the incidence of perineal pain was 95% (day 1) and 60% (day 7). With episiotomies, the incidence of perineal pain was 97% (day 1) and 71% (day 7), and with severe perineal trauma, it was 100% (day 1) and 91% (day 7). By six weeks, the frequency of pain was not statistically different between the trauma groups (Macarthur & Macarthur, 2004b).

Another study reported data from the “Hands On Or Poised” study (HOOP) (McCandlish et al., 1998) and found that 85% of all women experienced some form of perineal trauma

(Albers et al., 1999b) and that perineal pain declined over time with the lowest level of pain being reported by women who were intact and the highest level reported for women with mid/upper vaginal tears or severe perineal tears. Women reported more pain if they had perineal suturing and if having their first baby (Albers et al., 1999b).

Perineal pain can inhibit a woman from mobilising fully and make sitting uncomfortable. This may have a negative effect on her desire to breastfeed or continue breastfeeding (Greenshields & Hulme, 1993) (De Chateau & Winberg, 1977) (Salariya, Easton, & Cater, 1978) (Lundquist, Olsson, Nissen, & Norman, 2000). Perineal trauma can make it distressing to void or defecate and in the long-term perineal pain can impair a woman's ability and willingness to care for her newborn baby. It is also associated with relationship disharmony, which can lead to irritability, resentment, depression and maternal exhaustion (Steen et al., 2000) (Steen & Marchant, 2001).

Perineal pain can impair normal sexual functioning, with dyspareunia following vaginal delivery reported by 60% of women at twelve weeks and 30% at six months (Barrett et al., 2000) and 15% of women still experience painful sex up to three years later (Sleep & Grant, 1987). Women who have an intact perineum compared to those who experience perineal trauma are more likely to resume intercourse earlier; report less pain with the first sexual intercourse; have greater satisfaction with sexual experience (Klein et al., 1994); have greater sexual sensation and have an increased likelihood of orgasm at six months postpartum (Signorello et al., 2001). The more severe the perineal trauma, the higher the incidence of sexual problems (Signorello et al., 2001). For example, Signorello et al. (2001) found that women with severe perineal trauma were 270% more likely to report dyspareunia at three months postpartum compared to women with an intact perineum (Signorello et al., 2001).

Research indicates that women who have an intact perineum with their first baby have stronger pelvic floors. These women also make a quicker muscle recovery than women experiencing tears or episiotomies (Klein et al., 1994). Severe perineal trauma is associated with a greater incidence of faecal incontinence when compared to women who do not

experience third- and fourth-degree tears (Sultan & Thakar, 2002). Perineal trauma has not, however, been clearly associated with urinary incontinence (Woolley, 1995).

It is clear from the literature that postpartum morbidity for childbearing women is significant, and any measures that may reduce this morbidity should be researched and implemented if found effective.

9.3 Research questions of the study

This chapter continues to report on the secondary outcome measure of maternal comfort.

9.4 Methods

The method has been more fully described in Chapter 5. In hospital, postpartum data collection involved gathering information on perineal pain scores collected on days one and two (see Chapter 7); data related to the method of infant feeding on discharge; use of the early discharge service; length of hospital stay and pain relief used during hospital stay (Appendix 6). Unfortunately the only data that was reliably gathered in hospital, other than the pain scores, and able to be analysed, was the method of infant feeding on discharge and this is reported in this chapter. Infant feeding was divided into exclusively breastfeeding, bottle-feeding, and mixed breast/bottle feeding on discharge from hospital.

The final collection of data occurred at six and twelve weeks postpartum during a telephone interview. Data were collected on perineal pain and symptoms indicating the presence of ongoing perineal trauma and morbidity, such as, pain with walking; sitting; a bowel motion or when urinating (Appendices 7 and 8). Questions about resumption of sexual intercourse and associated pain were also asked. Women were asked questions about postpartum urinary incontinence. Women were also asked about the method of infant feeding at six and twelve weeks postpartum.

All women involved in the study were contacted by telephone at six and twelve weeks following the birth. If three messages were left on an answering machine, or three phone calls at different times of the day were made with no response, then the woman was not contacted again.

9.5 In-hospital postpartum data collection

Information about the method of infant feeding was obtained for 291 women (81%) in the warm pack group and 287 women (80%) in the standard care group (Appendix 6). Two hundred and eighty women (83%) in the warm pack group were exclusively breastfeeding and 255 (89%) of women in the standard care group were exclusively breastfeeding on discharge from hospital (Table 9.1). There was no statistical difference between the methods of feeding in the two groups.

Table 9.1: Method of infant feeding on discharge from hospital, by allocated group.

	Warm pack group	Standard care group
	n = 291	n = 287
	n (%)#	n (%)#
Breastfeeding on discharge	240 (82.5)	255 (88.9)
Bottle feeding on discharge	36(12.4)	20 (7)
Mixed feeding breast/bottle on discharge	15 (5.2)	12 (4.2)

Percentage within delivery types excluding missing data.

A chi-squared test was performed to examine differences between allocated groups: p=0.07.

9.6 Six weeks and twelve weeks postpartum data collection

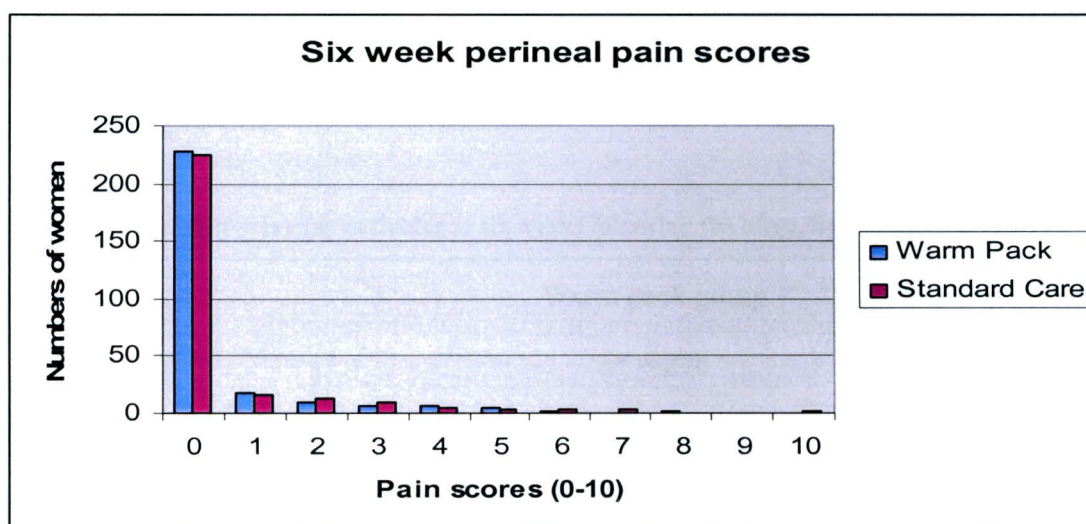
At six weeks, 276 women (77%) in the warm pack group and 277 women (78%) were interviewed. At twelve weeks, 268 women (74%) in the warm pack group and 263 women (73%) in the standard care group were interviewed. Women not interviewed were those

unable to be contacted due to an incorrect number, a disconnected telephone, or the woman having gone overseas. This last reason was surprisingly common, particularly with women from CALD backgrounds.

9.6.1 Perineal pain scores

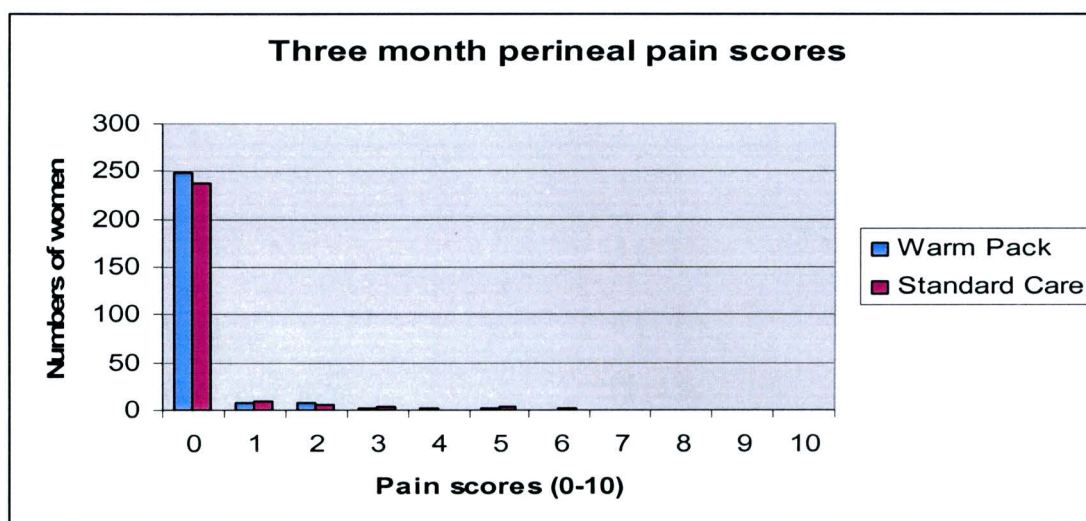
Perineal pain scores were obtained by asking the women to rate the pain they experienced in their perineum, at the time of the phone call, from ‘no pain’ to ‘the worst pain ever’ (0 – 10) (Figure 9.1). There were no statistically significant differences between the two groups in perineal pain reported at six or twelve weeks following the birth. Over eighty per cent of women said they had no perineal pain at six weeks (Figure 9.1) and over ninety per cent reported no perineal pain at twelve weeks (Figure 9.2). At six weeks, 19 women reported moderate to severe pain in the 5 – 10 range while at twelve weeks only six reported their pain as being 5 or 6, with none reporting pain levels higher than this.

Figure 9.1: Perineal pain scores at six weeks postpartum, by allocated group



A chi-squared test was performed to examine differences between allocated groups: $p=0.45$.

Figure 9.2: Perineal pain scores at twelve weeks postpartum, by allocated group



A chi-squared test was performed to examine differences between allocated groups: $p=0.43$.

9.6.2 Everyday activities

Perineal pain can make everyday activities, such as walking and sitting, problematic and can interfere with breastfeeding and care of a new baby. Women were asked at six and twelve weeks if they had any pain with walking, sitting, during a bowel motion or when urinating (Tables 9.2 and 9.3).

Table 9.2: Pain with everyday activities at six weeks following the birth, by allocated group

	Warm pack group	Standard care group
	n* = 276	n = 277
	n (%)	n (%)
Pain when walking	7 (2.5)	15 (5.4)
Pain when sitting	25 (9.1)	23 (8.3)
Pain during a bowel motion	31 (11.2)	32 (11.6)
Pain on urination	13 (4.7)	13 (4.7)

*Number of responses.

Table 9.3: Pain with everyday activities at twelve weeks following the birth, by allocated group

	Warm pack group	Standard care group
	n* = 268	n = 263
	n (%)	n (%)
Pain when walking	4 (1.5)	4 (1.5)
Pain when sitting	4 (1.5)	4 (1.5)
Pain during a bowel motion	13 (4.9)	11 (4.2)
Pain on urination	7 (2.6)	7 (2.6)

* Number of responses.

Pain with one or more everyday activities such as walking, sitting, bowel motions or urination affected 159 (29%) of women at six weeks and 54 (10%) of women at twelve weeks. The most common discomfort reported was pain during a bowel motion, but this declined significantly between six and twelve weeks. Warm packs had no effect on the everyday activities.

9.6.3 Resumption of sexual intercourse

Women were asked at six and twelve weeks if they had resumed sexual intercourse, and if so, at how many weeks had their first sexual encounter taken place (Table 9.4). Around one third of the women surveyed had resumed sexual intercourse by six weeks and nearly three quarters said they had by twelve weeks. There were two women who said they had no partner and therefore had not had sexual intercourse. There was no significant difference between the two groups of women in numbers of women resuming sexual intercourse.

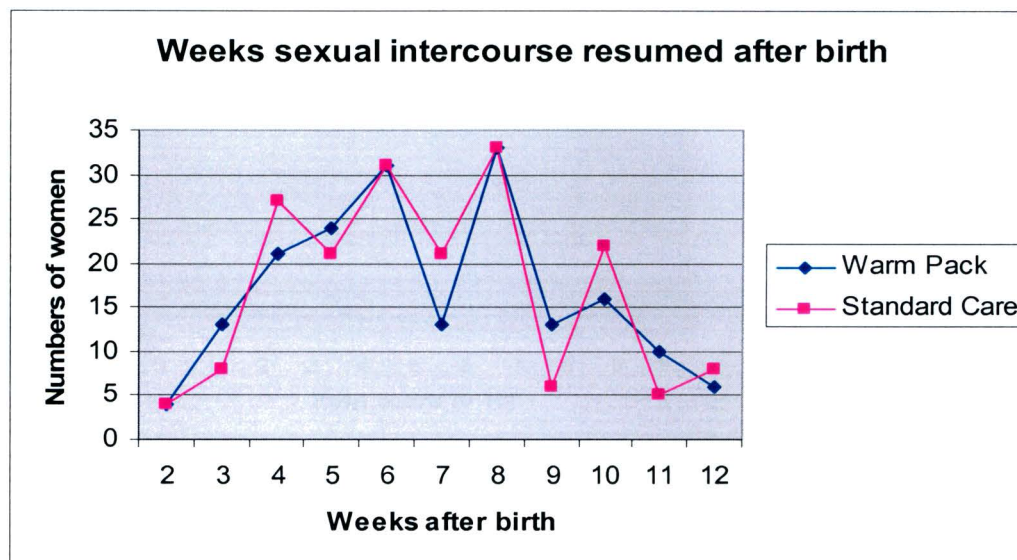
Table 9.4: Resumption of sexual intercourse by six and twelve weeks following the birth, by allocated group

	Warm pack group	Standard care group
	6 weeks n* = 276	6 weeks n = 277
	12 weeks n = 268	12 weeks n = 264
	n (%)	n (%)
Sexual intercourse resumed by 6 weeks	99 (35.9)	89 (32.1)
Sexual intercourse resumed by 12 weeks	197 (73.5)	191 (72.3)

*Number of responses.

Women were asked how many weeks after the birth they had their first sexual encounter. The mean (6.77 weeks), median (6.50 weeks) and mode (8 weeks) supported the comment women frequently made when interviewed, that they had sex around their six-week postpartum check, as they thought they were supposed to wait until then to resume sexual intercourse. There were no significant differences between the two groups in when the first sexual encounter after the birth took place (Figure 9.3).

Figure 9.3: Weeks following birth of first sexual encounter at three-month interview



9.6.4 Pain with sexual intercourse

Women were asked to rate the pain experienced with sexual intercourse at six and twelve weeks (Figures 9.4 and 9.5). Of the women who had resumed sexual intercourse, there was a large number who continued to experience some perineal pain at six weeks and twelve weeks. At six weeks, only 13% of women had no pain with sexual intercourse and by twelve weeks this had increased to 37%. At six weeks, 18% of women surveyed rated the pain they experienced with intercourse as moderate to severe (5 – 10). By twelve weeks, this number had declined to 11%. There was no significant difference between the two groups with regard to pain experienced with sexual intercourse.

Figure 9.4: Pain with sexual intercourse at six weeks, by group

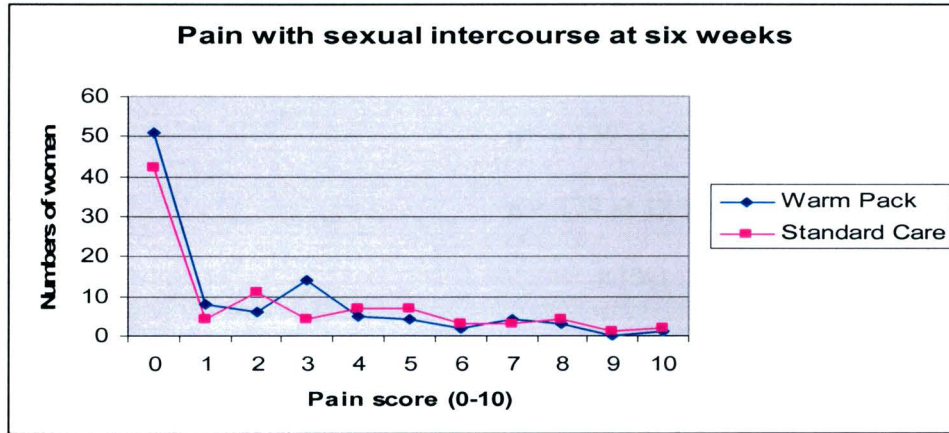
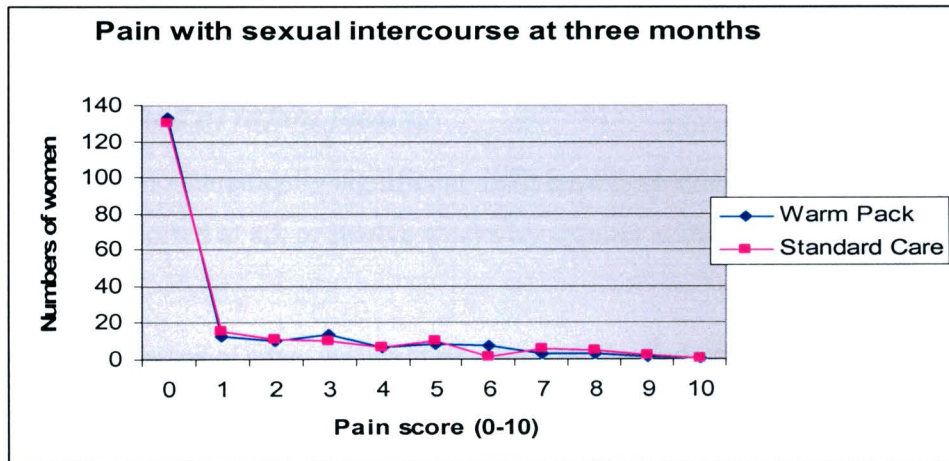


Figure 9.5: Pain with sexual intercourse at twelve weeks, by group



It is interesting to note that Asian women were significantly less likely to have resumed sexual intercourse by six ($p = 0.0001$) and twelve weeks ($p = 0.003$), compared with non-Asian women (Table 9.5). When women from all the different ethnic groups were compared, Asian women remained the least likely to have resumed sexual intercourse. They were not, however, any more likely to experience pain on resumption of sexual intercourse, compared with non-Asian women.

Table 9.5: Resumption of sexual intercourse by six and twelve weeks following the birth, by Asian and non-Asian women

	Asian women	Non-Asian women
	n* = 179 at 6 weeks	n = 374 at 6 weeks
	n = 174 at 12 weeks	n = 358 at 12 weeks
	n (%)	n (%)
Sexual intercourse resumed by 6 weeks	40 (22.3)	148 (39.6)
Sexual intercourse resumed by 12 weeks	111 (63.8)	277 (77.4)

* Number of responses

9.6.5 Method of infant feeding

There was no statistically significant difference between the groups in the method of infant feeding reported at six or twelve weeks by women in the study (Tables 9.6 and 9.7).

Table 9.6: Method of infant feeding at six weeks, by allocated group.

	Warm pack group	Standard care group
	n = 275	n = 277
	n (%)	n (%)
Exclusive breastfeeding at 6 weeks	166 (60.4)	168 (60.6)
Bottle feeding at 6 weeks	70 (25.5)	67 (24.2)
Mixed feeding breast/bottle at 6 weeks	39 (14.2)	42 (15.2)

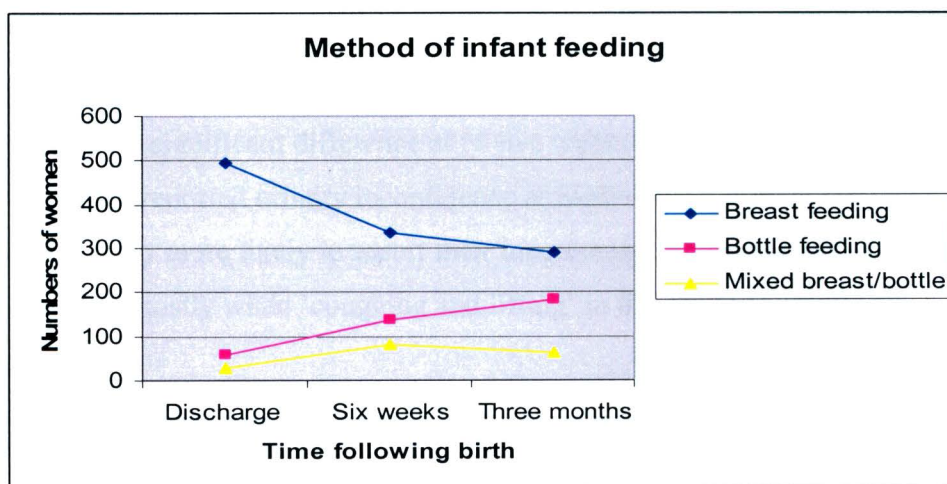
A chi-squared test was performed to examine differences between allocated groups: $p = 0.9$.

Table 9.7: Method of infant feeding at twelve weeks, by allocated group.

	Warm pack group n = 267 n (%)	Standard care group n = 263 n (%)
Exclusive breastfeeding at 12 weeks	143 (53.6)	144 (54.8)
Bottle feeding at 12 weeks	92 (34.5)	92 (35.0)
Mixed feeding breast/bottle at 12 weeks	32 (12)	27 (10.3)

A chi-squared test was performed to examine differences between allocated groups: $p = 0.8$.

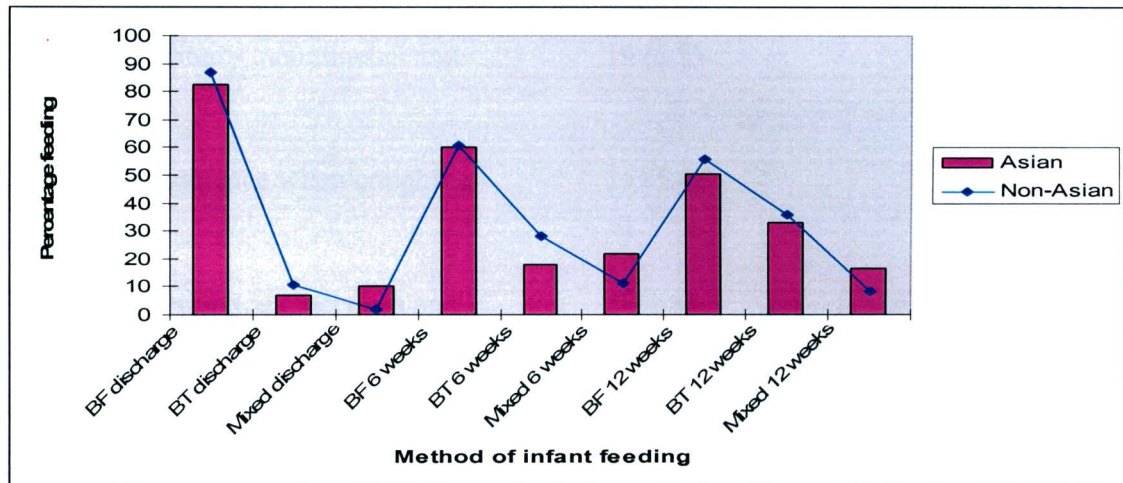
The rate of breastfeeding amongst all women declined from 86% of women at discharge from hospital to 61% at six weeks to 54% at twelve weeks (Figure 9.6). There was no difference in infant feeding between the groups. The following analysis combines the groups and examines trends in the population as a whole.

Figure 9.6: Method of infant feeding on discharge, at six weeks and twelve weeks for the combined groups

Asian women were significantly less likely to exclusively breastfeed on discharge from hospital, compared to non-Asian women, and more likely to bottle-feed and partially breast/bottle feed. The rate of exclusive breastfeeding continued to be lower at six and

twelve weeks for Asian women. However, the percentage of women giving their baby some breast milk was higher for Asian women compared to non-Asian women, when partial breastfeeding was taken into consideration (Figure 9.7).

Figure 9.7: Method of infant feeding for Asian and non-Asian women on discharge from hospital, at six and twelve weeks following the birth



NB: BF = breastfeeding; BT = bottle feeding; Mixed = breast and bottle feeding

9.6.6 Urinary incontinence

Whilst there was no statistically significant difference in the numbers of women experiencing urinary incontinence at six weeks (36/276 vs 46/277) (Table 9.7) there was a statistically significant difference at twelve weeks (Table 9.8). More women in the standard care group reported urinary incontinence at twelve weeks (26/277 vs 59/262). Women were significantly more likely to report their incontinence as 'occasional but improving' and occurring mostly when 'coughing and lifting' in the standard care group at twelve weeks.

Table 9.8: Urinary incontinence at 6 weeks, by allocated group.

	Warm pack group	Standard care group
	n = 276	n = 277
	n (%)	n (%)
Urinary incontinence	*36 (13)	46 (16.6)
Occasional urinary incontinence but improving	19 (6.9)	27 (9.8)
Urinary incontinence when coughing and lifting	15 (5.4)	18 (6.5)
Urinary incontinence most days and for no reason	5 (1.8)	1 (0.4)

* The numbers in the subgroups do not add up to the total incontinence numbers, as two women in the warm pack group selected more than one option.

A chi-squared test was performed to examine differences between allocated groups for incontinence: $p=0.15$

Table 9.9: Urinary incontinence at twelve weeks, by allocated group.

	Warm pack group n = 267 n (%)	Standard care group n = 263 n (%)
Urinary incontinence	*26 (9.7)	*59 (22.4)
Occasional urinary incontinence but improving	14 (5.2)	32 (12.3)
Urinary incontinence when coughing and lifting	12 (4.5)	24 (9.2)
Urinary incontinence most days and for no reason	3 (1.1)	2 (0.8)

* The numbers in the subgroups do not add up to the total incontinence numbers, as two women in the warm pack group selected more than one option and one woman in the standard care group said she had incontinence but no further information was reported.

A chi-squared test was performed to examine differences between allocated groups for urinary incontinence: $p=0.0001$.

9.7 Discussion

As already discussed in Chapter 6, no statistically significant differences were found between the two groups (warm pack and standard care) in: the numbers of women being sutured; the rates of intact perineum, or minor perineal trauma³⁹ (<2nd degree tear); or major⁴⁰ perineal trauma ($\geq 2^{\text{nd}}$ degree) or in the numbers of episiotomies. Given these outcomes were very similar, one would not expect any significant difference in related postpartum maternal health measures. For most of the outcomes, this is a correct assumption.

³⁹ No or minor perineal trauma was defined as intact, 1st degree, vaginal or labial tear.

⁴⁰ Major perineal trauma was defined as 2nd, 3rd, 4th degree tear and episiotomy.

However, as already discussed in Chapter 6, there was a statistically significant difference in severe perineal trauma, with women in the standard care group more than twice as likely (31/357 vs 15/360) to sustain a severe perineal tear than women in the warm pack group (OR 2.16, 95% CI 1.1 to 4.3, $p = 0.02$). Unfortunately, the sample size in the study was not large enough to determine a difference in this rare outcome. This outcome was not anticipated when the study was set up and, as a result, one of the limitations in the study is not asking women about faecal incontinence in the postpartum follow-up at six and twelve weeks. With the large difference in severe perineal trauma, this would have been a particularly valuable question.

There were no statistically significant differences in postpartum follow-up measures for method of infant feeding at discharge from hospital, at six weeks or twelve weeks between the groups. There were also no differences in perineal pain scores; the number of weeks after which sexual intercourse was resumed; the pain with sexual intercourse and pain with everyday activities (walking, sitting, bowel motion, urinating).

Not being able to use data collected on the postpartum use of analgesia, due to poor documentation, was a limitation. This may have added important supporting evidence to the finding that warm packs reduced perineal pain on days one and two following the birth.

Nearly 86% of women reported that they were exclusively breastfeeding on discharge from hospital following the birth. By six weeks this had dropped to 61% and by twelve weeks it had dropped even further to 54%. This is higher than is found in the United Kingdom, where 69% to 71% of infants are initially breastfed, with rates declining sharply within three months of birth and being significantly lower amongst primiparous and lower income women (Hamlyn, Brooker, Olerinikova, & Wands, 2002) (Kelly & Watt, 2005). In the Perineal Warm Pack Trial, Asian women were significantly less likely to be exclusively breastfeeding compared to non-Asian women at discharge from hospital but by six and twelve weeks they were more likely to be giving their baby some breast milk when partial breastfeeding was taken into consideration.

As expected, perineal pain had decreased at six and twelve weeks following the birth, compared with pain scores collected on days one and two following the birth. At six and twelve weeks, there were no longer any differences between perineal pain scores in the groups. At six weeks, over 80% of women said they had no perineal pain and over 90% reported no perineal pain at twelve weeks. At six weeks, 19 women reported moderate to severe pain in the 5 – 10 (VAS) range while at twelve weeks only six women reported their pain as being 5 or 6, with none reporting pain levels higher than this. This supports other studies that demonstrate a small but significant number of women who sustain perineal trauma experience pain following the birth. The perineal pain experienced is less than reported by some studies (Brown & Lumley, 1998) and similar to that reported by others (Thompson et al., 2000) (Sleep & Grant, 1987) (Glazener et al., 1995) (McCandlish et al., 1998).

Pain with one or more everyday activities, such as walking, sitting, bowel motions or urination, affected 29% of women at six weeks and 10% of women at twelve weeks, supporting similar findings in other studies (Thompson et al., 2000). While the incidence of this morbidity associated with everyday activity declines over time, it still can have a significant impact on women's early experiences of mothering.

Around half the women had resumed sexual intercourse by six weeks and nearly three quarters had by twelve weeks. Asian women were significantly less likely to have resumed sexual intercourse at both six and twelve weeks compared to non-Asian women. This may have been due to cultural beliefs or the fact that they suffered a greater degree of perineal trauma.

Of the women who had resumed sexual intercourse, there were a large number who continued to experience some pain at six weeks and twelve weeks. At six weeks, only 13% of women had no pain with sexual intercourse and by twelve weeks this had increased to 37%. At six weeks 18% of women surveyed rated the pain they experienced with sexual intercourse as moderate to severe (5 – 10). By twelve weeks this number had declined to 11%. This finding is supported by other studies showing dyspareunia following vaginal

delivery reported by 60% of women at twelve weeks and 30% at six months (Barrett et al., 2000). Women in the Perineal Warm Pack Trial were more likely to report having 'no pain' with intercourse if they were not sutured, as has been reported in previous studies (Klein et al., 1994) (Signorello et al., 2001). Once again there were no statistically significant differences in resumption of intercourse or pain between the groups.

As reported by previous studies, the postpartum morbidity childbearing women experience is significant enough to warrant further research into methods that improve overall wellbeing.

9.7.1 Urinary incontinence

An unexpected finding in the study was the statistically significant reduction of urinary incontinence in the warm pack group at twelve weeks following the study. Whilst there was no statistically significant difference in the numbers of women experiencing urinary incontinence at six weeks, there was a statistically significant difference at twelve weeks, with more than twice as many women in the standard care group reporting urinary incontinence.

This finding needs to be treated with caution due to several factors. The six-week and three-month data-collection forms were not piloted before the Perineal Warm Pack Trial commenced. As a result, a question asked on the history of urinary incontinence prior to or during pregnancy was poorly completed and could not be used. This was probably largely due to the way the data collection sheet was designed (Appendices 7 and 8). The data from this question would have been useful to gain a better understanding of why urinary incontinence was significantly reduced in the warm pack group. There is a chance that women in the standard care group had a higher incidence of pre-pregnancy or pregnancy incontinence, making them more predisposed to developing incontinence after the birth. However, the randomisation process should have minimised the chance of this occurring.

There was a significant reduction in urinary incontinence reported at twelve weeks following the birth in the warm pack group, although it is unclear as to why this is so, as there was no difference between the groups in factors associated with urinary incontinence, such as large-sized infants, long second stage of labour, instrumental birth or epidural anaesthesia. It was also unusual that there was no statistically significant difference in incontinence at six weeks. While many clinical studies have attempted to discover a particular obstetric event that causes urinary incontinence, no single event has been found responsible, suggesting that urinary incontinence arises from multifactorial physiological causes (Appendix 2).

Common reasons for urinary incontinence in women are stress incontinence and detrusor instability (Bewley & Cockburn, 2002). There is evidence that many women have urinary incontinence prior to childbirth, and that this is a significant contributing factor to postpartum urinary incontinence (Stainton et al., 2005). In this previous Australian research, 124 women were followed prospectively and the only variable to emerge as a statistically significant indicator for predicting those most at risk for developing postpartum urine leakage was a history of urine leakage prior to the first pregnancy. Women with an antenatal history were four times more at risk of leaking urine one year after giving birth than women without previous urine leakage. Other studies show that around 62% of primiparous women with incontinence said it started in pregnancy (Beck & Hsu, 1965) (Wilson et al., 1996) (Viktrup et al., 1992) and other studies have found that incontinence rarely starts after childbirth (Sultan et al., 1996). Postpartum incontinence appears to be greatest in those predisposed to it (King & Freeman, 1998). Unfortunately, in this study, data were not adequately collected on incidences of pre-pregnancy and pregnancy urinary incontinence.

There is strong evidence that stress incontinence is more likely related to hereditary factors and pregnancy rather than birth (Iosif, 1981) (Beck & Hsu, 1965). A study investigated the role of vaginal birth and familial factors in the development of urinary incontinence by comparing the prevalence between primiparous women and their parous sisters (Buchsbaum, Duecy, Kerr, Huang, & Guzick, 2005). The researchers found that in a sample

of 143 pairs of primiparous/parous postmenopausal sisters, urinary incontinence was reported by 48% of primiparous women and 50% of parous women. There was no statistical difference in severity or type of urinary continence between the groups; however, there was a high concordance in the continence status within biological sisters. The authors concluded that vaginal birth does not appear to be associated with urinary incontinence in postmenopausal women and an underlying familial predisposition towards the development of urinary incontinence may be present. Another large population-based cross-sectional study in Norway found daughters of mothers with urinary incontinence had an increased risk for urinary incontinence (Hannestad, Lei, Rortveit, & Hunskaar, 2004). A genetic predisposition appears to play a stronger role in incontinence than previously thought. Again, familial history was not obtained for this study.

As discussed in Chapter 4, childbirth practices such as coached pushing compared to un-coached pushing are associated with impaired pelvic floor function, with decreased bladder capacity and decreased first urge to void (Schaffer et al., 2005). In the original study of coached vs un-coached pushing, the second stage was approximately 13 minutes longer in the un-coached group (Bloom et al., 2006) and yet pelvic floor function was more likely to be impaired (Schaffer et al., 2005), showing there are several factors at play in incontinence and researchers are still unclear as to how to minimise this morbidity. The women in the Perineal Warm Pack Trial were more likely to have experienced coached pushing, as this was standard practice in the delivery wards where the study took place.

This study included only primiparous women, so was not complicated by women having subsequent births (Wilson et al., 1996). Women were matched for age, which is another risk factor, but weight and smoking, which are also risk factors for incontinence (Wilson et al., 1996) (Dwyer, Lee, & Hay, 1988) (Grodstein, Fretts, Lilford, Resnick, & Curhane, 2003) (Hannestad, Rortveit, Daltveit, & Hunskaar, 2003), were not reported, as they are known to be unreliably collected.

It is possible that had there been longer-term follow-up of the women in the Perineal Warm Pack Trial, that the significant difference in the incidence of urinary incontinence between

the two groups would have altered. On the other hand, there may be physiological changes brought on by the application of perineal warm packs of which researchers are still unaware. A larger study examining urinary incontinence with longer-term follow-up is needed before we can be convinced that perineal warm packs lead to a reduction in urinary incontinence that is not only statistically significant but also clinically significant. It is evident that the issue of 'obstetric-induced incontinence' is not straightforward but rather is multi-faceted and challenging to address (Homer & Dahlen, 2007).

9.8 Summary

This chapter has described postpartum findings whilst women were in hospital and at six weeks and twelve weeks following the birth. No significant differences were found between the groups at six weeks and twelve weeks in perineal pain and pain experienced when walking, sitting, during a bowel motion and on urination. There was also no difference in the numbers of women who had resumed sexual intercourse or had pain with sexual intercourse. Likewise, there was no difference in the number of women breastfeeding at discharge from hospital, six weeks or twelve weeks following the birth. Whilst there was no significant difference in the numbers of women experiencing urinary incontinence at six weeks, there was a significant difference at twelve weeks with more women in the standard care group reporting urinary incontinence.

Chapter 10, the final chapter, presents a synthesis and summary of the main findings from the research questions. It also discusses the limitations of the study as well as the implications of the Perineal Warm Pack Trial for second-stage care.

Chapter 10: Overview and discussion of the implications for second-stage care

“The birth of a child, especially a first child, represents a landmark event in the lives of all involved. For the mother particularly, childbirth has a profound physical, mental, emotional and social effect (Simkin, 1992, p.64).

10.1 Introduction

This is the final chapter in the thesis and presents a synthesis and summary of the main findings from the research questions. It also discusses the limitations of the study as well as the implications of the results for care in the second stage of labour. This study included a diverse range of women from different CALD populations, making it more generalisable.

As has been discussed previously, the application of perineal warm packs or compresses is widely advocated by midwives to reduce perineal trauma and improve comfort during the birth. This is the largest randomised trial to evaluate the effect of the use of the perineal warm packs during the late second stage on women’s perineal trauma and comfort and provide postpartum follow-up data.

10.2 Overview of the questions and findings

The study asked two specific questions, which were outlined in Chapter 1. These questions and relevant findings are discussed here.

10.2.1 Will applying warm packs to the perineum in the second stage of labour reduce perineal trauma?

Chapter 6 presented the maternal clinical outcomes from the study. The results demonstrated that there was no reduction in perineal suturing. There was also no difference

in any of the other measures of perineal trauma, such as major and minor perineal trauma or episiotomy. While the study was underpowered to assess the uncommon outcome of severe perineal trauma, and a possible protective effect from the warm packs may be a chance finding, there is enough clinical difference in the rates between the two groups to warrant further investigation. There is also physiological evidence, which was presented in Chapter 3, indicating that the thermosphincteric reflex is plausible and could possibly explain the finding.

There was a very low rate of severe perineal trauma (third- and fourth-degree tears) in a previous study into perineal warm compresses (Albers et al., 2005) compared to that found in the Perineal Warm Pack Trial. This may have been to do with the late second stage randomisation, low number of primiparous women and different ethnic mix in Albers et al's (2005) study (Albers et al., 2005). The high rate of severe perineal trauma (6.4%) amongst women in the Perineal Warm Pack Trial is partly explained by the fact that they were all primiparous and a large number (33%) were Asian-born. Both these factors have been shown to be strongly associated with severe perineal trauma in a previous study of women giving birth in these same two hospitals (Dahlen et al., 2007). Regardless of these findings, the rate is of concern and requires further investigation. Severe perineal trauma constitutes a serious morbidity, with a high incidence of faecal incontinence for women who experience it and any possible reduction in the incidence should be pursued with further research.

10.2.2 Will applying warm packs to the perineum in the second stage of labour increase maternal comfort?

Chapters 7, 8 and 9 all reported on the secondary outcome variable of maternal comfort. Women in the warm pack group had significantly lower perineal pain scores when giving birth, as well as on days one and two following the birth.

Likewise, women and midwives reported through questionnaires that they found the application of warm packs during the second stage to be highly acceptable. Women and

midwives reported that the warm packs were very effective in helping to relieve perineal pain and increase comfort and should be incorporated into pain-relief options available to women during childbirth. Women and midwives reported similar experiences of using perineal warm packs – especially the reduction in pain. This was again reflected in the women's pain scores reported when giving birth.

Postpartum follow-up was also undertaken, both whilst women were in hospital and at six and twelve weeks following the birth. There were no significant differences found between the groups at six weeks and twelve weeks in perineal pain, and pain experienced when walking, sitting, during a bowel motion and on urination. There was also no difference in the numbers of women who had resumed sexual intercourse or had pain with sexual intercourse at six weeks or twelve weeks following the birth.

10.2.3 Unexpected findings

There was one unexpected finding that warrants further discussion. Whilst there was no significant difference in the numbers of women experiencing urinary incontinence at six weeks, there was a statistically significant difference at twelve weeks, with more women in the standard care group reporting urinary incontinence. While the randomisation process should have minimised any chance that the two groups were not similar, there is a chance that women in the standard care group had a higher incidence of pre-pregnancy and/or pregnancy incontinence, making them more predisposed to developing incontinence after the birth. As has already been discussed, the question on pre-pregnancy and/or pregnancy incontinence was poorly completed, making it unreliable.

It is possible that had there been longer-term follow-up of the women in the Perineal Warm Pack Trial, that the significant difference in the incidence of urinary incontinence between the two groups would have altered. On the other hand, there may be physiological changes brought on by the application of perineal warm packs that researchers are still unaware of. A larger study examining urinary incontinence with longer-term follow-up is needed before we can determine that perineal warm packs lead to a reduction in urinary incontinence that

is not only statistically significant but also clinically significant. It is evident that the issue of 'obstetric-induced incontinence' is not straightforward but rather is multi-faceted and challenging to address (Homer & Dahlen, 2007).

10.2.4 Findings from historical and scientific literature review

Chapter 2, 3 and 4 provided an in-depth analysis into the historical, lay, professional and scientific literature on perineal care during pregnancy and birth. This provides useful insights into where our knowledge has come from, where our knowledge is now, and where we need to add to knowledge in the future. As these chapters provided significant answers to these important questions, they warrant further mention in the next section.

Chapter 2 traced the history of perineal care during labour and birth, with a particular focus on perineal warm packs. It also drew on anthropological studies that recorded perineal care in different cultures to support these historical observations. It followed the, at times, vague trails in history to show how the care of the perineum was influenced by ancient beliefs, following a predominantly social model of care, delivered by midwives, which generally aimed to protect and preserve perineal integrity and comfort the childbearing woman. The advent of the man-midwife, asepsis and pharmacological pain relief, supine birth positions and the episiotomy, pathologised the perineum, turning it into a surgical site. The concept of midwifery knowledge as an old wives' tales was explored and the way in which midwifery knowledge is often dismissed as not valid was also argued. The Perineal Warm Pack Trial was instigated, as described in Chapter 1, in order to validate an ancient midwifery art through science, turning what has been considered an 'old wives' tale' into established midwifery knowledge.

In Chapter 3 the reclamation of the perineum in the late 1970s was explored. The revival of a social model of care that now competes with the dominant surgical model came with the advent of the active birth movement and re-emergence of the belief that protection and preservation of the perineum, along with comfort of the childbearing woman in the second

stage was important. These two models, one social and the other surgical, continue to compete with one another today.

In Chapter 4, a literature review of factors that influence perineal trauma and maternal comfort during the late second stage of labour was undertaken. The areas reviewed were perineal massage (antenatal and intrapartum), pelvic floor exercises (antenatal), warm and cold packs, immersion in water (intrapartum), local anaesthetic spray, position in the second stage of labour, coached and uncoached pushing, hand manoeuvres, episiotomy, vacuum versus forceps delivery, epidural, support during labour, place of birth and midwife versus obstetric care during birth. A summary of the key conclusions for each practice reviewed was given along with recommendations for future research. The Perineal Warm Pack Trial now adds further support to the practice of applying warm packs to the perineum in the second stage as a comfort measure. Further research is still required into the potential beneficial effects of antenatal perineal massage using a massaging device; pelvic floor exercises; cold packs during the second stage, particularly where there is perineal oedema; different birth positions; coached and uncoached pushing; birth of the baby's head in between contractions, and the influence of the place of birth and accoucheur on perineal trauma and maternal comfort during the second stage.

10.3 Limitations of the study

The study had a number of limitations. These included having only primiparous women as participants; being only partially blinded; not including faecal incontinence in the six- and twelve-week postpartum assessment; not asking women about a previous history of urinary incontinence and having incomplete data collection.

Only primiparous women were included in the study in order to reduce the variables associated with a previous birth. Primiparous women are also more likely to suffer perineal trauma and experience longer second stages and thus more discomfort. However, as only primiparous women were included in the study, we cannot draw conclusions about the effects of warm packs on women who are having subsequent births.

We did not record the length of time the warm packs were applied to the perineum, which is another limitation. While midwives observed that most babies were born within 15 minutes of the warm packs being applied, it is possible that had the packs been applied for longer, the effect may have been more pronounced.

The inclusion of a third or even fourth group of women having a tepid or cold perineal pack applied would have been optimal. The tepid packs would have helped determine the extent of the placebo effect of the warm packs. It is possible that the warm packs were detrimental in some cases, such as in the presence of oedema. Midwives during the trial did remark on this and wondered if cold packs would have been more beneficial in some cases. Cold therapy in postnatal care has been researched but as has been discussed in Chapter 4 there is no research as to its effect in intrapartum care.

It was impossible to blind women to their allocated group. This knowledge of their allocation could have biased the amount of pain they reported both during and after the birth. Women who received warm packs may have experienced a placebo effect and experienced less pain as a result of the treatment. Women who did not receive warm packs may have been disappointed with their allocation and thus had a more negative perception of their births. Attempts were made to minimise this by having an independent midwife assessor, who was blinded to the group allocation, review all perineal trauma. In reality, this was hard to achieve, as midwives working closely together tend to have knowledge of events going on in the Delivery Ward. It is also possible that as warm packs were not a part of the midwives' clinical practice and they were not convinced as to their value, that this may have negatively influenced the midwives' evaluations of the warm packs. There was no difference in the perineal trauma that required suturing, or was classified as major or minor, or in the numbers of women who had an episiotomy. As many midwives were involved, rather than a couple of designated research midwives, the likelihood of systematic bias was reduced.

Another potential limitation is that the 20 – 25% of women who did not complete pain score assessments after the birth and on days one and two following the birth may have had different responses. However, as no women refused to complete the pain scores, and lack of completion was mostly due to the midwives forgetting or being too busy, this is less likely. While there was no difference in the demographics of respondents and non-respondents, it is of concern that midwives were less likely to obtain pain scores from women who had instrumental births. This shows a lack of understanding with intention to treat protocols. As these women were less likely to receive the treatment or standard care, it was unlikely to affect the final results. The primary outcome variable (suturing following birth) was obtained for 100% of the women who participated in the study.

Another limitation was not being able to use data collected on the postpartum use of analgesia, due to poor documentation. This may have added important supporting evidence to the finding that warm packs reduced perineal pain on days one and two following the birth.

Another limitation already discussed is the potential for a Type 1 error due to the number of different analyses embarked on. This is particularly relevant when considering the significant difference found in the incidence of severe perineal trauma between the groups.

The power analysis estimated that 694 participants were needed to show a 10% difference in suturing. Due to time factors, recruitment ceased at 717, despite only 599 women actually having the allocated treatment. It is highly unlikely that a further 95 women would have led to a statistically significant difference in the primary outcome measure.

That perineal pain scores remained statistically significantly lower in the warm pack group at days one and two, despite no difference in the incidence of suturing between the groups, is intriguing and points to a possible limitation in the study. There are a couple of possible explanations for this. Firstly, this may be due to the reality that the treatment could not be blinded and women who received the warm packs expected their pain to be lower. Women who did not receive the warm packs may have been disappointed and assumed they

suffered additional trauma because they did not receive the treatment. However, another possibility is that the warm packs somehow altered connective tissue on a superficial level leading to fewer small grazes, all, which may contribute to overall levels of pain. It is also possible that the presence of the warm pack on the perineum made midwives touch the perineum less, leading to reduced bruising. Secondly, as it was impossible to conceal the allocated treatment from the midwives, potential exists for reporting bias in data collection. However, this is unlikely as has already been discussed, as the midwives involved in the study had never used warm packs before and were generally not convinced of their value. Also, a large number of midwives contributed to the data collection, making systematic distortion unlikely.

It is possible that some of the 36 women who did not complete the questionnaires may well have been less positive about the effect of the warm packs and therefore avoided completing the questionnaire. Likewise, the 32 midwives' questionnaires not completed, may similarly have been influenced. It is possible that the impressions of women receiving the warm packs were influenced by the fact they were receiving additional attention from the midwife and therefore viewed the pain less negatively. The very act of applying the warm compress to the perineum may be seen as caring and therefore lead women to view the pain in a positive light. However, a majority of the women and midwives answering the questionnaires felt that the warm packs reduced perineal pain experienced during the birth. This is similar to the results of the pain scores at birth and on days one and two following the birth. Similar proportions of women and midwives felt that the warm packs had some effect in relieving perineal pain.

One of the limitations of this study that has already been discussed in Chapter 9 was that the incidence of faecal incontinence was not included in the postpartum follow-up. In light of the finding of an increased incidence of severe perineal trauma, this would have been valuable.

Another limitation in the study was not piloting the six-week and three-month data-collection forms before the Perineal Warm Pack Trial commenced, as was done with the

other data-collection forms. It would have been ideal to have piloted these data-collection forms prior to commencement of the study but due to the time lapse after the birth (12 weeks), this was not done. As a result, a question asked on the past history of urinary incontinence prior to or during pregnancy was poorly completed and could not be used. This was probably largely due to the way the data-collection form was designed. There is a chance that women in the standard care group had a higher incidence of pre-pregnancy or pregnancy incontinence, making them more predisposed to developing incontinence after the birth. However, the randomisation process should have minimised the chance of this occurring.

The fact that 22 – 27% of women could not be contacted for follow-up at six and twelve weeks postpartum is also a limitation, as results may have differed for these women. For example, they may have been less likely to return phone calls that midwives made if they were having a more difficult time in the postnatal period. The large CALD population meant that women were often unable to be contacted through one or both phone calls, as they had returned to their country of birth to introduce the new baby to their family. These women would also be rung when an interpreter was available and this was sometimes difficult. Other reasons such as the phone number being wrong or disconnected were also common. After three messages were left, we did not pursue the women any further to obtain the postpartum data. The fact that the data obtained during the postpartum follow-up showed no significant differences between the groups, except for urinary incontinence, is, however, reassuring.

10.4 Implications for second-stage care

The application of perineal warm packs during the second stage of labour is widely advocated by midwives to reduce perineal trauma and improve comfort during the birth. This is the largest randomised trial to evaluate the use of the procedure during the late second stage and to examine both women's and midwives' experiences.

Women and midwives who participate in the Perineal Warm Pack Trial reported that warm packs not only appeared to reduce pain felt during the birth but that they were highly acceptable as a method to relieve pain. The advancement of the foetal head, and stretching of the perineum in the minutes before giving birth, is accompanied by pain that has been reported to be severe. This was supported in this study by the large numbers (70.8%) of women reporting the pain of giving birth as severe ('bad pain' or 'the worst pain in my life'). Amongst the women who received the warm packs, 59.2% reported their pain as severe, whilst in the group of women not receiving warm packs 81.7% reported their pain as severe. Midwives also concurred with women, observing some reduction in pain in over 80% of women on whom they used perineal warm packs. Both midwives and women were positive about using warm packs in the future as part of second-stage care.

In the developed world, there has been a dramatic increase in caesarean section (NICE, 2004). Fear of the pain associated with labour has been reported as a reason why women may request a caesarean section (Kolas et al., 2003) (Nerum et al., 2006). Primiparous women, in particular, seem increasingly worried about the pain associated with labour and birth (Green et al., 2003). Perineal warm packs are an effective method of reducing pain experienced in the late second stage of labour without women having to resort to potentially harmful pharmacological pain relief. Any practice that reduces pain and improves comfort during the second stage should be encouraged and made widely available. The use of perineal warm packs in the second stage is one such practice that should be encouraged, especially as it is so accessible and involves minimal financial cost. The absence of harm associated with warm packs to the mother and baby, when correctly used is also an important consideration. Clinicians can reassure women that they can indeed soothe the 'ring of fire' without needing to resort to potentially harmful pharmacological methods.

10.5. Future research

More research is required into whether multiparous women would receive the same benefits in terms of improved comfort during and following birth that the primiparous women reported in this study. A previous study examining the effectiveness of warm packs, as one

of three second-stage practices included multiparous women and showed no benefits were gained with regard to reducing perineal trauma (Albers et al., 2005). Comfort gained from warm packs was not, however, examined in this study.

Further investigation into the possible beneficial effect of warm packs on reducing severe perineal trauma is also required. This could potentially be an important way to minimise severe perineal trauma and the associated maternal morbidity. Any future study needs to include postpartum follow-up of women for incontinence of faeces or flatus.

Further research is needed to determine whether the reduction in urinary incontinence continues to be statistically significant in the long term. Any future study would need to include questions that ascertained the pre-pregnancy and pregnancy history of incontinence. Any second-stage methods that potentially reduce the incidence of urinary incontinence should be pursued, as this serious morbidity affects millions of women worldwide.

10.6 Conclusion

The application of perineal warm packs or compresses is widely advocated by midwives to reduce perineal trauma and improve comfort during the birth. The origins of this practice are lost in history, but it is obvious from the historical literature that the application of warm packs to the perineum in the second stage is indeed a very ancient practice. This is the largest randomised controlled trial to date to evaluate the effect of perineal warm packs during the second stage on women's perineal trauma and comfort. Although the application of warm packs in labour did not decrease the likelihood of perineal suturing, there is evidence of other important benefits, including reducing the pain experienced during the birth and at days one and two following the birth. There is some evidence that severe perineal trauma and urinary incontinence could also be reduced, and this warrants further investigation.

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<http://answers.yahoo.com/question/index?qid=20061206065740AAnUMg%show=7>

Appendix 1: Risk factors for severe perineal trauma during childbirth. An Australian prospective cohort study

(Published, June 2007, *Midwifery*)

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Appendix 2: Obstetric-induced incontinence: A black hole of preventable morbidity? An 'alternative' opinion

(Published April 2007, Australian and New Zealand Journal of Obstetrics and Gynaecology)

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Appendix 3: Information for participants

Research study into the effect of warm packs applied to the perineum during delivery: information for participants

The midwives in the Delivery Ward would like to invite you to take part in a research study into the effect of warm packs applied to the perineum during the second stage of labour prior to giving birth. The objective is to discover whether applying warm pack to the perineum whilst the baby's head is crowning reduces pain and trauma to the mother.

Other studies have shown some benefits from using warm packs on women who are having subsequent babies. These studies have not been very large nor have they looked specifically at the effects on first-time mothers.

The study is being conducted by Hannah Dahlen, the Clinical Midwifery Educator and the midwives from the Delivery Ward at King George V Hospital.

Half the women who agree to participate in the study will have warm packs applied to their perineum when the baby's head begins to stretch it during delivery. The other half will not have the warm packs applied, as is currently our practice. The choice of using warm packs or current management will be made randomly after you have entered the trial. The temperature of the water used is uniform so there are no risks, discomfort or side-effects to you or your baby from the use of warm packs.

Your participation in this trial is voluntary and you are free to withdraw at any stage. Whatever your decision, please be assured that it will not affect your treatment or relationship with the midwives caring for you. Being involved in the trial will not alter any other care at all. All aspects of the study will be strictly confidential and all names and phone numbers will be destroyed once the study has been completed . A

report of the study may be submitted for publication but individual participants will not be identifiable in such a report.

You will be asked to fill out a simple questionnaire after you have had your baby. We will also make a follow-up phone call to you at home six and twelve weeks after you have given birth.

When you have read the information, the midwife caring for you will discuss it with you and answer any questions you may have. If you have any problems or enquiries at any time please contact Hannah Dahlen (Clinical Midwifery Educator) or any of the midwifery staff in the Delivery Ward on 9515 8444.

This study has been approved by the Ethics Review Committee of the Central Sydney Area Health Service. Any person with concerns or complaints about the conduct of this research study can contact the secretary of the Ethics Review Committee on 9515 6766.

Appendix 4: Participant consent form

Research Study into the effect of warm packs applied to the perineum during delivery: Participant Consent Form

I.....[name]
 of.....[address]
 [phone number] have read and understood the Information for
 Participants on the above named research study and have discussed the study
 with.....[name].

I am aware of the procedures involved in the study. I understand that I may or may
 not have warm packs applied to my perineum during delivery.

I freely choose to participate in this study and understand that I can withdraw at
 Any time.

I also understand that this research is strictly confidential and information released or
 published will not disclose my identity.

I hereby agree to participate in this research study.

NAME:.....

SIGNATURE:.....

DATE:.....

NAME OF WITNESS:.....

SIGNATURE OF WITNESS

Appendix 5: Data collection form

**THE DATA COLLECTION FORM IS TO BE FILLED OUT ON ALL WOMEN
WHO ENTER THE *WARM PACK TRIAL***

Case No. [] Unit No: ----- Phone Number-----

Warm Pack Group []

Normal Care Group []

A) Intrapartum (Fill out immediately post delivery)

1) Age of woman:------(years)

2) Ethnicity: Australian [] United Kingdom and Ireland []
 Middle Eastern [] New Zealand and Oceania []
 Central and South American [] European []
 North American [] Asian []
 African []

Aboriginality: Yes [] No []

3) Perineal Status: Intact []
 Graze/Tear Labial []
 Graze perineal []
 1st-degree tear []
 2nd-degree tear []
 3rd-degree tear []
 4th-degree tear []
 Vaginal lacerations []
 Other (please describe).....
 Episiotomy [] Indication for episiotomy.....

-N/A (Caesarean Section) []

*Sutured []

*Not sutured []

4) Length of second stage:

5) Use of analgesia in labour: Yes [] No [] (go to question 6.)

Nitrous Oxide []

Pethidine []

Epidural []

Other [] (please describe).....

6) Weight of baby: (grams).....

Position adopted for delivery: Semi-seated []

Other (please describe).....

8) Type of delivery: NVD [] Forceps [] Vacuum [] Caesarean []

Vaginal Breech []

Appendix 6: Postnatal data-collection form

TO BE COMPLETED ON ALL WOMEN ENTERED IN THE TRIAL

B) Postnatal (Fill out on day ONE and TWO post delivery and complete on DISCHARGE)

Case No. [] Unit No. -----

1) Breastfeeding on discharge home: Yes [] No [] Partial []

2) Care by Early Discharge Team: Yes[] No[]

3) Length of hospital stay: -----(days)

4) Pain relief used: Yes [] No []

Panadol [] amount in doses.....

Panadiene [] amount in doses.....

Ponstan [] amount in doses.....

Ponstan and Panadeine [] amount in doses.....

Digesic [] amount in doses.....

Other (describe)

5) Perineal Pain Score Day One

0-----1-----2-----3-----4-----5-----6-----7-----8-----9-----10
No pain Worst pain ever

6) Perineal Pain Score Day Two

0-----1-----2-----3-----4-----5-----6-----7-----8-----9-----10
No pain Worst pain ever

Appendix 7: Six weeks data-collection form

TO BE COMPLETED SIX WEEKS POSTNATALLY ON ALL WOMEN ENTERED
IN THE TRIAL

Case No. []

Unit No. -----

Date: ___/___/___

Phone No:.....

1) Perineal Pain Score:

0-----1-----2-----3-----4-----5-----6-----7-----8-----9-----10
No pain Worst pain ever

Pain when walking []

Pain when sitting []

Pain during a bowel motion []

Pain on urinating []

2) Sexual Intercourse: Resumed [] (at how many weeks post delivery?-----)

Not Resumed [] (go to question 3.)

Pain With Intercourse Score

0-----1-----2-----3-----4-----5-----6-----7-----8-----9-----10
No pain Worst pain ever

3) Bladder integrity: Incontinent []

Not incontinent [] (go to question 4.)

Occasional urinary incontinence but improving []

Urinary incontinence when coughing or lifting []

Urinary incontinence most days and for no reason []

Urinary incontinence Prior to pregnancy []

During pregnancy []

Never before []

Breastfeeding: Yes []

No []

Partial []

Appendix 8 Twelve weeks data-collection form

TO BE COMPLETED TWELVE WEEKS POSTNATALLY ON ALL WOMEN
ENTERED IN THE TRIAL

Case No. []

Unit No. -----

Date: ___/___/___

Phone No:.....

1) Perineal Pain Score:

0-----1-----2-----3-----4-----5-----6-----7-----8-----9-----10
No pain Worst pain ever

Pain when walking []

Pain when sitting []

Pain during a bowel motion []

Pain on urinating []

2) Sexual Intercourse: Resumed [] (at how many weeks post delivery?-----)

Not Resumed [] (go to question 3.)

Pain With Intercourse Score

0-----1-----2-----3-----4-----5-----6-----7-----8-----9-----10
No pain Worst pain ever

3) Bladder integrity: Incontinent []

Not incontinent [] (go to question 4.)

Occasional urinary incontinence but improving []

Urinary incontinence when coughing or lifting []

Urinary incontinence most days and for no reason []

Urinary incontinence Prior to pregnancy []

During pregnancy []

Never before []

4) Breastfeeding: Yes [] No [] Partial []

Appendix 9: Maternal questionnaire: warm pack

Case No. []

PLEASE CIRCLE OR TICK THE MOST APPROPRIATE OPTION FOR EACH QUESTION

1) Did you find the warm pack reduced the pain in your perineum?

A lot

A little

Not sure

Not at all

2) Did you get any comfort from the warm pack on your perineum?

A lot

A little

Not sure

Not at all

3) Did the warm pack on your perineum help you to feel more in control during the second stage?

A lot

A little

Not sure

Not at all

4) Do you think the warm pack numbed your perineum?

A lot

A little

Not sure

Not at all

(5) Did you dislike the warm pack on your perineum?

A lot

A little

Not sure

No

6) Did you like the warm pack on your perineum?

A lot

A little

Not Sure

Not at all

7) Would you like warm packs applied to your perineum during your next delivery?

Yes []

No []

Not sure []

8) Would you recommend warm packs to your friends?

Yes []

No []

Not sure []

9) Please circle the appropriate number that indicates the severity of the pain you experienced in your perineum when giving birth

1-----2-----3-----4-----5

No pain

Some
pain

Moderate
pain

Bad pain

The worst
pain in
my life

Appendix 10: Maternal questionnaire: standard care group

Case No.[]

Please circle the appropriate number that indicates the severity of the pain you experienced in your perineum when giving birth

I-----2-----3-----4-----5

No pain

Some
pain

Moderate
pain

Bad pain

The worst
pain in
my life

Appendix 11: Midwives' questionnaire: warm pack group

Midwives' Questionnaire (Warm Pack Group)

Case No []

**TO BE FILLED OUT BY MIDWIFE APPLYING THE WARM PACKS TO THE
PERINEUM.**

PLEASE TICK THE MOST APPROPRIATE OPTION FOR EACH QUESTION

1) Do you think the perineal warm pack reduced the woman's perineal pain in the second stage?

Yes [] Somewhat [] No [] Not sure []

2) Do you think the perineal warm pack reduced perineal damage?

Yes [] Somewhat [] No [] Not sure []

3) Do you think the perineal warm pack increased the woman's control in second stage?

Yes [] Somewhat [] No [] Not sure []

4) Do you think the perineal warm pack increased the stretching of the perineum?

Yes [] Somewhat [] No [] Not sure []

5) Do you think the perineal warm pack had any effect at all on the woman's second stage?

Yes [] Somewhat[] No [] Not sure []

6) Did you like using the perineal warm pack as part of your management of the second stage?

Yes [] Somewhat[] No [] Not sure []

7) Would you consider using perineal warm packs in the future?

Yes [] No [] Not sure []

8) Please write any comments you might have below.

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