Medical device-related pressure ulcers: a systematic review and meta-analysis

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ABSTRACT

Objective

To review observational studies reporting medical device-related pressure injuries and to identify the medical devices commonly associated with pressure injuries.

Design

A systematic review of primary research was undertaken, according to the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines.

Data sources

A comprehensive electronic literature search of AMED, CINAHL, MEDLINE, PsycINFO, Web of Science, British Nursing Database and Google Scholar was conducted from inception to 31st December 2018. Studies that reported the prevalence or incidence of medical device-related pressure injuries and published in English language were included in the review.

Review methods

The eligibility of studies was evaluated independently by three of the four authors and audited by an independent researcher. The titles and abstracts of all studies were screened to identify studies that met the inclusion criteria. Full-text articles of the remaining studies were obtained and screened against the inclusion criteria. Risk of bias was assessed using the Newcastle-Ottawa scale. Meta-analysis was conducted using the 'metaprop' routine, with estimates of medical device-related pressure injuries from the included studies pooled using DerSimonian-Laird random-effects model. Meta-regression analysis was also conducted to examine between-study heterogeneity.

Results

Twenty-nine studies (17 cross-sectional studies; 12 cohort studies) comprising data on 126,150 patients were eligible for inclusion in this review. The mean ages for patients were approximately 36.2 years (adults) and 5.9 years (children). The estimated pooled incidence and prevalence of medical device-related pressure injuries were 12% (95% CI 8 – 18) and 10% (95%

CI 6 – 16) respectively. These results should be interpreted with caution given the high levels of heterogeneity observed between included studies. The commonly identified medical devices associated with the risk of developing medical device-related pressure injuries include respiratory devices, cervical collars, tubing devices, splints, and intravenous catheters.

Conclusions

Medical device-related pressure injuries are among key indicators of patient safety and nursing quality in healthcare facilities. This systematic review and meta-analysis provide up-to-date estimates of the extent and nature of medical device-related pressure injuries, and the findings suggest that device-related pressure injuries are a public health issue of significance, especially as these injuries affect patients' wellbeing and increase the cost of care for both patients and providers. Further research is required to inform strategies for increasing the reporting and risk assessment of medical device-related pressure injuries.

Keywords: Pressure ulcer, Pressure injury, Medical devices, Medical devices pressure injuries

What is already known about the topic?

- Medical devices are an integral part of providing care in health facilities and are associated with the development of pressure injuries.
- Medical device-related pressure injuries affect patients' quality of life and increase the cost of care for both patients and providers.

What this paper adds

- This paper provides up-to-date pooled estimates of the incidence [12% (95% CI 8 – 18)] and prevalence [10% (95% CI 6 – 16)] of medical device-related pressure injuries in adult and paediatric populations,
- The medical devices implicated in device-related pressure injuries from the included studies comprise respiratory devices, cervical collars and cervical immobilisation

devices, tubing, splints, intravenous catheters, tapes, pulse oximeters, restraints/casts, stockings, and braces.

1 INTRODUCTION

Medical device-related pressure injuries are increasingly being recognised as a public health concern for healthcare facilities (National Pressure Ulcer Advisory Panel [NPUAP], 2014a). Medical device-related pressure injuries develop when skin or underlying tissues are subjected to a sustained pressure or shear from medical devices (NPUAP, 2014a). All medical devices could potentially cause pressure injuries (Byrant, 2012). Usually, medical device-related pressure injuries occur around or under medical devices often taking the shape of the devices (Haugen, 2015). Patients using medical devices are twice more likely to develop pressure injuries than patients not using medical devices (Black and Kalowes, 2016). Risk factors for developing a medical device-related pressure injury include: being aged over 75 years, having impaired mobility, impaired microclimate of the skin, compromised nutrition, and dependence on medical devices for survival (NPUAP, 2014a; National Institute for Health and Care Excellence [NICE], 2015). Common areas where medical device-related pressure injuries develop include: head, face, ears, heels, feet, neck, sacrum, and buttocks (NPUAP, 2014a).

Medical device-related pressure injuries affect patients' quality of life and increase the cost of care for both patients and providers (NPUAP, 2014a). Pressure injuries are expensive in human and economic terms. Findings of a recent systematic review estimated that the cost of treating pressure injuries per patient per day ranged from €1.7 - €470.5, while the cost of preventing pressure injuries was €2.6 - €87.6 (Demarre et al., 2015). Pressure ulceration can increase patients' length-of-stay in healthcare facilities. For instance, in the United Kingdom, it has been documented that pressure injuries increase length-of-stay by an average of 5-8 days (Dealey et al., 2012). These extended hospitalizations are often associated with increased cost of care and occurrence of nosocomial infections and life-threatening complications such as sepsis, tissue necrosis, and gangrene (Russo et al., 2006). However, the percentage of extended hospitalisation due to medical device-related pressure injuries is not known.

Medical device-related pressure injuries occur across hospital departments including intensive care units, maternity, paediatric units, trauma centres, and rehabilitation units (Holden-Mount and Sieggreen, 2015). However, current pressure injury risk assessment tools such as the Norton scale (Norton et al., 1962), Braden scale (Braden and Bergstrom, 1988), and Waterlow score (Waterlow, 2005), are often inadequate in predicting the risk of medical device-related pressure injury development among patients, as these risk assessment tools focus on patient immobility rather than the mobility of devices (Dyer, 2015). Therefore, nurses and other healthcare providers rely on clinical judgement and visual inspection of the skin to assess medical device-related pressure injury, meaning that some medical device-related pressure injuries are not recognised or recorded (Coleman et al., 2014; Dyer, 2015). Hence, a systematic review that comprehensively identifies, interrogates, presents and synthesises evidence about medical device-related pressure injury is needed. The aim of this review is to examine observational studies reporting medical device-related pressure injuries and to identify the medical devices commonly associated with pressure injuries. The review is relevant to clinical policy and consumer decision-makers in providing a robust review of current evidence, and to researchers and funders in highlighting areas of uncertainty that may be addressed by future research.

2 METHODS

2.1 Protocol Registration

The protocol for this review has been registered in the International prospective register of systematic reviews (PROSPERO) reference number: CRD42017079953 (Jackson et al., 2017).

2.2 Eligibility criteria

Studies were eligible for inclusion in the review if they reported incidence or prevalence of medical device-related pressure injuries. We include studies conducted on populations of all ages (adults and children) in all healthcare settings/facilities without limitations to type of facility. Only studies published in the English Language were eligible for inclusion in our review. Studies reporting experiments for testing the effectiveness of devices for preventing or managing pressure injuries were excluded. Other exclusion criteria included; studies reporting pressure injuries that were not device-related, studies that recruited home-dwelling participants, studies not reported in English language, expert reviews, or policy reports. (see table 1).

Table 1 Eligibility Criteria

Domain	Inclusion	Exclusion
Study design	Observational studies: - Cross-sectional studies (including secondary data analysis) - Cohort studies (including prospective and retrospective)	- Experimental studies testing the effectiveness of devices for preventing or managing pressure injuries (RCTs, quasi-experiments) - Expert reviews - Policy reports
Population/patients	Patients of all ages assessed in healthcare settings/facilities	Home-dwelling participants
Outcome	Medical device-related pressure injuries (specified as pressure injuries associated with the usage of medical devices, equipment, appliances, and support surfaces)	- Pressure injuries not caused by medical devices - Patients admitted with pressure injuries
Language	Studies published in English Language	Studies published in other languages

2.3 Search Strategy

A comprehensive electronic literature search of AMED, CINAHL, MEDLINE (via PubMed), PsycINFO, Web of Science, British Nursing Database (BND) and Google Scholar was conducted. The following MeSH and free-text terms were used; "pressure ulcer*", "pressure injury", "pressure sore*", "pressure damage", "decubitus ulcer", "device-related", "medical device*", "medical device related", "medical device-related", "prevalence", "frequency", "occurrence", "rate". For the detailed search strategy of this review see supplementary online material. All electronic sources of information were searched from inception to 31st December 2018. Google Scholar was searched using the search term “medical device-related pressure

injuries" to widen the literature search and to ensure that all eligible studies were included in the review. We imposed no restriction on date of publication in our literature search.

Reference lists of identified studies and bibliographies of reviews were hand-searched for additional studies. Grey literature was sought from the following sources up to 31st December 2018: Open Grey, European Pressure Ulcer Advisory Panel (EPUAP) website, National Pressure Ulcer Advisory Panel (NPUAP) website, and Wound Care Advisor website.

2.4 Study Selection Process

The eligibility of studies was evaluated independently by three of the four authors and audited by an independent researcher. The titles and abstracts of all studies were screened to identify studies that met the inclusion criteria. Full-text articles of the remaining studies were obtained and screened against the inclusion criteria. The Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) (Moher et al., 2009) flow diagram was used to illustrate the study selection (refer to Figure 1).

2.5 Data Extraction

The data from included studies was extracted independently by three of the four authors. Data extracted comprised of (1) the methodological information of the studies; first author, year of publication, aim of the study, operationalised definition of medical device-related pressure injuries, sample size, gender distribution of the sample, mean age, and specific devices implicated as causes of device-related pressure injury, (2) reported study outcomes; prevalence or incidence of medical device-related pressure injuries (see Table 2).

2.6 Quality Assessment

Quality assessment entailed evaluating the risk of bias for each included study using the Newcastle-Ottawa scale (Wells et al., 2014), a validated tool for assessing risk of bias in in observational studies. The Newcastle-Ottawa scale enables the classification of studies into low risk, moderate risk, high risk, or unclear based on the following domains: selection bias (selection of participants and representativeness of the sample), detection bias (outcome measurement and outcome assessment), and controlling for confounders.

2.7 Statistical Analysis

Meta-analysis was conducted using the *'metaprop'* routine (Nyaga et al., 2014) in Stata version 15 for Windows (Stata Corp., 2017). The *metaprop* routine entails the Freeman-Tukey double arcsine transformation procedure and DerSimonian-Laird random-effects model (Miller, 1978; DerSimonian and Laird, 1986). Specifically, the Freeman-Tukey double arcsine procedure transforms proportions from individual studies by stabilizing between-study variance. Subsequently, the DerSimonian-Laird random-effects model computes the weighted overall pooled estimates. Between-study heterogeneity was assessed by inspecting the forest plots and the chi-squared test for heterogeneity. I^2 statistic with a value above 50% was interpreted as representing high heterogeneity (Higgins and Thompson, 2002).

Results of the meta-analysis were reported as pooled prevalence and incidence of medical device-related pressure injuries with 95% confidence intervals (CIs), p-values <0.05 were considered statistically significant. Meta-regression analysis was performed to determine factors associated with heterogeneity. Specifically, as a priori plan we considered the common moderator variables associated with heterogeneity in meta-analyses, this include age, gender, and study type (Begum et al., 2012; Pei et al., 2016).

3 RESULTS

3.1 Study Characteristics

The literature search yielded 3,462 studies. After de-duplication, 952 titles and abstracts were screened, where a further 832 articles were excluded because they did not meet the inclusion criteria. Most of the 832 reported treatment, prevention, or management of pressure injuries, and some reported pressure injuries that were not device-related. Full text screening was conducted for the remaining 120 studies, where a further 91 studies were excluded for not meeting the eligibility criteria. Thus, 29 studies (17 cross-sectional studies; 12 cohort studies) were eligible for inclusion in this review (see Figure 1).

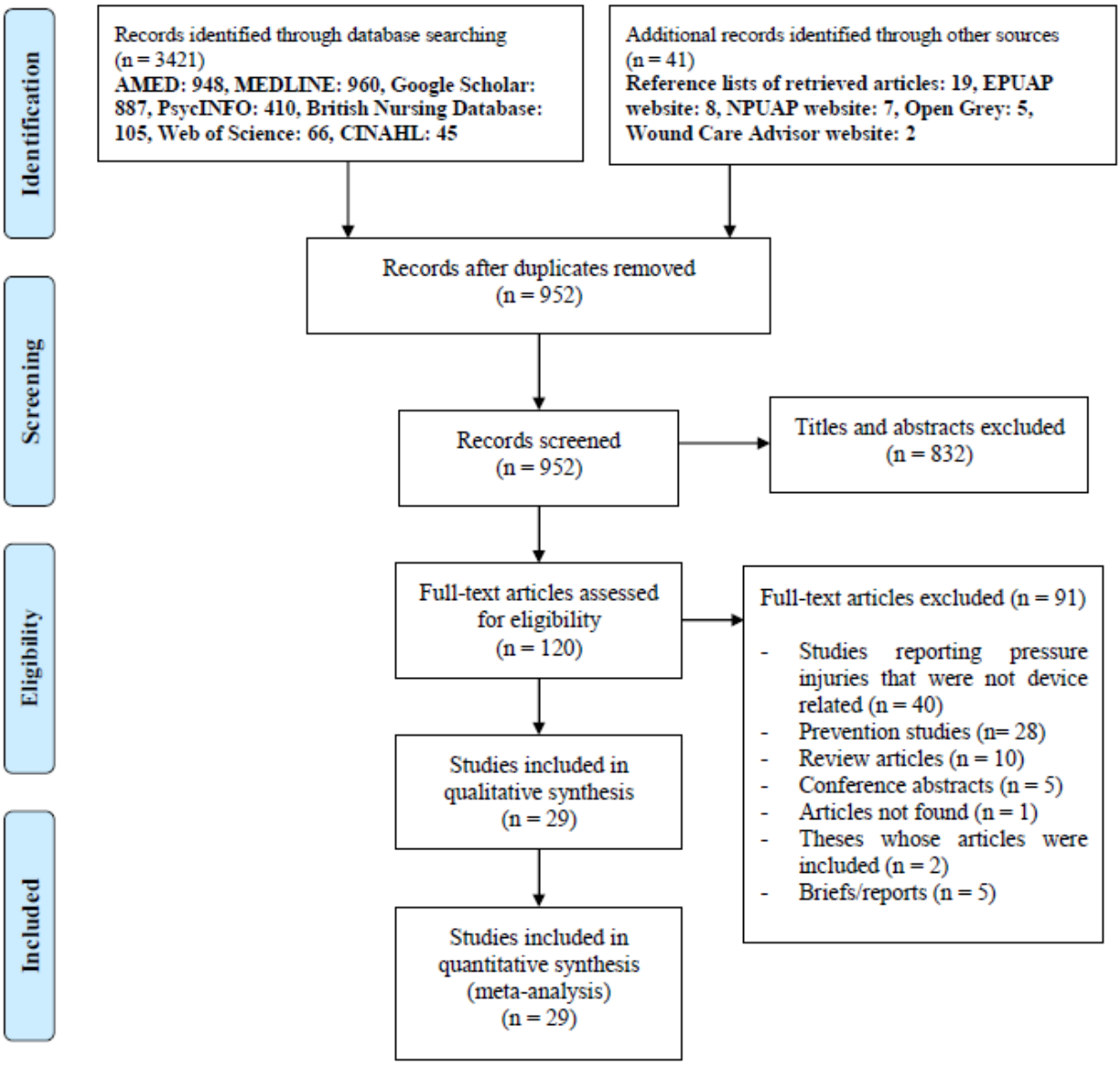


Figure 1 PRISMA flow diagram showing study selection

The included studies comprised data on 126,150 patients across 14 countries including the United States of America, Australia, Israel, United Kingdom, Saudi Arabia, Switzerland, Brazil, Jordan, Netherlands, Spain, Sweden, Turkey, Portugal, and Canada (see Tables 2 and 3).

All 29 included studies were hospital-based observational studies. Data were collected from the following medical environments adult intensive care units ([ICUs], n = 8), paediatric intensive care units ([PICU], n = 4), neonatal intensive care units ([NICU], n = 4), surgical intensive care

units ([SICU], n = 2), trauma units (n = 3), geriatric nursing units (n = 2), and acute care (n = 1). The remaining studies were either analysis of retrospective data or studies where the hospital ward/unit was not specified. The mean ages for patients were approximately 36.2 years (adults) and 5.9 years (children). The medical devices from the included studies that were implicated in developing device-related pressure injuries comprised respiratory devices, cervical collars and cervical immobilisation devices, tubing, splints, intravenous catheters, tapes, pulse oximeters, restraints/casts, stockings, and braces (refer to Tables 2 and 3). Stage of injury were not reported in almost all of the included studies. We surmise that it is likely many device-related pressure injuries could not be staged because they were on mucosal tissue. The National Pressure Ulcer Advisory Panel (2008), posits that pressure injuries on mucous membranes are difficult to be staged.

Table 2 Extracted data for studies reporting incidence of MDRPIs

First Author Year of publication Country	Aim	Operationalised definition	Study design	%Males	Mean age (years)	Sample size	Overall incidence %(n)	Medical device type (n)	Overall Quality Assessment
Chendrasekhar 1998 USA	To assess the incidence of cervical collar decubiti in patients with severe closed head injury	Decubiti formation associated with prolonged duration of cervical collar placement	Cross-sectional study	82.7	36.5	34	38(13)	Cervical collar (13)	Moderate
Curley 2003 USA	To describe the incidence, location, and factors associated with the development of pressure injuries in patients cared for in the paediatric intensive care unit (PICU)	Pressure injuries attributed to medical devices among paediatric patients cared for in a PICU.	Prospective cohort study	60	3	322	8.4(27)	Oxygen probe (14) Bilevel positive airway pressure device (3) Endo tracheal tube (3) Tracheostomy tube (2) Arterial line (1) Bladder catheter (1) Cerebrospinal fluid shunt (1) Splint (1) Central line (1)	High
Ackland 2007 Australia	To determine the incidence and risk factors associated with the development of cervical collar-related decubitus ulceration	Cervical collar decubitus ulceration	Cross-sectional study	74.6	40.7	299	9.7(29)	Cervical collar (29)	High

Schluer 2009 Switzerland	To describe the frequency of pressure injuries in a paediatric care setting and to identify the population at risk, as well as the factors predisposing to the development of pressure injuries	Pressure injuries associated with medical equipment such as tubes, splints or monitoring cable	Cross-sectional study	55.5	NP	155	27.7(43)	Splints Cables Tubes[#]	High
Jaul 2011 Israel	To document the occurrence, cause, prevention, assessment, and treatment of pressure injuries in atypical anatomical locations	Pressure injuries developed underneath strap holding tracheostomy tube, next to an indwelling urinary catheter, and abdominal wall next to the insertion site of a percutaneous gastrostomy tube	Prospective cohort study	47	71.5	32	18.8(6)	Tracheostomy tube (4) Urethral catheter (1) Percutaneous endoscopic gastrostomy (1)	High
Walker 2012 UK	To determine the incidence of pressure ulceration in patients treated with cervical spine immobilisation	Pressure ulcer related to the use of halo immobilisation device, halo vest, and cervical immobilisation device	Cross-sectional study	53	53.6	90	2.2(2)	Cervical immobilisation device (2)	High
Jaul 2014 Israel	To analyse the occurrence of atypical pressure injuries and the circumstances of the causation	Pressure injuries developed from the use of tapes, tracheostomy tube, oxygen mask,	Prospective cohort study	50	77.4	174	5.7(10)	Tape (4) Gastrostomy tube (1) Tracheostomy tube (1) Urethral catheter (2) Oxygen tube (2)	High

		oxygen tubing, and urinary catheter							
Tayyib 2015 Saudi Arabia	To identify pressure ulcer incidence and risk factors that are associated with pressure ulcer development in two adult intensive care units (ICU) in Saudi Arabia	Pressure injuries attributed to medical devices in the intensive care unit	Prospective cohort study	66.7	52.8	84	8.3(7)	Respiratory (7)	High
Nist 2016 USA	To standardize the assessment, documentation, and tracking of skin injuries among hospitalized neonatal patients and to determine the incidence of pressure injuries in the patients	Skin injuries associated with the use of medical devices specifically respiratory devices, intravenous and intra-arterial devices	Prospective cohort study	NP	NP	2299	15.3(352)	Constant positive airway pressure devices Gastrointestinal devices Intravenous devices Monitoring devices Other medical devices[#]	High
Alves 2017 Portugal	To study the prevalence and incidence of PU in an intensive care unit (ICU) and the difficulties of classification and characterization of the lesions in critical ill patients	Pressure ulcers associated with medical devices such as nasogastric tubes, endotracheal tubes, neck collars, ECMO cannulas, and external fixators	Retrospective cohort analysis	52.7	56.8	502	3(15)	Nasogastric tubes Endotracheal tubes Neck collars ECMO cannulas External fixators[#]	High

Ham **2017** **Netherlands**	To describe the incidence and characteristics of PUs and the proportions of PUs that are related to devices in adult trauma patients with suspected spinal injury	Pressure injuries related to devices in trauma patients with suspected spinal injury	Prospective cohort study	63.4	52	254	35.9(88)	Cervical collar (48) Wrist/ankle restraints (19) Linen saver (6) ET fixation (3) Urinary tubes (3) Nasogastric tubes (3) Cooling mattress (2) Endotracheal tube (2) Oxygen tube (1) Halo-vest (1)	High
Pellegrino **2017** **Brazil**	To identify the incidence and prevalence of pressure injuries (PIs) in children admitted to hospitals in the city of Sao Paulo, and assess the association between sociodemographic and clinical characteristics with hospital-acquired pressure injuries (HAPIs)	Medical device-related hospital-acquired pressure injuries	Cross-sectional study	57	NP	229	7.9(18)	Nasoenteral tube (9) Intravenous fixation/ bed containment (4) Constant positive airway pressure devices (3) Oximeter sensor (2)	High
Garcia-Molina **2018** **Spain**	To determine the incidence of Pus in hospitalised infants admitted to intensive and intermediate care units, along with relevant risk factors and preventive measures	Pressure injuries attributed to medical devices in the intensive care unit	Cross-sectional study	NP	NP	268	10.7(29)	Non-invasive ventilation Pulse oximetry ECMO Endotracheal tube Nasal cannulas Phototherapy cable[#]	High

NP = not provided, # = specific numbers not reported.

Table 3 Extracted data for studies reporting prevalence of MDRPIs

First Author Year of publication Country	Aim	Operationalised definition	Study design	%Males	Mean age (years)	Sample size	Overall prevalence %(n)	Medical device type (n)	Overall Quality Assessment
Garfin 1986 USA	To evaluate complications associated with the use of halo fixation device	Pressure sores that develop under the halo plaster cast or a prefabricated vest	Cross-sectional study	79.9	28.3	179	11(20)	Halo fixation device (20)	Moderate
Muller 1994 Sweden	To evaluate the effectiveness of Boston brace for halting the progression of scoliosis	Skin problems with an ulceration under the brace pad	Prospective cohort study	42.9	8.9	21	4.8(1)	Brace (1)	High
Watts 1998 USA	To determine the prevalence, location, degree, and predictors of skin breakdown in trauma patients, as well as the diagnosis groups most at risk	Skin breakdown associated with medical devices among trauma patients	Prospective cohort study	68	38	148	23.6(35)	Bed pressure (18) Cervical collar (9) Endo tracheal tube (4) Splint (3) Tape (1)	High
Dixon 2005 USA	To determine whether pressure injuries are, indeed, relatively uncommon in the paediatric population and	Pressure injuries attributed to the use of a continuous positive airway pressure device	Cross-sectional study	NP	NP	156	0.6(1)	CPAP (1)	Moderate

	the unique physiologic and psychosocial needs of children								
Noonan 2006 USA	To describe the spectrum of alterations in skin integrity and skin care needs of hospitalized infants and children	Pressure-related skin injury attributed to pulse oximetry, saturation probes, intravenous catheter hub, leg cast, and electroencephalogram electrodes	Cross-sectional study	52	4.5	252	5.2(13)	Pulse oximeter (10) Intravenous catheter hub (1) Leg cast (1) Electroencephalogram electrode (1)	High
VanGilder 2009 USA	To report the International Pressure Ulcer Prevalence Survey™ in the United States in 2008 and 2009	Facility acquired device-related pressure injuries	Cross-sectional cohort study	NP	NP	6589	11.9(785)	Other medical devices[#]	Moderate
Black 2010 USA	To quantify the extent of medical device related pressure injuries and identify the risk factors for pressure ulcer development in	Hospital-acquired injuries related to medical devices	Cross-sectional study	NP	NP	2079	1.9(39)	Anti-embolism stocking Endo tracheal tube Line tubing Neck collars Splints[#]	High

	hospitalised patients							
Schluer 2012 Switzerland	To assess the prevalence of and risk factors for Pus in pediatric care settings in 14 pediatric hospitals in the German-speaking part of Switzerland	Pressure injuries resulting from medical devices on the patient's body at the time of assessment	Cross-sectional study	NP	NP	337	33(131)	Tubes IV catheters CPAP Splints[#]	High
Coyer 2014 Australia & USA	To determine the prevalence, severity, location, aetiology, treatment and healing of medical device-related pressure injuries in ICU for up to 7 days	Pressure injuries from the use of peripheral IV lines, compression devices, BP cuffs, urinary catheters, oxygen probes, electrocardiogram leads	Prospective cohort study	67	56.0	483	3.1(15)	Endo tracheal tube Nasogastric tube Oxygen tubing Rectal thermometer probe Tracheostomy tube[#]	High
Habiballah 2016 Jordan	To record the prevalence, location and categories of pressure injuries in the inpatient paediatric wards, and to identify the characteristics	Pressure injuries attributed to the use of medical devices in the inpatient paediatric wards	Cross-sectional study	65.1	NP	166	5.4(9)	Other medical devices[#]	Moderate

	of pressure ulcer patients								
Hanonu 2016 Turkey	To determine the prevalence, risk factors, and characteristics of medical device-related hospital-acquired pressure injuries among all patients in five adult intensive care units in a university hospital in Turkey	Medical device-related hospital-acquired pressure injuries	Prospective cohort study	57.1	62.5	175	40(70)	Gastrointestinal/genitourinary devices Monitoring devices Respiratory devices Vascular lines[#]	High
Amirah 2017 Saudi Arabia	To measure the prevalence of MDRPI in the ICU, determine which medical devices were associated with MDRPI, estimate the proportion of MDRPI, and determine the relationship between MDRPI and the following; age, gender, BMI, patient's placement	Pressure injury resulting from medical devices used in the monitoring and treating patients in ICU in a large tertiary care hospital	Cross-sectional study	67.7	50.8	431	32.4(128)	ETT (47) Foley catheter (47) Neck collar (16) NGT (12) Traction equipment (2) Other medical devices (4)	High

	(unit), and hospital length of stay before the ICU admission								
Arnold-Long 2017 USA	To examine the epidemiology of medical device related pressure injuries in 3 long-term acute care hospitals	Medical device-related pressure injuries in long-term acute care hospital setting	Cross-sectional study	NP	NP	304	44.7(136)	Other medical devices (48) Splints/braces/boots (27) Oxygen tubing/ Constant and bilevel positive airway pressure devices (21) Tubing (urine or fecal) (21) Heel relief device (11) Percutaneous endoscopic gastrostomy flange (8)	High
Clark 2017 UK	To identify the prevalence of pressure injuries and incontinence-associated dermatitis in acute and community hospital patients in Wales	Pressure injuries caused through contact with medical devices	Cross-sectional study	44.3	NP	8365	0.4(33)	Other medical devices[#]	High

Hobson 2017 USA	To determine the prevalence of static graduated compression stocking (sGCS)-associated pressure injury among patients in surgical intensive care units	Static graduated compression stocking-associated pressure injury among patients in surgical intensive care units	Cross-sectional study	47.5	64.7	1787	3(54)	Graduated compression stocking (54)	High
Kayser 2018 USA & Canada	To examine the prevalence and characteristics of medical device-related pressure injuries (MDR PIs) in a large, generalizable database	Pressure injuries arising from the use of devices designed and applied for diagnostic or therapeutic purposes	Retrospective cohort analysis	NP	NP	99876	0.6(601)	Nasal Oxygen Ears (213) Cast/Splint (95) Airway Pressure Mask (72) Sequential Compression Devices (62) Endotracheal tube (60) Nasal Oxygen Nose (45) Tracheostomy Neck Plate (44) Nasogastric tube (40) Cervical collar (19) Other/Unknown (154)	High

NP = not provided, # = specific numbers not reported.

3.2 Quality Assessment of Included Studies

A summary of the quality assessment (risk of bias assessment) of included studies is presented in Table 4. There was low risk of selection bias, 86% of included studies reported random selection of participants, and 96% of studies provided sample size justification. Similarly, there was low risk of detection bias as 96% of the studies used validated tools for outcome measurement. However, only 35% of studies reported adjusting for confounders, suggesting high risk of bias in this domain. In addition, assessment of the outcome (medical device-related pressure injuries) was not blind in 80% of the studies, implying high risk of detection bias. With respect to selection and detection bias, the quality of evidence from the included studies is good overall. However, adjustment for confounders and outcome assessment was moderate.

Table 4 Risk of bias for included studies

Incidence Studies							
Publication Year	**First Author**	**Country**	**Selection of participants (selection bias)**	**Justification of sample size (selection bias)**	**Outcome measurement (detection bias)**	**Adjusting for confounders**	**Outcome assessment (detection bias)**
1998	Chendrasekhar	USA	A	A	A	B	B
2003	Curley	USA	A	A	A	A	A
2007	Ackland	Australia	A	A	A	A	B
2009	Schluer	Switzerland	B	A	A	A	A
2011	Jaul	Israel	A	A	A	B	A
2017	Walker	UK	A	A	A	B	A
2014	Jaul	Israel	A	A	A	B	A
2015	Tayyib	Saudi Arabia	A	A	A	A	A
2016	Nist	USA	A	A	A	B	A
2017	Alves	Portugal	A	A	A	A	A
2017	Ham	Netherlands	A	A	A	B	A
2017	Pellegrino	Brazil	A	A	A	B	A

2018	Garcia-Molina	Spain	A	A	A	B	A

Prevalence Studies

Publication Year	First Author	Country	Selection of participants (selection bias)	Justification of sample size (selection bias)	Outcome measurement (detection bias)	Adjusting for confounders	Outcome assessment (detection bias)
1986	Garfin	USA	A	A	B	B	B
1994	Muller	Sweden	A	B	A	A	A
1998	Watts	USA	A	A	A	A	A
2005	Dixon	USA	A	A	A	B	B
2006	Noonan	USA	A	A	A	B	A
2009	VanGilder	USA	B	A	A	B	B
2010	Black	USA	A	A	A	A	A
2012	Schluer	Switzerland	A	A	A	B	A
2014	Coyer	Australia & USA	A	A	A	B	A
2016	Habiballah	Jordan	B	A	A	B	A
2016	Hanonu	Turkey	A	A	A	A	A
2017	Amirah	Saudi Arabia	B	A	A	A	A
2017	Arnold-Long	USA	A	A	A	B	A
2017	Clark	UK	A	A	A	B	A
2017	Hobson	USA	A	A	A	B	A
2018	Kayser	USA & Canada	A	A	A	A	A

Key:

Selection of participants: (A) random sampling, (B) non-random sampling, (C) selected group of users, (D) no description of sampling strategy

Justification of sample size: (A) justified and satisfactory, (B) non-justification

Outcome measurement: (A) validated measurement tool, (B) tool described but non-validated, (C) tool not described

Adjusting for confounders: (A) adjusted for confounders, (B) no adjustment for confounders

Outcome assessment: (A) independent blind assessment, (B) record linkage, (C) self-report, (D) no description

3.3 Pooled Incidence of medical device-related pressure injuries

Thirteen studies reported incidence of medical device-related pressure injuries; amongst them, ten studies were conducted among adults, and, three studies were conducted in children. The estimated pooled incidence of medical device-related pressure injuries was 12% (95% CI 8 – 18). The incidence of medical device-related pressure injuries among the adult population was 14% (95% CI 8 – 21), while, the incidence of medical device-related pressure injury among children was 9% (95% CI 7 – 11). Studies conducted with adults had a considerable amount of heterogeneity (I^2 = 95.9%, p = <0.001), however, heterogeneity was not reported for studies conducted with children [perhaps owing to the small number of studies (n = 3)]. The reported heterogeneity between the two groups (adults and children) was not statistically significant (p = 0.125) (refer to Figure 2).

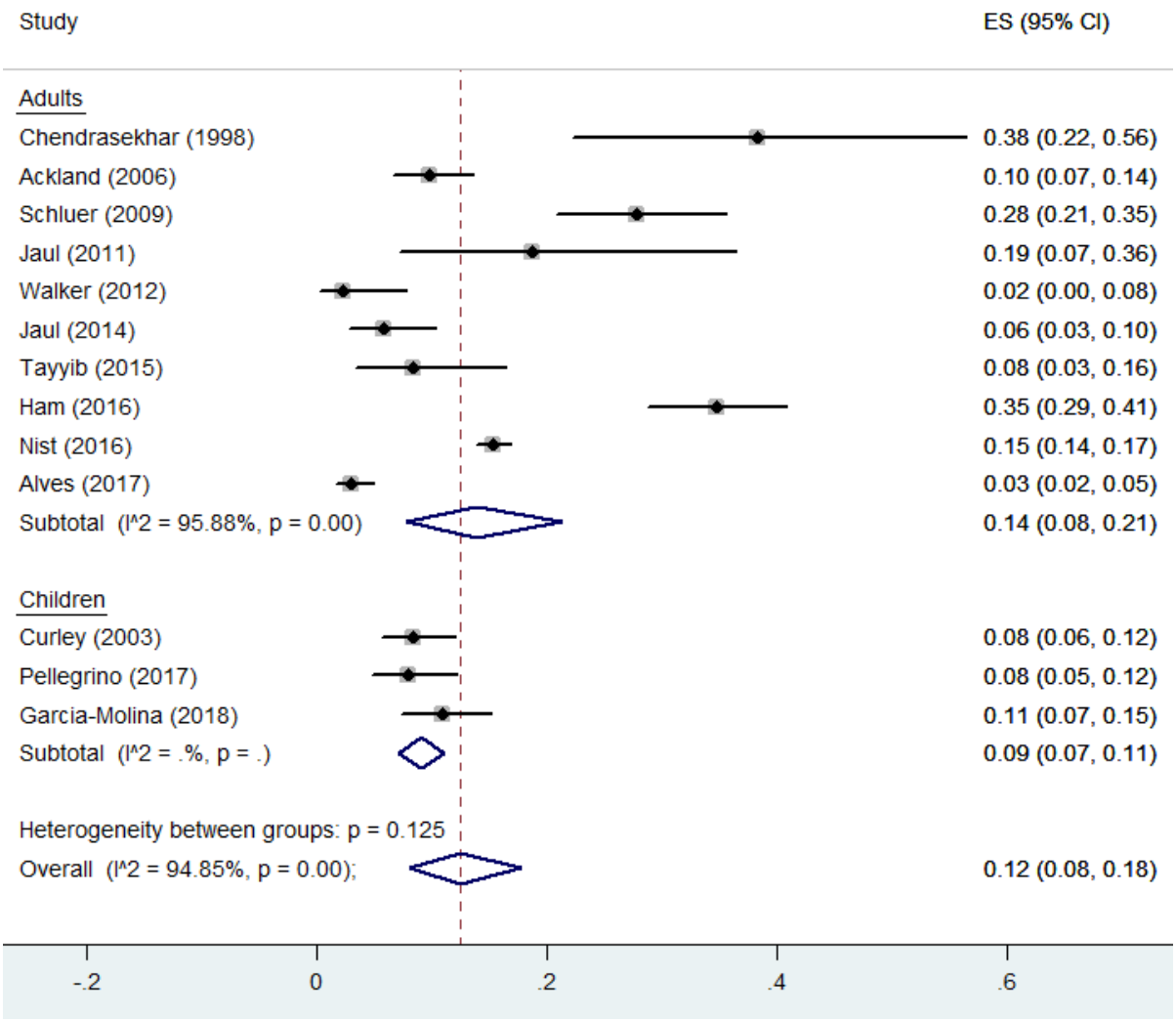


Figure 2 Forest plot showing incidence of medical device-related pressure injuries in adults, children, and overall

3.4 Pooled Prevalence of medical device-related pressure injuries

Fourteen studies reported prevalence of medical device-related pressure injuries, ten studies were conducted among adults, and, four studies were conducted in children. The estimated pooled prevalence of medical device-related pressure injuries was 10% (95% CI 6 – 16). The prevalence of medical device-related pressure injuries among the adult population was 11% (95% CI 6 – 18), while, the prevalence among children was 8% (95% CI 1 – 21). The heterogeneity between the two groups (adults and children) was not statistically significant (p = 0.66) (refer to Figure 3).

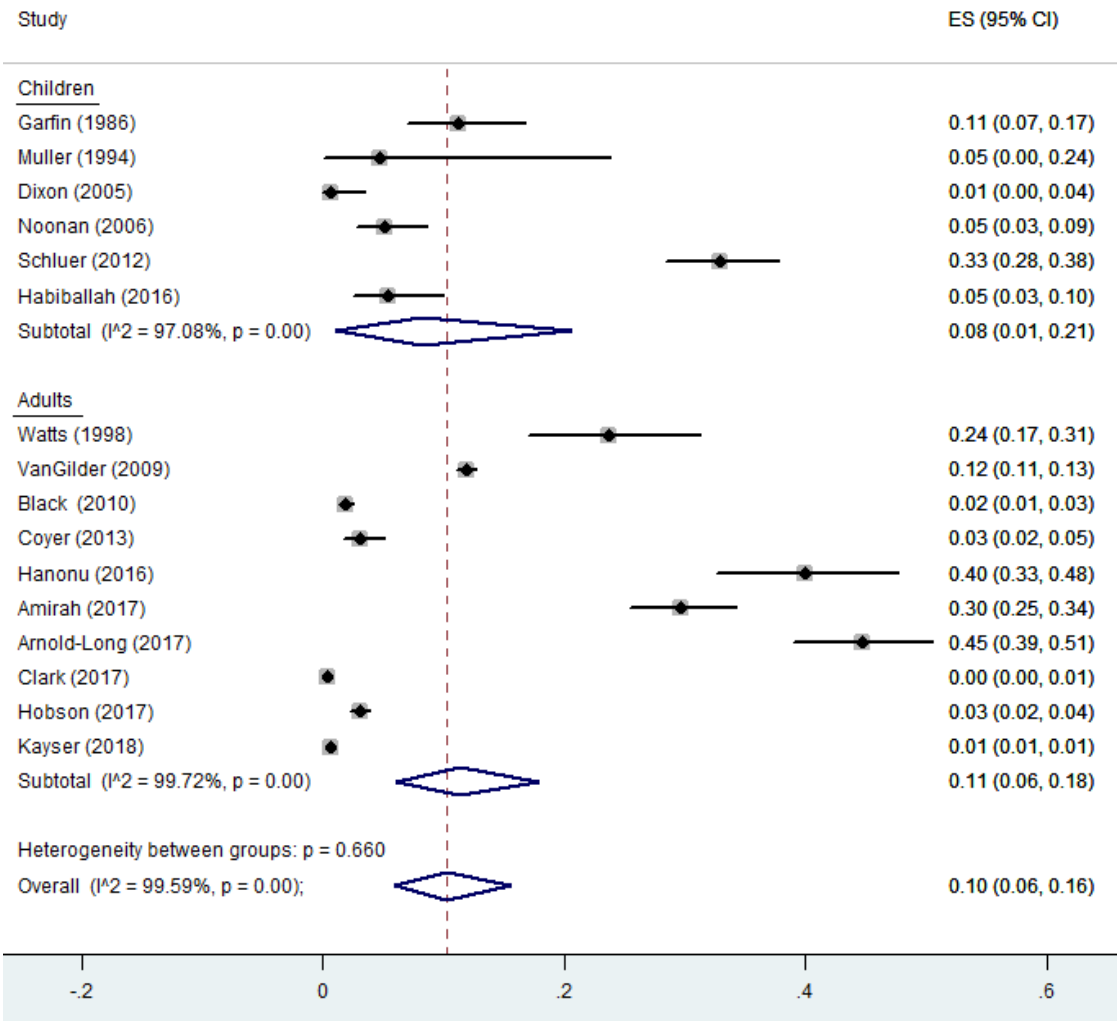
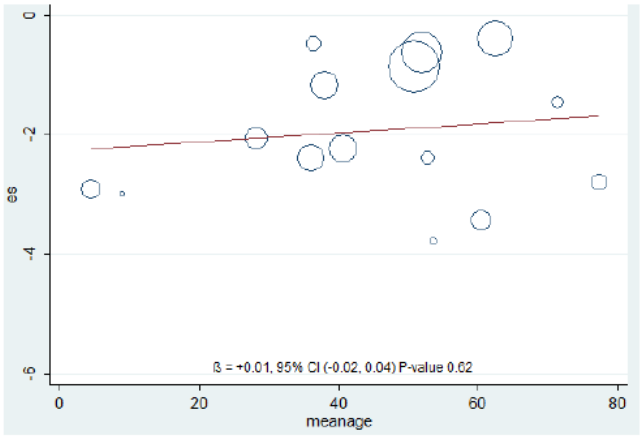


Figure 3 Forest plot showing prevalence of medical device-related pressure injuries in adults, children, and overall.

The major difference in the results of the two different study designs (cross-sectional vs cohort) was with respect to the quality assessment, where, the cohort studies were of higher quality than the cross-sectional studies. However, the sample sizes and measures of occurrence (prevalence and incidence) were comparable between the two study designs.

3.5 Results for Meta-regression Analysis

From the meta-regression analysis, differences in study design (β = +0.80, 95% CI [-0.36 to 1.95], p = 0.17), mean age (p = 0.62) and gender (p = 0.08) between studies did not account for the observed heterogeneity in this review (refer to Figure 4 for coefficients and 95% CI for mean age and gender).



4a: Meta-regression of MDRPIs against mean age

4b: Meta-regression of MDRPIs against gender

Figure 4 Bubble plots showing the results of meta-regression analysis

4 DISCUSSION

This systematic review and meta-analysis provides up-to-date knowledge on medical device-related pressure injuries in adult and paediatric populations, with identification of related medical devices. Both estimates of proportion (pooled incidence 12%; adults 14%, children 9%) and (pooled prevalence 10%; adults 11%, children 8%) from this review show that patients treated or managed with medical devices are prone to developing pressure injuries. From the risk of bias assessment of the included studies the strength of this evidence is reliable (see online supplementary material). These findings corroborate the results of other studies, for example, a literature review conducted to determine the frequency of pressure injuries among paediatric populations (Kottner et al., 2010) reported the incidence of pressure injuries at approximately 7% and the prevalence ranging between 2% - 28%. Similarly, an integrative review (Murray et al., 2013) on medical device-related hospital-acquired pressure injuries in children inferred that medical device-related pressure injuries are becoming more frequent in paediatric practice.

The commonly identified medical devices associated with the risk of developing medical device-related pressure injuries from this review include respiratory devices, cervical collars, tubing devices, splints, and intravenous catheters. The association of these medical devices with medical device-related pressure injuries have been reported in previous studies including (Baharestani and Ratliff, 2007; Apold and Rydrych, 2012; Black and Kalowes, 2016).

A strength of this this review is the inclusion of studies conducted with patients below 18 years of age including neonates and paediatrics- a significant patient population that are often excluded from pressure injuries studies due to anatomic and physiologic factors (Dixon and Ratliff, 2005). Specifically, the softer muscles and fat tissues of neonates and paediatrics compared to adults, and the unique set-up of neonatal and paediatric intensive care units (often overloaded with medical devices) predispose children to be easily vulnerable to skin deformations such as device-related pressure injuries (Levy et al., 2015). Other plausible reasons for the observed difference between the pooled estimates (prevalence and incidence) in adults and children could be insufficient reporting (Murray et al., 2013) and methodological limitations (Kottner et al., 2010) including variation in sampling, study design, and instruments used for assessing the pressure injuries.

Findings of this review have implications for practice, as medical devices are increasingly being used in the diagnosis, treatment, and management of patients (NPUAP, 2014b; Holden-Mount and Sieggreen, 2015; NICE, 2015). Moreover, given that these medical devices are associated with the development of pressure injuries, health care providers must develop robust prevention strategies for averting medical device-related pressure injuries. The prevention strategies could include higher levels of vigilance, involving nursing staff in product selection, and quality improvement initiatives (Haugen, 2015), and more efficient strategies for reporting and recognising devices that represent higher pressure ulceration, informing manufacturers and exerting pressure for device redesign to enhance patient safety.

In addition, policies and documentation of the prevention of medical device-related pressure injuries are required, as currently, commonly documented preventive measures include repositioning medical devices at regular intervals, adding protective layers between the skin and medical devices, securing devices with appropriate tapes to prevent continuous movement of the devices and friction to the skin, and monitoring skin moisture (Holden-Mount and Sieggreen, 2015; Latimer et al., 2017). Furthermore, the commonly used pressure injury risk assessment tools (Norton et al., 1962; Braden and Bergstrom, 1988; Waterlow, 2005) are inadequate in assessing risks of developing medical device-related pressure injuries for several reasons. Many medical device-related pressure injuries occur on mucosal tissue which does not respond to pressure in the same way as epidermal tissue, making current pressure assessment ineffective for

medical device-related pressure injury. Therefore, further research is required to develop risk assessment tools specifically for identifying patients at risk of developing medical device-related pressure injuries.

A major limitation of this review is that many of the included studies did not report baseline variables such as the socio-demographic characteristics of the participants (including age groups, gender, educational status, wealth status), and length of stay in the health facilities with the medical devices. This prevented a subgroup analyses to estimate the incidence or prevalence of medical device-related pressure injuries using each variable.

Estimates of prevalence and incidence of medical device-related pressure injuries from different countries were pooled in this meta-analysis, and as expected, high heterogeneity between studies was found. The observed high heterogeneity was explored by age and gender using a meta-regression analysis, although the results did not show any statistical significance, we hypothesize that the substantial amount of the heterogeneity across studies could be explained by factors such as differences in clinical environments, patient characteristics, types of devices, and stages of the pressure injuries. Despite the presence of a considerable amount of heterogeneity observed in this review, previous evidence has shown that meta-analyses are the preferred options to narrative syntheses for interpreting results in reviews involving quantitative data, (Higgins, 2008). It is also important to note that heterogeneity appears to be the norm rather than exception in published meta-analyses of observational studies (Higgins, 2008), in which case, it should be expected and quantified appropriately as was the case in this review.

In addition, possible relevant databases such as EMBASE and Scielo were not used. Reports in languages other than English were not included. It is likely that important information reported in languages other than English exists and exclusion from this study might limit this review. Many of the included studies reported more than one medical device responsible for the pressure injuries without a breakdown of the number of patients that were managed with each device, again preventing a subgroup analyses to determine the incidence or prevalence of medical device-related pressure injuries attributable to each device. Furthermore, all included studies reported hospital-based populations and so this review does not capture home-dwelling people with medical device related injuries.

5 CONCLUSION

Medical devices used for diagnostic, preventive, or therapeutic purposes may have unintended consequences on patients such as medical device-related pressure injuries. Device-related pressure injuries are among key indicators of patient safety and nursing quality in healthcare facilities. Hence, establishing preventive measures for medical device-related pressure injuries are required. In addition, further research is required to inform strategies for increasing the reporting and risk assessment of medical device-related pressure injuries. Future studies should also provide information on medical device-related pressure injuries by gender, age, socioeconomic status of patients, and total device days. Providing this information will inform effective strategies for preventing medical device-related pressure injuries in future.

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