Running title

Live birth rate and oocyte donor age

Title

Oocyte donor age has a significant impact on oocyte recipients' cumulative live birth rate: a population-based cohort study.

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CAPSULE

Recipients using oocytes from donors aged ≥35 years had a significantly lower cumulative live birth rate (CLBR) when compared to recipients using ooctyes from donors aged <35 years.

STRUCTURED ABSTRACT

Objective: To study the impact of the donor's and recipient's age on the cumulative live birth rate (CLBR) in oocyte donation cycles?

Design: A population-based retrospective cohort study

Setting: Data obtained from the Victorian Assisted Reproductive Treatment Authority (VARTA) in Victoria, Australia.

Patient(s): All women using donated oocytes (n = 1,490) in Victoria, Australia between 2009 and 2015 were included.

Intervention(s): None

Main Outcome Measure(s): The association between the donor's and recipient's age and CLBR was modelled by multivariate Cox proportional hazard regression with the following covariates adjusted for: male partner's age, recipient parity and cause of infertility. Donor age was grouped as <30, 30-34, 35–37, 38-40 and ≥41 years, and recipient age as <35, 35–37, 38–40, 41-42, 43-44 and ≥45 years.

Results: The mean age of the oocyte donors was 33.7 years (range 21 to 45 years) with 49% aged 35 years and over. The mean age of the oocyte recipients was 41.4 years (range 19 to 53 years) with 25.4% aged ≥45 years. There was a significant relationship between the

donor's age and the CLBR. The CLBR for recipients with donors aged <30 years and 30-34 years was 44.7% and 43.3% respectively. This decreased to 33.6% in donors aged 35-37 years, 22.6% in donors aged 38–40 years and 5.1% in donors aged ≥41 years. Compared with recipients with donors aged <30 years, recipients with donors aged 38-40 years had 40% less chance of achieving a live birth (AHR 0.60, 95% CI 0.43–0.86) and recipients with donors aged ≥41 years had 86% less chance of achieving a live birth (AHR 0.14, 0.04–0.44). The multivariate analysis showed no significant effect of the recipient's age on CLBR.

Conclusion: We demonstrate that the age of the oocyte donor is critical to the CLBR and is independent of the recipient woman's age. Recipients using oocytes from donors aged ≥35 years had a significantly lower CLBR when compared to recipients using ooctyes from donors aged <35 years.

Key Words: oocyte donor, oocyte recipient, cumulative live birth rate, donor age, ART

Introduction

Since the world's first live birth using donated oocytes was reported in 1984 (1) the number of oocyte donation cycles has grown considerably. Currently, in Australia, oocyte donation represents 5.6% of all assisted reproductive treatment (ART) cycles (2), while in Europe and the United States it accounts for approximately 4.5% (3) and 12% (4) respectively. Oocyte donation is an important component of ART particularly for women with age-related infertility, poor ovarian reserve, and for women who carry genetic abnormalities (5).

In Australia, only altruistic gamete donation is permitted. Altruistic donors are usually parous and cohabiting or married, unlike the majority of compensated donors who are nulliparous and single (6). This may partly explain why altruistic donors are on average are older than compensated donors. The average age of women donating oocytes in Australia in 2016 was 32.6 years, with 40.8% of cycles involving donors aged 35 or older (2). Apart from compensation for expenses incurred as a result of donating oocytes, a donor cannot receive any payment or other inducement as per the Prohibition of Cloning Act 2002 (7). Furthermore, the Australian National Health and Medical Research Council (NHMRC) Ethical Guidelines (8) and the Fertility Society of Australia Reproductive Technology Accreditation Committee (RTAC) Code of Practice (9) stipulate that children born as a result of oocyte donation have the right to access information about the donor when they reach the age of 18.

Cycle-based evidence shows that live birth rates with oocyte donation are dependent on the age of the donor, where recipients with younger donors have a higher live birth rate than those with older donors (10). There is also evidence showing a relationship between ART outcomes and uterine receptivity in older oocyte recipient women. In 2002, Toner et al. (11)

performed a retrospective analysis of oocyte donation data gathered by the Society for Assisted Reproductive Technology (SART) registry. They found ART outcomes declined in recipients >45 years and declined further in recipients >50 years. Similarly, Yeh and colleagues found that recipients on the SART database between 2008 and 2010 had stable rates of pregnancy outcomes <45 years but this declined in recipients >45 years (12). They conclude that there is relationship between ART outcomes, oocyte donor age and uterine receptivity in older women.

However, there is no international agreement on "how old is too old". It is known that women over 35 years have a higher aneuploidy rate and fewer oocytes retrieved following hormonal stimulation than younger women (13). Therefore, ideally oocyte donors are women in their 20's and early 30s, who are in good health and free from heritable conditions (14, 15). In Australia, it is recommended that clinics do not use oocytes provided by 'older' donors, though no upper age limit is specified (8). However, because of the shortage of donors, most recipients use a willing friend or relative as their donor and ART clinics accept them irrespective of their age (16). Hence, women older than 35 years are accepted when they donate to a specific recipient, who has been counselled about the implications of the donor's age. Similarly in countries in Europe, where commercial donation is prohibited, the upper age limits of oocyte donors may be interpreted flexibly in cases of direct donation because there is a great scarcity of donors and thus no alternative (13).

When a woman or couple enquire about oocyte donation they want to know if the treatment will result in a healthy baby (17). Artificial reproductive technology success rates following oocyte donation are usually presented as outcome per cycle or embryo transfer according to donor's age (18). However, Malizia and colleagues (17) maintain that this

statistic has limited value because it does not account for the additional chance offered by frozen embryos resulting from a stimulated cycle. It is argued that the CLBR has more significance for recipients and clinicians because it provides an overall estimate of the chance of having a baby following one stimulated cycle (19). The purpose of this population-based cohort study is to provide population statistics on the effect of the oocyte donor's and recipient's age on the CLBR in oocyte donation cycles.

Materials and Methods

Data

In the state of Victoria in Australia, only registered ART providers can offer ART. Data used in this study are collected from all registered ART providers in Victoria by the Victorian Assisted Reproductive Treatment Authority (VARTA) and the University of Technology Sydney (UTS). VARTA is a statutory authority funded by the Victorian Department of Health and Human Services in Victoria. Among its obligations, VARTA is responsible for monitoring and reporting on all ART procedures carried out in registered clinics.

All women using donated oocytes (n = 1,490) in Victoria, Australia between 2009 and 2015 were included. This included women since 2013, who obtained donor oocytes from The World Egg Bank in the United States.

Data collected for oocyte recipient cycles include age, parity, cause of infertility, number of oocytes donated and received, fertilization procedure (IVF or ICSI), stage of embryo at transfer, and number of fresh and thawed embryos created and transferred. Data on the outcomes of resulting pregnancies and births, including birth status, gestational age, birth weight and congenital anomalies, are also collected.

Data on fresh and frozen embryo transfers following oocyte donation undertaken from 1 July 2009 to 30 June 2016, or until a live birth was achieved, and resulting pregnancy and birth outcomes were extracted from the VARTA database and are included in this study.

Study factors

The donors' ages were calculated in completed years at the time of oocyte donation and classified into five groups: <30, 30-34, 35–37, 38-40, and ≥41 years. The recipients' ages were calculated at the time of first transfer and categorized into six groups: <35, 35–37, 38–40, 41-42, 43-44, and ≥45 years. The cause of infertility was classified as male factor infertility, female factor infertility, combined male-female factor infertility, unexplained infertility and not stated.

Previous pregnancy of ≥20 weeks gestation was grouped as yes, no and not stated. Fertilisation procedure was either IVF or ICSI. Stage of embryo development was grouped into cleavage or blastocyst stages. The number of embryos transferred in each cycle was grouped as one or two embryos.

Main outcome measure

The primary outcome was the cumulative live birth rate (CLBR), defined as at least one live birth following one oocyte donation, including fresh and any associated frozen embryo transfers. A live birth was defined as a baby showing signs of life with gestational age ≥ 20 weeks or birthweight ≥ 400 grams. The observed CLBR was reported using the conservative assumption that women who did not return for treatment did not have a pregnancy resulting in a live birth.

Statistical analysis

Chi-squared test was used for categorical variables. Cox regression was used to model the association between the donor's and recipient's age and CLBR. The adjusted hazard ratio (AHR) and 95% confidence intervals (CI) were calculated. Adjustment was made for the male partner's age, recipient parity (nulliparous/parous) and, cause of infertility (male only/female only/combined male-female/unexplained). A p-value <0.05 was considered statistically significant. All statistical analysis was performed using SPSS 24.0 software (Armonk, NY, USA: IBM Corp.).

Ethics

Ethics approval for this study was granted by the Human Research Ethics Committee of the University of Technology Sydney, Australia (UTS HREC REF NO. ETH16-0800). Access to the VARTA data was granted by VARTA.

Results

In all 1490 oocyte recipients had 2919 fresh and frozen embryo transfer cycles. Characteristics of donors and recipients are shown in Table 1. The mean age of the oocyte donors was 33.7 years (range 21 to 45 years) with 50.4% aged <35 years. The mean age of the oocyte recipients was 41.4 years (range 19 to 53 years) with one quarter (25.4%) aged ≥45 years. Overall one in five recipients (21.9%) had a history of a previous pregnancy ≥20 weeks. The mean number of oocytes received was 11.93 (range 11.28 to 12.51) and was similar across all recipient age groups.

Table I: Selected demographics of participants in oocyte donor/recipient cycles

	Oocyte recipients' age group (years)						
	<35 (n=191)	**35-37 (n=171)**	**38-40 (n=246)**	**41-42 (n=234)**	**43-44 (n=270)**	**≥45 (n=378)**	**All ages (n=1,490)**
Donors' age group (years)							
Mean (yr)	32.8	33.9	34.9	33.9	33.5	33.2	33.7
< 30	44(23.1)	31(18.2)	26(10.6)	40(17.1)	59(21.9)	93(24.6)	293(19.7)
30-34	80(41.9)	53(31.0)	75(30.5)	69(29.5)	73(27.0)	107(28.3)	457(30.7)
35-37	42(22.0)	57(33.3)	81(32.9)	72(30.8)	68(25.2)	94(24.9)	414(27.8)
38-40	23(12.0)	25(14.6)	46(18.7)	39(16.6)	51(18.9)	50(13.2)	234(15.7)
≥41	2(1.0)	4(2.3)	16(6.5)	12(5.1)	17(6.3)	27(7.1)	78(5.2)
Unknown	0(0)	1(0.6)	2(0.8)	2(0.9)	2(0.7)	7(1.9)	14(0.9)
All	**191(100)**	**171(100)**	**246(100)**	**234(100)**	**270(100)**	**378(100)**	**1490(100)**
Infertility diagnosis (%)							
Male factor	22(11.5)	24(14.0)	29(11.8)	26(11.1)	37(13.7)	45(11.9	183(12.3)
Female factor	54(28.3)	40(23.4)	59(24.0)	46(19.7)	63(23.3)	10126.7)	363(24.4)
Combined male/female	33(17.3)	34(19.9)	38(15.4)	44(18.8)	37(13.7)	61(16.1)	247(16.6)
Unexplained	18(9.4)	16(9.4)	27(11.0)	23(9.8)	27(10.0)	45(11.9)	156(10.5)
Not stated	64(33.5)	57(33.3)	93(37.8)	95(40.6)	106(39.3)	126(33.3)	541(36.3)
Previous pregnancy of ≥20 weeks gestation	27(14.1)	35(20.5)	55(22.4)	54(23.1)	50(18.5)	106(28.0)	327(21.9)

The proportion of blastocyst transfer observed in cycles of recipients aged <35 years (50.2%) was not significant when compared to older recipients (45.2%). Double embryo transfer accounted for 23.4% of all embryo transfers and was most common in recipients in the 35-37 years age group (29.9%) (Table 2). There were 44 twin births, of which 38 (86.4%) occurred following double embryo transfers. We observed that the age of the oocyte donor did not have an affect the number of embryos that were transferred to the recipient.

Table II: Treatment factors of embryo transfer cycles

	Oocyte recipient's age group (years)						
	<35 (n=191)	**35-37 (n=171)**	**38-40 (n=246)**	**41-42 (n=234)**	**43-44 (n=270)**	**≥45 (n=378)**	**All ages (n=1,490)**
Fertilization procedure							
ICSI[a]	227(83.2)	212(83.5)	342(89.8)	328(90.4)	393(88.1)	590(87.3)	2092(87.4)
Stage of embryo development							
Blastocyst	137(50.2)	117(46.1)	174(45.7)	159(43.8)	194(43.5)	316(46.7)	1097(45.8)
Number of embryos transferred							
1	207(75.8)	178(70.1)	289(75.9)	278(76.6)	333(74.7)	574(80.9)	1832(76.6)
2	66(24.2)	76(29.9)	92(24.1)	85(23.4)	113(25.3)	129(19.1)	561(23.4)
Total	**273**	**254**	**381**	**363**	**446**	**676**	**2393**

[a]Intracytoplasmic Sperm Injection

The CLBR ranged from 31.7% among recipients aged 38-40 years to 41.4% among recipients aged <35 years. The multivariate analysis showed no significant differences in the success by recipient's age (Table 3). The CLBR by cycle is provided in the Supplementary Tables (1-7).

Table III: Cumulative live birth rates in oocyte recipient cycles by age of recipients and donors

	Cumulative Live birth		
	Rate (%)	**HR hazard ratio**	**AHR adjusted hazard ratio**
Recipient's age (years)[a]			
<35	41.4%	Ref	Ref
35-37	38.0%	0.93(0.67,1.29)	1.07(0.73,1.56)
38-40	31.7%	0.71(0.52,0.97)	0.90(0.62,1.30)
41-42	32.9%	0.77(0.56,1.06)	0.88(0.59,1.30)
43-44	37.8%	0.88(0.65,1.17)	1.06(0.73,1.54)
≥45	33.3%	0.74(0.56,0.98)	0.92(0.63,1.33)
Donor's age (years)			
<30	44.7%	Ref	
30-34	43.3%	1.01(0.81,1.26)	1.07(0.84,1.36)
35-37	33.6%	0.75(0.59,0.96)	0.80(0.61,1.03)
38-40	22.6%	0.55(0.40,0.75)	0.60(0.43,0.86)
≥41	5.1%	0.13(0.05,0.36)	0.14(0.04,0.44)

[a]Adjustment was made for male age, parity and cause of infertility

There was a significant association between the donor's age and CLBR. The CLBR for recipients with donors aged <30 years and 30-34 years was 44.7% and 43.3% respectively.

This decreased to 33.6% in donors aged 35-37 years, 22.6% in donors aged 38-40 years and 5.1% in donors aged ≥41 years. Compared with recipients with donors aged <30 years, recipients with donors aged 38-40 years had 40% less chance of achieving a live birth (AHR 0.60, 95% CI 0.43–0.86) and recipients with donors aged ≥41 years had 86% less chance of achieving a live birth (AHR 0.14, 0.04–0.44) (Table 3).

When oocyte recipient and donor ages were combined the highest cumulative live birth rate was in recipients aged 35-39 years with donors aged <30 years (51.1%). The lowest cumulative live birth rate was in recipients aged ≥45 years and donors aged ≥40 years (5.3%) (Table 4).

Table IV Cumulative live birth rate by recipient and donor ages

Donor age	**Recipient age**				
	<35	**35-39**	**40-44**	**≥45**	**All**
<30	50.0%	51.1%	40.4%	44.1%	44.7%
30-34	46.3%	42.4%	47.2%	35.5%	43.3%
35-39	28.8%	30.7%	30.3%	33.8%	31.0%
≥40	37.5%	10.0%	10.4%	5.3%	10.5%
All	**41.4%**	**35.3%**	**34.8%**	**33.3%**	**35.4%**

Discussion

This population-based cohort study, on outcomes of oocyte donation, found that recipients with donors aged 35 years or older had a significantly lower CLBR, regardless of the recipient's age. To the best of our knowledge, there are no other studies that have evaluated the CLBR in women who have received donated oocytes.

The mean age of the oocyte donors in this study was 33.7 years. This is significantly older than the average age of donors in European (13) and United States (20) studies of 27.4 years

and 28 years respectively. In Australia, only altruistic gamete and embryo donation is permissible but there are no regulations that set an age limit for oocyte donation (8, 9). Artificial reproductive technology clinics accept older donors because the demand for donated oocytes exceeds supply (16). This may in part explain the finding that almost half (49%) of the oocyte donors in this study were 35 years of age or older. This is similar in the United Kingdom where only altruistic oocyte donation is permitted and the upper age limit of women donating oocytes may be interpreted flexibly because of the scarcity of donors (13).

The mean age of the oocyte recipients in this study was similar to the ages of recipients reported in studies in the United States (20) and the United Kingdom (13). A range of circumstances can lead women of advanced reproductive age to request oocyte donation to overcome age-related infertility such as having experienced repeated fertility treatment failure, being single or finding a partner later in life, being in a second long-term relationship, or having experienced the loss of a child (5, 21). Younger women may also need oocyte donation if their fertility has been compromised by gonadotoxic agents (for example due to chemotherapy) or if they have a genetic inheritable disorder or primary ovarian insufficiency (12).

In the current study we were not able to confirm if the women donating oocytes were known to the recipients because this information is not collected by VARTA. As Australian women must rely on altruistic egg donors, the donors are often family members, close friends, or colleagues who may be closer in age to the recipients than compensated donors might have been (22). Additional to local donation, patients in Victoria have legally been able to recruit oocyte donors from The World Egg Bank since 2013.

Intrafamily donation is not uncommon and generally regarded positively. One of the first studies to report on this was by Sauer and colleagues (23) who surveyed a small group of couples undergoing IVF with donated oocytes. They concluded that the acceptability of using a sister for gamete donation is high among couples desiring oocyte donation. More recent studies also demonstrate that women prefer sisters as their donors because they value the genetic connection with the child (24, 25). A recent survey of more than 2000 United States residents by Bortoletto et al. (26), reported that oocyte donation from a family member was viewed favourably by 86% of the respondents as it made access to oocytes a reality for infertile individuals or couples.

Oocyte Ageing

Previous studies on oocyte donation have indicated that oocyte ageing makes a much larger contribution than uterine deterioration to the age-related decline of fecundity and that oocytes from younger donors markedly improves the chances of pregnancy in women of advanced reproductive age (10, 27, 28). This is supported by the findings of the current study: when the oocyte recipients' and donors' ages were combined, (i) the highest CLBR was in recipients aged 35-39 years with donors aged <30 years (51.1%), and (ii) the lowest CLBR was in recipients aged ≥45 years with donors aged ≥40 years (5.3%). However, if a recipient woman aged ≥40 years received oocytes from a donor ≤34 years, they had a similar chance of having a live birth as a younger recipient with a young donor. In order to eliminate the possibility of a confounder, we adjusted for both the age of the donor and the age of the recipient and there was no similarity found between their ages.

When looking at the donor's age alone, the CLBR was 5.1% for recipients with donors aged over 41 years. The latest Australian and New Zealand Assisted Reproductive Data report

shows that the cycle specific live birth rate for women aged 40-44 years using their own eggs was 4.9% after the fourth cycle and 3.9% after eighth cycle (2). This indicates that the age of oocyte is a critical factor and lends support to the requirement for an upper age limit for oocyte donors. Recipients with donors aged 40 or younger can succeed one live birth per every five oocyte donation/recipient arrangements.

The need to move to reporting CLBR based on individual patient data, rather than live birth rates per cycle, has been highlighted (17, 19). Currently, the success rate of ART is generally reported as the number of clinical pregnancies or live births per single fresh or frozen/thaw embryo transfer. McLernon and colleagues (18) agree that the CLBR is more meaningful to women/couples and clinicians than cycle-based success rates making the results of this study relevant for clinicians and patients.

Study Limitations

A limitation of this population-based study is the lack of information available on clinic-specific protocols and processes for ART and the potential impact of these on clinical outcomes. The management of both female gametes (such as oocyte degeneration and choice of ICSI timing) and male gametes (such as DNA fragmentation) may affect the efficacy of ART treatments (29). Further studies are required to evaluate the influence of these kinds of technical aspects on clinical outcomes. Demographic confounders including obesity and cigarette smoking, medical complications and other residual confounders, which may have affected the findings of this study, are not recorded in the VARTA dataset. In addition, information about the cause of infertility was not recorded in around one third of cases. While judged as unlikely, these missing data may have influenced the study findings.

CONCLUSION

In conclusion, this study suggests that the age of the oocyte donor is critical to the CLBR and is independent of the recipient woman's age. The cumulative success rates derived from the present data can be used in the counselling of couples at the start of treatment or when making decisions about treatment continuation, if one or more cycles have been unsuccessful. The findings of this study lend support to the requirement for an upper age limit for oocyte donors. From a public health perspective, there is justification for advocating oocyte donors, ideally ≤35 years but under 41 years, with the aim to reach above 20% CLBR.

Author's roles

All authors contributed to the conceptualisation of the study. A.Y.W. designed the study; Z.L. carried out the statistical analyses; and R.H. drafted the manuscript. All authors contributed to the interpretation of the data and critically revised and approved the final manuscript.

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Conflict of interest

None

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