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Risks and Benefits of Single Blastocyst Transfer versus Double Blastocyst Transfer; Helping Patients Make Informed Choices

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Abstract

The rate of twin births has increased in Ireland by 22.5% since 2005. Twin pregnancies are associated with higher maternal and fetal morbidity, higher economic burden on families and health system. The aim of the study is to compare clinical pregnancy rates in patients, who underwent a single blastocyst transfer (SBT), double blastocyst transfer (DBT), or triple blastocyst transfer (TBT).

This is a retrospective study of women with a previous failed embryo transfer (ET) who underwent a subsequent frozen-thawed ET. All elective blastocyst transfers were analyzed in two centers from for 3 and 5 years respectively. Data was subdivided into 3 age groups: <35, 35- 39 and ≥ 40. Clinical pregnancy rates were evaluated within each group depending whether they had a SBT, DBT or TBT.

There were a total of 1335 women within study period. There were 294 (30.3%), 163 (47.0%) and 11 (58%) clinical pregnancies in the SBT, DBT and TBT groups respectively. In the SBT group, there were 9 twin pregnancies out of 294, (3.1%). In the DBT group, 43 of 163 (26.4%) were twin pregnancies. The DBT group showed an 8.5-fold increased rate of twin pregnancies, compared to the SBT group (P< 0.00001).In conclusion clinicians must take time to discuss the benefits of single blastocyst transfer and the risks associated with double blastocyst transfer ensuring patients informed decision.

Keywords: Single blastocyst transfer; Double blastocyst transfer; Assisted reproductive technology; Infertility; Patient information; Informed choice

Introduction

Today, 1 in 6 couples will experience some form of infertility at least once during their reproductive life. Ferraretti et al., [1] showed that the prevalence of infertility in Europe is around 14%. Infertility is an upsetting experience for couples; it can be primary where a couple has never conceived within one year of unprotected sexual intercourse or secondary where couples have previously conceived. The contributors to infertility consist of female factors (30%) such as tubal disease, endometriosis, cervical and ovulatory disorders; in addition to male factors (30%) such as poor sperm parameters and also genetic causes. Unexplained causes contribute to around 30-40% of infertility cases, were complex female and male factors may coexist (National Institute for Health and Clinical Excellence [NICE], 2013 [2], Clinical Guidance [CG] 156). The main influence on infertility in the 21st century is the delay of first births till an older age where reproductive ability is poorer. The mean age of women at the birth of their first child has increased in Ireland from 28.8 in the year 1980 to 32.7 in 2016 [3]. This is one of the causes of an increase in the use of assisted reproductive technology (ART). A study, by Cetin, Kumtepe, Kiran, & Seydaoglu [4], reported that success rates regarding ART are adversely affected by the progression of maternal age, resulting in a diminishing ovarian reserve and a falling anti-Mullerian hormone (AMH) where the quality of embryos produced decreases with a subsequent increased risk of aneuploidy [5].

AMH, produced by granulosa cells, can be used to assess ovarian function and reduction in ovarian reserve at an early stage [6]. AMH plays a vital role in evaluating ovarian reserve and its predictive abilities for controlled ovarian hyperstimulation (COH), according to Tobler et al. [5].

Women in their late 30's are described as being of advanced maternal age when trying to conceive. Implantation rates are adversely affected by maternal age, with a rate of 7% per year drop in implantation rates reported for women under the age of 37 and up to a 20% drop in implantation rates observed in women over 37 years of age [7]. Despite a drastic decrease in pregnancy and live birth rates amongst women over 40 years of age, the percentage of this age group seeking ART and IVF treatment is increasing, concluded by Serour et al., [8]. With the increase of pregnancies due to IVF treatment amongst the >40 age group, Min, Breheny, Maclachlan, & Healy's report [9], concluded that both maternal and fetal pregnancy complications are increasing, raising the economic burden on families and healthcare systems. IVF and ART pregnancies are associated with a higher risk of prematurity, low birth weight and increased hospital stay. It has been reported that singleton pregnancies secondary to ART have no significant increase in fetal growth restriction, aneuploidy, or fetal anomalies, though the use of IVF has been found to be associated with a significant increase in preeclampsia, gestational hypertension, placental abruption, placenta previa, and risk of cesarean delivery. Moreover, there is an increased risk in twinning and multiple gestations compared to non-IVF pregnancies due to the stimulation of surplus follicles and the transfer of two or more embryos to obtain adequate pregnancy rates [10]. These studies have also concluded that twin pregnancies, conceived via ART, are associated with a higher risk of prematurity, low birth weight and increased hospital stay (Caserta, 2014, pp. 64-69. Aims to improve IVF outcomes resulted in clinics undertaking extended culture to the blastocyst stage instead of transferring at the cleavage stage (day 2 to 3 post fertilization). Blastocyst transfer (day 5 to 6 post fertilization) allows optimal time for embryos to grow in culture in order to select out those embryos most likely to implant whilst deselecting the embryos less likely to implant [11].

Replacing only those embryos that do not exhibit any abnormal chromosome rearrangements or aneuploidy can increase implantation potential [12]. Pre- implantation Genetic Screening (PGS) is the technology that can allow cells to be removed from embryos prior to transfer to test for this aneuploidy although it remains to be determined if this test ultimately improves pregnancy outcome. The advances of blastocyst culture and PGS aim to promote the selection of just one healthy embryo for transfer instead of putting two or more back and increasing the multiple pregnancy rate. The use of PGS in women of advanced maternal age may have a positive effect on pregnancy rates in this group. The Single Embryo Transfer of Euploid Embryo (STAR) [13] trial reported that there was an improvement in ongoing pregnancy rates of 14% for women aged 35-40 in the preimplantation genetic screening (PGS) arm, with no difference observed in the pregnancy rates of younger women. Despite the success of blastocyst transfer associated with improving implantation rates; there are risks associated such as: "failure of blastulation, increased monozygosity, reduced embryo quality and an increase in transfer cancellations" [14].

Perinatal Statistics Report (Healthcare Pricing Office [GPO], Health Service Executive [HSE], 2016) [15] showed the rate of twin births has increased in Ireland to 18.5 per 1,000 deliveries in 2014; representing an increase of 22.5% since 2005. In comparison the report from human fertilization and embryology authority 2016-2017 [16] stated that 86% of IVF clinics have resulted in only 10% of the multiple births, thus reducing national multiple birth rate from 25% in 2009 to 11% at the time of the report.

It is therefore important to educate parents regarding the risks of multiple gestations in IVF pregnancies. The majority of twins following IVF are dizygotic (DZ) where double embryos have been transferred [17]. Conversely, the increase in use of ART has also lead to an increase in incidence of monozygotic (MZ) twins. The risk of MZ twins in non-IVF patients is 0.49% and 2.0% in IVF patients. Monochorionic Diamniotic twins account for 70% of MZ twins [18]. MZ and DZ twin pregnancies are at an increased risk of miscarriages, intrauterine growth restriction and preterm delivery. However MZ twins are at an increased morbidity due to vascular connections between the two fetal circulations in a single placenta. If a change in hemodynamics occurs between the vascular connections it can lead Twin-to-Twin Transfusion Syndrome (TTS) and Twin anemia polycythemia sequence (TAPS). Either syndromes occurring may result in fetal death and cerebral morbidity in the surviving twin. The complications are life threatening and need to be taken into consideration [19]. In addition to the increased risks of neonatal and maternal medical complications that can occur in multiple gestational pregnancies, non-medical complications such as post-natal depression may result in due to the an increased financial and emotional stresses that occur. It is believed that birth of multiple gestations is associated with an increase in divorce between couples when compared to singletons. In addition to the psychological effects of multiple gestations, the parents are at increased financial burden [20]. IVF clinicians should be responsible for educating the patients of such short and long-term effects of multiple gestation pregnancies and the impact on them and their families [21]. In 2009 the percentage of multiple gestation pregnancies following IVF in Europe decreased from 26.4% in 2000 to 20.2%, according to Ferraretti et al., [1]. This is a result of the implementation of the SBT (single blastocyst transfer) policy, which has replaced DBT (double blastocyst transfer) in the majority of countries. Several researchers commend the SBT policy as it has reduced the incidence of multiple pregnancies. SBT has provided better obstetric outcomes for the children and mothers of IVF, as there is a risk of multiple gestational pregnancies with DBT resulting in increased neonatal and maternal complications. SBT may not initially be as appealing to patient interests due to perceived lower pregnancy rates, despite adequate counseling of multiple gestation risks. However a meta-analysis of the clinical effectiveness of single embryo transfer versus double embryo transfer, showed the overall live birth rate following single embryo transfer in a fresh cycle (27%) which was lower than double embryo transfer (42%); yet the addition of a single embryo frozen cycle gave a cumulative birth rate (38%) which was comparable to double embryo transfer [22].

Material and Methods

This is a retrospective study of women with a previous failed embryo transfer who underwent a subsequent frozen-thawed embryo transfer. All elective day 5 or 6 blastocyst transfers were analyzed in two universities affiliated reproductive medicine centers from for 5 and 3 years respectively. The time difference was due to a later adoption of electronic healthcare records in the second center.

The aim of the study was to compare the clinical pregnancy rates in patients, who underwent a SBT, DBT, or TBT in a subsequent frozen thawed cycle after previous failed embryo transfer. The women were then subdivided into 3 groups: <35, 35-39 and ≥ 40. Clinical pregnancy rates were evaluated within each group depending whether they had a SBT, DBT or TBT.

Data was obtained from the electronic healthcare record databases from Human Assisted Reproduction Ireland, and Sims IVF. Any discrepancies were then verified by referring to the case notes. The maternal age referred to, is the age at which the embryo was stored which was not always the age at which the embryo was transferred. Clinical pregnancy is defined as a gestational sac (GS) present within or outside the uterus on transvaginal ultrasound (TVUS) 28-42 days after ET. Twin pregnancy is defined as 2 or more intrauterine pregnancies on TVUS 28-42 days after ET.

Statistical analysis

Statistical analysis was carried out using statistical software (R, version 3.1.0, R Foundation, Vienna, Austria). The Pearson χ^2 test (chi-square test) or Fisher exact test were used and results presented in the form of Wald test P-value. Statistical significance was defined by two-sided $P \leq 0.05$.

Results

There were a total of 1335 women, who had frozen thawed embryo transfer cycle, using a HRT protocol, after a previous failed transfer between both units over the study period. Of these 969 (72.6%) had a SBT, 347 (26.0%) had a DBT, and 19 (1.4%) had a TBT. In the SBT group there were 294 clinical pregnancies (30.3%) and in the DBT group there were 163 clinical pregnancies (47.0%). In the TBT group there were 11 pregnancies with a 58% clinical pregnancy rate.

In the SBT group there were 9 sets of twins out of 294 clinical pregnancies, giving an incidence of 3.1%. In the DBT group 43 of the 163 clinical pregnancies were twin pregnancies (26.4%). Table 1 summarizes clinical pregnancy rates and incidence of twins between 3 study groups.

When comparing the clinical pregnancy rate in the SBT and the DBT groups it was evident that the DBT group had a higher success rate, P <0.0001. When comparing the incidence of twins in the two groups, there is a statistical significance (p<0.0001) between the SBT and DBT group with the twin rate in the DBT group being 8.5 times

Table 1: Clinical pregnancy rates and incidence of twins within 3 groups.

(N=1335)*	Clinical pregnancy n (%) **	P value[a]	Twin pregnancy n (%)***	P value[b]
SBT group (N= 969)[c]	30.3 (294) 47.0 (163) 58 (11)	<0.0001	3.1 (9) 26.4 (43) N/Af	<0.0001 <0.00001
DBT group (N=347)[d]				
TBT group (N=19)[e]				

*Total number of women in the study;

**Clinical pregnancy is defined as a gestational sac present within or outside the uterus on transvaginal ultrasound 12- 14 days after ET; where n is number of positive cases and % is number of positive cases divided by total within group;

***Twin pregnancy is defined as 2 or more intrauterine pregnancies on TVUS 12-14 days after ET; where n is number of positive cases and % is number of positive cases divided by total within group;

[a]Shows statistical significance when clinical pregnancy rates compared to SBT group; [b]Shows statistical significance when incidence of twins compared to SBT group; [C]Total number of women in single blastocyst transfer (SBT) group; [d]Total number of women in double blastocyst transfer (DBT) group; [e]Total number of women in triple blastocyst transfer (TBT) group; [f]N/A – Not Applicable.

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Table 2: Clinical pregnancy and twin rates after single, double and triple blastocyst transfer within different age groups.

	Single Blastocyst Transfer group			Double Blastocyst Transfer group			Triple Blastocyst Transfer group		
	Total in group, n[a]	Clinical pregnancy y, %	Twin pregnancy y%	Total in group, n[a]	Clinical pregnancy y, %	Twin pregnancy, %	Total in group, n[a]	Clinical pregnancy, %	Twin pregnancy, %
< 35 years old (N=518)[b]	398	33.7	4.5	118	53.4*	36.5**	2	0.386	
35-39 years old (N=611)[b]	425	28.5	1.7	175	45.7*	20.0**	11	63.6	28.6
≥40 years old (N=206)[b]	146	26.7	2.6	54	37.0***	20.0***	6	33.3	50

*Statistically significant difference in clinical pregnancy rates comparing SBT and DBT in: <35 years old group p=0.0002; in 35-39 years old group, p=0.0001;

** Statistically significant difference in twin pregnancy rates comparing SBT and DBT in: <35 years old group, p <0.0001;

*** No statistically significant difference reached comparing DBT and SBT clinical pregnancy and twin pregnancy rates in ≥ 40 years old group: p=0.16 and p=0.07 respectively;

[a]Total number of women in SBT, DBT, TBT accordingly; [b]Total number of women in the <35; 35-39; ≥ 40 years old groups.

higher than the SBT group. There was a higher twin rate in the TBT as compared to the SBT group (8.8 fold; p < 0.00001).

The data was further analyzed depending on the patient's age. The groups identified; were women < 35 years of age, 35-39 inclusive, and women 40 years and over. Table 2 compares the pregnancy and twin rates after SBT, DBT blastocyst, and TBT on the different patient age groups. In the <35 group, there were 518 patients, 398 underwent a single transfer which resulted in a clinical pregnancy rate of 33.7% and a twin rate of 4.5%; 118 underwent a double transfer resulting in a 53.4% clinical pregnancy rate and 36.5% twin rate. Two patients underwent a triple embryo transfer on the patient's request. In the 35-39 age group, there were 611 patients, 425 underwent a SBT which resulted in a clinical pregnancy rate of 28.5% and a twin rate of 1.7%; 175 underwent a DBT resulting in a 45.7% clinical pregnancy rate and 20.0% twin rate. 11 patients underwent a TBT resulting in a clinical pregnancy rate 63.6% and a twin rate 28.6%, with no triplet pregnancies in this group. In the >40 group, there were 206 patients, 146 underwent a SBT which resulted in a clinical pregnancy rate of 26.7% and a twin rate of 2.6%; 54 underwent a DBT resulting in a 37.0% clinical pregnancy rate and 20% twin rate. 6 patients requested a TBT with a clinical pregnancy rate of 33.3% and a twin rate of 50%, with no triplets.

When comparing SBT and DBT in women under 35, DBT has a higher clinical pregnancy rate and is statistically significant (p=0.0002). DBT has a statistically higher twin rate than SBT (p<0.0001) and is over 8 times more likely to result in a twin pregnancy when successful. Women of the 35-39 age group are also more likely to get pregnant with a DBT (p=0.0001), and the twin pregnancy rate is almost 12 times higher when compared to SBT in this age group. There was a higher pregnancy rate with DBT than SBT in patients over 40, but this difference did not reach statistical difference, p=0.16, but there are fewer patient numbers in this group. The incidence of twins is also higher with a DBT, but again it is not statistically significant (p=0.07). There were no triplets in any of the groups following a failed transfer during the study period.

Discussion

The vision for IVF outcomes has improved over the years and a live healthy singleton baby at term with the optimal outcomes for mother and infant has now become the aim. Practicability of SBT will ultimately rely heavily on improving outcomes with cryopreserved embryos and techniques like vitrification due to similar birth rates following embryos cryopreserved and thawed and fresh transfers [23]. The number of embryos policy to be transferred must be case specific to accommodate the needs of patients with poor prognosis such as the >40 age group and the patients with poor quality of embryos [24].

The study data presented demonstrates a higher clinical pregnancy rate per transfer with DBT compared to SBT (47.0% and 30.3% respectively, P<0.0001) but at the expense of an 8.5 fold increase in the twin pregnancy rate in the DBT group (26.4% and 3.1% respectively, P<0.0001). The above data also suggests that regardless of the age of the patient the clinical pregnancy rate is similar once there is a good quality blastocyst to transfer. The incidence of monochorionic twins is also similar between age groups. Previous studies have similarly found that women who undergo DBT have a higher incidence of both clinical pregnancy rates and increase rates of multiple pregnancies than women who have SBT [23,24].

The quality of embryos will often dictate the outcome in a frozen thawed cycle. Each case should be dealt with individually, and potentially difficult cases could be discussed at a local multi-disciplinary team meeting.

Couples attending for IVF/ICSI treatment have often spent a long time prior starting treatment. With the rising maternal age and the length of time already lost couples are often anxious for a quick result. A higher pregnancy rate with a two-embryo transfer is often very appealing to couples. The rising incidence of twins in the community, also as a consequence of assisted reproductive technology, has almost become something of a norm in some societies with infertile couples not realizing the risks to the mother and fetus from these multiple pregnancies.

It is important to highlight that as clinicians we inform our patients of the risks of multiple birth to the mother such as an increased risk of caesarean section, PPH, post-natal depression, pregnancy induced hypertension and those to the fetus such as low birth weight, developmental delay, infection, respiratory distress and cerebral palsy in extreme prematurity. Discussing these risks with couples very often will guide them towards a SBT, yet some couples are still adamant to request the highest success rates per transfer, which would be achieved by DBT. It is important then to highlight that the cumulative pregnancy rate is similar with two SBTs compared to a single DBT. In health care systems where ART is not funded by the government the additional financial strain of another frozen-thawed embryo cycle, with previous failed SBT, is often a reason for couples to feel the need to have a DBT. But it is also imperative to note that the costs associated with the neonatal stay from extreme prematurity and very low birth weight babies are high for both the couple and also for health care systems.

Conclusion

In conclusion clinicians must take the time to discuss the benefits of a single blastocyst issues discussed above so patients can make an informed choice.

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