

Impact of frozen-thawed single-blastocyst transfer on maternal and neonatal outcome: an analysis of 277,042 single-embryo transfer cycles from 2008 to 2010 in Japan

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Objective: To evaluate the relationship between frozen-thawed single blastocyst transfer (BT) and maternal and neonatal outcomes of pregnancy.

Design: Retrospective analysis.

Setting: Japanese nationwide registry of assisted reproductive technology (ART) with mandatory reporting for all ART clinics in Japan.

Patient(s): Registered from 2008 through 2010 undergoing single embryo transfer cycles (n = 277,042).

Intervention(s): None.

Main Outcome Measure(s): Rates of preterm birth (PTB; <37 weeks' gestation), low birth weight (LBW; <2,500 g), small for gestational age (SGA), large for gestational age (LGA), placenta previa, placenta abruption, placenta accreta, and pregnancy-induced hypertension (PIH) after fresh/frozen-thawed and cleaved-embryo/blastocyst transfers were performed.

Result(s): Frozen-thawed embryo transfer (FET) was associated with a significantly reduced occurrence of PTB, LBW, and SGA but increased rate of LGA. FET was also associated with a higher incidence of placenta accreta (odds ratio 3.16) and PIH (odds ratio 1.58). BT was associated with a significantly decreased rate of SGA and increased rate of LGA. There was no significant association between BT and maternal complications.

Conclusion(s): Frozen-thawed BT is associated with improved general perinatal outcomes of pregnancy but significantly increased maternal risks of placenta accreta and PIH. This finding requires further investigation to assure maternal safety of patients undergoing ART treatment. (Fertil Steril® 2014;101:128–33. ©2014 by American Society for Reproductive Medicine.)

Key Words: Frozen-thawed blastocyst transfer, placenta accreta, pregnancy-induced hypertension

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The transition to single-embryo transfer (SET) has become the central strategy to realize high-quality safe assisted reproductive technology (ART) practice because SET is able to minimize the occurrence of multiple pregnancies (1, 2). At the same time, newly introduced technologies,

e.g., frozen-thawed embryo transfer (FET) and blastocyst transfer (BT), are practiced with the intention to improve cumulative pregnancy rates for each patient without extra multiples. It is a necessary consequence to assess the safety of these new technologies regarding maternal and neonatal outcomes. A number of valuable original papers (3–6), reviews, and meta-analyses (7, 8) have been published. However, it is very difficult to compare various outcomes after ART with spontaneously conceived patients owing to the difference of populations and various confounding variables. Moreover, it would require a large number of well controlled studies to describe safety issues, especially given the relative infrequency of adverse events during the perinatal period.

We previously reported, with the use of data from 20,886 clinical pregnancies after SET in the 2008 Japanese registry database, that frozen-thawed BT is associated with a reduced ectopic pregnancy risk compared with fresh cleaved embryo transfer (9). Because endometrial receptivity and placentation are possibly key factors in the prevalence of ectopic pregnancy, it seems to be appropriate to investigate other placenta-associated complications as potentially relevant factors during pregnancy. However, there were not a sufficient number of cycles in the registry to study the possible impact of frozen-thawed BT on relatively infrequent events and complications during pregnancy. In the present paper, we combined three consecutive years of the Japanese ART registry database from 2008 through 2010 to assess the potential association of selected perinatal and maternal outcomes regarding the comparison of frozen-thawed transfer cycle pregnancies with fresh transfer pregnancies and the comparison of single-blastocyst transfer cycle pregnancies with cleaved embryo transfer pregnancies.

MATERIALS AND METHODS

The data analyzed in this study are part of the Japanese ART registry database collected by the Japan Society of Obstetrics and Gynecology (JSOG) on a mandatory basis from all ART clinics through secure internet access in 2008 ($n = 609$), 2009 ($n = 625$), and 2010 ($n = 591$), as previously described in detail (9, 10). The dataset consists of cycle-specific data and certain outcomes of treatment as well as the fate of pregnancy and obstetrical outcome data. The population in this study includes fresh ET cases of IVF and intracytoplasmic sperm injection (ICSI) as well as FET from 2008 through 2010. All of the embryos transferred were autologous for couples, because donor gametes or embryos are not allowed to be used in ART in Japan. In addition, only the data of SET cycles were provided for the study, because the number of transferred embryos may affect the outcome of pregnancy and complications even if singleton pregnancy is selected for the final analysis. SET cycles constituted >70% of the total ET cycles during the period because since 2008 JSOG guidelines have made it mandatory for patients <35 years of age to undergo SET for the first and second ETs to reduce the multiple pregnancy rate.

Small for gestational age (SGA) and large for gestational age (LGA) were defined as >2 standard deviations below or

above the Japanese gestational age- and gender-specific growth standard published by the Japan Pediatric Society (11). Placenta previa, placenta abruption, placenta accreta, and pregnancy-induced hypertension (PIH) were diagnosed at each clinic and described in a webpage section. These descriptive data were electronically identified and presented as numbers and percentages. Risk factor analysis for preterm birth (PTB; <37 weeks' gestation), low birth weight (LBW; <2,500 g), SGA, LGA, placenta previa, placenta abruption, placenta accreta, and PIH was performed by multivariable logistic regression analysis. Variables extracted for this study included maternal age at the time of ART treatment, whether a frozen-thawed or a fresh embryo was transferred, whether a blastocyst or a cleaved embryo was transferred, and the sex of the infant. These independent variables were selected by means of backward elimination in each analysis. Crude odds ratio (COR) and adjusted odds ratio (AOR) with 95% confidence intervals (CIs) and P values of likelihood ratio test were calculated with the use of SAS software JMP version 10.0.2 and SAS version 9.1.3 SP4 (SAS Institute).

This study was planned by the registration and research subcommittee of the JSOG Ethics Committee. The dataset was provided as an Excel file for the research proposal after review and approval by the JSOG Board of Ethics, which is an independent reviewing body for research and investigational proposals. Institutional Review Board approval was not obtained, because the dataset was collected by JSOG from clinics and the data do not include any personally identifiable parameters.

RESULTS

For the period from 2008 through 2010, 277,042 SETs were registered in the JSOG database (Table 1). Even though the average maternal age was 36.3 ± 4.5 years and one-fourth of the cycles were for patients aged >40 years, 79,626 cycles (28.7%) resulted in clinical pregnancy, as defined by the International Committee Monitoring Assisted Reproductive Technologies (ICMART) glossary, following SET (12). Because some cases were lost to follow-up during the early stage of pregnancy, we knew pregnancy outcome in 93.6% of the cycles (74,539/79,626). The follow-up rates were similar for all subgroups: fresh cleaved 94.3%, fresh blastocyst 92.4%, thawed cleaved 92.1%, and thawed blastocyst 93.8%. We extracted the 53,023 singleton ongoing pregnancies (>21 weeks of gestation) for further analysis. Detailed obstetrical and neonatal information were available for 90.8% of the extracted cycles (48,158/53,023) and are described as numbers and percentages in Table 2. We used 48,158 cycles for the analysis of different variables.

Risk for Preterm Birth and Birth Weight of Infant

In Table 3 advanced maternal age is associated with both PTB before 37 weeks (AOR 1.02 [95% CI 1.01–1.03]) and LBW <2,500 g (AOR 1.01 [95% CI 1.00–1.02]). The AOR for PTB before 37 weeks was lower in FET (AOR 0.90 [95% CI 0.82–0.98]) as were the odds of LBW <2,500 g was lower (AOR 0.71 [95% CI 0.66–0.77]). BT did not have significant effects on these two parameters. Advanced maternal age

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