

Adverse pregnancy outcomes after in vitro fertilization: effect of number of embryos transferred and plurality at conception

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Objective: To evaluate risks for adverse pregnancy outcomes by number of embryos transferred (ET) and fetal heartbeats (FHB) in assisted reproductive technology–conceived singleton live births.

Design: Longitudinal cohort using cycles reported to the Society for Assisted Reproductive Technology Clinic Outcomes Reporting System between 2004 and 2008 among women who were treated and gave birth in Massachusetts.

Setting: Not applicable.

Patient(s): Assisted reproductive technology data on 6,073 births between 2004 and 2008 were linked to vital records and hospital data. Likelihood of ET ≥ 3 vs. 1–2, FHB >1 vs. 1, and risks of preterm birth (PTB, <37 weeks' gestation), low birth weight (LBW, $<2,500$ g), and small-for-gestational-age birth weight (SGA, <10 th percentile) with FHB >1 were modeled with binary logistic regression using a backward-stepping algorithm, and presented as adjusted odds ratios (95% confidence intervals).

Intervention(s): None.

Main Outcome Measure(s): ET ≥ 3 , FHB >1 , PTB, LBW, and SGA.

Result(s): Higher ET was significantly more likely with older maternal age, intracytoplasmic sperm injection, assisted hatching, cleavage-stage embryos, and thawed embryos. The likelihood of FHB >1 with ≥ 3 ET vs. 1–2 ET was 2.04 (1.68–2.48). Risks of PTB and LBW with FHB >1 were 1.63 (1.27–2.09) and 1.81 (1.36–2.39), respectively; the risk of SGA was not significant. Nulliparity was associated with higher risks of PTB (1.34 [1.12–1.59]), LBW (1.48 [1.20–1.83]), and SGA (2.17 [1.69–2.78]).

Conclusion(s): Number of embryos transferred was strongly associated with FHBs, with twice the risk of FHB >1 with ≥ 3 ET vs. 1–2 ET. Increasing FHBs were associated with significantly greater risks for PTB and LBW outcomes. (Fertil Steril® 2015;104:79–86. ©2015 by American Society for Reproductive Medicine.)

Key Words: Assisted reproductive technology, embryos transferred, fetal heartbeats, birth outcomes

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The outcomes of pregnancies conceived through assisted reproductive technology (ART) have been reported to be of lower birth weight (LBW) and shorter gestation, even when limited to singleton births (1–5).

It is unknown whether these decrements are due to parental characteristics or aspects of the ART treatment: this remains a primary challenge to infertility research (6–8). In particular, the effect of number of embryos transferred and plurality at conception vs. plurality at birth needs further evaluation (9–12). In addition, an acknowledged drawback of prior ART research in the United States has been the self-reported nature of the outcomes data, which is typically reported by the patient herself or by her obstetric provider. This study seeks to overcome these limitations by linking the Society for Assisted Reproductive Technology Clinic Outcomes Reporting System (SART CORS) data to birth certificate and hospital utilization data.

This is the third in a series of analyses evaluating the effect of ART diagnoses and treatment parameters on the course and outcome of pregnancy (13, 14). This within-ART set of analyses is part of a larger population-based study of ART in Massachusetts (13–21). The objective of this current analysis is to evaluate the effect of number of embryos transferred (ET) and plurality at the 6-week ultrasound (fetal heartbeats [FHB]) on the pregnancy and birth outcomes of singleton births, specifically prematurity, LBW, and small-for-gestational-age (SGA) birth weight. These associations will be examined overall and by maternal age groups.

MATERIALS AND METHODS

Study Design and Setting

This longitudinal cohort study included a woman's first singleton live birth of ≥ 22 weeks' gestation and ≥ 300 g birth weight in Massachusetts from July 1, 2004 through December 31, 2008 that linked to ART cycles in the SART CORS and the Pregnancy to Early Life Longitudinal (PELL) data system.

Data Sources

PELL data system. The PELL system, which functions within the Massachusetts Department of Public Health, links records from birth and fetal death certificates, hospital discharges, and program data from child health and development programs. The PELL data system has linked information on more than 99% of all births and fetal deaths in Massachusetts from 1998–2008 to corresponding hospital utilization data (hospital admissions, observational stays, and emergency room visits) for individual women and their children. The PELL system has linked information on 860,654 deliveries from 1998 through 2008. The Massachusetts Department of Public Health and the Massachusetts Center for Health Information and Analysis are the custodians of the PELL data. The PELL system is a relational data system composed of individual databases linked together by randomly generated unique IDs for mother and infant. The PELL data system is housed at the Massachusetts Department of Public Health.

SART CORS. The data source for ART data for this study was the SART CORS, which contains comprehensive data from

more than 90% of all clinics performing ART in the United States. Data were collected and verified by SART and reported to the US Centers for Disease Control and Prevention (CDC) in compliance with the Fertility Clinic Success Rate and Certification Act of 1992 (Public Law 102-493). The Society for Assisted Reproductive Technology maintains Health Insurance Portability and Accountability Act-compliant business associates agreements with reporting clinics. In 2004, after a contract change with the CDC, SART gained access to the SART CORS data system for the purposes of conducting research. The national SART CORS database for 2004–2008 contains 642,927 ART treatment cycles. The database includes information on demographic factors (age, race/ethnicity); ART factors (infertility diagnoses, oocyte source and state, use of micromanipulation [intracytoplasmic sperm injection, (ICSI), and assisted hatching], number of ET); treatment outcomes (number of FHB on early ultrasound, early pregnancy loss); and pregnancy outcomes (live born, still-born, duration of gestation, plurality, and genders). The data in the SART CORS are validated annually (22), with some clinics having on-site visits for chart review based on an algorithm for clinic selection. During each visit, data reported by the clinic were compared with information recorded in patients' charts. In 2012, records for 2,045 cycles at 35 clinics were randomly selected for full validation, along with 238 egg/embryo banking cycles (23). The full validation included review of 1,318 cycles for which a pregnancy was reported. Among the nondonor cycles, 331 were multiple-fetus pregnancies. Ten of 11 data fields selected for validation were found to have discrepancy rates of $\leq 5\%$. The exception was the diagnosis field, which, depending on the diagnosis, had a discrepancy rate between 2.1% and 9.2%.

Massachusetts Outcome Study of Assisted Reproductive Technology. The Massachusetts Outcome Study of Assisted Reproductive Technology (MOSART) project links data from the SART CORS with the PELL data system to evaluate pregnancy and child health outcomes on a population basis. A Memorandum of Understanding was executed between SART and the three entities that participate in the PELL project: Boston University, the Massachusetts Department of Public Health, and the CDC. Human subjects approval was obtained from all entities and participating Universities. The study had the approval of the SART Research Committee.

We constructed the MOSART database by linking the SART CORS and PELL data systems for all children born in Massachusetts hospitals to Massachusetts resident women between July 1, 2004 and December 31, 2008. The starting date was chosen on the basis of the availability of SART CORS data (January 1, 2004), to allow us to capture any births associated with ART, and the end date reflected the latest available data from both SART and PELL when we began the MOSART study. PELL data from July 1, 2004 and December 31, 2008 included 282,971 women with 334,152 deliveries resulting in 342,035 live births and fetal deaths; these were then linked to 42,649 ART cycles among 18,439 women from SART CORS using a deterministic five-phase linkage algorithm methodology (15).

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