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Trends and outcomes of gestational surrogacy in the United States

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Objective: To evaluate trends and reproductive outcomes of gestational surrogacy in the United States.
Design: Retrospective cohort study.
Setting: Infertility clinics.
Patient(s): IVF cycles transferring at least one embryo.
Intervention(s): Use of a gestational carrier.
Main Outcome Measure(s): Trends in gestational carrier cycles during 1999–2013, overall and for non-U.S. residents; reproductive outcomes for gestational carrier and nongestational carrier cycles during 2009–2013, stratified by the use of donor or nondonor oocytes.
Result(s): Of 2,071,984 assisted reproductive technology (ART) cycles performed during 1999–2013, 30,927 (1.9%) used a gestational carrier. The number of gestational carrier cycles increased from 727 (1.0%) in 1999 to 3,432 (2.5%) in 2013. Among gestational carrier cycles, the proportion with non-U.S. residents declined during 1999–2005 (9.5% to 3.0%) but increased during 2006–2013 (6.3% to 18.5%). Gestational carrier cycles using nondonor oocytes had higher rates of implantation (adjusted risk ratio [aRR], 1.22; 95% confidence interval [CI], 1.17–1.26), clinical pregnancy (aRR, 1.14; 95% CI, 1.10–1.19), live birth (aRR, 1.17; 95% CI, 1.12–1.21), and preterm delivery (aRR, 1.14; 95% CI, 1.05–1.23) compared with nongestational carrier cycles. When using donor oocytes, multiple birth rates were higher among gestational carrier compared with nongestational carrier cycles (aRR, 1.13; 95% CI, 1.08–1.19).
Conclusion(s): Use of gestational carriers increased during 1999–2013. Gestational carrier cycles had higher rates of ART success than nongestational carrier cycles, but multiple birth and preterm delivery rates were also higher. These risks may be mitigated by transferring fewer embryos given the higher success rates among gestational carrier cycles. (Fertil Steril® 2016;■:■–■. ©2016 by American Society for Reproductive Medicine.)
Key Words: Gestational carrier, surrogacy, in vitro fertilization (IVF), reproductive outcomes, multiple birth

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A gestational carrier is a woman who bears a genetically unrelated child for another individual or couple (the intended parent[s]), usually through IVF, an assisted reproductive technology (ART) procedure involving the fertilization of oocytes outside the body and transferring the resulting embryo(s) into a woman's uterus (1). The first reported successful pregnancy using a gestational carrier was in 1985 and has enabled those who cannot carry a pregnancy to have genetically related children (2). Since then, there has been growing interest in this form of ART. Little is known about the use of gestational carriers in the United States, the patients opting for gestational surrogacy, and the perinatal outcomes of these pregnancies compared with other ART cycles. Studies examining gestational carriers have been limited by small sample sizes or lack of appropriate comparison groups or have been conducted outside the United States (3–17).

Information on success rates and pregnancy outcomes of ART cycles using gestational carriers can help both intended parents and gestational carriers make informed decisions. Additionally, identifying current national estimates and trends for the use of gestational carriers can help inform policy makers in the realm of increasingly complex legal issues surrounding gestational surrogacy (18). The

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objectives of this study were to evaluate trends in ART cycles using a gestational carrier during 1999–2013 and to determine patient characteristics, ART treatment factors, and reproductive outcomes of gestational carrier cycles compared with cycles not using a gestational carrier.

MATERIALS AND METHODS

We used data from the Centers for Disease Control and Prevention's (CDC) National ART Surveillance System (NASS). All U.S. fertility clinics performing ART are required to report annual data on all ART procedures to the CDC (19). The CDC estimates that NASS captures information on over 95% of all ART procedures performed in the United States (20). Typically, less than 5% of data have been shown to be inaccurately collected or entered according to the annual validation of 7%–10% of clinics (20). NASS collects cycle-specific information, and patients are not linked across multiple cycles. The unit of analysis for the current study was an ART cycle.

A gestational carrier was defined as a woman who gestates an embryo that did not develop from her oocyte, with the expectation of returning the infant to its intended parent(s). An intended parent was defined as the individual who was contracting with the gestational carrier and planning to be the social and legal parent of the child and may or may not be genetically related to the child (1).

We included all IVF cycles initiated between January 1, 1999, and December 31, 2013, where at least one embryo was transferred. We excluded ART cycles that were performed only for research purposes or for banking (ART cycles that are performed with the intention to freeze eggs or embryos for later use). Finally, cycles that had missing information on the above exclusion criteria were also excluded.

To explore trends in the use of gestational carriers, the number and percent of all IVF cycles using gestational carriers that resulted in transfer were plotted against the study year. The number and percent of all initiated cycles using gestational carriers regardless of whether they proceeded to ET were also plotted. To examine whether trends were a result of changes in the number of clinics performing gestational carrier cycles over time, the number and percent of clinics among all reporting clinics performing one or more gestational carrier cycles were plotted against study year. Given that many countries restrict gestational surrogacy (21), we examined trends in gestational carrier cycles among patients who were not residents of the United States, but using U.S. ART clinics, by restricting the study population to gestational carrier cycles and calculating the percent of these cycles with the intended parent reported to be a non-U.S. resident. Trends among non-U.S. residents were tested for two different periods, 1999–2005 and 2006–2013, owing to a change in trend in 2005. Statistically significant trends were determined using the Poisson regression.

We restricted all further analysis to the most recent years of data available, 2009–2013, to account for ART practice trends. We compared patient demographic characteristics and ART treatment factors for gestational carrier cycles and cycles not using a gestational carrier (nongestational carrier cycles). Infertility diagnoses were not mutually exclusive. Additionally, for infertility diagnosis designated as "other," we examined free text entries for gestational carrier cycles and categorized them into non–mutually exclusive groups.

For nongestational carrier cycles, the patient was defined by reporting clinics as the woman undergoing the IVF cycle. For gestational carrier cycles, clinics defined the intended parent as the patient. However, in cases of male-male couples or single males using gestational carriers, clinics defined the gestational carrier as the patient and demographic information reported pertained to the carrier.

ART treatment factors included fresh versus frozen/thawed ET, donor versus nondonor oocytes, assisted hatching, intracytoplasmic sperm injection, preimplantation genetic diagnosis, stage of ET (day 2/3 or day 5/6 typically corresponding to cleavage- or blastocyst-stage embryos, respectively, or other), number of embryos transferred, elective single ET (the transfer of only one embryo when more than one embryo is available), and number of supernumerary embryos cryopreserved. Donor oocytes were retrieved from a donor and not derived from the gestational carrier or the intended parent. Nondonor oocytes were retrieved from the intended parent. The amount of missing data was less than 1% for all variables except for gestational carrier age (34.2%), donor age (56.2%), race/ethnicity (35.4%), U.S. residency status (2.7%), and the use of elective single ET (6.5%).

We compared the distribution of demographic characteristics and ART treatment factors between gestational carrier and nongestational carrier cycles using two-tailed χ^2 tests with a significance level of $P<.05$. We assessed the rates of the following reproductive outcomes among gestational carrier and nongestational carrier cycles: among all ET procedures we calculated implantation (the maximum number of fetal heartbeats seen on ultrasound or infants born, whichever is greater, divided by the number of embryos transferred, multiplied by 100), clinical intrauterine pregnancy, and live-birth rates; among all clinical pregnancies we calculated miscarriage rates; and among all live births, we calculated multiple live-birth, preterm delivery, and low birth weight rates. We used log-binomial regression models with generalized estimating equations for correlated outcomes within clinics to calculate unadjusted and adjusted risk ratios (aRRs) and 95% confidence intervals (CIs) for the association between reproductive outcomes and use of a gestational carrier. All models were restricted to fresh cycles because many ART treatment variables that are associated with outcomes were not available for frozen cycles (e.g., day of embryo transfer). Because ART outcomes are improved with the use of donor oocytes (22, 23), we stratified our analysis by nondonor and donor oocyte cycles. Analysis of preterm delivery and low birthweight were also stratified by plurality. Data were analyzed using SAS 9.3. This research was approved by the Institutional Review Board at CDC.

RESULTS

A total of 2,071,984 ART cycles were performed between 1999 and 2013. After applying our exclusion criteria, there were 1,664,844 cycles, of which 30,927 (1.9%) used a gestational