GYNECOLOGY

Accuracy of self-reported survey data on assisted reproductive technology treatment parameters and reproductive history

Judy E. Stern, PhD; Alexander C. McLain, PhD; Germaine M. Buck Louis, PhD; Barbara Luke, ScD, MPH; Edwina H. Yeung, PhD

BACKGROUND: It is unknown whether data obtained from maternal self-report for assisted reproductive technology treatment parameters and reproductive history are accurate for use in research studies.

OBJECTIVES: We evaluated the accuracy of self-reported in assisted reproductive technology treatment and reproductive history from the Upstate KIDS study in comparison with clinical data reported to the Society for Assisted Reproductive Technology Clinic Outcome Reporting System.

STUDY DESIGN: Upstate KIDS maternal questionnaire data from deliveries between 2008 and 2010 were linked to data reported to Society for Assisted Reproductive Technology Clinic Outcome Reporting System. The 617 index deliveries were compared as to treatment type (frozen embryo transfer and donor egg or sperm) and use of intracytoplasmic sperm injection and assisted hatching. Use of injectable medications, self-report for assisted reproductive technology, or frozen embryo transfer prior to the index deliveries were also compared. We report agreement in which both sources had yes or both no and sensitivity of maternal report using Society for Assisted Reproductive Technology Clinic Outcome Reporting System as the gold standard. Significance was determined using χ^2 at $P < 0.05$.

RESULTS: Universal agreement was not reached on any parameter but was best for treatment type of frozen embryo transfer (agreement, 96%; sensitivity, 93%) and use of donor eggs (agreement, 97%; sensitivity, 82%) or sperm (agreement, 98%; sensitivity, 82%). Use of intracytoplasmic sperm injection (agreement, 78%: sensitivity, 78%) and assisted hatching (agreement, 57%; sensitivity, 38%) agreed less well with self-reported use ($P < .0001$). In vitro fertilization (agreement, 82%) and frozen embryo transfer (agreement, 90%) prior to the index delivery were more consistently reported than was use of injectable medication (agreement, 76%) ($P < .0001$).

CONCLUSION: Women accurately report in vitro fertilization treatment but are less accurate about procedures handled in the laboratory (intracytoplasmic sperm injection or assisted hatching). Clinics might better communicate with patients on the use of these procedures, and researchers should use caution when using self-reported treatment data.

Key words: assisted reproductive technology, intracytoplasmic sperm injection, participant self-report, patient communication, survey study

More than 5 million babies have been born worldwide from assisted reproductive technology (ART), close to 3 million of these within the past 6 years.[1] Numerous studies suggest that there is an increase in adverse outcomes in pregnancies resulting from ART.[2-12] Not only is there a higher rate of multiple birth from these pregnancies,[13] but increases in low birthweight, prematurity, small-for-gestational-age babies, and malformations are found in ART deliveries, even in singletons.[14-17] Multiple authors have called for outcome studies evaluating the long-term health of these children and their mothers and have outlined the difficulties in getting these studies accomplished.[18-20]

Research on infertility can be performed using clinical diagnostic and treatment data, vital records data, or self-reported survey data, and there are relative strengths and weaknesses to each of these data sources. With regard to self-reported data, we have previously evaluated the accuracy of report of in vitro fertilization (IVF) treatment in Upstate KIDS surveys and found it to be accurate.[21] However, we have looked at treatment parameters in a very small group of 77 survey participants who underwent IVF treatment in Massachusetts and found mixed reporting accuracy.[22]

To use maternal self-reported data for research purposes, we must have confidence that treatment information is recalled and reported accurately. This study compared self-reported parameters of ART treatment in the maternal survey of the Upstate KIDS study with clinical data in the Society for Assisted Reproductive Technology Clinic Outcome Reporting System (SART CORS) database. Accuracy of maternal self-report of treatment type and treatment parameters on the index pregnancy was assessed.

The secondary objective was to investigate whether time to survey, age of the mother, previous ART use, or presence of male factor infertility (as reported in SART CORS and known to be associated with increased use of intracytoplasmic sperm injection [ICSI]) affect reporting accuracy.

Materials and Methods

Data sources

Data were obtained from 2 sources, the Upstate KIDS maternal questionnaires and the SART CORS clinical ART data.

The Upstate KIDS Study used the New York State's Perinatal Data System to identify all live births occurring to resident mothers of Upstate New York (57 New York counties excluding the 5 boroughs of New York City) between 2008 and 2010.[23] Upstate KIDS was

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designed to obtain a population based cohort of infants conceived with and without infertility treatment including ART for the assessment of children's growth and development.

All infants for whom the infertility treatment box was checked on their birth certificates as well as all infants of multiple births irrespective of treatment status were recruited. Women delivering singletons conceived without infertility treatment were recruited based on a paradigm including frequency matching at a 3:1 ratio to women delivering singletons conceived with treatment within the perinatal region of delivery.

The majority (93%) of Upstate KIDS mothers returned a self-administered questionnaire within 4-6 months of delivery. An incentive of $30 was provided to participants along with reminder calls and e-mails to achieve a high response rate. For this study we evaluated questions about ART treatment for the index delivery (question 23) as well as questions about the use of ART in previous pregnancies (question 25).

The Institutional Review Boards at New York State Department of Health and the University at Albany (State University of New York) approved the Study and served as the institutional review boards under a formal reliance agreement with the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, National Institutes of Health. All participants provided written informed consent prior to data collection.

The SART CORS database is used by the Society for Assisted Reproductive Technology to collect national ART data under the Fertility Clinic Success Rate and Certification Act of 1992 (Public Law 102-493) and to report these data to the Centers for Disease Control and Prevention. SART CORS collects data from more than 90% of US ART clinics and includes greater than 95% of the US ART cycles.

The data collected include patient demographic information (age, race, height, and weight); reproductive history (prior cycles of ART and intrauterine insemination and female infertility diagnosis); cycle-specific treatment data (fresh vs frozen cycle, use of autologous or donor oocytes or embryos, use of ICSI, assisted hatching (AH) and other laboratory techniques; numbers of embryos transferred and quality of embryos transferred); and outcome data (cancellation, treatment outcome, pregnancy outcome, birthweight, gestational age).

Data are validated annually through a review by the Society for Assisted Reproductive Technology and the Centers for Disease Control and Prevention with yearly site visits to a random selection of clinics to check records for completeness and accuracy of data collection and data entry (http://www.cdc.gov/art/ART2011/NationalSummary_appixa.htm). SART CORS data for this study included fields related to the use of donor gametes, micromanipulation, and prior treatment.

Linkage

Upstate KIDS deliveries were linked to ART cycles containing a birth outcome reported to SART CORS as previously described.[21] Briefly, deliveries were linked using identifiers for the mothers the infants and the delivery information. Approximately 89% of the women linking to SART CORS had been invited to participate. Overall participation into the study was 27%.

Statistical analysis

We analyzed how closely the 2 data sources agree and the rates of reports of each treatment type by each data source. For clinical treatment parameters, SART CORS was used as the gold standard; however, for prior treatment we used maternal self-report as the more accurate measure.

The process included the evaluation of the percentage agreement between the 2 data sources for each of the parameters: donor gametes (sperm or oocytes), use of ICSI (listed as some or all oocytes within SART CORS), AH (listed as some or all embryos in SART CORS), and the use of fresh or frozen embryos for ART transfer. We determined in which data source the reported use of each of these parameters was greater.

We also evaluated use of gamete intrafallopian transfer and zygote intrafallopian transfer and the use of a gestational carrier; however, for the index delivery, there was no SART CORS reporting of these procedures. In addition, we evaluated self-report of procedural treatments that are a part of ART treatment such as vaginal ultrasound and administration of medications. Because fresh and frozen ART treatment may make greater or lesser use of vaginal ultrasound, we evaluated this treatment in all cycles and separately in the cycles using fresh oocytes and embryos only.

Sensitivity was determined for each of these parameters treating SART CORS information from the index cycle as the gold standard. SART CORS is considered the gold standard for these items because these are clinical data and are validated as described in the previous text. Sensitivity was defined as the proportion of women with a certain ART parameter in SART CORS that were correctly reported in the maternal questionnaire, and 95% confidence intervals were calculated using the Agresti-Coull method.[24]

Logistic regression was used to estimate unadjusted odds ratios (OR) and their 95% confidence levels to identify participant characteristics (ie, maternal age, time to report, male factor, previous ART) associated with sensitivity (on parameters that had less than perfect agreement). The analytical sample included all women who had the procedures according to the gold standard, allowing assessment of sensitivity. It did not, however, include all women who did not have ART, and thus, specificity was not estimated.

Also, specificity would most likely be very high ($>$ 99%), given the relatively rare occurrence of ART compared with non-ART deliveries. In the sensitivity analysis, we also evaluated the effect that weighting the analyses by twins, whom are oversampled in this cohort, has on the results.

For comparing information on fertility treatment received to achieve a delivery prior to the index delivery, sensitivity estimates were based on maternal report as the preferred standard rather than SART CORS. This decision is based on previous observations by 2 of the authors (B.L. and J.E.S.) that the prior ART cycle fields do not agree with information on prior cycles

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