Assisted reproductive technology in the United States: 2001 results generated from the American Society for Reproductive Medicine/Society for Assisted Reproductive Technology registry

Society for Assisted Reproductive Technology and the American Society for Reproductive Medicine

Birmingham, Alabama

Objective: To summarize the procedures and outcomes of assisted reproductive technologies (ART) that were initiated in the United States in 2001.

Design: Data were collected electronically using the Society for Assisted Reproductive Technology (SART) Clinic Outcome Reporting System software and submitted to the American Society for Reproductive Medicine/SART Registry.

Participant(s): Three hundred eighty-five clinics submitted data on procedures performed in 2001. Data were collated after November 2002 so that the outcomes of all pregnancies would be known.

Main Outcome Measure(s): Incidence of clinical pregnancy, ectopic pregnancy, abortion, stillbirth, and delivery.

Result(s): Programs reported initiating 108,130 cycles of ART treatment. Of these, 79,042 cycles involved IVF (with and without micromanipulation), with a delivery rate per retrieval of 31.6%; 340 were cycles of gamete intrafallopian transfer, with a delivery rate per retrieval of 21.9%; 661 were cycles of zygote intrafallopian transfer, with a delivery rate per retrieval of 31.0%. The following additional ART procedures were also initiated: 8,147 fresh donor oocyte cycles, with a delivery rate per transfer of 47.3%; 14,509 frozen ET procedures, with a delivery rate per transfer of 23.5%; 3,187 frozen ETs employing donated oocytes or embryos, with a delivery rate per transfer of 27.4%; and 1,366 cycles using a host uterus, with a delivery rate per transfer of 38.7%. In addition, 112 cycles were reported as combinations of more than one treatment type, 8 cycles as research, and 85 as embryo banking. As a result of all procedures, 29,585 deliveries were reported, resulting in 41,168 neonates.

Conclusion(s): In 2001, there were more programs reporting ART treatment and a significant increase in reported cycles compared with 2000. (Fertil Steril® 2007;87:1253–66. ©2007 by American Society for Reproductive Medicine.)

Key Words: Assisted reproductive technology, in vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer, cryopreserved embryos, donor oocytes

In 1988, the Society for Assisted Reproductive Technology (SART) began publishing annual reports of assisted reproductive technologies (ART) activities (1). These annual reports were based on voluntary data submissions by programs and provided a forum for sharing information early in the development of the technology. In 1992, the U.S. Congress passed the Fertility Clinic Success Rate and Certification Act (2), which requires the Centers for Disease Control and Prevention (CDC) to publish clinic-specific pregnancy success rates for ART procedures in the United States. Through collaboration with SART and their data collection system, data from 1995 were first collected and published under the Act (3). In addition to the annual CDC report, SART has continued to review and analyze annual data to explore trends in ART activities in more detail. The purpose of the present report is to summarize the procedures and outcomes of ART procedures initiated in the United States in 2001. The format used for this report will follow that of the prior year to assist the reader when comparing this report with those of prior years.

SART has prepared this report in conjunction with the American Society for Reproductive Medicine (ASRM). It represents mandatory reporting by 385 programs offering ART, 355 (92.2%) of which were members of SART. Each clinic's submitted data were tabulated and summarized by SART and subsequently verified by each clinic's medical director, and all such data were subject to validation through on-site visits and medical record review.

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MATERIALS AND METHODS

Data collected prospectively and, in part, retrospectively for ART treatments initiated from January 1, 2001, through December 31, 2001, form the basis for this report. Programs collected patient- and cycle-specific data in electronic form, using the SART Clinic Outcome Reporting System, a software program designed for ART data collection. Prospective data reporting is required to maintain SART membership; accordingly, SART member clinics electronically report each cycle start within 3 days of treatment commencement. The ART programs submitted the final data in December of 2002 to permit reporting of outcomes of all pregnancies resulting from treatments initiated in 2001. Each reporting clinic submitted an export diskette and a clinic summary report signed and verified as accurate by the medical director. The export diskette was created using the SART Clinic Outcome Reporting System and contained patient demographic characteristics for each patient and history, diagnosis, medication, treatment methods, and outcomes for each cycle.

Data for patients who underwent more than one cycle of ART were collected and analyzed separately for each cycle. Therefore, the number of cycles reported is always equal to or greater than the number of patients. The data were then tabulated by SART and compiled to create the annual national data set. Each clinic was also sent a clinic summary table so that it could reconfirm outcome and treatment data. Analysis was completed over the 12 months after data submission.

From March to June of 2002, SART conducted validation visits at 40 randomly selected clinics. At each clinic, SART Validation Committee members comprehensively reviewed clinic records for up to 50 randomly selected treatment cycles as well as birth data on all reported live births. The CDC also analyzed the data collected during these validation visits. Summary results are available on the CDC Web site at http://www.cdc.gov/ART/ART01/appixa.htm.

The ART procedures were divided into several categories for reporting purposes: IVF, gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), cryopreserved ET, donor oocyte cycles, cryopreserved ETs from donor oocytes, and ART cycles for host uterus transfer. Programs also submitted information on cycles in which intracytoplasmic sperm injection (ICSI) was performed. Treatments that involved combinations of treatment types, embryo banking, and research cycles were included in total cycle counts but were not detailed in this analysis. In the annual ART report published by the CDC (4), embryo banking and research cycles were excluded from total cycle counts. Combination and gestational carrier cycles were included in other cycle classifications; accordingly, the statistics herein may not coincide with those presented in the CDC report.

The following definitions were used in measuring outcomes. A clinical pregnancy was defined as the occurrence of at least one ultrasound-confirmed gestational sac within the uterus (which excludes ectopic and biochemical pregnancies but includes heterotopic pregnancies). Ectopic pregnancies were reported separately. The number of pregnancies is equal to the sum of clinical, ectopic, and biochemical pregnancies. A pregnancy loss was defined as a clinical pregnancy that did not result in a delivery, which includes both spontaneous and therapeutic abortions. A live birth was defined by the delivery of at least one live born neonate, regardless of the number of other neonates and whether they were live born or stillborn. A live-born neonate was one that showed signs of life after the complete expulsion or extraction from the uterus. Signs of life were breathing, presence of a heartbeat, pulsation of the umbilical cord, or definite movement of the voluntary muscles, regardless of gestational age at birth. Heartbeats were to be distinguished from transient cardiac contractions, and respirations were to be distinguished from fleeting respiratory efforts or gasps. A stillbirth was defined by the delivery at 18 weeks or later from the date of transfer of one or more stillborn neonates and no live-born neonates. A stillborn neonate was one that showed no signs of life after the complete expulsion or extraction from the uterus and for whom no certificate of live birth was filed. The number of deliveries was equal to the sum of live births plus stillbirths. The number of neonates (infants born) was equal to the sum of live-born neonates plus stillborn neonates. An ART program or clinic is defined as a distinct legal entity, academic institution, or hospital that practices under state law and that provides ART to couples who have experienced infertility or are undergoing ART for other reasons. Clinics that operated from several locations reported as a single clinic. Age was determined by the female patient's age at the date of cycle start. For fresh nondonor cycles, the date of cycle start was the first day that medication to stimulate follicular development was administered. The date of cycle start for fresh donor cycles or thaw cycles was the first day the patient, donor, or recipient received exogenous sex steroids to prepare the endometrium; for unstimulated cycles, the first day of natural menses or withdrawal bleeding was used. Male-factor diagnosis was defined as a cycle in which one of the reported reasons for ART was male-factor infertility, which was defined by programs according to abnormal semen parameters or function. Research cycles were designated by SART if programs provided evidence of institutional review board approval of the research protocols and consent forms before initiation of the cycles. Approved research treatments were preimplantation genetic diagnosis for transmissible genetic disorders, immature oocyte retrieval and subsequent ET, cytoplasmic transfer, and round spermatid injection. Combination cycles involved more than one treatment modality (e.g., transfer of fresh and thawed cryopreserved nondonor embryos in the same cycle). Embryo banking was defined by the intent from cycle inception to fertilize oocytes and cryopreserve all the resulting embryos, with no intention of fresh transfer. Statistical analysis employed χ^2 testing using GraphPad InStat version 3.05