## Disparity in assisted reproductive technologies outcomes in black women compared with white women

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Objective: To compare success rates in black and white women undergoing IVF.

**Design:** Retrospective cohort study.

**Setting:** Society for Assisted Reproductive Technology member clinics in 1999–2000 that performed  $\geq$  50 cycles of IVF and reported race/ethnicity in >95% of cycles.

Patient(s): Women receiving 80,309 IVF cycles.

Intervention(s): IVF using nondonor embryos.

Main Outcome Measure(s): Live-birth rate per cycle started.

**Result(s):** Black, white, and other race/ethnicity women underwent 3666 (4.6%), 68,607 (83.5%), and 8036 (11.9%) IVF cycles, respectively. Spontaneous abortions were more common among black women. The live-birth rate was 26.3% (95% confidence interval [CI], 25.9%–26.7%) among white women compared with 18.7% (95% CI, 17.5%–20.1%) among black women (rate ratio, 1.41). After controlling for increased tubal and uterine factor infertility among blacks and other characteristics, black race was an independent risk factor for not achieving a live birth (adjusted relative risk, 1.21; 95% CI, 1.12–1.36 if no prior ART, and RR, 1.38; 95% CI, 1.20–1.57 if prior ART). For cryopreserved embryo cycles, live-birth rates were equivalent.

**Conclusion(s):** Black women, who represented 7.8% of married reproductive-age women in the United States at that time, were underrepresented among IVF recipients. Race is a marker for prognosis that is not explained by characteristics available in the registry data set. (Fertil Steril® 2008;90:1701–10. ©2008 by American Society for Reproductive Medicine.)

**Key Words:** Infertility, in vitro fertilization, assisted reproductive techniques, African Americans, black women, race, ethnic groups, socioeconomic factors, delivery of health care

Black women in the United States have experienced an increase in the prevalence of infertility at the same time that infertility is decreasing among white women (1). The population-based rates of 12-month infertility determined by the National Survey of Family Growth in 1982 and 2002 were 7.8% and 11.6%, respectively, for black women and 11.6% and 7.1%, respectively, for white women. Although 1% of all births now originate from some form of assisted reproductive technology (ART), few studies have evaluated differences in ART outcomes between black and white women (1–6).

Differences in clinical outcomes between blacks and whites have been assessed for a variety of other medical technologies in the United States. Cardiovascular procedures, renal transplantation, knee arthroplasty, and cancer surgery are examples of treatments that have been examined (7–13). Such analyses may help determine whether there are racial or ethnic variations in the severity of disease at presentation,

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Reprint requests: David B. Seifer, M.D., Genesis Fertility and Reproductive Medicine, Maimonides Medical Center, 1355 84th Street, Brooklyn, NY 11228 (FAX: 718-283-6580; E-mail: drseifer@genesisfertility.com). while the research results could help improve the accessibility and delivery of medical technologies.

There is no consensus among the existing research that compares the ART outcomes of black women with white women. Some studies have identified racial differences (2, (4, 5), while others have not (4, 5). Previous studies are limited by relatively small sample sizes, and this may explain the discrepant results. In an effort to help resolve this controversy, we examined the hypothesis that there may be racial differences in ART outcomes between black and white women in the United States by analyzing the Society for Assisted Reproductive Technology (SART) database for the years 1999–2000 (14–16). This time period is at the midpoint of the two most recent National Survey of Family Growth years, 1995 and 2002 (1, 17, 18). Analysis of the extensive SART database for possible racial disparities may also serve as a baseline for comparison at the beginning of the 21st century with future ART outcome studies.

#### MATERIALS AND METHODS

#### **Data Source and Inclusion Criteria**

This study was approved by the Institutional Review Board of the University of Kansas School of Medicine at Wichita. A retrospective cohort study was conducted. Deidentified data from the national registry of ART treatment cycles in the United States during 1999–2000 were analyzed. This registry, described in detail elsewhere (14-16), contains data collected by SART and maintained by the Centers for Disease Control and Prevention (CDC) in compliance with the Fertility Clinic Success Rate and Certification Act of 1992 (Pub. L. 102-493, October 24, 1992). Clinics submitted information about ART treatment cycles and outcomes according to a standardized protocol that included prompts for designating Hispanic ethnicity and for indicating race as white, Asian, black, Native American, or other. Clinics reported the woman's maximum historic cycle day 3 FSH level (in mIU/mL) and the laboratory's upper limit of normal. Samples of the data reported by ART clinics were validated independently by medical record review (14, 15). More than 90% of clinics complied with the mandate to report data, and it is believed that nonreporting centers were smaller than average practices (16).

To create the study data set, CDC selected the 184,173 IVF cycles reported by SART member clinics during the study period and then excluded 2755 (1.5%) cycles to limit the study data set to clinics providing 50 or more cycles in a given year. CDC used clinic identifiers to create an annual clinic volume variable in two categories split by the median volume and a variable in four quartiles representing the clinic's overall clinical intrauterine gestation (CIG) rate for fresh nondonor cycles among women <35 years old. Then clinic identifiers were deleted from the study data set. To minimize the likelihood of selection bias because of missing data on race, CDC excluded 87,836 (48.4%) cycles from the remaining 181,418 cycles to limit the study data set to clinics that reported race in  $\geq$  95% of cycles. CDC compared the 87,836 cycles excluded because of missing data on race to the remaining 93,582 cycles and found that the clinical pregnancy rate per cycle started was essentially the same for the excluded and included cycles (30.8% and 30.6%, respectively) and that the live-birth rates were identical (25.2%).

From the 93,582 cycles in the final study data set provided by CDC, we excluded 241 cycles with missing data on whether a CIG occurred, 1027 cycles that used a gestational carrier, 10,117 cycles that used embryos created with donor oocytes, and 1888 cycles with missing data on race, which left 80,309 cycles for analysis.

#### **Statistical Analysis**

Data were analyzed using SPSS (ver. 14.0; SPSS Inc., Chicago). The treatment cycle was the unit of analysis because personal identifiers were not available and cycles were not linked, precluding analysis by individual patient. Data among women with no prior ART were examined separately because these cycles most likely represent individual women. Diagnoses were examined individually to avoid obscuring relationships by using mutually exclusive categories such as multiple female factors or multiple male and female factors (6, 16). FSH ratios were obtained by dividing the FSH level by the upper limit of normal for the laboratory. Extreme values of FSH dosage (>80 ampules) that may have been coding errors were replaced by missing values. The implantation rate was calculated by dividing the number of fetal heartbeats on first trimester ultrasound in a given cycle by the number of embryos transferred in that cycle. Clinical pregnancy was defined as the presence of a gestational sac by ultrasound during the first trimester. A live birth was defined as birth of one or more living infants. Rates of both of these outcomes were calculated per cycle started.

Categorical variables were compared using  $\chi^2$ -tests. For continuous variables, groups were compared using Mann-Whitney tests because of skewed distributions. For our data and when using published data used for comparison purposes (14, 15), 95% confidence intervals (CIs) were calculated using the formula

$$p \pm Z_{1-\alpha/2}\sqrt{p(1-p)/n}$$

where p represents the proportion with the outcome and n represents the total number of cycles.

To estimate the independent contribution of race to treatment outcomes, multivariable logistic regression analyses were performed. Potential confounders found to be statistically significant in univariate analyses were included in the models. Backward conditional elimination was used to generate the most parsimonious models. If race was eliminated from the model, then results were presented for the last regression step that included race. To derive approximate relative risks (RRs) for outcomes that had a prevalence of 10% or greater, the adjusted odds ratios (Adj. ORs) were corrected using the formula, Adj. RR = Adj. OR /  $[(1 - p_0) + (Adj.$ OR  $\times p_0)]$  (19). All statistical tests were two-tailed and used  $\alpha = 0.05$ . Percentages in specific analyses did not total to 100 because of rounding, and there were different numbers of cycles in some analyses because of missing data.

### RESULTS

There were 80,309 nondonor cycles of ART during 1999–2000 that met study inclusion criteria. To facilitate comparisons with the United States population, the distribution of these ART cycles was examined by race and Hispanic origin. There were 3666 (4.6%) cycles among black non-Hispanic women and 68,607 (85.4%) cycles among white non-Hispanic women. We excluded from further analysis 3585 Asian non-Hispanic women, 4338 (5.4%) cycles among Mispanic women of any race, 66 (0.08%) cycles among Native American women, and 47 (0.06%) cycles among women of other races. This left a final study population of 72,273 cycles among white non-Hispanic women (referred to as white and black for the rest of this paper).

The baseline characteristics, treatment factors, and outcomes are provided in Table 1 for fresh nondonor cycles (3116 cycles among black women and 58,459 cycles among white women) and in Table 2 for cycles using cryopreserved embryos (550 cycles among black women and 10,147 cycles



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