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Are there ethnic differences in pregnancy rates in African-American versus white women undergoing frozen blastocyst transfers?

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Abstract

Objective—To determine whether frozen-thawed blastocyst transfer pregnancy rates (PR) are lower in African-American compared with white women.

Design—Retrospective review of frozen blastocyst cycles.

Setting—University-based assisted reproductive technology (ART) program.

Patient(s)—All patients who underwent a frozen blastocyst transfer between 2003 and 2008.

Intervention—None.

Main Outcome Measure(s)—Live birth rate.

Result(s)—One hundred sixty-nine patients underwent transfer of a frozen-thawed blastocyst. African-American women had a higher incidence of leiomyoma (40% vs. 10%) and tubal and uterine factor infertility. There was no difference in the live birth rate for African-American patients (28.0%) compared with white patients (30.2%). Of the patients who underwent a frozen-thawed blastocyst transfer, 58% (n = 98) had their fresh, autologous IVF cycle, which produced the cryopreserved blastocyst, at Walter Reed Medical Center. A higher peak serum E₂ level was noted in African-American patients (5,355 pg/mL) compared with white patients (4,541 pg/mL). During the fresh cycle, the live birth rates between African-American and white patients were significantly different at 16.7% versus 39.7%, respectively.

Conclusion(s)—Live birth rates after frozen blastocyst transfer are not different between African-American and white women despite a fourfold higher incidence of leiomyomas in African-American women.

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Keywords

Ethnicity; racial; disparities; live birth rate; infertility; IVF; ART

Since the advent of IVF clinicians have sought to optimize cycles and identify factors that impact pregnancy success. More recently ethnicity has been identified as an inherent, nonmodifiable factor that affects pregnancy outcomes. The reason for ethnic differences in IVF outcomes remains an enigma. The first US studies on ethnic differences in IVF emerged in 2000 and compared African-American women with white women (1–3). Sharara and McClamrock (3) demonstrated a lower African-American pregnancy rate (PR) in an inner city clinic, whereas subsequent studies revealed inconsistent results (1, 2, 4, 5). Although limited by small sample sizes these early studies established precedence for future investigation of racial and ethnic disparities in IVF outcomes.

One confounder in examining ethnic differences in IVF pregnancy outcomes is the underutilization of services by certain ethnicities. In an equal access to care facility, Feinberg and colleagues (6) found an approximate 20% reduction in live birth rates in an African-American cohort when compared with a white cohort. Since that time, more than 100,000 cycles have been examined by three large retrospective analyses, demonstrating significant reductions (25%–38%) in African-American live birth rates after IVF when compared with white cohorts (7–9). The reason for this ethnic disparity remains unknown, but increased prevalence of leiomyoma, tubal disease, and obesity in the African-American infertile population are possible explanations (1, 2, 4–6, 8–11).

Recent work suggests that endometrial receptivity in response to gonadotropin stimulation may explain ethnic differences in PRs in Asian women versus white women, as the quality of embryos at cleavage stage and blastocyst stage appear to be similar between both ethnic groups (12–14). In fresh nondonor IVF cycles, the PRs of Asian women were lower than that of white women (12–14). Interestingly, PRs with controlled hormonal replacement for endometrial preparation are similar using the oocyte donation model between Asian and white women (15).

At present numerous studies have confirmed the finding of decreased PRs and increased miscarriage rates in African-American women during fresh IVF/intracytoplasmic sperm injection (ICSI) cycles (3, 6–9, 16). We hypothesize that tubal and uterine factors are responsible for the ethnic disparity in pregnancy outcomes in fresh cycles, and the same disparity would be seen in frozen embryo cycles. The objective of this study was to determine whether an ethnic disparity exists in live birth rates between African-American and white women after frozen-thawed blastocyst ETs.

MATERIALS AND METHODS

Study Design

A retrospective cohort analysis of all patients undergoing frozen blastocyst ETs was performed. Institutional Review Board approval was obtained from the Walter Reed Army Medical Center (WRAMC) Division of Clinical Investigation. The main outcome analyzed was live birth rate. Other outcome measures included clinical PRs and spontaneous abortion rates.

Patients

Electronic records were evaluated for all patients who underwent a frozen blastocyst ET cycle between January 2003 and December 2008. One hundred eighty-six patients were

identified who underwent transfer of at least one frozen-thawed blastocyst. No frozen donor embryo cycles were performed. For patients who underwent multiple frozen ET cycles, only their first cycle was included in the analysis to maintain independent sampling. Demographic and IVF cycle characteristic data were recorded. Ethnicity was documented as reported by the patient on intake evaluation.

Blastocysts selected for cryopreservation met requirements as established by the embryology laboratory at WRAMC. No cleavage stage embryos were frozen. Blastocysts were required to be grade BB or better by modified Gardner grading scale. Due to the strict criteria, historically only 10% of the patients had embryos that met the cryopreservation requirements of our laboratory. As a result, the successful thaw/survival rate for frozen blastocysts within the laboratory exceeded 95%. There were no significant changes in cryopreservation techniques during the study period.

Patient Treatment Protocol

Patients were given SC leuprolide acetate (LA), 1 mg/d, starting in the midluteal phase of the preceding menstrual cycle or after 2–4 weeks of taking oral contraceptives (OC) (with a 5-day overlap). At baseline all patients had suppressed serum E₂ levels and a transvaginal ultrasound examination demonstrating an early proliferative pattern. If leiomyomas were present on ultrasound, their size and location were documented. Before the cycle start, all patients had saline sonohysterographic testing to ensure a normal uterine cavity. No patients included in the analysis had evidence of cavity distortion at cycle start.

The patients began sequentially increasing doses of oral micronized 17 β -E₂, starting at 2 mg once a day and increasing to a maximum dose of 2 mg three times a day. Serial serum E₂ measurements and transvaginal ultrasound evaluation of the endometrium were performed. Once E₂ levels exceeded 200 pg/mL and an appropriate trilaminar endometrial pattern was obtained, the GnRH agonist treatment was discontinued and P in oil, 50 mg/d IM, was initiated. The blastocyst transfer occurred 5 days after the start of P supplementation.

Blastocysts selected for transfer were based on morphological assessment. Each patient was placed in the dorsal lithotomy position without sedation. The blastocyst transfer was performed under ultrasound guidance. Serum quantitative hCG testing was performed 9 and 11 days after blastocyst transfer and transvaginal ultrasound was performed approximately 4 weeks later to confirm an intrauterine pregnancy. Pregnancy outcome data were collected.

Subgroup Analysis

For all study patients who underwent frozen-thawed blastocyst transfer, electronic medical records were reviewed to ascertain data for an antecedent fresh IVF or ICSI cycle that produced the cryopreserved blastocysts used in the frozen-thawed cycle. Ninety-eight patients had complete data for fresh, autologous IVF/ICSI stimulation (leading to a cryopreserved blastocyst) through WRAMC. Demographic, cycle, and pregnancy outcome data of this subset of patients were recorded. Similar to the frozen cycles, before the cycle start all patients had a saline sonohysterogram to ensure a normal uterine cavity without distortion. All fresh ETs were performed under ultrasound guidance.

Statistical Analysis

Statistical analyses were performed using Statistical Package for the Social Sciences (version 16.0.1, 2008; SPSS, Inc., Chicago, IL). For normally distributed data, a *t*-test was used to compare the mean values. For data that were not normally distributed, a Mann-Whitney rank sum test was used to compare the mean values. Differences in outcome rates

were analyzed using a χ^2 test or Fisher's exact test when appropriate. An α error of 0.05 was considered significant for all comparisons. All data were reported as mean $\pm$ SD.

RESULTS

There were 186 patients identified who underwent transfer of a frozen-thawed blastocyst between 2003 and 2008. Of these, there were 119 white women, 50 African-American women, and 17 women of other ethnicities (Hispanic, Asian, mixed). Only those patients of African-American or white ethnicity were included in this analysis.

The baseline characteristics of the 169 patients undergoing a frozen-thawed blastocyst transfer are seen in Table 1. African-American and white women had similar age (mean 34.1 and 34.7 years, median 35.0 and 35.0 years, respectively), gravidity, and parity. Leiomyomas were more frequently seen on ultrasound in the African-American patients than in white women (40% vs. 10%, $P<.001$). When examining patients with leiomyoma more than 3 cm, 12% of African-American women were affected compared with only 1% of white women ($P=.002$). During the treatment with oral E_2 , the African-American and white patients had a maximum endometrial thickness of 10.4 mm and 9.4 mm, respectively, before blastocyst transfer ($P=.01$). Although statistically significant, the 1-mm difference did not likely represent a clinically significant result. The mean number of blastocysts (2.1) transferred per patient was also similar between both groups. In Table 2 are the infertility diagnoses demonstrating that African-American women had a higher likelihood of tubal factor (64% vs. 31%) and uterine factor (40% vs. 10%), and a lower likelihood of anovulation (4% vs. 22%) when compared with white women.

Pregnancy outcome, the primary end point, is shown in Table 3. The overall PR after frozen-thawed blastocyst transfers for African-American women was 62.0% compared with 57.1% for white women ($P=.61$). The clinical PRs were 42% in African-American women and 39.5% in white women. The overall live birth rate (singleton and twins) for African-American patients was 28.0% compared with 30.2% in white patients ($P=.85$). Overall, there were no significant differences in pregnancy outcomes after frozen-thawed blastocyst transfer between the two ethnicities.

A subanalysis of pregnancy outcomes after the frozen-thawed blastocyst transfer was performed that excluded all patients with sonographically visible leiomyoma(s). Of the 30 African-American patients with no evidence of leiomyoma on ultrasound, the overall live birth rate was 23.3% compared with 31.5% in the 108 white women without leiomyomas (Table 3). There were no significant differences in overall PRs, clinical PRs, or spontaneous abortions in this subgroup.

Of the 169 patients who underwent a frozen-thawed blastocyst transfer, 58% ($n = 98$) had their fresh, autologous IVF or ICSI cycle, which produced the cryopreserved blastocyst, also at WRAMC. The data on fresh IVF/ICSI cycles were analyzed for 60.0% of the African-American patients (30/50) and for 57.1% of white patients (68/119). In Table 4, the characteristics and pregnancy outcomes are presented. In the fresh IVF/ICSI cycle, the mean age, basal antral follicle count, and FSH levels were all similar between the two ethnicities. The mean number of days of stimulation was 10.7 and 10.1 between African-American and white patients, respectively ($P=.02$). There was a higher peak serum E_2 level in African-American patients (5,355 pg/mL) compared with white patients (4,541 pg/mL) ($P=.078$). There was also a trend toward lower total gonadotropins received between African-American women (2,479 IU) and white women (3,045 IU) ($P=.057$). A similar number of embryos were transferred between the two groups. There were no differences in the proportion of cleavage stage (day 3) and blastocyst (day 5) transfers between the groups.

African-American women had 70% cleavage stage and 30% blastocyst transfers, compared with 65.2% and 34.8%, respectively, in white women ($P=.82$).

During the fresh IVF/ICSI cycle, the overall PR for African-American women was 46.7% compared with 61.8% in white women ($P=.19$). The clinical PR for African-American women was 40% compared with 50% in white women ($P=$ not significant [NS]), whereas spontaneous abortion rates were 23.3% versus 8.8%, respectively ($P=.06$). The live birth rates between African-American and white patients were significantly different at 16.7% versus 39.7%, respectively ($P=.035$, odds ratio [OR] 0.30, 95% confidence interval [CI] 0.10–0.89).

Finally, the cumulative live birth rate for the subset of patients who underwent both fresh IVF/ICSI stimulation cycles and frozen-thawed blastocyst transfer cycles at WRAMC was 54% overall. The cumulative live birth rate in whites was 62.2%, compared with only 37.5% in African-American women ($P=.01$).

DISCUSSION

Our data show that live birth rates after frozen blastocyst transfer are not different between African-American and white women despite a fourfold higher incidence of leiomyomas in African-American women. Our hypothesis that the increased prevalence of tubal and uterine factors was the only cause of ethnic disparities in fresh cycles is not supported by our observations in frozen embryo cycles. The cohorts did not have any change in their tubal/uterine status between fresh and frozen cycles, yet there is a clear divergence of pregnancy outcomes.

Our results are consistent with Huddleston et al. (15), who found similar pregnancy outcomes when comparing Asian and white oocyte donor recipient cycles. In both fresh autologous IVF cycles and oocyte donors undergoing gonadotropin stimulation, the investigators found higher peak E_2 levels in Asian women compared with white women (13, 15, 17). Our results also supported higher peak serum E_2 levels in African-American women compared with white women undergoing fresh IVF cycles, which is similar to other studies (3, 4). This difference in peak serum E_2 levels was identified, although these earlier studies were limited by small sample sizes. Our finding of increased peak E_2 levels in African-American women was present despite a trend toward a lower total amount of gonadotropins received.

Multiple studies have demonstrated a significantly lower live birth rate in African-American women undergoing fresh IVF cycles when compared with white women (3, 6–9, 16). Due to the increased prevalence of leiomyomas in African-American women, it has been assumed that the lower live birth rates are a direct reflection of uterine factors. Our data calls into question this theory as the relative difference of live birth rates between African-American and white women should be present (regardless of cycle type) if leiomyomas were the sole explanation. Previous studies have demonstrated higher rates of uterine and tubal factor infertility in African-American women, also consistent with our data (2–4). Because both leiomyomas and hydrosalpinges have a detrimental effect on implantation rates and pregnancy outcomes, we hypothesized that the ethnic disparities could be explained by the infertility diagnoses. Interestingly, despite a fourfold increase in leiomyomas visualized on ultrasound in African-American women, this increased prevalence did not translate to decreased live birth rates after frozen blastocyst ET in our study. This finding is contrary to prior beliefs that the increased rate of uterine leiomyomas in African-American women was the main reason for the disparity.

Consistent with our results, Seifer et al. (8) analyzed the cryopre-served nondonor embryo cycles of 550 African-American and 10,147 white women and also found no difference in live birth rates. One potential explanation for the equivalent PRs after frozen blastocyst ET may be due to selection bias with respect to the embryos. Although there is a demonstrated difference in fresh IVF cycle live birth rates, only those patients with high embryo quality and quantity would be candidates for a subsequent frozen cycle. Therefore, the notable difference in fresh cycle live birth rates may be attributed to the initial transfer of less optimal embryos in the African-American women. The ethnic discrepancy in live birth rates between fresh and frozen cycles may be a reflection of the quality of the embryo transferred. In addition, potential differential effects resulting from the cryopreservation and thawing process may contribute to the disparity. Given the differences in outcomes between fresh and frozen cycles, we suggest that gonadotropin stimulation and supraphysiologic hormone levels may have differentially deleterious effects on implantation and/or pregnancy outcome in African-American women compared with white women.

There are multiple strengths of this analysis. Importantly, data were collected from WRAMC, which is an equal access to care setting. As demonstrated previously, African-American women at WRAMC had a fourfold higher utilization of assisted reproductive technologies (ART) than the national average (6). In addition, a majority of the fresh cycles that preceded the frozen ETs were analyzed, which provided additional insight into the disparity. To our knowledge this is the first analysis comparing linked fresh and cryopreserved cycles of African-American and white women. Our data confirmed the previous findings of Feinberg et al. (6), showing decreased live birth rates in African-American women during fresh IVF cycles.

The primary weakness of any retrospective study is in the design that introduces a potential bias into the cohort analyzed. Retrospective identification of frozen blastocyst transfers with linked fresh nondonor IVF ETs would bias toward those fresh cycles in which successful pregnancies did not occur (i.e., failed fresh IVF cycles). To minimize this bias, all frozen blastocyst transfers were included in the analysis, including patients with and without a previous successful fresh IVF cycle. Whether the presence of such bias would adversely affect the subsequent frozen blastocyst outcomes of one ethnicity group is unknown. One particular challenge was acquiring a large enough population necessary to evaluate an end point such as live birth rate. As a result, post-hoc analysis revealed that this study would be able to detect an absolute difference in live birth rate of 20% (power 80%, $\alpha = 0.05$). Within this study, the observed difference in live birth rates after frozen blastocyst ET was only 2.2%, but there still remains the possibility of a type II error. The data for this study were originally collected in a prospective fashion and placed into an electronic database, therefore minimizing recall and collection bias. Due to the dynamic nature of the population receiving care at our institution, it was not possible to analyze the fresh cycles of all patients who underwent a frozen blastocyst transfer.

In conclusion, our study showed that live birth rates after frozen blastocyst ET are similar between white and African-American women despite a fourfold higher incidence of leiomyomas in African-American women. These data suggest that the ethnic disparity observed in fresh nondonor stimulated IVF cycles may result from causes other than leiomyomas or tubal disease. It is intriguing that this dataset did not support an intrinsic negative effect from leiomyomas on frozen ET pregnancy outcomes. Larger prospective studies are required to confirm and help determine the cause of the disparity after fresh IVF and frozen blastocyst cycles between these two ethnicities.

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TABLE 1

Baseline characteristics and cycle parameters between African-American and white women undergoing frozen-thawed blastocyst ET.

Characteristic	African-American women (n = 50)	White women (n = 119)	P value
Age (y)	34.1 ± 3.6	34.7 ± 4.2	.31
Gravidity	1.8 ± 2.2	1.5 ± 1.9	.54
Parity	0.6 ± 1.1	0.8 ± 0.8	.2
Leiomyoma present	20/50 (40%)	11/119 (10%)	< .001 ^a
Leiomyoma >3 cm present	6/50 (12%)	1/119 (1%)	.002 ^a
Peak E ₂ (pg/mL)	891 ± 792	909 ± 723	.89
Endometrial stripe (mm) ^b	10.4 ± 2.5	9.4 ± 1.9	.01 ^a
Embryos transferred	2.1 ± 0.6	2.1 ± 0.6	.75

Csokmay. Ethnic disparity in frozen embryo cycles. *Fertil Steril* 2011.

^a $P < .05$, statistically significant difference.

^b At the time of frozen-thawed blastocyst ET.

TABLE 2

Etiologies of infertility between African-American and white women undergoing frozen blastocyst transfer.

Infertility factor	African-American women (n = 50)	White women (n = 119)	P value
Tubal factor	32 (64%)	37 (31%)	<.0001 ^a
Uterine factor	20 (40%)	11 (10%)	<.001 ^a
Male factor	11 (22%)	19 (16%)	.38
Unexplained infertility	6 (12%)	22 (18%)	.37
Anovulation	2 (4%)	26 (22%)	.005 ^a
Endometriosis	4 (8%)	13 (11%)	.59
Diminished ovarian reserve	0	6 (5%)	.18

Note: Percentages total more than 100% due to some patients having two etiologies.

Csokmay. Ethnic disparity in frozen embryo cycles. *Fertil Steril* 2011.

^a*P* < .05, statistically significant difference.

TABLE 3

Pregnancy outcomes between African-American and white women undergoing frozen ET.

Pregnancy outcome	African-American women (n = 50)	White women (n = 119)	P value
All patients			
Pregnancy rate	62.0% (31/50)	57.1% (68/119)	.610
Clinical pregnancy	42.0% (21/50)	39.5% (47/119)	.864
Spontaneous abortion	14.0% (7/50)	10.1% (12/119)	.594
Live birth rate ^a	28.0% (14/50)	30.2% (36/119)	.854
Patients without leiomyoma			
Pregnancy rate	60.0% (18/30)	59.3% (64/108)	1.00
Clinical pregnancy	33.3% (10/30)	40.7% (44/108)	.530
Spontaneous abortion	10.0% (3/30)	10.2% (11/108)	1.00
Live birth rate ^a	23.3% (7/30)	31.5% (34/108)	.499

Csokmay. Ethnic disparity in frozen embryo cycles. *Fertil Steril* 2011.^aPregnancy resulting in at least one live birth.

TABLE 4

Characteristics of fresh nondonor IVF/ICSI cycles in a subset of African-American and white patients who subsequently used the cryopreserved embryos for frozen blastocyst transfer cycle.

Characteristic	African-American women (n = 30)	White women (n = 68)	P value
Age (y)	32.8 ± 3.1	32.7 ± 3.7	.897
Basal antral follicle count	16.0 ± 8.3	15.7 ± 8.7	.39
Basal FSH (IU/mL)	6.9 ± 2.1	6.5 ± 2.8	.35
Peak E ₂ (pg/mL) ^a	5,355 ± 2,567	4,541 ± 2,075	.078
Days of stimulation	10.7 ± 1.1	10.1 ± 1.3	.022 ^b
Total gonadotropins used(U)	2,479 ± 1,567	3,045 ± 1,384	.057
No. of embryos transferred	2.00 ± 0.37	2.16 ± 0.44	.085
Pregnancy rate	46.7% (14/30)	61.8% (42/68)	.189
Clinical pregnancy	40.0% (12/30)	50.0% (34/68)	.388
Spontaneous abortion	23.3% (7/30)	8.8% (6/68)	.061
Live birth rate	16.7% (5/30)	39.7% (27/68)	.035 ^b

Note: All values are presented as mean ± SD as appropriate. ICSI = intracytoplasmic sperm injection.

Csokmay. Ethnic disparity in frozen embryo cycles. *Fertil Steril* 2011.

^aSerum E₂ drawn on the day after hCG injection.

^b*P* < .05, statistically significant difference.