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Morbid obesity is associated with lower clinical pregnancy rates after in vitro fertilization in women with polycystic ovary syndrome

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Abstract

Objective—To determine if morbid obesity is associated with decreased pregnancy and live birth rates after IVF in women with PCOS

Design—Retrospective cohort study

Setting—University-based fertility center

Patients—72 women with PCOS who completed their first IVF cycle between 2001 and 2007

Interventions—IVF outcomes were compared between women with a BMI of less than 40 kg/m^2 versus those women with a BMI of 40 kg/m^2 or greater

Main outcome measures—Clinical pregnancy rate, live birth rate

Results—Morbidly obese women with PCOS (n=19) had significantly lower clinical pregnancy rates after IVF than PCOS patients who were not morbidly obese (n=53) (32% vs. 72%, RR 0.44, 95% confidence interval 0.22 to 0.87). Their live birth rates were lower too, although this difference was not statistically significant (32% vs. 60%, RR 0.52, 95% confidence interval 0.26 to 1.05).

Conclusions—Morbid obesity is associated with lower pregnancy rates in women with PCOS after IVF raising the question if weight loss may improve IVF success rates for morbidly obese PCOS patients.

Keywords

morbid obesity; polycystic ovary syndrome; pregnancy; in vitro fertilization

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Introduction

Polycystic ovary syndrome (PCOS) is a well recognized condition affecting fertility in many women of reproductive age. While anovulation is common among women with PCOS who seek fertility treatment, PCOS patients often vary dramatically in their other clinical presentation. The diversity among women with PCOS is particularly notable within the context of weight as approximately 50% of PCOS patients have body mass indices consistent with obesity (1), and an increasing number these of women may be morbidly obese (2).

While obesity is defined as a BMI 30 kg/m^2 or greater, morbid obesity, defined as a BMI of 40 kg/m^2 or greater, is a disease associated with increased risks of diabetes, cardiovascular complications, cancer, and death (2). Of additional concern for women hoping to conceive, morbid obesity is also associated with increased risks of gestational diabetes, preeclampsia, and the need for cesarean delivery (3). Despite knowledge that weight reduction can improve health and ovulation in obese women with PCOS (2–5), ovulation induction with oral pharmaceutical agents is typically used as first-line therapy for all infertile PCOS patients. For infertile PCOS patients who fail to conceive with oral agents, in vitro fertilization (IVF) is the common therapy (1).

There have been many clinical studies of the influence of obesity on IVF cycles (3, 7–11). Some have found that obesity is associated with lower clinical pregnancy rates (6–9), while others have not (10, 11). These study differences may be due to analysis of different degrees of obesity, with a BMI of 30 kg/m^2 being the most commonly analyzed, different ovarian stimulation protocols, different indications for IVF, as well as variation in control for PCOS in data analysis. While these studies provide some hints of what kind of success could be expected after IVF therapy for women who are morbidly obese with polycystic ovary syndrome, very little is actually known about the increasing clinical scenario of PCOS, morbid obesity, and IVF.

Given the lack of knowledge regarding the relationship between morbid obesity and IVF outcomes in women with PCOS, we sought to compare IVF outcomes in PCOS patients with a BMI less than 40 kg/m^2 versus a BMI of 40 kg/m^2 or greater.

Methods

This retrospective cohort study evaluating sequential patients with PCOS who underwent IVF through Washington University in Saint Louis was approved by the university's Institutional Review Board. Women with a diagnosis of PCOS who underwent their first cycle of IVF between January 1st, 2001 and December 31st 2006 were identified through a search of our clinic's SART reporting database. Once patients were identified, their charts were reviewed to verify the diagnosis of PCOS based on the 2003 Rotterdam consensus criteria (12). Inclusion was limited to women under the age of 38 to minimize the influence of age on response to ovarian stimulation. Women were excluded if they had known stage III or IV endometriosis, or if the sperm used in their procedure was retrieved via micro-epididymal sperm aspiration (MESA) or testicular sperm extraction (TESE).

Once the women in the study group were identified, they were divided into one of two groups on the basis of BMI less than 40 kg/m^2 vs. BMI of equal to or greater than 40 kg/m^2. BMI was determined for each patient using height and weight information obtained from each patient's chart. Height was routinely measured and recorded for each patient at their initial visit. Weight information was updated throughout the chart, and the weight recorded closest to the time of IVF stimulation was used to calculate each patient's BMI. In most cases the weight was recorded within a month of initiating IVF. Other data collected from

the chart included baseline patient characteristics including age, history of previous live birth, metformin use, pre-IVF use of oral contraceptive pills, and other coexisting infertility diagnoses including endometriosis, male factor, and tubal factor.

Women not undergoing COH with our standard long luteal phase gonadotropin-releasing hormone (GnRH) agonist protocol were excluded as this is the most commonly used protocol for PCOS patients in our center, and we wanted to exclude any effect other stimulation protocols may have on IVF cycle outcomes. Pre-IVF cycle treatment with oral contraceptive pills or insulin sensitizing agents was at the discretion of the treating physician. Pituitary desensitization was achieved with subcutaneous administration of the GnRH agonist leuprolide. Leuprolide was initiated on day 21 of the cycle preceding ovarian stimulation, and recombinant follicle stimulating hormone (FSH) was initiated 11–17 days later. The initial FSH dose was chosen based on the patient's age and antral follicle count. Subsequent FSH dosing was adjusted according to ovarian response as measured by serial ultrasounds and serum estradiol levels. In some cases human menopausal gonadotropin was added. When three follicles were 16–20 mm in diameter and the serum estradiol level was at least 500 pg/ml, the patient was triggered with human chorionic gonadotropin (10,000 international units of urinary product intramuscularly, or 250 ug recombinant drug subcutaneously). Cycles were canceled at the discretion of the treating physician.

Oocyte retrieval was performed 36 hours after hCG administration by ultrasound-guided transvaginal follicular aspiration. Oocytes were fertilized by conventional insemination or by intracytoplasmic sperm injection (ICSI). Fertilization rate was defined as the number of normally fertilized oocytes divided by the number of oocytes inseminated or injected. Patients with at least four good quality embryos at the seven-cell stage or greater on the morning of Day 3 were scheduled to undergo embryo transfer on Day 5. Embryo quality for each patient was determined by averaging the cell stage and degree of fragmentation of all embryos on the morning of Day 3 (13). Implantation rate was calculated by dividing the total number of sacs seen on initial ultrasounds divided by the total number of embryos transferred. All women received luteal phase support with 50 mg of intramuscular progesterone daily for eight weeks starting the day of their oocyte retrieval.

This study's primary outcome measure was clinical pregnancy rate after in vitro fertilization in morbidly obese women with PCOS versus that in women with PCOS who were not morbidly obese. Secondary outcomes measures included live birth rate and IVF cycle data including: number of days of stimulation, units of gonadotropin given, peak serum estradiol levels, number of follicles 12 mm or greater and 16 mm or greater seen by transvaginal ultrasound, number oocytes retrieved, use of intracytoplasmic sperm injection (ICSI), fertilization rate, markers of embryo quality, number of embryos transferred, day of embryo transfer (Day 3 or Day 5 of embryo culture), and implantation rate. Patients were excluded from the analyses of embryo quality if they had failed oocyte fertilization. Each patient's oocyte retrieval operative note was reviewed as well to determine if any difficulty was encountered in relation to BMI.

Univariate analyses were performed using student's T-test for continuous variables, and Chi Square or Fischer's exact test for dichotomous variables. Analyses were performed for continuous variables using Excel (Microsoft, Redmond, WA), or for dichotomous variables using Epi-Info software (Centers for Disease Control, Atlanta, GA). Values are expressed as mean ± standard deviation or a total number of cases. Differences were interpreted as significant at $p<0.05$.

Results

Of 95 patients screened, 79 patients were identified who fit study criteria. 72 of these patients completed IVF cycles, and seven patient cycles were canceled during stimulation. Nine patients were excluded from the study because they were stimulated with a GnRH antagonist protocol. Six women were excluded because they had known stage III/IV endometriosis, and another was excluded because she had TESE sperm used in her procedure. 25% of the women who fit study criteria were found to have body mass indices equal to or greater than 40 kg/m^2.

The patients in the BMI group of less than 40 kg/m^2 did not differ from the group of BMI 40 kg/m^2 or greater by age or presence of other infertility diagnosis including male factor, endometriosis, or tubal factor, nor did the two groups differ with regard to previous live birth or the use of ICSI in their IVF cycles. The two groups did not differ in pre-cycle use of oral contraceptive pills, or insulin sensitizing agents, nor did they differ in their risk of cycle cancellation. (TABLE 1) Of the women who had their cycles cancelled, three women hyperresponded to gonadotropins, and four women responded poorly. The women who hyperresponded all had a BMI less than 25 kg/m^2, and the women who responded poorly to gondatropin stimulation all had a BMI greater than 30 kg/m^2.

Morbidly obese PCOS patients completing IVF cycles required higher doses of gonadotropin to achieve the same number of mature follicles in their stimulation cycles (2606.8 international units vs 1924.6 international units, P=0.03). Despite having similar numbers of follicles seen by transvaginal ultrasound, the morbidly obese PCOS patients had significantly lower average peak estradiol levels (1478.7 pg/ml vs. 2144.5 pg/ml, P=0.002). The morbidly obese PCOS patients also had on average significantly fewer oocytes retrieved (8.9 vs. 13.6, P=0.0006). (TABLE 2)

Review of oocyte retrieval operative notes revealed that the procedure was difficult in seven of the morbidly obese women. The procedure was noted to be difficult in four of the women who were not morbidly obese (7/19 vs. 4/53, P=0.006). When the women with difficult retrievals were eliminated in the comparison in the number of oocytes retrieved between both groups, the difference in the average number of oocytes retrieved between the groups ceased to be significant (10.42 vs. 13.63, P=0.06).

Oocyte fertilization rates were lower in the morbidly obese women (59% vs. 69% P=0.03), and there was complete oocyte fertilization failure in three of the morbidly obese women but not in any of the women in the other group (3 vs. 0, P=0.02). As an aside, two of the women with complete oocyte fertilization failure underwent conventional insemination, and one underwent ICSI, and fertilization was no different between morbidly obese women who underwent ICSI fertilization versus conventional insemination (62% vs. 53%, P=0.37).

The average embryo cell stage achieved by the morning of Day 3 was not different between the two groups, however, embryo fragmentation was higher in the morbidly obese women compared to the other group of women (10.1 vs. 4.3, P=0.01). Only two of the morbidly obese PCOS patients met embryo criteria on Day 3 to push to Day 5 for embryo transfer (2 vs. 29, P=0.006). (TABLE 2)

The number of embryos transferred in both groups of women did not differ significantly (1.74 vs. 2.06, P=0.14) nor did the implantation rate (30% vs. 47% P=0.14) (TABLE 2). Clinical pregnancy rates were lower in the morbidly obese PCOS patients completing IVF cycles (32% vs. 72%, RR 0.44, 95% confidence interval 0.22 to 0.87) compared to the group of women with a BMI of less than 40 kg/m^2, and although not statistically significant, the live birth rate was also lower in the morbidly obese PCOS patients (32% vs. 60%, RR 0.52,

95% confidence interval 0.26 to 1.05). (TABLE 3) Lower clinical pregnancy rates continued to be statistically significant when women with cancelled cycles were kept in the data analysis. (TABLE 4)

Discussion

Our study was designed to investigate the effects of morbid obesity on IVF success in women with PCOS. We found that women with PCOS and a BMI of 40 kg/m^2 or greater experienced lower clinical pregnancy rates than other women with PCOS, and our results suggest that a larger study size would reveal that morbid obesity in the setting of PCOS is also associated with lower live birth rates. In addition to achieving lower clinical pregnancy rates, the morbidly obese women with PCOS required more gonadotropin to produce similar numbers of ovarian follicles on ultrasound, and their peak serum estradiol levels were lower. The morbidly obese women were also more likely to have difficult oocyte retrievals, they had less oocytes retrieved, and their oocyte fertilization was impaired compared to the women who were not morbidly obese. Embryos from the morbidly obese women demonstrated greater fragmentation, and these embryos were less likely to meet our center's embryo criteria to push for a Day 5 obligating most of the women in the morbidly obese group to Day 3 transfers.

Our study is unique in that we limited it to women with PCOS stimulated under the same gonadotropin protocol. Also, we chose to compare patients using a BMI cutoff of 40, rather than 30 as is commonly done in studies of obesity and IVF outcome. We chose to investigate the effects of morbid obesity in this population as morbid obesity is characterized by increased risks of disease (2, 3), and by abnormalities in circulating levels of hormones like leptin, adiponectin, and insulin, and substrates for energy production like glucose and free fatty acids (21–23). The pathologic effects of these aberrations on different tissues and organ systems have been the focus of many obesity-related studies, and it may be that such aberrations also have damaging effects on ovarian physiology that account for the high prevalence of anovulation with increasing body weight (14). The factors contributing to ovulatory dysfunction in obesity may also affect follicular development which could then affect subsequent oocyte quality and development of the resulting embryo. Issues with any of these steps in the reproductive process could account for the disparities seen between the two groups of PCOS patients in this study.

It could be argued that the lower pregnancy rates among the morbidly obese women in our study was a result of the high number of transfers in these women using cleavage stage embryos versus blastocysts. However, our clinic's criteria for pushing for a Day 5 transfer were carefully developed to prevent women from proceeding from Day 3 to Day 5 without having embryos surviving for transfer. Pushing these women for a Day 5 transfer would have likely decreased their pregnancy rates even more. We propose instead that some physiologic aberration of morbid obesity affects embryo quality and subsequent pregnancy outcome in morbidly obese women.

Embryos from the morbidly obese women in this study demonstrated a higher degree of fragmentation on Day 3 than those from women who were not morbidly obese. Numerous studies have shown that increasing amounts of fragmentation in embryos transferred on Day 3 are associated with decreasing pregnancy rates (15–17). Although the factors that lead to embryo fragmentation are unknown, one possible cause is adverse follicular conditions (18). Our finding of lower peak estradiol levels among morbidly obese women along with decreased oocyte fertilization may be a reflection of impaired follicular and oocyte development as similar numbers of seemingly mature follicles were visualized on transvaginal ultrasound in the morbidly obese women compared to the other group.

Alternatively, morbid obesity may impair gonadotropin absorption, and it may be that morbidly obese women simply require more gonadotropin or a different route of administration to achieve optimal follicular quality and estradiol levels in IVF. All of the women in this study received their gonadotropins by subcutaneous injection, but it has been suggested that intramuscular administration may be superior in obese women (18–20). Volume and systemic distribution of blood is also altered in the setting of morbid obesity (19). Traditional measures of serum estradiol for monitoring ovarian response and adjusting gonadotropin dose may also need to be modified to achieve optimal follicular development in morbidly obese women.

Regardless of the underlying factors that account for our study results, the question of how to counsel the morbidly obese PCOS patients seeking fertility treatment remains difficult. The morbidly obese PCOS patients in this study achieved acceptable pregnancy rates after IVF using standard protocols, but these pregnancy rates were decreased compared to non-morbidly obese PCOS patients. When coupled with the knowledge of increased pregnancy risks for obese women after IVF (10), our study results raise the question of whether or not the coexistence of morbid obesity with PCOS should prompt a different approach to infertility treatment than that typically followed for classic PCOS patients. This approach may include aggressive weight loss prior to proceeding to IVF in morbidly obese women with PCOS. Unfortunately, clinically significant weight loss through diet and exercise can be difficult to achieve in the setting of morbid obesity, and when reproductive years are limited, morbidly obese women may find traditional options for weight loss unacceptable. Other alternatives for achieving rapid weight loss should be discussed with these women. Bariatric surgery is one alternative that should be mentioned with the caveat that there is little data on IVF after bariatric surgery (20), but pregnancy after bariatric surgery is well documented (21, 22).

The American Society for Reproductive Medicine has not set forth guidelines to limit IVF treatment to obese women based on BMI, but the British Fertility Society has recently released recommendations to defer treatment in obese women until a BMI of less than 35 is reached (23). Such guidelines are helpful as obesity is a growing problem among women presenting for fertility care, and discrepancies may exist among different clinics on how to treat these women. Prospective clinical and translational work tracking fertility and reproductive outcomes in obese women is important as it will help guide informed and fair treatment of obese women in the future. Study of fertility and reproductive outcomes in obese women after aggressive approaches to weight loss will also help to delineate the effects of morbid obesity on different steps of the reproductive process including those that may account for the results of this study showing that morbid obesity harms IVF success in women with PCOS.

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Table 1

Characteristics for patients initiating IVF cycles

	BMI <40 kg/ m^2 n=59	**BMI ≥ 40 kg/ m^2 n=20**	***P* value**
Age in years	30.8 (± 3.6)	29.0 (± 3.2)	0.05
Body mass index kg/m^2	28.2 (± 5.7)	45.5 (± 4.0)	<0.0001
Endometriosis	3	0	0.56
Tubal factor	4	4	0.19
Male factor	7	3	0.71
Previous live birth	8	2	1
Metformin use	10	5	0.52
OCP use	11	4	1

Values are expressed as mean ± standard deviation or as total number of cases. Differences were interpreted as significant at $p<0.05$. Univariate analyses were performed using student's T-test for continuous variables, and Chi Square or Fischer's exact test for dichotomous variables.

Table 2

IVF cycle data for patients completing IVF cycles

	BMI <40 kg/ m^2 n=53	BMI ≥ 40 kg/ m^2 n=19	*P* value
Cycle cancellation[†]	6	1	0.7
Days of stimulation	10.8 (± 2.6)	11.9 (± 3.4)	0.18
Gonadotropin dose IU[§]	1924.5 (± 720.5)	2606.8 (± 1180.1)	*0.03
Follicles ≥ 12 mm	19.1 (± 6.8)	17.7 (± 8.0)	0.5
Follicles ≥ 16 mm	8.3 (± 3.7)	8.2 (± 3.5)	0.87
Peak estradiol pg/ml	2144.5 (±793.9)	1478.7 (±701.08)	*0.002
Oocytes retrieved	13.6 (± 5.1)	8.9 (± 4.5)	*0.0006
ICSI cases	22	12	0.19
Fertilization rate	69%	59%	*0.03
Complete failure to fertilize	0	3	*0.02
Average embryo cell stage	6.5 (± 1.2)	6.2 (± 0.5)	0.5
Average embryo fragmentation	4.3 (± 6.5)	10.1 (± 9.6)	*0.01
Day 3 embryo transfer	24	12[‡]	0.28
Day 5 embryo transfer	29	2	*0.002
# Embryos transferred	2.06 (± 0.4)	1.7 (± 0.87)	0.14
Implantation rate	47%	30%	0.14

Values are expressed as mean ± standard deviation or as total number of cases unless otherwise specified. Differences were interpreted as significant at $p<0.05$. Univariate analyses were performed using student's T-test for continuous variables, and Chi Square or Fischer's exact test for dichotomous variables.

[†]These patients were not included in the remainder of the analyses in this table as they were cancelled at various time points in their cycles and did not make it to oocyte retrieval

[‡]Two patients had a Day 2 transfer, and three patients had no embryos to transfer.

[§]IU = international units

Table 3

IVF outcomes for patients completing IVF cycles

	BMI <40 kg/ m^2 n=53	BMI ≥ 40 kg/ m^2 n=19	RR (95% CI)
Clinical pregnancies	38	6	*0.44 (0.22 to 0.87)
Live births	32	6	0.52 (0.26 to 1.05)

Values are expressed as total number of cases. Univariate analyses were performed using Chi Square analysis. RR = relative risk, CI = confidence interval

Table 4

IVF outcomes for patients initiating IVF cycles, including patients whose cycles were cancelled

	BMI <40 kg/ m^2 n=59	**BMI ≥ 40 kg/ m^2 n=20**	**RR (95% CI)**
Clinical pregnancies	38	6	*0.44 (0.23 to 0.93)
Live births	32	6	0.52 (0.27 to 1.12)

Values are expressed as total number of cases. Univariate analyses were performed using Chi Square analysis. RR = relative risk, CI=confidence interval