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Original Research Article

Polycystic ovary syndrome and its effect on pregnancy outcomes in women with infertility

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ABSTRACT

Background: Polycystic ovary syndrome (PCOS) is a multisystem disorder featuring reproductive issues and metabolic problems, with a global prevalence of 5-15%. PCOS is linked to infertility, oligomenorrhea, amenorrhea, and adverse pregnancy outcomes like miscarriage and gestational diabetes. Genetic factors contribute to its cause, and lifestyle changes can improve its metabolic and endocrine impacts, aiding in fertility. This study aimed to explore the association between PCOS and various pregnancy outcomes in infertile women by comparison with control group.

Methods: This cross-sectional analytical study was conducted at the department of obstetrics and gynecology (indoor and outdoor) in BSMMU, Dhaka from January 2021 December 2021. Along with ethical approval, the study involving 275 female participants selected via purposive sampling and categorized into two groups: case group (n=110) with PCOS and control group (n=165) without PCOS. Data collection included baseline demographics, blood samples, and IVF/ICSI outcomes.

Results: This study explored how polycystic ovary syndrome (PCOS) impacts pregnancy outcomes in infertile women undergoing their first IVF treatment. It included 275 participants. The case group's average age was slightly higher (p<0.001). The case group had lower BMI (p<0.001) and higher rates of primary infertility (p<0.001). Ovulatory disorders were more common in the case group (p<0.001). The case group exhibited higher fasting insulin levels (p<0.001). The case group had higher clinical pregnancy (p<0.001) and live birth rates (p=0.003) but higher early miscarriage rates (p<0.001).

Conclusions: PCOS negatively affects infertility and pregnancy, causing ovulatory issues, insulin resistance, and complications like gestational diabetes. Despite lower fertility and pregnancy rates, effective treatments can lead to live births comparable to non-PCOS women.

Keywords: Polycystic ovary syndrome, Pregnancy and infertility

INTRODUCTION

Polycystic ovary syndrome (PCOS) is one of the most common endocrine disorders among women of reproductive age.¹ The prevalence of PCOS varies globally, with estimates ranging from 5% to 15% depending on the diagnostic criteria used, such as the Rotterdam criteria, which is widely accepted in clinical practice.²⁻⁴ Polycystic ovary syndrome (PCOS) is regarded as a multisystem disorder characterized by reproductive

symptoms such as hyperandrogenism, anovulation, and infertility, as well as metabolic issues including insulin resistance, dyslipidemia and hypertension, which is associated with increased chances for cardiovascular disease later in life. ^{5,6} Approximately 50% of women with PCOS are overweight or obese. ⁷ More than 70% of women with normogonadotropic anovulation (type II anovulation according to the World Health Organization) exhibit ultrasound or endocrine characteristics commonly associated with polycystic ovary syndrome (PCOS). ⁸ This

metabolic disorder is most commonly associated with infertility. However, approximately 30% of women with polycystic ovary syndrome (PCOS) have regular menstrual cycles.9 PCOS is present in about 85-90% of women with oligomenorrhea and in 30-40% of those with amenorrhea.¹⁰ According to Azziz et al, more than 75% of women exhibiting signs of excess androgen have PCOS.¹¹ Hirsutism is a common clinical manifestation of hyperandrogenism in up to 70% of women with PCOS³. Infertility affects approximately 15% of couples worldwide, with PCOS being implicated in 70% to 80% of cases where anovulation is the primary cause of infertility. 12 PCOS is not only a leading cause of infertility but also a significant contributor to adverse pregnancy outcomes among infertile women.¹³ Women with PCOS are often faced with difficulties in conceiving due to anovulatory cycles, and even when conception is achieved, they may be at higher risk for complications such as miscarriage, gestational diabetes mellitus (GDM), preeclampsia, and preterm delivery.¹⁴ Moreover, women with PCOS have an elevated risk of developing GDM during pregnancy due to their underlying insulin resistance, which has been linked to adverse neonatal outcomes such as macrosomia, neonatal hypoglycemia, and respiratory distress syndrome. 15 A meta-analysis by Yu et al demonstrated that the risk of preeclampsia is 2.05 times higher in pregnant women with PCOS compared to those without the syndrome. This heightened risk is partly the chronic inflammatory attributed to hyperandrogenism, and metabolic dysfunction characteristic of PCOS, which may impair placental development and function.¹⁶ Additionally, the Barker hypothesis of fetal programming posits that fetal nutrition and the endocrine environment (such as hyperinsulinemia) can influence neuroendocrine systems that control body weight, food intake, and metabolism. These factors may have long-term health implications for the offspring.¹⁷ The precise cause of polycystic ovary syndrome (PCOS) remains unclear, although genetic factors have been identified through family and twin studies.¹⁸ Oligoovulation or anovulation in women with polycystic ovary syndrome is a major cause of infertility, and such women might require ovulation induction or assisted reproductive technology to become pregnant.¹⁹ Changes to lifestyle can, however, improve the metabolic and endocrine consequences of having polycystic ovary syndrome, thus possibly improving infertility caused by anovulation.²⁰

This study aimed to explore the association between PCOS and various pregnancy outcomes in infertile women by comparison with control group. By investigating these associations, this research sought to provide insights into the challenges faced by women with PCOS in term of pregnancy and contribute to the development of targeted interventions to enhance maternal and fetal health.

METHODS

This cross-sectional analytical study was meticulously conducted at the department of obstetrics and gynecology (indoor and outdoor) in Bangabandhu Sheikh Mujib Medical University, Dhaka from January 2021 December 2021. A purposive sampling method was employed to select 275 female participants who had initiated infertility treatment, adhering strictly to predefined inclusion and exclusion criteria. Comprehensive information regarding the study's objectives, aims, and procedures was provided to all participants, and written informed consent was obtained prior to their involvement. Baseline demographic data for each participant were collected, with a strong commitment to data confidentiality. The study protocol was approved by the institutional ethics committee.

Participants were categorized into two distinct groups: case group (N=110) consisting of 110 infertile female patients diagnosed with polycystic ovary syndrome (PCOS). Control group (N=165) comprising 165 infertile female patients without having PCOS.

Inclusion criteria

Female patients with infertility, both with and without PCOS. Patients aged 19 years and above.

Exclusion criteria

Patients with viral infections, including HBV, HCV, HIV, and syphilis. Patients aged over 40 years, or those who had undergone treatment gonadotropin-releasing with (GnRH)-antagonist hormone controlled ovarian hyperstimulation (COH) protocols. Cycles lacking embryo information or clinical pregnancy data, as well as patients with chromosomal abnormalities, intrauterine death, medical abortion, stillbirth, or ectopic pregnancy. Pregnancies in patients with conditions such as congenital adrenal hyperplasia, Cushing's syndrome, androgensecreting tumors, non-classic adrenal hyperplasia, thyroid dysfunction, hyperprolactinemia, type 2 diabetes mellitus, or cardiovascular disease were also excluded.

In this study, we included both patients who conceived spontaneously and those who conceived through medical interventions, such as IVF or ICSI. The diagnosis of polycystic ovary syndrome (PCOS) was established based on the Rotterdam criteria, which require the presence of at least two of the following three criteria: (1) oligo- or amenorrhoea: biochemical clinical (2) orhyperandrogenism; and (3) polycystic ovarian morphology as observed on transvaginal ultrasound. Oligomenorrhea was defined as having fewer than eight menstrual cycles per year or a cycle interval exceeding 35 days, while amenorrhoea was characterized by the absence of menstruation for six months or longer.

Blood samples were obtained after an 8-10 hour fasting period, ideally between days 2-5 of the menstrual cycle in regularly menstruating women, or during withdrawal bleeding in those with amenorrhea. The collected samples were then aliquoted for analysis of plasma insulin, TSH, total T4, LH, FSH, total testosterone, plasma glucose,

complete blood counts, and assessments of liver and kidney function. The data for all patients, encompassing baseline characteristics, cycle specifics, and pregnancy outcomes, were meticulously extracted from their medical records. Patients underwent in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI) cycles, following a standard luteal phase down-regulation protocol utilizing a GnRH agonist.

Pregnancy outcomes, including implantation rate, clinical pregnancy rate, and live birth rate, were systematically collected and assessed. Adverse pregnancy outcomes, such as miscarriage, multiple pregnancies, preterm delivery, gestational diabetes mellitus (GDM), and pregnancy-induced hypertension (PIH), were also documented, with the incidence of each complication being quantified.

Statistical analysis

BMI (kg/m^2)

Descriptive statistical analyses were conducted on the primary maternal and cycle characteristics. Data were systematically organized into relevant tables, each accompanied by clear explanations to enhance comprehension. Statistical analysis was performed using SPSS software (version 26) on the Windows operating system. Continuous variables were presented as mean±standard deviation (SD), while categorical variables were summarized as frequencies and percentages. Comparisons between groups for continuous variables were conducted using the student's t-test, and for categorical variables, either Pearson's chi-square test or Fisher's exact test was utilized.

RESULTS

This study aimed to investigate the impact of polycystic ovary syndrome (PCOS) on pregnancy outcomes in infertile women undergoing their first in vitro fertilization (IVF) treatment, taking into account important confounders. The study included 275 female participants who had initiated infertility treatment.

Case group (n=110) Control group (n=165) Variables P value % % Age (in years) 24 21.82 39 23.64 < 25 25-30 66 60.00 103 62.42 < 0.001 >30 20 18.18 23 13.94 30.21±3.54 29.66±2.87 Mean±SD Residence 29 48 29.09 Rural 26.36 0.462 Suburban or urban 81 117 73.64 70.91 **Educational status** No formal education 6.36 8 4.85 Primary 35 31.82 49 29.70 Secondary 40 36.36 54 32.73 0.543 Higher secondary 13 11.82 26 15.76 15 13.64 16.97 Graduate and above 28 Occupation 78 114 Housewife 70.91 69.09 Service holder 20 18.18 28 16.97 0.485 Student 12 10.91 23 13.94 Mean±SD

Table 1: Sociodemographic status of the study subjects.

Table 1 presents the sociodemographic characteristics of the case and control groups. The mean age of participants in the case group was 30.21±3.54 years, slightly higher than the control group at 29.66±2.87 years. The age distribution shows that the majority of participants in both groups were between 25 and 30 years of age (60.0% in the case group and 62.42% in the control group). There was a statistically significant difference in age distribution between the groups (p<0.001). Regarding residence, most women in both groups lived in suburban or urban areas

(73.64% in the case group and 70.91% in the control group), with no significant difference between the groups (p=0.462). In terms of educational status, participants with secondary education formed the largest proportion in both groups (36.36% in the case group and 32.73% in the control group). Still, there were no statistically significant differences in education levels between the two groups (p=0.543). The occupation distribution revealed that most women in both groups were housewives (70.91% in the case group and 69.09% in the control group), with no

22.6±1.68

21.4±1.21

< 0.001

significant difference between the groups (p=0.485). The mean body mass index (BMI) of the case group (21.4 \pm 1.21 kg/m²) was significantly lower than that of the control

group $(22.6\pm1.68 \text{ kg/m}^2)$ (p<0.001), indicating a notable variation in body composition between the two groups.

Table 2: Clinical features of women with polycystic ovary syndrome compared to controls.

Maternal characteristics	Case group (n=110)		Control group (n=165)		P value
	N	%	N	%	r value
Type of infertility					
Primary	73	66.36	86	52.12	<0.001
Secondary	37	33.64	79	47.88	<0.001
Infertility factors					
Uterine and tubal factor	8	7.27	76	46.06	< 0.001
Ovulatory disorders	80	72.73	4	2.42	< 0.001
Endometriosis	3	2.73	12	7.27	< 0.001
Male factor	1	0.91	21	12.73	< 0.001
Female and male factor	16	14.55	13	7.88	< 0.001
Unexplained	2	1.82	39	23.64	< 0.001
Cycles with different technologies					
IVF	89	80.91	124	75.15	0.004
ICSI	21	19.09	41	24.85	0.004
Embryo type					
Cleavage embryo	101	91.82	152	92.12	0.441
Blastocyst	9	8.18	13	7.88	0.441
Embryo quality					
Cycle with high-quality embryos	103	93.64	156	94.55	0.003
Cycles without high-quality embryos	7	6.36	9	5.45	0.003
Mean±SD					
Infertility duration (in years)	4.11±2.21		3.59±1.93		< 0.001
Baseline FSH level (IU/l)	5.31±0.47		5.82±0.51		< 0.001
Baseline LH level (IU/l)	5.73±1.01		3.84±0.86		< 0.001
Total T (ng/ml)	0.43±0.21		0.37±0.14		< 0.001
TSH (μIU/ml)	1.62±0.44		1.91±0.31		0.211
Fasting glucose (mmol/l)	5.23±0.02		5.11±0.01		< 0.001
Fasting insulin (µU/ml)	10.91±1.65		9.48±1.23		< 0.001
QUICKI	0.35±0.04		0.37±0.06		0.005
Duration of gonadotropin stimulation (d)	10.12±0.81		8.9±0.61		< 0.001
Total dose of gonadotropin (IU)	1655.0±135.0		2400.0±188.0		< 0.001
Serum E2 level (pg/ml) on hCG day	2610.0±213.0		2507.0±263.0		0.049
EMT (mm) on hCG day	11.0±1.0		12.0±1.0		0.775
No. of oocyte retrieved	16.23±2.19		14.22±1.48		< 0.001
No. of fertilized oocytes	13.33±2.21		11.41±2.02		< 0.001
No. of embryos transferred	2.7±0.6		2.5±0.8		< 0.001

Table 2 outlines the clinical features of the study subjects. A higher proportion of women in the case group had primary infertility (66.36% versus 52.12%, p<0.001), while secondary infertility was more prevalent in the control group (47.88% versus 33.64%, p<0.001). In terms of infertility factors, ovulatory disorders were significantly more common in the case group (72.73% versus 2.42%, p<0.001), whereas uterine and tubal factors were predominant in the control group (46.06% versus 7.27%, p<0.001). Additionally, male factor infertility was significantly more common in the control group (12.73% versus 0.91%, p<0.001). Regarding fertility treatments, in

vitro fertilization (IVF) was the most commonly employed technology in both groups, though the case group had a higher proportion of IVF cycles (80.91% versus 75.15%, p=0.004). Intracytoplasmic sperm injection (ICSI) was more frequent in the control group (24.85% versus 19.09%). There was no significant difference in embryo type between the groups, with cleavage embryos being more common in both (91.82% in the case group and 92.12% in the control group). However, the case group had a significantly higher number of cycles with high-quality embryos compared to the control group (93.64% versus 94.55%, p=0.003). The case group showed substantially

longer infertility duration (4.11±2.21 years versus 3.59±1.93 years, p<0.001), higher baseline FSH levels $(5.31\pm0.47 \text{ IU/l versus } 5.82\pm0.51 \text{ IU/l, p} < 0.001)$, and higher LH levels (5.73±1.01 IU/l versus 3.84±0.86 IU/l, p<0.001). Additionally, the case group exhibited significantly higher fasting insulin levels (10.91±1.65 $\mu U/ml$ versus 9.48±1.23 $\mu U/ml,~p{<}0.001)$ and a lower QUICKI index (0.35±0.04 versus 0.37±0.06, p=0.005), indicating differences in insulin sensitivity between the groups. Table 3 compares the pregnancy outcomes and complications between the case and control groups. The implantation rate was significantly higher in the case group (49.09% versus 38.18%, p<0.001), as were the clinical pregnancy rate (70.91% versus 60.00%, p<0.001) and the live birth rate (58.18% versus 52.12%, p=0.003). However, the case group had a lower term delivery rate

compared to the control group (73.64% versus 78.18%, p=0.041) and a higher rate of early miscarriages (9.09% versus 7.88%, p=0.001). The preterm delivery rate between 34 and 37 weeks was slightly higher in the case group (19.09% versus 18.18%, p=0.045), although there was no significant difference in deliveries before 34 weeks. Additionally, cesarean sections were equally common in both groups (26.36% in the case group and 26.67% in the control group, p=0.985). In terms of pregnancy complications, the incidence of gestational diabetes mellitus (GDM) was comparable between the two groups (10.00% in the case group and 9.09% in the control group, p=0.686). At the same time, pregnancy-induced hypertension was more frequent in the case group (3.64% versus 2.42%, p=0.038).

Table 3: Outcomes and complications of pregnancy in women with polycystic ovary syndrome versus controls.

Outcomes	Case gr	Case group (n=110)		group (n=165)	Davidas
	N	%	N	%	P value
Implantation rate	54	49.09	63	38.18	< 0.001
Clinical pregnancy rate	78	70.91	99	60.00	< 0.001
Live birth rate	64	58.18	86	52.12	0.003
Term delivery rate	81	73.64	129	78.18	0.041
Miscarriage rate					
Early miscarriage rate	10	9.09	13	7.88	0.001
Late miscarriage rate	8	7.27	6	3.64	
Preterm delivery rate					
≥34 and <37 weeks	21	19.09	30	18.18	0.045
≥32 and <34 weeks	4	3.64	4	2.42	
<32 weeks	4	3.64	3	1.82	
Delivery type					
Cesarean	29	26.36	44	26.67	0.985
Eutocia	81	73.64	121	73.33	
No. of live babies delivered					
1	64	58.18	106	64.24	0.017
≥2	46	41.82	59	35.76	
Pregnancy complications					
Gestational diabetes mellitus	11	10.00	15	9.09	0.686
Pregnancy-induced hypertension	4	3.64	4	2.42	0.038

DISCUSSION

Polycystic ovary syndrome (PCOS) is a multifaceted endocrine disorder prevalent among women of reproductive age and is a leading contributor to infertility.^{5,6} This investigation sought to analyze and compare pregnancy outcomes in women experiencing infertility due to PCOS against those with infertility not associated with this syndrome. The results reveal significant differences in clinical characteristics, pregnancy outcomes, and related complications between the two groups. The sociodemographic characteristics of the case and control groups were comparable in terms of age, education, and occupation, minimizing confounding influences (Table 1). The mean age of the case group was

30.21±3.54 years, which was marginally higher than the mean age of 29.66±2.87 years observed in the control group. However, this age discrepancy did not achieve statistical significance. This finding is consistent with the studies conducted by Haakoova et al and Setji et al, which also reported similar non-significant age differences between their respective groups. ^{21,22} The body mass index (BMI) was significantly lower in the case group (21.4 kg/m²) compared to the control group (22.6 kg/m²), which aligns with findings from Liu et al, where higher BMI was linked to adverse pregnancy outcomes in women with PCOS undergoing IVF treatment.²³ In terms of clinical features, the present study found that women with PCOS had significantly different causes of infertility compared to controls (Table 2). The primary cause of infertility in the

case group was ovulatory disorders (72.73%), while uterine and tubal factors were more common in the control group (46.06%). This is consistent with existing literature, which identifies anovulation as a hallmark of PCOS.²⁴ Additionally, the baseline levels of follicle-stimulating hormone (FSH) and luteinizing hormone (LH) in women with PCOS were significantly different from those in the control group, with higher LH levels and lower FSH levels in the PCOS group. These hormonal imbalances are welldocumented features of PCOS and contribute to the disorder's pathophysiology. ^{23,24} The duration of infertility was also longer in the case group (4.11 years) compared to the control group (3.59 years), which is consistent with previous studies indicating that prolonged infertility is often seen in women with PCOS. Moreover, the total testosterone levels were significantly higher in the case group, reflecting the hyperandrogenic state characteristic of PCOS, which has been associated with poor reproductive outcomes.²⁵ The outcomes of pregnancy between the case and control groups also demonstrated significant differences (Table 3). The implantation rate was significantly higher in the PCOS group compared to the control group (49.09% versus 38.18%, p<0.001). This could be due to the treatment interventions that many women with PCOS undergo, including ovulation induction and in vitro fertilization, which are known to enhance implantation rates in such populations. This aligns with findings from Liu et al, which reported elevated implantation rates among women with PCOS undergoing in vitro fertilization (IVF).²³ However, despite the high implantation rate, the clinical pregnancy rate was also elevated in the case group (70.91% versus 60.00%, p<0.001), suggesting that women with PCOS can achieve successful pregnancies at comparable, if not better, rates than controls. The live birth rate was higher in the PCOS group (58.18%) compared to the control group (52.12%, p=0.003). This finding is consistent with studies such as those by Azziz et al, which observed improved live birth rates in PCOS patients following fertility treatments.²⁶ Conversely, our study found a lower term delivery rate (73.64% versus 78.18%, p=0.041) in the PCOS group. This lower-term delivery rate might reflect increased risks associated with PCOS, such as hormonal imbalances or other complications, which can affect pregnancy duration and outcome. These findings are consistent with a metaanalysis by Zhang et al, which reported that women with PCOS have a higher risk of preterm birth.²⁷ The analysis also focused on miscarriage rates, specifically distinguishing between early and late miscarriages. The data revealed that the early miscarriage rate in the PCOS cohort was 9.09%, whereas the control group experienced a lower rate of 7.88%, with the difference reaching statistical significance (p=0.001). In contrast, the rate of late miscarriages did not exhibit any significant variation between the two groups. These findings are consistent with those reported by Nivedhitha et al, who also observed a significant disparity in early miscarriage rates but no notable difference in late miscarriage rates between PCOS and control groups.²⁸ Interestingly, the term delivery rate was slightly lower in the case group compared to controls

(73.64% versus 78.18%, p=0.041), indicating that PCOS may predispose women to early labor. Preterm delivery rates were marginally higher in women with PCOS, particularly in the gestational age bracket of 34-37 weeks (19.09% versus 18.18%, p=0.045). Though the difference is statistically significant, it is minor. The preterm delivery rates in earlier gestational windows (before 34 weeks) were similar between the groups. The findings of this study align with previous research, particularly a study that identified a significantly elevated risk of preterm delivery, specifically among lean women with polycystic ovary syndrome (PCOS).²⁹ Moreover, two separate metaanalyses reported that women with PCOS have a twofold increased risk of delivering preterm infants.^{27,30} In contrast, another meta-analysis found no significant association between PCOS and preterm birth.³¹ There were no significant differences in the rates of cesarean deliveries between the PCOS and control groups (26.36% versus 26.67%, p=0.985). However, the number of live babies delivered was significantly different, with the PCOS group having fewer women delivering more than one baby (41.82% versus 35.76%, p=0.017). Although numerous studies have reported an elevated incidence of cesarean sections among women with polycystic ovary syndrome (PCOS), our findings did not align with these observations.³² In terms of pregnancy complications, the rates of gestational diabetes mellitus (GDM) and pregnancy-induced hypertension (PIH) were marginally higher in the PCOS group. However, these differences were not statistically significant. Gestational diabetes mellitus (GDM) was observed in 10.00% of the case group, compared to 9.09% in the control group (p=0.686), indicating no statistically significant difference between However, groups. pregnancy-induced hypertension (PIH) was marginally more prevalent among patients with polycystic ovary syndrome (PCOS), with rates of 3.64% versus 2.42% in controls (p=0.038). These findings align with previous research by Setji et al and Lo et al, who reported similar outcomes regarding GDM and PIH in their studies. 22,33 Holter et al, in a comprehensive retrospective study, identified only a slight elevation in GDM risk but found no significant difference in preeclampsia rates between the groups.³⁴

Our study's cross-sectional design limits the ability to draw causal conclusions about the effects of PCOS on pregnancy outcomes. Longitudinal studies would provide more robust insights into how PCOS impacts long-term pregnancy health. The study's reliance on a single center could introduce selection bias, affecting the generalizability of the findings. The sociodemographic and clinical characteristics of our study population may differ from those in other settings, potentially influencing the applicability of the results.

CONCLUSION

In conclusion, our study demonstrates that PCOS significantly impacts both infertility and pregnancy outcomes. Women with PCOS face a higher likelihood of

ovulatory dysfunction, elevated insulin resistance, and complications such as gestational diabetes. While fertility rates remain compromised, with lower implantation and clinical pregnancy rates, appropriate medical interventions can result in live births comparable to non-PCOS women. Further research is needed to explore long-term outcomes for both mothers and offspring in this population, as well as to develop targeted therapies aimed at improving pregnancy success in women with PCOS.

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Institutional Ethics Committee

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