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Fetomaternal outcome of patients with PCOD in tertiary medical centre of South Bihar

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Abstract:
Background*: Polycystic ovary syndrome (PCOS) is one of the most common endocrine disorders in women of reproductive age affecting 5 to 10% of women worldwide. Rotterdam ESHRE/ASRM in the year 2003 standardized the definition of PCOS, which is characterized by a combination of oligomenorrhea / amenorrhea, clinical or endocrine signs of hyperandrogenemia and polycystic ovaries*
Materials and Methods*: This study was conducted at Obstetrics and Gynaecology department, Narayan medical college, Sasaram in pregnant women attending the antenatal clinic, satisfying the inclusion criteria. It is an Observational Longitudinal study. We have studied the outcome of pregnancy in the patients who were a known case of PCOS. The women met the following criteria for the diagnosis of PCOS. All Patients who were diagnosed cases of PCOS, following the inclusion and exclusion criteria was selected as cases and age matched control were selected from OPD. Patients was recruited till sample size reached*
Results*: The prevalence percentage of preeclampsia was more among women with PCOS 8 (10.7%) as compared to women without PCOS 6 (8%). Statistically, no significant association was observed regarding preeclampsia between women with PCOS and without PCOS. The prevalence percentage of intrauterine growth restriction was more among women with PCOS 7 (9.3%) as compared to women without PCOS 4 (5.3%). Statistically, no significant association was observed regarding intrauterine growth restriction between women with PCOS and without PCOS.*
Conclusion: *Women with PCOS are at increased risk of adverse pregnancy and birth outcomes and need increased surveillance during pregnancy. On the basis of our study we can conclude that GDM, Rate of miscarriage were higher in PCOS and statistically significant difference was found between PCOS and non PCOS women*
Key Word*: PCOS, PRE-ECLAMPSIA, GDM, APGAR SCORE*

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I. Introduction

Polycystic ovary syndrome (PCOS) is one of the most common endocrine disorders in women of reproductive age affecting 5 to 10% of women worldwide. Rotterdam ESHRE/ASRM in the year 2003 standardized the definition of PCOS, which is characterized by a combination of oligomenorrhea / amenorrhea, clinical or endocrine signs of hyperandrogenemia and polycystic ovaries.(1)

An understanding of role of PCOD in predicting adverse pregnancy outcomes is important for risk stratification which in turn may impact recommendations on antenatal screening and surveillance.(2)

Insulin resistance in pregnancy is a physiological adaptation to restrict maternal glucose uptake and to ensure shunting of nutrients to the growing fetus. It is mediated by increases in hormonal levels of estradiol, progesterone, prolactin, cortisol, human chorionic gonadotropin, placental growth hormone (PGH), and human placental lactogen (hPL) and PGH are the hormones mainly responsible for insulin resistance in pregnancy. hPL is responsible for adaptive increase in insulin secretion necessary for pregnancy and for diversion of maternal carbohydrate metabolism to fat metabolism in the third trimester. PGH , a paracrine growth factor probably regulating the metabolic and growth needs of the fetus partially.(3) The baseline insulin resistance seems to be exacerbated with pregnancy.(4)

The pathophysiology of PCOS is multifactorial, and it is believed that a genetic predisposition exists that is exacerbated by excess adiposity and sedentary lifestyle .It is thought that the pathophysiology of PCOS involves the interaction between abnormal ovarian morphology, due to excess androgen production by the PCO—hyperinsulinemia, and elevated luteinizing hormone (LH) levels decreases. Ovarian androgen production

in women with PCOS is accelerated due to the increased ovarian theca cell androgenic enzymatic activity of 3β-hydroxysteroid dehydrogenase (HSD) 17α- hydroxylase/C17, 20 Lyase, a product of CYP17.(5)

There are various studies to establish the association of PCOS to effect on pregnancy and its outcome. Following are the effect of PCOS in the mother and neonates. The most common effects among mother are:

There is a increased risk of miscarriage and early pregnancy loss. Increased risk of early pregnancy loss in 30 -50 % of PCOS women compared to 10 -15 % of normal women(6)

There is 3-4 times increased risk of pregnancy induced hypertension in women with PCOS. Women with PCOS also represent 3-4 fold increased risk of developing Preeclampsia during pregnancy

It is a commonly described pregnancy complication in women with PCOS. Early diagnosis and treatment significantly reduce the incidence of related maternal and neonatal complications.

PCOS is very prevalent in adolescent and affects pregnancy. As it involves insulin resistance and other hormonal involvement is also reported, so even after patient become pregnant, PCOS had its impact on mother and it involves neonates also. There are plenty of literature available explaining the fetomaternal outcome of PCOS but result is controversial. Hence this study was planned to assess the maternal and fetal outcome in pregnant patients with PCOS.

II. Material And Methods

1. To study the pregnancy outcome in the patients of PCOS and compare it with nonPCOS.
2. To study the incidence of pregnancy complications such as spontaneous abortions, preterm labour, gestational diabetes, gestational hypertension, preeclampsia, pregnancy and neonatal outcome in women with PCOS.

Procedure methodology

Methodology
This is an Observational Longitudinal type of study

Study Area- Study was carried out at Narayan Medical college, Sasaram, Bihar

Type of Study:- Observational Longitudinal study

Sample size
Assuming that the spontaneous abortion as one of the important adverse pregnancy outcomeamong patients with PCOS. As per the previous study the incidence of spontaneous abortion in patient with PCOS was 4.33 times higher than control (based on study by Nivedhitha VS et al, at 2-sided test with 95% confidence level (α=5%) and 80% power, expected sample size in both group is 66 each, i.e total 132, considering the dropout total 150 samplesize will be taken (75 with PCOS and 75 control group).

Formulas
The following formulas was used to compute sample size

$N1= (Z1-\alpha/2+ Z1-\beta)^2 \bar{P}\bar{q}(r+1)/r(p1-p2)^2$ Where,

The notation for the formulae are: N1 = sample size of Group1 (With PCOS). N2= sample size of Group2 (Control),

Z1-α/2 =standard normal deviate for two-tailed test based on alpha level (relates to theconfidence interval level) two-sided Z value (e.g. Z=1.96 for 95% confidence interval).

Z1-β = power, r = ratio of unexposed to exposed

p1 = proportion of exposed with disease and q1 = 1-p1 p2 = proportion of unexposed with disease and q2 = 1-p

$$\bar{p} = \frac{p_1 + rp_2}{r+1} \quad \text{and} \quad \bar{q} = 1 - \bar{p}$$

Period of Study: - September 2019 to May 2021
Location: - Narayan medical college , Sasaram, Bihar
INCLUSION CRITERIA
Pregnant women with PCOS and
Age ranging from 18 to 40 years
EXCLUSION CRITERIA:
Women with anovulation not due to PCOS

Women with obesity not due to PCOS.
Women with other medical illness

III. Methodology

This study was conducted at Obstetrics and Gynaecology department, Narayan medical college, Sasaram in pregnant women attending the antenatal clinic, satisfying the inclusion criteria. It is an Observational Longitudinal study. We have studied the outcome of pregnancy in the patients who were a known case of PCOS. The women met the followingcriteria for the diagnosis of PCOS.
Oligomenorrhoea (menstrual cycle longer than 35 days)
Anovulatory infertility on follicular study
Typical morphology of polycystic ovaries on ultrasound scan.

Increase level of at least one androgen (reference values for normal concentrations).Testosterone 0.5 -2.63nmol/L androstenedione1.57 - 5.4nmol/L, dehydroepiandrosterone 0.8 –10. nmol/l & DHEA-S (2.4-14.5micromol/L).

All Patients who were diagnosed cases of PCOS, following the inclusion and exclusion criteria was selected as cases and age matched control were selected from OPD. Patients wasrecruited till sample size reached. All these women with their controls were followed duringpregnancy in Narayan medical college, Sasaram and was interviewed personally to obtain the relevant information about their medical and family history. The diagnosis of Gestational diabetes mellitus was based on FBS and 2hr PPBS performed at 28 weeks of pregnancy. PIH defined as Gestational hypertension (B.P >140/90 mg) without proteinuria at 20wks of gestation on two or more occasions at least 4 hours apart and Preeclampsia (B.P > 140/90 mg) in combination with proteinuria > 0.3 gram/24 hours of urine after 20 weeks of gestation.)

In the family history first and second degree relatives (parents, siblings and grandparent) history of diabetes mellitus, hypertension or ischaemic heart disease (myocardial infarction)was considered positive if one or more first degree relative had onset of disease before the age of 45 yrs. Immediately after delivery, birth weight and APGAR scoring at 1 and 5 minutes were noted. . A case matched control group based on age and weight obtained from selection of women from our Antenatal OPD during this time period. The controls was alsointerviewed personally to obtain relevant information in their medical & family histories.

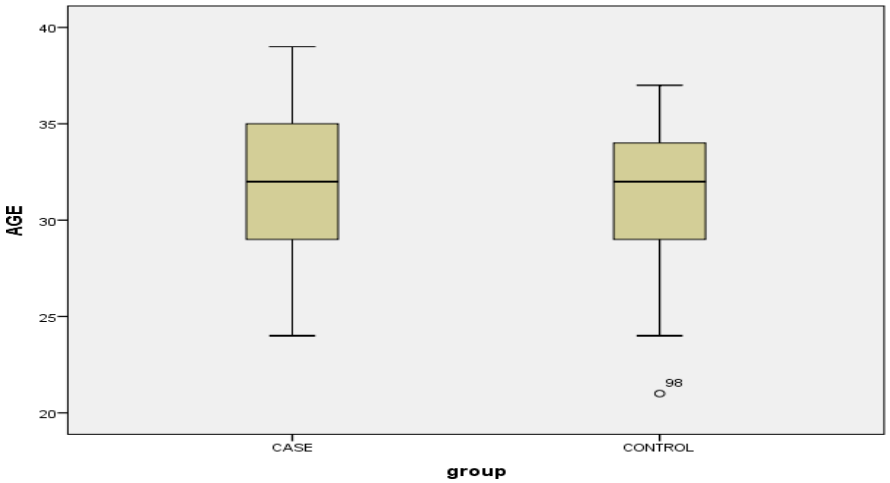
The maternal outcome in term of PIH, GDM, IUGR, Abortion, Preterm labor was compared among test and control group. Neonatal outcome were measured in terms of baby weight, APGAR score at 1 and 5 minute, NICU admission in both cases and control.

IV. Observations And Results

TABLE-1: DISTRIBUTION OF THE AGE WITH PCOS AND WITHOUT PCOSACCORDING TO THE AGE GROUP

AGE					
group	Mean	N	Std. Deviation	Minimum	Maximum
Pcos mother	32.11	75	3.311	24	39
Without pcosmother	31.41	75	3.072	21	37
Total	31.76	150	3.202	21	39
t test applied, t test - 1.32, P VALUE – 0.19 , non-significant association					

GRAPH-1: DISTRIBUTION OF THE WOMEN WITH PCOS AND WITHOUT PCOSACCORDING TO THE AGE GROUP



The age group in the present study was between 21-39 years. Statistically significant difference was observed between case and control in the age group distribution. The mean age of (32.11±3.31) women with PCOS were more than age (31.41±3.07) of women without PCOS. But statistically insignificant difference was found

TABLE-2 : COMPARISON OF MISCARRIAGE BETWEEN THE WOMEN WITHPCOS AND WITHOUT PCOS:

MISCARRIAGE	WITH PCOS	WITHOUT PCOS	TOTAL
YES	13 (17.33%)	6 (8%)	19 (12.66%)
NO	62 (82.67%)	69 (92%)	131 (87.55%)
TOTAL	75	75	150

CHI-SQUARE- 2.74.; P-VALUE- <0.05; SIGNIFICANT

The above table, showed the distribution of the women with PCOS and without PCOS according to the miscarriage. Majority of women with PCOS 62(82.67%) had no miscarriage and 69(92%) women without PCOS. Only 13(17.33%) women with PCOS and 6 (8%) without PCOS had miscarriage. Statistically significant difference was found regarding miscarriage between with orwithout PCOS with p value <0.05.

Fig -2: COMPARISON OF MISCARRIAGE BETWEEN THE WOMEN WITH PCOSAND WITHOUT PCOS

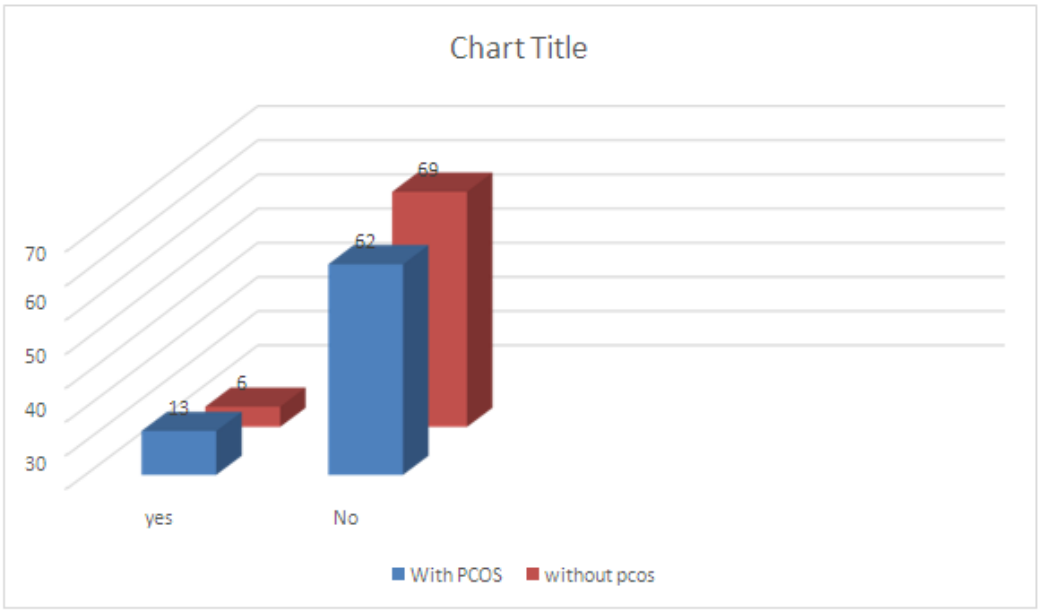


TABLE-3 : COMPARISON OF GESTATIONAL DIABETES MELLITUS (GDM)BETWEEN THE WOMEN WITH PCOS AND WITHOUT PCOS:

GDM		WITH PCOS	WITHOUT PCOS	TOTAL
YES		17 (22.66%)	4 (5.3%)	21 (14%)
NO		58 (77.34%)	71 (94.7%)	129 (86%)
TOTAL	75		75	150

CHI-SQUARE- 9.35; P-VALUE- 0.02; SIGNIFICANT

The above table shows the distribution of the women with PCOS and without PCOS according tothe gestational diabetes mellitus (GDM). 17 (22.66%) women with PCOS and 4 (5.3%) without PCOS had gestational diabetes mellitus. Statistically significant difference was found regarding gestational diabetes mellitus between with PCOS and without PCOS.

GRAPH-3 : COMPARISON OF GDM BETWEEN THE WOMEN WITH PCOS ANDWITHOUT PCOS:

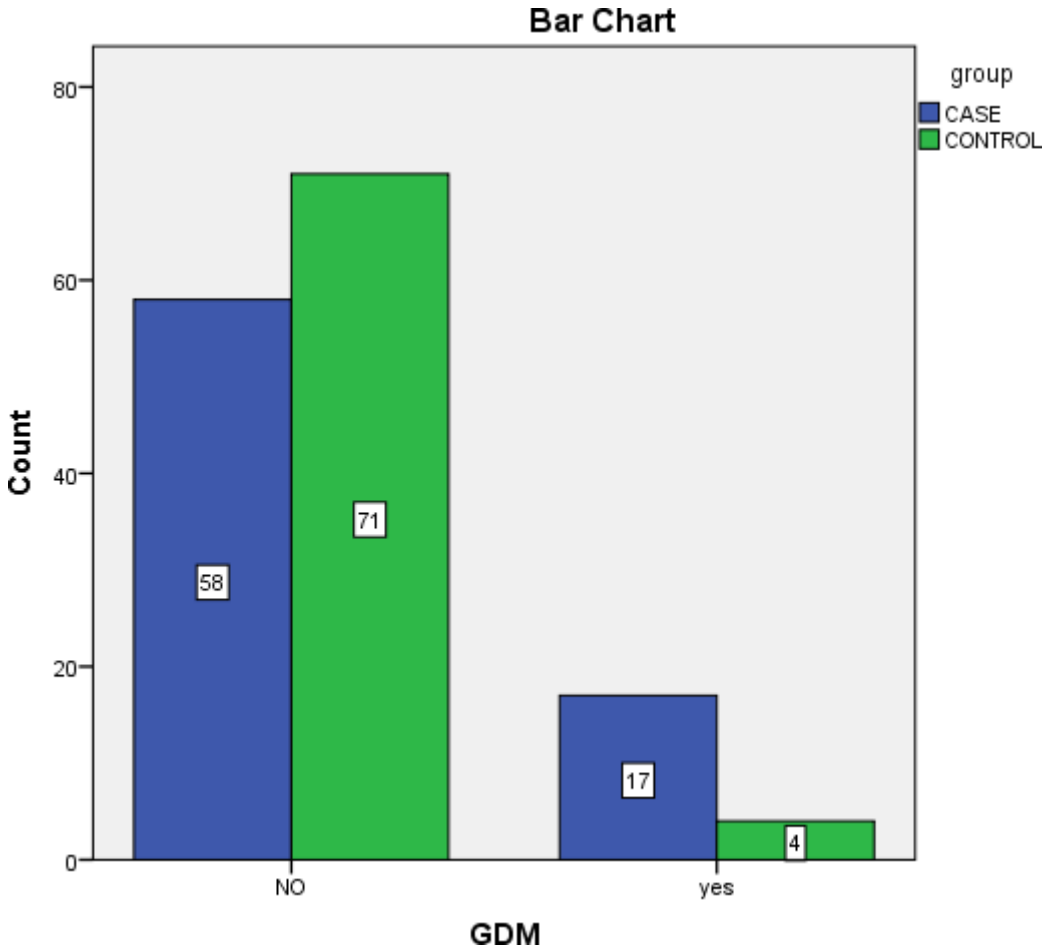


TABLE-4: COMPARISON OF PREGNANCY INDUCED HYPERTENSION (PIH)BETWEEN THE WOMEN WITH PCOS AND WITHOUT PCOS:

PIH		WITH PCOS	WITHOUT PCOS	TOTAL
YES	8 (10.7%)		4 (5.3%)	12 (8%)
NO		67 (89.3%)	71 (94.7%)	138 (92%)
TOTAL	75		75	150

CHI-SQUARE- 1.4; P-VALUE- 0.2; NON SIGNIFICANT

The above table shows the distribution of the women with PCOS and without PCOS according to the gestational diabetes mellitus (GDM). Only 8 (10.7%) women with PCOS and 4 (5.3%) without PCOS had pregnancy induced hypertension. Statistically non significant association wasfound regarding pregnancy induced hypertension between with PCOS and without PCOS.

GRAPH-4: COMPARISON OF PIH BETWEEN THE WOMEN WITH PCOS ANDWITHOUT PCOS:

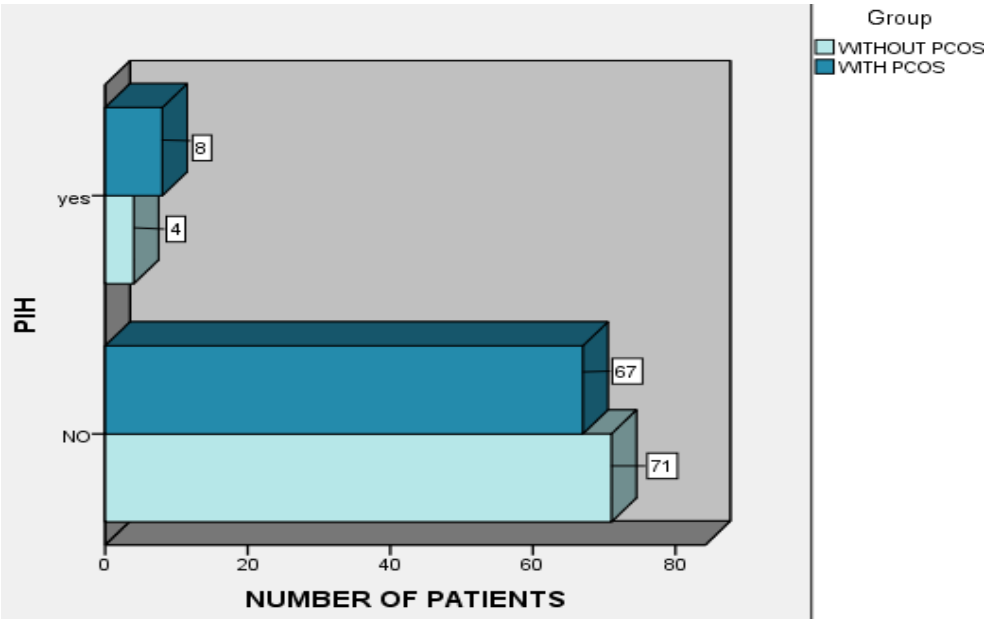


TABLE-5 : COMPARISON OF PREECLAMPSIA BETWEEN THE WOMEN WITHPCOS AND WITHOUT PCOS:

PREECLAMPSIA	WITH PCOS	WITHOUT PCOS	TOTAL
YES	8 (10.7%)	6 (8%)	14 (9.3%)
NO	67 (89.3%)	69 (92%)	136 (90.7%)
TOTAL	75	75	150

CHI-SQUARE- 0.3; P-VALUE- 0.5; NOT SIGNIFICANT

The above table shows the distribution of the women with PCOS and without PCOS according to the preeclampsia. The prevalence percentage of preeclampsia was more among women with PCOS 8 (10.7%) as compared to women without PCOS 6 (8%). Statistically, no significant association was observed regarding preeclampsia between women with PCOS and without PCOS.

GRAPH-5 : COMPARISON OF PREECLAMPSIA BETWEEN THE WOMEN WITHPCOS AND WITHOUT PCOS:

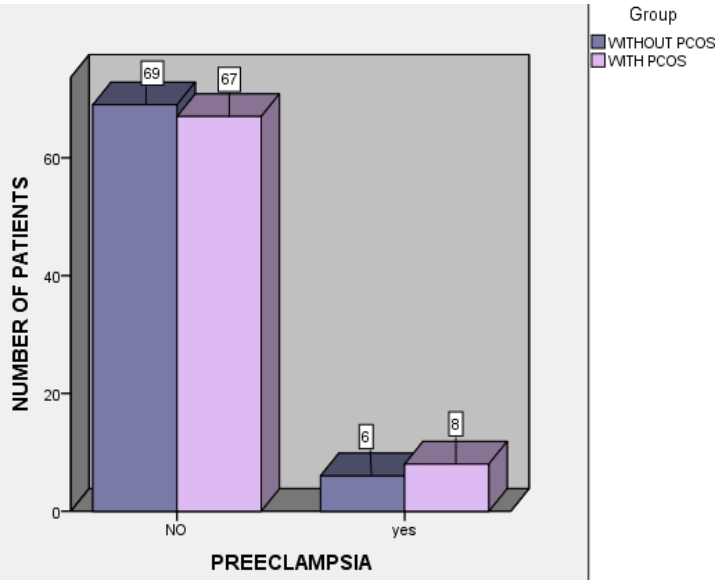

Group
WITHOUT PCOS
WITH PCOS
NUMBER OF PATIENTS
0
20
40
60
69
67
6
8
NO
yes
PREECLAMPSIA

TABLE-6 : COMPARISON OF IUGR BETWEEN THE WOMEN WITH PCOS ANDWITHOUT PCOS:

INTRAUTERINE GROWTH RESTRICTION (IUGR)	WITH PCOS	WITHOUT PCOS	TOTAL
YES	7 (9.3%)	4 (5.3%)	11 (7.3%)
NO	68 (90.7%)	71 (94.7%)	139 (92.7%)
TOTAL	75	75	150

CHI-SQUARE- 0.8; P-VALUE- 0.3; NOT SIGNIFICANT,

The above table shows the distribution of the women with PCOS and without PCOS according to the intrauterine growth restriction. The prevalence percentage of intrauterine growth restriction was more among women with PCOS 7 (9.3%) as compared to women without PCOS 4 (5.3%). Statistically, no significant association was observed regarding intrauterine growth restriction between women with PCOS and without PCOS.

GRAPH-6 : COMPARISON OF IUGR BETWEEN THE WOMEN WITH PCOS AND WITHOUT PCOS:

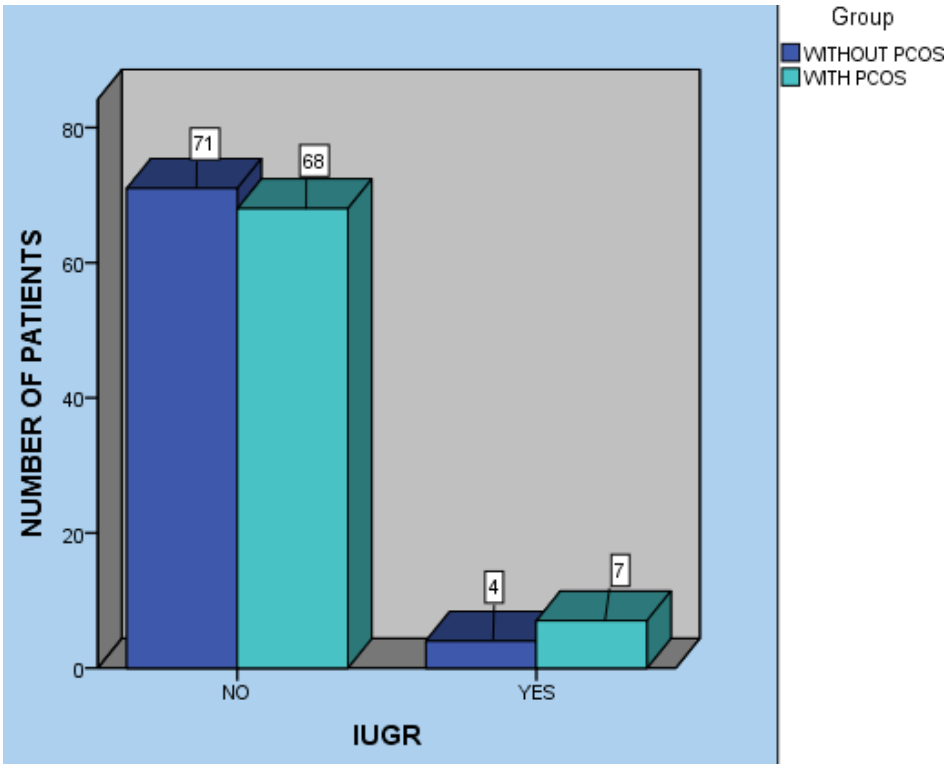


TABLE-7 : COMPARISON OF BIRTH WEIGHT OF NEONATE BORN TO MOTHERWITH AND WITHOUT PCOS:

BIRTH WEIGHT OF BABY (Kg)	WITH PCOS	WITHOUT PCOS
1kg - 3kg	23 (30.66%)	41 (54.7%)
3.1kg - 5kg	52 (69.33%)	34 (45.3%)
t-test value: -4.91; p-value-<0.01 significant		

The above table shows the comparison of birth weight of neonate born to mother with and without PCOS. Majority of neonate weight 41(54.7%) of mother without PCOS and 23(30.66%) subjects with pcos was between 1kg-3kg and 34 (45.3%) between 3.1kg-5kg in the mother without pcos whereas 52(69.33%) mother with PCOS had baby weight more than 3 kg. This is statistically significant with p value- <0.01

GRAPH-7 : COMPARISON OF BIRTH WEIGHT OF NENONATE BORN TO MOTHERWITH AND WITHOUT PCOS:

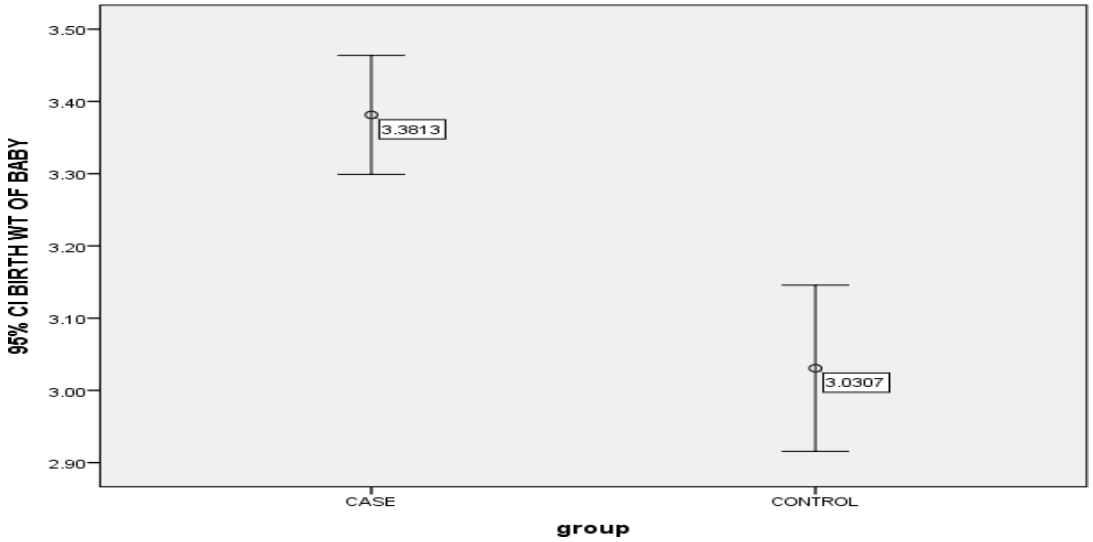


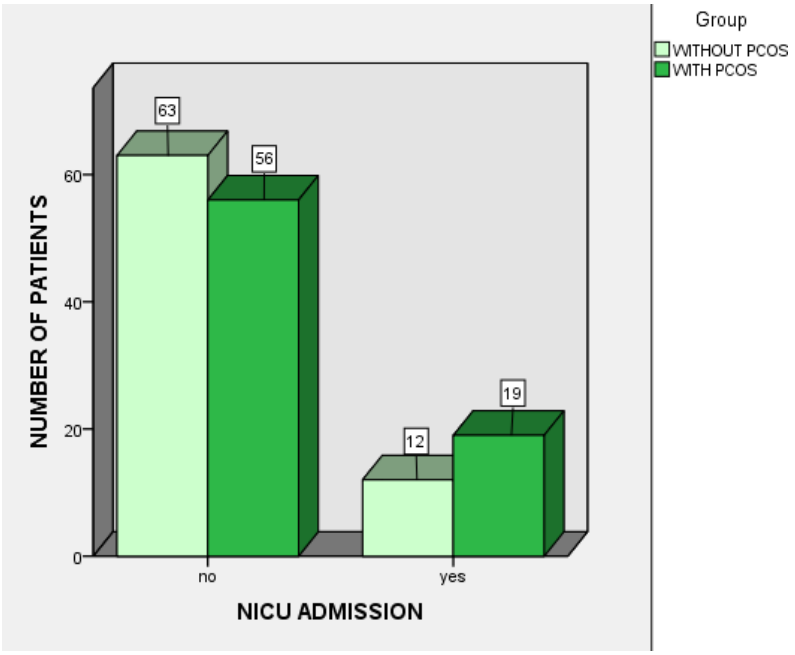
TABLE-8: COMPARISON OF NICU ADMISSION OF NEONATE BORN TO MOTHERWITH AND WITHOUT PCOS:

NICU ADMISSION	WITH PCOS	WITHOUT PCOS	TOTAL
YES	19 (25.3%)	12 (16%)	31 (20.7%)
NO	56 (74.7%)	63 (84%)	119 (79.3%)
TOTAL	75	75	150

CHI-SQUARE- 1.99 ;P-VALUE- 0.1; NOT SIGNIFICANT

In the above table, majority of neonate119(79.3%) was not admitted in NICU. In the mother with PCOS, only 19(25.3%) neonate was admitted in NICU and the mother without PCOS, only 12(16%) neonate was admitted in NICU. There was non significant association found in NICU admission between with or without PCOS mother.

GRAPH-8: COMPARISON OF NICU ADMISSION OF NENONATE BORN TOMOTHER WITH AND WITHOUT PCOS:



V. Discussion

In our study all the reported cases were between the age group of 21-39 years. The mean age of (32.11±3.31) women with PCOS were more than age (31.41±3.07) women without PCOS.there is statistically insignificant difference is there. Similar findigs in a study by Amita Gupta et al (2009)(7) where maximum prevalence (42.8%) of PCOS was seen in age group of 25-29 years and with minimum prevalence(1.7%) in 35-39years. In a study by Chaitra Shivananjaiah et al (2017)(1) the highest prevalence of PCOS, were in the between the age group 25 to 29 years, constituting to 48%. Mean age of PCOS women was 33 years and 35 years in control group in a study by Lynn Sterling et al (2015)(2). Maximum prevalence of PCOS was seen in age group 25 – 29 years in a study by U. Agnes Vijaya et al (2015)(3) The findings of these studies are in accordance of our study.

We recorded that Only 4(5.33%) women with PCOS and 1(1.33%) without PCOS had miscarriage showing higher miscarriage in women with PCOS and is significantly higher in PCOS. This may be due to placental inflammation, and placental site thrombosis occurs due to PCOS and may have effect on rate Of miscarriage. Recently, a large Australian study by Joham et al. (2014)(8) demonstrated that the miscarriage rate was more frequent in women with PCOS than in controls (20 versus 15%, respectively, P 1⁄4 0.003), which is similar to our study, This study shows although PCOS was not an independent risk factor for pregnancy loss but the miscarriage rate was strongly influenced by BMI. A higher miscarriage rate was observed in PCOS patients compared with non-PCOS patients in studies by Chen et al (2017)(9) and Okohue et al (2013)(10) which is in accordance with our study. However study like meta-analysis by Heijnen et al. (2006) (11) concerning women with and without PCOS undergoing IVF demonstrated no difference in miscarriage rates is differs from our study. This may be the due to the involvement of other factors in pathogenesis of miscarriage.

GESTATIONAL DIABETES MELLITUS (GDM)

In the present study 17 (22.66%) women with PCOS and 4 (5.3%)without PCOS had gestational diabetes mellitus showing significant difference between the PCOS and non-PCOS women, In a study by Ragnheidur Valdimarsdottir et al (2020)(12) 2.5% of women with PCOS include in the study had GDM. Similarly, Urman et al.(13) found PCOS women to be at increased risk of gestational diabetes independent of body mass index similar to our study. A study by Lynn Sterling et al (2015)(2) reported three times more chances of GDM in

PCOS women as compared to normal women. A study by Mei-Lien Pan et al (2015)(14) reported that among 7,629 eligible women with PCOS diagnosis, 3,109 (42.87%) had subsequent pregnancies. GDM occurred frequently among women with a history of PCOS as compared those without PCOS (20.46% vs. 10.54%, $p<0.0001$).The findings of all the studies are similar to our study hence establishing that GDM is significantly higher in PCOS women than without PCOS , this may be due to higher BMI, or may be insulin resistance had role in it.

PREGNANCY INDUCED HYPERTENSION (PIH)

In the present study only 8 (10.7%) women with PCOS and 4 (5.3%) without PCOS had pregnancy induced hypertension. Juhani Rantakallio et al (2020)(14) performed a study to investigate the prevalence of hypertensive disorders of pregnancy (HDP), and the roles of polycystic ovary syndrome (PCOS), where they reported that women with PCOS presented more often PIH compared with the non-PCOS controls 18.9% vs 13.3%, respectively which is almost similar to our study, and displayed also a slightly increased risk of HDP (OR=1.56 [95% CI: 1.03-2.37]). Radon PA et al.(15) showed a significant increase in incidence of PIH in women with PCOS women even after matching for BMI. In a study by U. Agnes Vijaya et al (2015)(3) rate of PIH was 8/56 in women with PCOS. These findings are almost in accordance with our study.

COMPARISON OF PREECLAMPSIA

The prevalence of preeclampsia was more among women with PCOS 8 (10.7%) as compared to women without PCOS 6 (8%).showing higher preeclampsia in PCOS patients as compared to non-PCOS. A study by Christ et al(16) states that there was more than a twofold increase in the risk of preeclampsia (5% vs. 2%) for women with PCOS in comparison to the national registry data and the respective rates of premature delivery were 11% vs. 7%.which is almost in accordance of our study. In a study by Ragnheidur Valdimarsdottir et al (2020)(12) 6.9% women with PCOS and 1.9% non PCOS showed preeclampsia. These findings are almost in accordance to our study. Li G, et al(2011)(17) showed an increased risk of GDM and preeclampsia in non- overweight/obese PCOS women and this risk seemed to be due to PCOS itself rather than to obesity.

NICU Admission

In the mother of PCOS in the present study, only 19(25.3%) neonate were admitted to NICU and the mother without PCOS, only 12(16%) neonate were admitted to NICU. Rate of NICU admission in a study by Dr. Surendra et al was 8/40 in PCOS women and 3/40 in normal women. In a study by Varun Manoharan et al (2020) (18) 12.9% PCOS women and 14.6% non PCOS women were admitted to NICU.

VI. Conclusion

This observational longitudinal study was conducted to assess the feto-maternal outcome of pregnant patients with PCOS. It affects mostly reproductive age women and it is very commonly encountered during OPDs. Women with PCOS are at increased risk of adverse pregnancy and birth outcomes and need increased surveillance during pregnancy. On the basis of our study we can conclude that GDM, Rate of miscarriage were higher in PCOS and statistically significant difference was found between PCOS and non PCOS women. Factors like pregnancy induced hypertension, preeclampsia, intrauterine growth restriction, were not significantly different in PCOS mother than non-PCOS mother

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