

A STUDY OF CLINICAL PARAMETERS IN THE DIAGNOSIS OF POLYCYSTIC OVARIAN SYNDROME

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ABSTRACT: BACKGROUND: PCOS is a disorder characterized by an amalgamation of symptoms rather than a single pathognomonic symptom and is of uncertain etiology. Although no single symptom is specific, still a collection of symptoms taken together can make a great contribution in its diagnosis. **AIM:** To study the value of clinical parameters in the diagnosis of PCOS. **SETTINGS & DESIGN:** This's a prospective observational study. **MATERIALS & METHODS:** The present study carried out among female patients attending Gynecologic outpatient department KIMS Medical College Amalapuram between October 2013 and august 2014. Fifty women with PCOS diagnosed on the basis of clinical, hormonal and ultrasound parameters using the Rotterdam criteria .women without PCOS , having regular cycles which were selected randomly comprised the control group (n = 50) taken all from the patient attending OPD. A detailed history was taken of each case and a thorough clinical examination was done. **STATISTICAL ANALYSIS USED:** All the data were analyzed by statistical software spss16. **RESULT:** Mean age of the women in PCOS cases was 24.061 ± 3.84 years as compared to 26.89 ± 5.62 years in control. The mean BMI in the women was: 25.533 ± 4.27 kg/m² compared to 22.64 ± 2.12 kg/m² which is statistically significant. 38% of cases are overweight, and 20% are obese. The mean waist hip ratio was 0.94 ± 0.081 , whereas that of control was 0.90 ± 0.091 . 66% (n=33) of the PCOS cases presents with oligomenorrhoea. 16 % (n=8) of women had clinical manifestations of Acanthosis in PCOS cases as compared to 4% (n=2) in control. 30% (n=15) of PCOS cases have acne compared to 8% (n=16) in control. 64% (n=32) of the PCOS cases have hirsutism compared to only 4% (n=2) in control. 16 % (n=8) of the PCOS cases are concerned about infertility (primary and secondary) compared to 4% (n=2) in controls. **CONCLUSION:** The study justifies the elaborate evaluation of clinical parameters like age, body mass index (BMI), waist hip ratio (whr), menstrual pattern, acanthosis nigricans, acne, hirsutism; infertility can make a great contribution in diagnosis of polycystic ovarian syndrome (PCOS) patients.

KEYWORDS: PCOS, Rotterdam criteria.

INTRODUCTION: Polycystic ovary syndrome is the most common female endocrine disorder affecting 5 - 10% of women of reproductive age (12 - 45years) and is thought to be one of the leading causes of female infertility.^[1] It is a disorder characterized by an amalgamation of symptoms rather than a single pathognomonic symptom and is of uncertain etiology although studies have suggested genetic etiology playing a major role.

PCOS is attributed as a major factor responsible for menstrual irregularities, infertility, excessive amounts or effects of androgenic hormones resulting in acne, hirsutism, insulin resistance, obesity, type 2 diabetes, high cholesterol levels in reproductive age group.

Most often, women with high testosterone levels develop male pattern hair growth (hirsutism) especially on their faces and chests.^[2]

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MATERIALS & METHODS: The present prospective observational study carried out among female patients attending Gynecologic outpatient department of KIMS Medical College Amalapuram between October 2013 and August 2014.

An informed written consent was obtained from all patients participating in the study. The protocol was approved by Obstetrics and Gynecology Department of V.S.S. Medical College, Burla, Sambalpur.

Fifty women with PCOS diagnosed on the basis of clinical, hormonal and ultrasound parameters using the Rotterdam criteria.

Two of the following features were applied to diagnose the PCOS:

1. Oligo-anovulation;
2. clinical or biochemical signs of hyperandrogenism;
3. Polycystic ovaries.

Women with PCOS (n = 50) diagnosed by this criteria comprises the study group and women without PCOS, having regular cycles which were selected randomly comprised the control group (n=50) taken all from the patient attending OPD of Obstetrics and Gynecology dept., V.S.S. Medical College, Burla.

Women in the control group were with other gynecological diseases, not on any hormonal medication, no known infertility and endocrinologic or dermatologic problems, and were apparently normal healthy women.

INCLUSION CRITERIA:

1. Women with oligomenorrhea defined as menstrual bleeding at intervals of greater than 35 days or abnormally infrequent menstrual bleeding characterized by three to six menstrual cycles per year.
2. No pre-existing medical illness.
3. Age 18-35 years.

EXCLUSION CRITERIA:

1. Pregnancy, lactation.
2. Menarche less than 2 years ago.
3. Known co-morbidity.
4. Women on drugs known to cause abnormal uterine bleeding- hormonal contraceptives drugs known to produce hirsutism/ galactorrhea (e.g. corticosteroids, androgens, cyclosporine, minoxidil, phenytoin, diazoxide, Cimetidine, Histamine-receptor blockade, Methyldopa, etc.)

A detailed history was taken of each case and a thorough clinical examination was done.

ANTHROPOMETRIC EVALUATIONS: Body weights were measured in light clothing and without shoes, and were recorded to the closest 0.5 kg.

Body heights were measured without shoes, and were recorded to the closest centimeter.

BMI was expressed as weight (Kilograms) per height (Meters) square.

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Weight status was classified using the following BMI categories according to the NIH Definition.

BODY MASS INDEX CATEGORIES:

Status	BMI (Kg/m ²)
Under weight	< 18.5
Normal	18.5-24.9
Over weight	25-29.9
Obesity	≥30
Morbid Obesity	≥40

Waist circumference was measured at the level of the umbilicus with the subject in the standing position and expressed in centimeters. Hip circumference was measured and expressed in centimeters. Waist hip ratio (WHR) was expressed as ratio of waist to hip circumferences. A cut off value of 0.8 was taken to indicate low risk.

WAIST HIP RATIO AND RISK PROFILES:

Waist to Hip Ratio Chart	
Female	Health Risk Based on WHR
0.80 or below	Low Risk
0.81 to 0.85	Moderate Risk
0.85 +	High Risk

All women were evaluated for the presence/absence of Acne, Galactorrhea and Thyromegaly, and the findings were recorded. Hair distribution was assessed using the modified Ferriman-Gallway score (mFG) in all Women. Hirsutism was categorized by Ferriman-Galaway score (FGS). Score 11-20 Grade-I; 21-30 Grade-II, 31-40: Grade-III and >40: Grade-IV Score <11 was considered normal.

Women with a score of >11 were categorized as being hirsute.

OBSERVATION:

Age in Total years	PCOS CASES (n=50)		CONTROL (n=50)		TOTAL	
	N	%	N	%	No.	%
18-20	12	24	5	10	17	17
21-25	24	48	10	20	34	34
26-30	11	22	14	28	25	25
31-35	3	6	21	42	24	24
Total	50	100	50	100	100	100

Table 1: DISTRIBUTION OF CASES ACCORDING TO AGE

P=0.0041 (S)

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- Mean age of the women in PCOS cases was 24.061 ± 3.84 years as compared to 26.89 ± 5.62 years in control which is statistically significant.
- 17% (n=17) patients were less than 20 years of age, and 51% (n=51) were below the age of 25, indicating that PCOS is a disease of the young.

BMI	PCOS CASES (n=50)		CONTROL (n=50)		TOTAL	
	n	%	n	%	No	%
Underweight	3	6	2	4	5	5
Normal body weight	18	36	28	56	46	46
Overweight	19	38	15	30	34	34
Obese	10	20	5	10	15	15
Total	50	100	50	100	100	100

Table 2: DISTRIBUTION OF CASES ACCORDING TO BODY MASS INDEX (BMI)

($p < 0.0001$).

- The mean BMI in the women was: 25.533 ± 4.27 kg/m² compared to 22.64 ± 2.12 kg/m² which is statistically significant.
- 38% of cases are overweight, and 20% are obese.
- 58% of the study population are either overweight or obese.
- None of them were morbid obese type.

WHR	PCOS CASES (n=50)		CONTROL (n=50)		TOTAL	
	N	%	N	%	No.	%
< 0.8	3	6	6	12	9	9
0.81-0.85	5	10	15	30	20	20
> 0.85	42	84	29	58	71	71
TOTAL	50	100	50	100	100	100

Table 3: DISTRIBUTION OF CASES ACCORDING TO WAIST HIP RATIO (WHR)

P=0.0223 (NS)

- The mean waist hip ratio was 0.94 ± 0.081 , whereas that of control was 0.90 ± 0.091 which is statistically insignificant. This might be explained by the fact that most of controls are adults or due to less number of controls in our study.
- Central obesity i.e. WHR > 0.8 was seen in 94% of the women.

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MENSTRUAL CYCLE	NO. OF PCOS CASES (n=50)		NO. OF CONTROLS (n=50)	
	N	%	N	%
REGULAR	7	14	50	100
OLIGOMENORRHOEA	33	66	0	0
SECONDARY AMENORRHOEA	3	6	0	0
PRIMARY AMENORRHOEA	2	4	0	0
MENORRHAGIA	5	10	0	0
TOTAL	50	100	50	100

Table 4: DISTRIBUTION OF CASES ACCORDING TO MENSTRUAL PATTERN

66% (n=33) of the PCOS cases presents with oligomenorrhoea, 4% (n=2) presents with primary amenorrhoea, 6% (n=3) of cases have secondary amenorrhoea and menorrhagia in 10% (n=5) of cases.

Group	PCOS CASES (n=50)		CONTROL (n=50)		TOTAL	
	N	%	N	%	No.	%
Acanthosis	8	16	2	4	10	10
No. acanthosis	42	84	48	96	90	90
Total	50	100	50	100	100	100

Table 5: DISTRIBUTION OF CASES ACCORDING TO ACANTHOSIS NIGRICANS

P<0.0001(S)

- 16 % (n=8) of women had clinical manifestations of Acanthosis in PCOS cases as compared to 4% (n=2) in control which is statistically significant.

Group	PCOS CASES (n=50)		CONTROL (n=50)		TOTAL	
	N	%	N	%	No.	%
Acne	15	30	4	8	19	19
No Acne	35	70	46	92	81	81
Total	50	100	50	100	100	100

Table 6: DISTRIBUTION OF CASES ACCORDING TO ACNE

P<0.0001(S)

- 30% (n=15) of PCOS cases have acne compared to 8% (n=4) in control which is statistically significant.

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Group	PCOS CASES (n=50)		CONTROL (n=50)		TOTAL	
	N	%	N	%	No	%
Hirsutism	32	64	2	4	34	34
No. hirsutism	18	36	48	96	66	66
Total	50	100	50	100	100	100

Table 7: DISTRIBUTION OF CASES ACCORDING TO HIRSUTISM

P<0.0001(S)

- 64% (n=32) of the PCOS cases have hirsutism compared to only 4% (n=2) in control, the difference of which is statistically significant.
- The mean mF-G score >8.
- Their mean mF-G score was 13.57 ± 4.82 . in PCOS cases.

Group	PCOS CASES (n=50)		CONTROL (n=50)		TOTAL	
	n	%	n	%	No	%
Infertility	8	16	2	4	10	10
No infertility	42	84	48	96	90	90
Total	50	100	50	100	100	100

Table 8: DISTRIBUTION OF CASES ACCORDING TO FERTILITY

P<0.0001(S)

- 16 % (n=8) of the PCOS cases are concerned about infertility (primary and secondary) compared to 4% (n=2) in controls which is statistically significant.

DISCUSSION: Polycystic ovary syndrome (PCOS) is a complex and heterogeneous disorder, affecting mostly women in reproductive age group. It is characterized by chronic anovulation, hyperandrogenemia, altered LH: FSH ratio (>2/3:1) and polycystic ovaries. Excess androgen levels lead to menstrual disturbances, development of ovarian cysts, hirsutism and other related disorders.

IR also increases the risk for development of glucose intolerance, type 2 diabetes mellitus (T2DM), hypertension, dyslipidemia and cardiovascular abnormalities in these women.

While the diagnosis is generally indicated by the clinical presentation, laboratory testing is necessary to exclude other possible conditions that may mimic PCOS.

So it will be appropriate to discuss the outcome of present work with main aim of observing various presentations of clinical features.

PCOS is one of the commonest endocrinopathies in women, affecting 5–10% of women in the reproductive age worldwide. [3]

In clinical gynecologic practice, women with polycystic ovarian syndrome are seen primarily for menstrual irregularity, androgen excess, and infertility.

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During the past decade, women with chronic anovulation and hyper androgenism have been observed to have an increased prevalence of diabetes and increased risk factors for coronary heart disease (CHD).

In addition, the chronic anovulation of polycystic ovarian syndrome implies, unopposed estrogen and, therefore, an increased risk of endometrial cancer.

These factors have led to a different clinical perspective about polycystic ovarian syndrome—one that recognizes the importance of addressing the immediate issues of irregular bleeding, hirsutism, and infertility, but also emphasizes the long-term goals of preventing diabetes, heart disease, and cancer.

SUMMARY: AGE: From table no. 1 it is seen that, PCOS is most common (48%) in the age 21 to 25 years of age group. About 72% of the cases are between 18-25 years. The mean age of presentation is 24.061 ± 3.84 years, which is in corroboration with the studies done by K. K. Maryam et al. (2012)^[4] study that's include age group between 14-38 years and found mean age of PCOS to be 23.67 ± 6.34 years which is in close to our study results. Sharquie et al. (2007)^[5] included patients in the age group of 15 – 39 years shows mean to be $(26.12 \pm 6.36\text{yrs})$ in their study.

BODY MASS INDEX (BMI): From table no. 2 it is observed that women with PCOS are on an average more obese than their non-PCOS counterparts, with 20% cases are obese, which is quite less as compared to the study done by Fouzia Adil et al. (2005)^[6] found 50% of patients were obese. Similarly Fouzi ahaq et al. (2007)^[7] found obesity in 68.5% of patients. Abdul Razzak et al. (2007)^[8] conducted a study and found 63.55% patients were obese.

But, 58% of the cases are either overweight or obese in our study, which is close to the observation found by Pasquali et al (1988)^[9] and who found that about 50% of the women with PCOS are obese or overweight. Similarly Kiddy et al (1990)^[10], found that about 35% of the women with PCOS are obese or overweight.

The mean body weight in PCOS group in the study was found to be 62.63 kg, The mean BMI in the study population is found to be $25.533 \pm 4.27\text{kg/m}^2$, which is very much similar to the studies done by Fouzia Nazir et al. (1999)^[11] Who reported 86.5% of patients with BMI > 25 kg/m². Lim et al, (2012)^[12] in a systemic review and meta-analysis concluded that with PCOS had a greater risk of overweight, obesity and central obesity.

WAIST HIP RATIO (WHR): This study as observed in table no.3 shows 94% of the PCOS women have central obesity, having WHR >0.80 and about 84% of the cases are having WHR >0.85.

The mean waist hip ratio was 0.94 ± 0.081 in cases group.

MENSTRUAL PATTERN: As seen from table no. 4, the present study found oligomenorrhoea in 66% cases which is quiet high in frequency, while the regular menses are seen in 14% cases, amenorrhea in 10% (both primary and secondary) and menorrhagia in 10 % in PCOS group. This result of our study matches to certain extent wit the study done by R Yousouf et al (2012)^[13] found oligomenorrhoea in 71%patients. Similarly Franks et al. (1989)^[14] study done on 300 PCOS patients indicates oligomenorrhoea and amenorrhea was found in 52% and 26%.

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However, other studies done by Balen et al. (1995)^[15] shows that among PCOS patient 47% had oligomenorrhea and 19.2% had amenorrhea which is very less as compared to our study. Also Goldzieher et al. (1981)^[16] Shows oligomenorrhoea and amenorrhea to be 29% and 51%, a study done on 1079 PCOS patients. This wide variation may be due to varying presentation of the disease and associated other medical disorders along with the primary PCOS.

ACANTHOSIS NIGRICANS: From table no. 5, acanthosisnigricans is seen in 16% PCOS cases as compared to 4% (n=2) in control group. Acanthosisnigricans is considered as an important cutaneous marker of hyperinsulinemia. The prevalence of acanthosis in adult obese patients has been estimated to be 74% by Hud et al. (1992)^[17]

ACNE: As seen in table no. 6, acne is present in 30 % in PCOS group which is more as compared to 8% in control group, which is very less as compared to a study by Balen et al, (1995)^[15] reported incidence of acne as 66.2%. Although there is a high incidence of acne in PCOS women, this clinical feature is not among the criteria for diagnosis of PCOS.

HIRSUTISM: Hirsutism is seen in 64% of PCOS group in our study which is very close to the results of the study done by Balen et al. (1995)^[15] who found hirsutism in 66% cases of his study on PCOS. Similarly Franks et al. (1989)^[14] found hirsutism associated with 64% of the PCOS cases.

Goldzie Her et al. (1981)^[16] found in 69% and R. Yousouf et al. (2012)^[13] found 31% patients to have hirsutism out of the PCOS cases he studied.

INFERTILITY: As seen from table no. 8, about 16 % patients in the PCOS group is having infertility problem, including primary infertility in 12% and secondary infertility 4% cases. This result of which is very low compare to the study done by Fouzia Nazir et al. (1999)^[11] found primary infertility in 75% of patients with PCOS, which may be due to the cases are from patients with PCOS attending infertility clinic.

CONCLUSION: Polycystic ovary syndrome remains a highly controversial topic because of its undetermined and potentially variable etiology and an undetermined phenotypic spectrum. In clinical and research practice, a conservative and broadly based definition of PCOS is warranted.

The study justifies the elaborate evaluation of clinical parameters like age, body mass index (BMI), waist hip ratio (whr), menstrual pattern, acanthosis nigricans, acne, hirsutism, infertility can make a great contribution in diagnosis of polycystic ovarian syndrome (PCOS) patients.

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