Original Research

A STUDY OF CLINICAL, BIOCHEMICAL &RADIOLOGICAL CORRELATION IN THE DIAGNOSIS OF PCOS

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ABSTRACT

Aims: To evaluate and compare the clinical, biochemical, radiological features in diagnosis of PCOS
Methods: The study was observational study at Medical College Hospital, Kolkata from February 2020 to June 2021. Women 15-35years, in Gynae OPD with history of oligo/ amenorrhea and/or features of hyperandrogenism were the study population. The followings were the study tools 1. Outpatient department tickets, 2. Informed Consent Form 3. Clinical examination 4. Relevant laboratory investigation: Blood for Hb, LH, FSH, AMH, TOTAL TESTOSTERONE, TSH, PROLACTIN, FBS, HbA1C. USG 5. Relevant Books and Journals. 6. Computer hardware and software
Result: The mean age group and BMI of our study were 24.95yrs & 25.57kg/m2 respectively; 48% of patients were Overweight & 13% of patients were obese. Women who had clinical features of PCOS had high BMI (69.7% of patient). Ovulatory dysfunction was present in 92% of patients; 88% oligomenorrhea, 4% amenorrhea and 8% normal cycle. In our study; features of HA were present in 81% of patients. Association of AMH (ng/ml) with Clinical Features of HA was statistically significant *(p<0.0001).* Association of Total Testosterone level with Radiological features of PCOS was statistically significant (*p=0.0496).* Association between Features HA with Radiological features of PCOS was statistically significant (p=0.0283). Association of LH: FSH with Radiological features of PCOS was statistically significant (*p=0.0268*).
Conclusion: Most of the PCOS patients can be diagnosed by proper history, thorough clinical examination and Ultrasonography of pelvis.

Keywords: Hirsuitism, Hyperandrogenism, Hyperinsulinemia, Menstrual Dysfunction Ovarian Cyst, Polycystic Ovary Syndrome.

INTRODUCTION

Polycystic ovary syndrome (PCOS) is the most common endocrine and metabolic disorder in women [1], with a prevalence of up to 17.8% and is characterized by hyperandrogenism, irregular cycles and polycystic ovaries. 40% -70% of PCOS exhibited elevated level of adrenal androgen, mostly DHEA. Increased peripheral insulin resistance contributing, in part, to the ovarian and /or adrenal hyperandrogenism. Although ovary is the principal source of adrenal androgen excess in most of these patients (4).
PCOS is the ovarian expression of metabolic syndrome like increased risk of type 2 diabetes, dyslipidaemia, cardiovascular disease and endometrial carcinoma [5-8].

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Rotterdam criteria were required in order to diagnose the condition, after exclusion of other causes of androgen excess. There is significant role of PCOS in reproductive, endocrine and metabolic morbidity, little is known about its different modes of presentation in Indian population.

Aims & Objectives

To evaluate & compare the clinical, biochemical, radiological features in diagnosis of PCOS, based on the revised Rotterdam criteria, 2003, in this part of our country.

MATERIALS AND METHODS

The study was a hospital based observational study which was carried out at Medical College and Hospital, Kolkata from February 2020 to June 2021. Women aged between 15-35years, attending in Gynae OPD with history of oligo/ amenorrhea and/or features of hyperandrogenism were the study population. A total of 115 women were enrolled for the study based on the inclusion criteria. However, 15 excluded from the analysis. Among the 15

women who were excluded, 6 had hyper prolactinemia, 7 had evidence of hypothyroidism & 2 had left to follow up. The total 100 women, diagnosed as PCOS, based on Rotterdam criteria were included in the study and analysis done.

Inclusion Criteria:

All the patient aged 15-35 years attending with features of PCOD: - 1. History of Ovulatory dysfunction [oligo or amenorrhea] 2. Features of hirsutism, acne, androgenic alopecia, acanthosis nigricans.

Exclusion Criteria:

1. Pregnant and 6 months after post-partum 2. Post-menopausal. 3. Neoplasm of genital organ 29 4. Underlying disease of the pituitary or adrenal glands. 5. Anaemia 6. Medical disorders like Hypo /Hyperthyroid, hyperprolactinemia, Heart disease, Hypertension, Diabetes 7. Menarche developed less than 2yrs back.

Informed consent was taken. Women were subjected to detailed questionnaire which included age of menarche, marital status, obstetric history and 30 detailed menstrual history. Anthropometric measurements (weight & height), signs of hyperandrogenism, galactorrhoea, and thyroid disorders were noted by thorough clinical examination. Biochemical & Hormonal analysis-like blood for Hb%, LH, FSH, AMH, TOTAL TESTOSTERONE, TSH, PROLACTIN, FBS & HbA1C were done. USG [Trans abdominal Sonography]-AFC & Ovarian volume were measured. All data were recorded and final results analysed. The followings were the study tools 1. Outpatient department (OPD) tickets, Gynae OPD-PCOD Clinic 2. Informed Consent Form (ICF) 3. Clinical examination 4. Relevant laboratory investigation: Blood for Hb, LH, FSH, AMH, TOTAL TESTOSTERONE, TSH, PROLACTIN, FBS, HbA1C. USG [TAS]-AFC (Antral Follicle Count) & OV Ovarian Volume) 5. Books and Journals relevant for the study topic. 6. Computer hardware and softwar.

RESULT AND ANALYSIS

For statistical analysis data were entered into a Microsoft excel spreadsheet and then analysed by SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and Graph Pad Prism version 5. Data had been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables. Two-sample t-tests for a difference in mean involved independent samples or unpaired samples. Paired t-tests were a form of blocking and had greater power than unpaired tests. One-way analysis of variance (one-way ANOVA) was a technique used to compare means of three or more samples for numerical data (using the F distribution). A chi-squared test ($\chi 2$ test) was any statistical hypothesis test wherein the sampling distribution of the test statistic is a chi-squared distribution when the null hypothesis is true. Without other qualification, 'chi-squared test' often is used as short for Pearson's chi-squared test. Unpaired proportions were compared by Chi-square test or Fischer's exact test, as appropriate. Explicit expressions that can be used to carry out various *t*-tests are given below. In each case, the formula for a test statistic that either exactly follows or closely approximates a *t*-distribution under the null hypothesis is given. Also, the appropriate degrees of freedom are given in each case. Each of these statistics can be used to carry out either a one-tailed test or a two-tailed test. Once a *t* value is determined, a *p*-value can be found using a table of values from Student's t-distribution. If the calculated *p*-value is below the threshold chosen for statistical significance (usually the 0.10, the 0.05, or 0.01 level), then the null hypothesis is rejected in favour of the alternative hypothesis. P-value ≤ 0.05 was considered for statistically significant.

Result & Analysis

1. Distribution of Patients According to Demographic Parameters

Variables	Group	Frequency	Percentage
Age	<=20	14	14%
	21-25	47	47%
	26-30	28	28%
	31-35	11	11%
BMI	18.5-24.9	39	39%
	25-29.9	48	48%
BMI	>=30	13	13%
Marital Status	Married	44	44%
	Unmarried	56	56%

2. Distribution Of Patients According to Clinical Features

	Clinical Features	Frequency	Percentage
1.Ovulatory Dysfunction	Absent	8	8
	Amenorrhoea	4	4
	Oligomenorrhoea	88	88

2Clinical Features of Hyperandrogenism (44% present)	Alopecia	26	26
	Acne	40	40
	Acanthosis	44	44
	Hirsutism	55	55

3. Distribution of Patients According to Laboratory Parameters

Parameters	Standard		Frequency	Percentage
1.LH:FSH	<2		52	52%
	>=2		48	48%
2.AMH	<4 ng/ml		32	32%
	>=4ng/ml		68	68%
3.Testosterone	<60ng/dl		*24*	24%
	>60ng/dl		76	76%
4.FBS	<120mg/dl		99	99%
	>120mg/dl		1	1%
5.HbA1c	<6.5gm%		93	93%
	>6.5gm%		7	7%
6.Radiological Features	LOFC	<12	22	22%
		>=12	78	78%
	LOV	<10	22	22%
		>=10	78	78%
	ROFC	<12	36	36%
		>=12	64	64%
	ROV	<10	37	37%
		>=10	63	63%

1. Association between BMI(kg/m2) & Clinical Features of HA

Clinical Features of Hyperandrogenism

BMI (Kg/m^2)	Absent	Present	Total
18.5-24.9 Row% Col%	16.0 41.0 66.7	23.0 59.0 30.3	39.0 100.0 39.0
25-29.9 Row% Col%	7.0 14.6 29.2	41.0 85.4 53.9	48.0 100.0 48.0
>=30% Row% Col%	1.0 7.7 4.2	12.0 92.3 15.8	13.0 100.0 13.0
CTota Row% Col%	24.0 24.0 100.0	76.0 76.0 100.0	100.0 100.0 100.0

Chi square Value -10.4269; **P value**: 0.0054

In our study, 76 patients who Had clinical features of HA; 12(15.8%) patients had BMI ≥30(obese), 41(53.9%) patients had BMI in between 25-29.9(overweight) and 23 (30.3%) patients had BMI in between 18.5-24.9(normal BMI); 24 patients who had absent clinical features of HA ; 16(66.7%) patients had BMI in between 18.5-24.9, 7(29.2%) patients had BMI in between 25-29.9 and 1(4.2%) patient had BMI ≥30.

Association of BMI (kg/m2) with Clinical Features of HA was statistically significant (p=0.0054).

2. Association Between Ovulatory Dysfunction and Radiological Features of PCOS

Radiological Features of PCOS

Ovulatory Dysfunction	Absent	Present	Total
Absent Row% Column%	0 0.0 0.0	8 100 9.6	8 100.0 8.0
Present Row%	17 18.5	75 81.5	92 100.0

Column%	100.0	90.4	92.0
Total	17	83	100
Row%	17	83.0	100.0
Column%	100.0	100.0	100.0

Chi Square Value: 2.78; **P Value**: 0.0120
In our study; Radiological features of PCOS was present in 83 patients; among them 75 patients had Ovulatory dysfunction and 8 patients did not have Ovulatory dysfunction.17 patients who had absent Radiological features of PCOS had ovulatory dysfunction.

3. Association Between Testosterone and Radiological Features of PCOS

Radiological Features of PCOS

Testosterone(ng/dl)	Absent	Present	Total
<60	3	21	24
Row%	12.5	87.5	100.0
Column%	17.6	25.3	24.0
>=60%	14	62	76
Row%	18.4	81.6	100.0
Column%	82.4	74.7	76.0
Total	17	83	100
Row%	17	83	100.0
Column%	100	100.0	100.0

Chi Square Value: 0.4532; **P Value:** 0.0308; **Odds Ratio:** 0.6327 (0.1654, 2.4199)
In our study; 83 patients had radiological features of PCOS positive, among them 62(74.7%) patients had Testosterone(T) value ≥60(ng/dl) and 21(25.3%) patients had Testosterone(T) value <60(ng/dl). 17 patients had absent radiological features of PCOS ; , among them 14(82.4%) patients had Testosterone(T) value ≥60(ng/dl) and 3(17.6%) patients had Testosterone(T) value <60(ng/dl).

4. Association between LH: FSH & Radiological Features of PCOD

Radiological Features of PCOS

LH: FSH	Absent	Present	Total
<2	7	45	52
Row%	13.5	86.5	100.0
Column%	41.2	54.2	52.0
>=2	10	38	48
Row%	20.8	79.2	100
Column%	58.8	45.8	48.0
Total	17	83	100
Row%	17.0	83.0	100.0
Column%	100.0	100.0	100.0

Chi Square Value: 4.9613, **P Value**: 0.0268; **Odd Ratio:** 0.5911 (0.2052, 1.7028)
In our study; 83(83%) patients had Radiological features of PCOS, among them 45 (54.2%) patients had LH: FSH ratio < 2 and 38 (45.8%) had LH: FSH ratio ≥2. 17(17%) patients had no Radiological features of PCOS, among them 7 (41.2%) patients had LH: FSH ratio < 2 and 10 (58.8%) had LH: FSH ratio ≥2. Association of LH: FSH ratio with Radiological features of PCOS was statistically significant.

5. Association between Clinical Features of HA & LH:FSH Ratio

LH: FSH Ratio

Clinical Features of HA	Ratio<2	Ratio>=2	Total
Absent	19	5	24
Row%	79.2	20.8	100.0
Column%	36.5	10.4	24.0
Present	33	43	76
Row%	43.4	56.6	100.0
Column%	63.5	89.6	76.0
Total	52	48	100

Row% Column%	52 100.0	48	100.0 100.0

Chi Square Value: 9.3374; **P Value:** 0.00224
In our study; 48 patients had LH: FSH ratio ≥2; among them 43(89.6%) patients had clinical features of HA; and 5 patients had absent clinical features of HA. The women who had <2 LH: FSH ratio 19 patients had absent clinical features of HA and 33 patients had presence of clinical features of HA.

6. Association between Ovulatory Dysfunction & Total Testosterone(ng/dl)

Total Testosterone

Ovulatory Dysfunction	<60	>=60	Total
Absent Row% Column%	2 25 8.3	6 75 7.9	8 100 8
Present Row% Col%	22 23.9 91.7	70 76.1 92.1	92 100 92
Total Row% Col%	24 24 100	76 76 100	100 100 100

Chi-square value: 0.0048; **P-Value:** 0.0449; **Odds Ratio:** 1.0606 (0.1996, 2.7018)
In our study; 76 patients had Total Testosterone level ≥60 (ng/dl); among them 70(92.1%) patients had Ovulatory Dysfunction and 6(7.9%) had no Ovulatory Dysfunction. Total Testosterone level was <60 (ng/ dl) in 24 patients; among them 22(91.7%) patients had Ovulatory Dysfunction and 2(8.3%) had no Ovulatory Dysfunction.

7. Association between Clinical & Biochemical Features of HA & Ovulatory Dysfunction

Ovulatory Dysfunction

Features of HA	Absent	Present	Total
Absent Row% Column%	0 0 0	19 100 20.7	19 100 19
Present Row% Col%	8 9.9 100	73 90.1 79.3	81 100 81
Total Row% Col%	8 8 100	92 92 100	100 100 100

Chi-Square Value: 2.0397; **P-Value:** 0.1532387523
In our study; Ovulatory Dysfunction was present in 92 patients, among them 73 (79.3%) patients had Clinical +Biochemical Features of HA & 19(20.7%) patients had no Clinical +Biochemical Features of HA. Association of Features of HA with Ovulatory Dysfunction was not statistically significant (p=0.1532).

8. Association between AMH (ng/ml) & Clinical Features of HA

Clinical Features of HA

AMH	Absent	Present	Total
<4ng/ml Row% Col%	17 53.1 70.8	15 46.9 19.7	32 100 32
>4 ng/ml Row% Col%	7 10.3 29.2	61 89.7 80.3	68 100 68
Total Row% Col%	24 24 100	76 76 100	100 100 100

Chi-Square Value: 21.8851; **P- Value :**< 0.0001; **Odds Ratio:** 9.8762 (3.4703, 28.1066

In our study, 76 patients had clinical features of HA; among them, 61 (80.3%) patients had AMH value >4(ng/ml) and 15 (19.7%) patients had AMH value <4(ng/ml). 24 patients who were negative for clinical features of HA; 7 (29.2%) patients showed AMH value >4(ng/ml) and 17 (70.8%) patients showed AMH value <4(ng/ml). Association of AMH (ng/ml) with Clinical Features of HA was statistically significant (p<0.0001).

9. Association between Features of HA & Radiological features of PCOS

Radiological Features of PCOS

Features of HA	Absent	Present	Total
Absent	0	19	19
Row%	0	100	100
Col%	0	22.9	19
Present	17	64	81
Row%	21	79	100
Col%	100	77.1	81
Total	17	83	100
Row%	17	83	100
Col%	100	100	100

Chi-Square Value: 4.8044; **P-Value:** 0.0283

In our study; 83 patients who had Radiological features of PCOS, 64 (77.1%) patients had Features of HA and 19 patients had absent features of HA.

DISCUSSION

The mean age group was 24.95 years. The mean BMI of our study was 25.57kg/m2; 48% of patients were Overweight & 13% of patients were obese. Women who had clinical features of PCOS had high BMI (69.7% of patient). The association between BMI and Clinical features of HA was statistically significant. In our study; ovulatory dysfunction was present in 92% of patients, among them 88% patients had oligomenorrhea and 4% had amenorrhea; 8% patients had normal menstrual cycle. In our study; features of HA were present in 81% of patients. Only clinical features of HA were present in 76% of patients; 40% patients had Acne, 26% patients had Androgenic Alopecia, 44% patients had Acanthosis Nigricans and 55% patients had Hirsutism . Maliqueo, M et al study revealed that only 38.8% presented as hyperandrogenic disorder[1] and Hirsutism affects 65% to 75%[1.] According to Azziz, R., et al., 50% to 70% patients having hyperinsulinemia as well as insulin resistance[2]. Serum Total Testosterone level was ≥60ng/dl in 76% patients; 87% patients had serum LH level ≥6.2 Miu/ml, mean value of LH was 12.8 Miu/ml; 89% patients had FSH value ≤ 10mIU/ml, mean value of FSH was 6.8 Miu/ml; 68% patients had AMH value ≥4ng/ml, mean value of AMH was 6.0mIU/ml; 48% patients had LH: FSH ratio ≥2:1. In our study; mean value of Hb% was 12.08%, FBS was 93.4 mg/dl, Hba1c was5.6%, TSH was 4.0340, Prolactin was 15.96 pg. /ml. In our study; LH: FSH ratio was significantly high in women who had Clinical Features of HA (89.6%) & association between LH: FSH ratio with Clinical Features of HA was statistically significant *(p=0.0022).* In our study; AMH value was also high in PCOS women who had clinical features of HA (80.3%). Association of AMH (ng/ml) with Clinical Features of HA was statistically significant *(p<0.0001).* It had been shown in our study that total Testosterone value was high; in women with ovulatory dysfunction (92.1%). Association of Ovulatory Dysfunction with Total Testosterone (ng/ dl) level was statistically significant *(p=0.0449*). In our study; Radiological features of PCOS was present in 90.4% of patients who had Ovulatory dysfunction. Polycystic ovaries presented in 75% to 90% of women with clinical diagnosis of PCOS according to Azziz, R[2]., et al .According to March, W.A., et al USG Based prevalence >= 20%, 60% -80% with increased androgen level, 60% - 70% Hirsutism with PCOS, 5% with PCOS+ alopecia, 33% with acne+ PCOS[3].Association of Ovulatory Dysfunction with Radiological features of PCOS was statistically significant (*p=0.0120*). In our study; the women who had Ovulatory Dysfunction 79.3% of them had Clinical +Biochemical Features of HA & 19(20.7%) patients had no Clinical +Biochemical Features of HA. Association of Features of HA with Ovulatory Dysfunction was not statistically significant (p=0.1532). In our study; 83 patients who had radiological features of PCOS; 62(74.7%) patients had high level of total Testosterone value. Association of Total Testosterone level with Radiological features of PCOS was statistically significant (*p=0.0496).*In our study; 83 patients who had Radiological features of PCOS, 64 (77.1%) patients had Features of HA. Association between Features HA with Radiological features of PCOS was statistically significant (p=0.0283). Franks S. study stated 12% -32% PCOS with biochemical evidence of exaggerated adrenarche[4] .In our study; 45.8% of patients with Radiological features of

PCOS had LH: FSH ratio ≥2. Association of LH: FSH ratio with Radiological features of PCOS was statistically significant (*p=0.0268*). In our study; 75% of PCOS patients had Ovulatory Dysfunction and Radiological features of PCOS (OD+PCOM), 73% of PCOS patients had Ovulatory Dysfunction and Features of HA (OD+HA), 64% of patients had Ovulatory Dysfunction and Features of HA ; 56 (56%) of patient was positive for all three (PCOM+ HA+OD) criteria of PCOS. Most of the PCOS patients can be diagnosed by proper history taking, thorough clinical examination and Ultrasonography of pelvis.

Limitation

- Small sample size.
- Short duration of study period.
- Free Testosterone level, SHBG, Fasting Insulin level could not be measured
- Due to unavailability of facility.
- Follow up not done.

CONCLUSION

In the present study it was found that 61% 0f patients had high BMI & it was more frequently associated with those women who had clinical features of HA. Only clinical features of HA were present 76% of patients. Features of HA (both clinical & biochemical) were present in 81% of patients. Ovulatory dysfunction was present in 92% of patients. Radiological features of PCOS were present in 83% of patients and left ovarian involvement was more. 75% of PCOS patients had Ovulatory Dysfunction and Radiological features of PCOS (OD+PCOM), 73% of PCOS patients had Ovulatory Dysfunction and Features of HA (OD+HA), 64% of patients had Ovulatory Dysfunction and Features of HA. ; 56 (56%) of patient was positive for all three (PCOM+ HA+OD) criteria of PCOS. Most of the PCOS patients can be diagnosed by proper history taking, thorough clinical examination and Ultrasonography of pelvis.

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