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Original Research Article

Clinical and hormonal profile of patients diagnosed with polycystic ovarian syndrome at tertiary care hospital in Tamil Nadu

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ABSTRACT

Background: In recent years due to the changing sedentary life style, irregular periods and infertility has become a major concern. There are many causes for infertility out of which ovulatory disorders contribute to a great extend. The main objective of the study was to assess the clinical and hormonal profile of patients diagnosed with polycystic ovarian disease at tertiary care hospital in Tamil Nadu.

Methods: This study was a cross sectional study and was carried out at the Department of Obstetrics and Gynaecology at a tertiary care hospital of Tamil Nadu. The study was done for a period of 6 months. For confirming polycystic ovaries, patients were interviewed thoroughly about their menstrual and fertility history. Blood investigations like LH, FSH were done on D2/D3 of menstrual cycle. 125 patients with PCOS were included in this study. The data was analysed with SPSS-IBM (V.22.0) software.

Results: The patients having polycystic ovaries were higher in women of 21-30 years of age. BMI was more than 25. Infertility was found that 57%, hirsutism 45%, oligomenorrhoea 21% and amenorrhea 20%. On day 2, mean serum LH was 5.9 ± 3.6 and serum FSH was 3.9 ± 2.3 . This study showed that the proportion of menstrual complaints is reported more in higher age group. Likewise lower income group presented with menstrual complaints. This was found to be statistically significant (P value <0.05).

Conclusions: The study showed that patients diagnosed to have PCOS overweight. PCO in obese women had more severe ovulatory dysfunction. Infertility was the most common complaint.

Keywords: Hormones, Obesity, PCO, Usg

INTRODUCTION

Polycystic ovarian syndrome was first described by Stein and Leventhal in 1935. Polycystic ovarian syndrome is a disorder of heterogeneous androgen excess with varying degrees of metabolic and reproductive abnormalities. This is greatly influenced by multiple genetic and environmental factors. Its clinical manifestations may include menstrual irregularities, signs of excessive androgens, and obesity. Elevated serum LH levels is a

common feature of PCOS.² The National Institute for Health (NIH) criteria 1990 was revised and Rotterdam's criteria is followed worldwide from 2003.³ Polycystic ovarian syndrome is one of the most common endocrinological disorder in reproductive age group affecting about 6-8% of women with a broad spectrum of clinical manifestations.⁴⁻⁶ Globally, estimation of prevalence of polycystic ovarian syndrome are highly variable ranging between 2.2 to as high as 26%.⁷⁻⁹ Various manifestations of polycystic ovaries usually start

from the time of menarche. Many of these features usually are in the evolutionary stage during the transitional phase of puberty which in later phase stabilizes and established. The 2003 Rotterdam ESHRE/ASRM - sponsored PCOS consensus workshop concluded that PCOS is a syndrome of ovarian dysfunction along with cardinal features of hyper androgenism and polycystic ovarian morphology. ^{10,11}

Using Rotterdam criteria, community based studies among reproductive age group has showed different prevalance values ranging from 2%-7.5% in China and 6.3% in Srilanka. 12-14 Using NIH criteria reported PCOS in the range of 5-8%. 15

There are very few Indian studies on PCOS, most of them done in schools and hospital setups in view of easy accessibility. These studies revealed the prevalence rate of PCOS as ranging from 9.13-36%. 16,17

The objective of the study was to access the clinical and hormonal profile of the patients diagnosed with PCOS at tertiary care hospitals in Tamil Nadu.

METHODS

The study was observational prospective study which was carried out in the department of gynaecology for a period of 6 months from Jan 2018 - Jun 2018 at Chettinad Hospital and Research Institute, Kelambakkam, Kanchipuram, Tamil Nadu. The study population included both married and unmarried women of 15-40 years of age. For participants less than 18 years of age, parentral consent was obtained. Girls aged 15-17 years who have attained menarchy atleast 3 years before were enrolled in the study. PCOS women who were included in the study were defined by using two out of the three diagnostic parameters of Rotterdam criteria (i) oligomenorrhoea/anovulation (ii) Hyperandrogenism (a) clinical hirsitusim of less commonly male pattern alopecia or (b) Biochemical (raised free testosterone) (iii) Polycystic ovaries on ultrasound. Exclusion criteria included pregnant women, women who take medications like OCPs and steroids, chronic illness such as diabetes congenital adrenal mellitus. hyperplasia, prolactinemia, hepatic or renal disease.

The patients were enrolled into the study based on the inclusion and exclusion criteria. Informed and written consent was obtained from all the patients enrolled in this study. All the enrolled patients were asked for detailed history about their menstural cycle, which included the cycle regularity, intermenstural bleeding interval and days of bleeding. Other histories like type of family (Nuclear or joint), type of habitat (rural or Urban) was also obtained. Blood investigation for hormonal analysis like blood glucose, LH, FHS, LHS:FHS ratio, was done on either the second or third day of menstural cycle. Clinical hyperandrogenism was determined by clinical features of hirsitusism assessed by Ferriman - Gallway

score of more than or equal to 8 over 9 body parts. ¹⁸ Ferriman Gallaway Score (FGS) was used for categorizing hirsutism. Score 11-20 (Grade I), Score 21-30 (Grade II), Score 31-40 (Grade III) and Score >40 (Grade IV). Score <11 → Normal.

Body mass index was calculated on the basis of WHO-Asian Indian Classification of BMI as below. 19-21 Under weight; BMI less than 17.9 kg/m², Normal: BMI equal to 18-22.9 kg/m², Overweight: BMI more than 23 kg/m², Obese: BMI more than 25 kg/m². Ultrasound diagnosis was based on the presence of antral follicles less than 12 in number and size less than 10 mm in either one or both the ovaries. 22

Sample size determination

For calculation of sample size, the formula used is,

$$n = \frac{Z^2 x(p) x (1-p)}{L^2}$$

where, n is the sample size, Z is the normal deviate at a level of significance (Z is 1.96 for 5% level of significance), L is the relative error, which is taken as 5% P is the proportion of the population with the disease under study i.e, prevalence of PCOD in India ranges from 9-26% in reproductive age group women. With prevalence of PCOD in a study done in south India* was at 9%

$$n = \frac{(1.96)^2 \times (0.09) \times (0.91)}{(0.05)^2} = \frac{3146}{25} = 125$$

n = 125 was the calculated sample size and 125 study participants were recruited in the study.

Statistical analysis

Data was analysed with statistical package for social sciences (SPSS-IBM) version 22.0. Proportions and means were calculated. Tests of significance were applied after assessing the normality of data. Chi square test was applied. P value <0.05 was considered significant.

RESULTS

Baseline characteristics of study participants

A total of 125 (100%) study participants were included in the study. The age of the study participants ranged between 15 years to 40 years. The mean±SD age of study participants was 28.54±5.95. Majority belongs to urban area 91 (72.8%) (Table 1).

Medical history

Among the study participants, menstural complaints were the presenting symptoms in 54(43.2%) of study participants. Around ninety one percent had these menstural complaints less than a year period. 74 (59.2%) study participants had history of other medical disorders (Table 2).

Table 1: Baseline parameters of study participants (n=125).

Profile of study participants	N=125, N(%)		
Age group			
15 -20 years	3 (2.4)		
21-25 years	46 (36.8)		
26-30 years	56 (44.8)		
31-40 years	20 (16)		
Residence			
Urban	91 (72.8)		
Rural	34 (27.2)		
Education			
Primary	11 (8.8)		
High School	58 (46.4)		
Graduate	42 (33.6)		
Post graduate	8 (11.4)		
Occupation			
Daily wages	14 (11.2)		
Self employed	13 (10.4)		
Professional	40 (32)		
Housewife	58 (46.4)		
Socio economic class			
Socio economic class I	6 (4.8)		
I	6 (4.8)		
I II	6 (4.8) 37 (29.6)		
I II III	6 (4.8) 37 (29.6) 59 (47.2)		
I II III IV	6 (4.8) 37 (29.6) 59 (47.2) 21 (16.8) 2 (1.6)		
I II III IV V	6 (4.8) 37 (29.6) 59 (47.2) 21 (16.8) 2 (1.6)		
I II III IV V Total family income per month (in	6 (4.8) 37 (29.6) 59 (47.2) 21 (16.8) 2 (1.6) n rupees)		
I II III IV V Total family income per month (in ≤ 5000	6 (4.8) 37 (29.6) 59 (47.2) 21 (16.8) 2 (1.6) 1 rupees) 12 (9.6)		
I II III IV V Total family income per month (in ≤ 5000 5001-10000	6 (4.8) 37 (29.6) 59 (47.2) 21 (16.8) 2 (1.6) a rupees) 12 (9.6) 43 (34.4)		
I II III IV V Total family income per month (in ≤ 5000 5001-10000 10001-20000	6 (4.8) 37 (29.6) 59 (47.2) 21 (16.8) 2 (1.6) 12 (9.6) 43 (34.4) 24 (19.2)		
I II III IV V Total family income per month (in ≤ 5000 5001-10000 10001-20000 >20000	6 (4.8) 37 (29.6) 59 (47.2) 21 (16.8) 2 (1.6) 12 (9.6) 43 (34.4) 24 (19.2)		
I II III IV V Total family income per month (in ≤ 5000 5001-10000 10001-20000 >20000 Type of family	6 (4.8) 37 (29.6) 59 (47.2) 21 (16.8) 2 (1.6) n rupees) 12 (9.6) 43 (34.4) 24 (19.2) 46 (36.8)		
I II III IV V Total family income per month (in ≤ 5000 5001-10000 10001-20000 >20000 Type of family Nuclear	6 (4.8) 37 (29.6) 59 (47.2) 21 (16.8) 2 (1.6) 12 (9.6) 43 (34.4) 24 (19.2) 46 (36.8) 80 (64)		
I II III IV V Total family income per month (in ≤ 5000 5001-10000 10001-20000 >20000 Type of family Nuclear Joint	6 (4.8) 37 (29.6) 59 (47.2) 21 (16.8) 2 (1.6) 12 (9.6) 43 (34.4) 24 (19.2) 46 (36.8) 80 (64)		
I II III IV V Total family income per month (in ≤ 5000 5001-10000 10001-20000 >20000 Type of family Nuclear Joint Hirsutism	6 (4.8) 37 (29.6) 59 (47.2) 21 (16.8) 2 (1.6) 12 (9.6) 43 (34.4) 24 (19.2) 46 (36.8) 80 (64) 45 (36)		
I II III IV V Total family income per month (in ≤ 5000 5001-10000 10001-20000 >20000 Type of family Nuclear Joint Hirsutism FG Score >40	6 (4.8) 37 (29.6) 59 (47.2) 21 (16.8) 2 (1.6) n rupees) 12 (9.6) 43 (34.4) 24 (19.2) 46 (36.8) 80 (64) 45 (36)		

Vital parameters and anthropometry

Vital parameters and anthropometric findings of participants are shown in the Table 3.

Hormonal and other blood parameters

Median value of LH, FSH, Prolactin, TSH, hemoglobin and RBS of participants was 5.41, 3.42, 10, 2.4, 10.5 and 92 respectively (Table 4).

LH/FSH ratio and Ultrasound findings

Mean (SD) LH/FSH ratio of study participants was 1.6 ± 0.748) with a median value of 1.497 (minimum to maximum: 0.22 to 5.6). Ultrasound findings were suggestive of PCOD in 91 (72.8%) of study participants. Rotterdam criteria was fulfilled with 84 (67.2%) of study participants.

Table 2: Distribution of study participants according to medical history (n=125).

Medical history	N=125 N (%)	
Age at menarche		
10-15 years	121 (96.8)	
16-20 years	4 (3.2)	
Duration of marriage		
<1 year	8 (6.4)	
1-5 years	72 (57.6)	
>5 years	45 (36)	
Medical disorders*		
Hypothyroidism	27 (21.6)	
Diabetes mellitus	15 (12)	
Hypertension	11 (8.8)	
None	51 (40.8)	
Presenting complaints*		
Oligomenorrhea	21 (16.8)	
Menorrhagia	13 (10.4)	
Amenorrhea	20 (16)	
Primary infertility	57 (45.6)	
Secondary infertility	14 (11.2)	
Hirsutism	45 (36)	
Acne	8 (6.4)	
Duration of menstural complaints	(n=54)	
<1 year	49 (90.7)	
1-2 years	3 (5.6)	
>2 years	2 (3.7)	
Days of menstural cycle		
0-10 days	5(4)	
11-20 days	55 (44)	
21-30 days	51 (40.8)	
31-45 days	5 (4)	
>45 days	9 (7.2)	
BMI classification**		
<18.5	28 (18.3)	
18.5-22.9	32 (20.9)	
23-24.9	29 (19)	
>25	64 (41.8)	

^{*}Multiple options,**Asian Indian criteria of BMI

Bi variate analysis was done to find any association between menstural and other complaints with selected variables such as age group, residence, socioeconomic status, family income and BMI classification and LH, FSH and prolaction levels. It was found that the proportion of other complaints was more in lower age group and menstural complaints are reported more in higher age group.

Table 3: Vital parameters of study participants (n=125).

Vital parameters and anthropometry	Mean±SD
Heart rate (per min)	71±19
Respiratory rate (per min)	16±8
Temperature (F)	98.5±1.1
Height (in cm)	157±6.6
Weight (in kg)	64±11
BMI (kg/m²)	25.6±3.7
Mean Ferriman Gallaway Score (FGS)	18.7±4.32

Likewise, higher income group presenting with other complaints were more and lower income group presented with menstural complaints. This was found to be statistically significant (p value <0.05). However, there was no significant difference among different complaints with respect to hormonal levels.

Table 4: Hormonal and other blood parameters of study participants (n=125).

Blood parameters	Mean±SD	Minimum	Maximum
LH	5.9±3.6	1.2	21.84
FSH	3.9 ± 2.3	1.10	16.57
Prolactin	9.5±4.2	2.10	22.36
TSH (IU/ml)	3.2±3.6	0.93	20.40
Hemoglobin (gm/dl)	10.4±2.0	6.8	13.6
Serum random blood sugar (gm/dl)	92±8	1.13	203

Table 5: Association between presenting complaints and selected variables (n=125).

Profile of study participants	Only menstrual complaints n = 54 N (%)	Other complaints* n = 71 N (%)	p value	
Age group				
15 -20 years	2 (3.7)	1 (1.4)	0.005	
21-25 years	20 (37)	26 (36.6)		
26-30 years	17 (31.5)	39 (54.9)	0.003	
31-40 years	15 (27.8)	5 (7)		
Residence				
Urban	40 (74.1)	51 (71.8)	0.780	
Rural	14 (25.9)	20 (28.2)		
Socio economic class				
I	2 (3.7)	4 (5.6)		
II	13 (24.1)	24 (33.8)	0.227	
III	25 (46.3)	34 (47.9)	0.237	
IV	12 (22.2)	9 (12.7)		
V	2 (3.7)	0		
Total family income per montl	h (in rupees)			
≤ 5000	11 (20.3)	1 (1.4)		
5001-10000	16 (29.6)	27 (38)	0.005	
10001-20000	10 (18.5)	14 (19.7)		
>20000	17 (31.5)	29 (40.8)		
BMI classification				
<18.5	8 (14.8)	20 (28.1)		
18.5-22.9	10 (18.5)	22 (30.9)	0.975	
23-24.9	12 (22.2)	17 (23.9)		
>25	24 (44.4)	12 (16.9)		
LH levels (Day 2)				
≤ 5.41	29 (53.7)	34 (47.9)	0.519	
>5.42	25 (46.3)	37 (52.1)		
FSH levels (Day 2)				
≤ 3.42	32 (59.3)	31 (43.7)	0.08	
>3.42	22 (40.7)	40 (56.3)		
Prolactin levels (Day 2)	· /	, ,		
≤ 10	37 (80.4)	31 (55.4)	0.008	
>10	9 (19.6)	25 (44.6)		
		, ,		

Chi square test applied, p value >0.05 is significant, *Infertility,acne and hirsutism etc.,

DISCUSSION

PCOS is one of the most important causes for irregular menstural cycle. In a study conducted by Balen et al, ammenhorea was present in 19.2% of patients as compared to 16% in our patients.²² Other clinical features include hirsutism, infertility and obesity. Obesity or increased BMI and increasing age of marriage can also be attributing to cause infertility. Hence these women should be taught a healthier life style. The importance of regular physical activity and having their BMI less than helps in correction of the menstural irregularities and increasing the success rate of treating infertility patients.²³ Optimal time for family initiation should also be taught.²³ It is found that there is significant decline in infertility with increasing BMI and age.24 Role of combined oral contraceptive pills in achieving regular menstural cycles is advised. Prevalance of PCOS is found to be more in younger age group (<35 years of age) than prevalence in older women. The attributing cause to this prevalence could be the physiological decline of the follicles thereby leading to a normal ovarian feature in the ultrasound. Our study showed that the mean age of the patients was 28.5±5.95 and a majority 44.8% belonged to age group between 26-30 years. Muralidhara et al in KMC, Mangalore did a study in 2012, where the mean age among patients with PCOS was 27±7.1 which is comparable to our study.²⁵ In a study done by Spandane et al in 2017, the mean age among PCOS patients was 27±5 which is comparable to the study.²⁶ In the present study, most of the PCOS patients lived in the urban area 72.8% and in rural area 34%. In a study done by Radha et al in 2016, 88 % of the PCOS patients lived in the urban area which is comparable to present study.²⁷ The prevalence of PCOS in infertile women in the study is 45.6% and this is comparable to 40% of infertility in PCOS women in a study conducted by Couzin.²⁸ In the study, androgenic features like acene in the PCOS patients was 8% which is comparable to a study conducted by Nandrelle K et al where acne was present in 9.2%.²⁹ Even small degrees of weight loss like 1-3kgs, may help in restoring and regularizing menstural cycle and ovulation.³⁰ It is important to be aware that around 75% of lean body women with polycystic ovaries will have insulin resistance and about 50% will have metabolic syndromes. In the study, the mean FG Score was 18.7±4.32 which is comparable to a study conducted by Atallah et al where the mean FG Score in PCOS was $20.1 \pm 7.8.^{31}$ The mean LH value in the study is 5.9 IU/L which is comparable to a study done by Shanmugam et al where the mean LH value is 5.6 IU/L.32 The incidence of cardiometabolic risk factors increase in women with polycystic ovarian syndrome.³³

CONCLUSION

The study showed that most of the PCOS patients were obese and hirsutism was present in almost majority of the patients. The most common presenting complaints in PCOS patients was primary Infertility and second most

common presenting complaint being oligomennorhoea. The study concludes that significant number of PCOS patients are obese and present with menstrual and infertility complaints. PCOS in obese women have more severe ovulatory dysfunction. It was found that the proportion of complaints like hirusitism and acne was more in lower age group and menstural complaints are significant in higher age group. Likewise, higher income group presented with other complaints and lower income group presented with menstural complaints. This was found to be statistically significant (P value <0.05). However, there was no significant difference found among different complaints with respect to hormonal levels. The significant number of patients in the study live in the urban area with nuclear type of family. Hence obese women with PCOS is one of the major cause for the infertility and it needs social awareness right from the school level.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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