

A Study on Prevalence and Management of Polycystic Ovarian Syndrome in a Tertiary Care Hospital.

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Abstract:

Background: Polycystic ovarian syndrome (PCOS) is the most prevalent endocrine disorder affecting females. Various factors such as heterogeneous disorder characterized by ovulatory dysfunction, hyperandrogenism, genetic factors and polycystic ovarian morphology. The potential complications of PCOS include obesity exacerbates and co morbidities of PCOS such as hypertension, diabetes, hypercholesterolemia, and heart disease.

Objective: To estimate the prevalence of PCOS with anthropometric measures and hormonal levels were analysed statistically. To study the prescribing pattern and appropriateness of medications utilised, then diet and co-morbid conditions were screened.

Methodology: A prospective observational study was conducted in the department of Obstetrics and Gynaecology of a 750 bedded multi-speciality tertiary care hospital. Patient below 15 years of age and above 45 years are of age excluded in the study.

Results and discussion : Total of 84 patients were screened in the study, according to age it lies between 22-28yrs (35%) indicates late diagnosis. 50% was overweight and 39.28% was with normal BMI. With respect to TSH 93% of population < 4.9 mIU/ml indicates hypothyroidism. Hyperinsulinemia occurs in accordance with increased BMI. Hypoprolactinemia and normal FSH were found. Co morbidities that has been associated with PCOS were, 10.71% diabetic and 9.52% as hypothyroidism then asthma (1.19%), seizure (1.19%), acute hepatitis (1.19%) and anaemia of about 1.19% respectively. OC's like Drospirinone, ethinyl estradiol (33%), Norethisterone (33%) are widely prescribed to reduce menstrual irregularities compared to letrozole and clomiphene.

Conclusion: Early diagnosis with appropriate treatment is recommended. Treatment is based on patient's individual symptoms. While during the study infertility among the study population was not certainly seen. Diet with the proper medications will reduces the symptoms.

Keywords: Polycystic ovarian disease, anthropometric measures, hormonal levels, oral contraceptives, dietary and lifestyle modifications.

Date of Submission: 01-03-2019

Date of acceptance:18-03-2019

I. INTRODUCTION

Polycystic ovarian syndrome (PCOS) is a heterogenous , multisystem endocrinopathy in women of reproductive age with the ovarian expression of various metabolic disturbances and wide spectrum of clinical features such as obesity, menstrual abnormalities and hyperandrogenism. This disease was discovered by Stein-leventhal in 1935 and known as 'Stein-leventhal' syndrome. Polycystic ovaries are slightly larger than normal ovaries and have twice the number of follicles(small cysts).

According to the following criteria Polycystic Ovarian Syndrome is further defined as.,

- ESHRE/ASRM (ROTTERDAM) (2003) criteria - Two of the three :- Clinical and / or chemical hyperandrogenism, Oligo -/ anovulation, Polycystic ovaries.
- NIH (1990) - Clinical and or biochemical hyperandrogenism. Oligo/anovulation.
- AE-PCOS (2006) - Clinical and or biochemical hyperandrogenism. Oligo-/ anovulation and or polycystic ovaries.

AE-PCOS - Androgen excess and PCOS Society, ASRM-American society for reproductive Medicines. NIH -National institute of health sciences, PCOS- polycystic ovarian syndrome.¹

Polycystic ovarian syndrome may set in early adolescent life, but clinically manifest in the reproductive age with long-term age implications of diabetes, hypertension, hyperlipidemia and cardiovascular disease; this cluster of disorders is known as the "X syndrome". Current incidence of PCOS (5-6%) is fast increasing lately due to change in life style and stress. It is also becoming a common problem amongst adolescents, developing soon after puberty. Amongst infertile women, about 20 % infertility is attributed to an ovulation caused by PCOS. It has an unknown etiology and accompanied with heterogeneous syndrome that present during adolescence characterized by an ovulation (amenorrhea, oligo menorrhea, irregular menstrual cycles) combined with symptoms of androgen excess primarily from ovary, (hirsute, acne, alopecia)²

(HAIRAN) syndrome is the hyper androgenic-insulin resistant – acanthosis nigricans also uncommon and consists of marked hyperandrogenism, severe insulin resistance, and acanthosis nigricans. Severe form of PCOS is a ovarian hyperthecosis, characterised by nests of luteinised theca cells distributed throughout the ovarian stroma. Exhibit the symptoms of severe hyperandrogenism and occasionally display frank virilisation signs such as temporal balding, clitoromegaly, and voice deepening accompanied with insulin resistance and acanthosis nigricans.³

However PCOS is a systemic syndrome, affects more than one body function, and the patients are at risk of other serious conditions. PCOS has several serious complications. Elevated estrogen levels, increasing risk of endometrial hyperplasia leads to endometrial cancer. Androgen levels are elevated leads to hirsutism. Hyperinsulinemia due to insulin resistance may be present and may contribute to increased ovarian production of androgens. Over long term androgen excess leads to cardiovascular disease. Depression also occurs in this condition.

Polycystic ovarian syndrome (PCOS) is a common female endocrine disorder with prevalence ranging from 2.2% to 26%. According to world statistics PCOS prevalence rates for underweight, normal-weight, overweight, mildly obese, moderately obese, and severely obese women were 8.2%, 9.8%, 9.9%, 5.2%, 12.4%, and 11.5% respectively. According to NIH/NICHD criteria, around 4-8% of study population are affected from PCOD. As per WHO class II oligo ovulation (euestrogenic normogonadotropic ovulatory dysfunction) 827 women with World Health Organization (WHO) and 456 (55 percent) were classified as having PCOS by the National Institutes of Health (NIH) 1990 criteria. 754 (91 percent) women are affected by PCOS with respect to Rotterdam 2003 criteria. Obese women referred for assistance with weight loss had a prevalence of PCOS of 28.3%.⁴

Both the ovaries are enlarged the volume is increased upto 10 cm³. Then Stroma is increased. The capsule is thickened and pearly white in color. Presence of multiple (greater than 12) follicular cysts measuring about 2-9 mm in diameter are crowded around the cortex.

Exact pathophysiology may be not clearly understood, it may deals with hypothalamic - pituitary compartment abnormality, androgen excess, an ovulation, obesity and insulin resistance, long – term consequences. PCOS involves primary defects in the hypothalamic – pituitary axis, insulin secretion and action, and ovarian function. In this condition elevated Gonadotropin releasing hormone (Gnrh) and LH (luteinizing hormone), FSH muted or unchanged (*ie.*, FSH:LH ratio is 1:2). Increased Gnrh level stimulates the ovarian theca cells there by induces the androgen levels. Follicular arrest is treated by either endogenous FSH Level or providing exogenous FSH level. Hyperprolactinemia is also seen⁵. Obesity also induces insulin resistance and hyperinsulinemia which in turn increases the gonadal androgen production. Long term consequences leads to excess androgens and diminished SHBG. Genetic studies says PCOS occur due to autosomal dominant transmission with decreased penetrance. Anti-mullerian hormone (AMH) increases follicle population and in women with PCOS has two-three fold circulating AMH level. The ovaries respond to excess insulin by producing androgens in turn causes anovulation. Ovary produces excess androgen due to stimulation of theca cells by high LH, P450C17 enzyme hyperfunction. Defective aromatisation of androgen to estrogens., then stimulation of theca cells by IGF-1 (insulin- growth factor-1).

Menstrual irregularities- are treated with oral contraceptive pills, OC and cyproterone acetate., OC and spironolactone. Studies reported that, Clomiphene induces ovulation in 80 % and 40-50 % conceive, but 25-40 % abortion rate is due to defect in the corpus luteal phase. Clomiphene with dexamethasone improves fertility rate. Hirsutism were treated with anti-androgens like cyproterone acetate is recommended for about 3-6months before the effect on hirsutism is noted. Dexamethasone (0.5mg) at night reduces androgen production. Clomiphene is the first line of treatment for PCOS is to be treated for in whom infertility is seen. It is suggested that any form of treatment is likely to give temporary relief and may be required to be repeated and should be changed at various times during her reproductive years. Long term treatment reduces the chances for diabetes and endometrial cancer. Surgery is reserved for infertile women, hyperstimulation, previous pregnancy losses.⁶

To estimate the prevalence of PCOS with anthropometric measures, hormonal levels and was analysed statistically. To study the risk and benefits of various management strategies in the selected study population as per the inclusion and exclusion criteria. Co-morbid condition, diet and lifestyle modifications of the patient were screened.

II. METHODOLOGY

A prospective observational study was conducted in the department of Obstetrics and Gynecology of a 750 bedded multi-speciality tertiary care hospital, after taking permission from the Hospital Ethics committee. The authorization from the Dean to carry out the study was obtained on SRH /FC 9-12-2017-2018. The study was conducted with expert guidance of clinical pharmacy professionals and senior physicians of the hospital. All the patient who are at reproductive age consulting the physician in outpatient department who are all subjected to have PCOS are taken into the study with their consultation. Patient below 15 years of age and above 45 years of age are excluded in the study. Subjects who are not willing to give or understand the informed consent were excluded from the study. PCOS is defined as a common endocrine disorder that affects 7% of reproductive age leads to an ovulation, with symptoms of androgen excess, hyperinsulinemia and elevated oestrogen levels. The case record sheets of the patient diagnosed as PCOS along with their co morbid conditions who are consulting the physician in gynecology department were reviewed. The information regarding patient demographic details, past medical and medication history, laboratory investigations, diagnosis, drug interactions, total number of drugs prescribed with dosage, frequency, duration are to be recorded in a pre-designed patient profile record form.

Information about patient demographic details, thyroid profile, blood sugar level, co morbid condition, hormonal levels like LH, FSH, Prolactin reports were collected and screened for its importance in detecting PCOS.

III. STATISTICAL ANALYSIS

Clinical and demographic details of the patients such as age, diagnostic parameters (including laboratory tests and other investigations), drug prescribed, their strength and dosing schedule are recorded. Written consent from the patient's bystander is obtained. The values obtained in study would be expressed as mean \pm standard error of the mean (SEM) and analysed using Graph Pad Prism Statistical software using ANOVA followed by Dunnett's test. $P < 0.005$ would be considered statistically significant. Tukey kamer comparison test is done.

IV. RESULTS AND DISCUSSION

We had conducted the study to identify the prevalence of polycystic ovarian syndrome from age, anthropometric measure (BMI), hormones involved in the disease condition, blood sugar level and comorbidities that has been associated with. We have found that altered levels of prolactin, thyroid hormone, follicular stimulating hormone and blood sugar leads to PCOS which was analysed statistically.

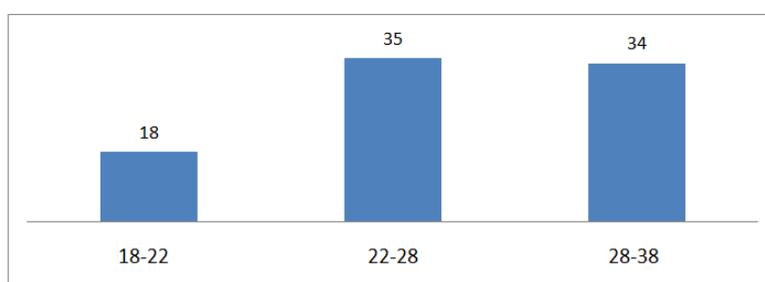


Fig 1 :- AGE related to pcos.

Women with the reproductive age are predominant to get PCOS so age is one of the factor to determine the disease condition. Here 35% of study population lies within 22-28 years indicates late diagnosis of PCOS, 18% of the people falls under category 18-22 years. Early diagnosis needed to prevent further risk. PCOS occurs during women with reproductive than late menopausal stage where diagnose using ultrasonography and thus incidence gradually decreases as age increases conducted by Tabassum k⁷. Another study well documented by Pothiraj Pitchai demonstrated that total 70% equally distributed in 21-25 years as well 18-20 years, 21% were 25-30 years and remaining 9 % of study participants were between age group of 30-35 years and the mean age of PCOS population were 23.38 ± 4.6 .⁸

The mean value for BMI lies between 25.563 ± 0.4285 implies overweight among the study population. FSH level ranges from 3.907 ± 0.2390 and it lies within normal level. Hyperinsulinemia is also associated with the disease condition and the mean value varies from 99.184 ± 2.015 . Raised TSH level indicates hypothyroidism leads to anovulation and their mean lies between 6.910 ± 2.565 . The mean prolactin level varied between 16.882 ± 0.8064 and indicates hypoprolactinemia.

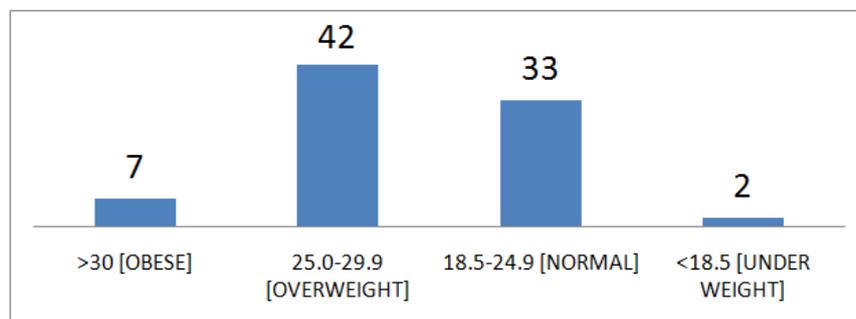


Fig 2 :- BMI in accordance with pcos.

Among the study population overweight was seen in 42% a borderline to attain obese were found to be detected with polycystic ovarian syndrome. Women with both lean body weight and overweight are prone to get the disease. Obesity will also interrupt in insulin signalling pathway leading to hyperinsulinemia. In adolescents overweight and obesity were associated with higher odds of PCOS identified by Shawna B Christensen *et al*⁹ and Similarly study was carried out by Bayan Hussein and Shala kareem Alaf on infertile women attending the infertility care and IVF center and found that women with PCOS had a higher mean BMI than women with non-PCOS group.¹⁰

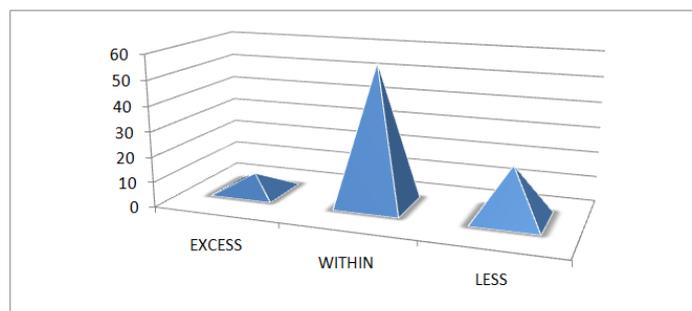


Fig 3 :- Determination of FSH in PCOS .

FSH:LH ratio is (1:2) in PCOS, as FSH remains normal where as LH level gets elevated leads to improper ovulation and menstrual irregularity. In the our study FSH was within the normal range (0.3-10mIU/ml) of about 56 patients and Georgopoulos *et al* identified that, PCOS conditions are seen with increased LH level and normal to low FSH levels where as an increased FSH level is seen in case of premature ovarian failure.¹¹ LH and LH/FSH are in abnormal range of 35% and 41-44% respectively well documented by Robinson *et al*.¹² The ratio of LH to FSH is greater than 3:1 in about 30 percent of women with PCOS and may be diagnostically helpful in non hirsute women with mild ovulatory dysfunction, but this determination is not routinely necessary if the clinical picture is otherwise clear conducted by Marilyn R. Richardson.¹³

Table 1 :- Comparison between TSH with T3, T4 and BMI with RBS by Tukey kramer comparison test:-

Comparison of TSH with T3 and T4.		
Comparison	mean diff	q value
TSH vs T3	-79.046	26.175***
TSH vs T4	-0.3488	0.1155 ^{ns}
T3 vs T4	78.697	26.060***
Comparison of Body mass index with random blood sugar.		
Comparison	mean diff	q value
RBS vs BMI	-73.615	24.377***

From 84 patients, 79% had TSH level greater than 4.9 ng/ml indicates hypothyroidism. PCOS can cause imbalance to the levels of thyroid hormones. TSH with respect to T3 and T3 with respect to T4 shows statistically significant is a major factor determines hypo or hyperthyroidism. Both hyper and hypothyroidism has the ability to cause oligo – or anovulation.. The adipose tissue (fat) is considered an endocrine and immunomodulatory organ., it secretes leptin., adiponectin and cytokines which interfere with insulin signaling pathways in the liver and muscle resulting in insulin resistance and hyperinsulinemia. Hypo and hyperthyroidism is commonly occurred with PCOS. The study concluded that PCOS is associated with high incidence of sub clinical hypothyroidism and autoimmune thyroiditis compared to normal population and poses increased risk of cardiovascular disorder in PCOS¹⁴. A prospective observational study was conducted among 446 patients and the study found that hypothyroidism was seen in 5(35%) of women.^(15,16,17)

Among 84 cases (48%) of patients had normal RBS level ranges from 90-110 mg/dl. Increase in BMI increases the insulin level and are statistically significant. Presence of hypothyroidism significantly increased severity of insulin resistance as well as obesity in PCOS which was documented by Ramanand *et al.*¹⁸

Prolactin has a prominent role in lactating women. Hyperprolactinemia women may present with signs of chronic hyperandrogenism such as hirsutism and acne, possibly due to increased dehydroepiandrosterone sulphate secreted from adrenal gland, as well as reduced sex hormone binding globulin leading to high free testosterone levels. However in our study hyperprolactinemia were not occurred. A similar study was conducted by Deepthi *et al.*, on twenty eight infertile women in the age group of 17 to 37 years was found that the prolactin level was 27.35 ng/ml was matched with study and control subjects.¹⁹

Table 2 :- Co-morbid condition :- (n=84).

S.No	CO-morbid condition	No. of. patients	PERCENTAGE(%)
1.	Diabetes mellitus	9	10.71
2.	Hypothyroidism	8	9.52
3.	Asthma	1	1.19
4.	Seizure	1	1.19
5.	Acute hepatitis	1	1.19
6.	Anemia	1	1.19

In our study among 84 patients 10.71% were diabetic and 9.52% were found to be hypothyroidism with PCOS. Apart from this the patient is also suffered from asthma (1.19%), seizure (1.19%), acute hepatitis and anaemia of about 1.19% respectively. The patient is prescribed with appropriate medications for the co morbid condition associated with. From this it is identified that most of the patients were diabetic and with reduced thyroid levels indicates hypothyroidism. In our findings mostly., hypothyroidism and diabetes mellitus were detected that leads to an ovulation and respectively. Obese women are prone to hypertensive, hirsute and intake of higher mean insulin when compared with non-obese women is the incidence among adolescent and young girls in Mumbai was conducted by Beena joshi *et al.*²⁰ Similarly key co morbidities such as anxiety, bipolar disorders, depression, eating disorders, infertility, obstructive sleep apnea , and diagnosed cardiovascular disease were suggested and documented by Sirmans M Susan *et al.*²¹

Table 3 :- Drugs prescribed among the study population.

DRUGS PRESCRIBED	PERCENTAGE (%)
Norethisterone.	36
Drospirinone + ethinyl estradiol.	33
Clomiphene.	0.31
Prednisolone	0.175
Letrozole.	0.1

Norethionesterone (36%), drospirinone (33%), ethinyl estradiol (33%) are widely prescribed hormonal formulations to treat PCOS and specifically menstrual irregularities . Apart from that letrozole (0.1%), prednisolone (0.175%) and clomiphene (0.31%) act as fertility medication act as an ovulatory stimulant are suggested as an alternative as less readily prescribed when compared with the oral contraceptives. Oral contraceptives were mostly prescribed to treat menstrual dysfunction when compared to letrozole and clomiphene as infertility was not seen in our study. Oral contraceptives pills and insulin sensitising agent are to treat irregular menstruation and hypoglycaemia respectively however long-term follow up is necessary to reduce further complications which was conducted by Shakunthala chabra²². The first line therapy for infertility is clomiphene and letrozole and for hyperglycemia metformin is recommended. Treatment option is based on patient's presentation and desire for pregnancy, weight loss and it was the study concluded regarding the treatment options by Tracy Williams *et al.*²³

Most of the patients were non-vegetarians and few were found to be vegetarians. Patients were suggested to take less oily foods, prefer more of greeny and leafy vegetables, then regular physical activities were advised to the patients and to their co-standers. However no dietary guideline is there for polycystic ovarian syndrome., which is recommended. Gordon W Bates and Richard S Legro identified that „as a first line intervention lifestyle modifications including dietary changes, increased exercise and weight loss are appropriate for many women with PCOS.²⁴ YM Jeanes *et al.*, concluded that weight management through diet and lifestyle modification with physical exercise is essential to reduce the symptoms for PCOS.²⁵

V. CONCLUSION

Polycystic ovarian disease is a heterogenous , multisystem endocrinopathy in women of reproductive age with the ovarian expression of various metabolic disturbances.TSH , LH and FSH ratio, hCG levels plays a vital role in diagnosing PCOS. Treatment is based on patient's individual symptoms. Major co-morbid conditions associated with PCOS are hypothyroidism and diabetes mellitus. Hypothyroidism leads to oligoovulation and anovulation .Oral contraceptives drospirinone, ethinyl estradiol, norethisterone are readily prescribed compared to clomiphene and letrozole. While study infertility among the study population was not seen. Diet with the proper medications will reduces the symptoms. Early diagnosis with appropriate treatment is needed.

ACKNOWLEDGEMENT

We are thankful to signify our vehement indebtedness to Thiru.R.Vijayakumar, our Managing Trustee, Dr. P. Sukumaran, Dean, Sri Ramakrishna Hospital and Dr. T.K. Ravi, Principal College of pharmacy, Sri Ramakrishna Institute of paramedical sciences and all the teaching staff of the Department of Pharmacy Practice and Department of Pharmacology, College of Pharmacy, SRIPMS for the support, guidance and encouragement throughout the study.

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Dr. Asok kumar. K. "A Study on Prevalence and Management of Polycystic Ovarian Syndrome in A Tertiary Care Hospital." *IOSR Journal of Pharmacy (IOSRPHR)*, vol. 9, no. 2, 2019, pp. 43-49.