

A Prospective Observational Study on Hormonal Imbalances, Complications and Quality of Life in Pcos and Endometriosis Patients

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Abstract: Polycystic Ovary Syndrome (PCOS) is an endocrine metabolic disorder characterized by multiple hormonal imbalances representing diverse clinical presentations dominated by clinical and biochemical signs of hyperandrogenism which results in short and long term consequences in female health. A suitable data collection form was designed to collect required information and analyze the data. The data collection form included the information related to patient demographics such as age, weight and name of the patient, date, native place, occupation, complications, symptoms, marital status, family members, present living with, social history and diagnostic parameters and questions included in quality of life scale. Our study concluded that psychological stress and obesity leads to hormonal imbalance in patients with PCOS and endometriosis. Hyperandrogenism is the main cause for PCOS, stress in female causes increased testosterone and decreased estrogen levels those results in bilateral ovarian cysts among study population. PCOS have no significant complications during and after pregnancy. There were more complications observed with PCOS rather than endometriosis, among them majority observed are weight gain and infertility.

Keywords: Polycystic Ovary Syndrome, hyperandrogenism, endometriosis, infertility

I. INTRODUCTION

Polycystic Ovary Syndrome (PCOS) is an endocrine metabolic disorder characterized by multiple hormonal imbalances representing diverse clinical presentations dominated by clinical and biochemical signs of hyperandrogenism which results in short and long term consequences in female health. It has a tremendous negative impact on the women's physiology and metabolism leading to metabolic alterations i.e., insulin resistance, hyperinsulinemia, abdominal obesity, hypertension and dyslipidemia culminating as serious long term consequences such as T2DM, endometrial hyperplasia and CVS diseases. The prevalence rate of PCOS in India was found to be 30 %. Teenagers are being most affected. PCOS is described as an oligogenic disorder with an interaction of genetic and environmental factors which determine the heterogeneous clinical and biochemical phenotype expression in PCOS women. The expression of PCOS is mainly due to polymorphism of genes like FBN-3, LHR, TNF- alpha and IL's. FBN-3 is involved in the regulation of TGF signalling. LHR have a role of LH, T stimulation, follicle development, LH surge induced ovulation in ovaries and LH stimulation of adipogenesis in adipocyte¹³. Diet, lifestyle and physical activity also have an influence on women health. LH/FSH ratio is elevated in PCOS women. The three common factors associated with PCOS are anovulation, clinical and biochemical hyperandrogenism (hirsutism, acne, alopecia) and polycystic ovaries. Insulin resistance, obesity, CVD, cancer, infertility, miscarriage, preeclampsia and gestational DM are commonly developed complications in women with PCOS. Treatment is mainly based on clinical presentation of the patients i.e., menstrual irregularities, hyperandrogenism and anovulation. Polycystic ovaries found on ultrasound scanning will often have no clinical effects, but PCOS is the most common diagnosis made in women presenting with amenorrhoea, oligomenorrhoea or heavy, irregular and prolonged periods. It is the commonest cause of hirsutism and of infertility due to anovulation. Women with PCOS have increased concentrations of circulating androgens and there is a marked association with insulin resistance, dyslipidaemia, obesity, gestational diabetes, type 2 diabetes and heart disease. In addition, it is an established cause of endometrial hyperplasia and it is therefore linked to endometrial cancer. The short- and long- term consequences of PCOS represent an increasing burden on health resources. In recent years there has been increasing consensus about the criteria required to establish the diagnosis of PCOS. Two out of the three features below are used when other causes of those clinical features have been

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excluded. The patient seeks a dermatology consultation for one or more complaints like acne, hirsutism, alopecia, acanthosis nigricans, skin tags and occasionally, darkening of complexion with weight gain. If irregular menstrual cycles or primary infertility are the main complaints, the patient may consult a gynaecologist. An endocrinologist may be consulted for hirsutism and the metabolic syndrome. Very rarely do patients present with all the clinical signs and symptoms of PCOS and some may not be forthcoming with information of concurrent treatment from a gynaecologist or an endocrinologist. An alert clinician should be able to link the symptoms together, pointing to a possible underlying defect of hyperandrogenism. The increasing development and availability of new medicines during the dawn of the 20th century resulted in the emergence of adverse drug reactions and other drug-related problems. Adverse drug reaction has been creating headlines over the last 40 years typified by the thalidomide tragedy of the early where pregnant women exposed to the drug for morning sickness gave birth to phocomelic babies. International attention to patient safety has been growing significantly since the publication of the US Institute of Medicine report "To err is human: building a safer health system. Earlier there were no standard definition of adverse drug reaction, therefore, earlier studies used their own definitions, which were indistinct and could be interpreted to include intentional and unintentional overdose, as well as some administrative errors. To estimate Hormonal Imbalance, Complications and Quality of life in patients with PCOS and Endometriosis.[1-5]

- To determine the hormonal imbalance in PCOS and Endometriosis patients.
- To determine complications in PCOS and Endometriosis patients.
- To assess quality of life in PCOS and Endometriosis patients.
- Pattern of experience of PCOS, Endometriosis patients.
- To assess the diagnostic criteria.
- To study the therapeutic management.
- To determine the outcomes of PCOS, Endometriosis patients in different treatment groups.

II. METHODOLOGY

The study was conducted on PCOS and Endometriosis

The study was prospective and observational study.

The study was conducted over a period of six months (July 2019 - December 2019).

300 PCOS and Endometriosis patients.

2.1 Study Criteria

Inclusion criteria

- Selection of inpatients and outpatients who are with PCOS and Endometriosis.
- Patients of all age 12-60 years all are female.
- Hormonal imbalances
- Associated risk factors and complications in PCOS and endometriosis patients.

Exclusion Criteria

- Patients with other gynecological disorders like uterine fibroids, hyperthyroidism, Hypothyroidism etc.
- Patients below 12 yrs of age and greater than 60 years of age who have no significance on hormonal imbalances.

2.2 Sources of Data

- Patients who are with symptoms of PCOS and Endometriosis visiting for the Amrutha nursing home and Shivananda maternity hospital for the diagnosis and treatment and patients with past medical history of PCOS and Endometriosis.
- Interviewing and interacting with patients and patient care takers.
- Primary data through questionnaire which includes
 - Name of the patient

- Age and gender
- Address
- Symptoms (hirsutism, Oligomenorrhea, Amenorrhea, weight gain, acne)
- Diagnosis(trans abdominal scan, transvaginal scan, USD scan)
- Hormone levels
- Complications
- Duration of treatment
- Secondary data through internet, magazines, journals, text books, articles and etc.

Data collection and assessment of the study results/observations

A suitable data collection form was designed to collect required information and analyze the data. The data collection form included the information related to patient demographics such as age, weight and name of the patient, date, native place, occupation, complications, symptoms, marital status, family members, present living with, social history and diagnostic parameters and questions included in quality of life scale.

The analysis was done by observational method which included the details of patient information like symptoms, complications, treatment pattern, hormone levels and quality of life scale.

Digitalization of data collection and assessment

All the data collected and analyzed was entered into Microsoft excel for the easy accessibility, retrieval and for plotting of charts and graphs.

Procedure of the Study

The study team had approached the head of the hospital and submitted study protocol, data collection form; a written/oral consent was obtained from the head of the hospital. All the case sheets were thoroughly reviewed about their demographic details, occupation, marital status, symptoms, complications, social history laboratory parameters including hormone levels and treatment pattern by the study team and noted down in data collection form and when necessary the patients or care takers were interviewed for medical history information, quality of life . The patients were counseled about the Symptoms, hormone levels and complications of PCOS and Endometriosis and how to manage them. All the collected data was subjected to suitable statistical test and analyzed for the results.[7-12]

III. RESULTS

This study is a prospective observational study on hormonal imbalances, complications and quality of life in PCOS and endometriosis patients conducted in Amrutha nursing home and Shivananda maternity hospital, Karimnagar. A total number of 300 subjects were included in our study.

Table: Distribution of Subjects According to Their Age

Age (years)	No. of patients	Percentage (%)
>18	21	7
18-20	25	8.33
20-30	95	31.6
30-40	85	28.3
40-50	29	9.6
50-60	25	8.3
<60	20	6.6

According to our study among 300 patients 20-30 (31.6%) and 30-40 (28.3%) years age groups people were most commonly identified with PCOS and Endometriosis and the least was recorded in 60 years age group.

Table: Distribution of Subjects According to their Marital Status

Marital status	No. of patients	Percentage (%)
Married	125	41.6
Unmarried	175	58.3
Total	300	100

Table: Distribution of Subjects According to their Nutritional Status

Nutritional status	No. of patients	Percentage (%)
Poor	71	23.6
Average	190	63.3
Good	39	13

Table: Distribution of Subjects According to their Hygiene Conditions

Hygienic condition	No. of patients	Percentage(%)
Average	189	63
Good	68	22.6
Excellent	43	14.3

Table: Distribution of Patients According to their Social Habits

Social habits	No. of patients	Percentage(%)
Smoking	13	4.3
Alcohol	9	9.6
Tobacco chewer	16	5.3
Toddy	14	4.6
None	228	76

Table: Distribution of Subjects According to their Increased Hormones

Hormones increased	No. of patients	Percentage(%)
TSH	48	16
LH	15	5
Testosterone	18	6
Insulin	55	18.3
Prolactin	44	14.6
RBS	46	15.3
Estrone	38	12.6
AMH	36	12

Definite-ADR :5-8= probable ADR, 1-4= possible ADR, 0= doubtful ADR

Action taken	No. of patients(n=69)	Percentage(%)
Drug withdrawal	6	8.6
Changing of time of administration	20	28.9
Addition of another drug	40	57.9
Total	69	100

IV. DISCUSSION

There is interrelation between PCOS and Endometriosis that is PCOS is one of the major risk factor leading to Endometriosis. Both PCOS and Endometriosis is an endocrinal disorders in which hormonal imbalances places a crucial role.

On one hand PCOS affect women's sex hormones which regulate menstrual cycle are imbalanced in PCOS the excess or increased androgen production leads to symptoms like acne, hirsutism etc., these hormonal imbalance cannot maintain the endometrial thickness which leading to irregular menses. On the other hand Endometriosis in which endometrial tissue dislocate from its normal location to the other parts like rectum, small intestine, outer parts of ovaries the exact pathophysiology is unknown this may be due to hormonal imbalance. PCOS can also cause Endometriosis the ovarian cyst and irregular menses cause dislocation of endometrial tissue, cause dysmenorrhea, dyschezia, dyspareunia, dysuria etc.

A study conducted by Nivetha.M and Susan .G.Suganya on Survey of Poly Cystic Ovariansyndrome (PCOS) Among The Girl Students of Bishop Heber College, Trichirapalli, Tamil Nadu, India they were revealed as about 47 girls of 23 – 25 years age group were identified with PCOS.Astudy conducted by Prabha Dey on Quality of life of women with polycystic ovarian syndromethey concluded as the Age category was maximum 31.7% for 26-31 years age range were identified with PCOS.

A study conducted by Parveen Parasar, on Endometriosis: Epidemiology, Diagnosis and Clinical Management the study revealed that Endometriosis is a debilitating disease that impacts the qualityof life of adult and adolescent patients. According to our study among 300 patients 20-30 (31.6%) years age group people were most commonly identified with PCOS and Endometriosis.

According to our study out of 300 patients comparing the marital status among married (41.6%) and unmarried (58.3%), unmarried people (58.3%) were most commonly affected with PCOS and Endometriosis patients.

A study conducted by Prabha Dey on Quality of life of women with polycystic ovarian syndrome they concluded as Most of the sample 56.7% was graduate were identified as PCOS. In our study among 300 patients comparing the primary (28.6%), secondary (53.3%) and tertiary (18%) educational status, the secondary (53.3%) are most commonly affected with PCOS and Endometriosis patients.

In our study out of 300 patients, subjects were classified according to their nutritional status as poor (23.6%), average (63.3%) and good (13%), average (63.3%) nutritional status patients were most commonly affected with PCOS and Endometriosis. And subjects were classified according totheir hygiene conditions as average (63%), good (22.6%) and excellent (14.3%), average hygiene condition patients were most commonly affected.

In our study out of 300 patients, subjects were classified according to their gestational status as pregnant (16.33%) and non-pregnant (83.6%) women non-pregnant women are most commonly affected.

A study conducted by Prabha Dey on Quality of life of women with polycystic ovarian syndrome they concluded as occupationally 75% of the sample was student and remainder 25% were employed, they were identified with PCOS. In our research among 300 patients, when we looked in to the occupation of the patients in our study, most of them are private job holders (23.3%), unemployed (20%), students (19.6%), and government job holders (18.3%). This clearly suggest that private job holders are mostly subjected to PCOS and Endometriosis.

A study conducted by Prabha Dey on Quality of life of women with polycystic ovarian syndrome they concluded as 61.7% of sample was belonging to nuclear family and 86.7% were non-vegetarian they are identified as PCOS. In our research subjects (300) were classified according totheir social habits of smoking (4.3%), alcohol (9.6%), tobacco chewers (5.3%), toddy (4.6%) and none (76%). It was seen that individuals with none (76%) among the above social habits, were diagnosed with PCOS and Endometriosis.

A study conducted by Goldzieher JW,et.al. Obesity is also a feature observed and estimated to effect 50% of PCOS women. Our study revealed out of 300 patients risk factors observed are genetics (12%), stress (27%), insulin resistance (11.3%), over weight (20%), sleep apnea (13.6%), oral contraceptive pills (12.3%), high blood pressure (3.6%), highest percentage of people with stress were most commonly effected with PCOS and Endometriosis.

According to our study subjects were classified according to comorbidity conditions with PCOS and Endometriosis patients and more percentage were observed in patients with thyroid dysfunction (24.6%), obesity (20.6%), hypertension (12%), diabetes (10%) have mostly subjected to PCOS and Endometriosis.

A study conducted by Nivetha et al on Survey of Poly Cystic Ovarian syndrome (PCOS) Among The Girl Students of Bishop Heber College, Trichirapalli, Tamil Nadu, India they were revealed as About 47 girls of 23 – 25 years age group 10 girls were with symptoms of PCOS. PCOS is a common endocrine disorder of female adolescence and adulthood with exact etiology unknown butpathophysiology rooted in insulin resistance, hyperandrogenism, and chronic anovulation. A

multitude of clinical factors can present including hirsutism, menstrual irregularities, metabolic abnormalities, acne, and increased BMI. History, physical exam, and laboratory tests are all components of making a diagnosis as some adolescents do not present with all clinical factors. In our study out of 300 patients Symptoms of PCOS and endometriosis in individuals are mostly amenorrhea (11.3%), oligomenorrhea (8.6%), acne (9.3%), hirsutism (14.3), alopecia (6.6%), dysmenorrheal (18%), dyspareunia (7%), weight gain (13.3%), dyschezia (5%), dysuria (6.3%), among these hirsutism (14.3%), weight gain (13.3%) is seen in almost all individuals of PCOS and Endometriosis.

A study conducted by Parveen Parasar et al, revealed that Endometriosis a semi/non-invasive diagnostic biomarker would be a useful tool to identify patients early in the disease process and thus improving outcomes, including less pain and better fertility.

According to Guttmann-Bauman I the prevalence of PCOS is traditionally estimated at 4% to 8% from studies performed in Greece, Spain and the USA. The prevalence of PCOS has increased with the use of different diagnostic criteria and has recently been shown to be 18% ($17.8 \pm 2.8\%$) in the first community-based prevalence study based on current Rotterdam diagnostic criteria.

V. CONCLUSION

Our study concluded that psychological stress and obesity leads to hormonal imbalance in patients with PCOS and endometriosis. Hyperandrogenism is the main cause for PCOS, stress in female causes increased testosterone and decreased estrogen levels those results in bilateral ovarian cysts among study population. PCOS have no significant complications during and after pregnancy. There were more complications observed with PCOS rather than endometriosis, among them majority observed are weight gain and infertility. It is also observed that quality of life is affected and varied among the study population of different age groups.

A clinical pharmacist plays a crucial role in educating the women especially teenagers about the sex hormones and their imbalances, risk factors, use of oral contraceptives and their adverse effects in human body to avoid hormone related gynecological disorders, thereby improving the QOL of women.

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