

A Prospective Observational Study on Hormonal Imbalances, Complications and Quality Of Life In Pcos and Endometriosis Patients

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Abstract:

Background: Polycystic Ovary Syndrome (PCOS) is an endocrine metabolic disorder characterized by multiple hormonal imbalances representing diverse clinical presentations as hyperandrogenism. 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.

Endometriosis is defined as the presence of normal endometrial mucosa abnormally implanted in locations other than the uterine cavity. Depending on the area identified, endometriosis is characterized as endopelvic or extrapelvic.

Materials and Methods: This prospective observational study was conducted over a period of 6 months to identify the hormonal imbalances, complications and Quality of life in PCOS and Endometriosis patients. Necessary information was collected from the patient prescription, Laboratory data, direct communication with patient and their care takers.

Results: Overall we enrolled 300 patients with PCOS and Endometriosis in our study where 225 are PCOS patients, 55 are Endometriosis patients and 20 are with both PCOS and Endometriosis. We calculated quality of life for 300 patients through the questionnaire, the laboratory data, physical examination, patient complaints using statistical techniques. We found that PCOS and endometriosis were affecting the quality of life of study population, which ranges in between 60-80% among patients in different age groups.

Conclusion: Our research also concluded that there is an interrelationship between PCOS and endometriosis which in turn leads to hormonal imbalances which further more leading to complications, and affecting Quality of life of patients.

Key Word: PCOS, Endometriosis, Quality Of Life, Hormonal imbalances, complications.

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 diseases¹⁻². 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 heterogenous clinical and biochemical phenotype expression in PCOS women.³

Clinical features:³

- Acne vulgaris
- Alopecia
- Acanthosis nigricans
- Hirsutism
- Irregular menses and fertility

Diagnosis:⁴⁻⁵

- Presence of at least two of these symptoms PCOS can be diagnosed
- Irregular periods
- Higher levels of androgen (male hormones) shown in blood tests or through symptoms like acne, male-pattern balding, or extra hair growth on your face, chin, or body
- Cysts in your ovaries as shown in an ultrasound exam
- Physical Exam
- Pelvic ultrasound (sonogram)
- Pelvic exam
- Hormone tests
- Blood test

Endometriosis is defined as the presence of normal endometrial mucosa abnormally implanted in locations other than the uterine cavity. Depending on the area identified, endometriosis is characterized as endopelvic or extrapelvic. The endopelvic ectopic implants are located in the minor pelvis, the ovaries, the fallopian tubes and the uterosacral ligaments posterior of the uterus, whereas, the more unusual extrapelvic implantation sites are the abdominal wall, scars of the perineum, the urinary and gastrointestinal tract, the thorax and the nasal mucosa. Endometriosis can affect any woman from premenarche until postmenopause, regardless the race or ethnicity and hermaternal status.⁶⁻⁹

Symptoms:¹⁰

- Painful periods (dysmenorrhea)
- Pain with bowel movements or urination
- Excessive bleeding
- Infertility
- Pain with intercourse
- Other signs and symptoms: fatigue, diarrhoea, constipation, bloating or nausea, especially during menstrual periods

Causes:¹¹

- Endometrial cell transport
- Retrograde menstruation
- Transformation of peritoneal cells
- Embryonic cell transformation
- Surgical scar implantation
- Immune system disorder

Diagnosis:¹²⁻¹³

- Transvaginal ultrasound
- Pelvic exam
- Ultrasound
- Magnetic resonance imaging (MRI)
- Laparoscopy

PCOS is a very complicated endocrine disorder. Blood tests to measure hormone levels, an ultrasound to look at your reproductive organs and thorough personal and family histories should be completed before a PCOS diagnosis is confirmed. Depending on your symptoms, your physician will determine exactly which tests are necessary. Assessing hormone levels serves two major purposes. First of all, it helps to rule out any other problems that might be causing the symptoms. Secondly, together with an ultrasound and personal and family histories, it helps your doctor confirm that you do have PCOS. Most often, the following hormone levels are measured when considering PCOS diagnosis:¹⁴

- Lutenizing hormone (LH)
 - Follicle-stimulating hormone (FSH)
 - Total and Free Testosterone
 - Dehydroepiandrosterone sulfate (DHEAS)
 - Prolactin
 - Androstenedione
 - Progesterone.
- Other hormones that may be checked include:
- estrogen
 - thyroid stimulating hormone (TSH)

In addition, glucose, cholesterol (HDL, LDL and triglycerides) levels might also be assessed.

Polycystic ovary syndrome (PCOS) is a common endocrine disorder that affects up to 12% of women of reproductive age. Following the Rotterdam criteria, PCOS is characterized by oligo- or anovulation, clinical or biochemical aspects of hyperandrogenism and the presence of polycystic ovaries on ultrasound. A growing body of evidence suggests that impaired mental health and a reduced health-related quality of life (HRQOL) may be significantly associated with this disorder. More specifically, several studies in different patient populations and meta-analyses of these studies have shown that women with PCOS have an increased risk of anxiety and depression symptoms and a reduced HRQOL. These scores are higher than those of healthy controls, but nevertheless are usually within the normal range. Additionally, in the current studies, the percentage ranges of women affected by anxiety and depression are extremely variable, especially when subgroup analyses are performed based on the body mass index and clinical signs of hyperandrogenism 15.

II. Material And Methods

The study was conducted on PCOS and Endometriosis patients in Amrutha nursing home and shivananda maternity hospital a with departments such as General Medicine, Cardiology, Neurology, Pediatrics, General Surgery, Gynaecology in Karimnagar..

Study Design:prospective and observational study.

Study Location: Amrutha nursing home in department of Gynaecology in presence of Dr.L.Geetha reddy and shivananda maternity in department of Gynaecology in presence of Dr Shailaja at karimnagar district, Telangana state.

Study Duration:The study was conducted over a period of six months (July2019 – December2019).

Sample size: 300 patients.

Sample size calculation: The sample size was estimated on the basis of a single proportion design. The target population from which we randomly selected our sample was considered 20,000. We assumed that the confidence interval of 10% and confidence level of 95%. The sample size actually obtained for this study was 96 patients for each group. We planned to include 300 patients (Group I- Control, Group II- Cases of 100 patients for each group) with 4% drop out rate.

Subjects & selection method: 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

Patients who are with symptoms of PCOS and Endometriosis visiting for the Amrutha nursing home for the diagnosis and treatment and patients with past medical history of PCOS and Endometriosis.

Interviewing and interacting with patients and patient care takers.

1. 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
2. Secondary data through internet, magazines, journals, text books, articles and etc.

Inclusion criteria:

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

Exclusion criteria:

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

Procedure methodology:

We 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.

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.

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 no 1: Showsdisease wise distribution of subjectsout of the study population it is found that 75% of the patients suffering from PCOS followed by endometriosis + pcos and endometriosis.

Table no 1: Shows disease wise distribution of subjects

Diseases	No.of patients	Percentage(%)
PCOS	225	75
Endometriosis	55	18.3
PCOS and Endometriosis	20	6.6

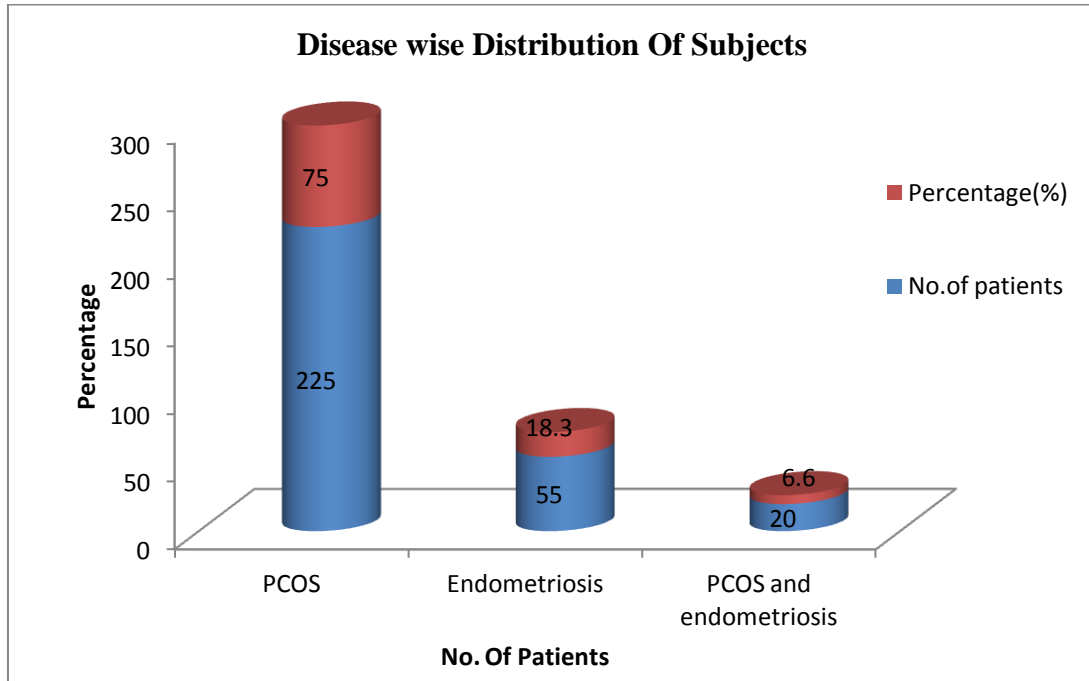


Table no 2: Distribution of subjects according to their age among 300 patients 20-30 (31.6%) and 30-40 (28.3%) years age group people were most commonly identified with pcos and endometriosis and the least was recorded in 60 years age group as hormones does not play a significant role.

Table no2: 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

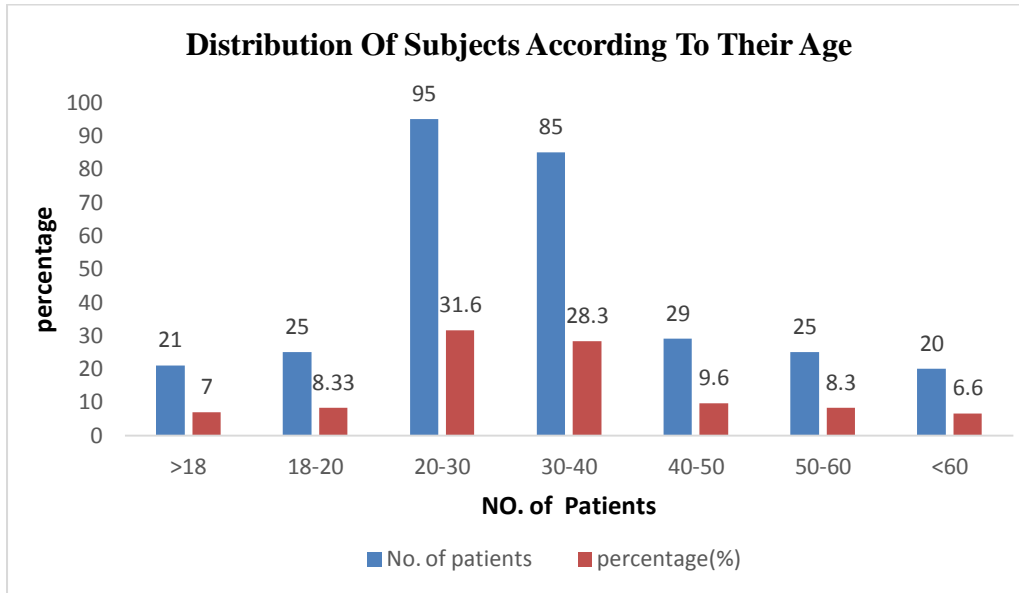


Table no3: Shows distribution of subjects according to their marital status, out of 300 patients comparing the marital status among married (41.6%) and unmarried (58.3%), unmarried people (58.3%) were most commonly affected with PCOS and endometriosis patients.

Table no 3: Shows distribution of subjects according to their maritalstatus.

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

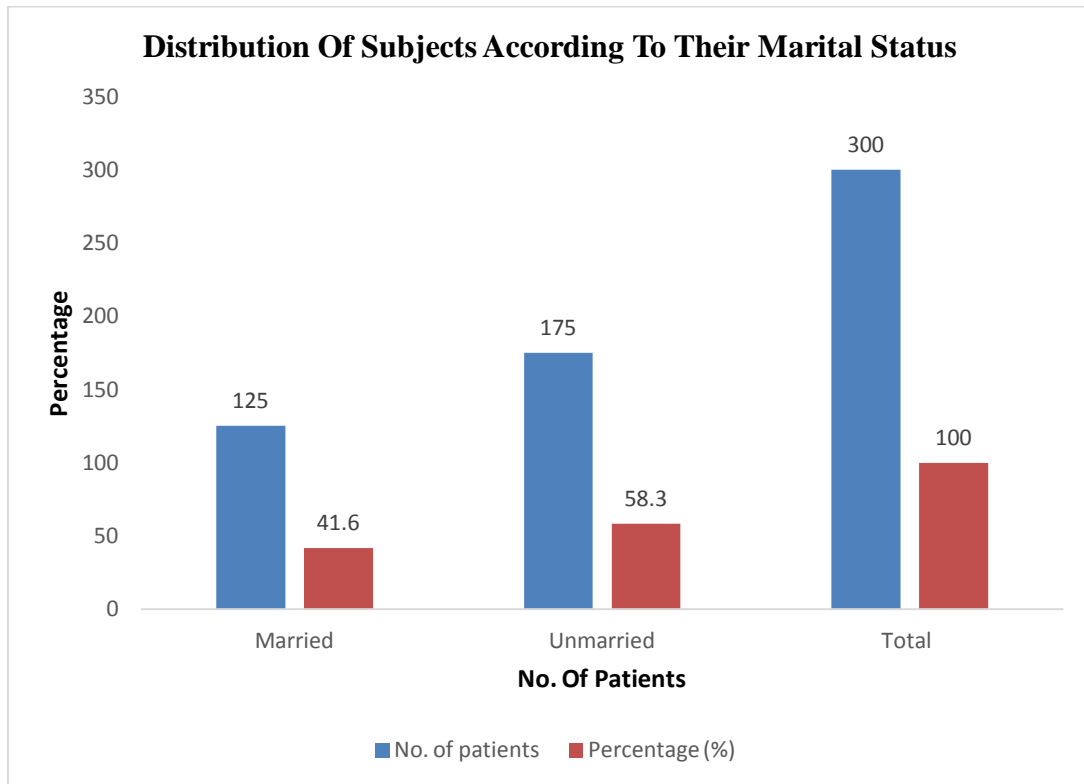


Table no4:Shows Distribution of patients according to their social habits of smoking (4.3%), alcohol (9.6%), tobaccochewers (5.3%), toddy (4.6%) and none (76%).it was seen that individuals with none (76%) among the above social habits, were diagnosed with PCOS and endometriosis.

Table no4:Distribution of patients according to their social habits

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

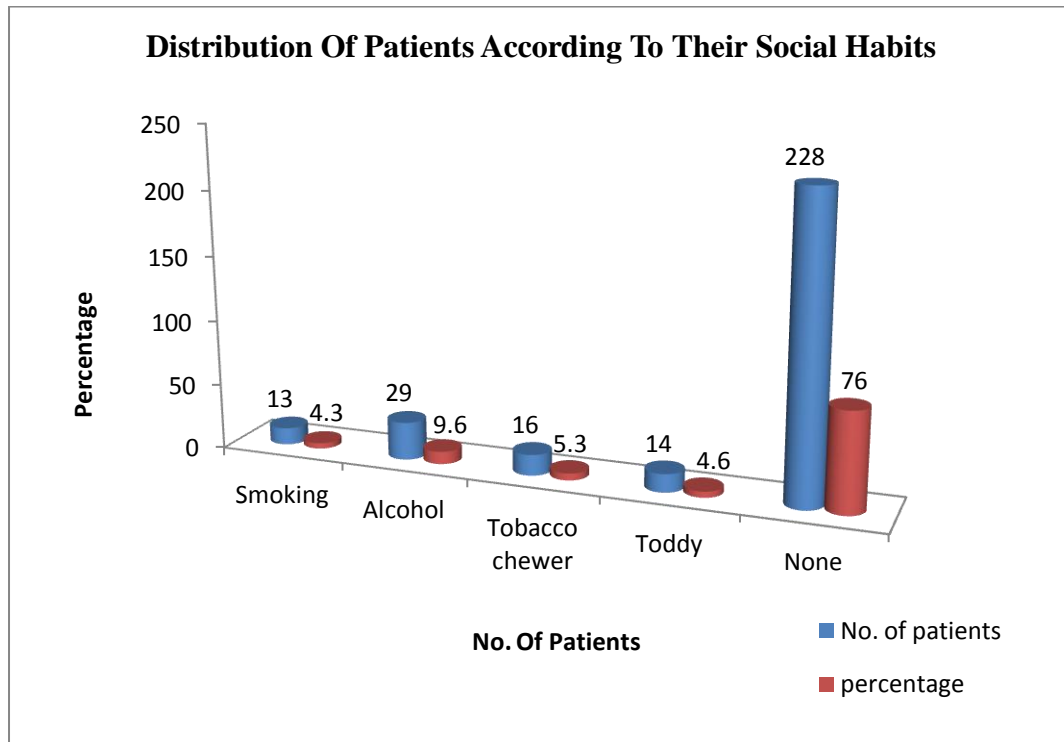


Table no 5 :Shows distribution of subjects according to their risk factors in our study out of 300 patients, subjects were classified according to their risk factors genetics(12%), stress(27%), insulin resistance(11.3%),over weight(20%), sleep apnea(13.6%), oral contraceptive pills(12.3%), high blood pressure (3.6%), people with stress were most commonly effected with PCOS and endometriosis.

Table no 5 Shows distribution of subjects according to their risk factors

Risk factors	No. of patients	Percentage (%)
Genetics	36	12
Stress	81	27
Insulin resistance	34	11.3
Over weight	60	20
Sleep apnea	41	13.6
OC pills	37	12.3
High blood pressure	11	3.6

Table no 6 Shows distribution of subjects according to their symptoms of PCOS and endometriosis in individuals are mostly amenorrhea (11.3%), oligomenorrhoea (8.6%), acne (9.3%), hirsutism (14.3), alopecia 6.6%), dysmenorrhea (18%), dyspareunia (7%), weight gain (13.3%), dysphasia (5%) dychezia (6.3%), among these hirsutism (14.3%), weight gain (13.3%) is seen in almost all individuals of PCOS and endometriosis.

Table no 6 Shows distribution of subjects according to their symptoms

Symptoms	No. of patients	Percentage (%)
Amenorrhea	34	11.3
Oligomenorrhoea	26	8.6
Acne	28	9.3
Hirsutism	43	14.3
Alopecia	20	6.6
Dysmenorrhea	54	18
Dyspareunia	21	7
Weight gain	40	13.3
Dysphasia	15	5
Dysuria	19	6.3

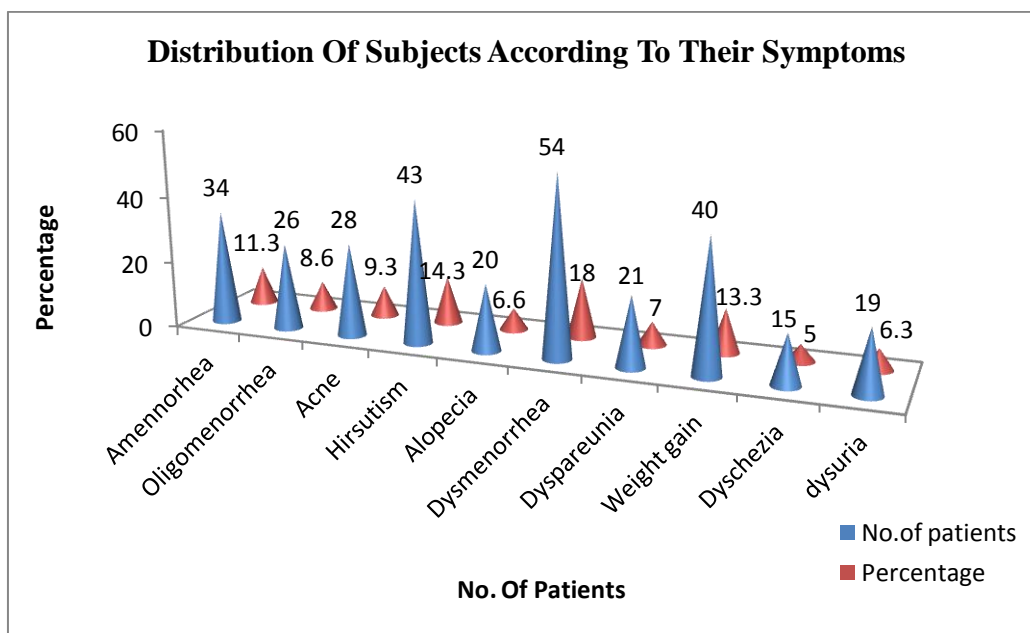


Table no 7 :Distribution of subjects according to their increased hormones among 300 patients mostly increased hormones are insulin (18.3%),TSH (16%), RBS (15.3%), prolactin (14.6%) and mostly decreased hormones are HDL (37.6%), estradiol (21.6%), progesterone (21%), FSH (19.6%).

Table no 7: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

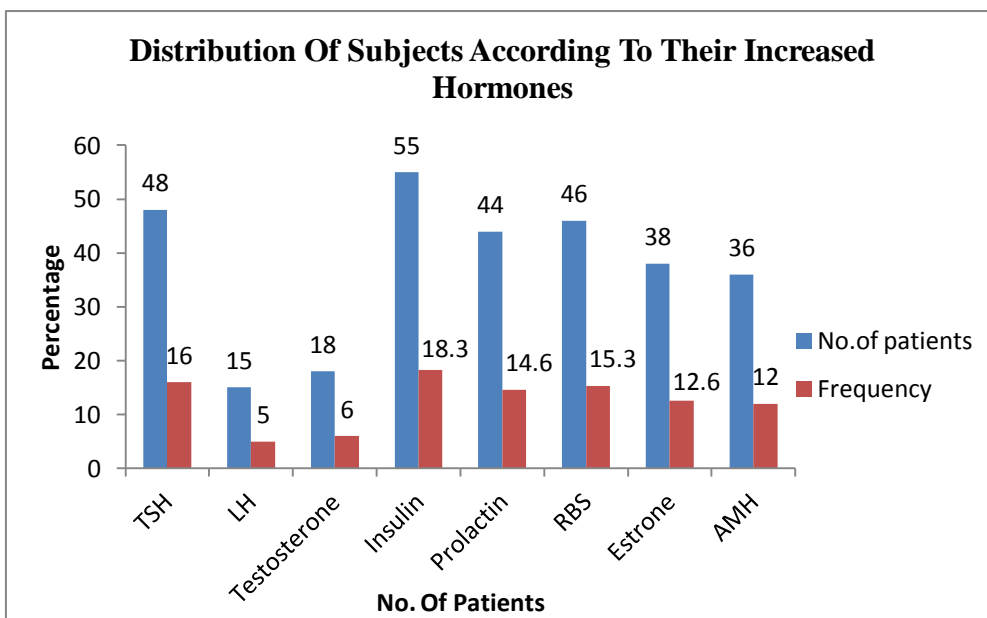


Table 8: Shows distribution of subjects according to their decreased hormones in our study among 300 patients mostly decreased hormones are HDL (37.6%) Estradiol (21.6%), progesterone (21%), and FSH (19.6%).

Table 8: Shows distribution of subjects according to their decreased hormones

Hormones decreased	No. Of Patients	Percentage (%)
FSH	59	19.6
Estradiol	65	21.6
Progesterone	63	21
HDL	113	37.6

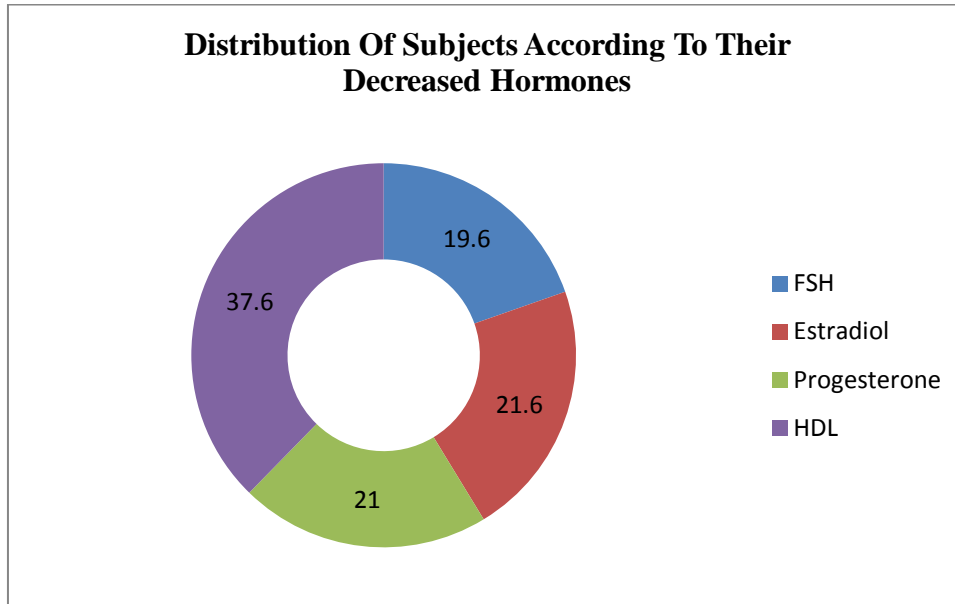


Table 9: Shows distribution of subjects according to their complication in 300 patients weight gain (17%), infertility (16.3%) and depression (13.3%) are major complications found in pcos and endometriosis patients.

Table 9: Shows distribution of subjects according to their complication

Parameters	No. Of patients	Percentage (%)
Weight gain	51	17
Pre diabetic	28	9.3
Cardiovascular diseases	8	2.6
Endometrial cancer	10	3.3
Type II diabetes	32	10.6
Metabolic syndrome	28	9.3
Insulin resistance	30	10
Infertility	49	16.3
Sleep apnea	14	4.6
Surgical complications	10	3.3
Depression	40	13.3

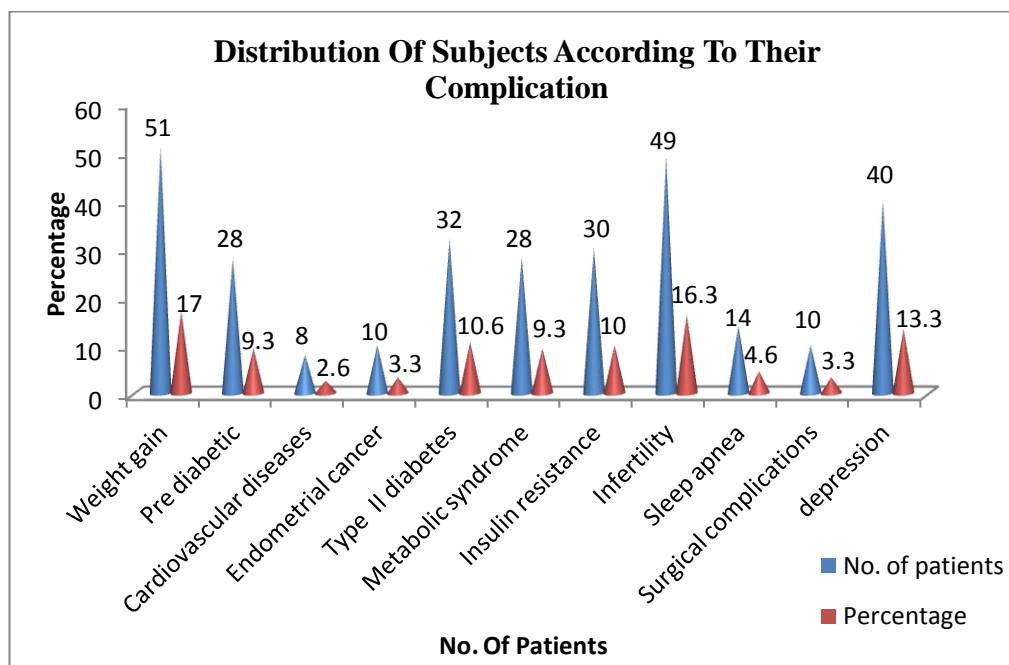


Table 10: Scoring domain of WHO QOL

For example for one patient the QOL is calculated as:

WHO Quality of Life Scale: Before we begin we would like to ask you to answer a few general questions about yourself by circling in the correct answer or by filling in the space provided.

1. What is your gender? Female
2. What is your date of birth? 07-07-1992 Day - Month - Year
3. What is the highest education you pursued? Graduation
4. What is your marital status Married
5. What is your age 27
6. What is your occupation Private Employee
7. What is your obstetric history pregnant/non pregnant
8. What is your nutritional status poor/average/good
9. What about your hygiene condition average/good/excellent

Sl.no	PSYCOLOGICAL	NOT AT ALL	LITTLE	MODERATE AMOUNT	VERY MUCH	EXTREME AMOUNT
01.	How much of the time have you felt depressed as a result of having pcos and endometriosis	0	1	2	<u>3</u>	4
02.	How much of the time have you felt easily tired	0	1	2	3	<u>4</u>
03.	How much of the time have you felt moody as a result of having PCOS and endometriosis	0	1	<u>2</u>	3	4
04.	How much of the time have you felt you had low self-esteem as a result of having PCOS and endometriosis	0	1	<u>2</u>	3	4
05.	To what extent have you worried about having PCOS and endometriosis	0	1	2	<u>3</u>	4
Sl.no	BODY HAIR	NOT AT ALL	LITTLE	MODERATE AMOUNT	VERY MUCH	AN EXTREME AMOUNT

A Prospective Observational Study on Hormonal Imbalances, Complications and ..

01.	Over the last two weeks to what extent have the growth of visible hair on your face been a problem for you	0	1	2	3	<u>4</u>
02.	Over the last two weeks to what extent has embarrassment about body hair been a problem for you	0	1	2	<u>3</u>	4
Sl.no	WEIGHT CONCERN	NOT AT ALL	LITTLE	MODERATE	VERY MUCH	AN EXTREME AMOUNT
01.	During the past two weeks how much of the time have you felt concerned about being overweight	0	1	2	<u>3</u>	4
02.	During the past two weeks how much of the time felt frustration with trying to loose weight	0	1	2	3	<u>4</u>
Sl.no	INFERTILITY CONCERN	NOT AT ALL	LITTLE	MODERATE	VERY MUCH	AN EXTREME AMOUNT
01.	During the past two weeks how much of time have you felt concerned with infertility problems	0	1	2	<u>3</u>	4
02.	During the past two weeks how much of the time have you felt afraid of not being able to have children	0	1	2	3	<u>4</u>
Sl.no	MENSTRUAL IRREGULARITY	NOT AT ALL	LITTLE	MODERATE	VERY MUCH	AN EXTREME AMOUNT
01.	How much were irregular menstrual period a problem for you	0	1	2	<u>3</u>	4
02.	How much were abdominal bloating a problem for you	0	1	2	<u>3</u>	4
03.	How much were a menstrual cramps a problem for you	0	1	<u>2</u>	3	4

First domain: $3+4+2+2+3=14$

Second domain: $4+3=7$

Third domain: $3+4=7$

Fourth domain: $3+4=7$

Fifth domain: $3+3+2=8$

Actual raw score= $14+7+7+7+8=43$

Lowest possible raw score = 7

$$= \frac{7+7+7}{3}$$

Possible raw score range = maximum possible raw score-lowest possible raw score

$$56-7 = 49$$

Transformed scale score = $\frac{(\text{actual raw score} - \text{lowest possible raw score}) \times 100}{\text{Possible raw score range}}$

$$= \frac{43-7}{49} \times 100$$

$$= 73\%$$

In our study we calculated quality of life for 300 patients through the questionnaire, the laboratory data, physical examination, patient complaints using statistical techniques. We found that PCOS and endometriosis were affecting the quality of life of study population, which ranges in between 60-80% among patients in different age groups.

IV. Discussion

There is interrelation between PCOS and Endometriosis leading to endometriosis, 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 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 were identified with PCOS. A study conducted by Prabha Dey on Quality of life of women with polycystic ovarian syndrome they 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 quality of 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 61.7% of sample was belonging to nuclear family and 86.7% were non-vegetarian they are identified as pcos and also, subjects were classified according to their social habits of smoking (4.3%), alcohol (9.6%), tobaccochewers (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 endomeriosis.

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%), sleepapnea (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.

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 PCOD. PCOS is a common endocrine disorder of female adolescence and adulthood with exact etiology unknown but pathophysiology 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 ammenorhea (11.3%), oligomenorrhea (8.6%), acne (9.3%), hirsutism (14.3), alopecia (6.6%), dysmenorrheal (18%), dyspareunia (7%), weightgain (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 Fernanda de Almeida Asencio et al on Symptomatic endometriosis developing several years after menopause in the absence of increased circulating estrogen concentrations: a systematic review and seven case reports the study concluded that estrogen intake or of a systemic increased production.

In our study among study population mostly increased hormones are insulin (18.3%), TSH (16%), RBS (15.3%), prolactin (14.6%) and mostly decreased hormones are HDL (7.6%), estradiol (21.6%), progesterone (21%), FSH (19.6%).

A study conducted by Syeda Sidra et al on Evaluation of clinical manifestations, health risks, and quality of life among women with polycystic ovary syndrome. All participants had ≥ 1 complication of PCOS, with the most common complication being obesity (80%), followed by hyperandrogenism (77.7%), diabetes (60.9%), and infertility (33.2%).

A study conducted by, Parveen Parasar, et al, on Endometriosis: Epidemiology, Diagnosis and Clinical Management the study revealed that Diagnostic delays are common and may lead to a decline in reproductive potential and fertility.

According to our study of the 300 patient's weight gain (17%), infertility (16.3%) and depression (13.3%) are major complications found in pcos and endometriosis patients.

A study conducted by Syeda Sidra, et al they concluded that Patients with PCOS exhibit poor QOL, which is associated with depression, acne, and hirsutism. Therefore, PCOS management guidelines should review the recommendations regarding the use of pharmacological agents for these conditions. The clinical conditions and complications associated with PCOS should be given due importance while selecting appropriate management plans for each patient considering the effects of these conditions on overall morbidity and QOL.

In our study we calculated quality of life for 300 patients through the questionnaire, the laboratory data, physical examination, patient complaints using statistical techniques. We found that PCOS and endometriosis were affecting the quality of life of studypopulation that ranges in between 60-80% among patients in different age groups.

V. Conclusion

Our study concluded that psychological stress, 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. Our research also concluded that there is an interrelationship between PCOS and endometriosis which inturn leads to hormonal imbalances which further more leading to complications, and affecting Quality of life of patients. We found that PCOS and endometriosis were affecting the quality of life of studypopulation, which ranges in between 60-80% among patients in different age groups.

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