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RESEARCH ARTICLE

STUDY OF DRUGS PRESCRIBED AND ADVERSE DRUG REACTION IN POLYCYSTIC OVARY SYNDROME AND MENSTRUAL DISORDERS IN GYNAECOLOGY DEPARTMENT AT INTEGRAL INSTITUTE OF MEDICAL SCIENCES & RESEARCH, LUCKNOW, INDIA

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Abstract

Polycystic ovary syndrome (PCOS) and menstrual disorders are prevalent gynecological conditions affecting a significant number of women worldwide. The management of these conditions often involves the prescription of various drugs to alleviate symptoms and improve overall reproductive health. However, the use of medications in these conditions is not without risks, as adverse drug reactions (ADRs) may occur,posing potential challenges to patient safety and treatment outcomes. This study aimed to investigate the drugs prescribed and document adverse drug reactions associated with PCOS and menstrual disorders in the Gynecology Department at IIMS&R Integral University, Lucknow, India.The study adopted a prospective observational design, analyzing medical records of female patients diagnosed with PCOS and menstrual disorders who sought care at the Gynecology Department. Data on prescribed drugs, dosage, duration of treatment, and patient demographics was extracted from electronic health records.Adverse drug reactions were identified through systematic review of patients' medical records, specifically focusing on any reported symptoms, complications, or changes in treatment regimens due to drug-related issues. All identified ADRs were assessed for severity, causality, and preventability following standard pharmacovigilance guidelines.The findings of this study have the potential to improve patient safety, enhance the quality of care, and contribute to evidence-based practices in the management of PCOS and menstrual disorders. Moreover, it can serve as a foundation for future research endeavors aimed at exploring alternative treatment strategies or novel therapeutics for these gynecological conditions.

Introduction:-

Polycystic ovary syndrome (PCOS)

Health is of paramount importance to individuals and societies worldwide (Yadav et al., 2021). A robust healthcare system ensures better quality of life, productivity, and economic growth(Ahsan et al., 2022). Among premenopausal

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women, polycystic ovary syndrome (PCOS) is one of the most prevalent endocrine and metabolic disorder. PCOS is characterized by a combination of signs and symptoms of androgen excess and is heterogeneous by nature (Morreale, 2018). 5-20% women of reproductive age have polycystic ovarian syndrome(Crespo et al., 2018).PCOS is characterized by polycystic ovarian morphology and irregular menstruation in addition to hyperandrogenism. It is also associated to a number of comorbid conditions, such as obesity, diabetes, and cardiovascular disease(Donaldson et al., 2023). Ovarian dysfunction continues to be the main feature which makes this syndrome the major cause of anovulatory associated with infertility.Most say 5%-10% of reproductive-age women are affected but some say 6.6%-8% and some others say PCOS is a disorder affecting up to 6%-10% of women in reproductive age(Mohammad &Seghinsara, 2017). PCOS symptoms include severe reproductive dysfunctions (such as infertility and pregnancy complications), unbalanced metabolic processes (such as insulin resistance, type 2 diabetes, etc.), psychological disorders (primarily including depression and anxiety), and other effects that disturb female patients whose ages range from adolescence to menopause(Gu et al., 2022).

Etiology

PCOS is a heterogenous syndrome, and its specific cause is yet unknown. Because it is a heterogenic condition, many different variables contribute to its emergence. Both lean and overweight women are likely to have insulin resistance and compensatory hyperinsulinemia, which are thought to be important etiological factors in PCOS(Rashid et al., 2022).Although the genetic etiology of PCOS is still unknown, a family history of PCOS is relatively common; however, familial links to PCOS are unclear. A formal segregation study is impossible without sufficient phenotypic data. Poor food habits and physical inactivity, as well as infectious diseases and pollutants, might worsen environmental variables linked to PCOS (such as obesity). With changes to one's lifestyle, such as losing weight and exercising, PCOS's reproductive and metabolic traits may occasionally be reversed (Ndefo, 2013). Table 1 represent sign and symptoms of polycystic ovary syndrome.

Sign and Symptoms of Polycystic Ovary Syndrome

Enlarged ovaries with numerous small cysts
Irregular Menstrual cycles
Pelvic pain
Hirsutism
Alopecia
Acne
Acanthosisnigricans
Skin tags

Table 1:- Data extracted from Ndefo UA, Eaton A, Green MR. Polycystic ovary syndrome: a review of treatment options with a focus on pharmacological approaches. P T. 2013 Jun;38(6):336-55. PMID: 23946629; PMCID: PMC3737989.

Pathogenesis

Many PCOS patients have been shown to have an abnormal concentration of gonadotropins,namely LH:FSH ratio, which is indicative of the pathophysiology of the condition. One more aspect of PCOS has been insulin resistance(Donaldson et al., 2023b); insulin helps to regulate ovarian function, and the ovaries respond to excess insulin by producing androgens, which can lead to an-ovulation.Follicularmaturation arrest is a hallmark sign that an ovarian abnormality exists (Ndefo, 2013).PCOS patients are also usually insulin resistant(Paoli et al., 2020). Figure 1 represent pathogenesis of polycystic ovary syndrome.

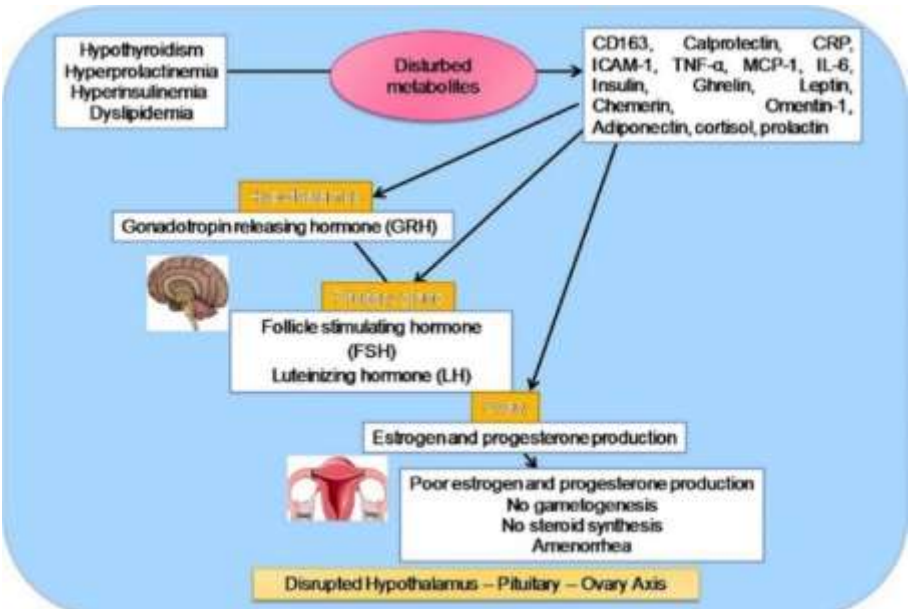

Figure 1:- Image extracted from Patel S. Polycystic ovary syndrome (PCOS), an inflammatory, systemic, lifestyle endocrinopathy. The Journal of steroid biochemistry and molecular biology. 2018 Sep 1;182:27-36.

A univocal therapy for PCOS does not exist; Because of this pathology's unusual heterogeneity, the treatment should be personalized, depending on the clinical presentation and needs of the patient(Amiri et al., 2020). All treatments aim to improve biochemical, and clinical outcomes of PCOS as well as the QOL (Vlachou et al., 2019). Table 2 represent diagnostic tools for polycystic ovary syndrome.

Diagnostic Tools for Polycystic Ovary Syndrome

NICHD/NIH CRITERIA (1990)	ESHRE/ASRMRotterdamCriteria (2003)	Androgen Excess Society (AES) Criteria (2006)
• Hyperandrogenism • Oligo-ovulation/anovulation • Exclusion of other related disorders	• Hyperandrogenism • Oligo-ovulation/anovulation • Polycystic ovaries	• Hyperandrogenism • Oligo-ovulation/anovulation • Polycystic ovaries • Exclusion of other related disorders

Table 2:- Data extracted from Ndefo UA, Eaton A, Green MR. Polycystic ovary syndrome: a review of treatment options with a focus on pharmacological approaches. P T. 2013 Jun;38(6):336-55. PMID: 23946629; PMCID: PMC3737989.

Treatment

Non-Pharmacological Approaches

Because the exact cause of PCOS is unknown, treatment primarily focuses on managing the associated symptoms. Weight reduction is particularly beneficial for obese patients with PCOS. Losing weight can help lower levels of androgens, luteinizing hormone (LH), and insulin. Additionally, it can help regulate ovulation, thereby improving the chances of achieving pregnancy. Laparoscopic ovarian drilling is a surgical procedure performed on an outpatient basis. During this procedure, multiple perforations are created in the ovarian surface and stroma. It is believed that this intervention destroys androgen-producing tissue, leading to a decrease in androgen levels. Laparoscopic ovarian drilling has been found to be as effective as medical interventions, without increasing the risk of multiple pregnancies.

Pharmacological Approaches

Clomiphene:

Clomiphene citrate is considered the preferred medication for inducing ovulation in women with PCOS. Clomiphene citrate has been found to result in successful pregnancies in approximately 30% of cases. However, it's worth noting that about 20% of these pregnancies may end in spontaneous abortions or stillbirths. It's important to be aware of

potential adverse effects associated with clomiphene citrate, which can include ovarian enlargement, ovarian hyperstimulation syndrome (OHSS), multiple pregnancies, hot flashes, and gastrointestinal (GI) symptoms such as distention, bloating, and discomfort.

Antidiabetic Agents:
Antidiabetic medications can be utilized to enhance fertility, alleviate insulin resistance, and lower circulating androgen levels. In comparison to a placebo, the use of metformin demonstrated significantly higher pregnancy rates (53.6% vs. 40.4%) and live birth rates (41.9% vs. 28.8%). These results indicate that metformin can be beneficial in improving pregnancy outcomes in women with PCOS (P = 0.014).

Gonadotropins:
Human menopausal gonadotropin (HMG) and FSH can also be used to induce ovulation if clomiphene and/or metformin therapy fails. Pregnancy rates were higher with FSH than with clomiphene (58% vs. 44%, respectively; **P** = 0.03), and there were more live births with FSH (52% vs. 39%, respectively; **P** = 0.04).

Oral Contraceptives:
Women with PCOS who do not wish to become pregnant may consider oral contraceptives (OCs). These drugs also reduce hirsutism, acne, and androgen levels. Estrogen and progestin combinations are the primary OCs used in the treatment of hirsutism and acne associated with PCOS.

Antiandrogens:
Spironolactone,flutamide, and finasteride are antiandrogens that work in PCOS by decreasing androgen levels, thereby reducing the signs of hirsutism and acne. These antiandrogens may also improve lipid levels, which can be elevated in patients with PCOS(Donaldson et al., 2023).

Menstrual Disorders
Menstrual disorders are very common in adolescence, and can be the cause of a significant amount of stress to both the patients and their parents. Variations of the menstrual cycle in this age are very broad and are mainly caused by the immaturity of the hypothalamic-pituitaryovarian (HPO) axis. Amenorrhea (either primary or secondary), abnormal uterine bleeding and dysmenorrhea are conditions that require careful evaluation through a stepwise and logical manner. The term primary amenorrhea refers to the condition when menarche fails to occur, while secondary amenorrhea refers to the cessation of menses once they have begun. The occurrence of irregular, prolonged or heavy abnormal uterine bleeding is one of the most urgent gynaecological problems in adolescence and the diagnosis of dysfunctional uterine bleeding should be used only when all other organic and structural causes of abnormal vaginal bleeding have been ruled out. Dysmenorrhea refers to painful menstruation and is the most common reason for which a young girl may refer to a gynaecologist. It is characterized as primary in the absence of an underlying organic disease, and as secondary when there is evidence of pelvic pathology. Appropriate and early management of the patient is necessary in order to minimize the possibility of future complications regarding woman's reproductive ability(Yaşa&Uğurlucan, 2020).

Abnormal uterine bleeding (AUB) is the most common gynecologic complaint of adolescents admitted to hospital. Heavy menstrual bleeding (HMB) is the most frequent clinical presentation of AUB. Anovulatory cycles, owing to immature hypothalamic-pituitary-ovarian axis, is the leading etiology of HMB and there is an accompanying bleeding disorder in almost 20% of patients with HMB. Additionally, endocrine disorders such as hypothyroidism, hyperprolactinemia and polycystic ovary syndrome are possible causes of AUB (Sidra et al., 2019).

Materials and Method:-

Study Design
The study was carried out for 6 months in PCOS women and women with Menstrual Abnormalities at Integral Institute of Medical Sciences and Research,Lucknow using a hospital-based prospective,non-experimental(observational)technique.The study setting encompassed both inpatient and outpatient division of hospital.100 patients with polycystic ovary syndrome and menstrual disorders were included in the study that willingly participated and were enrolled based on predefined inclusion and exclusion criteria.

Inclusion criteria encompassed patients aged between 18 – 45 years and pregnant and lactating patients with a history of PCOS and Menstrual Disorderswere also included.

On the other hand,exclusion criteria included patients who were mentally retarded and also who were not treated with drugs used to treat PCOS & Menstrual Abnormalities.Patients who were unable to comply and drug addicts were also excluded from the study.

Sources of Data
Data was collected from physicians prescribing records, patient medication profiles, medical records, treatment charts, nursing notes and direct patient interviews.

Data Collection
This study collected data using a structured questionnaire with open ended questions to interview the participants.Prior to the commencement of the study,written/verbal consent was obtained from all participants. The questionnaire was designed to obtained patient profile data such as age,sex,weight,patient address and marital status.Additionally,information on prescribed drugs,including their generic/brand name,dose and frequency was also collected.

Evaluation parameters
The following parameters were evaluated:types of drugs prescribed in PCOS and menstrual disorders,average number of drugs used in PCOS and menstrual disorders,average age-range of patients utilizing drugs,most commonly used agents of a particular class,occurrence and severity of adverse drug reactions due to drugs used in PCOS and menstrual disorders.

Result:-

1) Age distribution of study objects:
The total number of patients included in our study were from the age group between 18-45 years (Table 3; Figure 2).

Table 3:- Age distribution of study objects with different diseases.

Age (in years)	PCOS	Fibroids	Menstrual Disorders	Total
18-20	2	1	3	6
20-25	10	2	5	17
25-30	12	5	10	27
30-35	4	5	2	11
35-40	2	5	15	22
40-45	1	10	6	17

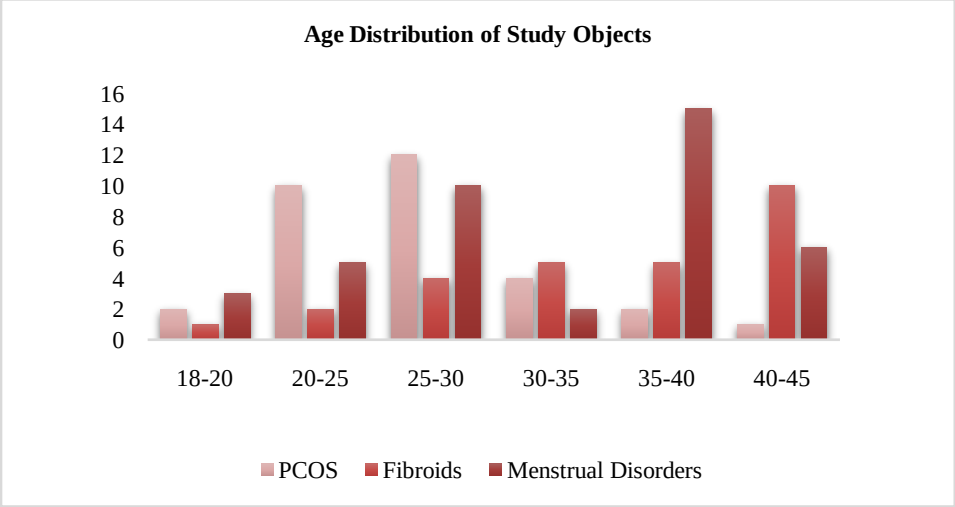

Figure 2:- Age distribution of study objects with different diseases.

2) Number of patients with PCOS/Fibroids/Other Menstrual Disorders
Among the Total 100 patients,30 patients were diagnosed with PCOS,20 were diagnosed with Fibroids and 50 were diagnosed with some other menstrual disorders (Table 4; Figure 3).

Table 4:- Number of patients with PCOS/Fibroids/Other Menstrual Disorders.

Disorders	No. of patients
PCOS	30
Fibroids	20
Menstrual Disorders	50
Total	100

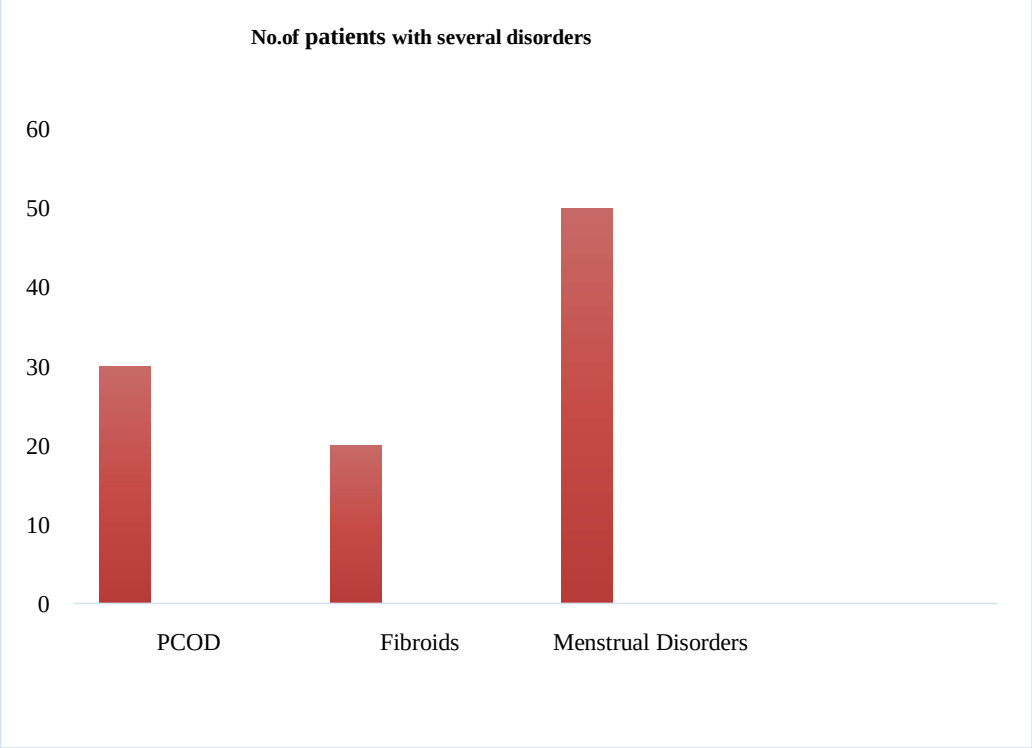

Figure 3:- Number of patients with PCOS/Fibroids/Other Menstrual Disorders.

3) Out-patient vs Inpatient distribution of study objects

Out of 100 patients,64 married and 10 unmarried patients were admitted in IPD whereas 11 married and 15 unmarried patients visited the OPD department (Table 5; Figure 4).

Table 5:- Out-patient vs Inpatient distribution of study objects.

Patients admitted	Married	Unmarried
No. of patients in IPD	64	10
No. of patients in OPD	11	15
Total	75	25

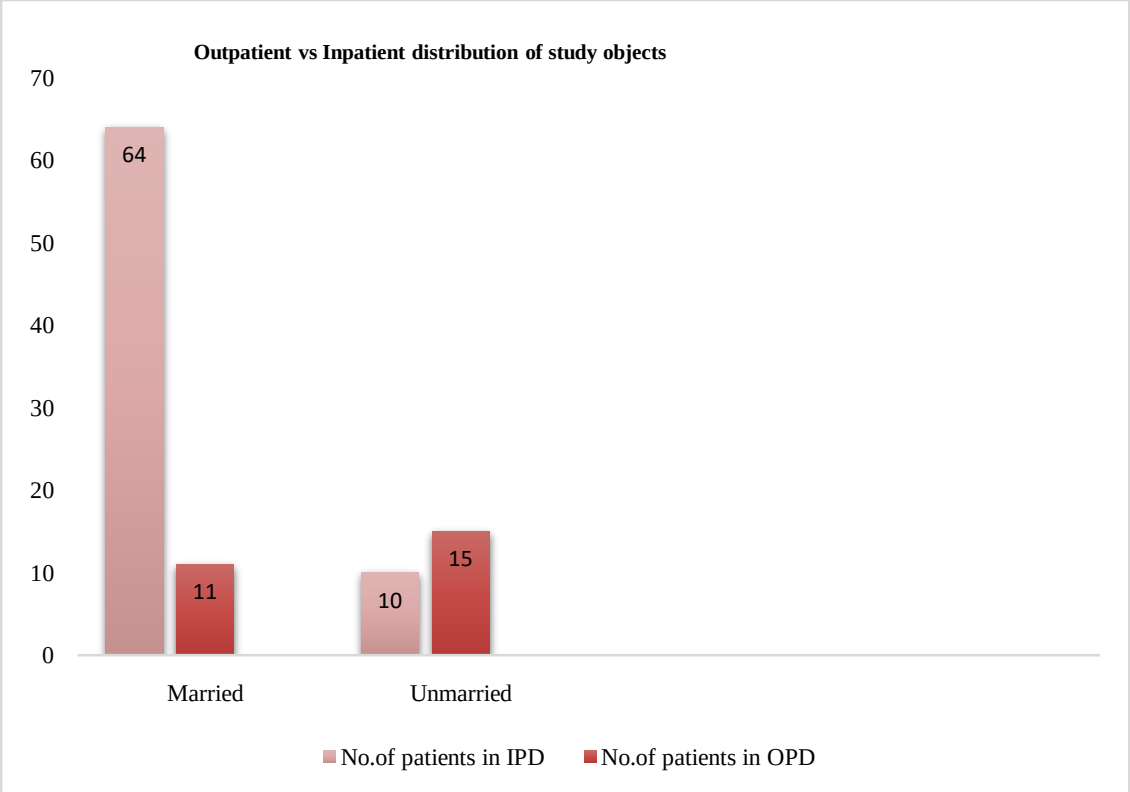

Figure 4:- Out-patient vs Inpatient distribution of study objects.

4) Types/Categories of drugs prescribed

In this study,100 prescriptions were analysed. During the study it was observed that the most frequently prescribed drugs were combined oral contraceptives (Table 6; Figure 5).

Table 6:- Types/Categories of drugs prescribed.

Prescribed drugs	Place in therapy	No. of drugs prescribed
Oral Contraceptives	Regulation of menstrual cycle	38
Clomiphene citrate	Ovulation induction	16
Metformin	Androgen excess,hyperinsulinemia,anovulation	7
Antifibrinolytics	Abnormal bleeding	25
NSAIDs	Dysmenorrhoea	14

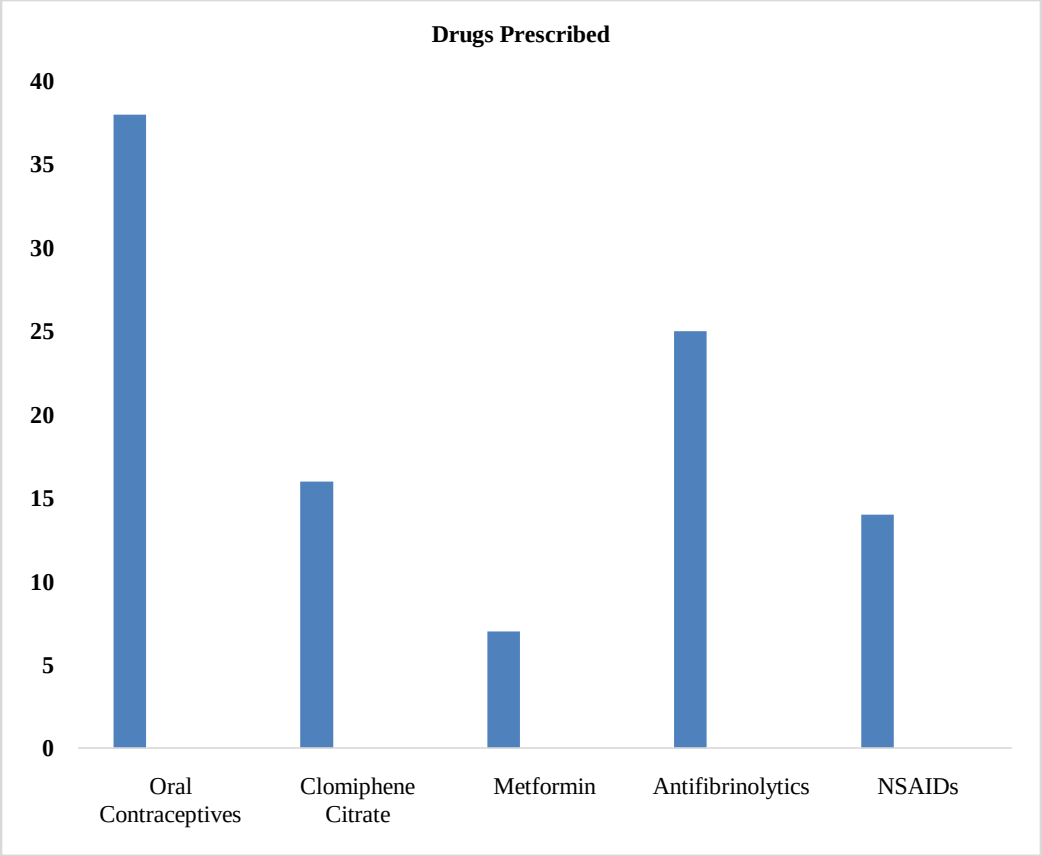

Figure 5:- Types/Categories of drugs prescribed.

5) Assessment of ADRs

Total three types of adverse drug reactions (ADRs) were reportedi.emetrorrhagia, pelvic pain and abdominal discomfort. The most prevalent ADR was metrorrhagia, which occurred in four patients who were taking oral contraceptives. Two patients experienced pelvic pain as a result of clomiphene citrate use. Additionally, one patient reported abdominal discomfort associated with metformin.

However,drugs commonly used to treat PCOS appear to be associated with very low risk of severe adverse effects (Table 7; Figure 6).

Table 7:- Assessment of ADRs.

Types of ADRs	No.of patients	Suspected drugs
Metrorrhagia	4	Oral Contraceptives
Pelvic pain	2	Clomiphene Citrate
Abdominal discomfort	1	Metformin

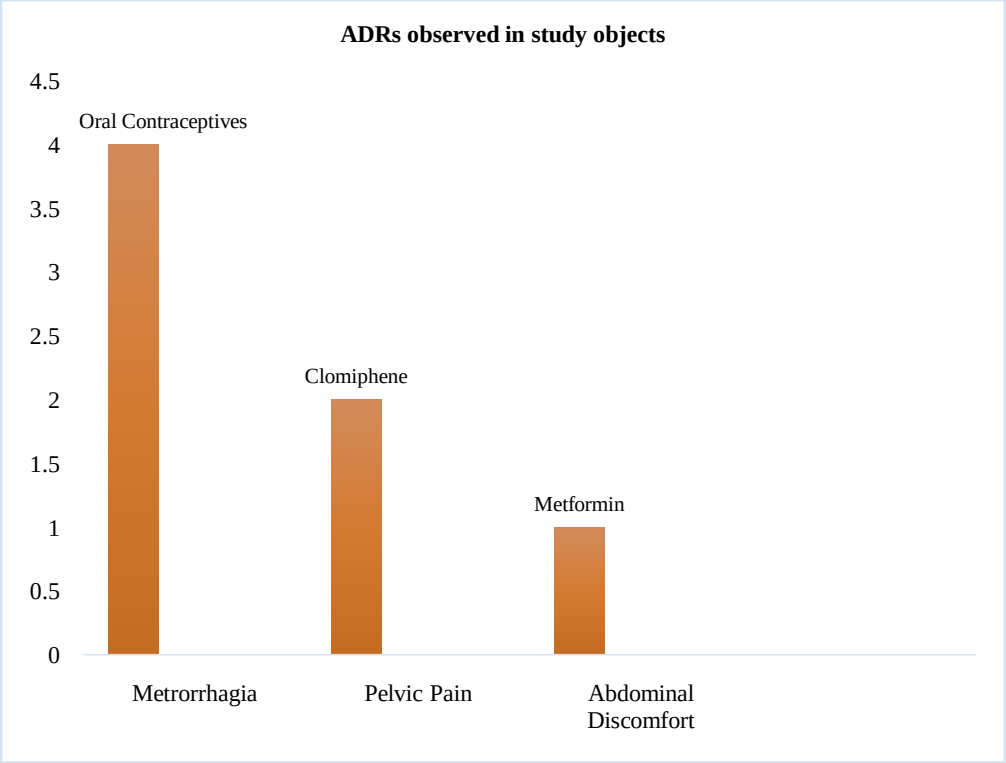

Figure 6:- Assessment of ADRs.

Discussion:-

The importance of a stout healthcare system in developing countries cannot be overstate (Wasim et al., 2023).Accessible and quality healthcare is crucial for improving overall well-being, reducing mortality rates, and fostering economic growth (Singh et al., 2021). In the global scenario, supporting healthcare in these nations is vital to tackle pandemics, achieve global health goals, and promote equitable healthcare for all (Tiwari & Siddiqui, 2018).

Polycystic ovary syndrome (PCOS) is a common hormonal disorder among women of reproductive age.It is characterized by a combination of symptoms, including irregular periods, excess androgen levels, and the presence of cysts on the ovaries.

In this study, we examined various aspects related to polycystic ovary syndrome (PCOS)& menstrual disorders and their management among 100 patients.The findings shed light on patient demographics, age distribution, types of disorders, drug treatments, and the role of lifestyle modifications in managing PCOS and menstrual disorders. It was found that (82.7%) of the patients diagnosed with PCOS were married and (17.3%) were unmarried(Sidra et al., 2019).Our analysis also revealed that a majority of the patients (75%) were married, while 25% were unmarried.However,future research could delve deeper into understanding the relationship between marital status, stress levels, lifestyle choices, and fertility goals in the context of PCOS.In a study it was found that maximum number of PCOS patients were from the age group of 15-30 years (Sidra et al., 2019).

In our study,it was found that the maximum number of PCOS patients fell within the age group of 25-30 years.This aligns with previous research indicating that PCOS is more prevalent among younger women.The hormonal changes and fluctuations during the reproductive years, coupled with various lifestyle factors, may contribute to the higher occurrence of PCOS in this age group.Among the patients, the most common disorders observed were polycystic ovary disorder (PCOD), fibroids, and menstrual disorders. PCOD accounted for 30% of the cases, followed by menstrual disorders (50%) and fibroids (20%).These findings highlight the significance of PCOD as a major concern in PCOS patients, consistent with its known association with multiple cysts on the ovaries.

In a certain study the most commonly prescribed drugs for PCOS were Oral Contraceptives (OCPs) (Pkhaladze et al., 2021).

In our study of 100 patients, the most frequently prescribed medication were oral contraceptives (OCPs) (38%). OCPs are commonly used to regulate menstrual cycles and reduce androgen levels in PCOS. Additionally, antifibrinolytics (25%), clomiphene citrate (16%), metformin (7%), and NSAIDs (14%) were prescribed to manage specific symptoms and conditions associated with PCOS.These medication choices were tailored based on individual patient characteristics, symptoms, and medical history.

While medication plays a crucial role, our study also highlighted the importance of lifestyle modifications in managing PCOS. Although only a few patients were treated with lifestyle modifications, incorporating regular exercise, a balanced diet, stress reduction techniques, and healthy sleep patterns can complement medical interventions and improve overall outcomes. Future research should further explore the effectiveness and long-term impact of lifestyle modifications in PCOS management.

Overall 3 types of ADRs were reported during the study. Metrorrhagia was the most common ADR observed in 4 patients whereas pelvic pain observed in 2 patients and abdominal discomfort was found in 1 patient.It was observed that physicians realized their role in spontaneous ADR reporting contributed immensely to the pharmacovigilance program.

Conclusion:-

This study on polycystic ovary syndrome (PCOS) & menstrual disorders among 100 patients provided valuable insights into various aspects of the disorder and its management. The age distribution of patients indicated that PCOS is more prevalent among younger women, particularly within the age group of 25-30 years, suggesting a possible link between hormonal changes during reproductive years and PCOS occurrence. Regarding the management of PCOS, Oral Contraceptives (OCPs) were the most frequently prescribed medication to regulate menstrual cycles and reduce androgen levels. Additionally, other medications like clomiphene citrate, metformin, antifibrinolytics and NSAIDs were used based on individual patient characteristics and symptoms. The study also highlighted the importance of lifestyle modifications in managing PCOS. Regular exercise, a balanced diet, stress reduction techniques, and healthy sleep patterns were identified as essential complements to medical interventions for improved outcomes. Further research is needed to explore the effectiveness and long-term impact of lifestyle modifications in PCOS management.

During the study, three types of adverse drug reactions (ADRs) were reported, with metrorrhagia being the most common, followed by pelvic pain and abdominal discomfort. The role of physicians in spontaneous ADR reporting was crucial in contributing to the pharmacovigilance program. The insights gained from this study can guide future research and clinical practices to better address the complexities of PCOS and provide optimal care for affected patients.However the study has its own limitation since follow up of some patients was not possible and hence the effectiveness of the drugs could not be assessed.

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Consent For Publication

All authors have given their concerns for the publication of this manuscript.

Availability Of Data And Material

All data have been mentioned in the manuscript, no other data are with the authors.

Competing Interests

The authors declare that there are no possible conflicts of interest concerning the research, authors, and/or publication of this article.

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Ethics Approval And Consent To Participate
This article contain studies with human participants. The work was approved by institutional ethics committee, IIMS&R Integral University, Lucknow having approval number (IEC/IIMS&R/2023/57).

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