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PATIENT-REPORTED ADVERSE DRUG EFFECTS IN PCOS TREATMENT: A QUESTIONNAIRE-BASED STUDY

Rutuja L. Kumare*[1], D. Bawankar[1], G. Wadhankar[1]

[1*]Department of Pharmaceutics, Anurag College of Pharmacy Warthi, Bhandara, Maharashtra, India.

ABSTRACT

PCOS, or polycystic ovarian syndrome, is a complex physiological disorder that primarily results in infertility in women who are of a reproductive age. Insulin resistance, polycystic ovaries, hyperandrogenism, and chronic anovulation are its hallmarks. Drug therapy and lifestyle changes are common components of management. However, adverse drug reactions (ADRs) are frequently linked to the medications used to treat PCOS, which can lower therapeutic efficacy and compliance. This case study aims to evaluate the adverse effects of first and second-line PCOS treatments. Despite their effectiveness, first-line medications like clomiphene, metformin, combined oral contraceptives and anti-androgens can result in lactic acidosis, thrombosis, ovarian hyperstimulation, gastrointestinal distress and hormonal imbalance. Hepatotoxicity, osteoporosis, hypertension and cardiovascular disease can result with second-line medications such as letrozole, flutamide, sibutramine and desogestrel/ethinyl estradiol. The adverse effects of these medications can have a substantial influence on long-term health outcomes, even while they treat problems like infertility, hirsutism and metabolic dysfunction. Through patient surveys and data analysis, this study emphasizes the significance of tailored treatment, cautious medication selection and ongoing ADR monitoring. Further research is needed to develop safer, more targeted medications that improve symptom management and the overall quality of life for women with PCOS.

KEYWORDS

Polycystic Ovarian Syndrome (PCOS), Adverse Drug Reactions (ADRs), Pharmacological treatment, Insulin resistance and Individualized therapy.

Author for Correspondence:

Rutuja L. Kumare,
Department of Pharmaceutics,
Anurag College of Pharmacy, Warthi,
Bhandara, Maharastra, India.

Email: rutukumare316@gmail.com

INTRODUCTION

The adverse effects of these medications can have a substantial influence on long-term health outcomes, even while they treat problems like infertility, hirsutism and metabolic dysfunction. Through patient surveys and data analysis, this study emphasizes the significance of tailored treatment, cautious medication selection, and ongoing ADR monitoring. To create safer, more focused treatments that enhance symptom management and the general quality of life for women with PCOS, additional research is required[1,2].

Swollen eggs and small cysts on the edge due to hormonal imbalances. The cause of polycystic ovary syndrome (PCOS), believed to be a combination of genetic and environmental factors, remains unclear. PCOS is the most common endocrine condition of women[1-6]. PCOS is an endocrine disorder that affects several bodily functions, causing growth, metabolic and psychological problems[7].

After observing a woman with abnormal menstruation, obesity and hirsutism, as well as cysts in her ovaries, Stein and Leventhal discovered PCOS in 1935. These women were once called "freaks" or "bearded women / ladies" a decade ago. Estrogen, progesterone, testosterone and androgen are hormones thought to be uncontrollable during PCOS[8].

WHAT IS PCOS?

Up to 10% of women in their reproductive years have PCOS, or polycystic ovarian syndrome, a common hormonal condition that makes them create more male hormones than they normally would. In order to maintain a healthy menstrual cycle, a woman's ovaries may have complications due to a difference in sexual hormones. Corresponding to that-women who have PCOS tend to have non-uniform periods and have problems getting pregnant. In addition to being the primary cause of infertility, irregular periods are also responsible for the growth of tiny, fluid-filled sacs in the ovaries known as cysts. only to discover they have PCOS after gaining a significant amount of weight or experiencing difficulty becoming pregnant[2,3].

SYMPTOMS

During the period of menarche during puberty, PCOS symptoms and indicators often develop. Sometimes women only discover they have PCOS after gaining a significant amount of weight or experiencing difficulty becoming pregnant.

PCOS has a variety of symptoms. Typical signs of PCOS include

Heavy bleeding during menstruation

If the uterine border takes longer than usual to enlarge, you should anticipate to experience more severe bleeding than usual.

Non- Uniform (or no) Periods

Ovulation prevented the uterine barrier from being destroyed every two months. Some women may not receive their period at all, while others may only get about eight periods annually.

Excess (Body) Hair Growth

Due to an overabundance of male hormones, women with PCOS frequently have hirsutism, or excessive face and body hair development.

Hormonal Acne

Male hormones cause an overabundance of oil to be produced, which is likely to manifest as acne on your face and upper back.

Hair Loss/Thinning

Because of all the male hormones, the hair on your scalp starts to thin as the rest of your body grows in excess.

Headaches

Headaches can be triggered by a variety of hormonal changes that people with PCOS experience.

Dark Complexioned Skin

Dark areas of skin, particularly on the neck, groin, and under the breasts, are common in women with PCOS.

Polycystic ovaries

The follicles that surround the egg may be accommodated by your enlarged ovaries. Additionally, the ovaries may not function regularly[3-5].

TYPES OF PCOS

Insulin Resistant PCOS

About 70% of patients have this kind of PCOS, which is the most common. Insulin resistance, commonly referred to as hyperinsulinemia, is mostly caused by the body having higher than normal levels of insulin[6].

Post-pill PCOS

Many people develop post-pill PCOS after stopping the oral contraceptive pill. Because it uses synthetic progestogen, this kind of PCOS is often associated with oral contraceptives like Ginet, Yasmin and Yaz. Although insulin resistance does not develop with this type of PCOS, your ovaries primarily throw a party after stopping the pill, causing an increase in androgens that can cause normal symptoms[9].

Adrenal PCOS

This PCOS as consequence of an atypical stress responce and influence about 10% of those diagnosed. This type of androgen woefully isn't frequentally tested, except on condition that you go through an endocrinologist or other specialist[10].

Inflammatory PCOS

In inflammatory PCOS, chronic pain triggers the ovaries to overproduce testosterone, which results in symptoms and ovulation problems. Inflammatory symptoms of this kind of PCOS include dermatitis, joint discomfort, migraine, unexplained exhaustion, and bowel issues, for example. Syndrome of Irritable Bowel[10].

DIAGNOSIS

It is impossible to definitively diagnose PCOS with any test. The patient's medical history, including any changes in weight or menstruation, would likely be reviewed by the doctor first. Acne signs, insulin resistance, and excessive hair growth will all be looked at during a physical examination. The physician might then suggest:

A pelvic exam

The doctor looks for growths, lumps, or other abnormalities in your reproductive organs by looking and physically examining them.

Blood tests

An analysis of your blood might reveal your hormone levels. This test can rule out possible causes of irregular menstruation or androgen excess that mimics PCOS. Your glucose tolerance, fasting cholesterol and triglyceride levels may be evaluated by additional blood tests.

An ultrasound

The appearance of your ovaries and the thickness of your uterine lining are examined by your physician. A transducer, which looks like a wand, is inserted into your vagina during transvaginal ultrasonography. On a computer screen, sound waves from the transducer are transformed into images. If a patient has been diagnosed with PCOS, a physician may recommend additional testing for issues.

Fasting Glucosre Level

You must abstain from food and liquids for at least eight hours before to the test. These examinations may consist of

Regular monitoring of blood pressure, glucose tolerance, triglycerides and cholesterol

Anxiety and depression screening.

Obstructive sleep apnea screening[11,12].

TREATMENT

The goal of PCOS treatment is to address each patient's unique issues, such as obesity, hirsutism, acne, or infertility. Medication or lifestyle modifications may be part of a specific treatment.

LIFESTYLE CHANGES

A doctor can suggest that a low-calorie diet and moderate exercise be used to help people lose weight. A minor weight loss, such as losing 5% of your body weight, may be beneficial for your condition. Losing weight may not only aid with infertility but also increase the effectiveness of PCOS medications that doctors prescribe.

MEDICATIONS

To regulate the menstrual cycle, a doctor might recommend the following:

Combination birth control pills

Progestin and estrogen-containing pills regulate estrogen and lower androgen production. You can treat acne, excessive hair growth, irregular bleeding and avoid endometrial cancer by managing your hormones.

Progestin therapy

Progestin should be taken for 10 to 14 days every one to two months to regulate your cycles and avoid endometrial cancer. Progestin therapy won't increase androgen levels or prevent pregnancy.

In order to facilitate ovulation, your physician may suggest:

Clomifene

This oral anti-estrogen medication is taken throughout the early stage of your menstrual cycle.

Letrozole (Femara)

This medicine for breast cancer may stimulate the ovaries.

Metformin

This oral therapy for type 2 diabetes lowers insulin resistance and insulin levels. If you have prediabetes, metformin can help you lose weight and slow the progression of type 2 diabetes.

Gonadotropins

These hormone medications are administered by injections.

In order to curb excessive hair growth, your doctor may suggest:

Birth control pills

These drugs lower testosterone production, which may result in excessive hair growth.

Spironolactone (Aldactone)

This medication stops the skin-damaging effects of androgens.

Eflornithine (Vaniqa)

This lotion can help women's facial hair grow more slowly[13-15].

MATERIAL AND METHODS

Place of study- Dr. Prinka Yerne Krushna Hospital

Study Design- Case control study

Sample Size- 30 - 50 Study group

Source of Data- All patient were recruited outpatient department of hospital.

QUESTIONNAIRE

Do you have irregular or heavy period?

Yes

No

Maybe

Do you often feel hungry or frequently have sugar craving?

Yes

No

Maybe

Did your physician asked you to avoid high intensity exercise?

Yes

No

Maybe

Do you often have joint pain or migraine?

Yes

No

Maybe

Are you having problem of persistent cough?

Yes

No

Maybe

If yes then your glucose or androgen level elevated or not?

Yes

No

Maybe

Do you have rapid heart beat and swollen legs, swollen face and swollen tongue?

Yes

No

Maybe

RESULTS AND DISCUSSION

Discussion

These days, polycystic ovarian syndrome, or PCOS, is a highly common endocrine disorder that affects women's health. PCOS is a chronic disorder that manifests physiologically and reproductively. Over time, it can lead to infertility and an increase in metabolic issues. Common side effects including vision disturbance, skin issues, gastrointestinal distress, multiple gestation and breast soreness might occasionally also have an impact on their way of life.

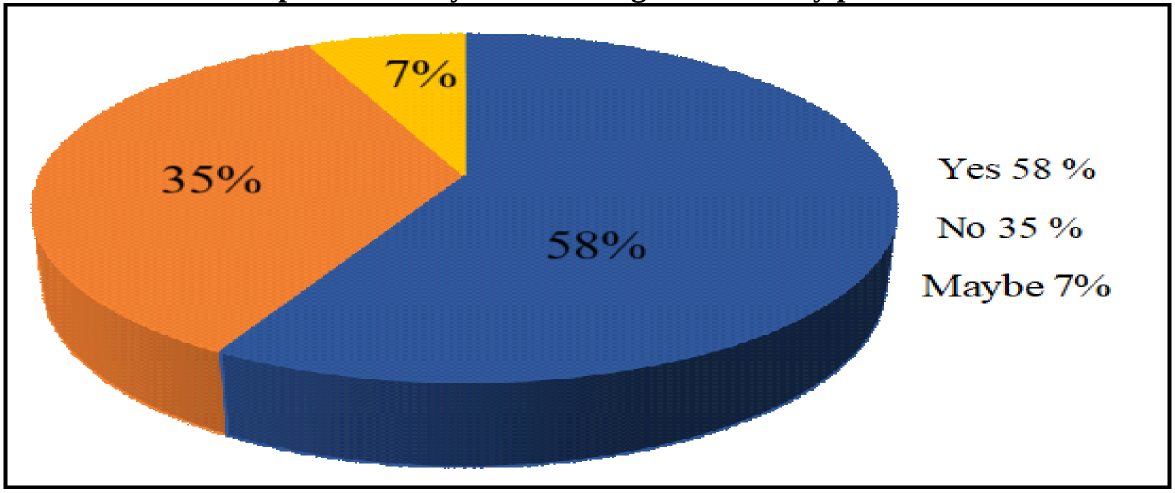
Table No.1: First line drug therapy

S.No	Drugs	Uses	Advers Drug Reaction (ADR)
1	Clomifene (clomid)	Ovulation Induction in Infertile Women	1.Multiple Pregnancy 2.Thromboembolism 3.Visual Disturbance 4.Multiple Gestation
2	Eflornithine (vanique)	Inhibit Hair Growth	1.Mild Skin Irritation
3	Metformin (Glucophase)	Insulin Sensitizing Agent	1. G.I Upset 2.Lactic Acidosis 3. Anorexia
4	Oral Contraceptive (Combination Pills, Progestin Only)	Regulation of the Menstrual Cycle	1. Breast Tenderness 2.Fluid Retention 3.Increse Risk of Thrombophlebitis
5	Pioglitazome (Actas)	Insulin Sensitizing Agent	1.Congestive Heart Failure 2.Edema
6	Spiranolactone (Aldactone)	Antiandrogenic	1.Hyperkalemia 2.Hypotension 3.Breast Tenderness
7	Gonadotropin	Ovulation Induction	1.Injection Site Reaction 2.Multiple Pregnancy[13]

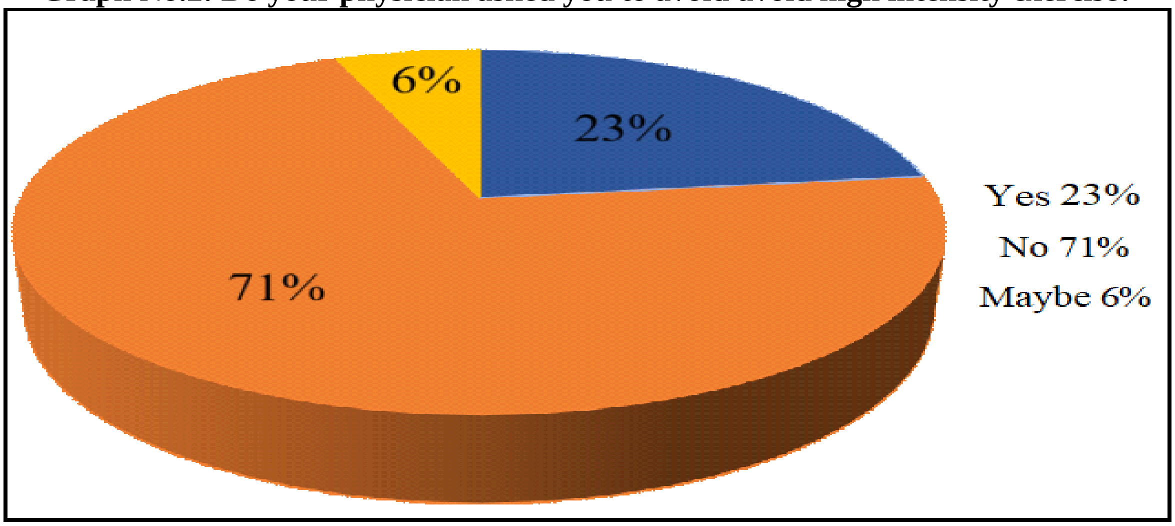
Table No.2: Second Line Therapy

S.No	Drugs	Uses	Advers Drug Reaction (ADR)
1	Acarbose (Precose)	Insulin Sensitizing Agent	1.G.I Upset
2	Desogestrol (Apri)	Oral Contraceptive	1.Increase Total Cholesterol 2.Thromboembolism 3.Sroke
3	Flutamide (Formerly Eulexin)	NSAID Nonsteroidal Antiandrogen used mostly in Prostate Cancer	1.Thrombocytopenia 2. Leucopenia 3. Liver Toxicity
4	Letrozole (Femora)	Nonsteroidal Competative Inhibitor of Aromatase	1.Osteoporesis 2.Myocardial Infraction 3.Anthralgia
5	Sibutramine (Meridia)	Centrally acting appetite suppresant	1.Tachycardia 2.Hypertension 3.Headache[13]

Graph No.1: Do you have irregular or heavy periods?



Graph No.2: Do your physician asked you to avoid avoid high intensity exercise?



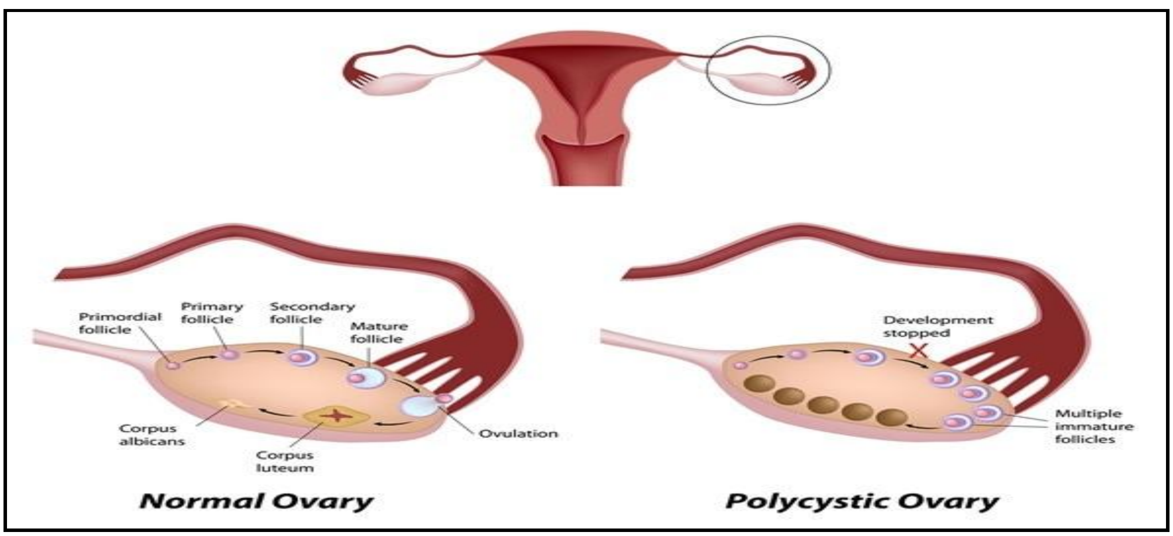


Figure No.1: Polycystic ovarian syndrome

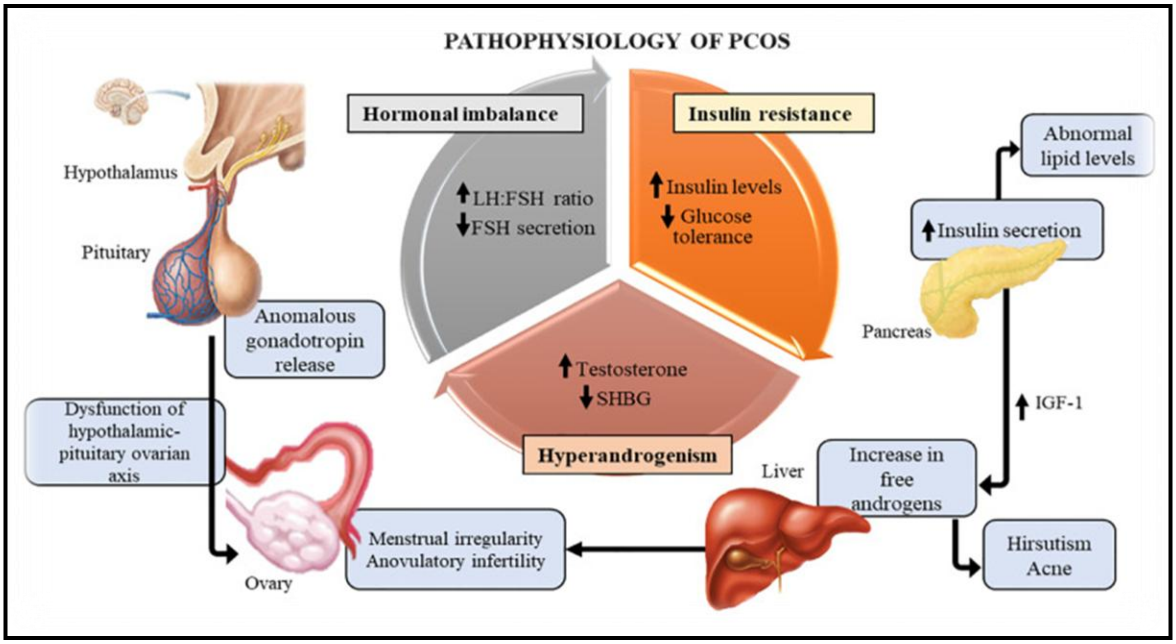


Figure No.2: Pathophysiology of PCOS

LIMITATIONS OF THE STUDY

There are several restrictions on this study. There are some serious risks associated with long-term PCOS medication use, however not all of the drugs used to treat the condition have complicated side effects.

CONCLUSION

In conclusion, our research, which was carried out on a representative sample of PCOS patients, shows that, unless the treatment is taken for an extended period of time, there are no significant side effects from PCOS drugs. We found that using specific medications increases the chance of osteopoeresis, heart failure, anorexia, multiple gestation and depression in women as well as physical weakness. Additionally, more research and study on this subject are needed.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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