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RESEARCH ARTICLE
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A PROSPECTIVE OBSERVATIONAL STUDY ON DRUG USED IN POLYCYSTIC OVARIAN SYNDROME IN WARANGAL REGION

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INTRODUCTION

Definition:

Polycystic Ovarian Syndrome (PCOS), also referred to as hyperandrogenic anovulation (HA), or Stein–Leventhal syndrome , is one of the most common endocrine system disorders that affect women in their reproductive age . Since it is described by Stein and Leventhal in 1935.

Polycystic ovary syndrome (PCOS) is a complex condition characterized by elevated androgen levels, menstrual irregularities, and small cysts in one or both ovaries. The disorder can be morphological (polycystic ovaries) or predominantly biochemical (hyperandrogenemia).

MATERIALS AND METHODS:

Study site: Laxmi Narasimha, Warangal.
Study design: Prospective and Observational studies
Study Period: Six months
Study criteria:

Inclusion criteria:

• Patients determined to have PCOS and on the treatment of medications for example clomiphene citrate, letrozole, medroxyprogesterone acetic acid derivation
• Outpatients.
• Patients with comorbidities
• Patients who are willing to give their assent

Exclusion criteria:

• Patients who are not able to give their education assent structure
• Pregnant ladies

Source of data:

All the relevant and necessary data will be collected from
• Patient case notes
• Patient prescriptions
• By meeting the patients
• Laboratory data

To ensure that all of the information is properly documented and accounted for, a reliable data collection form will be developed.

Methodology:

After getting moral freedom from the foundation, the review group moved toward suitable patients in emergency clinics.

Enrollment of subjects in the review will be based on incorporation standards.

All of the information about hospitalized patients who have signed up is gathered from their medicine graphs and notes, and this information is then recorded in a well-planned way.

All gathered information was examined utilizing an important factual strategy.

Study instruments:

The study team used a data collection form that includes the following details:

- Demographics of the patient (age, gender, ip.no, etc….)
- Past clinical history and clinical history of social and family ancestry
- Lab data including hormones levels i.e., TSH, FSH, AMH, LH, PROLACTIN
- Day-wise medication among the patients.
- Current patient explicit drugs.

STATISTICAL ANALYSIS:

People who took clomiphene citrate, letrozole, or medroxyprogesterone acetate were compared based on their clinical and procedural characteristics at the start of the study. Continuous variables were presented as means +/- standard deviations. Categorical variables were presented as percentages. Independent subjects with clomiphene citrate, letrozole, and medroxyprogesterone acetate were estimated using the "analysis of variance" model. Variables included were age, marital status, efficacy parameters, and safety parameters.

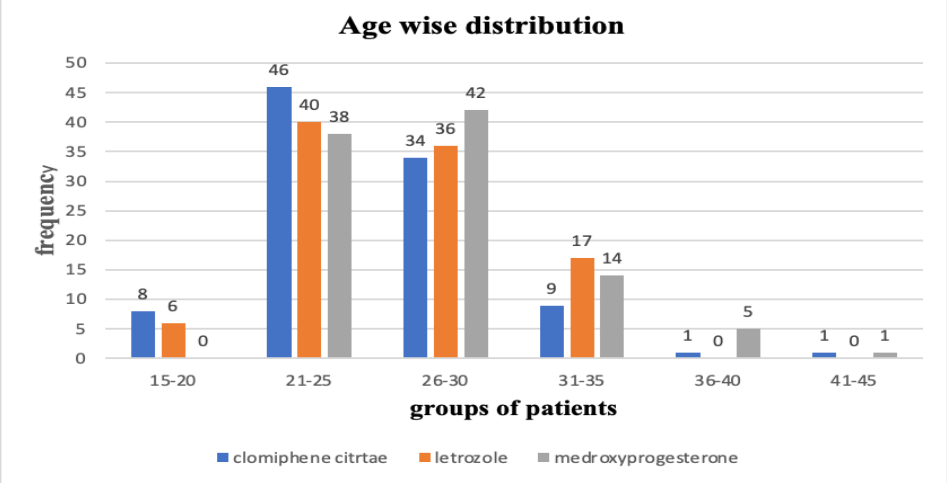
RESULTS & DISCUSSIONS

RESULTS:

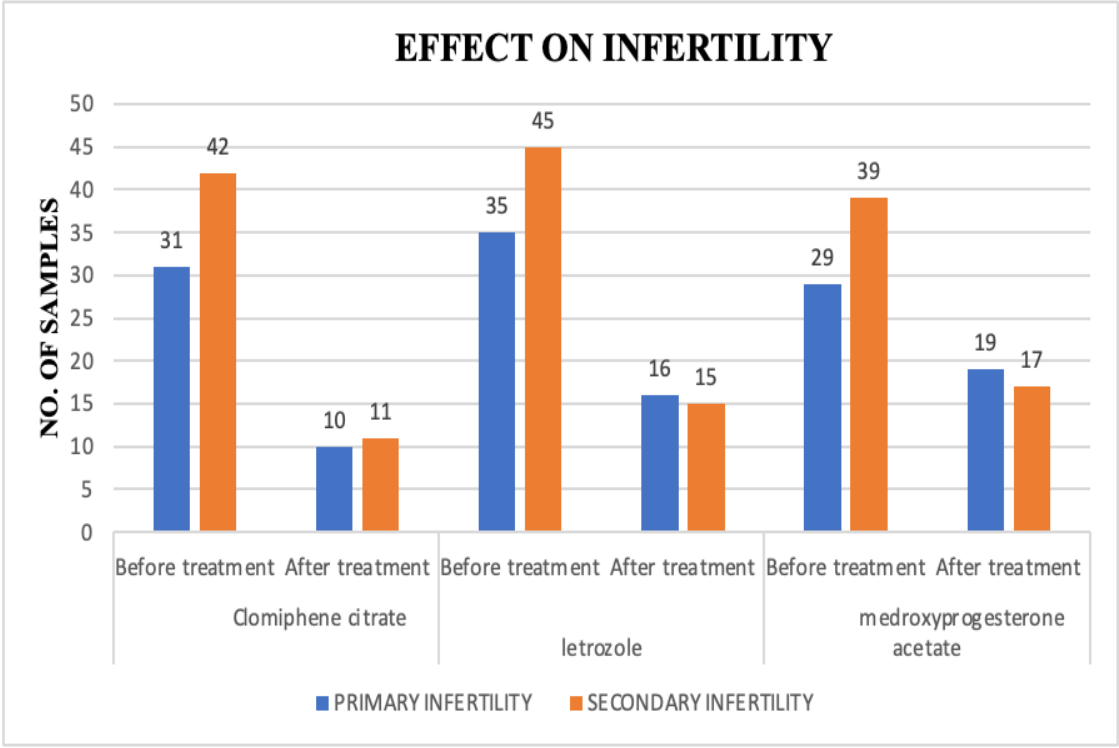
- In total, there were 300 samples used for this research project. Following this, one hundred patients were given treatment with clomiphene citrate, one hundred patients were given treatment with letrozole, and one hundred patients were given treatment with medroxyprogesterone acetate.

AGE-WISE DISTRIBUTION:

- The age groups were categorized from 15-20 to 41-45. The mean ages of the patients in the clomiphene citrate group, letrozole g group, and medroxyprogesterone acetate group were 25.46 +/- 4.04, 26.17 +/-4.07, and 30.48 +/-25.45, respectively. The distribution of ages among all the groups is shown in figure 1 and table 1.



Here, 31 patients had primary infertility before receiving clomiphene citrate, which was reduced to 10 patients after the treatment. It means that 21 patients were conceived after the treatment with clomiphene citrate. Similarly, in the cases of letrozole and medroxyprogesterone acetate, 19 and 10 patients were conceived, respectively. 42 patients were having secondary infertility before receiving clomiphene citrate, which was reduced to 11 after the treatment, so here, 31 patients were conceived after the treatment with clomiphene citrate. Similarly, 30 and 22 patients conceived after receiving letrozole and medroxyprogesterone acetate, respectively, and the effects of the 3 drugs on infertility were shown in table 6 and figure 9.



CHARACTERISTICS	CLOMIPHENE CITRATE n=100	LETROZOLE n=100	MEDROXYPROGESTERONE ACETATEn=100
MEAN+/-SD	25.46+/-4.04	26.17+/-4.07	30.48+/-25.4
AGE IN YEARS	Percentage	Percentage	Percentage
15-20	8%	6%	0%
21-25	46%	40%	38%
26-30	34%	36%	42%
31-35	9%	17%	14%
36-40	1%	0%	5%
41-45	1%	0%	1%

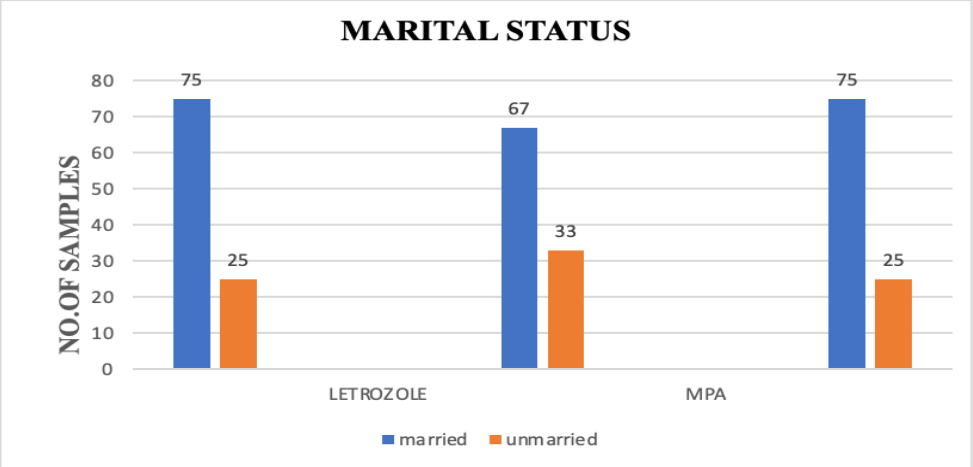
Table 1: AGE DISTRIBUTION

MARITAL STATUS:

Table 5 displays the marital status. Most married women were from groups 1, 3, and then 4. In a distribution of women who have never been married, most people came from groups 1 and 3.

Table 2: Marital Status

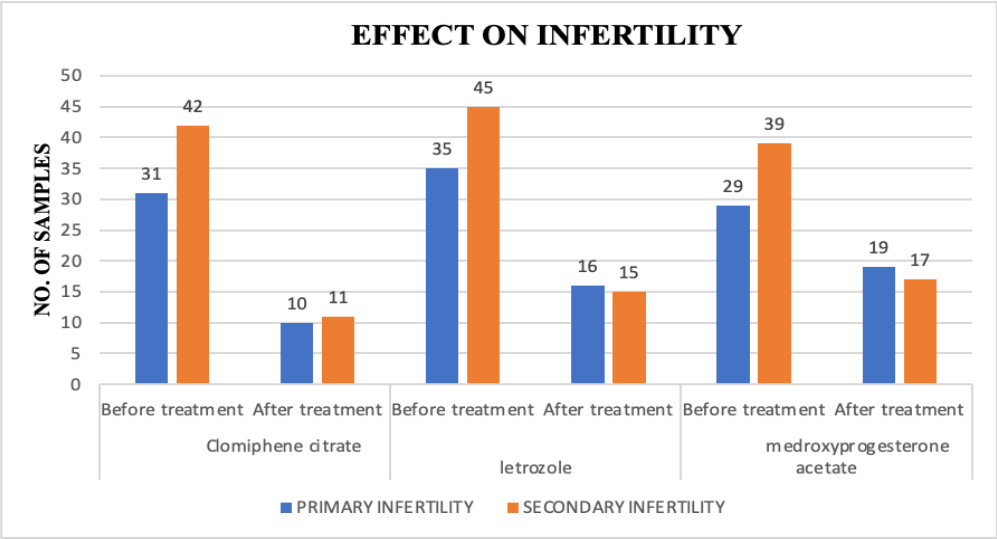
GROUP	MARRIED%	UNMARRIED%	TOTAL%
CLOMIPHENE CITRATE	75%	25%	100%
LETROZOLE	67%	33%	100%
MEDROXYPROGESTERONE ACETATE	75%	25%	100%



EFFECT ON INFERTILITY: Because PCOS causes oligo- or anovulation, it causes ovulatory dysfertility and infertility, which must be properly evaluated and treated. Clinical assessment was done monthly and at the end of three months, i.e., after therapy.

Table 3. EFFECT ON INFERTILITY

Here, 31 patients had primary infertility before receiving clomiphene citrate, which was reduced to 10 patients after the treatment. It means that 21 patients were conceived after the treatment with clomiphene citrate. Similarly, in the cases of letrozole and medroxyprogesterone acetate, 19 and 10 patients were conceived, respectively. 42 patients were having secondary infertility before receiving clomiphene citrate, which was reduced to 11 after the treatment, so here, 31 patients were conceived after the treatment with clomiphene citrate. Similarly, 30 and 22 patients conceived after receiving letrozole and medroxyprogesterone acetate, respectively, and the effects of the 3 drugs on infertility were shown in table 6 and figure 9.



PARAMETERS ASSESSED:

Clinical parameters:

High androgens are caused by high levels of LH and insulin resistance at the same time. Hyperandrogenism results in a variety of cutaneous manifestations, such as hirsutism, oily skin, acne, acanthosis nigricans, etc. Amongst all cases, 7.3% had hirsutism, 43% had acne, and 4.3% had acanthosis nigricans. As the authors are aware, PCOS is an oligo- or anovulation condition that results in ovulator dysfertility and infertility and requires proper evaluation and management. The effect of the clomiphene citrate group on skin problems is greater when compared to the letrozole group and the medroxyprogesterone acetate group, which is shown in table 7 and figure 10. Out of 52 patients with acne, 26 patients recovered after treatment with clomiphene citrate, which is more compared to other groups.

4: Clinical Parameters in PCOS.

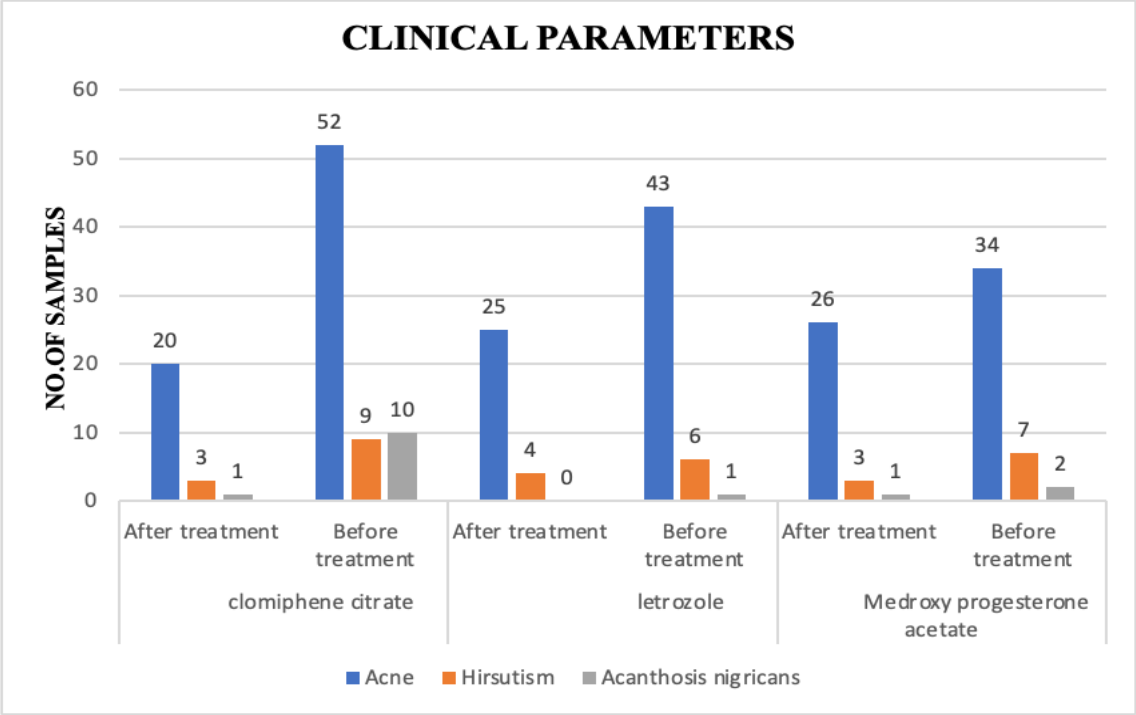


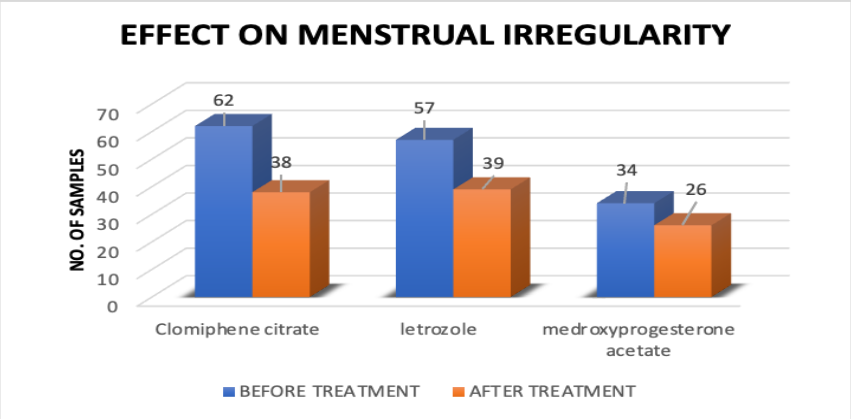
Figure 8: Effects of clomiphene citrate, letrozole, and letrozole medroxyprogesterone acetate on skin problems

IMPACT ON MENSTRUAL ABNORMITY:

While menstrual irregularity is the most common symptom of PCOS, if left untreated, it causes severe complications. So, it is important to get managed. In this study, 24 out of 62 patients (93.5%) improved when treated with clomiphene citrate, which is more when compared to other treatment groups. Table 8 and Figure 11 show the difference between the number of patients in different groups regarding menstrual abnormality.

Table 5: Effect of the drugs on menstrual abnormalities

TREATMENT DRUG	BEFORE TREATMENT	AFTER TREATMENT	POST-TREATMENT IMPROVEMENT %
Clomiphene citrate	62	38	93.50%
Letrozole	57	39	68.60%
medroxyprogesterone acetate	34	26	76.40%

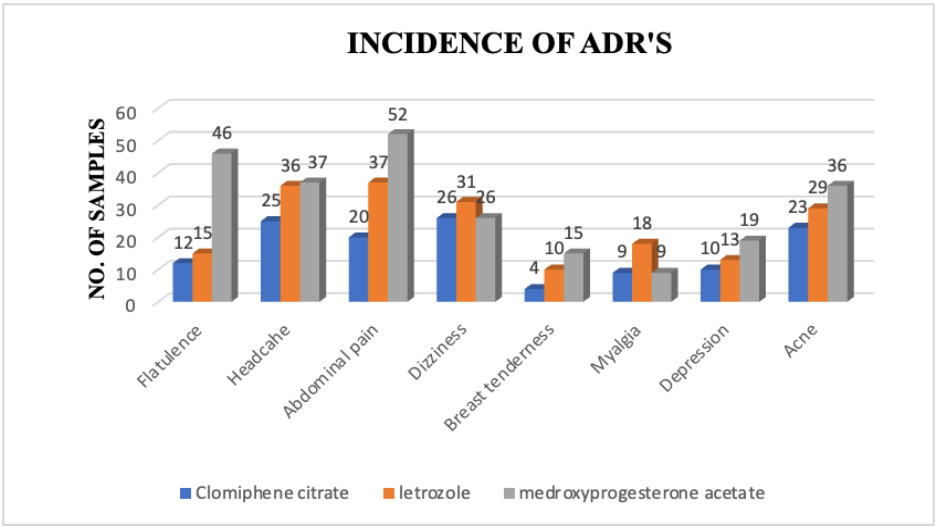


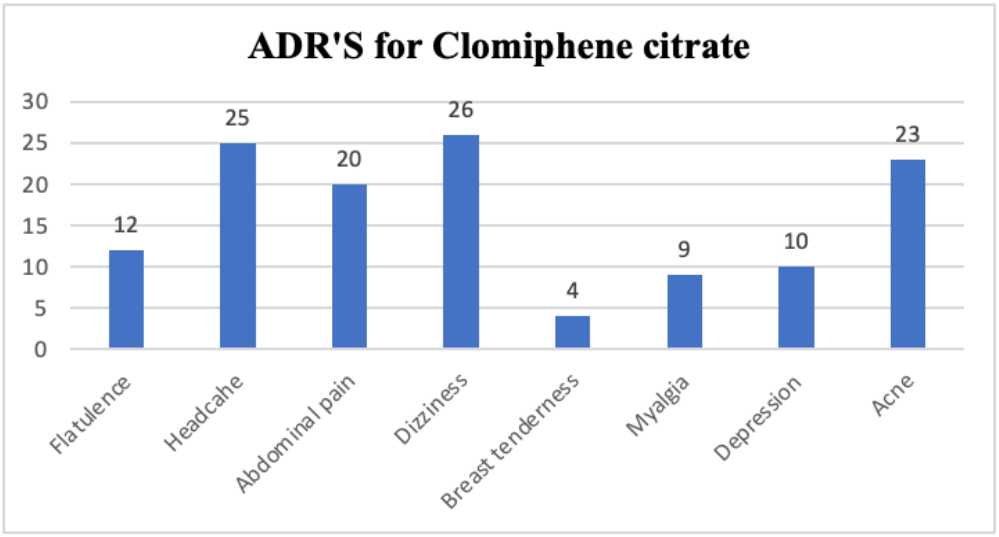
SAFETY PARAMETERS:

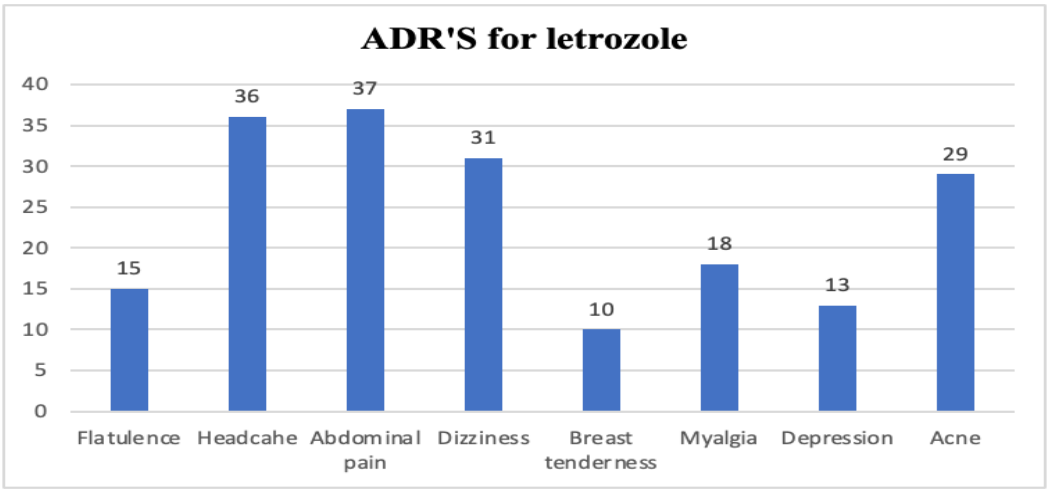
The patients were observed for side effects like flatulence, abdominal pain, headache, dizziness, myalgia, breast tenderness, depression, acne, etc. Any adverse effect reported by the patient was recorded in all the groups. A safety assessment was done at the end of the treatment period. The incidence of various drug reactions was shown in Table 9 and Figure 12. The adverse effects reported were mild in the case of the clomiphene citrate group when compared to the letrozole and medroxyprogesterone acetate group.

Table 6: ADRs that occurred during the treatment period

ADVERSE EFFECTS	Clomiphene citrate	letrozole	medroxyprogesterone acetate	TOTAL
Headache	25	36	37	98
Abdominal pain	20	37	52	109
Dizziness	26	31	26	83
Flatulence	12	15	46	73
Breast tenderness	4	10	15	29
Myalgia	9	18	9	36
Depression	10	13	19	42
Acne	23	29	36	88







DISCUSSION:

• The present analysis at the LAXMI NARASIMHA HOSPITALS investigated the "ASSESSMENT OF SAFETY AND EFFICACY OF FEW COMMONLY USED MEDICATIONS FOR THE TREATMENT OF PCOS" by a prospective observational study

• The treatment for PCOS depends on the severity of the disease. The choice of the drugs and dose of the drugs is based on the patient's age, marital status, type of infertility, irregularity of the menstrual cycle, and lifestyle. Since the drugs prescribed for PCOS will have more adverse drug reactions, it is necessary to evaluate the safety and effectiveness of the drugs in PCOS patients.

LIMITATIONS

• Drug determination depended on the tact of treating gynecologists.

• Prescription consistency and the span of the medication treatment during the follow-up are not entirely settled and add to time changing relationship with clinical results.

• Information on the past clinical history and way of life of the patients was not accessible.

• Information on the follicular review reports of the patients was not accessible.

CONCLUSION

• It is recommended that the patient's specific treatment for PCOS be improved to reduce the risk of adverse reactions (ADRs). An important goal for the improvement of the nation's overall health is the development of effective, low-cost, and risk-free treatments for infertility.

• In general, or according to the results of the upcoming observational study, it seems as though clomiphene citrate is excellent in terms of the ovulation rate. In infertile women with PCOS, the use

of clomiphene citrate was associated with higher rates of both live birth and ovulation when compared to the use of letrozole and derivatives of medroxyprogesterone acetate.

• Clomiphene citrate, a specific estrogen receptor modulator that displaces the negative criticism component of estrogen at the nerve center with a subsequent expansion in ovarian excitement by endogenous gonadotropin, has been used for this sign for quite some time, and it was demonstrated once more that it is a more secure and effective medication for treating PCOS. Clomiphene citrate has been used for quite some time, and it was demonstrated once more that it is an effective medication for treating PCOS.

REFERENCES

1. El Hayek, Samer et al. "Poly Cystic Ovarian Syndrome: An Updated Overview." *Frontiers in physiology* vol. 7 124. 5 Apr. 2016, doi:10.3389/fphys.2016.00124.Accessed March 23,2022[Front Physiol. 2016; 7: 124.Published online 2016 Apr 5]Frontiers in Physiology.
2. Sirmans, Susan M, and Kristen A Pate. "Epidemiology, diagnosis, and management of polycystic ovary syndrome." *Clinical epidemiology* vol. 6 1-13. 18 Dec. 2013, doi:10.2147/CLEP.S37559. Accessed march 20, 2022[Clinical Epidemiology. 2014; 6: 1–13.Published online 2013 Dec 18]Dove press.
3. El Hayek, Samer et al. "Poly Cystic Ovarian Syndrome: An Updated Overview." *Frontiers in physiology* vol. 7 124. 5 Apr. 2016, doi:10.3389/fphys.2016.00124Accessed march 21, 2022[Front Physiol. 2016; 7: 124.Published online 2016 Apr 5]Frontiers in Physiology.
4. Ganie, Mohammad Ashraf et al. "Epidemiology, pathogenesis, genetics & management of polycystic ovary syndrome in India." *The Indian journal of medical research* vol. 150,4 (2019): 333-344. doi:10.4103/ijmr.IJMR_1937_17. Accessed march 22, 2022[Indian J Med Res. 2019 Oct; 150(4): 333–344].