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Original Research Article

Prospective observational study on prescribing pattern of infertility treatment options and their success rates in women with polycystic ovary syndrome at tertiary care teaching hospital

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ABSTRACT

Background: Polycystic ovary syndrome or in shortcut PCOS previously called as Stein-Leventhal syndrome is a primary and major cause of anovulatory infertility in women of child bearing ages. 3 in every 5 women with PCOS have trouble getting pregnant. Various therapeutic options are available in managing several PCOS symptoms and in increasing chances of pregnancy. The aim of the study was to observe the prescribing pattern of infertility treatment options and their individual success rates.
Methods: The study was conducted in out-patient department of obstetrics and gynaecology, tertiary care teaching hospital, Telangana, India. The study included women aged between 18-37 years who were seeking treatment for infertility due to PCOS. Patients were divided into two categories based on their age and treatment they received which was further grouped accordingly.
Results: The frequency of infertility was found to be significantly higher among PCOS women of age group between 23-27 when compared to other age groups. Among infertility treatment options, ovulation induction drugs were mostly prescribed and among supplements folic acid and myo-inositol were widely prescribed as supplements as well as an adjuvant. Patients who received treatment with ovulation inducing drugs showed high success rate.
Conclusions: Lifestyle modifications were chosen as primary therapeutic option. Ovulation induction drugs among infertility treatment options, folic acid and myo-inositol among supplements were the mostly prescribed medicines to treat or improve infertility in PCOS women. Ovulation inducing drugs showed high success rate.

Keywords: PCOS, Stein-Leventhal syndrome, Infertility, Ovulation induction drugs, Supplements, Myo-inositol

INTRODUCTION

Polycystic ovary syndrome (PCOS) is a heterogenous, metabolic and reproductive disorder characterized by multiple fluid filled sacs or cysts on one or both ovaries, elevated androgen levels, menstrual irregularities often associated with psychological symptoms affecting 1 in 10 women of reproductive age.[1-6] PCOS serves as one of the major causes of anovulatory infertility in women with prevalence varying between 70-80%.[1,6-9] The therapy for infertility in PCOS women includes lifestyle modifications, pharmacological and non-pharmacological regimen. The first line choice of treatment often includes life style modifications such as weight loss, physical activity accompanied with healthy diet.[12] The 5-10% weight loss showed significant improvement in PCOS

symptoms and ovulation.[10-13] Metformin, ovulation inducing agents, gonadotropins, *in vitro* fertilisation or IVF, intrauterine insemination or IUI, surgical procedures such as laparoscopic ovarian drilling and other nutritional supplements are the therapeutic approaches to improve PCOS symptoms and increase the fertility chances. Metformin either given alone or combined with lifestyle modifications had significant improvement in symptoms.[19] Clomiphene citrate (CC) and letrozole are the most commonly used drugs that induce ovulation increasing the chances of pregnancy. CC and letrozole either given alone or in combination with metformin or myo-inositol serves as the first line choice of treatment and has shown to have beneficial aspects in treating infertility.[20-23] Recombinant follicle stimulating hormone and human chorionic gonadotropin are the exogenous gonadotropins are preferred as second line choice of infertility treatment in PCOS women when treatment with ovulation induction drugs fail or in patients who ovulated but failed to conceive or in those women who are opting for IUI technique.[14] Intrauterine insemination or IUI also referred as artificial insemination is a technique used alone or in combination with ovulation inducing agents or gonadotropins. Some studies have proved that IUI along with gonadotropins has an increase in the chance of pregnancy.[24] Laparoscopic ovarian drilling is a safe and effective surgical procedure and second line choice of treatment chosen as an alternative to gonadotropins and in those who are CC and letrozole resistant.[26,27] *In vitro* fertilisation or IVF is considered as the third line choice of treatment to treat infertility.[9,14] IVF is said to have 70% chance of pregnancy.[28] IVF is often initiated along with low dose gonadotropins to minimize the side effects.[9] Supplements such as inositol, folic acid, zinc, magnesium, vitamin D, vitamin C are added to the chosen therapy as an adjuvant due to their beneficial aspects in not only managing PCOS symptoms but also to increase the fertility chances.[29,35-38]

Aim and objective

Aim and objectives were to observe and study the choice and prescribing pattern of infertility treatment options and their individual treatment success rates in women with polycystic ovarian syndrome visiting infertility OP at tertiary care teaching hospital.

METHODS

A prospective, observational, comparative study was conducted for a period of six months starting from Sep-2019 to Mar-2020 in the department of obstetrics and gynaecology at a tertiary care teaching hospital, Secunderabad, Telangana, India.

The study population included women of age group between 18-37 years who were having trouble getting pregnant due to PCOS.

Women visiting infertility department due to other reasons, PCOS women below 18 years of age and who are not facing infertility issues are not included in study.

Ethical statement

Ethical approval not applicable for the study.

Procedure

Patient's age, various health parameters along with physiological parameters, previous and present treatment, result of previous treatment, progress of present treatment were taken into considerations. Choosing and prescribing patterns of drugs and treatment options among various PCOS patients seeking treatment for infertility observed.

Based on the age, patients were divided into 4 groups viz; Group 1: 18- 22 years, group 2: 23-27 years, group 3: 28-32 years and group 4: 33- 37 years.

Patients who were treated with similar medicine were put into one group viz; Treatment group 1: Lifestyle modifications, treatment group 2: Metformin, treatment group 3: Ovulation inducing drugs, treatment group 4: Gonadotropins, treatment group 5: Ovarian drilling, treatment group 6: Intrauterine insemination (IUI); treatment group 7: *In vitro* fertilisation (IVF) and treatment group 8: Supplements.

Active follow up was done and progress of treatment was observed.

All the collected and observed information has been documented using self-prepared patient proformas.

Observation of age prevalence, prescribing pattern, progress of treatment and their success rate was done carefully.

End point of study

Number/ percentage population conceived upon treating with various treatment options.

Statistics

Odds ratio was calculated to determine odds (end point of study).

RESULTS

The study included 58 patients of age group between 18-37 years. After observing all the patients, women suffering with infertility due to PCOS was found to be more prevalent among age group 23-27 years accounting for 9% of total sample size. The least number of patients who were suffering with PCOS infertility was observed among the women aged between 33-37 years accounting for 4% of total sample count (Table 1 and Figure 1).

Table 1: Age wise distribution of PCOS patients visiting infertility OP for infertility treatment.

Age groups (in years)	No. of patients
18-22	11
23-27	24
28-32	18
33-37	5

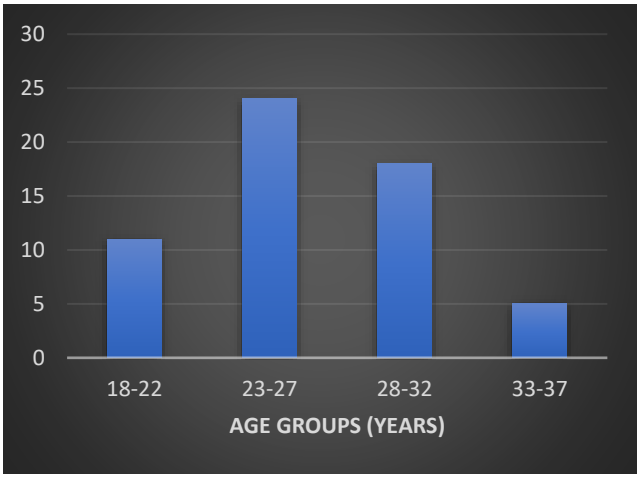

Figure 1: Age wise distribution of PCOS patients visiting for infertility treatment.

From the view of prescribing pattern of fertility boosting drugs, we learnt that ovulation inducing or ovulation induction drugs were prescribed mostly among pharmacological options. Observing the prescribing pattern of drugs and treatment options we found that 31 of 58 patients were put on lifestyle modifications at beginning. The 25 patients were prescribed with drug metformin, 38 patients with ovulation inducing drugs, 15 patients with gonadotropins, 14 patients were suggested ovarian drilling. As well IUI was performed on 13 patients, 5 patients opted for IVF and all 58 patients were prescribed supplements. In some cases, tablet metformin or myo-inositol was added to lifestyle modifications so as to improve symptoms and increases chances of pregnancy (Table 2 and Figure 2).

Observing the outcomes of the prescribed drugs or chosen treatment options, it was found that 18 patients out of 58 patients conceived accounting for 31% of success rate while remaining 40 i.e., 69% patients were still on treatment (Table 3 and Figure 3).

Table 2: Conceived rate of patients during treatment.

Treatment results	No. of patients	Percentage (%)
Conceived	18	31
Patients still on treatment	40	69

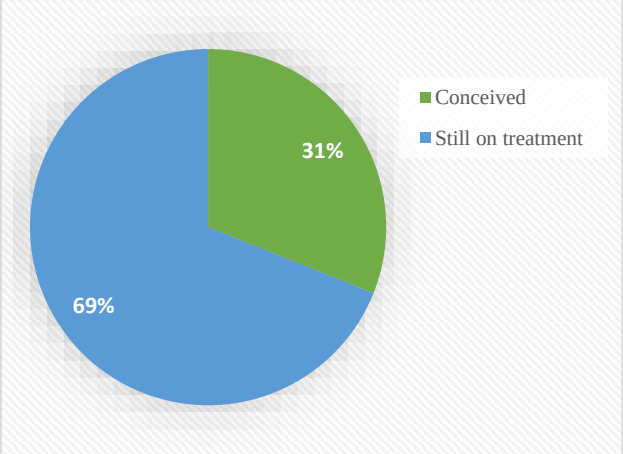

Figure 2: Conceived rate of patients during treatment.

Table 3: Category wise choice of treatment prescribed to the patients.

Choice of treatment	No. of Patients	Percentage (%)
Lifestyle modifications	31	16
Metformin	25	13
Ovulation inducing drugs	38	19
Gonadotropins	15	8
Ovarian drilling	14	7
Intrauterine insemination (IUI)	13	6
Invitro fertilisation (IVF)	5	2
Supplements	58	29

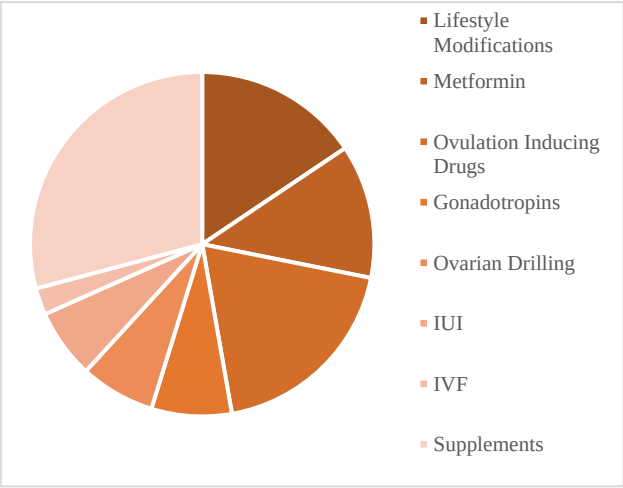

Figure 3: Category wise prescribing pattern of infertility treatment options to the patients.

Supplements are prescribed to all 58 patients. T. Myo-inositol, T. folic acid, T. iron, T. calcium/ vitamin D3, T. multivitamin and T. vitamin C are the supplements prescribed to the patients along with other treatment

options. Among the supplements T. folic acid was mostly prescribed to every patient (Table 4 and Figure 4).

Table 4: Category wise prescribing pattern of supplements.

Supplement name	No. of patients
T. Myo-inositol	35
T. folic acid	53
T. iron	14
T. calcium/ vitamin D3	47
T. Multivitamin	43
T. vitamin C	24

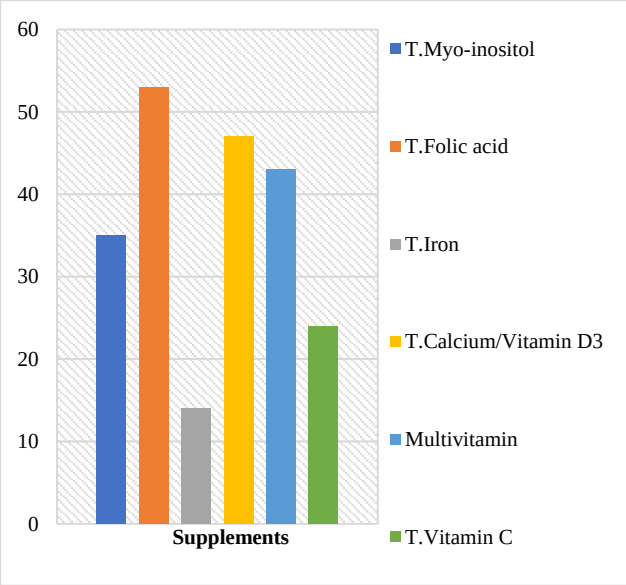

Figure 4: Category wise prescribing pattern of supplements to the patients.

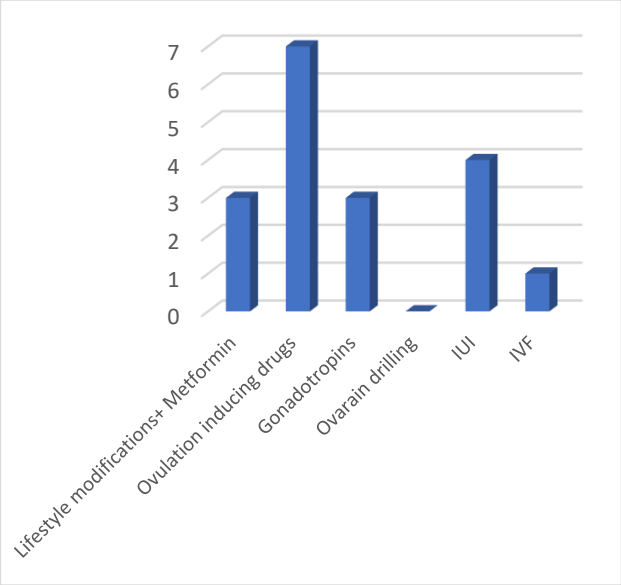

Figure 5: Success rate of individual treatment option prescribed to patients.

Table 5: Success rate of individual treatment option prescribed to patients.

Treatment option	Patients who conceived (%)	Odds ratio
Lifestyle modifications + metformin	3 (17)	0.2
Ovulation inducing drugs	7 (39)	0.64
Gonadotropins	3 (17)	0.2
Ovarian drilling	0 (0)	0
Intra uterine insemination (IUI)	4 (22)	0.28
Invitro fertilisation (IVF)	1 (6)	0.06

Perceiving the prescribing pattern and success rate of all the treatments chosen and prescribed to all the patients, ovulation inducing dugs were primarily chosen and prescribed as first line pharmacological agent when lifestyle modifications failed. Ovulation inducing drugs were found to show high success rate compared to all treatments prescribed, helping 7 patients to bear pregnancy (OR=0.64) while 4 patients got pregnant with the help of IUI (OR=0.28), 3 patients with lifestyle modifications combined with metformin (OR=0.2) and 3 patients with the help of gonadotropins (OR=0.2), 1 patient succeeded in bearing pregnancy with the help of IVF (OR=0.06) whereas, ovarian drilling helped no patient in conceiving (OR=0) (Table 5, Figure 5).

DISCUSSION

PCOS has become so prevalent that 1 in every 10 women of reproductive age are affected.[3] Of all the complications that a PCOS cause, anovulatory infertility is the major one that affects 70-80% of women.[1,6-9] Symptoms of PCOS include hair loss, hirsutism, acne, menstrual irregularities, fertility issues, metabolic and psychological disturbances.[4-6] Therefore, the treatment for PCOS infertility not only aims at boosting fertility rates but also aim at treating symptoms.[6] However, before initiating infertility treatment in PCOS women, detailed examination is performed to identify the actual cause of infertility other than ovulation related problem(s).[13] Evaluation of tubal patency with laparoscopy or hysterosalpingography and semen analysis are also performed to decide and to enhance the best possible and chosen treatment.

Insulin sensitizing drugs, ovulation induction drugs, gonadotropins and other nutrient supplements are the pharmacological approaches to treat PCOS infertility.[12] Laparoscopic ovarian drilling, intrauterine insemination or IUI and invitro fertilisation or IVF are the non-pharmacological approaches.[12] Metformin, an oral hypoglycaemic drug is used in PCOS symptom management due to its properties to treat insulin sensitivity, hyperandrogenism and restore ovulation.[13,19] Inositol or myo-inositol a vitamin like substance has gained popularity in managing PCOS symptoms such as

improving weight loss, insulin sensitivity, hyperandrogenism, ovarian function, normalising FSH/LH ratio, regularising menstruation and in increasing the chances of pregnancy.[30-32] Ovulation inducing drugs such as letrozole and CC are the 1st line choice of pharmacological agents used to induce ovulation and are administered at a dose of 2.5-7.5 mg/day beginning on 3-7 days and at dose of 50-150 mg/day beginning on 2-5 days of menstrual cycles respectively.[13,20-23] Patients are said to have/be letrozole or CC failure or resistant when either letrozole or CC fail to result in pregnancy respectively. Synthetic or exogenous gonadotropins such as human chorionic gonadotropin or hCG are preferred 2nd line choice of pharmacological agents in treating infertility when ovulation induction drugs fail and when a woman opts for IUI technique.[9] Treatment with gonadotropins begin with the dose of 50-75 IU/day in step-up protocol or with 150 IU/day in step-down protocol during 7-14 days of menstrual cycle until follicle matures.[13]

When the pharmacological agents fail, non-pharmacological options such as laparoscopic ovarian drilling, IUI and IVF techniques are chosen to improve pregnancy rates in women. Laparoscopic ovarian drilling or LOD often focuses on destroying the ovarian tissue that produce high testosterone levels and other ovarian tissue that are thought of causing difficulties in pregnancy thus helping the women to conceive naturally.[26,27] Intrauterine insemination or IUI involves direct injection of washed sperm into women's uterus. IUI is usually performed when the follicles mature i.e., when the follicles reach the size of 16-20 mm in diameter so as to increase the chances of pregnancy.[24,25] *In vitro* fertilisation or IVF a technique in which invitro fertilised zygote is introduced into the woman's uterus is considered as a 3rd line choice of treatment or a final option to improve pregnancy rates in a woman.[9,14] Supplements are the beneficial medicines that help not only in improving PCOS symptoms but also to improve egg quality and overall fertility chances. For PCOS patients, supplements such as myo-inositol, folic acid, multivitamin, calcium/ vitamin D3, vitamin C are prescribed to improve symptoms such as regularise menstrual periods, reduce hirsutism, normalize circulating hormones, improve egg quality and increase fertility chances and outcomes.[29,35-38]

In the study, women of age 18-37 years who were receiving treatment for infertility due to PCOS were included and observed. Among all the patients, women aged between 23-27 years were more accounting for 41.4% of total sample size followed by women of age group 28-32 years with 31.4%. All patients had cystic ovaries and were experiencing infertility and other symptoms of PCOS. Before initiating any treatment in the patients, they were given preconception counselling and were advised to follow lifestyle modifications such as cutting down alcohol, smoking, stress, to include proteins, carbohydrates and high fibre food in diet, to perform physical activity for 30 min at least 3-5 days a week and to practice regular intercourse on days 12-16 of menstrual cycle as to increase pregnancy chances in a natural way. Patients in whom life style modifications did not result in pregnancy were put on pharmacological agents. The primary pharmacological agent chosen was letrozole either prescribed alone or in combination with insulin sensitizing agents. If patients were observed to have letrozole failure, CC was the next drug chosen. When either of the ovulation induction drugs did not result in pregnancy, gonadotropins were administered to the patients on days 7-14 so as to increase the egg size. When either of the pharmacological agents did not result in pregnancy, non-pharmacological options were approached to increase fertility chances.

Among the non-pharmacological approaches laparoscopic ovarian drilling was preferred 1st technique in patients where lifestyle modifications did not result in positive outcomes. IUI was preferred when patient had developed enough egg size but had other problems in conceiving such as partner's low sperm count. IVF was chosen when the above mentioned all techniques did not achieve desired results.

After observing the choosing pattern of infertility treatment options in PCOS women, ovulation inducing agents or ovulation induction drugs are primarily prescribed among the pharmacological agents. Myo-inositol prescribed from the supplements showed improvement in terms of managing PCOS symptoms.

Limitations

The limitations of the study were that it was a single institution and the sample size was small.

CONCLUSION

Ovulation inducing drugs and supplements are primarily chosen and widely prescribed. Odds ratios of the individual treatment success rates were not enough significant to say that particular treatment(s) showed high success rate but in terms of visual comparison, it can be said that the treatment with ovulation inducing drugs yielded better positive outcomes when compared to other treatment options.

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