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Prescribing Patterns in the Management of Polycystic Ovary Syndrome at a Tertiary Care Teaching Hospital: A Retrospective Observational Study

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ABSTRACT

Background: Polycystic ovary syndrome (PCOS) is a common endocrine disorder associated with reproductive and metabolic morbidity. Although evidence-based management guidance exists, real-world prescribing may vary across settings.
Aim and objective: To describe prescribing patterns for PCOS management in a tertiary care teaching hospital and compare management between women with and without documented infertility.
Materials and methods: This retrospective observational prescription audit was conducted in the Department of Obstetrics and Gynaecology, Chamarajanagar Institute of Medical Sciences (CIMS), Karnataka, India. Medical records of women diagnosed with PCOS between July 2021 and January 2023 were reviewed. PCOS diagnosis was based on the Rotterdam 2003 criteria (after exclusion of mimicking endocrinopathies). Prescribing patterns were summarized as frequencies and percentages. A pragmatic comparison of any pharmacotherapy (yes/no) between infertility groups was assessed using a two-sided Fisher's exact test; $p < 0.05$ was considered statistically significant.
Results: A total of 167 women with PCOS were identified; 160 (95.8%) had complete follow-up information. Among women with complete records, 132 (82.5%) had no documented infertility and 28 (17.5%) had infertility. In women without infertility, lifestyle modification alone was documented in 50 (37.9%), oral contraceptive pills (OCPs) in 30 (22.7%), metformin in 28 (21.2%), and OCP plus metformin in 24 (18.2%). Among infertile women, letrozole was used in all cases: 12 (42.9%) received letrozole alone and 16 (57.1%) received metformin plus letrozole. Any pharmacotherapy differed between infertility groups (two-sided Fisher's exact $p = 0.0000$). The mean number of pharmacologic agents among drug-treated patients was 1.36.
Conclusion: Prescribing patterns varied by reproductive intent. Women without infertility were commonly managed with lifestyle advice and menstrual/hyperandrogenism control, whereas infertile women were managed predominantly with letrozole-based ovulation induction. Prospective studies linking prescribing to outcomes are needed.

Keywords: *Polycystic ovary syndrome; prescribing patterns; prescription audit; letrozole; metformin; oral contraceptive pills; tertiary care hospital.*

INTRODUCTION

Polycystic ovary syndrome (PCOS) is a common endocrine disorder in women of reproductive age and is a major public health issue worldwide. PCOS causes anovulatory infertility and irregular periods, with typical features of high androgen levels, ovulatory problems, and multiple cysts on the ovaries. First described in 1935 by Irving F. Stein Sr. and Michael L.

Leventhal, PCOS is now seen as a multisystem disorder with long-term metabolic and heart-related effects, not just a reproductive issue [1].

Estimates suggest that PCOS affects about 8-13 percent of women of reproductive age worldwide, though this range varies depending on diagnostic criteria and study populations. Globally, the prevalence is reported between 4 and 20 percent. In India, reported prevalence varies widely, from 3.7% to 35%, influenced by regional, methodological, and diagnostic differences. A significant proportion of PCOS cases remain undiagnosed, playing a part in the overall disease burden [2].

PCOS's causes are complex, involving genetic factors, hormone disruptions, low-level inflammation, and metabolic problems, especially insulin resistance. About 60-80% of affected women have insulin resistance, which leads to high insulin and increased androgen production[3]. This causes arrested follicle growth, ongoing anovulation, and signs of high androgens. Obesity worsens insulin resistance, but even lean women with PCOS show metabolic issues, highlighting the disorder's complexity [4].

PCOS is defined by irregular periods, infrequent or absent periods, infertility, excess hair growth, acne, and hair thinning. Beyond reproductive problems, PCOS raises the risk of type 2 diabetes, abnormal cholesterol, high blood pressure, and heart disease [5]. It also causes complications like endometrial hyperplasia and cancer due to long-term unopposed estrogen from the ongoing lack of ovulation. Recent evidence also points to high rates of anxiety and depression, reducing quality of life [6].

PCOS is a long-term condition that needs an individualized approach due to the chronic nature and systemic effects of the syndrome. Pharmacological treatment is also primarily symptom-oriented and geared towards managing reproductive and metabolic features. Combined hormonal contraceptives (CHCs) are recommended as first-line therapy for menstrual irregularity and hyperandrogenism in women with no immediate pregnancy intention. CHCs suppress ovarian androgen production, increase sex hormone-binding globulin levels, and protect the endometrium. Low-dose ethinyl estradiol with progestins of low androgenicity is usually preferred. Antiandrogens, such as spironolactone, may be added with appropriate contraception since they are teratogenic when used to treat persistent hirsutism [7].

Ovulation induction is recommended for women with PCOS who wish to conceive. The aromatase inhibitor letrozole is preferred as a first-line option due to higher ovulation and live birth rates than clomiphene citrate, though clomiphene remains suitable in selected cases. Gonadotropin therapy should be reserved for those who do not respond to oral agents, with careful monitoring for ovarian hyperstimulation and multiple gestation [8].

Metformin (a biguanide insulin sensitizer) is primarily used in women with PCOS who have insulin resistance, impaired glucose tolerance, or type 2 diabetes mellitus. It may improve menstrual regularity and metabolic parameters, but metformin is less effective than ovulation-induction agents when pregnancy is a goal, and should be supplemented by lifestyle interventions. Lifestyle changes, involving dietary adjustment and physical activity, are beneficial for all PCOS phenotypes [9].

Despite available guidelines, doctors differ widely in how they prescribe for PCOS. Real-world drug use varies with doctor experience, patient cases, hospital policies, drug supply, and new evidence. Teaching hospitals may manage more complex PCOS cases, which can affect treatment plans and whether combination drugs are used [10].

Although many studies have examined the prevalence of PCOS and its metabolic consequences, there is a lack of comprehensive research specifically documenting real-world prescription patterns and medication use among PCOS patients in tertiary care settings, particularly within India. As a result, there remains limited insight into whether current pharmacological management aligns with established clinical guidelines or adequately addresses patient needs in these environments. This research gap is important because understanding prescription patterns can help assess the appropriateness and quality of drug use and inform improvements in patient care. By systematically evaluating medication use in a tertiary hospital context, this study aims to fill this gap and provide valuable evidence on how PCOS is currently managed in an Indian tertiary care setting [11].

Based on this, a retrospective study was conducted to evaluate medication use trends among patients diagnosed with PCOS at Chamarajanagar Institute of Medical Sciences, Chamarajanagar. The analysis considers demographic attributes, clinical presentations, comorbid conditions, and pharmacological interventions administered during the study period, and aims to provide an overview of current treatment practices at this tertiary care teaching hospital.

MATERIALS AND METHODS

This was a retrospective, observational study of drug utilization in the Department of Obstetrics and Gynecology at Chamarajanagar Institute of Medical Sciences (CIMS), Chamarajanagar, Karnataka, India. CIMS is a tertiary teaching hospital focused on gynecological and endocrine care for both urban and rural populations in the Chamarajanagar district

and surrounding areas. The research examined medical records of women diagnosed with Polycystic ovary syndrome (PCOS) who visited the Gynecology outpatient department (OPD) in July 2021 and January 2023. Hospital case records and prescription registers were reviewed to extract relevant information and assess trends in medication use.

The research population included women of childbearing age diagnosed with PCOS during the study period. Eligible patients were aged 15 to 45 years. They were diagnosed with PCOS based on clinical, biochemical, or ultrasonographic tests aligned with standard criteria. These patients received at least one pharmacological therapy for PCOS and had complete, retrievable medical records. Patients below 15 or above 45 years, those with incomplete records, and individuals with endocrine or pathological diseases mimicking PCOS—such as hypothyroidism, hyperprolactinemia, ovarian tumors, adrenal tumors, and Cushing syndrome—were excluded.

Retrospective data collection used a structured data abstraction form specific to the study. Extracted variables included demographic data, clinical presentation, anthropometric measurements, comorbidities, laboratory results, and details of pharmacological management. Drug information, medication class, dosage, frequency, therapy duration, and combination therapy details were also collected.

The protocol was approved by the Institutional Ethics Committee of Chamarajanagar Institute of Medical Sciences (Approval No.: CIMS/IEC/2023/25). Since this was a retrospective, record-based study using anonymized patient data, the Ethics Committee waived the requirement for informed consent. All data were de-identified before analysis to respect patient confidentiality and to comply with national ethical standards and the principles outlined in the Declaration of Helsinki.

RESULTS

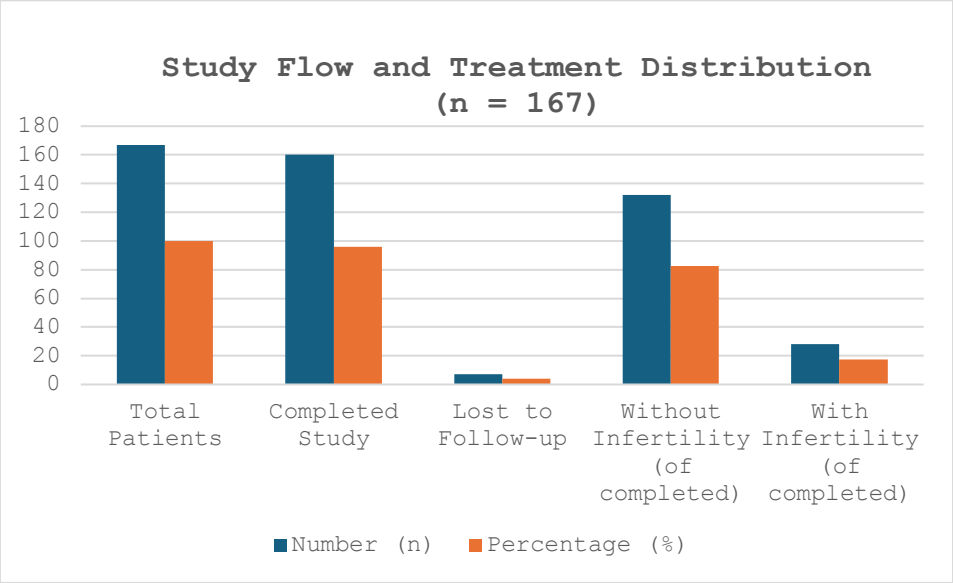
Study Population

During the study period, 167 patients diagnosed with Polycystic Ovary Syndrome (PCOS) were identified from medical records. All were included in the analysis. Of these patients, 160 (95.8%) had complete follow-up data. Seven patients (4.2%) were lost to follow-up. Among the 160 patients with complete records, 132 (82.5%) did not have documented infertility. The remaining 28 (17.5%) had infertility documented in their clinical profile.

Table 1. Study Flow and Treatment Distribution (n = 167)

Variable	Number (n)	Percentage (%)
Total Patients	167	100
Completed Study	160	95.8
Lost to Follow-up	7	4.2
Without Infertility (of completed)	132	82.5
With Infertility (of completed)	28	17.5

Data are expressed as absolute frequencies and corresponding percentages. Percentages for infertility status were derived using the total number of patients who completed follow-up (n = 160) as the denominator.



Values are presented as number (n) and percentage (%). Percentages for infertility categories were calculated based on the number of patients who completed the study (n = 160). PCOS = Polycystic Ovary Syndrome.

Treatment Patterns Among Patients Without Infertility

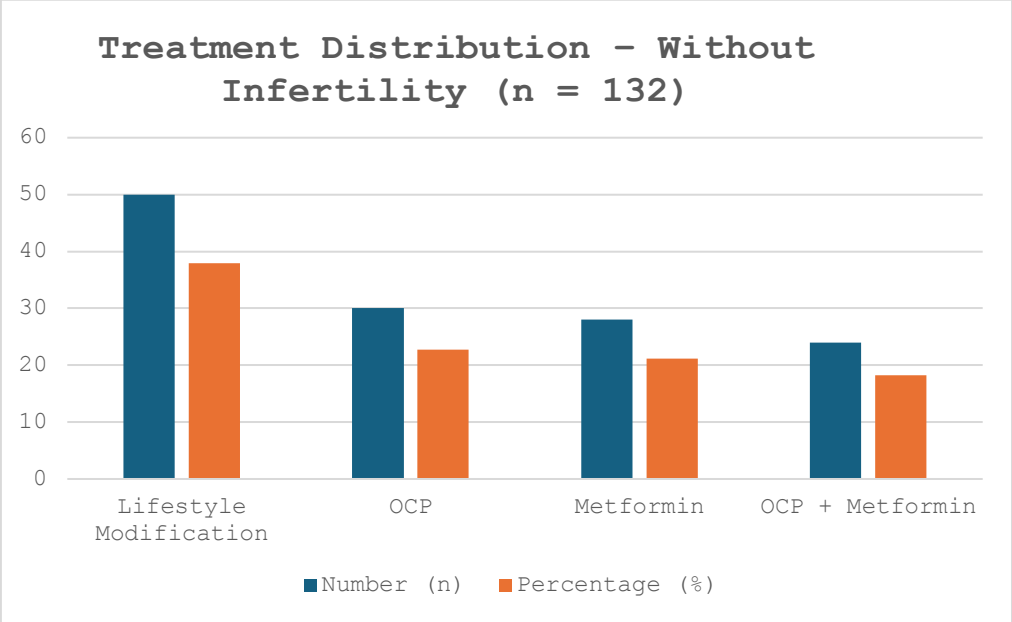
Among patients without infertility (n = 132), lifestyle modification alone was documented in 50 patients (37.9%), representing the most frequently recorded management approach in this subgroup.

Pharmacological therapy included oral contraceptive pills in 30 patients (22.7%) and metformin monotherapy in 28 patients (21.2%).

Combination OCP plus metformin therapy was used in 24 patients (18.2%).
These findings indicate that lifestyle-based and hormonal therapies constituted the predominant management strategies in non-infertile PCOS patients.

Table 2. Treatment Distribution – Without Infertility (n = 132)

Treatment	Number (n)	Percentage (%)
Lifestyle Modification	50	37.9
OCP	30	22.7
Metformin	28	21.2
OCP + Metformin	24	18.2



Values are expressed as number (n) and percentage (%). Percentages were calculated based on the total number of patients without infertility (n = 132). OCP = Oral contraceptive pill.

Treatment Patterns Among Patients With Infertility

Among patients with infertility (n = 28), ovulation induction therapy was documented in all cases.
Twelve patients (42.9%) received letrozole monotherapy, while 16 patients (57.1%) were treated with a combination of metformin and letrozole.

The predominance of letrozole in treatment regimens reflects current ovulation induction practices in this tertiary care setting.

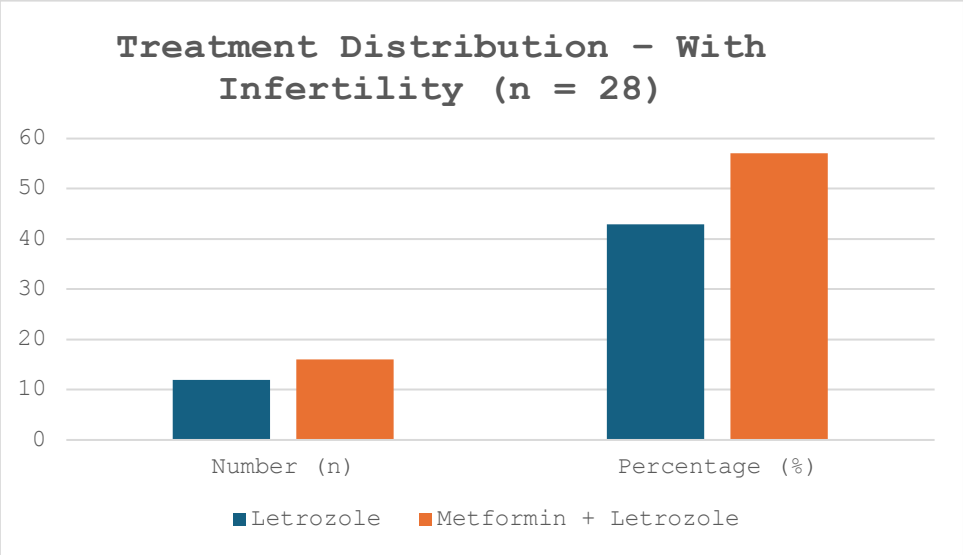
The retrospective analysis of medical records revealed that management strategies varied according to clinical presentation. Patients without infertility primarily received lifestyle interventions and hormonal regulation, whereas infertile patients were predominantly treated with letrozole-based ovulation induction regimens.

Table 3. Treatment Distribution – With Infertility (n = 28)

Treatment	Number (n)	Percentage (%)
Letrozole	12	42.9

Metformin + Letrozole	16	57.1

Values are presented as number (n) and percentage (%). Percentages were calculated based on the total number of patients with infertility (n = 28).



Values are expressed as number (n) and percentage (%). Percentages were calculated based on the total number of patients with infertility (n = 28).

This study evaluated prescribing patterns for polycystic ovary syndrome (PCOS) management at a tertiary care teaching hospital, providing insight into real-world pharmacological practices in India. The findings indicate a symptom-oriented and reproductive-intent-based approach consistent with international guidelines.

In this cohort, 82.5% of patients presented without infertility, reflecting the broad clinical spectrum of PCOS, where menstrual irregularity and hyperandrogenic symptoms often predominate. This observation aligns with Bozdag et al. (2016), who emphasized the heterogeneity of PCOS phenotypes and diverse presenting complaints. Indian prevalence studies similarly report that many women present with menstrual disturbances and metabolic features rather than infertility alone (Deswal et al., 2020).

Lifestyle modification was the most frequently recommended intervention for women without infertility (37.9%). This aligns with the 2023 International Evidence-Based Guideline for PCOS, which endorses lifestyle changes as foundational therapy across all phenotypes regardless of body mass index [12]. Patel (2019) similarly reported that lifestyle advice is integrated into first-line management in tertiary care, particularly for patients with metabolic risks.

Combined oral contraceptive pills (22.7%) were commonly prescribed for menstrual regulation and hyperandrogenism, consistent with international recommendations endorsing combined hormonal contraceptives as first-line pharmacotherapy in women not seeking pregnancy [13]. These contraceptives suppress ovarian androgen production and increase sex hormone–binding globulin levels, thereby reducing circulating free testosterone. Legro et al. (2018) reported similar prescribing patterns in their guideline update, reinforcing combined hormonal contraceptives as standard therapy for menstrual dysfunction.

Metformin was prescribed either as monotherapy (21.2%) or in combination with oral contraceptive pills (18.2%), reflecting recognition of insulin resistance as a central pathophysiological mechanism in PCOS. Dunaif (2017) reported that insulin resistance affects 60–80% of women with PCOS and significantly contributes to hyperandrogenism. Consequently, metformin combination therapy targets both reproductive and metabolic dysfunction. Supporting this approach, a systematic review by Morley et al. [14] found that metformin improves metabolic parameters and menstrual cyclicity, although its efficacy for ovulation induction is inferior to that of aromatase inhibitors.

Among infertile patients, letrozole was the predominant ovulation induction agent, prescribed either alone (42.9%) or in combination with metformin (57.1%). This prescribing pattern aligns with contemporary evidence positioning letrozole as the first-line therapy for ovulation induction in PCOS due to its superior ovulation and live birth rates compared with clomiphene citrate [15.] Legro et al., demonstrated improved reproductive outcomes with letrozole, which has replaced clomiphene as first-line therapy in most guidelines. The relatively high use of combination therapy (metformin plus

letrozole) may reflect efforts to address underlying metabolic abnormalities while enhancing ovulatory response, a strategy supported in selected phenotypes with insulin resistancec1[7-18].

Compared to prescribing patterns a decade ago, these findings suggest improved adherence to updated evidence-based recommendations. Earlier Indian studies showed greater reliance on clomiphene citrate and inconsistent use of insulin sensitizers; the current shift toward letrozole-based regimens reflects the integration of guidelines into routine practice. These strengths, variability in combination therapy, highlight ongoing heterogeneity in clinical decision-making. Factors such as patient phenotype, clinician expertise, drug availability, and socioeconomic status may influence this. These findings highlight the need for continued drug utilization audits and structured protocols to ensure rational prescribing. al standards for PCOS management. Nonetheless, to further assess these strategies, prospective outcome-based studies are needed to evaluate their long-term reproductive and metabolic effectiveness.

CONCLUSION

This retrospective drug utilization study provides valuable insights into real-world prescribing practices for PCOS at a tertiary care teaching hospital. The findings demonstrate a predominantly individualized, phenotype-driven approach consistent with current international guidelines. Lifestyle modification and hormonal contraceptives were common among women without infertility, while letrozole-based ovulation induction was preferred for infertile patients. The transition toward evidence-based, individualized PCOS management in a tertiary care setting is evident. Ongoing efforts to harmonize clinical practice with updated guidelines, supported by regular audits, are essential for further progress. Ultimately, integrating structured protocols and outcome evaluations will enhance the effectiveness and rationality of PCOS management.

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