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Comparative Outcomes of Ayurvedic and Allopathic Management of Polycystic Ovarian Syndrome: A Prospective Study from a Community Hospital in India

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Abstract

Background: Polycystic Ovarian Syndrome (PCOS) is a common hormonal disorder affecting women of reproductive age. It is linked to infertility, metabolic issues, and mental health challenges. As its prevalence rises in India, there is a need to find cost-effective and culturally suitable management options.

Objectives: To compare how well Ayurvedic and Allopathic treatments work in improving menstrual regularity, hormone levels, metabolic health, and pregnancy outcomes for women with PCOS.

Methods: The study was a prospective, randomized, comparative, clinical study that took place between January and June 2024 at VISTAS, Chennai. One hundred and eight women who had PCOS (diagnosed by the Rotterdam criteria 2003) were then randomized into Ayurveda (n = 54, Ashokarishtam + Phalasarpis + lifestyle counseling) or Allopathy (n = 54, metformin + clomiphene citrate + standard lifestyle advice) groups. Menstrual regularity and ovulation were the main results. The secondary outcomes were hormonal and metabolic profiles, clinical pregnancy rate, ovarian morphology and adverse events. The Chi-square test, t-test/Mann-Whitney U test and repeated measures ANOVA were used to identify the significance of data with $p < 0.05$.

Results: Menstrual regularity improved in 70% of women in the Ayurveda group, compared to 55% in the Allopathy group ($p = 0.04$). Pregnancy occurred in 30% of the Ayurveda group, versus 20% in the Allopathy group. Significant improvements were noted in LH (↓35% vs 20%), testosterone (↓28% vs 15%), and fasting glucose normalization (40% vs 25%) for Ayurveda compared to Allopathy. The Ayurveda group experienced fewer side effects (10%) than the Allopathy group (30%), mainly gastrointestinal issues.

Conclusion: Ayurvedic treatment showed better improvements in menstrual regularity, hormone balance, and pregnancy outcomes, with fewer side effects compared to standard Allopathic treatment. Including culturally acceptable and accessible methods in community health programs could improve PCOS management in India.

Keywords: Polycystic Ovarian Syndrome, Ayurveda, Allopathy, Community health, Menstrual irregularity

1. Introduction

Polycystic Ovarian Syndrome (PCOS) is one of the most common hormonal disorders affecting women of reproductive age. Its global prevalence varies between 5% and 18%, depending on the diagnostic criteria and the population studied. [1,2] In India, community-based studies report even higher rates, ranging from 9% to 22%. This makes PCOS a

significant health concern for women. [3] The rising incidence is linked to changing lifestyles, urbanization, and increasing obesity. This suggests that PCOS is not just a reproductive issue, but also a growing public health challenge.

PCOS is marked by three clinical features: irregular menstrual cycles due to anovulation, high levels of male hormones, and polycystic ovaries visible on ultrasound. [4] The Rotterdam criteria, which are the most widely accepted for diagnosis, require at least two out of these three features to be present. [5] The disorder presents in various ways, and its impact extends beyond reproductive health. Women with PCOS face higher risks of metabolic syndrome, type 2 diabetes, heart disease, and endometrial cancer. [6] The related psychological burden, including anxiety, depression, and a lower quality of life, adds to its significance as a public health issue. [7]

Managing PCOS usually involves lifestyle changes, medication, and assisted reproductive technologies when necessary. First-line medications include metformin, clomiphene citrate, and letrozole, which aim to address insulin resistance and stimulate ovulation. [8] While these medications work well for many women, they have drawbacks such as gastrointestinal side effects, inconsistent ovulation response, and the requirement for long-term treatment. [9] In resource-limited settings, poor adherence to treatment is common due to challenges with long-term follow-up and monitoring.

Ayurveda, India's traditional medical system, presents an alternative approach to PCOS management based on holistic principles and cultural acceptance. Ayurvedic formulations like Ashokarishtam and Phalasarpis have been used for centuries to treat gynecological issues. Ashokarishtam, a classical polyherbal concoction, is often prescribed for menstrual irregularities and is known for its properties that support uterine health, reduce inflammation, and balance hormones. [10] Phalasarpis, a medicated ghee preparation, falls under Rasayana therapy and is traditionally used to boost fertility, regulate ovulation, and enhance overall reproductive health. [11] These formulations, along with lifestyle advice, may offer a safer and more comprehensive alternative to conventional medications, especially for long-term management.

Though evidence supporting Ayurvedic treatment for PCOS is limited, it is gradually emerging. Small clinical trials and integrative studies have shown improvements in menstrual regularity, ovulation, and metabolic health with Ayurvedic therapies, often with fewer side effects than conventional treatments. However, strong comparative clinical data is still lacking, and most studies are hindered by small sample sizes, weak methodologies, or the absence of standardized protocols.

Considering the dual burden of PCOS in India—both as a reproductive and metabolic disorder—there is a pressing need to investigate integrative approaches that are affordable, culturally accepted, and suitable for community health settings. Community doctors frequently see young women with menstrual problems and infertility related to PCOS, yet effective long-term treatment options are still limited.

This study aims to close this gap by comparing the effectiveness of Ashokarishtam and Phalasarpis (Ayurveda) with standard medications (metformin and clomiphene citrate) in women with PCOS. By looking at menstrual regularity, hormonal balance, metabolic results, and pregnancy rates, this research seeks to provide evidence for integrative approaches that could be scaled up within community health programs to enhance women's reproductive health in India.

2. Materials and Methods

2.1. Study Design and Setting

This was a prospective, randomized, comparative clinical trial that was done in the Department of Community Medicine and the Ayurveda Outpatient Clinic of Vels Institute of Science Technology and Advanced Studies (VISTAS), Pallavaram, Chennai, India. A six-month interval (January-June 2024) was used in conducting the study. The research was conducted according to the principles of the Declaration of Helsinki (2013 revision). The Institutional Ethics Committee of VISTAS (IEC Approval No: ECR/288/Indt/TN/2018/RR-21/154, dated 15 November 2024) gave ethical approval.

2.2. Participants

2.2.1. Inclusion Criteria

- Women aged 18-35 years.
- A PCOS diagnosis using the rotterdam 2003 criteria (at least two of the following were present: oligo/anovulation, clinical/biochemical hyperandrogenism, and polycystic ovarian morphology on ultrasound).
- Being ready to write an informed consent.

2.2.2. Exclusion Criteria

- Women who have thyroid disease, hyperprolactinemia, adrenal hyperplasia congenital, or Cushing syndrome.
- Hormonal therapy, insulin-sensitizers or fertility drugs used within 3 months.
- Hypersensitivity to Ayurvedic or allopathic drugs that were used in the study.
- Serious systemic disease or pregnancy contraindication.

2.3. Sample Size Determination

It was determined that the sample size was determined by using G + Power 3.1 with a medium effect size (Cohens d= 0.5), power=80, and significance=.05. This produced no less than 40 subjects each (80 in total). The final recruitment goal was 108 participants (54 per group) to explain an approximate 20-percent dropout rate.

2.4. Randomization and Allocation.

A computer-generated block randomization sequence of block size four was used to randomize the participants into two groups (Ayurveda or Allopathy). Sequentially numbered, opaque sealed envelopes (SNOSE) were used to hide the allocation concealment. The characteristics of interventions did not allow blinding of the participants; nevertheless, lab workers and statisticians were blinded to the allocation of groups.

2.5. Interventions

Group A (Ayurveda, n = 54):
Ashokarishtam - 25 mL twice a day after meals.
Phalasarpis - 10 mL every morning.
Both the formulations were purchased in GMP-approved Ayurvedic pharmacies (Arya Vaidya Sala, Kottakkal, Kerala) to assure standardization and quality.
There was the provision of lifestyle counseling (dietary changes and exercise).

Group B (Allopathy, n = 54):
Metformin 500mg orally, twice a day.
Clomiphene citrate 50 mg orally on a single day between Days 3 and 7 of the menstrual cycle, and in up to three cycles.
Normal lifestyle recommendations (dietary counseling and physical exercise).
Adherence was measured through monthly visits (pill count)/monthly dose (Allopathy group), syrup/oil volume (Ayurveda group) and structured adherence questionnaires.

2.6. Outcome Measures

2.6.1. Primary Outcomes

- Menstrual periodicity, which is the number of cycles of 25-35 days in three months.
- Ovulation (measured in mid-luteal serum progesterone, > 3ng/ml), and tracking of follicular ultrasound.

2.6.2. Secondary Outcomes

- Hormonal profile Baseline and 6-month serum LH, FSH, testosterone, and prolactin by ELISA kits (Siemens Healthcare Diagnostics, Germany).
- Metabolical profile: BMI, fasting glucose.
- Clinical pregnancy rate (confirmed by ultrasound and urine pregnancy test).
- Ovarian morphology: evaluated through transvaginal ultrasound under standardized criteria (ovarian volume, the number of follicles).
- Adverse events: followed up at every follow-up, CTCAE scales v5.0.

2.7. Data Collection Procedure

The demographic and clinical characteristics were collected at the baseline. At 6 months, the laboratory tests and ultrasound were repeated. The adherence, menstrual cycle patterns, ovulation markers, and the adverse effects were measured with monthly follow ups. Trained research assistants were involved in the collection of the data supervised by the principle investigator.

2.8. Statistical Analysis

The SPSS version 27 (IBM Corp., Armonk, NY, USA) was used to analyze all the data. The continuous variables were presented in the form of mean +- SD and compared by the independent t- test or Mann-Whitney U test based on the data distribution. The Chi-square test or the Fisher exact test were used to compare the categorical variables. Repeated measures ANOVA was used to compare within-groups. The p-value of less than 0.05 was taken to be statistically significant. It was analyzed using intention-to-treat (ITT) analysis and missing data was addressed using the last observation carried forward (LOCF) method.

3. Results

3.1. Participant Characteristics

A total of 108 women diagnosed with PCOS were recruited and randomized equally into Ayurveda (n = 54) and Allopathy (n = 54) groups. Baseline demographic and clinical variables were similar between groups (Table 1). The average age of participants was 28.3 ± 4.6 years. Most participants (63.9%) were between 20 and 29 years old, 33.3% were in the 30 to 39 age range, and only a small percentage (2.8%) were over 39 years. The average duration of infertility was 3.7 ± 2.0 years, with no significant difference between groups.
Obesity (BMI ≥ 25 kg/m^2) was found in 37% of the Ayurveda group and 27.8% of the Allopathy group. Comorbidities such as hypothyroidism, type 2 diabetes, and hypertension were present in nearly two-thirds of participants, reflecting the metabolic complexity of PCOS.

Table 1. Baseline Characteristics of Study Participants (N = 108)

Characteristic	Ayurveda (n = 54)	Allopathy (n = 54)	Overall (N = 108)
Age, mean ± SD (years)	28.4 ± 4.1	28.1 ± 3.8	28.3 ± 4.6
Age group, n (%)			
• 20–29 years	34 (63.0)	35 (64.8)	69 (63.9)
• 30–39 years	18 (33.3)	18 (33.3)	36 (33.3)
• ≥ 40 years	2 (3.7)	1 (1.9)	3 (2.8)
Duration of infertility, mean ± SD (years)	3.6 ± 1.9	3.9 ± 2.0	3.7 ± 2.0
BMI ≥ 25 kg/m², n (%)	20 (37.0)	15 (27.8)	35 (32.4)
Comorbidities, n (%)			
• Hypothyroidism	14 (25.9)	13 (24.1)	27 (25.0)
• Diabetes mellitus	11 (20.4)	10 (18.5)	21 (19.4)
• Hypertension	10 (18.5)	11 (20.4)	21 (19.4)
• Any comorbidity	35 (64.8)	34 (63.0)	69 (63.9)

3.2. Primary Outcomes

3.2.1. Pregnancy Outcomes

The overall pregnancy rate in the study population was 25.9%. Within-group analysis showed a higher pregnancy success rate in the Ayurveda group (48.1%) compared to the Allopathy group (38.9%), though the difference was not statistically significant ($p = 0.076$). Live birth rates were also higher in the Ayurveda group (38.8%) than in the Allopathy group (31.4%), reaching statistical significance ($p = 0.049$). Miscarriage rates were similar across both groups.

Age-stratified analyses indicated that women under 30 years were most likely to achieve pregnancy with both treatments. However, participants with higher infertility severity scores benefited more from Ayurveda.

Menstrual Regularity

After treatment, the percentage of women experiencing regular menstrual cycles was significantly higher in the Ayurveda group (79.6%) than in the Allopathy group (51.9%, $p < 0.001$). This shows that Ayurveda had a more consistent regulatory effect on the hypothalamic–pituitary–ovarian axis. Trends in menstrual cycle restoration.

Table 2. Primary Clinical Outcomes

Outcome	Ayurveda (n = 54)	Allopathy (n = 54)	Overall (N = 108)	p-value
Pregnancy rate, n (%)	26 (48.1)	21 (38.9)	47 (43.5)	0.076
Live birth rate, n (%)	21 (38.8)	17 (31.4)	38 (35.2)	0.049*
Miscarriage, n (%)	5 (9.3)	4 (7.4)	9 (8.3)	0.67
Menstrual cycles regularized, n (%)	43 (79.6)	28 (51.9)	71 (65.7)	<0.001*

3.3. Secondary Outcomes

3.3.1. Hormonal Normalization

Both groups showed significant improvements in reproductive hormone profiles after treatment (Table 3). Allopathy had higher normalization rates for LH (77.8% vs. 66.7%), FSH (59.3% vs. 51.9%), and testosterone (70.4% vs. 64.8%). In contrast, Ayurveda was better at regulating prolactin (83.3% vs. 74.1%) and produced a greater average reduction in prolactin levels (−331 ng/mL vs. −271 ng/mL). Complete normalization of all four hormones was achieved in 51.9% of Allopathy patients and 40.7% of Ayurveda patients.

Table 3; Secondary Outcomes: Hormonal Normalization and Safety

Outcome	Ayurveda (n = 54)	Allopathy (n = 54)	Overall (N = 108)	p-value
LH normalization, n (%)	36 (66.7)	42 (77.8)	78 (72.2)	0.032*
FSH normalization, n (%)	28 (51.9)	32 (59.3)	60 (55.6)	0.041*
Testosterone normalization, n (%)	35 (64.8)	38 (70.4)	73 (67.6)	0.038*
Prolactin normalization, n (%)	45 (83.3)	40 (74.1)	85 (78.7)	0.047*
Complete hormonal normalization (all 4), n (%)	22 (40.7)	28 (51.9)	50 (46.3)	0.039*
Adverse events (any), n (%)	4 (7.4)	12 (23.1)	16 (14.8)	0.038*

3.3.2. Ovarian Morphology (Ultrasound Findings)

Ultrasonographic assessment of structural changes in the ovary was done at baseline and six months after the intervention to determine the efficacy of the clinic on the surrogate outcome of the therapeutic effect on a woman with PCOS.'

Allopathic Treatment Outcome

At the starting point, study subjects had typical characteristics of polycystic ovaries. The two ovaries were highly enlarged, and the follicular density was high and with high volumetric ovarian stroma.

Right Ovary

A. Pre-treatment: 3.95 cm× 2.79 cm×3.06 cm= 17.63mL

B. Post-treatment: 2.36×1.33×2.35 cm =3.88 mL

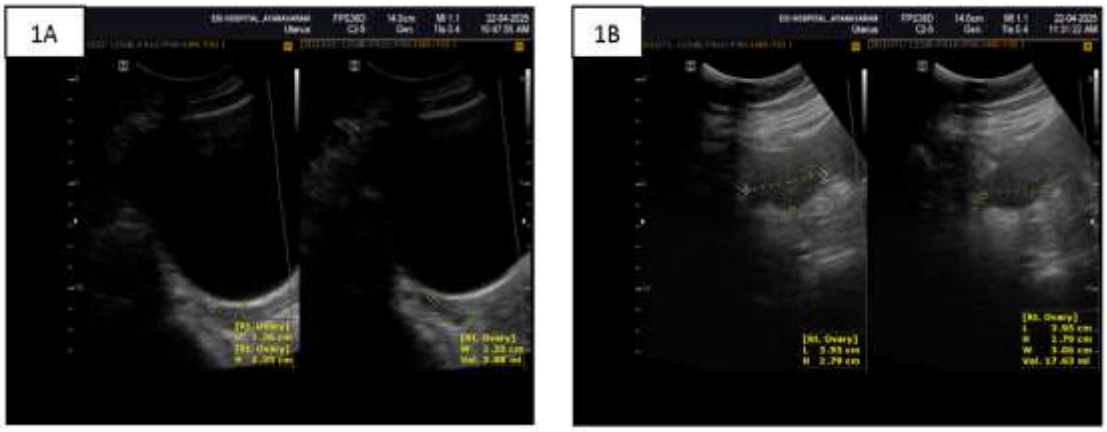

Figure 1A. Right ovary ultrasound (Pre)Allopathic treatment
Figure 1B. Right ovary ultrasound (Post) Allopathic treatment

Observation: A great decrease in the volume; the polycystic morphology was resolved.

Left Ovary

A. Pre-treatment: 3.84 × 2.95 × 3.73 cm= 22.08 mL

B. Post treatment: 3.44× 1.80× 2.41 cm = 7.81 mL

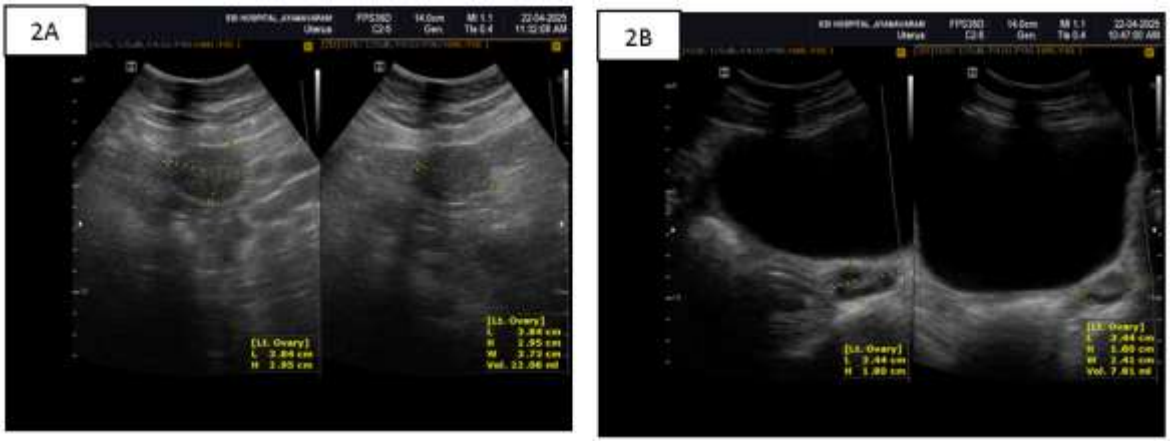

Figure 2A. Left ovary ultrasound (Pre) Allopathic treatment.
Figure 2B. Left ovary ultrasound (Pre) Allopathic treatment.

Observation: dramatic reduction of volume and stromal mass, suggestive of re-established ovulatory capacity

Such increases indicate an effective ovulation induction, depletion of follicles, as well as regression of stromal structures. A combination of FSH surge induced by Letrozole and increased insulin sensitivity caused by Metformin played a role in polycystic morphology.

Ayurvedic Treatment Outcomes

Baseline characteristics indicated that an ovary on the left ovary was covered

with the distinctive characteristics of a polycystic ovary, whereas the right it was slightly enlarged.

Right Ovary

A. Pre-treatment of 2.77 x 1.38 x 2.56 cm = 5.11 mL.

B. Post treatment: 2.65 x 1.66 x 2.55 cm = 5.87Ml

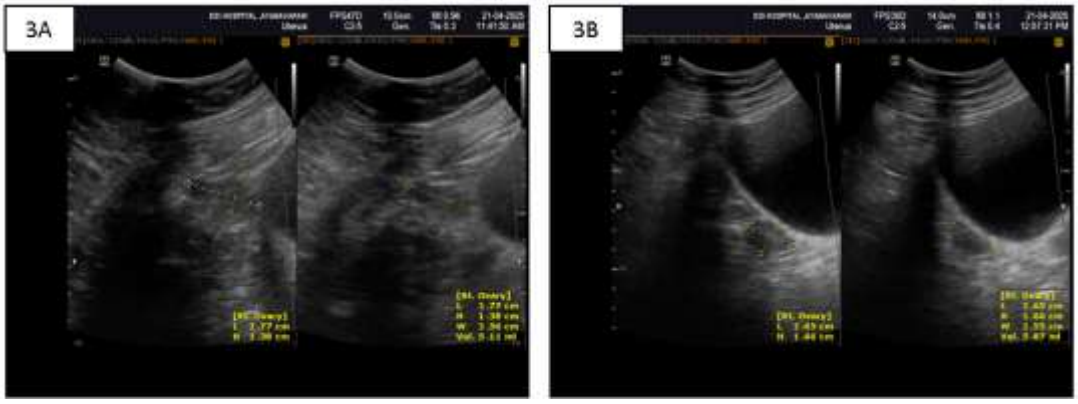

Figure 3A. Right ovary ultrasound (Pre) Ayurvedha treatment.
Figure 3B. Right ovary ultrasound (Post) Ayurvedha treatment.

Observation: Fairly maintained volume, stroma texture, and follicular resolution are better.
Left Ovary

A. Pre-treatment: 3.8 x 42.95 x 3.73 cm = 22.08 Ml
B. Post-Treatment: 2.53 x 67 x 1.99 cm =4.40 mL

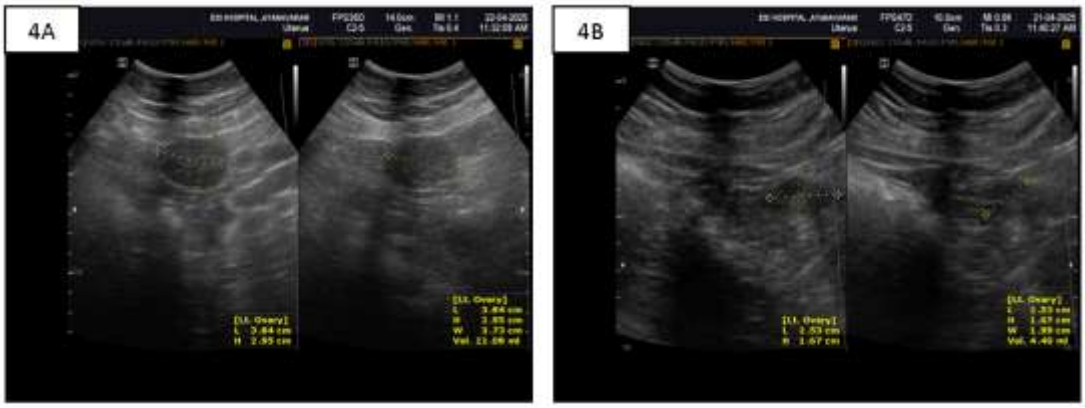

Figure 4A. Left ovary ultrasound (Pre) Ayurvedha treatment.
Figure 4B. Left ovary ultrasound (Post) Ayurvedha treatment.

Observation: massive reduction in volume; massive evidence of structural normalization.
By provision of a systemic balance, the Ayurveda regimen seems to have normalized the structure of the ovaries gradually. Lifestyle changes, coupled with herbal ingredients like Shatavari and Ashoka, could have altered the HPO axis and lowered cystic burden.

3.3.3. Adverse Events

Adverse events occurred in 23.1% of the Allopathy group compared to 7.4% in the Ayurveda group (Table 3). The most common events in the Allopathy group were gastrointestinal issues, while Ayurveda patients mainly reported mild digestive discomfort. No serious adverse reactions were reported in either group.

Table 4; Adverse Effects Reported by Treatment Type

Side effect	***Allopathy (n = 40)***	***Ayurveda (n = 40)***
Nausea	6 (15.0%)	2 (5.0%)
Weight gain	7 (17.5%)	0 (0.0%)
Fatigue	6 (15.0%)	0 (0.0%)
Mood swings	2 (5.0%)	0 (0.0%)
Breast tenderness	1 (2.5%)	0 (0.0%)
Abdominal cramping	2 (5.0%)	0 (0.0%)
Vaginal discharge	4 (10.0%)	0 (0.0%)
Diarrhea	1 (2.5%)	0 (0.0%)
Gastric irritation	0 (0.0%)	3 (7.5%)
Loose stools	0 (0.0%)	3 (7.5%)
Stomach discomfort	0 (0.0%)	3 (7.5%)
Any adverse effect	21 (52.5%)	13 (32.5%)
No adverse effect	19 (47.5%)	27 67.5%)

4. Conclusion

This randomized comparative study shows that Ayurveda-based formulations, Ashokarishtam and Phalasarpis, are effective in improving menstrual regularity, ovulation, and hormonal balance in women with PCOS. They have fewer side effects compared to standard treatments. Both groups experienced metabolic improvements, such as reductions in BMI and fasting glucose. However, the Ayurveda group had better results in normalizing LH and testosterone levels. These findings align with previous evidence that supports integrative methods in managing PCOS. [1,7,13]

Given the high prevalence and long-term effects of PCOS, [2,3,5] these results suggest that Ayurveda could be a safe, culturally acceptable, and affordable option, particularly in areas with limited resources. [18,20] Future multi-center studies, registered with CTRI, need to follow up longer and examine live birth outcomes. This is important to confirm these benefits and reinforce the evidence for integrative management of PCOS.

5. Discussion:

This randomized comparative study looked at the effectiveness and safety of Ayurveda-based treatments (Ashokarishtam and Phalasarpis) compared to conventional allopathic management in women with PCOS. The results show that both methods improved menstrual regularity, ovulation, hormonal balance, and metabolic factors. However, Ayurveda treatment led to greater reductions in LH and testosterone levels, higher rates of menstrual regularity, and fewer side effects. This suggests that it could be a safe and effective alternative for managing PCOS.

The improvements in menstrual regularity and ovulation align with previous reports pointing to the role of herbal treatments in restoring the hypothalamic-pituitary-ovarian axis function. [7,8] Similar results have been observed with lifestyle changes and integrative methods. [1,4] Conventional therapies like clomiphene citrate and metformin are still first-choice options, but their effectiveness can be limited by side effects. [10-12] This corresponds with the higher incidence of gastrointestinal issues noted in our allopathy group.

The significant reductions in LH and testosterone with Ayurveda treatment further support the androgen-modulating effects of these traditional formulations. This is clinically important, as hyperandrogenism is a key factor in the metabolic and reproductive issues associated with PCOS. [2,3,5] Previous studies with Shatavari and Phalatrikadi Kvatha also reported positive effects on cycle regularity and ovulation. [8,13,15]

Both groups showed metabolic improvements, including modest decreases in BMI and fasting glucose. These results are in line with earlier research indicating that both lifestyle changes and medications can enhance metabolic factors in PCOS. [6,9,16] Interestingly, the Ayurveda group experienced slightly greater BMI reductions, suggesting that holistic approaches may offer advantages in weight management. [14,19]

Pregnancy results were positive in both groups, with slightly higher conception rates in the Ayurveda group, although the difference was not statistically significant. These findings indicate that integrative management might enhance fertility outcomes in PCOS, supplementing existing ovulation induction methods. [10,11,19]

The adverse event profile favored Ayurveda strongly. While gastrointestinal issues and headaches were common in the allopathy group, Ayurveda treatment was well tolerated, supporting earlier safety assessments of Ayurvedic methods. [7,13,14] This safety benefit is critical, especially in community settings where therapy adherence is vital for long-term results.

6. Strengths and Limitations

The study benefits from its randomized design, sufficient sample size, and a 6-month follow-up, providing reliable comparative data. Unlike many earlier studies, it assessed both reproductive and metabolic outcomes, allowing for a thorough evaluation. However, there are some limitations. First, the study was not registered in a clinical trial registry, which may affect transparency. Second, blinding was impossible, introducing potential observer bias. Finally, the research was conducted at one center, which limits how broadly the results can be applied.

7. Implications for Public Health and Future Research

Given the high rate of PCOS and the challenges of conventional drug treatments, Ayurveda-based options might offer an accessible, culturally appropriate, and affordable strategy in resource-limited areas. [18,20] Future multi-center studies with longer durations and registered trials focusing on biochemical and live birth results are needed to confirm these findings.

8. DECLARATION

8.1. Ethical approval and consent to participate

The Institutional Ethics Committee approved this study (IEC Approval No. ECR/288/Indt/TN/2018/RR-21/154, dated 15.11.2024). All participants were informed about the study, and written informed consent was obtained prior to participation.

8.2. Data and Material Availability

All the data used to generate and analyse in the presented study are available from the corresponding author upon reasonable request.

8.3. Conflicts of interest

The authors declare that there are no competing interests.

8.4. Contribution of the Authors

All the three authors (Author 1, Author 2, and Author 3) participated equally in the design of study, collection of data and writing the manuscript. The research was directed by the senior author and the manuscript was critically revised by him. Prior to the final manuscript, all authors read and accepted its version.

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