Integrative Ayurvedic and Biomedical Management of Polycystic Ovary Syndrome: A Longitudinal N-of-1 Observational Study with Clinical and Reproductive Outcomes

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ABSTRACT

background: Polycystic Ovary Syndrome (PCOS) is a chronic endocrine–metabolic disorder marked by hyperandrogenism, anovulation, and insulin resistance. Integrative approaches combining classical Ayurveda with modern biomedical therapy are frequently used in India, yet systematically documented real-world outcomes remain scarce.

Objective: To document longitudinal menstrual, metabolic, and reproductive outcomes in a woman with PCOS following an integrative Ayurvedic–biomedical therapeutic regimen.

Methods: An N-of-1, eight-month prospective observational study was conducted on a 25-year-old woman with ultrasound-confirmed PCOS. Therapy included metformin and myo-inositol along with classical Ayurvedic formulations targeting Kapha–Vata Dushti, Agnimandya, and Srotorodha. Outcomes included menstrual cyclicity, ultrasound-based ovulation tracking, serial haemoglobin trends, symptomatic changes, and conception status. All biomedical safety parameters (LFT, KFT) were monitored.

Results: Menstrual cycles gradually normalized (from >45 days to 28–32 days). Ovulation was confirmed by follicular ultrasound. Haemoglobin increased from **7.3 g/dL to 10.2 g/dL** over the observation period. A spontaneous conception occurred in January 2025. Safety parameters remained within normal limits. Causality cannot be inferred due to concurrent biomedical therapy and absence of hormonal markers.

Conclusion: Integrative care in this single-subject study was associated with improved cycle regularity, ovulatory function, hematological restoration, and conception. Controlled trials with standardized protocols are required to evaluate efficacy and mechanisms.

Keywords: PCOS, Integrative Medicine, Ayurveda, Ovulation, Infertility, Hemoglobin, N-of-1 Study

INTRODUCTION

Polycystic Ovary Syndrome (PCOS) is among the most common endocrine disorders in women of reproductive age, with a prevalence between 8–13% globally (Teede et al., 2018). Its pathophysiology includes hyperandrogenism, chronic anovulation, insulin resistance, and systemic inflammation (Azziz et al., 2016; Barber et al., 2020). Standard biomedical treatment focuses on metabolic correction and induction of ovulation; however, long-term outcomes remain variable, and many women seek complementary medical approaches.

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In Ayurveda, PCOS-like presentations are understood under Aartava Kshaya, Nashtartava, and Kaphaja Yonivyapad. These arise from Kapha-dominant metabolic stagnation, Agnimandya (reduced digestive–metabolic fire), and Srotorodha (obstruction of physiological channels), leading to disordered folliculogenesis (Caraka Saṃhitā, Sūtrasthāna 28; Suśruta Saṃhitā, Cikitsā Sthāna 2).

Integrative Ayurvedic–biomedical therapy is practiced widely, yet peer-reviewed, systematically documented real-world evidence is limited. N-of-1 observational designs can offer valuable preliminary insights, especially when causal claims are avoided.

This paper presents longitudinal observations from eight months of integrative therapy in a woman with PCOS, focusing on measurable clinical outcomes.

MATERIALS AND METHODS

2.1 Study Design

A prospective N-of-1, longitudinal observational study was conducted over eight months (May 2024–January 2025). The design aimed to document naturalistic clinical progression without inferring causality.

2.2 Ethical Approval and Consent

Approved by the Institutional Ethics Committee, P.V. Belhekar Ayurved Medical College Approval No.: **IEC/2024/PCOS/017**, dated **15 March 2024**.
Written informed consent was obtained.

2.3 Participant

A 25-year-old woman with:

- Ultrasound-confirmed bilateral polycystic ovarian morphology
- Oligomenorrhoea since 2.5 years
- Clinical signs of hyperandrogenism (acne, hirsutism)
- Chronic anemia (Hb 7.3 g/dL)
- Desire to conceive

Baseline investigations included CBC, LFT, KFT, and pelvic ultrasonography.

2.4 Biomedical Treatment

- **Metformin 500 mg** twice daily
- **Myo-inositol 600 mg** twice daily

These are evidence-based insulin-sensitizing agents (Nestler, 2008).

2.5 Ayurvedic Interventions

Formulations targeted:

- Agnideepana and Amapachana
- Srotoshodhana
- Rasa–Rakta–Artava dhatu poshana

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Full quantitative compositions are detailed in **Appendix 1** (WinPCO Capsule, WinPCO Plus Tablet, Setmense Syrup, etc.).

2.6 Outcome Measures

1. **Menstrual cyclicity**
2. **Ovulation confirmation** (follicular USG)
3. **Serial haemoglobin values**
4. **Symptom trends** (acidity, bloating, acne, hirsutism)
   Pregnancy outcome
5. **Safety monitoring** (LFT, KFT)

RESULTS

3.1 Menstrual Patterns

Cycles normalized from irregular (>45–60 days) to regular (28–32 days) by Month 5.

3.2 Ovulation

Follicular study showed:

- DF 15×14 mm → 21×20 mm
- Rupture observed on Day 18

This indicated **restored ovulation**.

3.3 Hematological Improvement

Month	Hemoglobin (g/dL)
May 2024	7.3
Sept 2024	8.0
Dec 2024	10.2

A steady upward trend was observed, attributed to nutrition optimization and improved digestive capacity—though causality cannot be claimed.

3.4 Conception Outcome

Spontaneous conception occurred in **January 2025**, confirmed by UPT and ultrasound (5 weeks 4 days gestation).

3.5 Safety

Liver and kidney function tests remained normal throughout the study.

DISCUSSION

This N-of-1 observational study documented improvements associated with an integrative therapeutic protocol

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in a woman with PCOS. Modern research confirms that insulin resistance, low-grade inflammation, and androgen excess contribute to chronic anovulation (Rosenfield & Ehrmann, 2016). Ayurvedic frameworks describe analogous processes—Kapha-Vata Dushti, Agnimandya, and Srotorodha—that impair folliculogenesis.

However, because the patient received *metformin* and *myo-inositol*—both potent insulin-sensitising agents—the improvements cannot be attributed to Ayurveda alone. Instead, Ayurveda may have provided supportive benefits through digestive-metabolic regulation, symptom reduction, and lifestyle discipline.

Why This Study Is Valuable

- Provides real-world, longitudinal documentation
- Shows indicators of ovulatory recovery
- Demonstrates improvement in anaemia
- Reports successful conception

But it purposefully avoids causal claims.

5. Limitations

- Single-subject design (N=1)
- Absence of hormone assays (LH, FSH, AMH, androgens)
- Anthropometric trends are not tracked monthly
- Potential confounding from biomedical therapy
- No standardised symptom scoring
- Results cannot be generalised 6. FUTURE RESEARCH DIRECTIONS

For publication-grade research, future studies should include:

- Randomised controlled trials
- Standardised Ayurvedic formulations
- Hormonal profiles
- HOMA-IR and metabolic markers
- Acne and hirsutism scoring
- Multi-arm comparison (Ayurveda vs. biomedical vs. integrative)
- Qualitative patient-reported outcomes

CONCLUSION

This N-of-1 longitudinal study documents meaningful improvements in menstrual regularity, ovulation, hematological status, and conception during integrative Ayurvedic–biomedical management of PCOS. While the observational nature restricts causal conclusions, the findings support further controlled research into integrated care models for PCOS.

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APPENDIX 1 — FULL FORMULATION COMPOSITION WinPCO Capsule

- Pushpadhanwa Rasa – 60 mg
- Raspachak (Indrajav, Patol, Kutki) – 60 mg
- Haridra – 50 mg
- Neem Patra (Ghan) – 100 mg
- Jambhul Beej (Ghan) – 60 mg
- Nagarmotha – 60 mg ● Kalmegh – 60 mg
- **Bhavana dravya:** Gudmar – 200 mg, Latakaranj – 100 mg, Karle – 220 mg

Ingredient	**Botanical Name**	**Form (Ghan / Powder / Sal)**	**Quantity / 5 ml**
Ashok Sal	*Saraca asoca*	*Sal*	***1800 mg***
Manjishtha Root Ghan	*Rubia cordifolia Ext.*	*Ghan*	***75 mg***
Lodhra Stem Ghan	Symplocos racemosa Ext.	Ghan	**250 mg**
Gulvel Stem Ghan	Tinospora cordifolia Ext.	Ghan	**100 mg**
Anantmool Root Ghan	Hemidesmus indicus Ext.	Ghan	**75 mg**
Ashwagandha Root Ghan	Withania somnifera Ext.	Ghan	**100 mg**
Shatavari Root	Asparagus racemosus	Powder / Extract	**100 mg**
Bala Mool	Sida cordifolia	Powder	**50 mg**
Umber Sal	Ficus glomerata	Sal	**50 mg**
Punarnava Root	Boerhaavia diffusa	Powder	**75 mg**
Gokharu Fruit	Tribulus terrestris	Powder	**100 mg**
Dashmool	—	Mool	**75 mg**
Ulatkambal Sal	Abroma augusta	Sal	**100 mg**
Amla Fruit	Phyllanthus emblica	Powder	**75 mg**
Khair Sal	Acacia catechu	Sal	**75 mg**
Raspachak	(Traditional Digestive Corrective)	Churna	**50 mg**

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WinPCO Plus Tablet

- Pushpadhanwa – 80 mg
- Garcinia Ext – 60 mg
- Navak Guggul – 60 mg
- Neem Ext

- Jambhul Ext – 60 mg
- Haridra Ext – 60 mg
- Raspachak – 60 mg ● Kalmegh – 60 mg
- **Bhavana:** Phalghruta – 100 mg, Gudmar – 100 mg, Karle – 100 mg, Latakaranj – 200 mg

Setmense Syrup

Ositate M 500/600 mg

- Metformin
- Myo-inositol

PCOFER Ointment

- Herbal anti-inflammatory topical formulation