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OUTCOMES OF A STANDARDIZED AYURVEDA-BASED FERTILITY PROTOCOL IN INFERTILITY: A MULTICENTER PROSPECTIVE STUDY

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ABSTRACT

Background: Infertility is a growing reproductive health challenge in India, with Polycystic Ovarian Disease (PCOD), unexplained infertility, and low Anti-Müllerian Hormone (AMH) representing a significant proportion of clinical cases. This clinical study was initiated to evaluate the effectiveness of a standardized Ayurveda-based fertility protocol across multiple clinics in India. **Objective:** To assess conception outcomes following a structured, protocol-driven Ayurvedic fertility intervention across four primary infertility cohorts. **Methods:** A multicenter, prospective observational study was conducted from May 2025 onwards across India, enrolling 534 women diagnosed with PCOD (delayed and regular cycles), unexplained infertility, and low AMH. Standardized treatment protocols involving Ayurvedic formulations, ovulation tracking, male fertility support, and structured follow-up framework were implemented. The study was designed for a 90-day follow-up period; however, substantial loss to follow-up beyond 60 days resulted in primary outcome analysis based on available data during the active observation period. **Results:** Out of 534 enrolled patients, 167 achieved conception, resulting in an overall conception rate of 31% during the observation period. Conception rates varied across cohorts: PCOD delayed (45%), PCOD regular (27%), unexplained infertility (27%), and low AMH (33%). Patient engagement declined over time, limiting complete follow-up for a proportion of participants beyond 60 days. **Conclusion:** A structured Ayurveda-based fertility protocol integrated with ovulation tracking and standardized follow-up demonstrated moderate conception outcomes in real-world clinical settings. However, variability in adherence, diagnostic accuracy, and patient engagement significantly influenced outcomes. Further controlled studies are required to validate efficacy and optimize protocol adherence.

KEYWORDS: Infertility, Ayurveda, Polycystic Ovary Syndrome (PCOS), Conception Rate, Unexplained infertility, Low AMH.

INTRODUCTION

Infertility affects a significant proportion of couples globally, with rising prevalence in India due to lifestyle, endocrine, and reproductive health disorders. The most commonly encountered clinical categories include Polycystic Ovarian Disease (PCOD), unexplained

infertility, and diminished ovarian reserve, commonly assessed through Anti-Müllerian Hormone (AMH) levels.[1]

PCOD is an endocrine–metabolic disorder characterized by chronic anovulation, hyperandrogenism, and polycystic ovarian morphology. Clinically, it presents with menstrual irregularities such as oligomenorrhea or amenorrhea, along with features including acne, hirsutism, weight gain, and subfertility. The primary mechanism of infertility in PCOD is disrupted or absent ovulation, which leads to reduced fecundability. Patients may present with either delayed menstrual cycles (35–60 days) or relatively regular cycles (21–35 days) with underlying ovulatory dysfunction.[2]

Unexplained infertility is diagnosed when a couple is unable to conceive after at least 12 months of regular, unprotected intercourse, despite normal findings in standard fertility evaluations, including evidence of ovulation, patent fallopian tubes, and normal semen parameters. It is considered a diagnosis of exclusion and may involve subtle dysfunctions such as impaired oocyte quality, reduced endometrial receptivity, or unexplained gamete interaction abnormalities that are not detectable through routine investigations.[3]

Diminished ovarian reserve refers to a reduction in the quantity and/or quality of oocytes, often reflected by decreased Anti-Müllerian Hormone (AMH) levels. AMH is produced by granulosa cells of pre-antral and small antral follicles and serves as a reliable marker of ovarian reserve. While menstrual cycles may remain regular, fertility potential is reduced due to a diminished follicular pool, often resulting in a reduced response to ovulation induction and lower per-cycle conception probability.[4]

Despite advancements in assisted reproductive technologies, accessibility and affordability remain major barriers. In addition, the hormonal medications used during treatment carry risks that may further disrupt the female reproductive system. Ayurveda-based fertility interventions are increasingly explored as alternative or complementary approaches; however, the lack of standardization and large-scale outcome data has limited their integration into mainstream reproductive care.[5]

This study was designed to address this gap by implementing a standardized, protocol-driven Ayurveda fertility model across multiple clinics, with the aim of improving conception outcomes through structured treatment pathways, ovulation tracking, and continuous patient monitoring.

MATERIALS AND METHODS

Study Design

Multicenter prospective observational cohort study conducted across fertility clinics in India.

Study Duration

The study was initiated in May 2025 with a planned follow-up period of 90 days for each participant. However, this interim analysis includes data collected between May and June 2025. Due to progressive loss to follow-up and declining patient engagement beyond the initial observation period, the present analysis is based on outcomes available during the first two months of active follow-up.

Sample Size

Total enrolled patients: 534

MATERIALS AND METHODS

Study Population: Inclusion Criteria

- Women aged 18–40 years with infertility (failure to conceive after 12 months of regular unprotected intercourse, or 6 months if >35 years).
- PCOD with regular cycles (21–35 days) or delayed cycles (35–60 days); PCOD defined by Rotterdam criteria.
- Unexplained infertility: regular cycles, confirmed bilateral tubal patency (HSG/SSG/laparoscopy) and partner semen normal by WHO standards.
- Diminished ovarian reserve: low AMH with regular cycles (21–35 days) and non-elevated FSH.
- Documented baseline investigations within 6 months (AMH, FSH/LH/estradiol, TSH, prolactin, pelvic ultrasound).
- Negative pregnancy test at screening; not currently breastfeeding.
- No hormonal fertility treatment within the past 3 months (washout).
- Willing and able to comply with timed intercourse, ovulation tracking, study visits, and informed consent.

Exclusion criteria

- Current pregnancy or breastfeeding.
- Uterine or adnexal pathology impairing fertility (submucous fibroid/polyp >2 cm, untreated intrauterine adhesions, significant adenomyosis) or confirmed endometriosis.
- Positive STI screen (HIV, Hepatitis B/C).
- Hyperprolactinemia (any active or uncontrolled case).
- Current use of hormonal fertility treatments or ovulation-inducing agents within the past 3 months.
- Uncorrected thyroid disease.
- Severe systemic illness (decompensated liver disease, stage ≥4 chronic kidney disease, uncontrolled cardiopulmonary disease).
- Multiple concurrent gynecologic conditions likely to confound outcomes (e.g., PCOD plus significant fibroids or active PID).
- Severe oligomenorrhea/amenorrhea (cycle length >60 days) without spontaneous menses.
- Medications affecting reproduction or contraindicated in pregnancy within 1 month of screening.

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- Participation in another investigational drug trial within 1 month.
- Known hypersensitivity to study drug ingredients.
- Male patient with any severe condition like azoospermia
- Any condition or circumstance that, in the investigator's judgment, poses risk or would confound study results.

A standardized Ayurveda-based protocol was implemented

Eligible participants were managed using a standardized, protocol-driven Ayurveda-based fertility intervention designed to ensure uniformity of treatment across cohorts while allowing targeted personalization based on diagnosis.

1. Female Treatment Protocol

All participants received a structured three-component herbal regimen:

- General fertility support: *Tablet Poshini* administered to improve overall reproductive health and endometrial receptivity
- Ovulation regulation therapy:
- Patients in the PCOD (regular cycles), unexplained infertility, and low AMH cohorts received *Tablet Upaja* throughout the menstrual cycle and *Tablet Rutuja* from Day 6 to Day 16 of the menstrual cycle for ovulation induction. Patients with PCOD and delayed or irregular menstrual cycles received *Tablet Vamha* throughout the treatment period along with *Tablet Rutuja* from Day 6 to Day 16 of the menstrual cycle.
- Ovulation monitoring was conducted through follicular scans and/or home ovulation kits. In cases of absent ovulation, *Tablet Rutuja* was replaced with *Tablet Tulha* as per protocol, and treatment was continued until cycle completion.
- Disorder-specific formulation:
- *Tablet Myrha* for PCOD
- *Tablet Supraja* for unexplained infertility
- *Tablet Vardhani* for low AMH

Table 1: Treatment for Female Patient.

Medicine given	Ingredients/Contents	Dosage
Tab. Myrha (1g)	*Kutaj Twak Churna, Patola Churna, Katuki Churna, Shuddha Shilajit, Trikatu Churna, Trijat Churna, Yashad Bhasma, Kanchanar, Varuna, Ashwagandha, Haridra, Amalaki, Methi, Saptarangi, Asana, AVartika, Jambu, Meshashringi, Mamejava, Guduchi, Bilva, Nimba, Karvellak, preservatives and excipients.*	2 pills after breakfast and 2 pills after dinner
Tablet Upaja (500 mg)	*Kumari, Shuddha Kasis, Dalchini, Sonth, Gulkand*	2 pills after breakfast and 2 pills after dinner
Tablet Poshini (600 mg)	*Shuddha Hingul, Bang Bhasma, Shivlingi, Shatavari, Ashwagandha, Jivanti, Putranjivak*	2 pills after breakfast and 2 pills after dinner
Tablet Rutuja (300 mg)	*Kumari, Shuddha kasis, Shuddha Tankan, Hingu*	2 pills after breakfast and 2 pills after dinner
Tab. Tulha (600 mg)	*Kumari, Shatavari, Dashmool, Devdaru, Kulattha, Ulatkambal, Manjistha, Eranda, Pippali, Shatapushpa, Haritaki, Krishna Jeeraka, Gajar Beeja, Karpas Beeja, Rason, Jyotishmati, Sunthi, Tankan Bhasma, Hingula Rasa, and Kasis Bhasma.*	2 pills after breakfast and 2 pills after dinner

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2. Male Treatment Protocol

Male partners were concurrently managed based on their clinical presentation. General reproductive support was provided using *Tablet Beehj* for baseline fertility enhancement. In cases with abnormalities in semen parameters, including reduced sperm count, motility, or abnormal morphology, additional Ayurvedic formulations such as *Tablet Kavachbeej and Makar* were prescribed. These interventions were also utilized in patients presenting with sexual dysfunction, including erectile dysfunction and premature ejaculation.

Table 2: Treatment for Male Patient.

Medicine given	Ingredients/Contents	Dosage
Tablet Beehj (500mg)	*Shweta Musali, Shuddha Kaucha, Gokshur, Ashwagandha, Guduchi, Vriddhadaru, Shatavari, Bala, Amalaki, Varahi Kanda, Kokilaksha, Vidarikanda, Jivanti, Akkalgaru, Jayphal, Swarnamakshik bhasma, Swarna Bang, Shuddha Shilajit, Salab Mishri Churna*	2 pills after breakfast and 2 pills after dinner
Kavachbeehj (300 mg)	*Kaunchbeejh*	2 pills after breakfast and 2 pills after dinner
Makar (250 mg)	*Makardhwaja Rasa Powder, Jatiphala, Karpura, Marich, Javitri*	1 tablet at night

3. Follow-Up and Monitoring Protocol

Participants underwent structured follow-up evaluations across three consecutive treatment cycles. Each follow-up visit included:

- Assessment of ovulation status using follicular study and/or ovulation prediction kits
- Reinforcement of medication adherence and lifestyle recommendations
- Modification of ovulation-inducing therapy based on treatment response, including transition to *Tablet Tulha* in cases where ovulation was not achieved
- Review of clinical progress and counseling regarding the subsequent treatment cycle

Follicular monitoring (ovulation scan) was recommended from the first treatment cycle onward, with the timing generally scheduled from Day 10 of the menstrual cycle (calculated as LMP + 10 days). Laboratory investigations and additional assessments were performed during follow-up visits according to the study protocol.

4. Behavioral Adherence Framework

Participants were advised to follow a structured behavioral and lifestyle adherence framework throughout the treatment duration, which included:

- Adherence to the prescribed medication regimen
- Regular ovulation tracking using recommended monitoring methods
- Monthly clinical consultations for progress assessment and treatment guidance
- Maintenance of structured meal timings following the 8–2–8 dietary schedule
- Engagement in regular physical activity, including a minimum of 30 minutes of walking daily
- Ensuring adequate sleep duration of approximately 8 hours per night

Outcome Measure

The primary outcome measure was the achievement of clinical conception within the period of enrollment.

RESULTS

Overall Outcomes

1. A total of 534 patients were included in the study cohort. Among these, 167 patients achieved clinical conception within the study period, resulting in an overall conception rate of 31%.
2. Monthly Distribution of Outcomes

Table 3: Summary Table (Overall + Monthly Outcomes)

Metric	Value
Total patients	534
Total conceptions	167
Overall conception rate	31%

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Table 4: Month-wise conception.

Month	Enrollment	Conceptions	Conception rate
May	205	81	40%
June	329	86	26%

May cohort: Of the 205 patients enrolled, 81 achieved conception, corresponding to a conception rate of 40%.
June cohort: Of the 329 patients enrolled, 86 achieved conception, corresponding to a conception rate of 26%.

3. Cohort-Wise Conception Rates

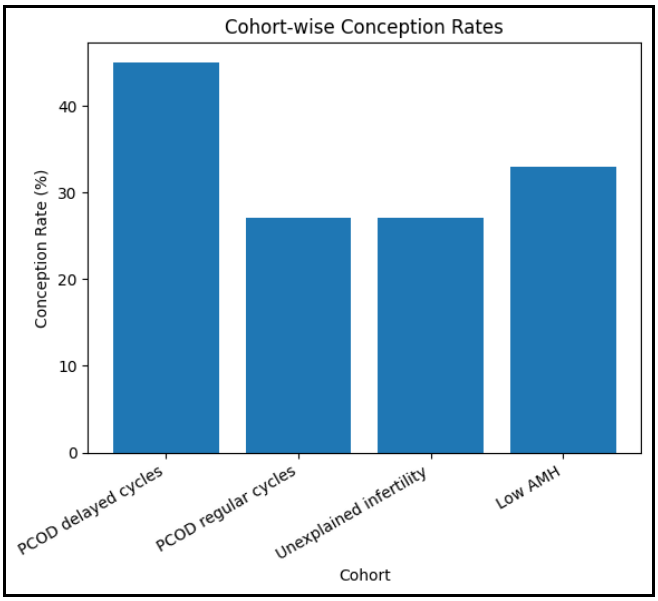

Figure 1: Cohort- wise conception rates across infertility cohort.

Cohort-wise analysis demonstrated variation in conception rates across different infertility subgroups. The highest conception rate was observed among patients with PCOD associated with delayed menstrual cycles (45%), followed by the low AMH cohort (33%). Patients with PCOD and regular menstrual cycles, as well as those with unexplained infertility, showed comparable conception rates of 27%. These findings suggest that treatment outcomes differed according to the underlying infertility profile, with particularly favorable outcomes observed in the PCOD cohort with delayed cycles.

DISCUSSION

This multicenter prospective observational study evaluated a standardized Ayurveda-based fertility protocol in 534 women with PCOD, unexplained infertility, and diminished ovarian reserve. A 31% overall conception rate within 60 days suggests that structured integrative fertility care, when combined with systematic ovulation tracking and standardized follow-up, may offer a clinically meaningful non-invasive option in routine practice. The highest conception rate was observed in PCOD with delayed menstrual cycles (45%), followed by the low AMH cohort (33%). PCOD with regular cycles and unexplained infertility showed similar conception rates of 27%. These differences likely reflect underlying pathophysiological variation across infertility types. PCOD with delayed cycles, often driven by pronounced anovulation, may respond more rapidly to interventions that restore follicular development and ovulation. Unexplained infertility, being heterogeneous, may involve subtle defects in oocyte quality, sperm function, endometrial receptivity, or implantation, which can limit short-term response despite normal ovulation. In low AMH cases, the moderate response suggests that while ovarian reserve is reduced, conception remains achievable when cycle regulation and reproductive environment are optimized, though variability in oocyte quality and quantity influences outcomes.

When benchmarked against published ART data in comparable populations, in the low AMH subgroup, a 33% conception rate in the current study compares favorably with IVF outcomes reported for women with low ovarian reserve (20–35% in some Indian centers, and as low as 13–18% in older age cohorts), where success declines sharply with age and AMH level. Similarly, in unexplained infertility, the 27% 60-day conception rate contrasts with conventional per-cycle pregnancy estimates of approximately 2–4% with expectant management, 5–10% with tablet-based stimulation plus IUI, and 7–20% with gonadotropin-IUI. In PCOD-related anovulatory infertility, where lifestyle modification, ovulation induction agents (clomiphene,

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letrozole), and IUI or IVF typically yield cumulative pregnancy rates in the 20–40% range over several cycles, the current protocol demonstrated its highest response in the delayed-cycle PCOD cohort (45%), followed by low AMH (33%), and somewhat lower but comparable rates in PCOD regular-cycle and unexplained infertility groups (27% each). [6] to [25]

Table 5: Low AMH, Unexplained Infertility, PCOD Results – current study vs IVF - Data derived from references 6-25.

Population / Condition	Current Study – Conception / Pregnancy Rate	ART / Standard Care Pregnancy Rate
Low AMH cohort	**33%**	4.4% – 35%
Unexplained infertility	**27%**	~5% – 20%
PCOD with delayed periods	**45%**	20% – 30%
PCOD with regular periods	**27%**	20% – 30%

An important temporal trend in this study was the higher conception rate during early recruitment (40% in May) compared with later phases (26% in June). This decline coincided with reduced patient engagement and waning adherence to protocol-based monitoring, suggesting that behavioral factors and follow-up intensity exert a substantial influence on outcomes, irrespective of the therapeutic modality. Adherence challenges were also evident in ovulation tracking: only about half of the participants initiated monitoring within the first month, and reliance on home ovulation prediction kits was associated with an estimated 40% interpretation error. Suboptimal timing of intercourse due to misinterpreted ovulation windows may therefore have attenuated the achievable conception rates. These observations highlight the importance of clinician-guided or better-standardized ovulation monitoring, structured patient education, and simple, user-friendly tracking tools in integrative fertility programs.

The observed decline in outcomes over time may also reflect “treatment fatigue”, a phenomenon commonly seen in fertility care, in which prolonged monitoring, repeated cycles, and delayed success lead to reduced motivation and compliance. Within this context, strategies such as reinforced counseling, digital reminders, simplified monitoring schedules, and periodic re-assessment of patient goals may be critical for sustaining engagement and preserving protocol efficacy. Nonetheless, the multicenter design, standardized treatment framework, and real-world setting enhance ecological validity and offer practical insight into implementation at scale.

Overall, the findings suggest that a structured Ayurveda-based fertility protocol integrated with ovulation tracking and close follow-up may yield promising short-term conception outcomes across diverse infertility phenotypes, including those traditionally considered prognostically challenging, such as low AMH. At the same time, treatment success appears strongly modulated by patient engagement, monitoring accuracy, and adherence over time. Future studies should prioritize randomized controlled designs, robust comparator arms (e.g., expectant management or standard ovulation induction), improved digital adherence and monitoring tools, and more precise phenotyping to better isolate treatment effects and refine patient selection for integrative fertility interventions.

CONCLUSION

This multicenter prospective study demonstrates that a standardized Ayurveda-based fertility protocol, implemented with structured ovulation tracking and a defined follow-up framework, achieves encouraging short-term conception rates across diverse infertility phenotypes in real-world clinical settings. The overall 31% conception rate within the active observation period is particularly notable, with especially strong responses in clinically important subgroups: 45% in women with PCOD and delayed cycles, 33% in women with low AMH, and 27% in both PCOD with regular cycles and unexplained infertility. These outcomes compare favorably with published rates for conventional approaches in comparable populations, including IVF in low AMH women and ovulation induction plus IUI in unexplained infertility.

Overall, these findings support the clinical promise of a protocolized Ayurveda-based fertility intervention as a meaningful option in routine reproductive care. The strong subgroup responses, standardized delivery, and practical applicability highlight the potential for this model to improve access to effective fertility care while maintaining patient-centered, holistic management.

CONFLICT OF INTEREST

The authors declare no conflicts of interest relevant to this article.

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