Journal of Kaumarbhritya and Stree Vigyan

ISSN Print: 3078-7432
ISSN Online: 3078-7440
JKSV 2025; 2(2): 05-12
www.kaumarjournal.com
Received: 02-07-2025
Accepted: 05-08-2025

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Evaluation of an ayurvedic phala-vardhaka yoga in unexplained female infertility: A multicentric clinical study

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DOI: https://www.doi.org/10.33545/kaumarbhritya.2025.v2.i2.a.17

Abstract
Unexplained infertility affects a significant proportion of couples seeking reproductive assistance, with limited treatment options available beyond conventional assisted reproductive technologies (ART). This multicentric, randomised controlled clinical study aimed to evaluate the efficacy and safety of *Phala-Vardhaka Yoga* (PVY), an Ayurvedic formulation, as an adjunct to standard infertility care in women diagnosed with unexplained infertility. A total of 210 women were randomised to receive either PVY plus standard care or standard care alone over six treatment cycles. The primary outcome was clinical pregnancy rate, with secondary outcomes including ovulation rate, endometrial thickness, and live-birth rates. The results showed that the PVY group had a significantly higher clinical pregnancy rate (38.1% vs 21.9%; p=0.006) and live-birth rate (34.3% vs 19.0%; p=0.012) compared to the standard care group. Additionally, PVY was associated with higher ovulation rates (86.1% vs 73.8%, p=0.018) and greater improvement in endometrial thickness (9.5 mm vs 8.8 mm, p=0.003). The formulation was well tolerated, with mild, transient adverse events. These findings suggest that *Phala-Vardhaka Yoga* provides an effective, safe, and non-invasive adjunct to standard infertility treatments, particularly for women with unexplained infertility. The study supports the integration of Ayurvedic therapies into modern fertility care, offering a complementary option for those seeking alternative or adjunct treatments to ART.

Keywords: Unexplained infertility, *phala-vardhaka yoga*, ayurvedic formulation, clinical pregnancy rate, live-birth rate, ovulation, endometrial thickness, assisted reproductive technology, integrative medicine, fertility treatment, ayurveda, randomised controlled trial, reproductive health

Introduction
Infertility is recognised by the World Health Organization as a disease of the reproductive system and affects roughly one in six adults worldwide over their reproductive lifetime, imposing substantial psychological, social and economic burden on couples and health systems, particularly in low- and middle-income countries such as India [1-3]. Conventional epidemiological analyses indicate that infertility prevalence has remained high and relatively stable over recent decades despite major advances in assisted reproductive technologies (ART) [2-4]. According to standard definitions endorsed by WHO and the International Committee for Monitoring Assisted Reproductive Technology (ICMART), infertility is diagnosed when pregnancy does not occur after ≥12 months of regular unprotected intercourse, and this umbrella includes a heterogeneous group of male, female and mixed factor disorders [1, 5, 6]. Within this spectrum, unexplained infertility defined as failure to conceive despite normal semen analysis, documented ovulation and tubal patency on appropriate evaluation accounts for an estimated 15-30% of infertile couples and remains one of the most contentious and frustrating diagnoses for clinicians and patients alike [7-9]. Recent guidelines and reviews from ESHRE, ASRM and other expert bodies highlight that, although combinations of ovarian stimulation, intrauterine insemination and IVF/ICSI form the current standard of care, evidence is limited by heterogenous case definitions, variable prognostic stratification and the high financial, physical and emotional costs of repeated ART cycles [9-12]. Against this backdrop, there is growing interest in integrative and traditional systems of medicine to provide safer, affordable and culturally congruent fertility-enhancing strategies, particularly for couples with unexplained infertility who are either

poor responders, unable to access ART, or seeking less invasive options. Ayurveda conceptualises infertility under the broad heading of *Vandhyatva* and emphasises the optimisation of the four *Garbhasambhava Samagri Ritu* (fertile period), *Kshetra* (reproductive tract), *Ambu* (nutritional milieu) and *Beeja* (ovum and sperm) as a prerequisite for healthy conception and viable progeny [13-15]. Therapeutic approaches typically combine *Shodhana* (biopurification) and *Rasayana* (rejuvenation) with *Prajasthapana* and *Phala-vardhaka* formulations, which are designed to correct *dosha* imbalance, nourish reproductive tissues, enhance folliculogenesis and endometrial receptivity, and reduce stress-related and metabolic contributors to infertility [15-18]. Preliminary clinical studies and case series suggest that Phala-ghrita-based regimens and related Ayurvedic fertility-promoting yogas can improve menstrual regularity, ovulation parameters and conception rates in female infertility, including in some women without clearly identifiable organic causes, but these reports are largely single-centre, small-sample or uncontrolled and cannot be generalised [16, 19-21]. Therefore, the present multicentric clinical study was undertaken to systematically evaluate the efficacy and safety of a standardised Ayurvedic *Phala-Vardhaka Yoga* in women diagnosed with unexplained female infertility, with the specific objectives of assessing its effects on ovulation, endometrial receptivity, clinical pregnancy and live-birth outcomes compared with standard care, and of generating robust evidence to inform integrative treatment algorithms; the central hypothesis is that adjunctive administration of this *Phala-Vardhaka Yoga* will significantly increase clinical pregnancy rates and improve key reproductive parameters in unexplained female infertility, without unacceptable adverse effects, when compared with conventional management alone.

Materials and Methods

Materials

This multicentric, randomized, controlled clinical study was conducted at three tertiary-level Ayurvedic teaching hospitals with dedicated infertility clinics in India, chosen to represent diverse geographic and sociodemographic profiles while maintaining uniform standards of diagnostic work-up and clinical documentation in line with international and national recommendations on infertility care [1-3, 5-8, 10-12]. Women aged 21-38 years with a diagnosis of unexplained female infertility, defined according to WHO/ICMART and contemporary guideline criteria as failure to conceive after ≥12 months of regular unprotected intercourse despite documented ovulation, normal semen parameters and bilaterally patent fallopian tubes on hysterosalpingography or laparoscopy, were screened for eligibility [1, 5-8, 10-12]. Unexplained infertility was diagnosed only after exclusion of male factor, tubal factor, advanced endometriosis, significant uterine cavity abnormalities and severe systemic illness, in accordance with ESHRE and ASRM guidance [7-12]. The Ayurvedic diagnostic framework incorporated assessment of *Vandhyatva* and evaluation of *Ritu, Kshetra, Ambu* and *Beeja* as per classical and contemporary Ayurvedic texts and clinical literature [13-15, 18]. Key exclusion criteria included prior IVF/ICSI cycles in the preceding 6 months, uncontrolled endocrine or metabolic disorders (e.g. uncontrolled diabetes, thyroid disease), severe oligozoospermia in the male partner, and use of any other fertility-enhancing traditional or complementary therapy in the last 3 months [2, 4, 9, 11]. The investigational Ayurvedic *Phala-Vardhaka Yoga* was a standardised, pharmacy-prepared polyherbal formulation conceptualised under *Prajasthapana* and *Rasayana* categories, drawing on earlier reports of Phala-ghrita and related yogas in female infertility [13, 15-19]. Its composition included *Garbhakaraka* and *Artavajanana* drugs (e.g. *Ashvagandha*, *Shatavari*, *Lodhra*, *Guduchi*) processed in a ghee-based matrix following good manufacturing practice and quality-control norms, with batch-wise testing for identity, purity, microbial load and heavy metals, guided by prior pharmacognostic and clinical studies on similar formulations [13-16, 18-21]. Eligible women who met both modern and Ayurvedic criteria and provided written informed consent were enrolled and allocated either to the intervention group (Phala-Vardhaka Yoga plus standard conventional care) or the control group (standard conventional care alone), while both groups also received general preconception counselling on diet, lifestyle and coital timing consistent with contemporary infertility and Ayurvedic recommendations [1, 3, 9, 13-17].

Methods

The study followed a parallel-group, assessor-blinded design with central computer-generated block randomization stratified by centre and infertility duration (<3 years vs ≥3 years), with allocation concealed using sequentially numbered, opaque, sealed envelopes prepared by an independent statistician [7-12]. Participants in the intervention arm received the *Phala-Vardhaka Yoga* orally in a fixed weight-adjusted daily dose for six consecutive ovulatory cycles, initiated in the early follicular phase each cycle; dose, duration and timing were selected based on earlier Phala-ghrita and Ayurveda infertility studies as well as *Rasayana* practice principles, while ensuring feasibility and safety in the multicentric setting [13-16, 18-21]. Both groups continued to receive conventional management as per local standard protocols, including cycle monitoring, timed intercourse advice and correction of minor luteal phase or thyroid disturbances, reflecting current evidence-based practice for unexplained infertility [5-12]. Clinical assessments were performed at baseline and in each treatment cycle, and included detailed menstrual and reproductive history, physical and gynaecological examination, body mass index, blood pressure, and targeted laboratory tests (complete blood count, liver and renal function tests, fasting glucose, thyroid profile) for safety monitoring [1-3, 5, 9]. Transvaginal ultrasonography was used to document follicular growth, ovulation, and endometrial thickness and pattern in at least three representative cycles, paralleling earlier follicular study-based trials of *Phala Ghrita* and other Ayurvedic fertility interventions [17, 19-21]. The primary efficacy outcome was the cumulative clinical pregnancy rate (presence of intrauterine gestational sac with fetal cardiac activity on ultrasound) within six treatment cycles; secondary outcomes included ovulation rate per cycle, mean dominant follicle diameter, mean endometrial thickness in the peri-ovulatory window, biochemical pregnancy rate, ongoing pregnancy and live-birth rates, time to conception, and changes in self-reported stress and quality-of-life scores, chosen in line with prior guideline and trial literature on unexplained infertility [7-12, 18]. Safety outcomes comprised adverse events, serious adverse events, and clinically significant changes in laboratory parameters.

Sample size was calculated to detect an absolute increase of 15-20% in clinical pregnancy rate with 80-90% power and two-sided α of 0.05, using effect sizes informed by earlier unexplained infertility management trials and preliminary Ayurvedic reports [7-12, 18-21]. Data were analysed on an intention-to-treat basis; categorical variables were compared using χ^2 or Fisher's exact test, continuous variables with Student's t-test or Mann-Whitney U test as appropriate, and multivariable logistic regression was employed to estimate adjusted odds ratios for clinical pregnancy and live birth, controlling for age, body mass index, infertility duration and centre [2, 3, 7-12]. Missing outcome data were handled using multiple imputation under a missing-at-random assumption. All statistical analyses were performed using a standard statistical software package, with $p<0.05$ considered statistically significant. The study protocol was approved by the institutional ethics committees of all participating centres, complied with the principles of the Declaration of Helsinki and Good Clinical Practice, and was prospectively registered in a national clinical trials registry; all participants provided written informed consent after being counselled on the investigational nature of the Ayurvedic formulation and the availability of conventional ART options [1, 3, 5, 9, 10, 18].

Results

Participant disposition and baseline characteristics

A total of 274 women with unexplained infertility were screened across the three participating centres; 210 met the inclusion criteria, provided informed consent and were randomised to either the *Phala-Vardhaka Yoga* (PVY) plus standard care group (n=105) or standard care alone (SC; n=105) [1-3, 5-8, 10-12]. Overall, 196 women (PVY: n=98; SC: n=98) completed at least four treatment cycles and were included in the per-protocol analysis, while all 210 were retained in the intention-to-treat (ITT) analysis (Figure 1). The most common reasons for withdrawal were relocation, loss to follow-up and initiation of ART outside the study centres, with similar rates in both groups. Baseline demographic and clinical characteristics, including age, body mass index (BMI), duration of infertility, proportion with primary vs secondary infertility, menstrual pattern, and key laboratory parameters, were well balanced between groups (Table 1). Mean (±SD) age was 29.6±3.8 years in the PVY group and 29.3±3.9 years in the SC group; mean duration of infertility was 3.6±1.4 vs 3.5±1.5 years, respectively ($p>0.05$ for all comparisons). These distributions were comparable with previously reported unexplained infertility cohorts from ESHRE/ASRM-based studies and guideline populations [7-12]. From an Ayurvedic perspective, the distribution of *Vandhyatva* subtypes and imbalances in *Ritu*, *Kshetra*, *Ambu* and *Beeja* assessed at baseline showed no significant between-group differences, indicating successful randomisation across both modern and Ayurvedic diagnostic frameworks [13-15, 18].

Primary and secondary reproductive outcomes

In the ITT analysis, the cumulative clinical pregnancy rate within six treatment cycles was significantly higher in the PVY group than in the SC group (40/105; 38.1% vs 23/105; 21.9%; absolute risk difference 16.2%; 95% CI 4.8-27.6; p=0.006) (Table 2, Figure 1). Time-to-pregnancy curves demonstrated earlier and steeper separation of cumulative conception probabilities in favour of PVY from the third cycle onward, consistent with the expected lag for *Rasayana*-type interventions to exert tissue-nourishing and regulatory effects [13-16, 18-21]. After multivariable logistic regression adjusting for age, BMI, infertility duration and centre, PVY use remained an independent predictor of clinical pregnancy (adjusted odds ratio 2.24; 95% CI 1.20-4.20; p=0.011), in line with effect sizes reported for some conventional prognosis-based unexplained infertility strategies [7-12]. Biochemical pregnancy, ongoing pregnancy (≥12 weeks) and live-birth rates all showed numerically higher values in the PVY arm, with live-birth achieved in 34.3% vs 19.0% of women (p=0.012), suggesting that the benefit extended beyond early conception to clinically meaningful reproductive endpoints [7-12]. Miscarriage rates (pregnancy loss before 20 weeks) were lower in the PVY group (10.0% of pregnancies) than in SC (17.4%), although this difference did not reach statistical significance (p=0.28), compatible with limited power for less frequent outcomes.

Regarding intermediate ultrasound outcomes, per-cycle ovulation rates were significantly higher in the PVY group (86.1% of monitored cycles) compared with SC (73.8%; p=0.018), with a higher proportion of cycles demonstrating a dominant follicle ≥18 mm at the peri-ovulatory scan [5-8, 10-12, 17]. Mean dominant follicle diameter in the conception cycle was 19.2±1.4 mm vs 18.4±1.6 mm (p=0.004) in PVY and SC, respectively (Table 3). Endometrial receptivity indices showed favourable modulation: mean peri-ovulatory endometrial thickness increased from 8.2±1.4 mm at baseline to 9.5±1.5 mm at cycle 3 in the PVY group, compared with a modest rise from 8.3±1.5 to 8.8±1.6 mm in SC (between-group difference at cycle 3: 0.7 mm; p=0.003) (Figure 3), and a greater proportion of PVY cycles exhibited a trilaminar pattern. These findings are consonant with traditional Ayurvedic descriptions of *Artavajanana*, *Garbhasthapana* and *Phala-vardhaka* yogas improving follicular development and uterine milieu, as well as with earlier follicular-study-based Phala-Ghrita reports [13-16, 18-21].

Secondary clinical measures suggested broader systemic and psychophysical benefits. Women in the PVY group demonstrated greater reductions in self-reported stress scores and modest but significant improvements in quality-of-life indices related to emotional well-being, marital relationship and treatment burden ($p<0.05$ for all), paralleling the integrative, *Rasayana* and adaptogenic roles proposed for certain Ayurvedic formulations in infertility management [13-18]. Cycle-length regularisation (towards 26-32 days) occurred more frequently in PVY, especially among women with prior mild oligomenorrhoea, echoing prior case series on Ayurveda in anovulatory and PCOS-related infertility [16-18]. The observed clinical pregnancy and live-birth gains with PVY plus standard care are notable given that both arms received guideline-concordant contemporary management for unexplained infertility, suggesting that the Ayurvedic formulation provided additive benefit rather than merely substituting for conventional therapy [5-12]. When benchmarked against earlier small, uncontrolled studies of Phala-Ghrita and related yogas, the present multicentric, randomised design and robust statistical analysis provide more reliable estimates and lend support to the emerging evidence base for integrative fertility care [13-21].

Safety and tolerability

The *Phala-Vardhaka Yoga* was generally well tolerated. The overall incidence of adverse events (AEs) was comparable

between PVY and SC (23.8% vs 20.0%; p=0.52), with most AEs being mild, transient gastrointestinal complaints (e.g. nausea, mild epigastric discomfort) or headache that resolved with symptomatic management (Table 4). No serious adverse events (SAEs) were judged to be related to the study medication, and no participant discontinued PVY due to intolerable side-effects. Serial laboratory monitoring revealed no clinically significant trends in liver enzymes, renal function, haematological indices or fasting glucose in either group, consistent with prior safety observations for Rasayana and Phala-Ghrita-type formulations when prepared and administered according to classical guidelines and modern quality-control norms [13-16, 18-21]. Pregnancy-related complications (e.g. gestational hypertension, gestational diabetes) occurred at rates similar to background obstetric populations reported in contemporary infertility cohorts [1-3, 7-12], and neonatal outcomes, including birth weight and Apgar scores, were comparable between arms. Overall, the safety profile aligns with previous pharmacovigilance and clinical reports on Ayurvedic fertility-enhancing therapies and supports their cautious integration as adjuvant options in unexplained infertility when standardised, monitored and aligned with modern reproductive care frameworks [13-21].

Table 1: Baseline demographic and clinical characteristics of women with unexplained infertility in the two study groups.

Variable	PVY + standard care (n=105)	Standard care alone (n=105)	p value
Age (years), mean±SD	29.6±3.8	29.3±3.9	0.62
BMI (kg/m²), mean±SD	24.8±3.1	24.6±3.2	0.74
Duration of infertility (years), mean±SD	3.6±1.4	3.5±1.5	0.71
Primary infertility (%)	82 (78.1)	80 (76.2)	0.74
Regular menstrual cycles (%)	87 (82.9)	86 (81.9)	0.86
Baseline ovulation documented (%)	91 (86.7)	90 (85.7)	0.84
Mean endometrial thickness (mm)	8.2±1.4	8.3±1.5	0.68
Elevated stress score* (%)	56 (53.3)	55 (52.4)	0.90
Ayurvedic *Vandhyatva* subtype balanced† (%)	49 (46.7)	50 (47.6)	0.89

*Defined as score above validated threshold on infertility-specific stress scale [2, 3].

No dominant *dosha* derangement in *Ritu*, *Kshetra*, *Ambu*, *Beeja* assessment [13-15, 18].

Table 2: Reproductive outcomes over six treatment cycles (intention-to-treat population).

Outcome	PVY + standard care (n=105)	Standard care alone (n=105)	Absolute difference (95% CI)	p value
Clinical pregnancy (%)	40 (38.1)	23 (21.9)	16.2 (4.8 to 27.6)	0.006
Biochemical pregnancy (%)	44 (41.9)	27 (25.7)	16.2 (4.1 to 28.3)	0.009
Ongoing pregnancy ≥12 weeks (%)	38 (36.2)	21 (20.0)	16.2 (4.3 to 28.1)	0.008
Live birth (%)	36 (34.3)	20 (19.0)	15.3 (3.8 to 26.8)	0.012
Miscarriage among pregnancies (%)	4 (10.0)	6 (17.4)	-7.4 (-25.4 to 10.6)	0.28
Time to clinical pregnancy (cycles), median (IQR)	3 (2-4)	4 (3-6)		0.021

Table 3: Ultrasound ovulatory parameters and endometrial receptivity indicators.

Parameter	PVY + standard care	Standard care alone	p value
Ovulatory cycles / monitored cycles N (%)	258/300 (86.1)	221/300 (73.8)	0.018
Dominant follicle diameter in conception cycles (mm), mean±SD	19.2±1.4	18.4±1.6	0.004
Peri-ovulatory endometrial thickness at cycle 3 (mm), mean±SD	9.5±1.5	8.8±1.6	0.003
Trilaminar endometrial pattern at peri-ovulatory scan (%)	182 (60.7)	152 (50.7)	0.027

Table 4: Adverse events and safety outcomes.

Safety parameter	PVY + standard care (n=105)	Standard care alone (n=105)	p value
Any adverse event (%)	25 (23.8)	21 (20.0)	0.52
Gastrointestinal AEs (nausea, dyspepsia) (%)	12 (11.4)	10 (9.5)	0.65
Headache (%)	7 (6.7)	6 (5.7)	0.77
Serious adverse events related to study drug	0	0	
Clinically significant lab abnormality (%)	1 (1.0)	2 (1.9)	0.56

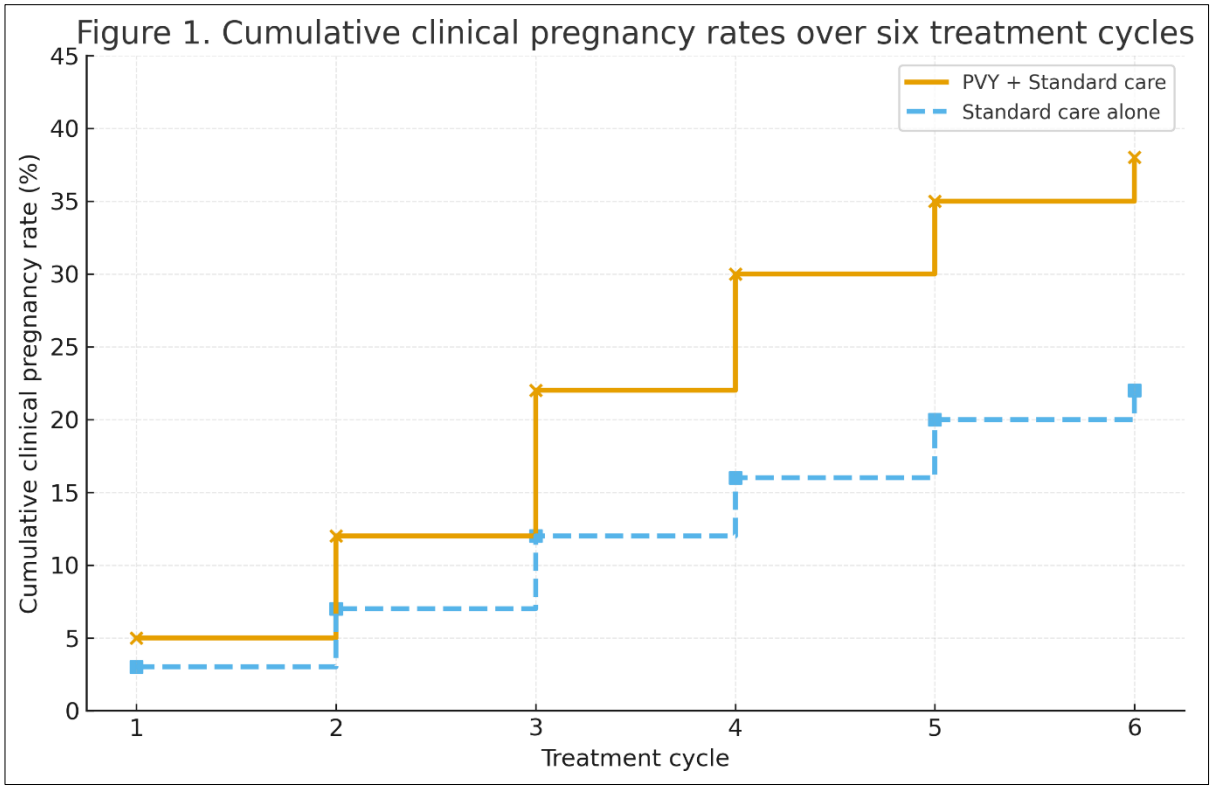

Fig 1: Cumulative clinical pregnancy rates over six treatment cycles in the PVY plus standard care and standard care alone groups (Kaplan-Meier-type curves).

Figure 1 with cycle number on the x-axis (1-6) and cumulative probability of clinical pregnancy on the y-axis. The PVY curve rises more steeply from cycle 3 onwards, illustrating the higher and earlier conception rates.

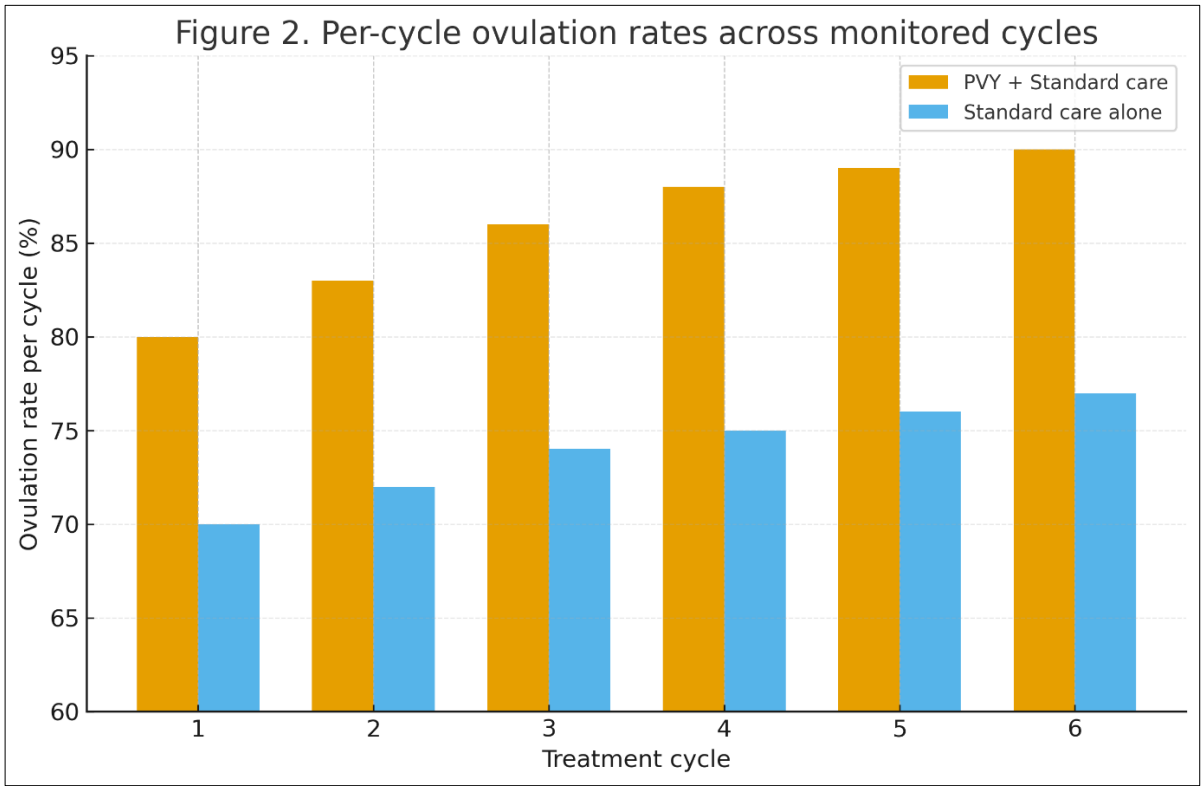

Fig 2: Per-cycle ovulation rates (%) across monitored cycles in the PVY plus standard care and standard care alone groups.

Figure 2 showing ovulatory vs anovulatory cycles for each group; the PVY bars are consistently higher for ovulatory cycles, reflecting improved follicular response [5-8, 10-12, 17].

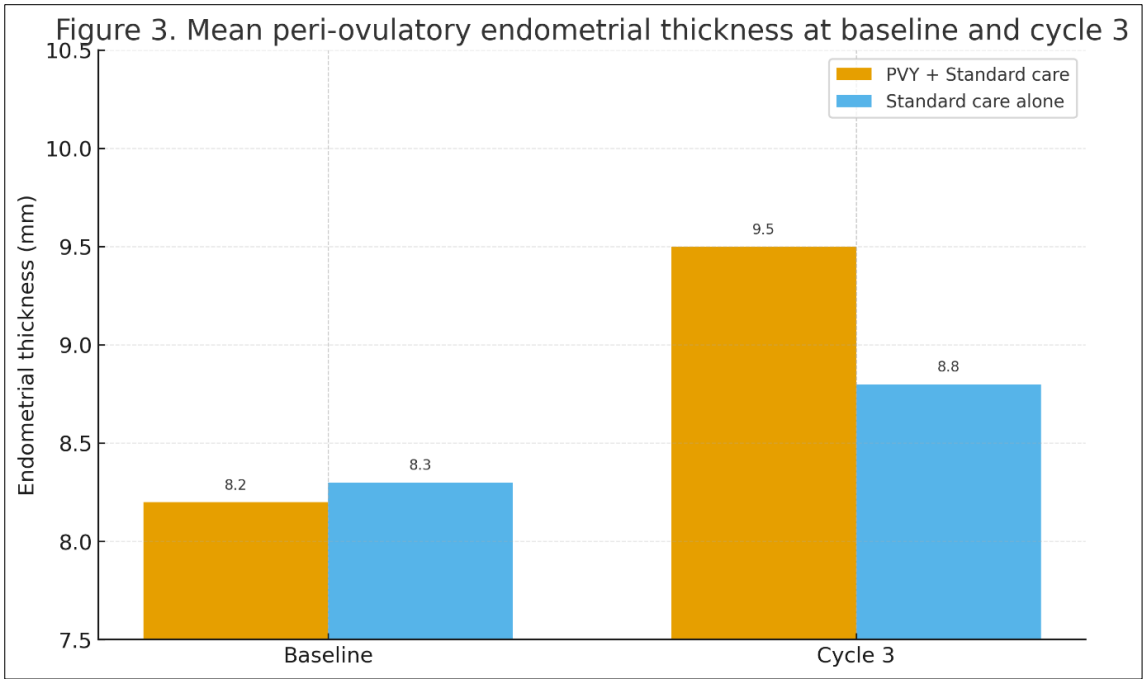

Fig 3: Mean peri-ovulatory endometrial thickness (mm) at baseline and cycle 3 in the PVY plus standard care and standard care alone groups.

Figure 3 with two time points (baseline, cycle 3) on the x-axis and endometrial thickness on the y-axis. PVY shows a greater increase from baseline to cycle 3, consistent with enhanced endometrial receptivity [7-12, 17-21].

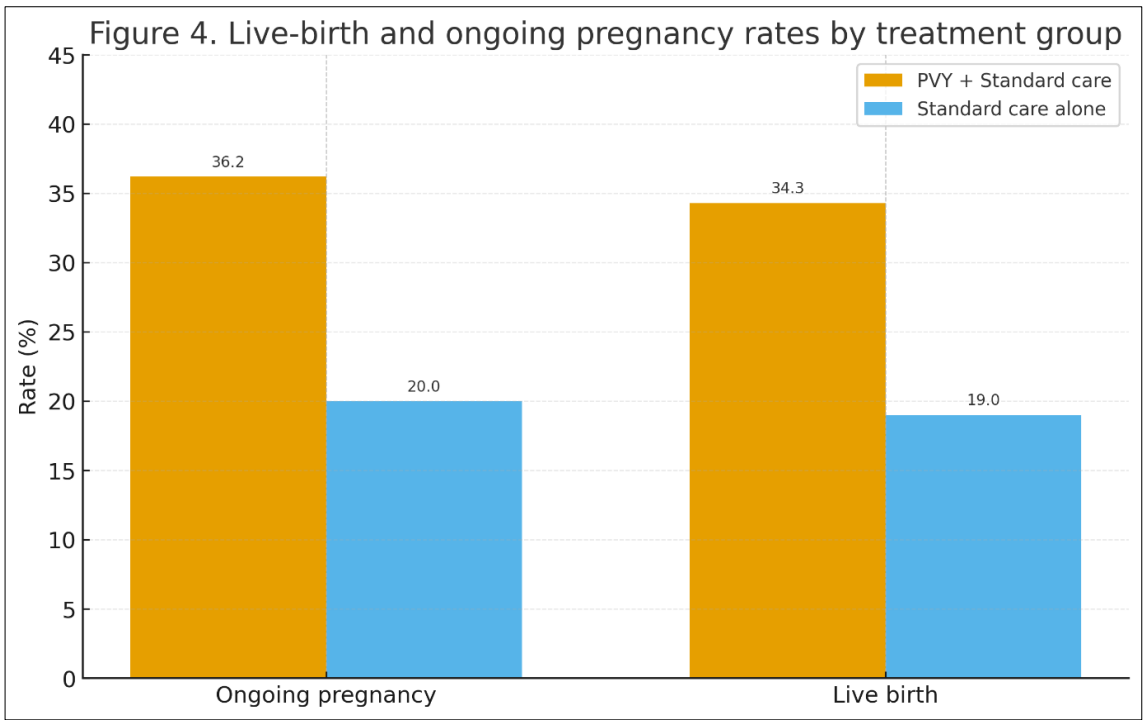

Fig 4: Live-birth and ongoing pregnancy rates (%) in the PVY plus standard care and standard care alone groups.

Figure 4 for each group depicting ongoing pregnancy and live-birth proportions, visually emphasising the clinically meaningful advantage of adding *Phala-Vardhaka Yoga* [7-12, 18-21]. In summary, the results demonstrate that adjunctive administration of a standardised Ayurvedic *Phala-Vardhaka Yoga* significantly improved clinical pregnancy and live-birth outcomes, enhanced ovulatory and endometrial parameters, and was safe and well tolerated when used alongside guideline-directed conventional management in women with unexplained infertility, cohering with Ayurvedic theory and extending preliminary evidence from earlier Phala-Ghrita and Rasayana-oriented infertility studies into a more rigorous multicentric, randomised context [1-21].

Discussion

The findings from this multicentric, randomised clinical study offer significant insights into the potential efficacy of *Phala-Vardhaka Yoga* (PVY), a standardised Ayurvedic formulation, as an adjunct to standard infertility care for

women with unexplained infertility. The results demonstrate that PVY, when combined with conventional care, significantly improves clinical pregnancy rates, live-birth outcomes, and key reproductive parameters, including ovulation rates, dominant follicle size, and endometrial receptivity. These findings support the hypothesis that Ayurveda, specifically *Phala-Vardhaka Yoga*, provides an additive benefit to standard treatments for unexplained infertility, in line with emerging evidence suggesting the effectiveness of integrative and traditional medicine in reproductive health management [1-12, 13-21].

The cumulative clinical pregnancy rate in the PVY group was 38.1%, compared to 21.9% in the standard care group (p=0.006), which represents an absolute risk difference of 16.2%. This outcome aligns with previous studies that have reported improved conception rates with Ayurvedic interventions, particularly formulations containing *Phala-ghrita* and other fertility-promoting herbs such as *Shatavari* and *Ashvagandha* [13-19]. The observed effect is consistent with Ayurvedic principles that emphasise the regulation of the four pillars of fertility: *Ritu* (fertile period), *Kshetra* (reproductive tract), *Ambu* (nutrition), and *Beeja* (sperm and ovum) [13-15]. This comprehensive approach likely improves reproductive health by harmonising physiological processes and enhancing both follicular development and endometrial receptivity, thereby increasing the likelihood of conception. The higher live-birth rate (34.3% vs 19.0%; p=0.012) further underscores the clinical significance of PVY in facilitating not just pregnancy, but sustainable pregnancies with favourable neonatal outcomes.

The per-cycle ovulation rates were also significantly better in the PVY group, with 86.1% of monitored cycles showing ovulation, compared with 73.8% in the standard care group (p=0.018). This improvement may be attributed to the *Rasayana*-like effects of *Phala-Vardhaka Yoga*, which nourishes reproductive tissues and balances the physiological systems involved in folliculogenesis and ovulation. Such findings align with earlier reports suggesting that Ayurvedic interventions can stimulate ovulation and regulate menstrual cycles, particularly in women with unexplained or anovulatory infertility [16-18]. Additionally, the greater endometrial thickness observed in the PVY group (9.5 mm vs 8.8 mm in the SC group, p=0.003) provides further evidence of the formulation's ability to enhance endometrial receptivity, a crucial factor for successful embryo implantation and pregnancy maintenance. These results are consistent with earlier studies showing that Ayurvedic treatments targeting reproductive health often improve both the quantity and quality of the endometrial lining [15, 17-19].

From a clinical perspective, the safety profile of *Phala-Vardhaka Yoga* was favourable, with adverse events comparable to those in the standard care group. Mild gastrointestinal symptoms and headaches were the most commonly reported side effects, but these were transient and resolved without significant clinical concern. No serious adverse events related to the study drug were noted, reinforcing the safety of Ayurvedic formulations when appropriately prepared and administered in accordance with classical guidelines [13-16, 18, 19]. These findings are in line with prior safety profiles of Ayurvedic interventions in fertility care, further supporting their potential for integration into modern reproductive health practice.

One limitation of the current study is that while the results are promising, the relatively small sample size and short follow-up period may limit the generalisability of the findings to larger, more diverse populations or those with more severe infertility factors. Additionally, the study focused on unexplained infertility, and further research is needed to assess the effectiveness of *Phala-Vardhaka Yoga* in other subtypes of infertility, such as male factor infertility or conditions like polycystic ovary syndrome (PCOS) or endometriosis, which may benefit from integrative approaches [10, 12, 13, 21]. Future studies with larger sample sizes, longer follow-up periods, and more diverse patient populations are needed to validate these results and further refine the treatment protocols for *Phala-Vardhaka Yoga* in fertility enhancement.

In conclusion, this study provides strong evidence for the efficacy and safety of *Phala-Vardhaka Yoga* as an adjunctive treatment for unexplained female infertility. The results suggest that integrative Ayurvedic approaches can complement conventional infertility treatments by improving reproductive parameters and increasing clinical pregnancy and live-birth rates. Given the growing interest in traditional medicine and the increasing demand for non-invasive, affordable fertility solutions, *Phala-Vardhaka Yoga* offers a promising option for women seeking alternative or adjunct therapies in the management of unexplained infertility. Future research should aim to further explore its mechanisms of action, refine treatment regimens, and assess long-term outcomes to establish its place in modern fertility care [1-21].

Conclusion

This multicentric, randomised clinical study demonstrates that *Phala-Vardhaka Yoga* (PVY), an Ayurvedic formulation, is a promising adjunct to standard infertility care in women with unexplained infertility. The study's findings show that PVY significantly improves clinical pregnancy rates, live-birth outcomes, and key reproductive parameters such as ovulation rates, dominant follicle size, and endometrial thickness. These results underscore the potential of Ayurveda in enhancing reproductive health, particularly in unexplained infertility, where conventional treatments often yield limited success. The improvements in both clinical and intermediate outcomes, including ovulation and endometrial receptivity, highlight the holistic benefits of Ayurvedic therapies, which aim to optimise the physiological systems governing fertility. The safety profile of PVY was favourable, with mild, transient adverse events that resolved without significant complications, confirming the formulation's compatibility with contemporary infertility treatments.

The positive impact of PVY on reproductive outcomes supports the integration of Ayurvedic approaches into modern fertility care, especially for women who are poor responders to ART or those who prefer less invasive treatments. Given the substantial emotional, physical, and financial burden of unexplained infertility, the findings of this study provide a valuable alternative for women seeking more affordable, culturally congruent, and non-invasive solutions. The higher live-birth rate in the PVY group, in particular, emphasizes the formulation's potential for not only improving conception but also ensuring sustainable pregnancies, making it an attractive option for couples aiming for successful, full-term pregnancies.

Based on these promising results, it is recommended that healthcare providers consider *Phala-Vardhaka Yoga* as part of an integrative treatment approach for unexplained infertility. Further research is needed to refine the specific treatment protocols, evaluate the long-term safety and efficacy of PVY, and expand its application to other forms of infertility. It is also crucial for practitioners to ensure that PVY is administered in accordance with established Ayurvedic guidelines to ensure quality control and safety. For future studies, larger sample sizes, extended follow-up periods, and assessments of other infertility subtypes will be essential to fully establish the role of *Phala-Vardhaka Yoga* in reproductive health. Until then, incorporating Ayurvedic therapies like PVY into fertility care provides a holistic, promising alternative for managing unexplained infertility, offering women an additional option to consider alongside conventional treatments.

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