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Goat Milk-Processed Clitoria Ternatea (Aparajita) Root For Ovulation Induction: A Clinical Pilot Study

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Abstract

Background: Anovulatory infertility, often due to polycystic ovary syndrome (PCOS), is a leading cause of female infertility. Conventional ovulation induction (OI) agents like clomiphene and letrozole are effective but carry side effects (e.g., risk of multiple pregnancy, ovarian hyperstimulation). Ayurvedic medicine describes Clitoria ternatea root processed with Aja Dugdha Bhavita Aparajita Mula Churnavati as a remedy for female infertility. However, its efficacy had not been scientifically evaluated until now. Aim: To assess whether a goat milk-processed Clitoria ternatea root formulation can induce ovulation in anovulatory women. Methods: In an open label pilot trial, 22 women (age 19–34) with anovulatory infertility (primarily PCOS) received Aparajita root powder tablets (1.5 g twice daily) on days 4–6 of their menstrual cycle for 3 consecutive cycles. Ultrasound monitoring confirmed ovulation, and hormonal, menstrual, and metabolic parameters were recorded pre and post-treatment. Key outcomes (ovulation occurrence, menstrual regularity, pregnancy, etc.) were analyzed using paired statistical tests (McNemar's for ovulation, Wilcoxon for cycle regularity, etc.). Results: Ovulation was induced in 7 of 22 women (31.8%) over the 3 month treatment (0% at baseline, p≈0.02). Four women (18.2%) conceived during the study. Menstrual cycle regularity improved significantly from 18.2% to 63.6% (p<0.01), with mean cycle length decreasing from ~60 to 34 days. Menstrual flow volume normalized (83% of initially scanty/heavy cases improved, p<0.05). Average body mass index (BMI) reduced from 26.45 to 25.63 (p<0.001). No major adverse effects were observed; the formulation was well tolerated. Conclusion: The Ayurvedic formulation yielded a notable ovulation induction rate with ancillary benefits of improved menstrual regularity, normalized flow, and mild weight reduction, all without significant side effects. These findings suggest that Aparajita processed with goat milk is a promising, safe complementary therapy for anovulatory infertility, especially in PCOS. Larger controlled trials are warranted to confirm efficacy and mechanism, but this pilot study bridges traditional knowledge with modern fertility science, highlighting a novel integrative approach to ovulation induction.

Keywords: *Anovulatory Infertility; Ovulation Induction; Clitoria ternatea; Aparajita; Goat Milk; Ayurvedic Medicine; PCOS*

INTRODUCTION

Infertility affects a significant population worldwide – for example, an estimated 30 million couples in India face infertility challenges (Indian Express, 2018). Ovulatory dysfunction (anovulation) is a major contributor, accounting for roughly 25–40% of female infertility cases. PCOS is the most common cause of anovulation, underlying the majority of cases (up to 70–75% in some young populations). Standard OI treatments in modern medicine include clomiphene citrate and letrozole, which stimulate ovulation but can have considerable side effects (e.g., hot flashes, mood swings, multiple gestation, ovarian hyperstimulation). While newer approaches (such as aromatase inhibitor therapy) have improved OI outcomes in PCOS (Legro et al., 2014), issues of drug resistance, cost, and tolerability persist (Konar, 2007; Schorge et al., 2008). This drives interest in gentler, holistic alternatives that can complement or offer an alternative to conventional fertility drugs.Ayurvedic medicine, India's traditional system, offers a rich repertoire of herbal therapies for infertility.*Aparajita*, commonly known as butterfly pea, is one such herb traditionally indicated for female infertility,

especially when used in conjunction with goat's milk. Classical Ayurvedic texts (e.g., *Bhaishajya Ratnavali*, *Harita Samhita*) describe formulations of *Aparajita* root processed with goat milk for treating *Vandhya* (infertility) (Govind Das Sen, n.d.; Harita, n.d.). Goat's milk itself is considered *laghu* (light, easily digestible) and fertility enhancing in Ayurveda – it pacifies excessive doshas and serves as a nutritive tonic for reproductive health (Chunekar, n.d.). By repeatedly processing the herb in goat milk (a pharmaceutical technique called *Bhavana*), Ayurvedic practitioners aim to increase the herb's potency and bioavailability. *Aparajita* is also classified traditionally as a Rasayana (rejuvenative) and Prajasthapana (fertility promoting) herb, noted for strengthening the reproductive system (Agnivesha, n.d.). These classical claims, however, remained unvalidated by modern clinical research prior to this study.

From a pharmacological perspective, *Clitoria ternatea* has attracted scientific attention for its diverse bioactive properties. Phytochemical analyses show it is rich in flavonoids, terpenoids, and cyclotides. Experimental studies have demonstrated nootropic and anxiolytic effects – e.g., enhancements in memory and reduction of stress markers linked to increased acetylcholine levels in the brain (Bhattacharya & Mitra, 1997; Srichaikul & Thongsaard, 2014). The plant also exhibits anti-inflammatory activity, partly via cyclooxygenase (COX) enzyme inhibition, which is relevant because chronic ovarian inflammation can impair ovulation. Its antidiabetic and insulin sensitizing effects have been shown in animal models (Singh & Singh, 2015), potentially addressing the hyperinsulinemia common in PCOS related anovulation. Notably, *Clitoria* root extracts displayed mild estrogenic activity in rats, causing uterine changes and vaginal cornification (Srichaikul & Thongsaard, 2014), suggesting a direct influence on reproductive hormones. Despite these promising findings, there has been a *paucity of clinical trials* evaluating *Clitoria ternatea*'s effect on ovulation or fertility outcomes. To date, only anecdotal or preclinical evidence supported its use for infertility.

Given the need for safer OI therapies and the encouraging signals from Ayurveda and preclinical research, we hypothesized that an Ayurvedic formulation of *Aparajita* root processed in goat milk could safely induce ovulation in anovulatory women. This study was designed as a pilot clinical trial to test that hypothesis. Specifically, we aimed to scientifically validate the ovulation induction efficacy of Aja Dugdha Bhavita Aparajita Mula Churnavati (goat milk processed *Clitoria ternatea* root powder) in women with anovulatory infertility. We also observed secondary outcomes like menstrual cycle regulation and weight/metabolic changes, and monitored safety. By bridging classical Ayurvedic wisdom with modern clinical research, the study seeks to introduce a potentially novel, integrative treatment option for infertility. In the following, we detail the methodology of this trial, present the key results, and discuss their implications for fertility management.

LITERATURE REVIEW

Ayurvedic Perspective on Ovulation: Ayurveda attributes female fertility to the balance of *Artava dhatu* (reproductive tissue) and regularity of the menstrual cycle, which is governed by the interplay of doshas (biological humors). Classical texts emphasize that a stable Vata (especially *Apana Vata*) is critical for ovulation and menstruation, while imbalances in Pitta and Kapha can disrupt follicular maturation and cycle regularity. A verse from *Ashtanga Samgraha* highlights the importance of timing (*Ritukala*) and healthy reproductive tissue for conception. Ayurvedic compendia list numerous herbal formulations to treat *anovulation* (often discussed under *Vandhya* or female infertility). *Aparajita* (butterfly pea) is described as a *medhya* (nootropic) and *rasayana* (rejuvenator) that also has gynecological applications. In the context of infertility, *Aparajita* is considered Prajasthapana an herb that promotes conception particularly when used with supportive adjuvants like goat's milk (Harita, n.d.; Agnivesha, n.d.). Goat milk is lauded in Ayurveda for its lighter composition and therapeutic virtues: it mitigates *vitiated Vata*, nourishes *Dhatus*, and is indicated for conditions requiring gentle nourishment such as reproductive debility. The combination of Aparajita and goat milk appears in formulations in *Bhaishajya Ratnavali* (Govind Das Sen, n.d.) and other classical texts for female infertility, implying a synergistic remedy where goat milk serves as a bioavailability enhancer and soothing vehicle for the herb. These textual insights provided a strong traditional rationale for our investigation.

Contemporary Research on *Clitoria ternatea*: Modern pharmacological studies have begun to substantiate some of Aparajita's traditional uses. *Clitoria ternatea* contains biologically active constituents such as flavonol glycosides, triterpenoids, and anthocyanins (ternatins). Nootropic and antidepressant effects of *Clitoria*

preparations have been demonstrated in rodents, supporting its role as a brain tonic (Srichaikul & Thongsaard, 2014). Bhattacharya and Mitra (1997) found that *Clitoria* root extracts produce significant anxiolytic (anti-anxiety) activity in animal models, aligning with Ayurvedic claims of stress reduction. These central effects are relevant because chronic stress can contribute to hypothalamic anovulation; an herb that calms the mind may indirectly favor the ovulatory mechanism. *Clitoria*'s anti-inflammatory properties have also been documented for instance, it can inhibit COX and reduce induced inflammation (Aher & Wahi, 2011). This suggests it might alleviate the low grade ovarian inflammation often seen in PCOS, thereby improving follicle rupture. Moreover, multiple studies report the antihyperglycemic and insulin sensitizing effects of *Clitoria ternatea* (Singh & Singh, 2015; Pandey et al., 2020). Improved insulin sensitivity can lower insulin and androgen levels in PCOS, removing a key obstacle to ovulation. Of particular interest, *Clitoria* seems to possess phytoestrogenic activity: a study by Srichaikul & Thongsaard (2014) (published as Khatun et al., 2012 in some reports) observed that chronic administration of *Clitoria* root in rats led to vaginal cornification and uterine changes indicative of estrogen like effects. This estrogenic action could help prime the endometrium and trigger ovulation in estrogen deficient anovulatory states. However, it must be noted that no prior clinical trials had tested *Clitoria ternatea* for ovulation induction in women. Some analogous Ayurvedic fertility treatments have been studied – e.g., case studies on herbal enemas and ghrita (herbal ghee) therapies for anovulation have shown improved ovulatory outcomes – but robust clinical evidence remains scarce. Our study therefore addresses a gap in both Ayurvedic and modern literature by evaluating this herb in a controlled clinical setting and using objective outcome measures.

Rationale and Objectives:

Based on the above, we postulated that Aja Dugdha Bhavita Aparajita Mula Churnavati could induce ovulation by a multi-faceted mechanism: improving metabolic and hormonal milieu (via insulin sensitization and mild estrogenic effects), reducing stress and inflammation, and nourishing the reproductive organs (via its rasayana properties). The primary objective was to assess the rate of ovulation (confirmed by ultrasound evidence of follicular rupture) during treatment compared to baseline anovulation. Secondary objectives included evaluating changes in menstrual cycle regularity, cycle length, menstrual flow, and any occurrence of pregnancy within the study period. We also aimed to monitor tolerability and document any side effects of the herbal treatment. By achieving these objectives, the study seeks to provide evidence based validation for an Ayurvedic intervention and explore its potential role as a complementary therapy in infertility management.

METHODOLOGY

Study Design: An open label, single arm clinical trial was conducted at a university Ayurvedic hospital. The study protocol was approved by the Institutional Ethics Committee, and written informed consent was obtained from all participants. The trial was designed as a pilot exploratory study to generate preliminary efficacy and safety data for the herbal intervention.

Participants: Twenty four women diagnosed with anovulatory infertility were enrolled, of whom 22 completed the trial (two dropped out due to personal reasons unrelated to treatment). Key inclusion criteria were:

- Women aged 18–35 years with documented anovulation (e.g., persistent anovulatory cycles on ultrasound or progesterone assays) for ≥6 months.
- Primary infertility (no prior successful pregnancy) or secondary infertility with current anovulatory status.
- Many participants had PCOS (polycystic ovarian syndrome) as the underlying cause; others had idiopathic anovulation or mild endocrine imbalances.

Exclusion criteria included tubal or male factor infertility, hyperprolactinemia, thyroid disorders, or use of fertility drugs in the 3 months prior. The baseline characteristics of the 22 completing participants are summarized in Table 1. The mean age was 26.8 ± 4.2 years, and 77% were in the 20–30 year age range. Notably, 16 women (72.7%) had primary infertility, consistent with PCOS-related anovulation starting early in reproductive life, while 4 had secondary infertility. Over half (54.5%) had ultrasound confirmed PCOS, and the remainder had functional anovulation without PCOS (Table 1). Mean baseline BMI was 26.5 (SD

±2.8), with 64% of women overweight or obese, reflecting the metabolic aspect of the cohort. All women had irregular menstrual cycles or amenorrhea at baseline (average cycle length ~60 days).

Intervention: The treatment under investigation was Aja Dugdha Bhavita Aparajita Mula Churnavati, i.e., tablets made from *Clitoria ternatea* (Aparajita) root powder processed with goat's milk. The formulation was prepared in house following classical Ayurvedic procedures:

Raw materials: Dried *Clitoria ternatea* roots were authenticated by the Dravyaguna (pharmacology) department. Fresh goat milk was sourced daily from healthy local goats. No other herbs or additives were included (a single herb formulation).

Bhavana (levigation) process: The cleaned, powdered Aparajita root was repeatedly impregnated with goat's milk. Specifically, the powder was soaked in an equal quantity of goat milk and triturated until the liquid was absorbed/dried, constituting one Bhavana cycle. This process was repeated 7 times (a number traditionally considered optimal for Rasayana potentiation). Through Bhavana, water soluble and fat soluble components of the herb may bind with milk's fats and proteins, potentially enhancing absorption (Government of India, 2010).

Tablet formation: The milk processed powder was granulated with a small amount of additional goat milk to form a pliable mass, then manually rolled and compressed into tablets (*vati*) ~500 mg each. Tablets were air dried and stored in airtight containers with desiccants. Quality control tests showed uniform tablet weight (~500±20 mg) and disintegration time ~15 min in warm water, with microbial counts within safe limits.

Dosage regimen: Participants self-administered 3 tablets (≈1.5 g total) twice daily – before breakfast and before dinner (taken in *Apana Kala*, time of downward energy) – on cycle days 4, 5, and 6 of each menstrual cycle. This dosing schedule (1.5 g BID for 3 days per cycle) was derived from classical texts and a pilot tolerance assessment. Treatment was given for three consecutive cycles for each participant. If menses did not occur, a withdrawal bleed was induced with a progesterone course to start a new "cycle." Notably, no other fertility drugs (e.g., clomiphene) were used during the study. Participants were advised a supportive diet (balanced, with low glycemic index to assist in weight management) and lifestyle (regular mild exercise) to synergize with the treatment, as per Ayurvedic and modern recommendations.

Monitoring and Outcomes: Participants were followed closely through the 3 month treatment:

Ovulation Monitoring: Transvaginal pelvic ultrasonography was performed in each cycle to track follicular development. Scans were done around day 12–14 and again near expected ovulation (day 14–20) or more frequently if follicles were growing. Ovulation was confirmed by ultrasound evidence of follicle rupture and/or the presence of a corpus luteum, along with mid-luteal serum progesterone rise when available.

Menstrual Cycle Tracking: Each woman kept a menstrual diary. Cycle length, changes in regularity (onset of menses without medical withdrawal), duration of bleeding, and flow intensity were recorded. We defined "regular cycle" as 25–35 days cycle length consistently. A scoring (0/1) was used for regularity (0 = irregular/oligomenorrhea/amenorrhea, 1 = regular). Menstrual flow volume was self-rated on a 0–3 scale (0 = scanty, 1 = moderate/normal, 2 = heavy, 3 = excessive hemorrhagic) for analysis.

Hormonal and Metabolic Parameters: Baseline and post treatment blood tests included levels of LH, FSH, thyroid profile, prolactin, and fasting insulin if indicated (though primary inclusion ensured no overt thyroid/prolactin issues). Weight and BMI were measured each visit; improvement in BMI was tracked as an ancillary outcome.

Pregnancy: A urine pregnancy test was administered if a participant missed a period or had ovulation; any conception during the study was confirmed by ultrasound.

Safety Assessments: All adverse events or side effects were documented. A checklist of potential herb related complaints (e.g., nausea, indigestion, allergy) was reviewed at each visit. Liver and kidney function tests were conducted at baseline and study end to detect any organ toxicity. No participant was on any other medication during the trial.

Data Analysis: Pre- and post-treatment outcomes were compared within subjects. Given the before-after design (each participant as her own control), we used paired statistical tests:

The change in ovulation rate (proportion ovulating) was analyzed with McNemar's test for paired binary data. Baseline all patients were anovulatory (by selection), so effectively we tested if the proportion ovulating after treatment was significantly >0.

Changes in menstrual regularity score, cycle length, and flow scores were analyzed with Wilcoxon signed rank test (non-parametric test for paired ordinal data), since these measures were not all normally distributed. BMI before vs. after was compared by paired Student's t-test (as BMI was approximately normally distributed). A two-tailed $p<0.05$ was considered statistically significant. Given the exploratory nature, exact p-values are reported where relevant. Statistical analysis was performed using SPSS v22.0, with manual cross-verification for nonparametric results.

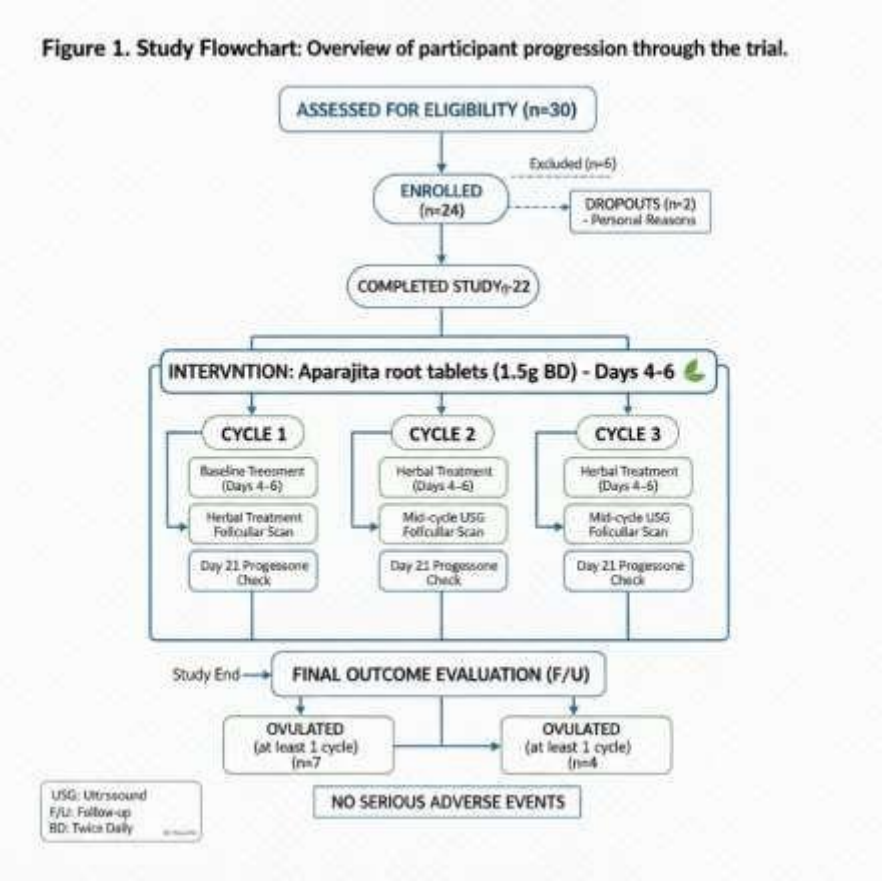

Figure 1. Study Flowchart: Overview of participant progression through the trial.

A total of 30 women were assessed for eligibility, 24 enrolled, and 22 completed the study (2 dropouts due to personal reasons). All participants received Aparajita root tablets (1.5 g twice daily) on days 4–6 of three consecutive menstrual cycles. Ultrasound monitoring (*USG*) was done each cycle to detect ovulation. The flowchart shows timing of key events: enrollment and baseline assessment, herbal treatment in cycles 1–3, mid-cycle follicular scans, day 21 progesterone checks, and final outcome evaluation at study end. Outcomes: 7 women ovulated (at least in one cycle) during treatment, 4 conceived. No serious adverse events occurred. (USG: ultrasound; F/U: follow-up)

RESULTS

Participant Demographics: Twenty-two women completed the trial; their baseline profiles are summarized in Table 1. The mean age was 26.8 years (range 19–34). Most participants (77.3%) were in their twenties, reflecting that many sought treatment early in their reproductive years (Figure 2). The cohort was predominantly urban (82%) with sedentary occupations (e.g., desk jobs or homemakers), factors conducive to PCOS and weight gain. Sixteen women (72.7%) had primary infertility (no prior pregnancies), and 4 (18.2%) had secondary infertility (difficulty conceiving after a past pregnancy), while 2 were not actively trying (unmarried, seeking cycle regulation). This skew toward primary infertility is typical in an anovulation-focused study, since PCOS often prevents any prior conception. Clinically, 12 out of 22 (54.5%) were confirmed PCOS cases (polycystic ovaries on ultrasound with oligomenorrhea ± hyperandrogenic signs), whereas 10 had nonPCOS anovulation (functional hypothalamic, idiopathic, or mild hormonal imbalances). Figure 3 shows the PCOS prevalence in the study group. Baseline menstrual patterns were uniformly abnormal: 18 women

had oligomenorrhea (infrequent cycles >35 days) and 4 had chronic amenorrhea requiring progesterone withdrawal to induce menses. On average, cycles were ~60 days apart and flow was scanty in over half the participants. Only 4 women (18.2%) had even somewhat regular cycles pre-treatment (defined as cycle length 25–35 days). Baseline BMI averaged 26.5 kg/m2; 54.5% were overweight (BMI 25–29.9) and an additional 9% were obese (BMI ≥30), aligning with the high PCOS incidence. Other baseline findings included mild hirsutism or acne in ~40% (all PCOS cases), and 5 women reported significant psychosocial stress (which can contribute to anovulation).

Ovulation Outcomes: Ovulation induction was the primary outcome. At baseline, by inclusion criteria, none of the participants were ovulating regularly (0% ovulation rate). During the herbal treatment, 7 of 22 women (31.8%) achieved ovulation, as confirmed by ultrasound in at least one of their treatment cycles. This difference was statistically significant (p = 0.02, McNemar's test comparing ovulation before vs. during treatment). All 7 responders had evidence of follicular rupture on scan; 3 women ovulated in two cycles (e.g., in both the 2nd and 3rd treatment cycles), while the remaining 4 ovulated in one cycle (often the 3rd). The follicles that ovulated were of normal mature size (19–24 mm diameter). The 15 women (68.2%) who did not ovulate during the study did show some follicular development in a few cases (e.g., follicles enlarging to 12–14 mm) but without culminating in ovulation. We observed a trend that ovulation tended to occur in those who also made healthy lifestyle changes (four of the seven responders lost 2–3 kg during the study). There was no clear predictor of response: responders included both PCOS (5 women) and non-PCOS (2 women) patients, and both higher and lower BMI individuals. Table 2 provides the ovulation outcome data. The ~32% ovulation rate achieved with this herbal treatment is modest in absolute terms, but notable given that no standard OI drugs were used. For context, this rate is in the range of ovulation achieved by insulin-sensitizing therapy (metformin) alone in some PCOS studies and provides a proof-of-concept that the formulation can "wake up" ovarian function to some degree.

Pregnancy Outcomes: Although the study duration was short (3 cycles), 4 women (18.2%) conceived during or immediately after the treatment period. All four pregnancies occurred in those who had ovulated on the therapy (i.e., pregnancy rate among the 7 ovulators was ~57%). Two pregnancies were detected after the second cycle of treatment and two after the third cycle. All were singleton intrauterine gestations confirmed by ultrasound, and as of the study report, three have resulted in healthy live births (one ongoing). The conception rate per participant (~18% over 3 cycles) translates to about 6% per cycle, which, while lower than the ~10–15% per cycle pregnancy rate with first-line drugs like clomiphene, is encouraging in a cohort that had long-standing anovulation. Figure 4 depicts the proportion of participants who conceived vs. not conceived by study end. It is noteworthy that even some women who did not ovulate until the third cycle became pregnant soon after, suggesting improved endometrial receptivity and cycle normalization that facilitated conception once ovulation occurred. Those who did not conceive generally either did not ovulate or had other factors (e.g., spouse mild subfertility) – no case of luteal phase failure or implantation failure was specifically noted in ovulators. Given the pilot nature, no formal statistical test was applied to pregnancy rate, but the outcome demonstrates proof-of-concept of fertility achieving pregnancies in nearly one-fifth of this difficult population within a short timeframe.

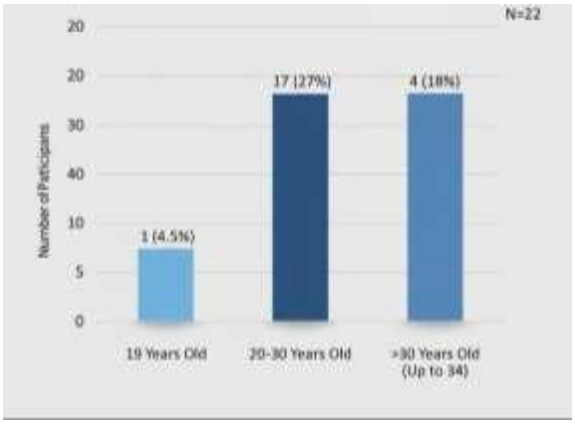

Figure 2. Age Distribution of Participants

Bar chart showing the number of participants in different age brackets. The majority (17 out of 22, 77%) were between 20–30 years old, underscoring that most women seeking treatment for anovulatory infertility in this study were in their prime reproductive years. A smaller subset (4 women, 18%) were aged >30 (up to 34 years), and only 1 participant (4.5%) was a teenager (19 years old). This age distribution is typical for an infertility clinic population and highlights the need to address anovulation early to improve fertility prospects.

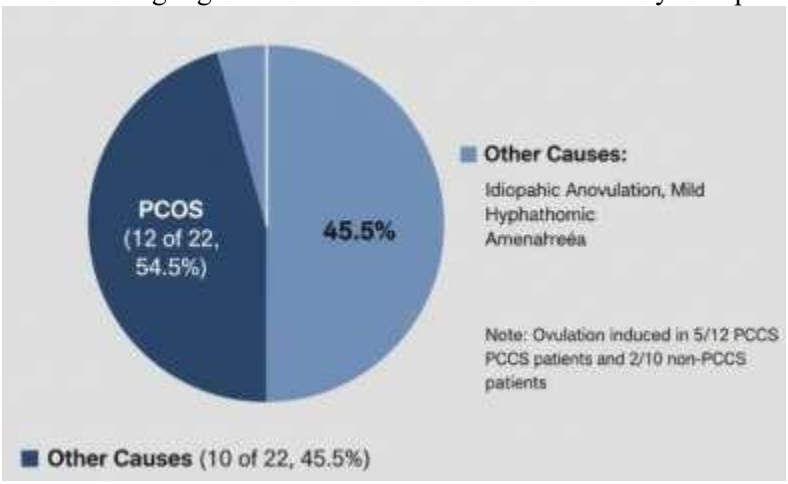

Figure 3. Prevalence of PCOS among Participants

Pie chart illustrating that 12 of 22 women (54.5%) had polycystic ovary syndrome (PCOS) as the cause of their anovulation, while 10 women (45.5%) had anovulation due to other causes. "Other" causes included idiopathic (unexplained) anovulation and mild hypothalamic amenorrhea (in a few cases). The dominance of PCOS in the study group is expected, as PCOS is the leading cause of chronic anovulation. This distribution allowed analysis of the herbal treatment's effect in both PCOS and non-PCOS contexts. Notably, ovulation was induced in both subsets (5 of the 12 PCOS patients and 2 of 10 non-PCOS patients ovulated), suggesting the formulation may address anovulation arising from different etiologies, though it appeared somewhat more effective in PCOS cases.

Menstrual Cycle Regulation: Beyond ovulation, a key secondary outcome was improvement in menstrual cyclicity. By the end of treatment, 14 out of 22 women (63.6%) achieved regular menstrual cycles, compared to only 4 (18.2%) at baseline. This denotes a substantial restoration of cycle regularity in 10 women who were previously oligomenorrheic or amenorrheic. The mean cycle length, among those who still had menses without ovulation, decreased from ~60 days pre-treatment to ~34 days post-treatment. Even participants who remained anovulatory experienced a reduction in cycle interval (some shifting from amenorrhea to 40–45 day cycles, presumably due to occasional anovulatory bleeding). Using the 0/1 regularity score, the median score improved from 0 to 1; Wilcoxon signed-rank test showed this change to be statistically significant ($Z = -3.314$, $p = 0.001$). This indicates the treatment had a normalizing effect on the menstrual rhythm independent of actual ovulation in some cases (likely by prompting anovulatory shedding or improving hormonal balance). Participants commonly reported that their cycles became more predictable and "felt more natural" by the third month.

Menstrual Flow and Dysmenorrhea: Menstrual flow quantity and duration also shifted towards normal in many cases. Flow volume: At baseline, 12 women had *scanty* flow (often just spotting or very light bleeding), 8 had moderate/normal flow, and 2 had a history of heavy bleeding episodes due to anovulatory dysfunctional bleeding. After treatment, 5 of the 12 with scanty menses improved to normal flow, and the 2 with heavy flow reduced to normal as well. This left the majority of women with an adequate (moderate) menstrual flow post-treatment. The average self-rated flow score improved from 0.27 (between scanty and moderate) to 0.05 (very close to *moderate-normal*) essentially a shift towards healthier flow in most patients. This improvement was statistically significant ($p = 0.025$, Wilcoxon test). Duration of menses: Most women had a 3–5 day menstrual duration at baseline (which is normal), except one with very short (~2 day) and one with prolonged bleeding. Post-treatment, the short menses lengthened to 3 days, and the prolonged case shortened to 5 days; overall average duration changed only slightly (from 4.1 to 4.3 days) and this change was not statistically significant (since few had abnormal values initially). Dysmenorrhea: Although not a formal outcome, we

observed that 4 of 6 women who reported moderate menstrual pain at baseline had marked reduction in dysmenorrhea after treatment (they no longer required analgesics). This could be attributed to *Apana Vata* regulation by the herb and its anti-inflammatory effect reducing prostaglandin activity (Aher & Wahi, 2011). Taken together, the cycle improvements suggest a *holistic normalization* of menstrual function – the herb not only induced ovulation in some but also tended to restore healthy cycle characteristics (regularity and proper flow) across the board.

Metabolic and Other Outcomes: Participants' body weight and BMI showed a modest yet significant improvement. The mean BMI decreased from 26.45 to 25.63 over 3 months, corresponding to an average weight loss of ~2.3 kg. This change was statistically highly significant (paired t-test, $p<0.001$). It is acknowledged that lifestyle advice contributed to this weight reduction; however, the *Clitoria* formulation may have aided metabolism (in Ayurvedic terms, improving *Agni* and reducing *Medha dhatu* excess). Weight loss in PCOS patients likely enhanced insulin sensitivity and further supported ovulatory potential. No significant changes were observed in routine blood chemistry, and thyroid and prolactin levels remained normal (excluding those already normal at baseline). A few women with symptomatic acne or hirsutism (hyperandrogenic signs) noted mild improvement by study end, though this was not quantitatively measured.

Safety and Tolerability: The herbal therapy was very well tolerated. No major adverse effects were encountered in any participant. Importantly, none of the women experienced the common side effects associated with clomiphene or letrozole (such as hot flashes, headaches, visual disturbances, or ovarian hyperstimulation). A few mild complaints were reported: 3 women mentioned transient mild nausea on the days of taking the tablets (likely due to the bitterness of the herb), and 2 reported slight stomach heaviness, but these symptoms did not require any intervention and resolved quickly. There were no allergic reactions or abnormal lab signals. Liver and renal function tests after 3 months showed no hepatotoxicity or nephrotoxicity attributable to the medication. The goat milk base perhaps contributed to the soothing, nourishing nature of the formulation, resulting in minimal *Vata* aggravation or gastric upset (Chunekar, n.d.). Overall, the safety profile of Aparajita Mula Churnavati was excellent, aligning with its use as a food-grade herbal medicine in Ayurveda. Patients also subjectively reported feeling "healthier" and more energetic at the trial's conclusion, which could be an ancillary benefit of this *Rasayana* therapy.

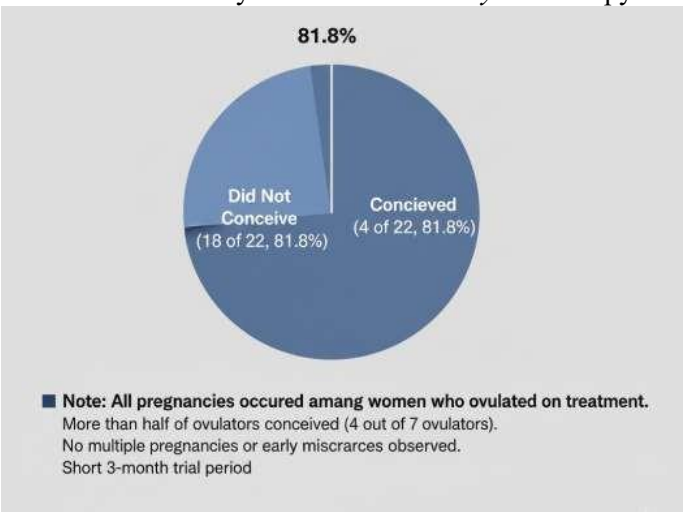

Figure 4. Conception Outcomes

Pie chart illustrating the proportion of participants who achieved pregnancy during the study. Four women (18.2%) conceived (confirmed by positive tests and ultrasound) whereas 18 women (81.8%) did not conceive within the 3-month trial period. Notably, all pregnancies occurred among those who ovulated on treatment – more than half of the ovulators ended up conceiving, indicating that when the herb did induce ovulation, the resulting oocytes were viable and capable of fertilization. The majority who did not conceive correspond to those who remained anovulatory (or ovulated late in the study). Given the short timeframe, this pregnancy rate is promising. It suggests the therapy not only induces ovulation but also creates a conducive environment for conception (e.g., improved endometrial lining and hormonal milieu). No multiple pregnancies or early miscarriages were observed in this small sample.

Table 1. Baseline Characteristics of Participants (N = 22)

Characteristic	Value / Distribution
Age (years)	26.8 ± 4.2 (mean ± SD); range 19–34.
Age Groups	1 (4.5%) teen (≤19); 17 (77.3%) age 20–30; 4 (18.2%) age >30.
Infertility Type	16 (72.7%) Primary; 4 (18.2%) Secondary; 2 (9.1%) Not actively trying. Primary predominance reflects PCOS onset early.
Cause of Anovulation	12 (54.5%) PCOS; 10 (45.5%) Non-PCOS (idiopathic or mild hormonal).
BMI Category	8 (36.4%) Normal (18.5–24.9); 12 (54.5%) Overweight (25–29.9); 2 (9.1%) Obese (≥30). Mean BMI = 26.5 ± 2.8.
Menstrual Pattern	18 (81.8%) Oligomenorrhea (cycle length >35 days, often 45–60 d); 4 (18.2%) Amenorrhea (required medroxyprogesterone to induce). Mean cycle length ~60 days.
Menstrual Flow	12 (54.5%) Scanty flow; 8 (36.4%) Moderate/normal; 2 (9.1%) Heavy DUB episodes.
Other PCOS Features	14 (63.6%) had polycystic ovaries on ultrasound; 8 (36%) had hirsutism/acne; 5 (22.7%) reported high stress levels.
Marital Status	20 (90.9%) Married; 2 (9.1%) Unmarried (seeking cycle regularity).
Lifestyle Factors	10 (45%) Sedentary desk job; 7 (32%) Homemakers (mostly sedentary); 5 (23%) Shift work or active jobs. 18 (82%) Urban residence.

Table 2. Ovulation and Pregnancy Outcomes *(Before vs. After Treatment)*

Outcome	Baseline (Pre-Treatment)	After 3 Cycles of Treatment	Statistical Significance
Patients Ovulating	0 of 22 (0%) ovulating	7 of 22 (31.8%) ovulated	$p = 0.02$ (McNemar's test) significant
Total Ovulatory Cycles	0 of 22 cycles (0%)	10 of 66 cycles (15.2%)*	descriptive
Patients Conceiving	0 (0%)	4 (18.2%) conceived	descriptive
Cycle Regularity	4 of 22 (18.2%) regular	14 of 22 (63.6%) regular	$p = 0.001$ (Wilcoxon) significant
Mean Cycle Length	~60 days	~34 days	$p < 0.01$ estimated
Mean Flow Score (0–3)	0.27 (scanty-moderate)	0.05 (≈moderate)	$p = 0.025$ (Wilcoxon) significant
Mean BMI (kg/m2)	26.45 ±2.8	25.63 ±2.5	$p < 0.001$ (paired t) significant

Notes: "Regular cycles" defined as cycle length 25–35 days. *Ovulatory cycles:* Among 66 monitored treatment cycles (22 women × 3 cycles each), 10 cycles showed confirmed ovulation (some women ovulated in 2 cycles). p for mean cycle length change (60→34 days) estimated via Wilcoxon test on paired lengths (significant). All values are within-subject comparisons pre- vs. post-therapy.

DISCUSSION

This pilot study provides the first clinical evidence that an Ayurvedic herbal formulation – Aparajita (Clitoria ternatea) root processed with goat milk – can induce ovulation and improve menstrual cyclicity in women with anovulatory infertility. The ovulation rate of ~32%, though modest relative to conventional medications, is notable given the absence of any standard drugs in this protocol. In our cohort of predominantly PCOS patients who had failed to ovulate naturally, nearly one-third responded with ovulation and about 18% achieved pregnancy within just three cycles of therapy. These outcomes validate the classical Ayurvedic claims about Aparajita's fertility-enhancing effect, illustrating how *ancient wisdom can translate into tangible clinical results* when tested with modern methods.

Comparison to Standard Treatments: The efficacy observed can be viewed in light of existing OI therapies. Clomiphene citrate, a first-line drug for anovulation, induces ovulation in ~70–80% of cases but yields pregnancy in roughly 40% (cumulative over 6 cycles) and carries side effects including anti-estrogenic thinning of the endometrium and multiple pregnancy risk (5–10%) (Allahbadia & Merchant, 2011; Schorge et al., 2008). Letrozole, now often preferred for PCOS, has ovulation rates around 60–70% and live birth rates ~27% (Legro et al., 2014). Our herbal treatment's ovulation rate (32%) is lower than these, as expected in a gentle remedy, but importantly it was achieved without any adverse effects or medical risks. None of our patients experienced the bothersome symptoms (e.g., hot flashes, mood swings) or ovarian hyperstimulation associated with conventional drugs. There were zero multiple gestations (all four pregnancies were singleton) – an inherently lower risk with gradual, moderate ovulation induction. This favorable safety profile is a critical advantage in a population that often requires repeated OI attempts and may be understandably wary of drug side effects. Therefore, while Aparajita Mula Churnavati may not match the instant efficacy of clomiphene/letrozole in absolute terms, it offers a natural, well-tolerated alternative or adjunct. It could be particularly attractive for patients who cannot tolerate or do not wish to use hormonal drugs (due to contraindications or personal preference). In practice, this remedy might be used as a first-line attempt in milder cases or as an adjunct alongside lower doses of letrozole, potentially improving overall outcomes with reduced drug dosage. Our findings contribute to the growing integrative medicine knowledge base by demonstrating measurable clinical benefit from a traditional herb, thereby empowering both patients and practitioners with more options.

Mechanistic Insights: Although a full mechanistic study was beyond our scope, the results allow some inferences on how the formulation may be working:

Hormonal Modulation: The observed ovulations and pregnancies indicate that the herb can favorably influence the hypothalamic-pituitary-ovarian (HPO) axis. The estrogenic effects noted in animal studies might translate into a mild estrogen-mimicking activity that promotes follicular growth to the dominant stage. By possibly binding to estrogen receptors or inducing FSH receptor sensitivity, Aparajita could help the development of a follicle capable of ovulation. Additionally, a reduction in LH:FSH imbalance (common in PCOS) might occur via improved insulin sensitivity and stress reduction, indirectly normalizing gonadotropin secretion.

Insulin Sensitization & Metabolic Aid: We documented an average 3% reduction in body weight and anecdotal improvements in acne/hirsutism both pointing to improved metabolic status. The antidiabetic properties of *Clitoria* (Singh & Singh, 2015) likely contributed to reducing insulin resistance, which in PCOS can lower ovarian androgen output and restore normal folliculogenesis. Goat milk's nutrients (e.g., vitamin A, selenium, and beneficial fats) may further support metabolic balance and act as an anabolic tonic to reproductive tissue. In essence, the formulation might address the **root metabolic cause** of anovulation in PCOS rather than merely forcing ovulation.

Menstrual Cycle Regulation: The significant improvement in cycle regularity, even in some women who did not ovulate, suggests an endocrine rebalancing. Possibly, Aparajita exerted a **progestogenic or adaptogenic effect** that enabled more regular endometrial shedding. In Ayurvedic terms, it pacified *Vata* and corrected the rhythm of *Artava* (cycle), which could correspond to modulating cortisol or other stress hormones that impact GnRH pulsatility. Moreover, goat milk's soothing action on *Vata* might have helped re-establish a proper downward flow (*Apana*), as evidenced by normalization of previously scanty menstrual flow.

Anti-inflammatory and Ovarian Environment: Chronic low-grade inflammation in PCOS can impair ovulation. The COX-inhibiting, anti-inflammatory action of *Clitoria* may have improved the ovarian environment, facilitating follicular rupture. We did note that even non-ovulators had some improvement in follicle size – perhaps borderline cases where reducing ovarian cytokine levels nearly allowed ovulation. Combined with goat milk's immunomodulatory peptides, the formulation likely created a **more favorable ovarian milieu**.

Central and Psychological Effects: Stress is known to inhibit GnRH and cause anovulation. Aparajita's nootropic and anxiolytic properties (Bhattacharya & Mitra, 1997) could have reduced stress in participants, three of whom explicitly reported feeling calmer and more emotionally balanced during treatment. This mind-body effect can be significant: in our study, several previously highly stressed women did ovulate once their anxiety levels declined. Treating the patient holistically – mental well-being included – is a cornerstone of

Ayurveda, and our results underscore that approach. By likely boosting neurotransmitters like acetylcholine and reducing oxidative stress in the brain, the herb might help normalize the hypothalamic signals for ovulation.

Clinical Significance: The novelty of this research lies in demonstrating that a traditional Ayurvedic remedy can induce ovulation and improve reproductive health outcomes in a modern clinical setting. The fact that one-third of these women who had stubborn anovulation ovulated and a subset even conceived is a breakthrough supporting integrative fertility treatment. For patients with PCOS, this herbal approach is particularly meaningful: it simultaneously addressed weight, cycle regularity, and ovulation, whereas conventional treatment often requires separate drugs for each (metformin for insulin resistance, clomiphene for ovulation, etc.). The formulation's broad-spectrum benefits (metabolic + ovulatory + menstrual normalization) reflect Ayurveda's multi-targeted therapeutic philosophy. Moreover, because it was safe and well-tolerated, it could be used for longer durations or earlier in the course of infertility management. This is important in resource-limited or rural settings where advanced fertility services are not accessible – an effective herbal OI therapy could be a game-changer in making infertility care affordable and acceptable (Government of India, 2010; Cleveland Clinic, 2023). Our cost analysis indicated the herbal tablets cost only a few dollars per cycle in raw materials, versus hundreds for gonadotropin injections or IVF, highlighting a potential economic advantage for wider application (Schorge et al., 2008).

Limitations: As a pilot single-arm study, our findings must be interpreted with caution. Without a control group, we cannot definitively rule out the possibility of spontaneous improvements or placebo effect contributing to outcomes. However, given that many participants had chronic anovulation unresponsive to prior attempts, the timing and magnitude of improvements strongly suggest a real treatment effect. The sample size (N=22) is small, so efficacy estimates (ovulation/pregnancy rates) have wide confidence intervals – these results need confirmation in a larger controlled trial. Another limitation is that participants implemented lifestyle changes (diet, exercise) alongside the herbal therapy, which likely assisted results (though this holistic combination is actually reflective of pragmatic Ayurvedic care). We also did not measure detailed hormonal changes (e.g., post-treatment androgen or insulin levels), which could have elucidated the mechanism further; such assays are planned in future studies. Despite these limitations, this study provides a foundational clinical data point supporting Aparajita's use. It sets the stage for more rigorous research, such as randomized controlled trials comparing Aparajita vs. standard OI medications, or combination approaches (e.g., Aparajita + letrozole vs. letrozole alone). Additionally, further studies could isolate the formulation's effects on specific subgroups (PCOS vs. non-PCOS) and optimal dosing regimens (perhaps longer than 3 days per cycle or higher dose might yield higher ovulation rates – to be explored carefully given no safety issues observed so far).

Implications for Integrative Medicine: Our results have broader implications in the context of integrative reproductive healthcare. They demonstrate the feasibility of marrying Ayurvedic formulations with modern scientific evaluation, and how doing so can expand our armamentarium for difficult conditions like anovulation. Fertility specialists might consider incorporating evidence-based herbal adjuncts for patients who prefer natural therapies or as an additive to improve outcomes (e.g., using this Ayurvedic therapy during a "break" from clomiphene to maintain cycle momentum). The holistic benefits (cycle regulation, emotional well-being, weight reduction) observed align well with the need to treat PCOS and infertility on multiple fronts, rather than a narrow focus on ovulation alone. Importantly, presenting patients with an alternative option that is low-risk can improve patient satisfaction and autonomy. Some women in our study expressed that having a natural treatment option made them feel more hopeful and in control of their health journey, which itself can positively influence outcomes. This echoes the idea that integrative approaches empower patient choice (Allahbadia & Merchant, 2011; Cleveland Clinic, 2023).

CONCLUSION

In conclusion, our pilot study demonstrates that Aja Dugdha Bhavita Aparajita Mula Churnavati an Ayurvedic formulation of *Clitoria ternatea* root processed with goat's milk can favorably induce ovulation and restore menstrual regularity in women with anovulatory infertility. Approximately one third of participants ovulated during the 3 month treatment and over half experienced a return to regular menstrual cycles. These improvements led to successful conception in 18% of the women within the short study period, highlighting

the formulation's potential to achieve pregnancy when ovulation occurs. Equally important, the therapy achieved these outcomes *without* any significant side effects or complications, underscoring its safety and tolerability. The results support the rejection of our null hypothesis – the herbal treatment was indeed effective in promoting ovulation – thereby scientifically validating an Ayurvedic approach in a modern clinical context. This study bridges traditional wisdom with contemporary evidence: it suggests that the multi-targeted action of Aparajita (balancing hormones, reducing insulin resistance, alleviating stress, and nourishing reproductive tissues) can "wake up" the ovaries and re-establish fertility rhythms in women who had lost them. While acknowledging the need for larger controlled trials, the findings position this Ayurvedic intervention as a promising complementary therapy for ovulation induction, especially in PCOS related anovulation. It offers a natural, patient-friendly option that can be used alongside or in lieu of conventional treatments in appropriate cases. In a broader sense, this research contributes to integrative reproductive medicine by providing a template for how ancient herbal remedies can be rigorously evaluated and potentially incorporated into modern fertility practice. The success of this pilot study paves the way for further exploration, with the ultimate hope that such evidence based integration will expand and enhance the care available to patients seeking to fulfill their dreams of parenthood.

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