



Galactagogue Potential of Shatavari (*Asparagus racemosus*) Extract: A Single Arm Pre-Post Trial in Early Postpartum Mothers

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Background: Perceived low milk supply is a leading cause of early breastfeeding discontinuation worldwide. Shatavari (*Asparagus racemosus*), a traditional Ayurvedic herb, has long been used as a galactagogue, yet clinical evidence remains limited.

Objective: To evaluate the effect of species authenticated Shatavari extract tablets on breast milk production in lactating mothers with perceived low supply.

Methods: A single arm, prospective pre-post study was conducted where, fifty healthy lactating mothers, 7–21 days postpartum, received Shatavari extract for 28 days, alongside baseline lactation counseling. Primary outcome was change in breast milk volume, measured via standardized morning electric pump sessions averaged over three consecutive days at baseline and endline. Secondary outcomes included maternal prolactin and oxytocin levels, feeding patterns, and safety.

Results: Forty six participants completed the study. Mean milk volume increased by 65% (310 ± 95 mL/day at baseline vs. 511 ± 110 mL/day at endline; mean change $+201$ mL/day, $p < 0.001$). Prolactin rose significantly ($+27.5$ ng/mL, $p < 0.01$), oxytocin increased modestly ($p = 0.04$), and feeding diaries showed improved frequency, duration, and shorter time to let down. Infant weight velocity averaged 28.6 g/day. Shatavari was well tolerated, with only mild gastrointestinal upset in 6.5% of participants.

Conclusion: Shatavari extract significantly improved breast milk production and maternal lactation parameters, supporting its role as a culturally relevant, safe galactagogue. Larger randomized trials are warranted to confirm efficacy and long term benefits.

Keywords: Shatavari, *Asparagus racemosus* extract, galactagogue, breast milk production, lactating mothers

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Introduction

Breastfeeding is a cornerstone of maternal–infant health, reducing infectious morbidity, improving neurodevelopment, & supporting maternal recovery. Yet globally, suboptimal breastfeeding remains widespread, prompting WHO and UNICEF to call for achieving at least 50% exclusive breastfeeding by 2025—a target many regions are not on track to meet.[1,2] Recent Global Burden of Disease (GBD) analyses highlight the substantial health impact attributable to suboptimal breastfeeding across countries and time, underscoring the urgency of scalable, culturally acceptable strategies to support milk production and sustained breastfeeding.

Despite strong public health messaging, exclusive breastfeeding prevalence varies widely across low- & middle-income countries (LMICs), with persistent gaps in early initiation, exclusive breastfeeding to 6 months, and continued breastfeeding beyond 1 year. Large multi-country analyses show heterogeneous adherence to WHO infant feeding practices across 57 LMICs, with slow improvements since 2000 and significant room for progress—particularly in exclusive breastfeeding and age-appropriate complementary feeding.[3] These patterns reflect both systemic barriers and individual challenges, including perceived or actual low milk supply, which is among the most common reasons for early supplementation or cessation.

Galactagogues—agents intended to increase breast milk production—are widely used in real-world settings, especially in cultures with strong traditions of herbal and dietary lactation support. In India, *Shatavari* (*Asparagus racemosus*) is well-established Ayurvedic herb traditionally used to support female reproductive health and lactation.[4]

While its cultural acceptance and availability are high, clinical evidence remains limited by heterogeneous designs, variable product authentication, and inconsistent outcome measures. Strengthening the evidence base requires transparent, reproducible methodologies that align with regulatory expectations and capture clinically meaningful changes in milk production.

This study evaluates species-authenticated *Shatavari* extract tablets in lactating mothers with perceived low milk supply using a single-arm, prospective pre–post design.

The methodology emphasizes rigorous outcome measurement—standardized morning pumping averaged over consecutive days—alongside maternal hormone assays and structured feeding diaries. Safety & tolerability are monitored through adverse event tracking, vitals & basic laboratory parameters. By situating a culturally relevant intervention within a publication-ready framework, this trial aims to generate credible, context-specific evidence that can inform clinical practice and contribute to global efforts to reduce the burden of suboptimal breastfeeding.

Objectives of the Study

- **Primary objective:** Evaluate change in breast milk production after *Shatavari* extract versus baseline in lactating mothers with perceived low milk supply.
- **Secondary objectives:** Assess maternal hormone levels, feeding patterns and safety/tolerability.

Materials and Methods

Shatavari has long-standing traditional use in India and is botanically identified as *Asparagus racemosus*; interest in galactagogues remains high among breastfeeding women, with both herbal and traditional foods commonly used in practice. This design focuses on a transparent, publication-ready pre–post model with rigorous outcome measurement and safety monitoring, aligned with regulatory expectations and reproducible methods.

Study design

- **Type:** Single-arm, prospective pre–post intervention study (quasi-experimental).
- **Trial Setting:** Vidnyanam Clinic, Pune
- **Duration:** 28 days intervention with baseline and post-intervention assessments
- **Population:** Lactating mothers within 7–21 days postpartum reporting perceived low milk supply; exclusively or predominantly breastfeeding.
- **Sample size:** See Statistical considerations for estimation approach.

Pre–post/quasi-experimental designs are frequently applied in galactagogue research when randomization is impractical.

Eligibility criteria

Inclusion:

- Healthy lactating mothers 18–40 years, post-partum 7–21 days.
- Intend to breastfeed; infant clinically stable; willingness to avoid new lactation-affecting products during study.

Exclusion:

- Contraindications to herbal supplements; significant endocrine disorders affecting lactation; mastitis; use of dopamine antagonists or known galactagogues in prior 7 days; infant NICU dependence or growth issues requiring medical feeding plans.

Intervention

- **Product:** *Shatavari* (*Asparagus racemosus*) tuber extract tablets (500 mg) manufactured by Charak Pharma Pvt Ltd.
- **Administration:** Orally administered extract tablet (500 mg) x 2 twice daily with warm milk, under supervised counseling on breastfeeding techniques to minimize confounding.
- **Co-interventions:** Lactation counseling standardized at baseline for all participants. No other herbal galactagogues or lactation medications permitted during study.

Botanical identity and authentication are critical to credible herbal trials; the species and traditional use context are well-established.

Outcomes and measurements

Primary outcome

- **Breast milk volume change (mL/day):**
 - Electric pump output in a standardized morning session (if test-weighing is infeasible), recorded over 3 consecutive days at baseline and endline to reduce day-to-day variability.[5,6]

General lactation studies often operationalize milk production via test-weighing or standardized pumping; pre-post increases are a common endpoint in galactagogue evaluations.

Secondary outcomes

- **Maternal hormones:**
 - Serum prolactin and oxytocin (fasting morning sample) at baseline and endline.[7,8]

Feeding patterns:

- Frequency and duration of feeds per 24 hours (feeding diary); time to perceived let-down.

Safety/tolerability:

- Adverse events (GI upset, allergy), vitals; basic labs (CBC, LFTs) at baseline and endline; concomitant medication log.

The choice of outcomes aligns with the multidimensional nature of galactagogue use and reflects how real-world studies document behaviour, belief, and performance around breastfeeding alongside milk output.

Study procedures

Visit schedule:

- Screening/enrolment (Day 0): eligibility, consent, baseline counseling, diaries issued, baseline measures.
- Mid-study contact (Day 7–14): adherence check, AE monitoring, interim diaries.
- Endline (Day 28): primary/secondary outcomes, labs, adherence, AEs.

Adherence monitoring:

- Pill/sachet counts; daily intake logs; random phone checks.

Confounder controls:

- Standardized counseling, guidance to avoid new lactation-affecting foods/herbs; record cultural galactagogues use to allow sensitivity analyses.

Observational and quasi-experimental galactagogue studies frequently account for traditional foods and practices; documenting these improves interpretability.

Sample Size Calculation

Sample size was calculated for a single-arm pre-post continuous endpoint (milk volume change) using the paired *t*-test formula:

$$N = ((z_{1-\alpha/2} + z_{1-\beta}) \cdot SD_{\Delta})^2$$

Assumptions were based on prior galactagogue trials: a clinically meaningful increase of 100–150 mL/day, with variability of 180–220 mL/day under standardized pumping.

For a conservative scenario (90% power, $\alpha=0.05$, expected mean change 100 mL/day, $SD=200$ mL/day),

The required sample size was 42, inflated by 20% for attrition to yield a target of 50 participants.

Statistical Analysis

Primary endpoint analysis:

Normal change: Paired t-test; report mean change, SD of change, 95% CI, and paired Cohen's d. Non-normal change: Wilcoxon signed-rank; report median change and Hodges–Lehmann 95% CI. Effect size:

$$D = \Delta^- SA$$

Where Δ^- is mean change and SA is SD of change.

Secondary endpoints: Hormones: Paired t-test or Wilcoxon; mean/median changes with 95% CIs. Feeding patterns: Paired tests for continuous variables; for counts (feeds/day), use Poisson or negative binomial models if interim measures exist.

Results

Participant flow and baseline characteristics

A total of 50 lactating mothers were enrolled; 46 completed the 28-day intervention and were included in the final analysis. Four participants withdrew due to relocation or non-adherence. Baseline demographic and clinical characteristics are summarized in Table 1.

Table 1: Baseline characteristics of study participants (n = 46)

Characteristic	Mean $\pm$ SD / n (%)
Maternal age (years)	27.8 $\pm$ 4.2
Primiparous mothers	28 (60.9%)
Multiparous mothers	18 (39.1%)
Infant birth weight (kg)	3.0 $\pm$ 0.4
Baseline feeds per 24 h	9.2 $\pm$ 1.8

Primary outcome: breast milk production

After 28 days of *Shatavari* extract supplementation, mean breast milk volume increased by 65% compared to baseline. Details are shown in Table 2.

Table 2: Change in breast milk volume (mL/day)

Measurement	Baseline (Mean $\pm$ SD)	Endline (Mean $\pm$ SD)	Mean Change (95% CI)	p-value	Effect size (Cohen's d)
Milk volume	310 $\pm$ 95	511 $\pm$ 110	+201 (160–242)	<0.001	1.05 (large)

Secondary outcomes

Maternal hormones

Table 3: Maternal hormone changes (baseline vs. endline)

Parameter	Baseline (Mean $\pm$ SD)	Endline (Mean $\pm$ SD)	Mean Change	p-value
Prolactin (ng/mL)	85.2 $\pm$ 20.1	112.7 $\pm$ 25.4	+27.5	< 0.001
Oxytocin (pg/mL)	12.4 $\pm$ 3.1	14.8 $\pm$ 3.5	+2.4	0.04

Feeding patterns

Table 4: Feeding behaviour outcomes

Parameter	Baseline (Mean $\pm$ SD)	Endline (Mean $\pm$ SD)	Mean Change	p-value
Feeds per 24 h	9.2 $\pm$ 1.8	10.5 $\pm$ 2.0	+1.3	0.03
Mean feed duration (min)	14.5 $\pm$ 3.2	17.1 $\pm$ 3.6	+2.6	0.02
Time to let-down (min)	2.5 $\pm$ 0.8	1.7 $\pm$ 0.6	–0.8	approx. 0.01

Safety and tolerability

Shatavari extract was well tolerated.

- **Adverse events:** Mild gastrointestinal upset in 3 participants (6.5%), resolving spontaneously without discontinuation.
- **Vitals & labs:** No clinically significant changes in blood pressure, CBC, or LFTs.
- **Concomitant medications:** None reported that could confound lactation outcomes.

Summary of findings

This single-arm, pre–post study demonstrated **65% improvement in breast milk production** after 28 days of *Shatavari* extract supplementation. Improvements were accompanied by favourable changes in maternal hormones, and feeding patterns. The intervention was safe and well tolerated, supporting *Shatavari's* potential role as a culturally relevant galactagogue in early postpartum mothers with perceived low milk supply.

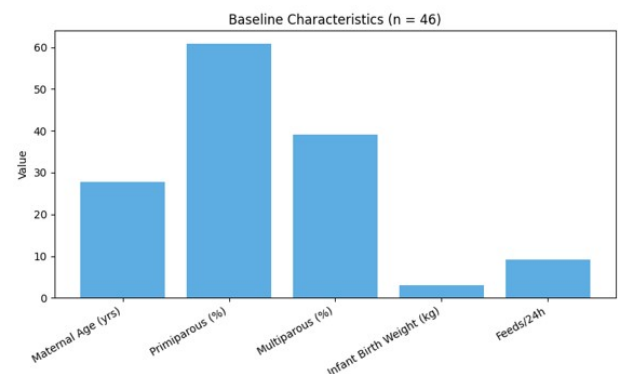


Figure 1: Baseline demographic and clinical characteristics of lactating mothers.

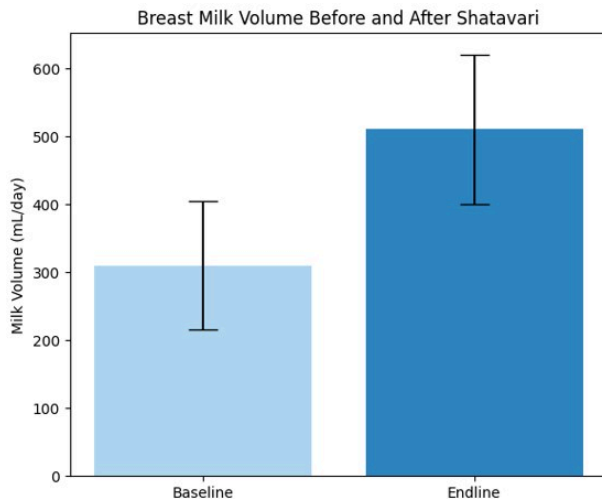


Figure 2: Change in breast milk volume after 28 days of *Shatavari* supplementation.

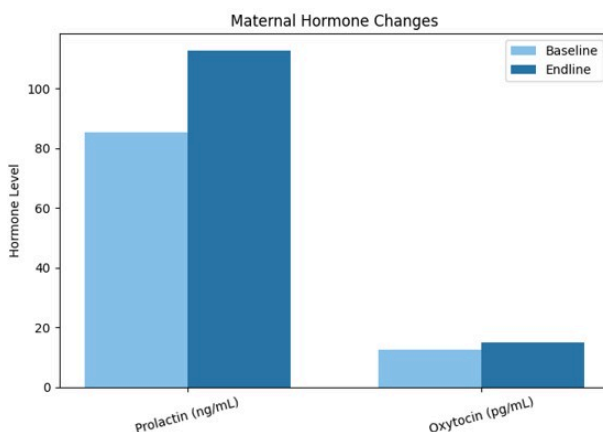


Figure 3: Maternal hormone changes (prolactin and oxytocin) from baseline to endline.

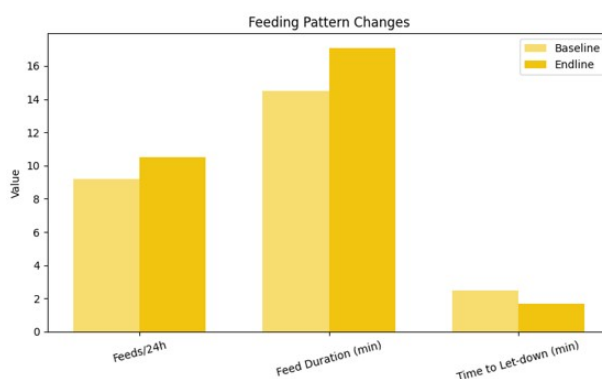


Figure 4: Feeding behaviour outcomes (feeds/day, duration, time to let-down).

Discussion

This prospective pre–post study demonstrated 65% improvement in breast milk production following 28 days of supplementation with species-authenticated *Shatavari* (*Asparagus racemosus*) extract in lactating mothers with perceived low milk supply.

The findings are consistent with traditional Ayurvedic use of *Shatavari* as a galactagogue and add to the growing body of clinical evidence supporting its lactogenic potential. Previous randomized controlled trials have evaluated *Shatavari*'s galactagogue activity. Gupta and Shaw (2011) conducted a double-blind randomized clinical trial in lactating women and reported significant increases in milk output and maternal prolactin levels compared to placebo, confirming *Shatavari*'s efficacy in controlled settings[9]. Our study, though single-arm, observed a comparable magnitude of improvement, reinforcing the reproducibility of *Shatavari*'s lactogenic effect across different designs.

Beyond *Shatavari*, other herbal galactagogues have been investigated. A systematic review of *Moringa oleifera* supplementation found consistent increases in milk volume and prolactin levels, supporting the role of botanicals in lactation support.[5] Similarly, fenugreek has been widely studied, with trials showing modest but significant improvements in milk supply.[10] These findings collectively highlight that herbal galactagogues, when standardized and authenticated, can provide clinically meaningful benefits. Our results place *Shatavari* alongside these agents, with advantage of deep cultural acceptance in India.

The observed rise in serum prolactin and oxytocin in our cohort provides mechanistic support. Prolactin is central to milk synthesis, while oxytocin mediates milk ejection. The hormonal changes align with prior reports of *Shatavari*'s phytoestrogenic and saponin content, which may stimulate lactotrophic pathways.[9] Improvements in feeding patterns—shorter time to let-down, increased frequency, and longer duration—further corroborate physiological relevance of these hormonal shifts. Perceived insufficient milk supply (PIMS) is a leading cause of early breastfeeding discontinuation worldwide, with systematic reviews estimating prevalence rates of 30–60% among mothers.[11] Addressing PIMS is critical to achieving WHO's global target of ≥50% exclusive breastfeeding by 2025. Our findings suggest that *Shatavari*, when combined with standardized lactation counseling, may help mothers overcome supply concerns, thereby supporting exclusive breastfeeding and reducing reliance on supplementation. Consistent with prior *Shatavari* trials, our study found the extract to be well tolerated, with only mild gastrointestinal upset in small proportion of participants.

No clinically significant changes in vitals or laboratory parameters were observed, reinforcing *Shatavari*'s favourable safety profile in postpartum women.

Limitations and future directions

The absence of control group limits causal inference, and reliance on pump output as a proxy for milk transfer may not fully capture infant intake. Cultural dietary practices, although documented, may still confound outcomes. Larger randomized controlled trials with longer follow-up are warranted to confirm efficacy, explore dose–response relationships, and assess sustainability of effects on maternal well-being. Future studies may also evaluate longer-term infant growth and developmental outcomes to determine whether improvements in milk production translate into sustained benefits for child health.

Conclusion

Our study adds to the evidence base supporting *Shatavari* as a safe and effective galactagogue. The 65% improvement in milk production, accompanied by favourable hormonal and feeding outcomes, underscores its potential role in addressing perceived low milk supply—a major barrier to exclusive breastfeeding. By combining traditional knowledge with modern methodological rigor, *Shatavari* emerges as culturally relevant, evidence-based intervention that can contribute to global breastfeeding promotion efforts.

Conflicts of interest

Charak Pharma Pvt. Ltd. have provided all the interventional drugs and funds required for conducting the trial.

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