A Randomized Open-Label Comparative Clinical Study of *Bilwadi Kwatha* with *Sharkara* versus *Shunthi Bilwa Kwatha* with *Yava Saktu* in Mild *Garbhini Chardi* (Nausea and Vomiting of Pregnancy)

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Submission: 05.08.2026 Acceptance:25.09.2026 Publication: 06.11.2026

https://www.doi.org/10.63778/CIJISM-ARJCPL/2026_112612

Abstract

Background: *Garbhini Chardi*, correlated with nausea and vomiting of pregnancy (NVP), is very common in early pregnancy; its severe form, hyperemesis gravidarum (HG), may be associated with dehydration, weight loss and nutritional depletion. *Bilwadi Kwatha* with *Sharkara* (*Sahasrayogam*) and *Shunthi Bilwa Kwatha* with *Yava Saktu* (*Yogaratnakara*) are classical formulations whose constituents carry both antiemetic and nutritive attributions. **Objective:** To compare the efficacy and safety of the two formulations in mild *Garbhini Chardi*. **Methods:** In this randomized (lottery method), open-label, two-arm comparative study, 30 women with mild NVP (PUQE-24 score ⩽ 6, HELP score ⩽ 19, gestation up to 22 weeks) were allocated to Group A (*Bilwadi Kwatha* with *Sharkara*, n = 15) or Group B (*Shunthi Bilwa Kwatha* with *Yava Saktu*, n = 15). Each received 48 mL of *Kwatha* twice daily before food with *Koshna Jala* for 14 days, with follow-up to Day 21. Outcomes were the PUQE-24 score, HELP score, subjective and objective parameters. Within-group change was analysed by the Friedman test with Wilcoxon signed-rank post hoc tests, between-group differences by the Mann–Whitney U test, and effect size as $r = Z/\sqrt{N}$. The trial was registered with CTRI (CTRI/2025/03/082641).

Results: All 30 participants completed the study. Both groups improved significantly from baseline in PUQE-24 and HELP scores ($p < 0.001$; large effect sizes). PUQE-24 did not differ between groups (Day 14 $p = 0.562$; Day 21 $p = 1.000$), nor did the composite overall grading (Day 14 $p = 0.065$; Day 21 $p = 0.223$). Overall improvement was 80.92% in Group A and 78.27% in Group B, with a highly significant response in 12/15 (80%) versus 8/15 (53.33%) participants. In exploratory, unadjusted comparisons, Group A had a lower HELP score at follow-up ($p = 0.044$) and greater improvement in salivation ($p = 0.001$), thirst ($p = 0.017$), loss of appetite ($p = 0.038$) and pain above the umbilicus ($p < 0.001$ post-treatment; $p = 0.008$ follow-up); Group B had a higher baseline HELP score ($p < 0.001$). No adverse drug reaction was reported and compliance was 100%. **Conclusion:** Both formulations were associated with clinical improvement and were well tolerated over 14 days in mild *Garbhini Chardi*, with comparable control of nausea and vomiting. Secondary differences favouring *Bilwadi Kwatha* with *Sharkara* are hypothesis-generating and need confirmation in adequately powered, blinded, controlled trials; without an untreated or placebo arm, spontaneous resolution cannot be excluded.

Keywords: *Garbhini Chardi*, Nausea and Vomiting of Pregnancy, Hyperemesis Gravidarum, *Bilwadi Kwatha*, *Shunthi Bilwa Kwatha*, PUQE-24, HELP Score, *Kashaya Kalpana*

Introduction

Maternal physiology undergoes continuous adaptation throughout pregnancy, with nausea and vomiting being among its most common manifestations. The Ayurvedic classics describe *Chardi* as one among the *Vyakta Garbha Lakshanas*, a recognisable sign of established pregnancy[1]. It is regarded as physiological so long as it produces no deleterious effects on the mother or fetus; when it begins to compromise maternal health and daily activities, it assumes a pathological character corresponding to Hyperemesis Gravidarum.

Nausea and vomiting affect some 70–85% of pregnant women, while hyperemesis gravidarum occurs in an estimated 0.3–3.6% of pregnancies; an Indian study reported a prevalence of 1.66[2]. Adequate nutrition in early pregnancy is essential for fetal growth, yet persistent nausea and vomiting may prevent sufficient intake, resulting in dehydration, fatigue, weight loss exceeding 5% of pre-pregnancy body weight, ketonuria, electrolyte imbalance and psychological distress; in severe cases, prolonged nutritional deprivation may rarely lead to starvation ketoacidosis.

The *Acharyas* compare the care of a *Garbhini* to the handling of a vessel filled to the brim with oil (*Tailapoorna Patra*), emphasising that any *Aushadhi* administered during pregnancy should possess *Sukha-Sukumara* properties[3]. In contrast, *Samanya Chardi Chikitsa* includes *Langhana* and

Shodhana, which are not appropriate during pregnancy. The *Chikitsa* of *Garbhini Chardi* should therefore comprise gentle measures that alleviate the condition while supporting maternal health and fetal growth, with *Sthambana* and *Brimhana* as the principal therapeutic considerations.

Contemporary pharmacotherapy for NVP includes doxylamine–pyridoxine, metoclopramide, promethazine and ondansetron. These are effective for many women, but adverse effects and concerns about drug exposure in early pregnancy limit acceptability for some, and they offer no nutritive support. A safe, palatable and well-tolerated adjunct is therefore of interest.

Classical Ayurvedic texts describe several therapeutic options for *Garbhini Chardi*[2–4]. *Yogaratnakara* mentions *Bilwa*, *Shunthi*, *Dhanyaka*, *Laja* and *Yava Saktu* in its management, while *Kashyapa Samhita* mentions *Mudga* and *Charaka Samhita* includes *Bala* under *Prajasthapana Gana*. In *Sahasrayogam*, *Bilwadi Kwatha* (*Chardihara Kashaya*), administered with *Sharkara*, is described with *Deepana*, *Pachana*, *Rochana*, *Hridya*, *Chardihara*, *Dahaprashamana*, *Tarpana* and *Kapha-Vatahara* properties[5]. *Shunthi Bilwa Kwatha* with *Yava Saktu*, described in the *Strirogadhikara* of *Yogaratnakara*, is indicated for *Garbhini* and is attributed with *Ruchivardhaka*, *Agnideepaka* and *Amapachaka* properties[6].

Both *Yogas* are simple *Kwatha* preparations that are classically indicated for *Garbhini Chardi* (*Chardihara*). Since they differ in their constituent *Dravyas* and *Prakshepaka Dravya*, the present study compared their efficacy and safety. Their safety in pregnancy, although supported by classical indication, requires clinical verification.

Aim and objectives: The aim was to compare *Bilwadi Kwatha* with *Sharkara* and *Shunthi Bilwa Kwatha* with *Yava Saktu* in mild *Garbhini Chardi*. The primary objective was to compare change in PUQE-24 and HELP scores from baseline to Day 14 and Day 21. Secondary objectives were to compare change in subjective and objective parameters and to record safety and compliance.

Materials and Methods

Study Design and Setting

A randomized, open-label, comparative clinical study with a pre-test and post-test design was conducted in the Department of Post Graduate Studies in *Prasuti Tantra* and *Stree Roga*, Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru. Thirty-five women were screened; 30 fulfilling the diagnostic criteria were selected from the OPD and IPD, irrespective of religion, caste, race or socio-economic status, and were randomized into two groups of 15 by the lottery (chit) method. The study was approved by the Institutional Ethics Committee (IEC Ref. No. SSIEC/315/2024), Sri Sri College of Ayurvedic Science and Research, Bengaluru, and was registered with the Clinical Trials Registry–India (CTRI/2025/03/082641). Written informed consent was obtained from all participants. The a priori sample size was 120, but 30 participants were enrolled.

The study was open-label and outcome assessors were not blinded.

Drugs and Preparation

Raw drugs were procured from an authentic source, identified by the Department of *Dravyaguna* and prepared in the Teaching Pharmacy of *Rasa Shastra* and *Bhaishajya Kalpana*. For Group A, *Bilwa*, *Dhanyaka*, *Bala*, *Shunthi*, *Laja* and *Mudga* were taken at 8 g each; for Group B, *Shunthi* and *Bilwa* at 25 g each. All the drugs were dried and individually crushed to a coarse (*Yavakuta*) powder. The individual powders were then combined in the prescribed proportions and thoroughly mixed to obtain a uniform formulation for preparation of the *Kwatha*.

Both groups received two packets of 25 g/day of *Kwatha Choorna* with two packets of 6 g/day of the respective *Prakshepaka Dravya*.

Kwatha was prepared by boiling 25 g of *Choorna* in 400 mL water (16 parts) over mild fire until reduced to one-eighth, i.e. 50 mL. In Group A, 6 g of *Sharkara* was added directly to the prepared *Kwatha*. In Group B, 6 g of *Yava Choorna* was triturated with 5–6 drops of water to form a thick paste and was then added to the prepared *Kwatha*. Both *Prakshepaka Dravyas* were dispensed separately rather than incorporated into the *Choorna*, protecting it from hygroscopic change. Subjects consumed 48 mL of freshly prepared *Kwatha* morning and evening before food, with *Jala* as *Anupana*, for 14 days.

Diagnostic, Inclusion and Exclusion Criteria

Diagnosis was based on ICD-11 code JA60.0 (classified as SC0Z under ICD-11 TM1 guidelines), together with the symptoms of *Garbhini Chardi* and of mild Hyperemesis Gravidarum.

Inclusion criteria: Pregnant women aged 18–45 years, with gestational age up to 22 weeks, primigravida or multigravida with singleton or multiple gestation, diagnosed with *Garbhini Chardi*, having a PUQE-24 score $\leqslant 6$[6] and HELP score $\leqslant 19$ [7], with mild hypoglycaemia, hyponatraemia[8] or dehydration, and willing to provide written informed consent were included.

Exclusion criteria: Women with PUQE-24 score 7–15 or HELP score 20–60; molar pregnancy; diabetes mellitus; psychiatric or other systemic illnesses such as cardiac disease or tuberculosis; moderate-to-severe hypoglycaemia,

hyponatraemia or dehydration; or vomiting secondary to medical, surgical or gynaecological causes were excluded.

Assessment Criteria and Statistical Analysis

Assessment was carried out at Day 0 (BT), **Day 7 (DT)**, Day 14 (AT), and Day 21 (FU). All subjective and objective parameters together with investigations were assessed on Day 0 and Day 14, while subjective parameters, the PUQE-24 score and the HELP score were assessed at all four visits. The primary outcomes were the PUQE-24 score, which quantifies duration of nausea and frequency of vomiting and retching over 24 hours[6], and the twelve-component HELP score, which additionally captures micturition frequency, response to medication, functional disability, percentage weight loss, mental status, food intake pattern, antiemetic requirement, change in symptom severity and frequency of medication use[7]. The subjective parameters were salivation, thirst, loss of appetite, dryness of mouth and pain above the umbilicus, the last graded using the Numerical Pain Rating Scale and the Wong-Baker Faces Pain Rating Scale[9]. The objective parameters comprised haemoglobin, contents of vomitus, a four-sign dehydration scale, urine specific gravity, urine ketone bodies, serum sodium, potassium and chloride, and random blood sugar. No biochemical marker of nutritional status was included.

Data were analysed using SigmaStat (Systat Software Inc., San Jose, CA, USA). Normality was tested by the Shapiro–Wilk test; as most variables were non-normally distributed or constant, non-parametric tests were applied uniformly. Within-group comparison across the four time points used the Friedman Repeated Measures ANOVA on Ranks with Wilcoxon signed-rank post-hoc tests, with data presented as Median (25th–75th percentile); between-group comparison used the Mann–Whitney U test. Effect size was calculated as $r = Z/\sqrt{N}$ and interpreted as small ($r < 0.3$), medium ($0.3 \leqslant r < 0.5$) and large ($r \geqslant 0.5$). A p value below 0.05 was considered significant and below 0.001 highly significant.

Because many secondary parameters were compared between groups, these comparisons are considered exploratory and p values were not adjusted for multiplicity.

Demographic Profile and Intervention

Thirty-five subjects were screened and 30 registered; all completed the 14-day treatment course with no dropouts or withdrawals. The majority (56.70%) belonged to the 26–30 year age group, with 86.70% concentrated in the 21–30 year range, consistent with the peak childbearing age. Sixteen (53%) had a normal BMI, 11 (37%) were underweight and 3 (10%) were overweight; BMI was recorded at baseline only and was not tracked over the study period. 21 (70%) were in the first trimester, 24 (80%) were primigravida and all 30 (100%) had a singleton pregnancy.

Drug compliance was 100% in both groups. Group A was well accepted from the outset, *Sharkara* rendering it palatable, whereas Group B met mild initial resistance owing to the thicker consistency imparted by *Saktu*, though overall compliance remained good. No adverse drug reaction was reported in either group, no rescue medication was required and no gastrointestinal disturbance occurred. Improvement was largely maintained after stopping medication, with no rebound of symptoms.

PUQE-24 Score

Within Group A the PUQE-24 score fell from a median of 6 (IQR 6–6) at baseline to 3 (IQR 3–4) at Day 14 and 1 (IQR 1–2) at Day 21, a highly significant reduction ($p < 0.001$, BT–FU) with a large effect size ($r = 0.63$). Within Group B it fell from 6 (IQR 5–6) to 3 (IQR 3–3.5) and then to 1 (IQR 1–2), likewise highly significant ($p < 0.001$, $r = 0.63$). Component-wise, Group A achieved 92.31% improvement in duration of nausea, 75% in frequency of vomiting and 100% in frequency of retching, while Group B achieved 73.33%, 100% and 100% respectively; Group B thus attained complete resolution of vomiting and retching comparable to Group A, whereas Group A showed better early improvement in nausea duration. In both groups the most substantial improvement occurred between Day 0 and Day 7, indicating early onset of therapeutic action. On between-group comparison, the PUQE-24 score showed no statistically significant difference at any time point (AT $p = 0.562$; FU $p = 1.000$).

HELP Score

Within Group A the HELP score fell from a median of 12 (IQR 10–12) at baseline to 5 (IQR 5–6) at Day 14 and 1 (IQR 1–2) at Day 21 ($p < 0.001$, $r = 0.62$); within Group B from 15 (IQR 14–15.5) to 5 (IQR 4–6) and then 2 (IQR 1.5–3) ($p < 0.001$, $r = 0.62$). In Group A, functional disability and percentage weight loss resolved completely by Day 7 and mental status by Day 14, with 80% improvement in severity of nausea and 86.67% in frequency of vomiting. In Group B, functional disability and mental status resolved by Day 14 and percentage weight loss by Day 21, with 26.67% improvement in frequency of vomiting and 86.67% in response to medication. On between-group comparison a statistically significant difference existed at baseline ($p < 0.001$, $r = 0.85$, large), Group B having entered with significantly greater functional impairment despite randomization; the two groups converged at Day 14 ($p = 0.425$, $r = 0.14$, small), and at follow-up Group A recorded a significantly lower HELP score ($p = 0.044$, $r = 0.35$, medium).

Subjective and objective parameters

Parameter	Group A BT	Group A AT	Group A FU	% Improvement / *p* value
Salivation	1 (1–1)	—	0 (0–0)	$p<0.001$; $r=0.70$
Thirst	1 (1–1)	—	0 (0–0)	$p<0.001$; $r=0.70$
Loss of appetite	12	—	3	$p=0.003$; $r=0.54$
Pain above umbilicus	2 (1–2)	—	0 (0–0)	$p=0.002$; $r=0.57$
Dryness of mouth	1 (1–1)	0 (0–0)	0 (0–0)	$p<0.001$; $r=0.68$
Urine specific gravity	Normal	Normal	Normal	—
Urine ketone bodies	Negative	Negative	Negative	—
Serum Na^+ , K^+ , Cl^-	Normal	Normal	Normal	—
Blood sugar	Normal	Normal	Normal	—
Haemoglobin score	15	40	—	—
Contents of vomitus	Present	—	Absent	—
Clinical dehydration	5	—	0	100%

Parameter	Group B BT	Group B AT	Group B FU	% Improvement / *p*
Salivation	1 (1–1)	—	0 (0–0)	$p<0.001$; $r=0.68$
Thirst	1 (1–1)	—	0 (0–0)	$p<0.001$
Loss of appetite	13	—	0	$p<0.001$; $r=0.65$
Pain above umbilicus	1 (1–1.5)	—	0 (0–1)	$p=0.010$; $r=0.47$
Dryness of mouth	1 (1–1)	0 (0–0)	0 (0–0)	$p<0.001$; $r=0.68$
Urine specific gravity	Normal	Normal	Normal	—
Urine ketone bodies	Negative	Negative	Negative	—
Serum Na^+ , K^+ , Cl^-	Normal	Normal	Normal	—
Blood sugar	Normal	Normal	Normal	—
Haemoglobin score	15	43	—	—
Contents of vomitus	Present	—	Absent	—
Clinical dehydration	5	—	0	100%

Overall Assessment

Within Group A the overall grading of *Garbhini Chardi* fell from a median of 6 (IQR 4–6) at baseline to 0 (IQR 0–1) at Day 14 and 0 (IQR 0–0) at Day 21, a highly significant reduction ($p < 0.001$, BT–FU) with a large effect size ($r = 0.62$). Within Group B it fell from 5 (IQR 4–5.5) to 1 (IQR 0.5–2) at Day 14 and 0 (IQR 0–1) at Day 21 ($p < 0.001$, $r = 0.63$). Between groups, the overall grading did not differ significantly (Day 14: $p = 0.065$, $r = 0.32$; Day 21: $p = 0.223$, $r = 0.18$). On composite percentage improvement, Group A achieved 80.92% against 78.27% in Group B, with a subjective total of 96.05% versus 90.54%. On per-subject grading, 12 of 15 subjects (80%) in Group A achieved a Highly Significant response and 3 (20%) a Significant response, whereas Group B recorded 8 (53.33%) Highly Significant and 7 (46.67%) Significant; no subject in either group showed a Non-Significant response. Two subjects in Group A with pre-existing headache and three subjects with irregular bowel habit reported improvement; these were unsolicited observations and were not systematically assessed.

Discussion

On the Disease

In Ayurveda, *Chardi* is described as the forceful expulsion of the contents of the *Amashaya* through the *Mukha* due to the *Urdhvagati* of vitiated *Doshas*[10]. In *Garbhini*, the pathogenesis may be understood through *Vata Vaigunya*, *Aapannasatwa* and *Dauhruda Avamana*. The physiological demands of the growing *Garbha* may influence maternal *Rasa Dhatu* and *Agni*, which, when disturbed, may result in *Agnimandya* and *Vata Prakopa*. The growing *Garbha* may also cause *Aavarana* and alter the normal movement of *Apana Vayu*, contributing to the upward movement of vitiated *Doshas*[10,11]. *Aapannasatwa*, described by *Acharya Sushruta*

and explained by *Dalhana*, refers to the state of pregnancy and its associated physiological changes. In *Dauhruda Avamana*, unfulfilled desires of the pregnant woman are described as contributing to *Vata Vriddhi* and *Agni Dushti*[12].

The *Samprapti* may be described as *Nidana Sevana* → *Agnimandya* → *Ama Sanchaya* → *Dosha Prakopa* → *Utklishta Dosha* → *Amashaya Kshobha* → *Urdhvagati* and expulsion through the *Mukhamarga*[10,11]. The *Samprapti Ghataka* include *Dosha*-predominantly *Vata* with *Kapha-Pitta* involvement; *Dushya-Rasa Dhatu*; *Agni-Jatharagni*; *Srotas-Annavaha* and *Rasavaha Srotas*; *Udbhava Sthana* and *Adhisthana-Amashaya*. The classical features of *Chardi*, including *Hridayotklesha*, *Kapha Praseka*, *Annadwesha* and *Udgararodha*[11], were assessed in the present study using the PUQE-24 score, HELP score, and subjective and objective parameters.

The Ayurvedic understanding can be discussed alongside current evidence on nausea and vomiting of pregnancy. The onset and peak severity of symptoms commonly occur during the first trimester, coinciding temporally with rising and peak human chorionic gonadotropin (hCG) concentrations. Progesterone-related gastrointestinal motility changes have also been proposed as contributing factors. More recent evidence identifies growth differentiation factor 15 (GDF-15), produced predominantly by the placenta, as an important mediator of nausea and vomiting in pregnancy through its interaction with the GDNF family receptor alpha-like (GFRAL) receptor in the hindbrain. The predominance of first-trimester cases in the present cohort is consistent with the established clinical pattern of nausea and vomiting of pregnancy.

Rationale of the Formulations and *Rasa Panchaka* Analysis

The *Sahasrayogam* verse describes *Bilwadi Kwatha* with *Sharkara* as destroying *Chardi*[5], an explicitly *Tridoshashamaka* antiemetic, while the *Yogaratnakara* verse for *Shunthi Bilwa Kwatha* with *Yava Saktu* is addressed directly to the *Garbhini*. *Rasa Panchaka* analysis (percentages are proportions of constituent drugs with a given attribute, and a drug may have more than one *Rasa*) shows distinct profiles. **Group A** was predominantly *Madhura Rasa* (57%), with *Kashaya* (43%), *Katu* and *Tikta* (29% each); *Laghu Guna* (57%) predominated, with *Snigdha* (29%); *Virya* was predominantly *Sheeta* (57%) and *Madhura Vipaka* (57%) supported *Brimhana*. These attributes are consistent with *Deepana-Pachana*, *Brimhana*, *Pittashamana* and *Chardighna* actions and an overall *Tridoshashamaka* effect.

Group B was predominantly *Katu* and *Kashaya Rasa* (67% each), with *Madhura Rasa* (33%). *Laghu Guna* (67%) and *Ushna Virya* (67%) predominated, while *Katu Vipaka* (67%) supported *Ama-Pachana* and *Vata Anulomana*. The overall profile was predominantly *Kapha-Vata Shamaka*.

Group A is thus a *Madhura*-dominant, *Brimhana*-weighted formulation, whereas Group B is predominantly *Katu* and *Deepana* in nature. This comparison is descriptive and was not tested; it offers a framework for interpreting why emesis control was comparable while some secondary measures favoured Group A.

Possible Mode of Action

Both formulations contain *Shunthi* and *Bilwa*, which may explain the comparable control of emesis: gingerols and shogaols of *Shunthi* have reported antiemetic activity partly through serotonergic pathways, and constituents of *Bilwa* may reduce gastrointestinal irritation and spasm. Group A additionally contains *Dhanyaka*, *Bala*, *Laja* and *Mudga* with *Sharkara*; reported GABAergic and anti-inflammatory effects of *Dhanyaka* and the pyridoxine content of *Laja* could relate to nausea perception and associated symptoms. *Yava Saktu* in Group B provides complex carbohydrate and β-glucan that may support mucosal protection. Pregnancy-related hormonal changes can delay gastric emptying, and volatile constituents of *Shunthi* (e.g. zingiberene) and hordenine in *Yava Saktu* have been reported to support motility.

These are hypotheses drawn from composition. Nutritional status, ketone levels and mechanistic markers were not measured. The 6 g of *Sharkara* per dose supplies only a small energy load (about 24 kcal), so nutritional or anti-ketotic effects cannot be inferred from this study.

Interpretation of the Results

Both formulations were associated with significant within-group improvement in PUQE-24 and HELP scores ($p < 0.001$) and in most subjective parameters. Because there was no untreated or placebo group, this improvement cannot be attributed to the interventions alone: NVP often improves spontaneously (70% of participants were in the first trimester), baseline PUQE-24 sat at the upper limit of the inclusion range ($\leqslant 6$), and the open-label design may inflate subjective outcomes. PUQE-24 did not differ between groups at any time point, which is compatible with the shared presence of *Shunthi* and *Bilwa*.

Group A showed a lower HELP score at follow-up ($p = 0.044$, $r = 0.35$), with improvement in composite items such as functional disability, mental status, food intake pattern and percentage weight loss. This single, unadjusted difference may reflect the baseline imbalance and chance, and any *Brimhana* or *Balya* explanation remains speculative.

In classical terms, Group A's advantage in salivation, thirst and appetite may reflect better control of *Kapha Utklesha* through the *Deepana-Pachana* and *Rochana* attributes of its additional drugs; this is an interpretation, not a demonstrated mechanism. The clearest between-group difference was in pain above the umbilicus (post-treatment $p < 0.001$; follow-up $p = 0.008$). Smooth-muscle relaxant constituents of *Bilwa* and anti-inflammatory constituents of *Dhanyaka* have been proposed as possible contributors, but *Bilwa* is also present in Group B and the mechanism is speculative. *Mukhashosha* resolved equally in both groups.

Urine ketones, serum electrolytes and random blood sugar were normal throughout, indicating that the cohort was metabolically uncompromised at entry; metabolic state was therefore maintained rather than corrected, and anti-ketotic efficacy could not be assessed.

Statistical Considerations

Despite randomization, Group B entered with a significantly higher baseline HELP score (median 15 versus 12; $p < 0.001$; $r = 0.85$), a chance imbalance inherent to small lottery-allocated samples. This complicates comparison of absolute follow-up scores; analysis of change from baseline or ANCOVA is recommended. Group B nevertheless improved highly significantly. The two groups converged at Day 14 ($p = 0.425$) and differed at follow-up ($p = 0.044$), a finding to be regarded as exploratory.

The composite overall grading did not show a statistically significant between-group difference at either assessment (Day 14: $p = 0.065$, $r = 0.32$; Day 21: $p = 0.223$, $r = 0.18$). However, a higher proportion of subjects achieved a highly significant response in Group A (80%) than in Group B (53.33%). The absence of significance may relate to the small sample ($n = 15$ per group, against an a priori target of 120) and the low follow-up scores in both groups. Overall, improvement was comparable, with Group A showing more marked responders and a lower HELP score at follow-up. Because many between-group comparisons were made without adjustment for multiplicity, the secondary-parameter differences should be regarded as hypothesis-generating.

Safety

Safety was assessed through the occurrence of adverse drug reactions, requirement for rescue medication, gastrointestinal symptoms, withdrawals, and laboratory parameters including serum sodium, potassium, chloride and random blood sugar. No adverse drug reaction, rescue medication requirement, diarrhoea, constipation, abdominal pain or treatment withdrawal was observed in either group. Further, serum sodium, potassium, chloride and random blood sugar remained within normal limits in all 30 participants throughout the assessment period, with no clinically evident electrolyte or glycaemic disturbance. These findings indicate that both formulations were well tolerated during the study period.

Classical textual support, such as the description of *Bala* under *Prajasthapana Gana* by Acharya Charaka and the indication of *Shunthi Bilwa Kwatha* in *Garbhini*, is supportive only and does not establish safety. The present safety conclusion rests on clinical observation and laboratory parameters over 14 days in 30 women; rare adverse events cannot be excluded at this sample size, and maternal, fetal and neonatal outcomes were not followed.

Palatability was not measured on a scale. By investigator observation, Group A, with predominantly *Madhura Rasa*, was readily accepted, whereas Group B met mild initial resistance because of the thicker, granular consistency of *Saktu*; compliance was good in both groups.

Limitations and Future Scope

This study has several limitations. There was no untreated or placebo control, so natural resolution and placebo effects cannot be separated from treatment effects. The design was open-label with self-reported outcomes, and allocation by lottery may not have been concealed. Only 30 of the 120 planned participants were enrolled, so the study is underpowered, particularly for between-group comparisons. A baseline imbalance in HELP score was present, many secondary comparisons were unadjusted for multiplicity, and baseline PUQE-24 was restricted to the mild range. Follow-up after treatment was only 7 days, recruitment was single-centre, haemoglobin was categorical, the overall grading scheme is not externally validated, and nutritional status, ketones and obstetric or fetal outcomes were not assessed. Future studies should be double-blind, multicentre and adequately powered (the authors suggest at least 50 participants per group), include a placebo or standard-care comparator, use direct nutritional and obstetric outcome measures, cover the full severity spectrum including hyperemesis gravidarum, and have longer follow-up.

Conclusion

In this small, open-label, randomized study of women with mild *Garbhini Chardi*, both *Bilwadi Kwatha* with *Sharkara* and *Shunthi Bilwa Kwatha* with *Yava Saktu* were associated with significant improvement in PUQE-24 and HELP scores over 14 days, with no adverse drug reaction and complete compliance. Control of nausea and vomiting was comparable between groups. Group A showed a higher proportion of highly significant responders, a lower HELP score at follow-up and greater improvement in selected symptoms, but these secondary findings are exploratory and may be influenced by baseline imbalance and multiple testing. The findings support further evaluation of both formulations, particularly *Bilwadi*

Kwatha with *Sharkara*, in adequately powered, blinded, controlled trials that include a comparator and obstetric outcomes; they do not establish efficacy over spontaneous recovery or safety in pregnancy.

Source of Support: Nil

Conflict of Interest: Nil

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