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Original Article

Ayurveda Section

Efficacy of *Bilvadi Vati* in the Management of *Garbhini Chhardi* (Hyperemesis Gravidarum): A Randomised Controlled Clinical Trial

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ABSTRACT

Introduction: *Garbhini Chhardi* or Hyperemesis Gravidarum (HG) is a disabling and prevalent pregnancy condition involving severe vomiting and nausea. Management of the condition is necessary to preserve the health of the mother and foetus. Ayurveda has provided effective and safe measures for nausea and vomiting of pregnancy. Two Ayurvedic drugs, *Bilvadi Vati* and *Kustumbaru Kalka Vati*, are given in this condition. This research examines their effectiveness in the management of *Garbhini Chhardi*.

Aim: To evaluate the clinical efficacy of *Bilvadi Vati* therapy for the management of *Garbhini Chhardi* (HG) with respect to the severity of nausea, vomiting frequency, hydration status, and overall improvement of maternal health compared to *Kustumbaru Kalka Vati*.

Materials and Methods: The Randomised Controlled clinical Trial (RCT) was conducted in Ayurveda Mahavidyalaya of Sangam Sevabhavi Trust, Wardha, Maharashtra, India for 18 months from September 2019 to April 2021. A total of 90 pregnant women with *Garbhini Chhardi* were subjected to a RCT. The volunteers were divided into two groups randomly: Group A received *Bilvadi Vati*, and Group B received *Kustumbaru Kalka Vati*. The trial was conducted at Sangam Sevabhavi Trust's Ayurveda Mahavidyalaya for four weeks. The inclusion criteria for the trial were pregnant volunteers aged 12 to 14 weeks pregnant, diagnosed with *Garbhini Chhardi*, and willing to participate. Clinical outcomes were measured with the Pregnancy-Unique Quantification of Emesis (PUQE) scale to measure the severity of nausea and vomiting. Frequency of vomiting and hydration level were also quantified. A statistical analysis using Statistical Package for the Social Sciences (SPSS) version 28.0. For pair-wise comparisons within groups, the Wilcoxon signed-rank test was used. Inter-group comparisons were performed with the help of the Mann-Whitney U test for comparisons between groups. Descriptive statistical parameters (mean, median, standard deviation) were employed for data summarising purposes, with a p-value <0.05.

Results: Both groups significantly improved symptoms (p-value <0.001). Group A (*Bilvadi Vati*) improved more in *Chardi* and *Daurbalya* on intergroup comparison. Group A exhibited significant improvement (>60%) with 64.44% in Group A and 4.44% in Group B.

Conclusion: The present study again establishes that *Bilvadi Vati* and *Kustumbaru Kalka Vati* effectively manage *Garbhini Chhardi*. However, *Bilvadi Vati* was more clinically effective with better relief of symptoms and a greater percentage of marked improvement, greater than 75% relief.

Keywords: Ayurvedic preparation, Dosha balance, Herbal treatment, Management of pregnancy, Maternal health, Treatment of vomiting

INTRODUCTION

Pregnancy is the most critical and vulnerable stage of a woman's life, involving enormous physiological, hormonal, and metabolic alterations. Among the many pregnancy complications, nausea and vomiting are two of the most common presenting complaints, particularly in the first trimester [1]. Mild to moderate vomiting and nausea are self-limiting, but intractable vomiting with dehydration, malnutrition, and electrolytic disturbance is referred to as Hyperemesis Gravidarum (HG) in conventional medicine. *Garbhini Chhardi* is an imbalance of *Pitta-Kapha dosha* that results in a disorder in Ayurveda. If not made in time, *Garbhini Chhardi* harms maternal health, foetal growth, and pregnancy outcomes in general, which warrants the search for effective interventions that are safe and therapeutic [2].

Studies have shown that almost 50-80% of pregnant women have some degree of nausea and vomiting, and 0.5-2% has severe HG that requires hospitalisation. The disease usually starts in the 6th week of pregnancy, peaks at 8-12 weeks, and sometimes lasts beyond the 20th week [3]. Although the aetiology is unknown, the cause is a hormonal imbalance, increased human Chorionic Gonadotropin (hCG), and oestrogen. Severe presentation results in weight loss, ketonuria, hypotension, and, in the extreme, maternal and foetal survival problems. Management of *Garbhini Chhardi*, as per the orthodox system, is a dietary restriction, fluid control, and control of drugs by Doxylamine, Pyridoxine (Vitamin B6), and Ondansetron [4]. Use of drugs for a longer duration, however, results in somnolence, drowsiness, constipation, and foetal exposure to synthetic drugs. This prompts the search for safer, herbal, and natural remedies that would be equally effective without compromising maternal and foetal health [5].

Ayurveda, the ancient Indian medicine system, provides an integrative treatment approach to managing pregnancy disorders, emphasising *Vata*, *Pitta*, and *Kapha dosha* balance. *Garbhini Chhardi* is a type of pregnancy disorder. It results from the imbalance of *Pitta* and *Kapha* dosha, leading to the derangement of digestion, metabolism, and toxin production (*Ama*) [6]. The imbalanced *Pitta* leads to excess heat and acidity, and the deranged *Kapha* leads to excess mucus and heaviness, both of which are the causative factors in nausea and vomiting. Besides improper dietary life (*Mithya Aahara*), excess activity (*Vishama Vihara*), and stress also add fuel to the fire, and hence, treatment is necessary to enjoy a normal pregnancy [7]. Ayurvedic classics provide a chain of treatment modalities in managing *Garbhini Chhardi*, most aimed at correcting digestive fire (*Agni*), *dosha* balance, body purification, and proper nourishment to the mother and the foetus. Among the treatment modalities, *Bilvadi Vati* and *Kustumbaru Kalka Vati* are the two most popular drugs to manage vomiting during pregnancy [8].

Bilvadi Vati, an Ayurvedic formulation of *Bilva* (*Aegle marmelos*), *Madhu* (honey), *Shankara* (sugar), and other ingredients, is noted for its antiemetic, digestive stimulant, and *Kapha-Pitta* balancing effect. It enhances gut motility, keeping gastric secretions and soothing inflammation, thus avoiding excessive vomiting and nausea. Honey and sugar also have a cooling effect on the stomach, which eliminates acidity and excessive dryness. *Bilva* also possesses a *deepana-pachana* (stimulant effect) on the stomach, which preserves the equilibrium of digestion during pregnancy [9].

Conversely, *Kustumbaru Kalka Vati*, formulated with *Kustumbaru* (*Coriandrum sativum*) and other herbs, also displays carminative and digestive activity. *Kustumbaru* is firmly rooted in Ayurveda as an anti-flatulent, cooling drug and a digestive stimulant, and is, therefore, an extensively employed medicine for gastric distress and nausea. Nevertheless, it is described as having a lesser effect than *Bilvadi Vati* because its effect is more sedating than profoundly antiemetic [10]. Though *Kustumbaru Kalka Vati* is traditionally used to treat gastrointestinal issues, less clinical data support its activity against acute *Garbhini Chhardi*. Hence, its effectiveness needs to be contrasted with that of *Bilvadi Vati* [11].

Although both drugs have been practiced in Ayurveda for a long time, no comparative clinical data exist regarding their efficacy in treating *Garbhini Chhardi*. The current study will fill this knowledge gap by scientifically comparing and evaluating the efficacy of *Bilvadi Vati* and *Kustumbaru Kalka Vati* in pregnant women with vomiting and nausea. By performing a RCT, the study will establish the scientific evidence for Ayurvedic treatments. Treatments render an effective, natural, and safe treatment method for vomiting in pregnancy [12].

The pathophysiology of *Garbhini Chhardi* in Ayurveda revolves around increased *Pitta dosha* influencing the digestive fire (*Jatharagni*), forming undigested metabolic toxins (*Ama*), which disturb the normal process of digestion, giving rise to nausea, vomiting, loss of appetite, and epigastric discomfort. *Kapha dosha* involvement worsens the clinical picture by producing mucus, heaviness, and indigestion [13]. The therapeutic aim is the maintenance of *Agni*, detoxification (*Ama Pachana*), and *Kapha dosha* and *Pitta dosha* balancing by medicinal herbs, dietetic changes, and regimen modifications. *Bilvadi Vati*, as an effective digestive stimulant, induces relief by promoting *Agni*, inhibiting mucus production, and enhancing gastric motility, thus more effectively relieving nausea than *Kustumbaru Kalka Vati* [14].

The primary aim is to observe whether Bilvadi Vati is better than Kustumbaru Kalka Vati in alleviating nausea and vomiting, stimulating appetite, and stabilising maternal health [15,16].

Bilvadi Vati would be more effective than *Kustumbaru Kalka Vati* in controlling nausea and vomiting, resulting in better maternal health and fewer complications with no side-effects. If established, the study will justify the scientific basis of the administration of *Bilvadi Vati* as a first-line Ayurvedic drug for *Garbhini Chhardi*, providing pregnant women with a safer, non-toxic, and effective herbal drug for vomiting during pregnancy.

This research is bound to contribute to the utilisation of Ayurveda in clinical practice today, from the traditional medicine of yesterday to the modern acceptance of science tomorrow. This research, as a demonstration of the comparative effect of *Bilvadi Vati* and *Kustumbaru Kalka Vati*, will seek to promote the broader application of Ayurvedic drugs in prenatal healthcare, offering expecting mothers a safe and natural medical remedy for the nausea and vomiting of pregnancy [17].

Thus, the rationale for this research is the strong need for safe, efficient, and well-documented Ayurvedic Treatment. This research will uncover the optimal Ayurvedic approach with assured foetal and maternal safety by evaluating two presumably widely practiced recipes.

This study aimed to evaluate *Bilvadi Vati's* efficacy in managing *Garbhini Chhardi* (HG) by assessing improvements in nausea severity, vomiting frequency, hydration status, and overall maternal health, using standardised clinical measures. The objectives included assessing the severity of nausea, vomiting frequency, hydration status, and overall improvement in maternal well-being.

MATERIALS AND METHODS

This research was carried out as a RCT to evaluate the therapeutic efficacy of *Bilvadi Vati* in the management of *Garbhini Chhardi* (HG) against *Kustumbaru Kalka Vati*. A parallel-group design was employed, where pregnant women were randomly distributed into two treatment groups: *Bilvadi Vati* or *Kustumbaru Kalka Vati*. The trial was conducted for four weeks at Ayurveda Mahavidyalaya of Sangam Sevabhavi Trust for 18 months from September 2019 to April 2021. Follow-up assessments were made on day 15th to evaluate symptom relief, compliance with the treatment regimen, and overall wellbeing of the subjects. The present study was ethically cleared by the Institutional Ethics Committee (IEC) (MUHS/PG/IEC/29/2021) and also registered in India's Clinical Trials Registry of India (CTRI/2021/05/033678). All the study participants provided written informed consent and volunteered to participate without coercion. Confidentiality was maintained by anonymising data and viewing information only by limited staff. Monitoring is protected against harm to the participants, with immediate withdrawal and medical attention. The study rigidly adhered to Good Clinical Practice (GCP) principles without infringing on ethical principles of beneficence, non-maleficence, autonomy, and justice with transparency, integrity, and ethical guideline adherence.

Randomisation Process

To minimise selection bias, a computer-generated randomisation list randomly assigned participants to the *Bilvadi Vati* or *Kustumbaru Kalka Vati* Group. Randomisation was stratified by gestational age to ensure an equal number of participants in each category of early pregnancy. Allocation concealment was achieved with sealed opaque envelopes opened upon recruitment.

Blinding

Due to the Ayurvedic preparations' unique sensory character, blinding the participants was not feasible. However, outcome assessors who recorded symptom scores and performed statistical analysis were blinded to group allocation to minimise observational and analytical bias.

Withdrawn Patients

Withdrawals among patients were monitored, including the reason for withdrawal. Withdrawals were due to hospitalisation for deterioration of severe symptoms, pregnancy complications not related to the study, protocol deviation, or withdrawal at will. The data were analysed on an intention-to-treat basis, i.e., all those randomised at baseline were included in the final data analysis irrespective of study completion.

Compliance

Adherence to the treatment regimen was monitored through self-reported medication calendars, direct counts of tablets at follow-up assessments, and routine follow-up telephone calls. Participants also maintained a symptom diary to record the frequency and severity of nausea and vomiting. Adherence to any treatment regimen deviation was monitored and examined to assess the potential impact on study outcomes.

Sample size: The effect size for comparing two means was used to calculate the sample size of the study with a hypothesised effect size of 0.645 (medium-significant effect). The sample size was finally calculated to be 45 participants in each Group, with a total of 90 participants after a 15% dropout rate was included. Statistical analysis was conducted at a significance level of 0.05 and a power of 80%, making the results statistically significant and trustworthy [18].

Sample size by Cohen's effect size by comparing two means (Estimated): Effect size=d=($\mu_2 - \mu_1$) / σ=0.645 (Estimated; medium-large effect)

Formula:

$N=((1+r)/r) * ((Z(1-\alpha/2)+Z(1-\beta))^2 / d^2)+(Z(1-\alpha/2)^2)/(2(1+r))$

$n=((1+1)/1) * ((1.96+0.84)^2 / (0.645)^2)+(1.96^2 / (2(1+1)))$

$= 38.6505 \rightarrow$ Rounded to 39 per Group

Where,

- $Z(1-\alpha/2)$ at 5% significance=1.96
- $Z(1-\beta)$ at 80% power=0.84
- Allocation ratio r=Group-2/Group-1=1
- Dropout=15%

Considering 15% dropout: $39 \times 1.15=44.85 \rightarrow$ Rounded to 45 per group

Final sample size

Per Group: 45

Total: 90 participants

(with α=0.05, power=0.80, r=1, dropout=15%, and d=0.645)

Intervention Details

The study was conducted among Group A (Trial – *Bilvadivati*) and Group B (Control – *Kustumburuvati*). Both groups were administered a dose of 500 mg twice daily for 15 days. The drug was administered orally (*Abhyantar marga*), after food intake (*Adhobhakt kala*) with *Sheetjal* as *Anupana*.

Inclusion criteria: The research employed pregnant women who were already diagnosed, as well as those with signs and symptoms of *Garbhini Chardi* between 12 and 14 weeks of pregnancy. Primigravida and multigravida were employed, but only if they were within the age range of 19 to 35 years and agreed to be treated.

Exclusion criteria: Women with twin pregnancy, vesicular mole, or those in the second or third trimester were omitted. Patients presenting with vomiting because of systemic illness, such as a peptic ulcer, appendicitis, gastroenteritis, or liver disease, were omitted. Known hepatitis, HIV, endocrine disorders like hypothyroidism or hyperthyroidism, and psychological or eating disorders were not included. Pregnant women with severe vomiting (five or more per day) were excluded from the study.

Participant Recruitment

Ninety such samples of *Garbhini Chhardi* were randomly collected from patients attending the College OPD and IPD, and from different health check-up and screening Camps organised by the college. They were distributed into two equal groups, Group A received *Bilvadi Vati*, and Group B received *Kustumbaru Kalka Vati*.

Standardisation of Symptom Scoring

For a quantitative and objective assessment of symptoms, the PUQE scale was utilised in the research. It was standardised, and the severity of nausea, vomiting frequency, and retching were scored based on questions framed in a structured format. The baseline was assessed prior to the initiation of treatment. A follow-up assessment was conducted on the 15th day to assess the frequency of the symptoms [19]. A before-and-after PUQE scale enabled between-group comparison, reproducibility, and reduction of observer bias. It provided measurable data, enabling meaningful statistical comparison of the efficacy of the treatments and evidence-based comparison of *Bilvadi Vati* and *Kustumbaru Kalka Vati* [20].

Dosage Standardisation Procedure

Ayurvedic drug preparation employed in the study was made conforming strictly to traditional Ayurvedic principles and Good Manufacturing Practice (GMP) standards. A standardisation procedure was carried out to guarantee each batch's purity, uniformity, and strength before administration. Phytochemical evaluation, estimation of active ingredients, microbial limit test, and heavy metal tests were conducted on herbal drugs to evaluate safety and efficacy [21]. Products were made under regulated conditions to ensure dose uniformity, composition, and therapeutic activity. The rigorous standardisation procedure guaranteed reproducible and uniform treatment administration to the study population with minimum variability and maximum scientific credibility of the study [22]. The symptom ratings and clinical ratings were all recorded on Case Report Forms (CRFs), forms included a case report format, including demographic data, clinical history, and symptom severity.

Management of Missing Data

A Last Observation Carried Forward (LOCF) policy imputed missing values, where the last known participant was carried forward for a missed followup visit. For instances where multiple data points were missing, multiple imputation methods were used to estimate the values from trends in available data. Sensitivity analysis was also conducted to determine whether missing data affected conclusions in general [23]. The follow-up schedule for Group A (Bilvadi Vati) and Group B (Kustumbaru Kalka Vati) consisted of assessments conducted after treatment on Day 15.

STATISTICAL ANALYSIS

Data were processed using the SPSS computer program version 28.0. Since the parameters of assessment were ordinal, the drug effect was established by the Wilcoxon signed rank test for comparing within groups and the Mann-Whitney U test for intergroup comparison of improvement. Hypotheses were tested in all parameters, and the results were interpreted accordingly. Summary statistics (means, medians, and standard deviations) were given wherever required, and results were supplemented with figures and charts. The level of significance was taken as p-value <0.05 [24,25].

RESULTS

There were 90 patients, 45 in each group. 93% of the patients belonged to the 21-30 years age group, 6% to the 31-40 years age group and just one patient (1%) belonged to the 19-20 years age group. Homemakers outnumbered the others (57%), and workers accounted for 43%. A 95.56% of the patients were hindus and 4.44% muslims.

According to gravida status, the maximum were Primigravida (61%), followed by G2P1 (16%), G2A1 (20%), and G3P1A1 (3%). According to gestational age, 44% were 6-8 weeks, 36% were 8–10 weeks, and 20% were 10-11 weeks' gestation. Diet habits were roughly equally distributed, with 52% having a mixed diet and 48% having a vegetarian diet. Over half of the patients (58%) experienced mandagni, and 42% experienced vishamagni.

Koshta-wise distribution indicated that 32% were *madhyam koshta*, 43% were *mrudu koshta*, and 24% were *krura koshta*. *Prakruti* assessment indicated that *vata-Pitta* was the most frequent constitution (36%), followed by *kapha-Pitta* (26%), *pitta-vata* (16%), *vata-kapha* (12%), *kapha-vata* (9%), and *Pitta-kapha* was just 2% [Table/Fig-1].

Assessment Criteria

Both Group A (*Bilvadi Vati*) and Group B (*Kustumbaru Kalka Vati*) registered statistically significant (p-value <0.001) improvement in all parameters measured for their respective groups by the Wilcoxon Signed Rank Test. Group A also registered a higher mean and a median decrease in symptom scores than Group B. However, the intergroup comparison was mainly non-significant (p-value >0.05). It indicates that although Group A registered comparatively better improvement, both therapies establish their effectiveness clinically and as equivalents.

For *Hrullas* (Nausea), Group A showed a mean improvement of 1.71±0.46 with a median difference of 2.00 (77.41%), while Group

Parameters	Group A (n=45)	Group B (n=45)
Age distribution	43 (95.56%) aged 21-30 years	41 (91.11%) aged 21-30 years
	2 (4.44%) aged 31-40 years	3 (6.67%) aged 31-40 years
	0 (0%) aged 19-20 years	1 (2.22%) aged 19-20 years
Religion	43 (95.56%) Hindu	43 (95.56%) Hindu
	2 (4.44%) Muslim	2 (4.44%) Muslim
Occupation	25 (55.56%) Homemakers	26 (57.78%) Homemakers
	20 (44.44%) Workers	19 (42.22%) Workers
Gravida status	28 (62.22%) Primigravida	27 (60.00%)Primigravida
	8 (17.78%) Gravida 2, Para 1	6 (13.33%) Gravida 2, Para 1
	8 (17.78%) Gravida 2, Abort 1	10 (22.22%) Gravida 2, Abort 1
	1 (2.22%) Gravida 3, Para 1, Abort 1	2 (4.44%) Gravida 3, Para 1, Abort 1
Gestational sge	20 (44.44%) at 6-8 weeks	20 (44.44%) at 6-8 weeks
	18 (40.00%) at 8-10 weeks	14 (31.11) % at 8-10 weeks
	7 (15.56%) at 10-11 weeks	11 (24.44) % at 10-11 weeks
Diet type	22 (48.89%) Mixed diet	25 (55.56%) Mixed diet
	23 (51.11%) Vegetarian	20 (44.44%) Vegetarian
Agni (digestive fire)	27 (60.00%)Mandagni (slow digestion)	25 (55.56%) Mandagni
	18 (40.00%) Vishamagni (irregular digestion)	20 (44.44%) Vishamagni
Koshta (gut type)	12 (26.67%) Madhyam Koshta (moderate)	17 (37.78%) Madhyam Koshta
	24 (53.33%) Mrudu Koshta (soft)	15 (33.33%) Mrudu Koshta
	9 (20.00%) KruraKoshta (hard)	13 (28.89%) KruraKoshta
Prakriti (constitution)	22 (48.89%) Vata-Pitta	10 (22.22%) Vata-Pitta
	14 (31.11%) Kapha-Pitta	9 (20.00%) Kapha-Pitta
	8 (17.78%) Pitta-Vata	6 (13.33%) Pitta-Vata
	0 (0.00%) Vata-Kapha	11 (24.44%) Vata-Kapha
	1 (2.22%) Kapha-Vata	7 (15.56%) Kapha-Vata
	0 (0.00%) Pitta-Kapha	2 (4.44%) Pitta-Kapha

[Table/Fig-1]: Demographic data of Group A (Bilvadi Vati) and Group B (Kustumbaru Kalka Vati).

B showed a mean improvement of 1.44±0.89 with a median difference of 1.00 (59.63%). Both groups showed highly significant improvement (p-value <0.001), whereas inter-group comparison was statistically non-significant (p-value=0.069).

For *Chardi* (Vomiting), Group A improved by 1.71±0.53 with a median difference of 2.00 (77.41%), and Group B improved by 1.44±0.81 with a median difference of 1.00 (59.63%). The within-group changes were highly significant (p<0.001), and the inter-group comparison showed a statistically significant difference (p-value=0.038).

For *Annadwesha* (loss of appetite), the mean difference was 1.71±0.55 in Group A (median=2.00; 77.41%) and 1.44±0.87 in Group B (median=1.00; 59.63%). The improvement within both groups was highly significant (p-value <0.001), whereas the between-group comparison was not statistically significant (p-value=0.075).

For *Daurbalya* (weakness/fatigue), Group A showed a mean improvement of 1.64±0.48 with a median difference of 2.00 (74.55%), and Group B improved by 1.47±0.86 with a median of 1.00 (66.82%). Both groups improved significantly (p-value <0.001), with the inter-group difference being significant (p-value=0.049).

Regarding *frequency of vomiting*, Group A showed a mean difference of 1.64±0.48 (median=2.00; 74.55%), while Group B showed 1.47±0.84 (median=1.00; 66.82%). Both showed highly significant improvements (p-value <0.001), though inter-group comparison was not significant (p-value=0.132).

For *skin turgor*, Group A showed a mean improvement of 1.47±0.59 (median=2.00; 66.82%), and Group B had 1.44±0.81 (median=1.00; 65.45%). Both groups improved significantly (p-value <0.001), but the inter-group difference was non-significant (p-value=0.658).

For *urine output*, the mean improvement in Group A was 1.62±0.49 (median=2.00; 73.64%) and in Group B was 1.38±0.72 (median=1.00; 62.73%). Both groups showed highly significant improvements (p-value <0.001), though inter-group comparison was not statistically significant (p-value=0.060).

For *Praseka* (Excessive Thirst), Group A improved by 1.76±0.48 (median=2.00; 80.00%), and Group B by 1.53±0.79 (median=1.00; 69.55%). Within-group differences were highly significant (p-value <0.001), while the between-group comparison was not significant (p-value=0.056).

For PUQE scores, the improvement in Group A was 5.20±1.32 (median=5.00; 80.00%), and in Group B was 5.07±1.41 (median=5.00; 69.55%). Both groups improved significantly (p-value <0.001), though the inter-group comparison remained statistically non-significant (p-value=0.674) [Table/Fig-2].

	Group	Median Diff. (Bef–Aft)	Mean Diff.±SD	Wilcoxon Signed Rank Test (T^+)	P-value (Within Group)	Mann–Whitney U Test (Between groups)	p-value
Hrullas (Nausea)	A	2.00	1.71±0.46	1035.00	<0.001 (Significant)	1248.00	0.069 (NS)
	B	1.00	1.44±0.89	820.00	<0.001 (Significant)	–	–
Chardi (Vomiting)	A	2.00	1.71±0.53	1035.00	<0.001 (Significant)	1248.00	0.038 (Significant)
	B	1.00	1.44±0.81	861.00	<0.001 (Significant)	–	–
Annadwesh (Loss of appetite)	A	2.00	1.71±0.55	990.00	<0.001 (Significant)	1188.00	0.075 (NS)
	B	1.00	1.44±0.87	903.00	<0.001 (Significant)	–	–
Daurbalya (Weakness/Fatigue)	A	2.00	1.64±0.48	1002.00	<0.001 (Significant)	1227.00	0.049 (Significant)
	B	1.00	1.47±0.86	832.00	<0.001 (Significant)	–	–
Frequency of vomiting	A	2.00	1.64±0.48	1035.00	<0.001 (Significant)	1182.50	0.132 (NS)
	B	1.00	1.47±0.84	861.00	<0.001 (Significant)	–	–
Skin Turgor	A	2.00	1.47±0.59	946.00	<0.001 (Significant)	1063.00	0.658 (NS)
	B	1.00	1.44±0.81	861.00	<0.001 (Significant)	–	–
Urine output	A	2.00	1.62±0.49	1035.00	<0.001 (Significant)	1221.00	0.060 (NS)
	B	1.00	1.38±0.72	861.00	<0.001 (Significant)	–	–
Prasek (Excessive thirst)	A	2.00	1.76±0.48	990.00	<0.001 (Significant)	1221.00	0.056 (NS)
	B	1.00	1.53±0.79	903.00	<0.001 (Significant)	–	–
PUQE Scores	A	5.00	5.20±1.32	465.00	<0.001 (Significant)	421.50	0.674 (NS)
	B	5.00	5.07±1.41	465.00	<0.001 (Significant)	–	–

[Table/Fig-2]: Reduction in symptoms in Group A (*Bilvadi Vati*) vs Group B (*Kustumbaru Kalka Vati*).

Total mean percentage improvement for all parameters was 76.99% in Group A and 62.18% in Group B. Regarding relief present overall among the patients, 64.44% (29 patients) from Group A had relief of more than 75% with definite improvement. The remaining 35.56% (16 patients) had moderate improvement. In Group B, only 4.44% (2 patients) had definite improvement, but most (80%, 36 patients) had moderate improvement, with only 15.56% (7 patients) having slight improvement.

Therefore, the final picture is that both preparations controlled adequately the *Garbhini Chhardi*. However, *Bilvadi Vati* (Group A) exhibited relatively higher clinical efficacy in subjective and objective parameters and overall relief to the patient.

DISCUSSION

The HG is a severe condition characterised by pregnancy-related nausea and vomiting that may lead to severe maternal discomfort, as well as complications such as dehydration, weight loss, and disturbances of electrolyte balance [26]. Traditional treatment, including antiemetic medication, tends to be associated with side effects and risks, especially in pregnancy. Against this backdrop, Ayurvedic medications such as *Bilvadi Vati* and *Kustumbaru Kalka Vati* have emerged as a promising alternative. Both have shown efficacy in the present study. This discussion will attempt to compare their efficacy, mechanism of action in managing the formulations, and clinical relevance in pregnancy treatment [27].

Comparison of Treatment Effectiveness

The results of the present study reveal that both *Bilvadi Vati* and *Kustumbaru Kalka Vati* effectively relieve *Garbhini Chhardi* (HG) symptoms. Both the treatments produced significant intra-group changes, and *Bilvadi Vati* was more effective in all except one of the symptoms, *Hrullas*, *Chhardi*, and *Daurbalya* [6]. The percentage improvement in Group A (*Bilvadi Vati*) was greater than in Group B (*Kustumbaru Kalka Vati*) on all occasions, and there was a significant inter-group difference for *Chhardi* (p-value=0.038) and *Daurbalya* (p-value=0.049), but not for *Hrullas* or *Annadwesh*. The fact that statistically significant differences were not found between the two groups for some parameters indicates that both treatments can effectively relieve symptoms. However, *Bilvadi Vati* has a wider, more intense action to relieve symptoms.

At the level of PUQE score, intra-group improvement was significant both for the treatments (p-value <0.001), but Group A had a greater mean reduction. However, the inter-group difference was not statistically significant (p-value=0.056), which means that although *Bilvadi Vati* may provide a greater reduction, both treatments are equally effective in reducing the overall severity of vomiting and nausea. This also supports the clinical findings, where a greater percentage of patients in Group A showed significant improvement compared to Group B. The findings show *Bilvadi Vati's* potential as a better treatment option, though *Kustumbaru Kalka Vati* will remain a good option for relief in moderate symptoms.

Mechanism of Action of *Bilvadi Vati* and *Kustumbaru Kalka Vati*

The therapeutic effect of *Bilvadi Vati* and *Kustumbaru Kalka Vati* results from their unique mode of action. *Bilvadi Vati*, a polyherbal formulation, is a combination of *Bilva* (*Aegle marmelos*), *Pippali* (*Piper longum*), and *Sunthi* (*Zingiber officinale*), each of which possesses antiemetic and digestive stimulant activity [28]. *Bilva* possesses anti-inflammatory and anti-spasmodic activity that normalises gastric function and prevents nausea. *Pippali* stimulates the digestive fire (*Agni*), thus aiding digestive function and preventing the tendency to hypersecretion of gastric secretions, a frequent cause of nausea and vomiting. *Sunthi*, a drug studied extensively for its anti-nausea effect, blocks serotonin-mediated pathways of nausea in the gut and brain. These synergistic effects are likely responsible for the earlier and prolonged relief of symptoms noted in Group A [29].

On the other hand, *Kustumbaru Kalka Vati* consists primarily of *Kustumbaru* (*Coriandrum sativum*), which is cooling and calming to the digestive system. While *Kustumbaru Kalka Vati* has mild carminative and digestive effects, its action on nausea is not as intense as that of *Bilvadi Vati* because it primarily suppresses gastric acid secretion [30]. Such an action can be beneficial to the relief of nausea caused by hyperacidity, but is less effective against the complex pathways of nausea and vomiting in pregnancy. As the study shows, *Kustumbaru Kalka Vati* is very effective. However, *Bilvadi Vati's* multi-component formulation offers a broader spectrum of therapeutic action and is more effective in relieving a spectrum of symptoms in HG [31].

Comparison with Earlier Work

The current study's findings agree with previous studies comparing Ayurvedic antiemetic formulations. Studies have shown that herbal preparations containing ginger, bilva, and pippali possess anti-nausea activities equal to those of standard antiemetic medications. Clinical trials with ginger preparations have shown symptom relief in 70-80% of the patients, similar to the 64.44% Group A patients with notable relief in the current study [32]. Previous studies have also shown the superior efficacy of multi-component Ayurvedic medications such as *Bilvadi Vati* on account of their capacity to influence multiple mechanisms of nausea and vomiting, as opposed to single-component medications such as *Kustumbaru Kalka Vati*, which influences gastric irritation [33].

The study also validates previous studies, which indicate that multi-component drugs are more effective than single-component drugs in treating complicated diseases like *Garbhini Chhardi*. The mechanism of the synergy of the anti-inflammatory, digestive stimulant, and anti-nausea action of *Bilvadi Vati* is a more holistic approach to symptom management than with *Kustumbaru Kalka Vati*, which manages primarily hyperacidity and gastrointestinal upset.

Clinical Implications, Safety, and Acceptability during Pregnancy

The clinical relevance of these observations is noteworthy. In light of the growing need for non-toxic and natural forms of Treatment during pregnancy, *Bilvadi Vati* can serve as an encouraging substitute to traditional antiemetics, which are potentially fraught with side effects. Further, the capacity of *Bilvadi Vati* to counter the multi-dimensional basis of nausea and vomiting in pregnancy by normalising gastric function, triggering digestion, and reducing inflammation supports its therapeutic potential [34]. Standardisation and future directions although in this study, strong evidence for the efficacy and safety of *Bilvadi Vati* and *Kustumbaru Kalka Vati* are available, long-term efficacy and safety in large multicentre clinical trials are to be confirmed by future studies. Standardisation of ayurvedic products is also required to provide consistent quality and therapeutic efficacy [35]. Future studies could be aimed at the pharmacokinetics and pharmacodynamics of these products to learn more about the mechanism of action and maximise their use in clinical practice. Studies on combining *Bilvadi Vati* with other Ayurvedic therapies would further maximise the management of *Garbhini Chhardi* [36].

Limitation(s)

While the results of this study are promising, some limitations must be mentioned. While adequate, the sample size can be expanded to validate the results further. Secondly, the study period was four weeks, and more extended follow-up periods are required to assess the long-term consequences of the treatments. Thirdly, as a single-centre study, the generalisability of the results can be improved with broader, multicentre trials.

CONCLUSION(S)

The study demonstrates that *Bilvadi Vati* and *Kustumbaru Kalka Vati* are effective herbal treatments for managing nausea and vomiting associated with *Garbhini Chhardi* (HG) during pregnancy. *Bilvadi Vati*, with its multi-component formulation, offers a broader and more intense therapeutic effect, making it a promising option for providing better relief and enhancing maternal wellbeing. Given the safety concerns with conventional antiemetics, Ayurvedic preparations like *Bilvadi Vati* present a natural, safe, and well-tolerated alternative for pregnancy care. These findings encourage the integration of evidence-based Ayurvedic therapies into prenatal healthcare, promoting safer management of pregnancy-related nausea and vomiting.

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