



Research Article

A COMPARATIVE CLINICAL STUDY OF *BILVA MAJJA CHURNA* AND *KUSTUMBARI KALKA* IN *GARBHINI CHARDI* W.S.R. TO EMESIS GRAVIDARUM

Indresh Bhasker^{1*}, Sandhya Rav², B. Pushpalatha³, K. Bharathi⁴

¹P.G. Scholar, ²Ph.D Scholar, ³Associate Professor, ⁴Professor & HOD, P.G. Department of Prasutitantra and Striroga, National Institute of Ayurveda Madhav Vilas Palace, Jorawar Singh Gate, Amer Road, Jaipur.

³Ph.D Scholar, Tilak Ayurveda Mahavidyalaya, Pune, India.

KEYWORDS: *Garbhini chardi*, Emesis gravidarum, *Bilva majja churna*, *Lajambu*, *Kustumbari kalka*, *Tandulodaka*, *Sharkara*.

ABSTRACT

Pregnancy is a dynamic state, during this period a lot of physiological and hormonal changes take place. These hormonal changes produce different kind of major to minor abnormalities in the pregnant women. Minor disorders are nausea, vomiting, constipation, gastric irritation, hemorrhoids, low back pain etc. *Garbhini chardi* (nausea and vomiting in pregnancy) is foremost common ailment encountered in clinical practice. If this nausea and vomiting are present in excess then it is called as emesis gravidarum. If not tackled effectively before or in time it may affect woman's quality of life.

The present study is taken up to evaluate clinically the effect of *Bilva majja churna* with *Lajambu* (Group-A), and *Kustumbari kalka* with *Tandulodaka* mixed with *Sharkara* (Group-B) and to compare the effect of both groups (15 in each group) of diagnosed patients of *Garbhini chardi*.

Study revealed statistically extremely significant improvement was observed in both groups but on comparing the symptomatic improvement of both groups, it was found that average percentage of relief was higher in Group-A i.e. 71.66%, followed by Group-B i.e., 60.39%. It shows that *Bilva majja churna* with *Lajambu* is comparatively better to cure *Garbhini chardi* than *Kustumbari kalka* with *Tandulodaka* mixed with *Sharkara*.

*Address for correspondence Dr. Indresh Bhasker

P.G. Scholar, PG. Department of Prasutitantra and Striroga, National Institute of Ayurveda Madhav Vilas Palace, Jorawar Singh Gate, Amer Road, Jaipur, India.

Email: indreshnia@gmail.com

Mobile no. 9461046230

INTRODUCTION

The woman is considered as one of the most essential factor of the continuity of human race and pregnancy is the biggest gift conferred on females by the nature, same as stated by sage Charaka as 'Women is the origin of the progeny'.^[1] Pregnancy is a time of physical and hormonal changes and emotional and psychological preparation for motherhood. During this nine months long journey, pregnant women may suffer from minor to major ailments which are specific to pregnant state. *Hrillasa* and *Chardi* are the commonest minor ailments experienced during the first trimester of the pregnancy.

All most all compendiums and therapeutic lexicons of Ayurveda dealt in detail about *Chardi* as independent disease as well as a symptom of

different diseases. *Garbhini chardi* is described as a sub-division of a type of *Chardi*. It is also mentioned under the clinical features of *Vyaktagarbha*.

Sushruta while describing the causes along with intake of different food materials etc., *Apannasatva* or *Garbhini* is also mentioned. He has classified *Chardi* into five types and under fifth type that is *Agantuja Chardi* the *Dauhridaja* is also enumerated as a cause.^[2] Dalhana explained that *Dauhridaja* means that is caused by *Vimanana* (insulting of desires) of *Dauhrida* (dual hearted i.e. pregnant woman) or it may be caused by *Garbha* (presence of fetus).^[3]

Harita has described eight *Garbha Upadravas* which afflict the pregnant women, and *Hrillasa*, *Chardi* are included among them.^[4]

Kashyapa have not used the word *Dauhridajanya* or *Garbhajanya chardi* under *Antaravatnichiktisa* but he explained management of *Doshaja chardi* in pregnant woman. It appears that he mentioned about the associated type of vomiting. The commentator of *Madhukosha* on *Madhavanidana* described *Utpidana of Garbha* as a causative factor for vomiting during pregnancy. Sharangadhara has mentioned seven types of *Chardi* and included *Garbhadhan* as seventh one. [5]

Emesis gravidarum (nausea and vomiting) are the common complaints during the first half of pregnancy. They are of varying severity usually commenced between the first and second missed menstrual period and continue until 14 to 16 weeks. Although nausea and vomiting tend to be worse in the morning-thus erroneously termed morning sickness, they frequently continue throughout the day. Lacroix and co-workers (2000) have found that nausea and vomiting were reported by three fourth of pregnant women and lasted an average of 35 days. Half of them had relief by 14 weeks, and 90% by 22weeks. In 80 percent of women, nausea was lasted all through the day. [6]

Hyperemesis gravidarum is defined variably and is sufficiently severe to produce weight loss, dehydration, ketosis, alkalosis from loss of hydrochloric acid and hypokalemia. [7] Hyperemesis gravidarum if prolonged or left untreated may leads to severe damage to maternal as well as fetus, sometimes it may even cause abortion. [8]

Rationality for selection of trial drugs

In Ayurvedic texts many effective formulations are described for the management of *Garbhini chardi*, with the drugs having soft, sweet, cold, pleasing and gentle properties. [9] Keeping this in view an attempt has been made to control *Garbhini chardi* on the principles of Ayurvedic formulation through *Bilva majja churna* and *Kustumbari kalka*. [10] This formulation is safe, palatable, and good in taste, potent, cost effective and having *Hridya, Rochana, Deepana, Pachana* and *Samgrahi* property, thereby improving the health and well-being of both mother and baby ultimately.

Material and Methods

Present study is carried out on pregnant women diagnosed with *Garbhini chardi vis-à-vis* Emesis gravidarum to evaluate the clinical efficacy of Ayurvedic drugs under two groups. All the subjects were recruited into the trial from OPD/IPD of P.G. Department of *Prasutitantra* and *Striroga*, National Institute of Ayurveda, Jaipur, strictly as per the criteria of inclusion.

Inclusion Criteria

1. Pregnant women diagnosed as *Garbhini chardi* in first-trimester of pregnancy.

Exclusion Criteria

1. Subjects in whom *Chardi* is seen in second and third trimester of Pregnancy.
2. Subjects with Hyperemesis gravidarum.
3. Subjects with twin pregnancy.
4. Subjects with vesicular mole.
5. Vomiting caused due to other systemic disorders like peptic ulcer, appendicitis etc.
6. Subjects suffering from severe infections.
7. Subjects suffering from chronic systemic diseases.

Withdrawal criteria

1. During the course of trial any serious condition develops.
2. Subjects herself wants to withdraw from the clinical trial.
3. Irregular follow up.

Investigations

1. Urine pregnancy test
2. Blood tests -CBC, ESR, RBS, LFT, RFT, HBsAg, HIV, VDRL, T3, T4, TSH
3. Urine test- Routine & Microscopic
4. USG
5. S. β - hCG (if possible)
6. Other investigations according to the need.

DESIGN OF STUDY

1. Study type: Interventional
2. Study design: Randomized trial
3. Intervention model: Two group assignment
4. Allocation: Randomized
Randomization method: Randomization is done through randomization table generated by Graph pad quickcalcs randomize 2 software.
5. Masking: Open label
6. Purpose: Treatment
7. Duration:
 - Trial-14 Days
 - Follow up-
During treatment-3rd, 7th and 14th day.
After treatment- One week after completion of trial.
8. End point: Efficacy
9. Sample size: 15 patients in each group.
10. Ethical Clearance – Present trial is started after obtaining Ethical Clearance

Institutional Ethics Committee Clearance No.- IEC/ACA/2016/39

Administration of drugs: Clinically diagnosed and randomly into two groups. In each group trial has registered subjects of *Garbhini chardi* divided completed on 15 subjects.

Group	No. of patients	Drug
A	15	<i>Bilvaphala majja churna</i> , 3gm/QID with <i>Lajambu</i> (200 ml)
B	15	<i>Kustumbari kalka</i> , 3gm/QID with <i>Tandulodaka</i> (200 ml) mixed with <i>Sharkara</i> 5 gm

Assessment Criteria

Assessment criteria for Chief complains

Pregnancy- unique quantification index (PUQE) score

In the last 24 hours, for how long have you felt nauseated or sick to your stomach? Duration.....	More than 6 hours	(5)
	4-6 hours	(4)
	2-3 hours	(3)
	1 hour or less	(2)
	Not at all	(1)
In the last 24 hours have you vomited or thrown up? Duration.....	7 or more	(5)
	5-6 times	(4)
	3-4 times	(3)
	1-2 times	(2)
	I did not throw up	(1)
In the last 24 hours how many times have you had retching or dry heaves without bringing anything up? Duration.....	7 or more	(5)
	5-6 times	(4)
	3-4 times	(3)
	1-2 times	(2)
	No time	(1)

Calculation:- If Total score is sum of replies to each of the three questions (PUQE-24 score) ≤ 6 = Mild; 7-12= Moderate; 13-15= Severe.

Assessment criteria for Associated complains

Complain	Scale	Criteria of Scaling
Anorexia	0	Take food with interest
	1	Mild (able to eat food without interest)
	2	Moderate (take food forcefully)
	3	Severe (cannot take food at all)
Constipation	0	Nil (no constipation)
	1	Mild (once in a day with hard stool)
	2	Moderate (once in 2-3 day with difficulty in defecation)
	3	Severe (once in >3 day or after taking purgative)
Fatigue	0	Nil (no Fatigue)
	1	Mild (in morning)
	2	Moderate (some time)
	3	Severe (whole day)

OBSERVATIONS

Table 1: Age wise distribution of patients (n=30)

AGE (years)	No. of Patients		TOTAL	%
	Group A	Group B		
18-21	03	03	06	20.00
22-25	07	05	12	40.00
26-29	02	02	04	13.33
30-33	03	05	08	26.67
Total	15	15	30	100%

Above table shows that the maximum incidence of *Garbhini chardi* i.e.12 (40.00%) patients was found in age group ranging from 22-25 years followed by 8 (26.67%) patients were from age group 30-33 years. 6 (20.00%) patients were from age group ranging from 18-21 years and 4 (13.33%) patients were from 26-29 years.

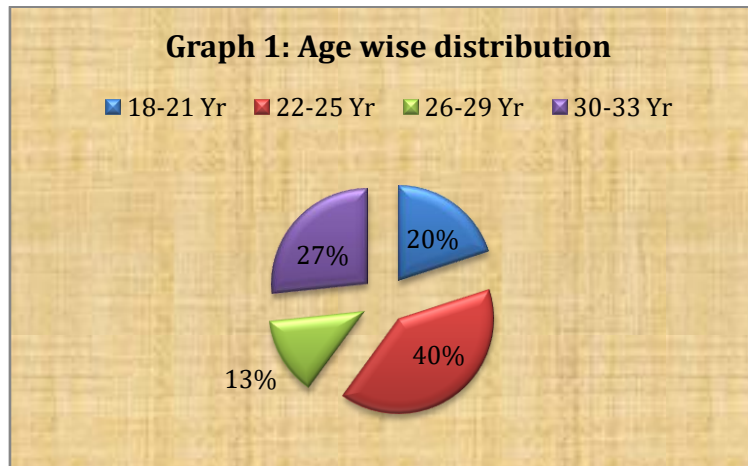


Table 2: Occupation wise distribution of patients (n=30)

Occupation	No. of Patients		Total	%
	Group A	Group B		
Housewife	14	15	29	96.67%
Service class	00	00	00	0.00%
Labour class	01	00	01	3.33%
Total	15	15	30	100%

On considering the nature of occupation, it was found that 29 (96.67%) patients were housewife and 01 (3.33%) patients belong to labour class group.

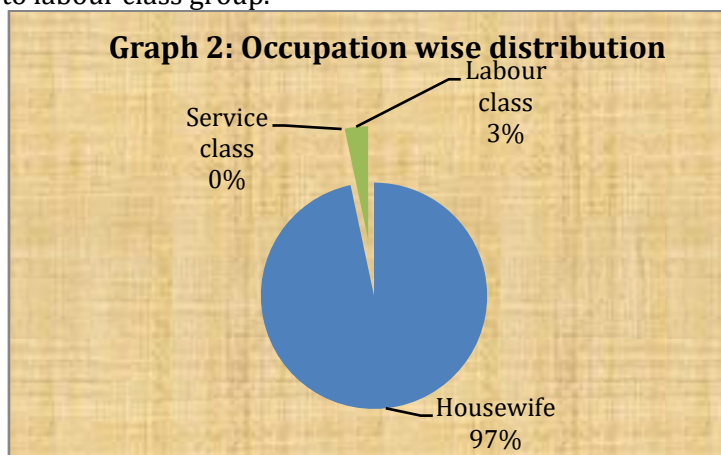


Table 3: Habitat wise distribution of patients (n=30)

Habitat	No. of Patients		Total	%
	Group A	Group B		
Urban	12	11	23	76.67%
Rural	03	04	07	23.33%
Total	15	15	30	100%

On considering habitat wise distribution of patients, study reveals that maximum patients i.e. 23 (76.67%) patients were belonging from urban habitat, while 07 (23.33%) patients were belonging from rural area.

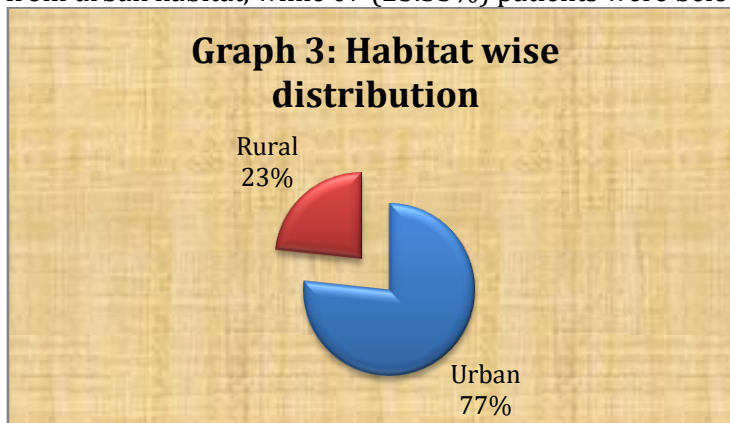


Table 4: Socioeconomic status wise distribution of patients (n=30)

Socioeconomic status	No. of Patients		Total	%
	Group A	Group B		
Lower	1	5	6	20.00%
Upper Lower	3	1	4	13.33%
Middle	10	8	18	60.00%
Upper Middle	1	1	2	6.67%
Upper	0	0	0	00.00%
Total	15	15	30	100%

This study revealed that the maximum number of patients i.e. 18 (60%) patients were belonging from middleclass, whereas 6 (20.00%) patients belonging from Lower class and 4 (13.33%) patients were belonging from Upper lower class.

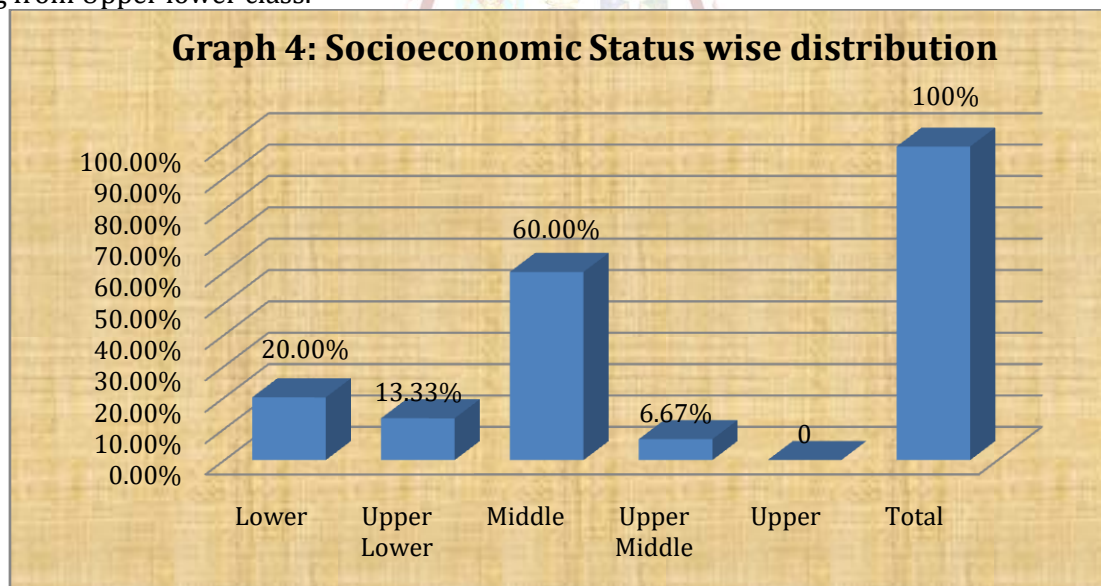


Table 5: Obstetrical history wise distribution of patients (n=30)

Obstetrical history		No. of Patients		Total	%
		Group A	Group B		
Gravida	Primi gravida	07	05	12	40.00%
	Gravida 2	03	04	07	23.33%
	Gravida 3	03	01	04	13.33%
	Gravida 4	01	05	06	20.00%
	Gravida >4	01	00	01	3.33%
	Total		15	15	30

In this study, maximum 12 (40%) patients belong to Primigravida followed by gravida two 7 (23.33%) patients. In gravida four group, 6 (20%) patients while in gravida three group 4 (13.33%) patients were present and only 1 (3.33%) belongs to more than 4 Garvida.

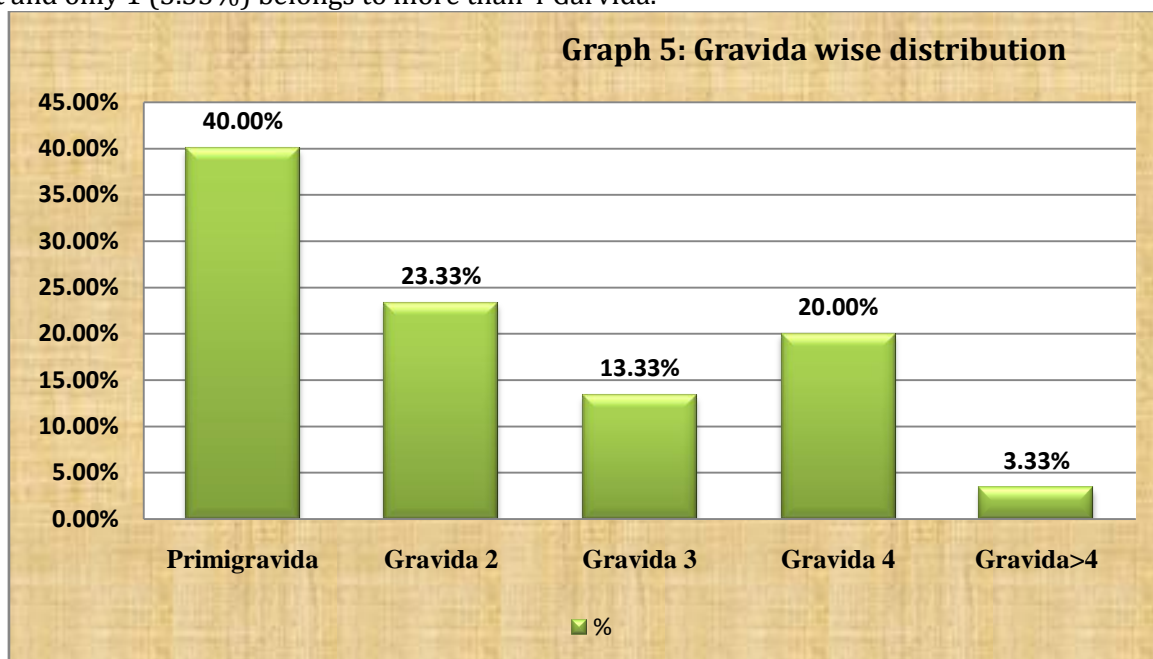
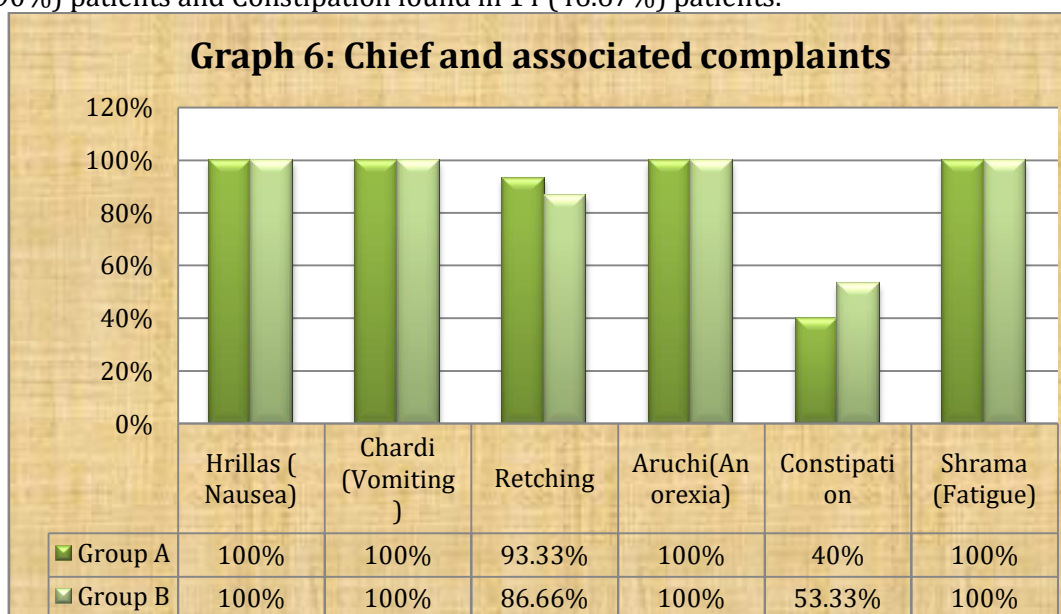


Table 6: Chief and Associated Complaints wise distribution of patients (n=30)

Chief Complaints & Associated Complaints	No. of Patients				Total	%
	Group A		Group B			
	No.	%	No.	%		
Nausea (<i>Hrillas</i>)	15	100	15	100	30	100%
Vomiting (<i>Chardi</i>)	15	100	15	100	30	100%
Retching	14	93.33	13	86.67	27	90.00%
Anorexia (<i>Aruchi</i>)	15	100	15	100	30	100%
Constipation (<i>Vibandha</i>)	06	40	08	53.33	14	46.67%
Fatigue (<i>Shrama</i>)	15	100	15	100	30	100%

It reveals from above table that among chief complaint & Associated Complaints of patients Nausea, Vomiting, Anorexia and Fatigue were found in all patients i.e. 30 (100%) patients followed by Retching were found in 27 (90%) patients and Constipation found in 14 (46.67%) patients.



Results**Clinical Improvement****Table 1: Relief of Subjective Parameters in Group-A (n= 15)**

S. No.	Symptoms	Mean		Mean Dif.	% of Change	SD	SE	P	Results
		BT	AT						
1.	Nausea	3.6	1.133	2.467	68.52%	0.915	0.236	<0.0001	E.S.
2.	Vomiting	2.86	1.133	1.733	60.46%	.9612	0.248	0.0001	E.S.
3.	Retching	3.73	1.33	2.4	64.28%	0.986	0.254	0.0001	E.S.
4.	Anorexia	1.87	0.40	1.47	78.57%	0.743	0.192	0.0001	E.S.
5.	Constipation	0.87	0.27	0.60	69.23%	0.632	0.163	0.0078	V.S.
6.	Fatigue	2.4	0.27	2.13	88.89%	0.743	0.192	<0.0001	E.S.

E.S. = Extremely significant (By- Wilcoxon matched-pairs signed-ranks test)

V.S. = Very significant

Table 2: Relief of Subjective Parameters in Group-B (n=15)

S No	Symptoms	Mean		Mean Dif.	% of Change	SD	SE	P	Results
		BT	AT						
1.	Nausea	3.60	1.133	2.267	62.96%	1.10	0.284	<0.0001	E.S.
2.	Vomiting	2.93	1.33	1.60	54.54%	0.507	0.130	<0.0001	E.S.
3.	Retching	2.80	1.40	1.40	50.00%	0.910	0.235	0.0002	E.S.
4.	Anorexia	1.67	0.40	1.27	76.00%	0.457	0.118	<0.0001	E.S.
5.	Constipation	0.87	0.47	0.40	46.15%	0.507	0.130	0.0313	S.
6.	Fatigue	2.20	0.60	1.60	72.72%	0.910	0.235	0.0001	E.S.

E.S. = Extremely significant, (By- Wilcoxon matched-pairs signed-ranks test)

S. = Significant

Table 3: Intergroup comparison of Group-A & B (Mann Whitney test) (Group-A n=15, Group-B n=15)

Symptoms	group	Mean Diff.	S.D.±	S.E.±	P	Result
Nausea	A	2.467	0.9155	0.2364	.5146	N.S.
	B	2.267	1.1000	0.2840		
Vomiting	A	1.733	0.9612	0.2482	0.7987	N.S.
	B	1.600	0.5071	0.1309		
Retching	A	2.400	0.9856	0.2545	0.0081	N.S.
	B	1.400	0.9103	0.2350		
Anorexia	A	1.467	0.7432	0.1919	0.3749	N.S.
	B	1.267	0.4577	0.1182		
Constipation	A	0.600	0.6325	0.1633	0.4075	N.S.
	B	0.400	0.5071	0.1309		
Fatigue	A	2.133	0.7432	0.1919	0.0959	N.Q.S.
	B	1.600	0.9103	0.2350		

N.S. =Not Significant N.Q.S. =Not Quite Significant

In Inter Group comparison there is statistically no significant changes observed in all Parameters.

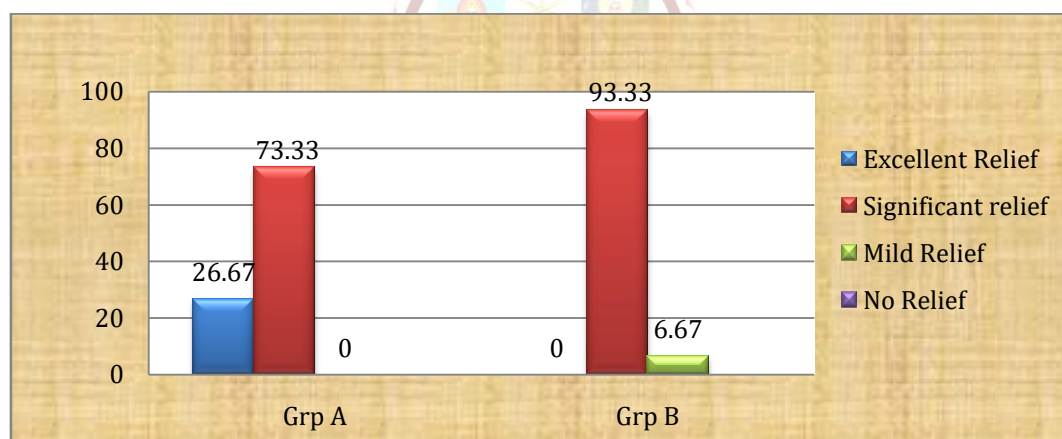
Table 4: Relief of Subjective Parameters in Group-A and Group-B(Group-A n=15, Group-B n=15)

Symptoms	Result in percentage	
	Group A	Group B
Nausea	68.52%	62.96%
Vomiting	60.46%	54.54%
Retching	64.28%	50.00%
Anorexia	78.57%	76.00%
Constipation	69.23%	46.15%
Fatigue	88.89%	72.72%
Average Percentage of relief	71.66%	60.39%

Average Percentage of relief
Overall effect of therapy

Table No. 5: Overall effect of therapy

S.No.	Effect of therapy	Result	No. of patients			
			Group A	%	Group B	%
1	Excellent Relief	>75%	04	26.67	00	00
2	Significant relief	51-75%	11	73.33	14	93.33
3	Mild Relief	25-50%	00	00	01	6.67
4	No Relief	<25%	00	00	00	00



DISCUSSION

Present clinical study is carried out to evaluate the efficacy of certain classical Ayurvedic formulations in the management of *Garbhini chardi* (Emesis gravidarum). Study carried out under two groups, Group-A and Group-B; all the selected patients were assigned Group-A and Group-B randomly by using simple random technique. Total 34 patients were recruited into the trial, but 30 patients have completed the study. Group-A patients were given *Bilvaphala majja churna* 3gms four times a day along with *Lajambu* (200 ml) and Group-B *Kustumbari kalka* 3gms four times a day along with *Tandulodaka* (200 ml) mixed with *Sharkara* 5 gm. Majority of the women belongs to

22-25 years age group (40 percent), followed by 30-33 years age group (27 percent).

Comparing the symptomatic improvement in both groups it was found that Average percentage of relief was higher in Group-A 71.66%, in comparison to Group-B 60.39%. It shows that effect of therapy was more in Group-A in comparison to Group-B.

Overall result of therapy, in Group-A, 04 patients (26.67%) showed excellent relief while in Group-B none of the patient has got excellent relief. In Group-A, 11 patients (73.33%) showed significant relief while in Group-B, 14 patients (93.33%) showed significant relief. In Group-A, no

patient showed mild relief while in Group-B, only 01 patient (6.67%) showed mild relief.

Modus operandi of trial drugs

Group-A: *Bilvaphala majja churna* was the main drug containing *Bilva* (*Aegle marmelos* (L.) Correa Ex. Schultz), having *Kashaya*, *Tikta rasa*, *Laghu*, *Ruksha guna*, *Ushna veerya*, *Katu vipaka*, and *Kapha*, *Vata shamaka* properties. *Chardi* occurs due to vitiated *Vata* and irritation of vagus nerve (*Vidaghdha ahara* and *Kapha dosha* are responsible for it). By the *Vata kapha shamaka* property it helps in correction of Nausea and vomiting.

Bilva is having *Deepana* (Carminative), *Pachana* (Digestive), *Grahi* (Absorbant), *Mridurechana* (mild laxative), *Pittasaraka* (Liver stimulant) properties,^[11] these properties helps in regulation of gastric motility and thus helps in correction of nausea and vomiting in pregnancy. Anti-emetic property of the *Bilvaphala majja* can be attributed to its anti-emetic, anti-oxidative, anti-bacterial (might be due to killing of *H. pylori*) properties, sedative property^[12] and it is also having high nutritional value containing carbohydrate, protein, fibre, fat, calcium, phosphorus, iron, vitamin C, Riboflavin, Thiamine, Niacin,^[13] hence it also helps in supplying essential nutrients to the fetus.

Lajambu– Main ingredient of *Lajambu* is *Laja* (parched rice). *Laja* is having *Kashaya*, *Madhura rasa*, *Lagu*, *Rukshaguna*, *Sheeta Veerya*, *Madhura vipaka*, and hence pacifies *Pitta* and *Kapha*, having *Deepana*, *Balya* properties.^[14] *Laja* is having digestible nutrients like protein 7.1%, fats 0.2%, 88.7%, Ash 0.4%, and fuel value per pound is 1,754 k. cal. It is containing nutritional values – vitamins of B complex like Pyridoxine.^[15] Rice based solutions work like oral rehydration solutions and they are proved effective in improving the intestinal absorption, even in acute diarrhoea.^[16] In cases of Emesis gravidarum, there is severe loss of nutrients and that hampers or retards the growth of the embryo and foetus. *Bilvaphala majja* adding with *Lajambu* works in synergy in reducing such type of nutritional deficiency and prevents adverse effects of nutrition loss on foetus. It can be said that this non-chemical oral rehydration solution have best bio-availability and compatible to the human intestine.

Group-B

Kustumbari kalka

Main ingredient of *Kustumbari kalka* is *Kustumbari* i.e. *Dhanyaka* (*Coriandrum sativum* Linn). According to Ayurveda, vitiation of *Vata*, specially *Udana* and *Vyana* is the main aetiology of

induction of *Chardi* (Vomiting), *Kustumbari* is having *Tridosahara* property, *Madhura rasa*, *Ushna veerya*, *Snigdha gunas* hence it controls *Vata*.^[17] Gastrointestinal dysmotility is one of the causes of induction of vomiting and vitiation *Udana vata* can be considered as a cause for dysmotility. *Kustumbari*, through its *Deepana*, *Rochana*, *Pachana* properties;^[18] stomachic, carminative, stimulant actions it might have given relief in vomiting.

In addition, this drug is also having the cidal activity on *H. pylori* infection in stomach.^[19] Case reports and case series suggest that treatment and eradication of *H. pylori* can decrease the nausea and vomiting during pregnancy.^[20] Anti-anxiety activity^[21] of this drug might also contributed in reducing anxiety that arose naturally during pregnancy, there by vomiting also.

Tandulodaka along with *Sharkara*

Tandula of *Shali* rice is having *Madhura rasa*, *Kashaya anurasa*, *Laghu*, *Snigdha guna*, *Sita veerya*, *Madhura vipaka*, *Hridya*, *Pittahara*, *Ruchikara*, *Brimhana* properties.^[22] It possesses nutrients of rice like Carbohydrates, Proteins, Fats, Crude Fibre, Minerals, Calcium, Iron, Phosphorus, Carotene, Thiamine, Riboflavin, and Niacin.^[23] In the present study Red rice is used which are more nutritious in comparison to white rice and rich in iron, zinc, minerals and possess antioxidant properties.^[24]

Sharkara is having *Madhura rasa*, *Snigdha guna*, *Sita veerya*, *Madhura vipaka*, *Vatapitta shamaka*, *Hridya*, *Ruchikara*, *Balya*, *Brimhana*, *Daha nashaka*, *Chardi* and *Trishnahara* properties.^[25] It possesses nutrients like Carbohydrates, Proteins, Calcium, Iron, Phosphorus etc. As vomiting is caused due to carbohydrate starvation,^[26] presence of fructose and glucose in the drug helps to supplement it, thus preventing vomiting.

Tandulodaka might have acted as carrier to supply the active principles of *Kustumbari* and, in association with that it might have acted in synergy in curing vomiting and associated factors due to the presence of B complex vitamins.

CONCLUSION

Effect of Therapy

- Therapeutic effect of Group-A (*Bilva majja churna* with *Lajambu*) shown maximum percentage of relief i.e. 68.52 % in Nausea, 60.46% relief in Vomiting, 64.28% in Retching, 78.57% in Anorexia, 69.23% in Constipation and 88.89% in Fatigue.
- Therapeutic effect of Group-B (*Kustumbari kalka* and *Tandulodka anupana* mixed with *Sharkara*) shown Maximum percentage of relief i.e. 62.96% in nausea, 54.54% in Vomiting,

50.00% in Retching, 76.00% in Anorexia, 46.15% in Constipation and 72.72% in Fatigue.

- On comparing the symptomatic improvement in both groups, it was found that average percentage of relief was higher in 'Group-A' i.e. 71.66%, where as in 'Group-B' it was 60.39%.

OVERALL EFFECT OF THERAPY

- In Group-A, 04 patients (26.67%) showed excellent relief, while in Group-B, none of the patient got excellent relief.
- In Group-A, 11 patients (73.33%) showed significant relief, while in Group-B, 14 patients (93.33%) showed significant relief.
- In Group-A, none of the patient showed Mild relief while in Group-B, only 01 patient (6.67%) showed Mild relief.

It can be concluded that drug of the both groups are very effective in curing the *Chardi* and its associated symptoms in pregnancy and better result is observed in short duration without any adverse effect.

In the present study one group was given *Bilva majja churna with Lajambu* and other group *Kustumbari kalka with Tanduladaka* mixed with *Sharkara*. Both drugs are effective but *Bilva majja churna with Lajambu* is comparatively better to cure *Garbhini chardi*.

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