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"A clinical study to evaluate the efficacy of Bilwadi kashaya in Garbhini chardi (Emesis Gravidarum)"

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Abstract

Pregnancy is essentially a physiological process. The patient complains of nausea and occasional sickness on rising in the morning. It may however occur at other times of the day. In early months of pregnancy altered physiology initiates vomiting. As a results certain physiological changes take place among which Garbhini Chardi or emesis gravidarum is one. While explaining regarding Chikitsa in Garbhini, Acharyas have mentioned that she should be given things which are easily palatable, Hrudya and the one which is liked by her. In this study Bilwadi Kashaya with Sharkara has been evaluated for its efficacy in the management of Garbhini Chardi. It will be given for 45 days duration as a dose of 20 ml qid by oral route, before food, and follow up for 15 days once. The patient is assessed clinically, pathologically before and after treatment and the finally the results were analysed. Ayurvedic classics has described many formulations for management of Garbhini Chardi. In this study Bilwadi Kashaya with Sharkara has been evaluated for its efficacy in the management of Garbhini Chardi.

Key Words - Garbhini Chardi, Bilwadi Kashaya, Sharkara

Introduction

Vomiting in pregnancy is the first and foremost symptom of pregnancy. Emesis Gravidarum is a worldwide common obstetrical problem seen in the first trimester of pregnancy in about 50-60% of pregnant women. Ayurvedic classics have mentioned Garbhini Chardi as one among the Vyakta Garbha Lakshanas, which can be correlated with Emesis Gravidarum. The present study drug Bilwadi Kashaya is used for the management of Garbhini chardi. Ayurvedic classics has described many formulations for management of Garbhini Chardi. In this study Bilwadi Kashaya with Sharkara has been evaluated for its efficacy in the management of Garbhini Chardi. Achievement of motherhood is the cherished desire of every woman. Garbhini Chardi (Vomiting in pregnancy) is a

common symptom in obstetrics practice. Slight vomiting is so common in early pregnancy which is considered as a symptom of pregnancy.When the pregnant women suffer from any disorders due to fetus the disorders are known as Garbhopadrava. Acharya Harita has described eight Garbhopadravas as follows. Shosha, Hrullasa, Chardi, Shopha, Jwara, Aruchi, Atisara and Vivarnatva. All the classics have mentioned excessive salivation, nausea, vomiting as symptoms of normal pregnancy. In the description of Chardi, Sushruta and Bhavaprakasha has enlisted pregnancy among causative factor of fifth type of Chardi i.e Agantuja Chardi. Acharya Charaka and Vagbhata has included Garbhini Chardi under Dwishtarthaja Chardi. Acharya Vagbhata and Bhavprakasha has enumerated Dauhrida in etiology. Dalhana Acharya has also explained non fulfillment of Dauhrida causes vomiting. Emotional factors undoubtedly contribute to the severity of nausea and vomiting. If this condition is not treated well early or in time emaciated women may suffer from hyperemesis gravidarum. Proper consumption of folic acid, vitamins is very essential but due to intense disaster mother cannot take sufficient quantity of nutrients and it may provoke some development anomalies in the fetus. Garbhini Avastha is termed as delicate state. Shamana chikitsa is suggested instead of Shodhana chikitsa. There is a need for an alternative, rational, safe and patent remedy. While explaining regarding Chikitsa in Garbhini; Acharya's have mentioned that the drugs which are easily palatable, must be given during pregnancy. The formulation contain - *Bilwa, Dhanyak, Bala, Shunthi, Laaja, Mudga* taken along with *Sharkara.* The above said drugs are the drugs along with sharkara will be beneficial in alleviating symptom of chardi.

Aims and Objectives:

To evaluate the efficacy of Bilwadi Kashaya in the management of Garbhini Chardi.

- **Material and Methods:**
- **Study Design:**
  1. **Literary study**- It was compiled and critically analyzed with the help of ancient texts of *Ayurveda* and the modern parallels along with latest research papers.
  2. **Clinical study**- By analyzing the data from results obtained through clinical trial.
- **Source of Data**:

The study was conducted over 50 patients of OPD of Prasuti Tantra, Sir Sundar lal Hospital, Institute of Medical Sciences, Banaras Hindu University, Varanasi.

- **Criteria of Selection of Drugs:**

Selection of the drugs with the following properties

a. *Balya-bringhana-Ojovardhak-kantivardhak, Grahi.*
b. Anti-emetic, Antioxidant of properties drugs.
c. Easy availability.
d. Economic.
e. Free from controversy.

1.Method of Administration of Drugs:

Drug	Dose	Route	Duration	Follow up	Follow up without Drugs
1. Bilwadi Kashaya	20 ml QID	Oral	45 Days	Total 3 follow-ups at regular interval of 15 days.	Last follow-ups without drugs regular interval of 15 days.

Oral administration of freshly prepared *Bilwadi Kashaya* (80 ml) was advised in QID (4 divived dose) after food for 45 days. Four (4) follow-ups were done at every 15th day. Three (3) follow-ups were done with medication and 4th follow-up was done without medication.

- **Criteria of Selection of The Patients:**

On the basis of inclusion and exclusion criteria the patients were selected after thorough interrogation, clinical examination, and laboratory investigations and enrolled for the clinical study.

Inclusion Criteria:

- Patients willing to participate in the research work after giving well informed written consent.
- Patients within the age group of 20-35 years.
- Patients Diagnosed as *Garbhini Chardi (Emesis Gravidaram)* in first trimester of pregnancy.
- Both *Primi* & *Multi Gravida*
- Patients who were ready for necessary investigations and agreed to come for follow up regularly.
- Patients who were ready to sign the informed consent. Patients willing to participate in the research work after giving well informed written consent and Patients who were ready to sign the informed consent.

Exclusion Criteria:

- Pregnant women with hyperemesis gravidarum.
- Vomiting caused due to other systemic disorders like peptic ulcer, renal calculi, appendicitis etc.
- Patients suffering from systemic diseases like TB, DM, bronchial asthma, jaundice, cardiovascular disease, renal problem and infection with rubella, toxoplasma, cytomegalovirus or *Herpes simplex* virus.
- Twin Pregnancy.
- Molar Pregnancy.
- Patient having history of any drug allergy, psychological disorders and Unconscious patient.
- Patients having any specific pathology of genital tract i.e., benign or malignant tumor, tubo-ovarian abscess etc.
- Patients not giving consent to participation in the study.
- Patient who is participating in any other research study.
- Patients who can't attend follow up regularly.

- **Investigations:**

Urine Pregnancy test

- **Hematological investigations**

- ABO-Rh
- Complete blood count
- Erythrocyte sedimentation rate
- Blood sugar
- Liver function test/Renal function test
- HIV 1 and II
- VDRL
- HBsAg, Anti HCV

- **Urine examination**
  - Urine- routine and microscopic
  - Urine for culture and sensitivity
- **Specific investigation**
  - Ultrasound obstetric (USG obs.)
  - Serum Electrolytes.

- **Research Design:**

The method adopted in present study was an open labelled single arm clinical trial. The study had a clearance from the Institutional Ethics Committee and CTRI registration was done.

- **Nature of study-** Current study is an open labeled, interventional, clinical trial.

CRITERIA FOR SCORING:

2.Criteria of Scoring For Clinical Features and follow-ups

Scoring for all signs & symptoms in ***Garbhini Chardi*** given according to severity from 1 to 5 (initially and in all Three follow ups) -

Score / Question	1	2	3	4	5
Question 1. For how long have you felt nauseated or sick to your stomach?	Not at all	< 1 hour	1 to 3 hours	3 to 6 hours	> 6 hours
Question 2. How many times do you vomit or throw up?	Never	1 to 2	3 to 4	5 to 6	$\geq$ 7
Question 3. How many times have you had retching or dry heaves without bringing anything up?	Never	1 to 2	3 to 4	5 to 6	$\geq$ 7

3.

	F-0	FU-1	FU-2	FU-3	FU-4	Total Score
Question 1. For how long have you felt nauseated or sick to your stomach?						
Question 2. How many times do you vomit or throw up?						
Question 3. How many times have you had retching or dry heaves without bringing anything up?						

- **SCORING:**

4.Pregnancy-Unique Quantification of Emesis and Nausea (PUQE) total score.

PUQE Score		Result
Mild	3-6 points	
Moderate	7-12 points	
Severe	More than 13 points	

5.Associated symptoms (1. Aruchi (Anorexia) **2.**Anaha (Constipation)**3.** Gas Formation **4.** Chest Burn) with present or absent

Associated Symptoms	F-0	FU-1	FU-2	FU-3	FU-4
Aruchi (Anorexia)					
vibandha (Constipation)					
Fullness of abdomen					
Chest Burn					

- **FOLLOW- UPS:**

Total four follow-ups were done at regular interval of 15 days to see the changes in sign and symptoms of chardi. Three follow-ups were done with medication and fourth follow-up was done without medication.

- **Result**
- **Criteria of Result**

Following criteria for result was adopted:

- **Improvement:** Relief in any of the symptoms mentioned.
- **No improvement/Unchanged / worsened:** None of symptoms disappeared or aggravation of any symptom.

Table 6: Showing Incidence of PUQE Score in Total Cases

PUQE		Initial		1FU		2FU		3FU		4FU	
Grade	**Score**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**
Mild	**1**	**00**	**00**	**14**	**28**	**37**	**74**	**42**	**84**	**41**	**82**
Moderate	**2**	**50**	**100**	**36**	**72**	**13**	**26**	**8**	**16**	**9**	**18**
Severe	**3**	**00**	**00**	**00**	**00**	**00**	**00**	**00**	**00**	**00**	**00**
TOTAL		**50**	**100**	**50**	**100**	**50**	**100**	**50**	**100**	**50**	**100**

Wilcoxon test	**Initial v/s I FU**	**Initial v/s II FU**	**Initial v/s III FU**	**Initial v/s IV FU**
Z	3.742	6.083	6.481	6.403
p	.000	.000	.000	.000

The above table No.6 and graph No.1 show that initially out of total, 50(100%) cases were found to have moderate PUQE score while no patient was having mild and severe score.

During I and II follow-ups, number of patients with mild scoring was raised due to some relief in and conversion of it into mild grade. Hence, mild grade was observed in 14 (28%) and 37 (74%) women. Subsequent relief was observed during III and IV follow-ups and mild scoring was noticed in 21 (63.6%), 42 (84%) and 41 (82%) cases respectively.

On comparison between initial and different follow-ups, the changes were found highly significant during I, II, III and IV follow-ups.

Graph 1:

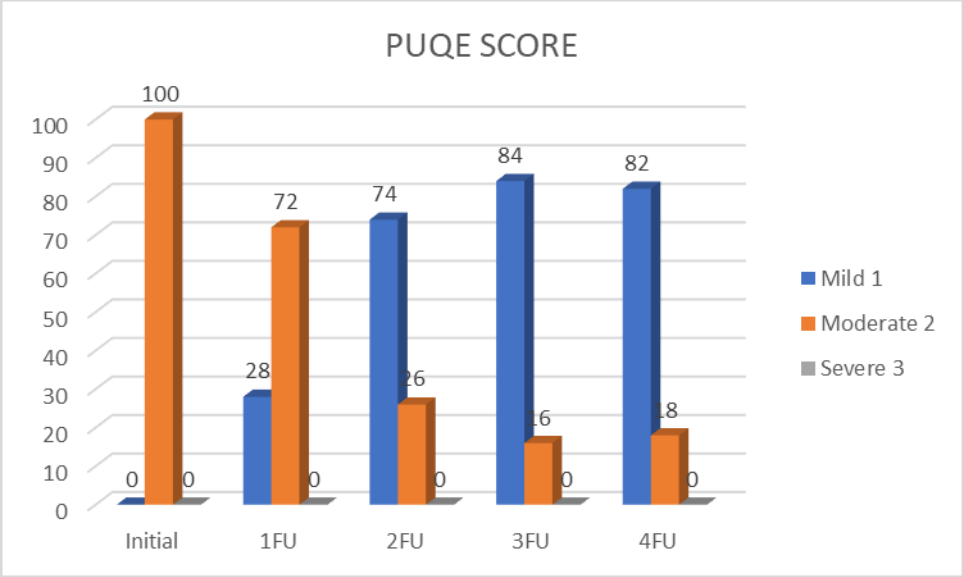


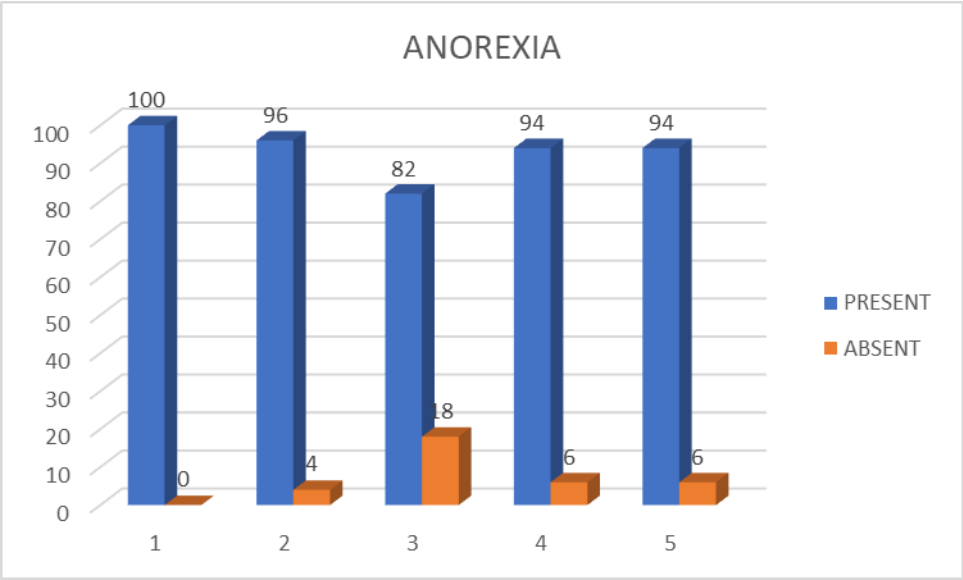
Table 7:

	Values	Initial v/s I FU	Initial v/s II FU	Initial v/s III FU	Initial v/s IV FU
Anorexia	**P**	.500	.004	.016	.250
Constipation	**P**	.500	.063	.002	.002
Chest burn	**P**	1.000	.063	.008	.008
Fullness of abdomen	**P**	.063	.063	.016	.063

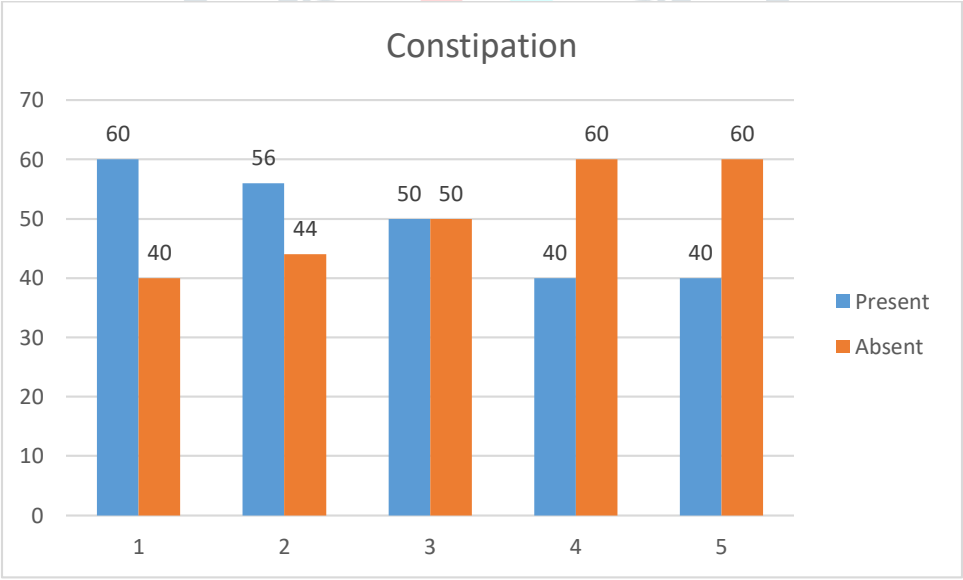
Table 8:

Assosiated symptom	Grade	**Initial**		**1FU**		**2FU**		**3FU**		**4FU**		
		No.	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	
Anorexia	Present	50	100	48	96	41	82	43	94	47	94	
	Absent	00	00	02	04	09	18	07	06	03	06	
Constipation	Present	30	60	28	56	25	50	20	40	20	40	
	Absent	20	40	22	44	25	50	30	60	30	60	
Chest burn	Present	20	40	18	36	15	30	12	24	12	24	
	Absent	30	60	32	64	35	70	38	76	38	76	
Fullness of abdomen	Present	25	50	20	40	20	40	18	36	20	40	
	Absent	25	50	30	60	30	60	32	64	30	60	

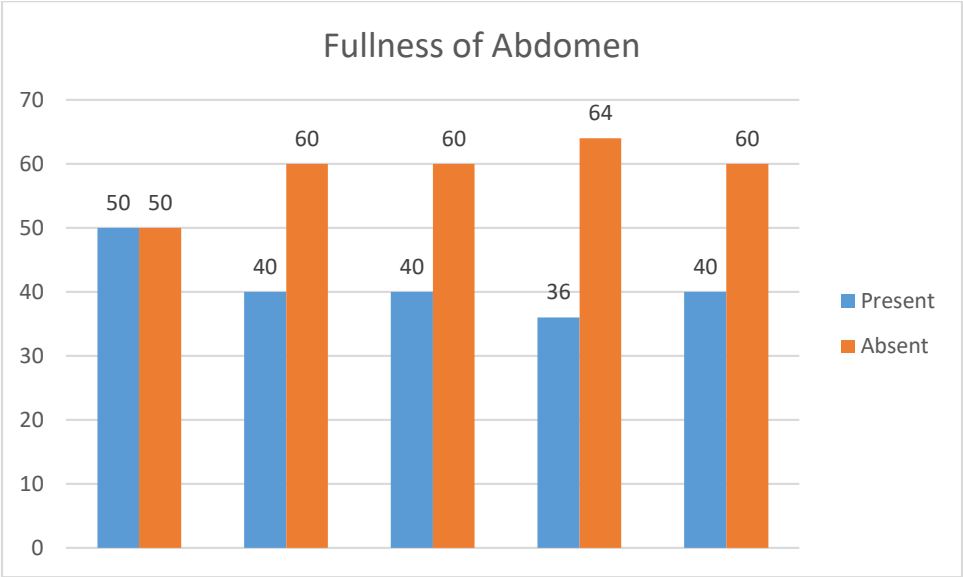
Graph 2:



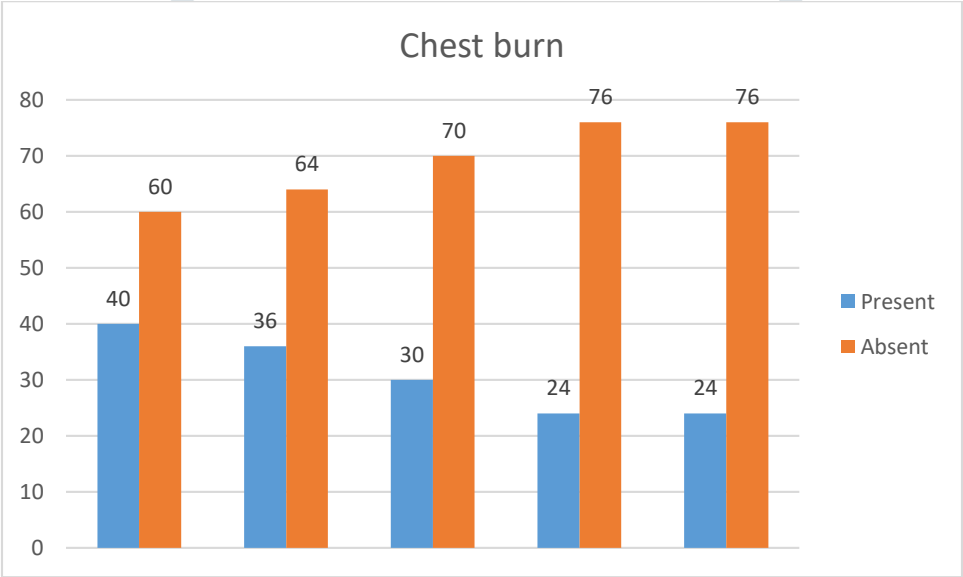
Graph 3:



Graph 4:



Graph 5:



As evident from table no. 8 and graph no. 2 that initially Anorexia was present in all patients. Then mild relief was seen during I and II follow-ups and it was present in 48 (96%) and 41 (82%) cases respectively.

During III and IV follow-up number of patients with anorexia was increased and it was 43 (86%) and 47 (94%) cases respectively.

On comparison between initial v/s III and initial v/s IV follow-ups the results were not significant.

Initially constipation was present in 30 (60%) patients. Then subsequent relief was seen during next follow-ups and it was 28 (56%), 25 (50%), 20 (40%) and 20 (40%) in I, II, III and IV follow up respectively. No recurrence was seen during I, II, III and IV follow-ups.

On comparison between initial v/s different follow-ups the results were not significant.

Initially fullness of abdomen was present in 25(50%) patients. Then subsequent relief was seen during different follow-ups. It was found in 20 (40%), 20 (40%) and 18(36%) during I ,II and III follow-ups respectively. But during last follow -up without medication 20(40%) was found .

On comparison between initial v/s follow-ups the results were not significant.

Initially chest burn was present in 20(40%) patients. Then subsequent relief was seen during different follow-ups. It was found in 18 (36%), 15 (30%), 12 (24%) and 12 (24%) during I, II, III and IV follow-ups respectively.

On comparison between initial v/s follow-ups the results were not significant

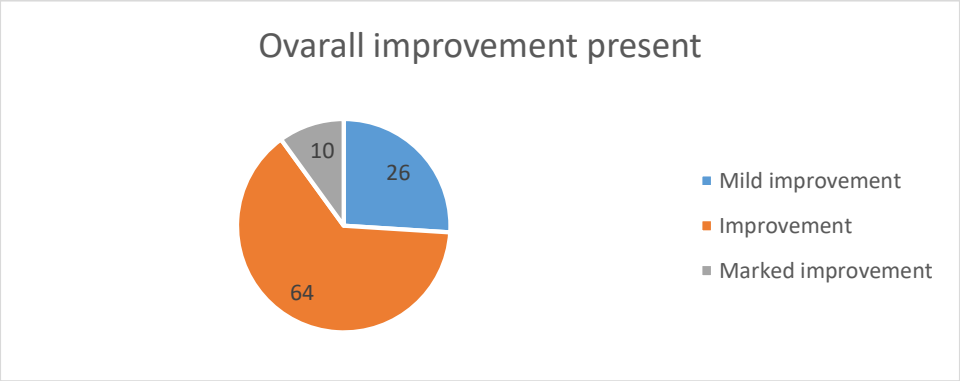
Overall improvement was determined based on presence and absence of five symptoms before treatment and at last follow-up.

Table no. 9

The result is show as below.

Overall improvement present	No.	Percentage
Mild improvement (≤ 30%)	13	26.00
Improvement (31-60%)	32	64.00
Marked improvement (61-100%)	05	10.00

Graph 6:



As per the results mild improvement was observed in 13(26%) patients while improvement and marked improvement was seen in 32 (64%) and 05 (10%) patients respectively.

RESULTS

After analyzing above given parameters, results were assessed on the following basis:

- Out of total, 13(26%) cases were Mild improvement, 32(64%) cases were Improvement and 05 (10%) cases were marked improved. (Table no. 9 and Graph No.6).

CONCLUSION

Bilwadi Kwatha with sharkara is very effective in the management of Garbhini Chardi, with the use of this drug no adverse effect were noted. Besides Chardi the oral administration of Bilwadi Kwatha with sharkara also reduced symptoms like nausea, epigastric burning, diarrhoea and headache. Early medication and following

dietic regimen are the key to overcome symptoms. Appropriate steps should be taken to diagnose and treat possible underlying diseases.

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