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A Comparative Clinical Study on the Effect of *Dhanyaka Kalka and Dhanyaka Avalehya* with Anupana of *Sharkara mixed Tandulodaka in Garbhini Chardi*

Research Article

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Abstract

Garbhini Chardi (vomiting in pregnancy) is a blazing issue in obstetric enactment. About 50-60% of all pregnant females agonize from vomiting in pregnancy most apparently in first trimester. If not tackled effectively before or in time, it may affect the quality of life of pregnant woman and pregnancy consequences. A yurvedic classics have described many formulations for management of Garbhini Chardi. In this study *Dhanyaka kalka* and *Dhanyaka Avaleha* was taken both with *Anupana* of *Sharkara* mixed Tandulodaka. Aim: To compare the effect of Dhanyaka Kalka and Dhanyaka Avaleha with Anupana of Sharkara mixed with Tandulodaka in Garbhini Chardi. Materials and Methods: Single blind clinical study with pre-test and post-test was designed. 60 patients complaining of *Chardi* in 1st trimester were randomly divided into the two groups: Group A and Group B, each comprising of 30 patients. Medicine used for Group A was Dhanyaka Kalka with Anupana of Sharkara Mixed Tandulodaka (rice, water or gruel) and medicine used for Group B was Dhanyaka Avaleha with Anupana of Sharkara mixed Tandulodaka. Those cases, which were in regular follow ups for 5 weeks were taken for clinical study. The criteria of assessment were mainly on the symptomatic relief. Intermediate follow ups were recorded at interval of two weeks. Results: In Group A, overall percentage relief in chief complains was calculated as 59.44% whereas in Group B this value was 66.5%. Conclusion: In present clinical study efficacy of Dhanyaka Avaleha has been proven beneficial in comparison to Dhanyaka Kalka. The trial drug is highly significant in the management of Garbhini Chardi. This study needs to be done on large scale and for longer duration.

Keywords: Dhanyaka Avaleha, Dhanyaka Kalka, Garbhini Chardi and Tandulodaka

Introduction

A Woman has been the torchbearer of the society for centuries. She is responsible for the miracle of birth. Pregnancy is truly an amazing and glorious time in women's life.

The growing foetus depends entirely on mother's body for all its requirements therefore a pregnant lady must take measures to remain healthy and well-nourished to have a healthy child which is a motive of every human being. Garbhini Chardi is mentioned as Vyakta Garbha Lakshana with other Lakshanas like Artava Adarshan, Asyasamsravana, Arochaka, Gurugatrata, Stanamandala Krishnata etc (1, 2). All these Lakshana are seen due to presence of Garbha. When Chardi is seen as a Lakshana there is no much harm on growing foetus as well as mother, as this is included in physiological changes (3). When vomiting during pregnancy is seen as excess, it may

cause discomfort and irritation for the pregnant lady (4). It is mandatory to take care and treat these conditions in initial stage and prevent further complications.

Emesis Gravidarum is a worldwide common obstetrical problem seen in the first trimester of pregnancy in about 50-60% of pregnant women. Nausea and vomiting tend to be worse in the morning termed Morning sickness, they frequently continue throughout the day. For such physiological alterations, if proper care is not given, it may lead to complication like severe dehydration, tiredness, weight loss, etc. which may affect mother and growing foetus. So one should take care to treat this condition in initial stage and prevent complications (5).

While explaining regarding the *Chikitsa* in *Garbhini*; *Acharyas* have mentioned that she should be given things which are easily palatable, *Hridaya* and the one which is liked by her (6). Keeping this view an attempt is being made to control *Garbhini Chardi* on principles of *Ayurvedic* formulation called *Dhanyaka Kalka* and *Dhanyaka Avaleha* both with *Anupana* of *Sharkara* mixed *Tandulodaka* (7). These formulations can be easily prepared and administered. These two formulations are having *Hridaya*, *Rochana*, *Deepaniya*, *Grahi*, *Pachana* properties (8).

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Study Objective

In the view of various limitations of use and complication associated with drug use in the management of vomiting during pregnancy, the present research work is planned with the following objectives:

- To evaluate the effect of *Dhanyaka Kalka* with *Anupana* of *Sharkara* Mixed *Tandulodaka* in *Garbhini Chardi*.
- To evaluate the effect of *Dhanyaka Avaleha* with *Anupana* of *Sharkara* Mixed *Tandulodaka* in *Garbhini Chardi*.
- To compare the effect of both *Dhanyaka Kalka* and *Dhanyaka Avaleha* with *Anupana* of *Sharkara* Mixed *Tandulodaka* in *Garbhini Chardi*.

Materials and Methods Design of study

This is a single-blind observational clinical study with pre-test and post-test design.

Source of data

Patients attending OPD and IPD of the Department of *Prasuti Tantra* and *Stree Roga*, Rishikul Campus, Haridwar has been randomly selected. A comparative clinical study has been conducted on 70 selected pregnant women, having classical symptomatology of *Chardi* in *Garbhavasta*.

Reason for dropouts

Initially 70 patients were registered for the study out of which 10 patients were dropped out in due course. Out of dropped 10 patients, 3 patients dropped due to miscarriage, 1 patient had twin pregnancy which was diagnosed later and was excluded from the study and 6 patients dropped out due to unknown reason.

Inclusion criteria

Patients diagnosed as *Garbhini Chardi* between 19 to 36 years of age in first-trimester of pregnancy in both primi and multi *Gravida*.

Exclusion criteria

- Patients in whom Chardi seen in second and third trimester.
- Patients with hyperemesis gravidarum.
- Patients with twin pregnancy and vesicular mole.
- Vomiting caused due to other systemic disorders like peptic ulcer, appendicitis,
- Hypertension, uraemia etc

Criteria for Withdrawal

- Personal matters
- Intercurrent illness
- Aggravation of complaints
- Any other difficulties

Assessment Criteria

In this section, parameter of study, criteria of scoring and criteria for assessment of therapy has been discussed.

Parameters of the Study

- Nausea and *Chardi Vega*, which are chief complain in *Garbhini Chardi*, are fundamental criteria for clinical assessment of improvement in patients.
- Nausea and *Chardi Vega*, itself are subjective parameters and it is hardly possible to fix it in available objective parameters, thus in such a case physician has to believe totally and keeps faith in the patients saying, even then for research purpose these Criteria has to be classified properly.

Criteria for scoring of Chief complains - In present study Nausea and *Chardi Vega* has been graded on its increasing severity on scale having gradation 0-3 [Table 1].

Table 1: Criteria of scoring Chief complaints

Complaint	Scale	Criteria of scaling	
	0	Nil	
	1	Mild (Feel Discomfort, does	
Nausea re		routine work)	
	2	Moderate (Impact normal	
		routine work)	
	3	Severe (Unable to do routine	
		work properly)	
	0	Nil	
Chardi	1	Mild (One to two times in a	
Vega		day)	
	2	Moderate (Three to four	
		times in a day)	
	3	Severe (More than four	
		times in a day)	

Criteria for scoring of Associated complains

In Present study Loss of Appetite, Headache, Constipation, Fatigue, Weight and Hb% are used as associated complains. Associated complains Appetite, Headache, Constipation and Fatigue has been graded on its increasing severity on scale having gradation 0-3 [Table 2].

Table 2: Criteria for scaling Associated complaints

Complaint	Scale	Criteria of scaling	
Appetite	0	Good	
	1	Average	
	2	Below average	
	3	Less	
	0	Nil (Not Present)	
Headache	1	Mild (Occasionally)	
	2	Moderate (1-2 times in a day)	
	3	Severe (2 times in a day)	
Constipa-	0	Nil (No constipation)	
	1	Mild (Frequency once in day but hard stool pass)	
tion	2	Moderate (Frequency of stool alternative day and patient feels difficulty in defecation)	
	3	Severe (Patient cannot pass stool without any purgative- agent. Even after 3-4 days)	



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Complaint	Scale	Criteria of scaling
	0	Nil (No Fatigue)
Fatigue	1	Mild (morning Fatigue)
	2	Moderate (2 times in a day)
	3	Severe (Always)

Follow up and Results

Those cases, which were in regular follow ups for 5 weeks were taken for clinical study. Those who were not regular in follow up were excluded from study. The criteria of assessment were mainly on the symptomatic relief. Intermediate follow ups were recorded at interval of two weeks. Observation for relief in sign and symptoms in first follow up was done. Last follow up was recorded to see the improvement in sign and symptoms

Criteria for selection of drug

Dhanyaka Kalka and Dhanyaka Avaleha both with Anupana of Sharkara Mixed Tandulodaka has been selected for the present study. The drug preparation has been done at Ras Shastra Department of Rishikul Mini pharmacy, Haridwar.

The Selection of drug for the study was based on the following fundamentals points-

- Easy Availability of well identified drug in sufficient quantity
- Easy Administration
- Economy
- Palatability

Determination of dose with duration

Following dose had been given to patients based on the selected group:

Group A: Dhanyaka Kalka with Anupana of Sharkara Mixed Tandulodaka was given initially for 2 weeks. **Dose:** 1/2 TSF (3gram) 6 hourly i.e. 4 times in a day.

Group B: *Dhanyaka Avaleha* with *Anupana* of *Sharkara* Mixed *Tandulodaka* was given initially for 2 weeks. **Dose:** 1 TSF (6 gram) 6 hourly i.e.4 times in a day.

Tandul was given to the patients of both above groups in Yavkutta form. Tandulodaka consumption was approximately 80 ml per day (i.e 20ml in each dose). It had 10 grams of Yavkutta Tandul and 80 ml of Udaka (Ratio of Tandul to Udaka should be 1:8). Dose of Sharkara was 1 TSF (6 gram) mixed with 80 ml of Tandulodaka

Criteria for *Upashaya*

Cured – Patients having effect of 67-100% Improved – Patients having effect of 34-66 % Not cured – Patients having effect of 0-33%

Results

Effect of treatment was assessed both clinically as well as based on laboratory parameters. Following are effect of treatment on individual signs and symptoms of chief complain, associated complains and investigation parameters [Table 3].

Table 3: Statistical comparison between effect of dhanyaka kalka and dhanyaka avalehya on chief complaint during study.

Statistical Properties	Dhanyaka Kalka		Dhanyaka Avaleha	
	Nausea	Chardi Vega	Nausea	Chardi Vega
Mean of BT	1.56	1.80	1.53	1.80
Mean of AT	0.70	0.73	0.53	0.60
Difference (BT – AT)	0.86	1.07	1.00	1.20
S.E.	0.128	0.122	0.09	0.089
t Value	5.47	5.96	5.80	6.70
% change	55.31%	59.25%	65.21%	68.42%
p Value	< 0.001	< 0.001	< 0.001	< 0.001

In Group A, overall percentage relief in chief complains has been calculated as 59.44% whereas in Group B this value is 66.5% [Figure 1]. Hence, in present clinical study efficacy of *Dhanyaka A valeha* has been proven beneficial in comparison to *Dhanyaka Kalka*.

On Chief Symptoms

The effect of drugs on chief complains and associated complains are shown below:

Nausea: In Group A, 50% patients got cured, 23.33% patients got improvement remaining 26.66% patients remain unchanged at end of the study. In Group B, 53% patients got cured, 30% patients got improvement remaining 16.66% patients remain unchanged at end of the study.

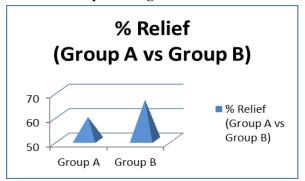
Chardi Vega: In Group A, 50% patients got cured, 26.66% patients got improvement remaining 23.33% patients remain unchanged at end of the study. In Group B, 53.33% patients got cured, 33.33% patients got improvement remaining 13.33% patients remain unchanged at end of the study.

On Associated sign and symptoms

In **Group A**, 30% patients got cured, 46.66% patients got improvement remaining 23.33% patients remain unchanged at end of the study.

In **Group B**, 40% patients got cured, 40% patients got improvement remaining 20% patients remain unchanged at end of the study.

Figure 1: Group A Vs Group B—Comparison of percentage of relief





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Impact of therapy has been concluded better in Group A compared to Group B even on the basis of percentage change in chief symptoms and associated symptoms [Figure 2 and Figure 3].

Figure 2: Group A Vs Group B - Percentage change in symptoms.

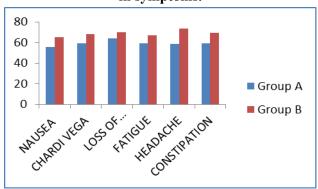
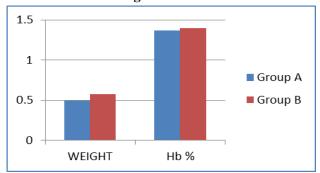


Figure 2: Group A Vs Group B - Percentage change in weight and Hb %.



Discussion

The present research work has been framed to undertake a critical literary, conceptual, clinical and trial drugs study to evaluate and compare the effect of *Dhanyaka Kalka* and *Dhanyaka Avaleha* with *Anupana* of *Sharkara* mixed *Tandulodaka* in *Garbhini Chardi*.

Dhanyaka is taken in the form of Kalka and Avaleha. As per research result, Dhanyaka Avaleha is slightly more effective than *Dhanyaka Kalka*. In my outlook, Avaleha is much better form as it is prepared from dry seeds and kalka prepared from leaves so as per availability Dhanyaka seeds are always available and Dhanyaka leaves is available in particular seasons. The transportation of Kalka is not easy as its self-life is one day and transportation of Avaleha is much easier as its self-life is one year [Table 4]. Kalka is among the Panchvidha Kashaya Kalpana and as per its Guna, it is Guru than Kwatha. Avaleha is prepared from Kwatha, so it is Laghu than Kalka. Kashaya is kept on fire to become thick thus by the Samyoga of Agni also it is Lagu than Kalka. Therefore assimilation and absorption of Avaleha is better than Kalka.

Dhanyaka contains Madhura Rasa, Tikta Rasa, Kashaya Rasa, Katu Rasa, Ushna veerya and Madhura Vipaka (9). Due to presence of Madhura, Tikta and Kashaya Rasa, along with Madhura Vipaka it is Vata and Pitta shamaka (10). Due to presence of Katu Rasa and Ushna Veerya, it is Kapha Vata Shamaka (11,12).

Table 4: Propertied of drugs for comparison

Properties	Dhanyaka Kalka	Dhanyaka Avaleha	
Part-used	Dhanyaka leaves	Dhanyaka seeds	
Availabilit y	In particular season	Every season	
Storage	Not easy	Easy	
Self-life	One day	One year	
Guna	Guru	Laghu	

Madhura Rasa acts as Bringhana and Tarpana which does Pitta Shamaka and helps in nourishing the Dhatus there by doing Poshana of the Garbha (13). Tikta Rasa is Aruchi Nashaka. It increases perception of taste by activating the taste receptors. It acts as Agnideepaka, Ahara Pachaka, Daha Shamaka, Trishna Nigrahana, Krimihara and maintains texture of Twaka and Mamsa. In Garbhini Chardi, patient complains of Aruchi, Agnimandya, Daha, Trishna and dryness in mouth. Tikta Rasa by its action helps in curing all these Lakshanas and helps in controlling Chardi (14). Kashaya Rasa is Sansamana and Sangrahi. It has antiinflammatory action, it helps in absorption of excess Kleda .It pacifies Kapha Pitta and Rakta Dosha. Predominantly it contains stagnation property thus this Rasa has Chardi Hara property (15). Katu Rasa acts as Mukha Shodhaka, Agnideepaka, Indriya Prasadaka, Srotovisrutikaraka and Kapha Shamaka. By Mukha Shodhaka property, it cures Aruchi by increasing the perception of taste. By Agnideepana property, it cures Ama and does Ahara Pachana which helps in formation of Rasadi Dhatus by which proper Poshana to the Garbha is maintained. Ushna Virya is Kapha Shamaka and Madhura Vipaka is Vata Shamaka. Tandulodaka along with Sharkara has Sheeta potency, and Sheetal Drava is always Stambhaka (16). It acts as good vehicle in bringing out pharmacological actions of other ingredients in the formulation with the presence of sugar in the drug it becomes palatable as the taste receptors are stimulated which helps in excessive secretion of saliva. It is readily assimilated and accepted by the stomach hence uptake of the nutrients take place easily Due to Laghu and Snigdha Guna of Dhanyaka, its assimilation and absorption becomes quick by the stomach, its action is by modulating vestibular impulses to the autonomic centers of the central nervous system and also by increasing the intestinal motility by preventing stasis of food in the stomach for longer time and has gastro kinetic effect i.e. It helps in moving the contents of stomach earlier. So it can be used as adjuvant with other drugs that interfere with gastric motility as it acts like *Vatanulomaka* and helps in controlling *Vata* there by controlling *Chardi* (17).

As vomiting is caused due to carbohydrate starvation presence of fructose, glucose in the drug helps to supplement it thus preventing vomiting (18). *Dhanyaka and Sharkara* contain calcium, iron, Carbohydrate, vitamins like B, C etc these are very much essential during pregnancy as there is increased demand of these during pregnancy. This will also help



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for the proper development of the fetus and she will not suffer from vomiting, anemia etc conditions during pregnancy. Thus *Dhanyaka* with its property of *Brihmana, Ruchivardhaka, Agnideepaka, Amapachaka and Dhatu Poshaka,* maintains *Vata* in normal proportion there by controlling *Chardi* and nourishing *Garbha* (19).

Since it is small sample study, a clinical study on large sample is required before coming into any conclusion regarding the total pharmacodynamics and pharmacokinetics of the drug. But the outcome of present study definitely gives as inspiration to proceed with the study of this drug in disease Garbhini Chardi for research scholars in this field in future.

Conclusion

Vomiting in pregnancy is the commonest disorder found in between 19 to 24 years of age. It is found more in primigravida and also women who had nausea and vomiting in their first pregnancy are more prone to have such symptoms in subsequent pregnancy.

By the clinical trial on 60 patients with 30 patients in each group (Group A-Dhanyaka kalka with Anupana of Sharkara Mixed with Tandulodaka) and Group B (Dhanyaka Avaleha with Anupana of Sharkara Mixed with Tandulodaka), the results in group B was more effective in reducing Chardi Vega,, Nausea, Loss of appetite, Constipation, Fatigue, Headache and Hemoglobin percentage than Group A. Both the groups were effective in maintaining the weight of the Garbhini. Research efforts can be instituted in larger samples for further precision.

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