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CLINICAL EFFICACY OF BHUNIMBASHARKARA VATI IN GARBHINI CHHARDI (EMESIS GRAVIDARUM).

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ABSTRACT:

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 Subidhabala khand is used for the management of Garbhini chardi. **Methodology:** This single arm clinical trial study was conducted among 60 pregnant women pre and posttest design. The drugs of Bhunimba & Sharkara were collected in the form of raw material and BhunimbaSharkara Vati was prepared at GMP certified pharmacy. Drug Standardization and authentication was done before the clinical trial. These patients were selected based on the criteria of inclusion, exclusion and assessment were done as per the standard parameters. 60 patients were given BhunimbaSharkara Vati orally in a dose 500mg thrice a day before food with jala as Anupana from 8th to 14th week of pregnancy. The response to the treatment was recorded and therapeutic effects were evaluated by symptomatic relief and based on assessment criteria. **Aim:** To evaluate the therapeutic efficacy of BhunimbaSharkara Vati in Garbhini Chhardi. **Objective:** To observe the add-on benefits of BhunimbaSharkara Vati in relieving the symptomatology of Garbhini Chardi and its effect on fetal and maternal wellbeing. **Result:** In the present study, BhunimbaSharkara Vati was having good effect in reducing Chardi, relief was found and adverse effects were observed during the study period. **Conclusion:** In these, 6 patients taken irregular medicine and given irregular follow up were withdrawal, 1 patient was having missed abortion in 10 th week after 2nd follow up hence withdrawal, 1 patient was detected as GDM as raised Bsl, 2 patients was given allopathic treatment after 2 follow up as symptoms was not relieved hence withdrawal, Rest 60 patients had given regular follow up hence in the study significant improvement ($P < 0.005$) was observed in symptomatology.

KEYWORDS: Emesis gravidarum, Garbhini Chardi, bhunimbasharkara vati.

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INTRODUCTION:

Pregnancy is unique phase of woman's life. The growing foetus depends entirely on the mother for all its need. Acharya Charaka has given specific importance to pregnant woman.¹ It is very delicate stage. There are many physiological and hormonal changes seen in pregnant women due to growing foetus. In Ayurveda, Vyapadas appear in Garbhini due to Garbha are called as 'Garbhodravas'. Garbhini Chhardi is mentioned in eight Garbhodravas in Harit Samhita.²

Garbhini Chhardi is a lakshana seen due to Kaphotklesha and Rasvrudhi. In Garbhini Chhardi Garbhavrudhi and Daurhuda Avamana causes kaphotklesha and Vilomgati of Vyan. This leads to Mukhpurnata. Bhunimba has Tikta Ras, Sheet Virya, and laghu, Ruksha Guna. Tikta Rasa acts as Aampitta pachan, Laghu, Rukshaguna reduces Kaphotklesha. And Sheet Virya acts a Pitta Shamak. With the above information, decided to choose single drug that is readily available, cost effective, potent and when formulated in form of Vati is more palatable. Saviryata avadhi of Vati is more than Kalka. Therefore, quality of drug is preserved for more time. Also, Vati can be given in exact dosage as compared to

Kalka. Emesis Gravidarum is a common obstetric problem throughout the world. 70 % of women worldwide experience nausea & vomiting in pregnancy. Hyperemesis, the most severe form, affects 1.1% primiparous women born in India & Sub-Saharan Africa were three times more likely to develop Hyperemesis Gravidarum than those born in Norway. Prevalence is found to be different according to maternal country of birth.⁴ Excessive vomiting in pregnancy causes electrolyte imbalance. It has negative effects on mother & baby. If not treated on time, effects like APH, preterm delivery, LBW baby, thromboembolic disorder, peripheral neuropathy, hypoglycemia, malnutrition.⁵

Recent research in fetal programming indicates that prolonged stress, dehydration and malnutrition during pregnancy can put the fetus at risk for chronic disease, such as diabetes or heart disease, later in life, or neurobehavioral issues from birth.⁶ Hence the need of indigenous and potent drug to overcome the primary system which if ignored and not treated on time can turn out to be fatal.

In Harit Samhita, Garbhini Chhardi is to be treated with Bhunimba Kalka and Sharkara in Samabhaag as

mentioned. As pregnant woman have nausea and vomiting the preparation in the form of kalka is not palatable so decided to choose the preparation in the form of Vati.

Aim and Objectives:

Aim: To study the effect of Bhunimba Sharkara Vati in Garbhini Chhardi.

Objectives: To study the effect of Bhunimba Sharkara Vati in Garbhini Chhardi.

MATERIALS AND METHODS:

1. **STUDY DESIGN-** Single group clinical study.

2. **SETTING** (location of study) - Study will be conducted in OPD and IPD patients from Streerog and Prasutitantra department.

3. **DURATION OF STUDY** – Duration of study will be 14 months.

4. **METHOD OF SAMPLE SELECTION** – Purposive Sampling.

5. **STATISTICAL TEST** - Wilcoxon Sign Rank Test.

6. **SAMPLE SIZE** – 60

The clinical study was done to evaluate the basic principles of Ayurveda and the various drug preparation described in Ayurveda for the treatment. The trial was duly registered under CTRI (clinical trial registry of India)

1) A total number of 60 patients of Garbhini Chhardi were selected

randomly on the basis of clinical examination.

2) While selection, lakshanas of Garbhini Chhardi were present in all of the patients.

3) Bhunimba Sharkara vati was 500 mg three times per day given to all patients for 45 days.

4) Each vati weighed 500 mg, the followup was taken on 8th, 10th, 12th and 14th week.

Informed consent –

Informed and written consent was taken of each patient prior to the commencement of the clinical trial.

Follow up –

1. Follow up of each patient was taken on 8th, 10th, 12th and 14th week.

2. Observations were carried out as well as noted on each follow up and data collected at the end of the research work was subjected to statistical analysis.

SELECTION CRITERIA

INCLUSION CRITERIA:

All Garbhini patients with signs and symptoms of Chhardi irrespective of age, parity. Garbhini with gestational age 8th to 14th weeks (45 days) having vomiting.

1) EXCLUSION CRITERIA-

1. Patients with multiple pregnancy and vesicular mole.

2. Garbhini with complaints of Krumija Chhardi and Ajirnaja Chhardi.
3. Garbhini with hemorrhagic disorder.
4. Pregnant women with vomiting due to other reasons such as intestinal obstruction, appendicitis, cholecystitis, uremia, hypertension.
5. Known case of diabetes mellitus/ gestational diabetes mellitus.

2) WITHDRAWAL CRITERIA-

1. Patient not willing for further trial.
2. Patient having irregular follow up.
3. If patient develops any allergic condition or adverse effect or unbearable aggravation.
4. Patient develops complications like severe dehydration and ketoacidosis was managed in emergency department.

OBSERVATION AND RESULTS-

Observations were recorded and presented in form of demographic and clinical data. Following data were included in the study as assessment criteria-

- 1) CHHARDI
- 2) HRULLASA
- 3) ANANNABHILASHA
- 4) URODAHA
- 5) DAURBALYA

Age:

Total out of 60 patients 28(46.7%) patient were in between age 18-22 years which child bearing age, 26

patient (43.3%) is of 22-26 year and only 6 patient (10%) is in 26-30 year as age wise patient was present in child bearing age.

Weight:

In this study of 60 patient 13 patient (21.7%) included had weighed between 30-40 kg, 18 patient (30.3%) weighed between 40-50 kg, 20 patient (33.3%) weighed between 50-60 kg, 4 patient (6.7%) between 60-70 kg and 5 patient (8.3%) between 70-80 kg. however, there is no significance between age and chhardi.

In present clinical trial out 60 patient 56 patients i.e., 93.3% patients were housewives, 3 patients i.e. 5% patients were school teacher and 1 patient i.e. 1.7 % patients were computer operator professionally. Housewives are more prone to develop symptoms as during their daily household work that is during preparing food, the smell of 'Tadaka', aggravates nausea and vomiting and also during dusting and cleaning symptoms increase as noted in study. 3 patient were school teacher due their work schedule and lack of rest and travelling were more prone to developed Chhardi.

In present clinical study among 60 patient, 39 patient i.e 65% patient were primi gravida 16 patient i.e 26% second

para, 4 were third para i.e 6% and only 1 patient was fourth para so from this study it is noted that Chhardi was more common in primi gravida patient also mentioned in literature study and primi gravida were found more nervous and anxious leading to developed more symptoms in this study also noted that 4 patient among second para out of 16 had the same complaints in previous pregnancy also having recurrence of chhardi in second pregnancy.

CHHARDI :

1. There was no patient of absent Chhardi before treatment in present study as Chhardi is main variable and after treatment it was absent in 39 patient out of 60 means decreased in 65% patient.
2. Mild Chhardi i.e 1-3 episode of vomiting daily was present in 18 patient before treatment and 21 patients after treatment means mild chhardi cured in 35%. 3 patient was having mild vomiting after treatment had severe vomiting before treatment.
3. Moderate Chhardi i.e 4-5 episode of vomiting in a day was present in 33 patient before treatment and had complete relief after treatment
4. Severe Chhardi i.e 5-10 episode in 24 hours was present in 9 patient before treatment had complete relief after treatment.

Symptoms of vomiting got relieved up to 81.08%. the median score before treatment was 2 which got decreased till 0, follow up shows that therapy used is effective.

1) HRULLASA:

1. In present study of 60 patients Hrullasa was present in all 60 patient. 1. Mild Hrullasa i.e able to eat responsible intake was present in 11 patient before treatment had same complaint of Hrullasa after treatment also i.e patient do not have relief after treatment in mild Hrullasa.

2. Moderate Hrullasa i.e continuous sensation of nausea for some food intake reduce significantly was present in 46 patient i.e 76.7% before treatment had significant relief after treatment. 44 patient was having complete relief only 2 patient was having the same complaints after treatment.

3. Severe Hrullasa i.e continuous sensation of nausea was present in 2 patient before treatment was having complete relief after treatment.

Symptoms of nausea got relieved upto 86.24%. the median score before treatment was 2 which was decreased till 0, follow up shows that therapy used is effective.

2) ANNANABHILASHA

Annanabhilasha was present in 37 patient out of 60 patient in a present clinical study out of that,

1. Mild Annanabhilasha i.e does not affect weight gain during pregnancy was present in 35 patient having no symptoms after treatment in 33 patient. Only 2 patient did not had relief after treatment.

2. Moderate Annanabhilasha i.e affect weight gain during pregnancy was present in 1 patient had no symptoms after treatment.

3. Severe Annanabhilasha i.e causes weight loss during pregnancy was present in 1 patient had relief after treatment.

Symptoms of anorexia got relived upto 95%.the median score before treatment was 1 which was decreased till 0, follow up shows that therapy used is effective.

4. URODAHA.

Total out of 60 patient Urodaha was present in only 17 patients.

1. Mild Urodaha i.e Urodaha present only after intake of spicy food was found in 11 patient before treatment had same complaint in 9 patient after treatment also didn't had complete relief in those patient. 2 patient didn't had urodaha after treatment.

2. Moderate Urodaha i.e Urodaha present by intake of any kind of food seen in 7 patient before treatment had complete relief in 6 patient after treatment only 1 patient had the same complaint after treatment also.

3. No patient of severe Urodaha was found in present study.

Symptoms of Urodaha got relieved upto 56%.The median score before treatment was 1 which got decreased till 0, follow up shows that therapy used is effective.

3) DAURBALYA

In the present study of 60 patient Daurabalya was present in 49 patient.

1. Mild Daurabalya i.e Daurabalya only at morning present in 35 patient before treatment had complete relief in 21 patient after treatment and 14 patient had the same complaint after treatment also.

2. Moderate Daurabalya i.e Daurabalya by doing any kind of work was present in only 1 patient didn't had symptoms after treatment.

3. Severe Daurabalya i.e Daurabalya constant through out day was present in 13 patient before treatment had relieved the symptoms in 10 patient after treatment only 3 patient didn't had relief after treatment.

Symptom of Daurbalya got relieved upto 69.74%. The median score before treatment was 1 which got decreased till 0, follow up shows that therapy used is effective.

Overall effect of therapy:

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy. From above table we observe that P-Value is less than 0.05. Hence, we conclude that effect observed is significant. The median score before treatment was 6 which after treatment got reduced to 1 which shows that the Bhunimba Sharkara is effective (80.17%) in Garbhini Chhardi.

GESTATIONAL AGE:

In this study, patients were selected from 8 weeks to 14 weeks, in which 1 patient (1.7%) was from 6-7 week GA, 21 patients (35.0%) of GA between 7-8 weeks, 23 patients (38.3%) had GA between 8-9 weeks, 13 patients (21.7%) had GA between 9-10 weeks, 2 patients (3.3%) had GA 10-11 Weeks, the symptoms of Garbhini Chhardi are mostly seen between 8-14 weeks, here in this study also we can conclude that the symptoms seen were between 6-11 weeks of GA.

DISCUSSION:

Bhunimba reduces Kapha Pitta doshas with it Tikta Rasa, Katu Vipaka and

Laghu Ruksha Guna. The content of the drug selected i.e. Bhunimba Churna and Sharkara are Tridosahara, Aampachak and improves Agni. In Ayurveda Samprapti Vighatan is a Chikitsa Mantra. Bhunimba reduces Garbhini Chhardi by counteracting the increased Doshas. During pregnancy there is considerably increased gastric secretions. Kiratatikta significantly reduces the gastric secretions. Emotional factor and psychiatric illness undoubtedly contribute to the vomiting in pregnancy. Kiratatikta has been studied for its antipsychotic activity in animals. Its gentianin extract inhibited induced aggressive behavior in them. The present clinical study entitled "Role Of Bhunimba Sharkara vati In Garbhini Chhardi" was aimed to evaluate the role of Kiratatikta with same amount of Sharkara in Garbhini Chhardi. Bhunimbasharkara Vati action in Garbhini Chhardi:-vomiting in pregnancy is mainly due to Kapha and Pitta Utklesha. The property and action of Bhunimba is Kapha Pittahara. Pitta vrudhhi is mainly due to Dravaguna and Kleda increase due to Kaphotklesha. Tikta Rasa has Laghu and Ruksha Guna which has absorbs Dravatva and Kledatva of Kapha Pitta Doshas. The Sheeta Virya of Bhunimba and Sharkara subsides Pittotklesha.

Aampitta Pachan and Agnimandya is subsides due to Tikta Rasa.

CONCLUSION:

Garbhini Chhardi is commonest disorder found in between primi para patient with age of 18-22 years. It is more prone to develop in house wife and low socio economic status. Bhunimba Sharkara Vati is significantly effective in Garbhini Chhardi and its associate symptoms like Hrullasa, Annanabhilasha, Urodaha and Daurbalya. No any side effect of Bhunimba Sharkara Vati noted in maternal and foetal health. Present study indicate that the treatment is safe, effective and harmless. Early medication and following dietic regimen is the key to overcome the symptoms.

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