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CLINICAL STUDY OF GARBHA SRAVI VANDHYA INPRECONCEPTION CARE AND ANTENATAL CARE IN FIRST TRIMESTER

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ABSTRACT

Introduction: The pregnancy period is grossly divided intothree stages and is called trimesters. More than 80% of abortions occur within the first 12 weeks of gestation. In the present clinical study, Drugs mentioned in Ayurveda were evaluated for the trial. Aim Objective: To evaluate the effect of Garbharaksha Vatiinpreventing First Trimester Abortion. Materials & Methods: 72 pregnant women irrespective of parity fulfilling the criteria of inclusion were registered for the study and informed written consent was taken. Assessment parameters, such as spotting per vagina, lower abdominal pain, nausea and vomiting, anorexia, giddiness (Bhrama), gland, morning sickness having significant improvement after the trial. Discussion & Conclusion: All the subjects even with symptoms and signs of threatened abortion continued the pregnancy. The maternal wellbeing as well as fetal growth represented Garbhasthapaka, Garbhaposhaka, Garbhavruddhikara Prabhavaof Garbharaksha Vati.

Key Words: Ayurveda, Garbhasrava, Garbharaksha Vati, Pregnancy, Frist Trimester

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INTRODUCTION:

Background: Woman is a special creation of God gifted with the ability to keep the

human species thriving through reproductive function and appropriate care. Multiple

drug are mentioned in ayurvedic texts for the treatment and prevention of Garbhasrava

and Garbhapata. Garbharaksha Vati²⁻⁴was selected for the trial with Garbhasthapaka,

Garbhaposhaka, Garbhavruddhikara Prabhava and was modified as Vati for ease of

administration and palatability. The clinical trial aimed to establish the drug efficacy and

rule out the adverse effects and their additional benefit in the pregnancy period. There

was a directly proportional relationship between the success of the treatment and the

genuineness of the medicine.

CLINICAL SIGNIFICANCE:

Incidence of abortion: The world health organization estimates that worldwide 210

million women become pregnant each year and that about a third of them or

approximately 80 million ends in miscarriage, stillbirth or induced abortion. More than

40% of women will have miscarriages sometime in their reproductive life. Approximately

20% of all pregnancies end up in miscarriages (spontaneous abortion) and about 80% of

these occur in the first trimester, within 2-3 months of gestation⁵

MATERIALS & METHODS -

Site of Study: Patients were selected from the OPD and IPD of Department of Prasuti

Tantra Evum Stree Roga, Parul Ayurved Hospitaland Parul Sevashram Hospital, Vadodara.

DRUGS:

The raw drugs for Garbharaksha Vati (Table.1.) were obtained from Vadodara and

authenticated in the Pharmacognosy Laboratory of PIA (Ref.no-PU/PIA(Dg)Certi-9. and

Vatiwas prepared in the Department of Rasashastra GMP Certified Pharmacy (GA/1842)

(Table.2).

60

Table No 1. Ingredients of Garbharaksha Vati according to the months of gestation:

S.no	Garbharaksha Vati-1st	Garbharaksha Vati-2 nd	Garbharaksha Vati-3 rd
1.	Yasthimadhu	Krishna Tila	Shatavari
2.	Sakha beeja	Manjishta	Priyangu
3.	Devadaru	Shatavari	Nagakesara
4.	Shweta Chandana	Kamalanala	Anantamula
5.	Rakta Chandana	Nagakesara	Bandhaka
6.	Draksha		
7.	Shatavari		

ETHICAL CLEARANCE: -

Ethical clearance with no of PU / PIA / IECHR/2019/54 was obtained from the Institutional Ethical Committee of Parul University. CTRIRegistration: Present research had been registered in Clinical Trial Registry of India, vide no. CTRI 2019/07/020473 (Dt.31/07/2019).

INCLUSION CRITERIA: -

Married women aged 20-35 years, H/o spontaneous abortions in the first trimester, C/o threatened abortion, chorio-decidual haemorrhage, UPT positive case with H/o of habitual abortion, Unexplained causes of abortion, women with a family history of recurrent abortion, endocrine and metabolic diseases like thyroid dysfunction, diabetes mellitus were incorporated in the study.

EXCLUSION CRITERIA: -

Women with H/o consanguineous marriage, women agedbelow 20 years above 35 years, genetic causative factors for abortion, chromosomal abnormality, anatomical abnormalities uterus, immunological disorders were excluded from the trial.

ASSESSMENT CRITERIA: -

A specially designed proforma was prepared and assessment was done based on subjective and objective parameters and by developing a special scoring pattern.

Table No 2-: Grouping & Posology

Group -1 Preconceptional n= 10	Garbharaksha Vati - 1, Tab Folic acid	500mg 5 mg	Tablet Tablet	Cow's milk/ Water	Thrice a day, before food Once a day, after food
Group - 2Preconceptional n=10	Tab Folic acid	5mg	Tablet	Water	Once a day, after food
Group -3ANC-Trial POG-4 th -12 th Week n=32	Garbharaksha Vati- 2,3	500mg	Tablet	Cow's milk	Thrice a day, before food
Group -4 ANC-Control POG-4 th -12 th Week n=20	Cap-SUSTAIN	200mg twice a day	Capsule	Water	Twice a day, after food

STATISTICAL ANALYSIS-

The information data collected based onvariables and observations were subjected to statistical analysis using SPSS Version 20.

OBSERVATIONS AND RESULTS-

In the present study, maximum number of patients i.e. 47.2 % belonged to age 23-27 years, 55.8% of patients were primigravida, 80.6% of patients were from Hindu community, 30.6% patients were graduate, 59.7% were belonging to middle class, 72.2% patients were housewives, 50% had Vata-Kaphaja Prakruti, 66.7% patients had no history of any contraceptive measures, 63.9% patients were Mixed habit of diet, 77.8% was having regular type of diet habit, 79.2% patients were habituated for tea intake, 58.3% were having intake of 1-2 lit/day of water, 79.2% of patients were having no addiction of alcohol,tobacco, smoking, 83.3% were no history of exercise, 76.4% had appropriate sleep, 73.6% had regular bladder habits, 58.3% were having regular bowel habits, 80.6% patients had no family history of recurrent abortion, delayed conception or

infertility, 66.7 % patients had no history of previous major surgery or history of D&C and D&E, 82.7% patients had no positive history of coital act during pregnancy, 84.6% patients had no history of travelling.

ASSESSMENT CRITERIA: -

For ordinal data with two independent groups(Group 3 and Group 4) to compare the values, a non-parametric Mann-Whitney test was carried out to test whether there was any significant difference in the BT and AT values of the following variables of the four independent treatment groups.(Table.3, 4)

Table no-3: Assessment of overall outcome in Group-1,2

	Frequency	Percentage
Not conceived	11	55%
Conceived after one month of medicine	1	5%
Conceived after two months of medicine	7	35%
Total	19	95%
Missing	1	5%
	100	

Table no-4: Assessment of overall outcome in group-3,4

Continuation of pregnancy thorough out 3 months with or without any complication	45	62.5%
Continuation of pregnancy beyond 3 months with complications	3	4.2%
Abortion	4	5.6%
Total	52	72.2%

DISCUSSION: -

In registered patients n=9 completed in group-1, n=10 completed in group-2, n=32 completed in group-3,n=16 completed in group-4 in that 4 patients aborted during treatment. In the preconception group-5.3% of patients conceived after one and half months of treatment, 36.8% of patients conceived after two months of study duration. 86.5% of patients continued the pregnancy throughout initial three months without any complication, 5.8% had continued pregnancy beyond 3 months with complications, and 7.7% of patients aborted in the control group. Studying the results of GarbharakshaVati groups during the treatment or after the trial period, no abortion were observed. The maternal, as well as fetal growth, was representing Garbhasthapaka, Garbhaposhaka andGarbhavruddhikara Prabhava which was predominantly taken care of by Garbharaksha Vati. So, the alternative hypothesis is accepted and the null hypothesis is rejected. (Fig.1)

Probable Mode of Action of Garbharaksha Vati⁶⁻²⁰ -

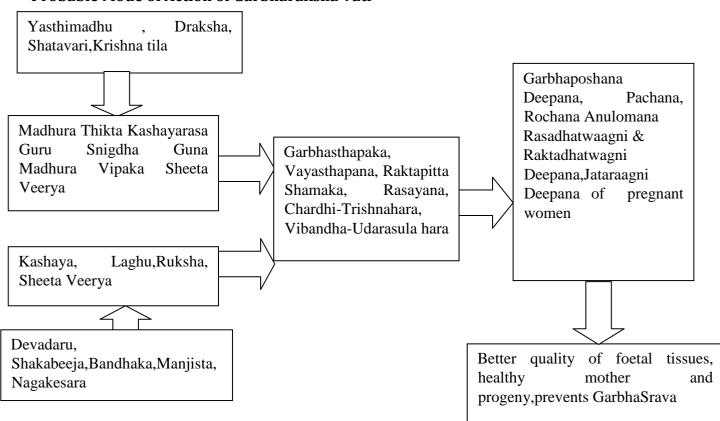


Fig.No. 1. Probable Mode of Action of Garbharaksha Vati

The chemical analysis of the Garbha Raksha Vati shows the presence of Alkaloids, Flavonoids, Steroids, Tannins, Saponins, Proteins, Resins²⁰. Having significant amount of alkaloids responsible for most varied type of pharmacological actions and had effect on

International Journal of AYUSH; 2022: 11 (4); 59-67

central nervous system probably help in relieving the cause of infertility and

maintenance of pregnancy with overall influence on the body and foetus. Flavonoids are

protective in action. These are considered as naturally dietry biologic response

modifiers, disease preventing and health promoting may be effective in the management

of infertility and pregnancy. Steroids have influence on endocrine system. As these are

precursors for synthesizing sex hormones especially progesterone and estrogen whice

basic factors for infertility. These are also anabolic agents. Hence, main the functioning of

agni in both conditions of infertility as well as pregnancy. Tannins are contributory to

over come the possible haemorrhagic or other discharges of yoni and helps conception,

content of that has the capacity to combine with the tissue protein may assist

sthirikarana of the conceited matter. Saponins are the glycosides which may have similar

or synergistic influence as steroids. They have role in rectifying the abnormalities

responsible for infertility or maintaining normal pregnancy, polysaccharides,

carbohydrates are nutritive, help for conception and maintain the pregnancy and

promotes the normal delivery. vata act as catalyst also for health promotion. Drugs have

triterpenoids suggesting their action of anabolism, weight promotion, rectification of

agni, soothing, diuretic. all these therapeutic activities are essential for achieving a non

complicated pregnancy.the lipid content in these drugs may also help in rectifying

disturbance responsible for infertility

CONCLUSION

Garbharaksha Vati augmented both maternal wellbeing and foetal development. In the

preconception group, 5.3 per cent of women were pregnant after one and a half months

of therapy, and 36.8% of patients became pregnant after two months. In the control

group, 86.5 per cent of patients continued their pregnancy for another three months

without any health problems, 5.8 per cent had to continue their pregnancy for another

three months with complications, and 7.7% of patients aborted. Ayurvedic treatment

with Masanumasika Garbha Sravachikitsa was found beneficial in preconception and

prenatal care to prevent Garbha Srava in first-trimester abortion.

Conflicts of Interest: Nil

Source of Support- Nil

65

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