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Controlled clinical study to evaluate protective role of *Garbhapalras* in *Garbhini Avastha*.

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Abstract:

The prophylactic value of antenatal supervision is so much tested and recognized in the advanced countries. This care is very much essential to prevent or to detect the medical and obstetrical complications at the earliest. Another main aim of antenatal care is "to bring healthy offspring" into the society. Through best maternal care, the fetal risks can be avoided or at least prevented. Foetal health can be achieved through proper maternal nutrition and well–being. *Garbhpal ras*, a Herbomineral drug mentioned in the *Ayurveda* text namely '*Ras Chandanshu*' is being used in pregnant woman since many decades. It is said that *Garbhpal ras* can be used to treat diseases of pregnant woman and it should be taken from 1st month to 9th month of pregnancy. The aim of present study was to assess the efficacy of *Garbhpal ras* in pregnancy with respect to maternal and fetal wellbeing. In present study, 100 pregnant women (after 20 weeks of gestation) were registered. Haematological and biochemical parameters were observed. Ultrasonography parameters like FL/AC ratio, Fetal weight, AFI, Umbilical artery S/D ratio, were assessed. Normal haematological results and biochemical tests show non-toxic nature of *Garbhpal ras* when given in 125mg BID with milk. Improvement in haemoglobin percentage in trial group was found during study. *Deepan, pachak, kledaghna, rasayan* properties of *Garbhapal ras* improves *Jatharagni* and *Dhatvagni* (metabolism) and helps in the formation of good quality of *Aahar rasa*. This helps to produce '*Uttarottar Sara Dhatu and Upadhatu'* in *garbhini.*

Keyword:

Garbhapal ras, pregnancy,Garbhini, Rasayan, Garbhsthapak, Gabhashaybalya.

Introduction:

Ayurveda has described Anti-natal care in the form of '*Garbhini paricharya*.'
In *Ashtang sangraha Indu teeka* three motives of antenatal care have been explained – *Anupaghatay* (Safety of mother and baby), *Paripurnatvaya* (Complete care of mother and baby), *Sukhaprasavay* (Labour without complications). In *ayurveda* classics there is description of *Garbhopaghatakarbhav*, *Garbhopadrava* [1], *Garbhavyapada* which has to be taken care for the formation of good physical health of mother and well-being of foetus. *Aahara Rasa* plays a vital role in the formation of cells in human body. Foetal growth and development solely depends upon mother and maternal *Ahara-rasa* [2]. *Agnimandya* causes formation of *Apakva Ahara rasa* and it may lead to various medical conditions or complications during pregnancy i.e *Garbhopdravas*. Various known and unknown factors can complicate this process creating a life threatening conditions for mother and fetus. *Garbhpal ras* a Herbomineral drug mentioned in the *Ayurveda* text namely '*Ras Chandanshu'* is being used in pregnant woman since many decades. This drug is also mentioned in *Ayurved sarasangraha*, *Rasatantra sar siddha prayog sangraha* [3]. It was claimed that *Garbhpal ras* can be used to treat diseases of pregnant woman and it should be taken from 1st month to 9th month of pregnancy [4,5,6]. '*Garbhpal Ras'* contains minerals like *'Hingula'* (Cinnabar), '*Vang*' (Tin), '*Nag*' (lead)and '*Loh bhasma'* (Iron). Herbal contents of *'Garbhpal Ras'* include *'Dalchini'* (Cinnamomum zeylanicum), *'Ela'* (Elettaria cardmomum), *'Tejpatra'* (Cinnamomum tamala), *'Shunthi'* (Zingiber officinale), *'Marich'* (Piper nigrum), *'Dhanyak'* (Coriandrum sativum), *'Chavya'* (Piper retrofractum), *'Krishna jeerak'* (Carum bulbocastanum), *'Devdaru'* (Cedrus deodara) and '*Draksha'* (Vitis vinifera). All ingredients in equal quantity except *'Loh bhasma'* (half quantity than others) were taken and triturated in extract of '*Vishnukranta'* (Clitoria ternatea). In the present study the efficacy of *Garbhpal ras* in pregnancy with respect to maternal and fetal wellbeing was evaluated. Protective role of *garbhapal ras* and possible mechanism of action of *Garbhapal ras* in pregnancy was studied in the present study. Observation and results of the study are discussed in this article.

Aims_and_Objects:

The aim of the study was to study the effect of *Garbhapalras* in *garbhini-avastha* with respect to maternal well-being and Foetal well-being.

Materials_and_Methods

Inclusion Criteria:

1) All normal ANC patients, between 20 to 28 weeks of gestational age calculated according to LMP.
2) Patients having age between 18-35yrs
3) Patients having Haemoglobin more than 8gm%

Exclusion Criteria:

1) Patients with less than 20 weeks of gestation.
2) Patients having Haemoglobin less than 8 gm%.
3) Patients having any systemic and metabolic disorders.
4) Patients having STDs, HIV, HBsAg positive.

5) Patients with Toxemia of pregnancy.
6) Patients having any fetal anomaly detected.

For conducting clinical study total 100 patients were selected and randomly divided into two groups namely Trial group and Control group. Patients in the trial group were treated with *Garbhapalras* tablets 125 mg twice a day with Milk *anupan*. Patients in the control group were treated with placebo drug (Glucose tablet) tablet, one tablet twice a day. This study was carried out for three months. Follow up of patients was done at one month interval for three consecutive months and record was maintained. Along with this routine iron and calcium preparations were continued for administration.

Group A- This group is termed as a 'Trial group'.
Number of patients : 50 patients were included.
Treatment : '*Garbhapalras'* **Dose** : 125 mg tablet twice a day with milk *anupan.*
Duration of Treatment : 3 months

Group B - this group was termed as 'Control group'.
Number of patients : 50 patients were included. **Treatment** : Placebo tablet (glucose tablet) **Dose** : 1 tablet twice a day. **Duration of Treatment** : 3 months

Patient assessment was done on following parameters :
Clinical parameters- Weight of mother, Blood Pressure, Pedal oedema, Anaemia
Hematological and Biochemical parameters- Haemoglobin, TLC, BSL Fasting and Post-Prandial, Serum SGPT, Total Bilirubin, serum albumin, serum protein, serum creatinine, Urine routine and microscopic
Ultrasonography parameters- Fetal weight, Umbilical artery S/D ratio , AFI / Liquor abnormalities , Femur Length/Abdominal Circumference ratio , *Garbhashosha* (IUGR).

Observations and Result:

Results were assessed on the basis of differences in clinical parameters, ultrasonography findings and haematological and bio-chemical blood parameters. (Refer table 1,2,3,4,5)

Table 1 showing effect on parameters of 50 patients of Trial group by paired 't' test.

Sr.No	PARAMETER	Mean ± SD	Mean ± SD	Mean of Difference	SE	t	P
		BT	AT				
1.	HB%	10.798 ± 1.283	11.428 ± 1.604	-0.6300± 1.388	0.1964	3.208	0.0024
2	TLC	8068.4± 2521.6	7069.4± 3034.8	999.00± 3975.6	562.23	1.777	0.0818
3	BSL F	81.240± 9.108	94.840± 17.838	-13.600± 17.465	2.470	5.506	< 0.0001
4	BSL PP	90.500±	95.920±	-5.420±	1.633	3.320	0.0017

		7.473	8.078	11.544			
5	SGPT	16.820± 8.113	14.200± 3.648	2.620± 8.317	1.176	2.227	0.0305
6	SR. ALBUMIN	3.820± 0.5237	4.130± 0.3512	-0.3100± 0.5614	0.07940	3.904	0.0003
7	T.BILIRUBIN	0.7800± 0.4815	0.7540± 0.1474	0.02600± 0.5158	0.07294	0.3564	0.7230
8	SR. CREATININE	0.6620± 0.1308	0.6660± 0.05573	-0.00400± 0.1324	0.01873	0.2136	0.8317
9	SR. PROTEIN	6.874 ± 0.6321	7.342± 0.6421	-0.4680± 0.8115	0.1148	4.078	0.0002
10	FL/AC USG	21.700± 1.216	22.000± 0.8081	-0.3000± 1.474	0.2085	1.439	0.1565
11	S/D UMBILICAL ARTERY	2.997± 0.6564	2.541± 0.2281	0.4558± 0.6315	0.08931	5.103	<0.0001
12	FETAL WEIGHT	501.27± 220.10	2510.7± 441.30	-2009.4± 383.02	54.168	37.096	<0.0001
13	LIQUOR	0.9800± 0.1414	1.040± 0.2828	-0.06000± 0.3136	0.04435	1.353	<0.0001
14	MATERNAL WEIGHT	52.440± 9.643	58.060± 10.007	-5.620± 1.828	0.2586	21.736	<0.0001

Table 2 showing effect on parameters of 50 patients of Control group by paired 't' test.

Sr.No	PARAMETER	Mean ± SD	Mean ± SD	Mean of Difference	SE	t	P
		BT	AT				
1	HB%	10.300 ± 1.297	9.808± 1.098	0.4920± 1.218	0.1723	2.856	0.0063
2	TLC	8542.4 ± 2265.0	8387.0 ± 1930.4	155.40± 2989.4	422.76	0.3676	0.7148
3	BSL F	84.920 ± 8.063	102.68 ± 16.892	-17.760± 19.226	2.719	6.532	<0.0001
4	BSL PP	87.120 ± 8.366	99.760 ± 13.528	-12.640± 19.054	2.695	4.691	<0.0001
5	SGPT	18.860	19.740	-0.8800±	1.517	0.580	0.5645

		± 6.596	± 8.637	10.726		1	
6	SR. ALBUMIN	0.7560 ± 0.09293	0.7620 ± 0.0753	0.00600±0.1284	0.01816	0.3304	0.7425
7	T.BILIRUBIN	3.858± 0.2778	3.738± 0.2547	0.1200± 0.2770	0.03918	3.063	0.0036
8	SR. CREATININE	0.6840 ± 0.1037	0.7060 ± 0.1132	-0.0220± 0.1375	0.01944	1.132	0.2633
9	SR. PROTEIN	6.956± 0.4021	6.802± 0.3426	0.1540± 0.4773	0.06750	2.281	0.0269
10	FL/AC USG	21.780 ± 89.520	22.220 ± 344.74	-0.4400± 323.42	0.1718	2.561	0.0136
11	S/D UMBILICAL ARTERY	2.982 ± 0.1815	2.624± 0.2076	0.3580± 0.2963	0.04190	8.544	<0.0001
12	FETAL WEIGHT	473.90 ± 89.520	2514.1 ± 344.74	-2040.2± 323.42	45.739	44.606	<0.0001
13	LIQUOR	0.9800 0.1414	1.040± 0.2828	-0.0600± 0.3136	0.04435	1.353	0.1824
14	MATERNAL WEIGHT	50.380 ± 7.137	55.760 ± 7.639	-5.380± 1.640	0.2319	23.197	< 0.0001

Table 3 showing comparison between two group by Unpaired 't' test.

Sr.No	PARAMETER	Mean difference± SD	Mean difference ± SD	SE	t	P
		Gr.A	Gr.B			
1	HB	0.6300 ±1.388	-0.4920 ±1.218	0.1723	4.295	< 0.0001
2	TLC	999.00± 3975.6	-155.40± 2989.4	422.76	1.641	0.1040
3	BSL F	13.600± 17.465	17.760± 19.226	2.719	1.132	0.2602
4	BSL PP	5.420 ± 11.544	12.640± 19.054	1.517	2.292	0.0241
5	SGPT	-2.620±	0.8800 ±	1.176	1.823	0.0713

		8.317	10.726			
6	T.BILLIRUBIN	-0.02600± 0.5158	-0.1020± 0.2676	0.03785	0.9248	0.3573
7	SR.PROTEIN	0.4680± 0.8115	-0.1540 ± 0.4773	0.06750	4.672	< 0.0001
8	SR.ALBUMIN	0.3100 ± 0.5614	-0.1020 ± 0.2676	0.03785	4.684	< 0.0001
9	SR.CREATININE	0.004000 ± 0.1324	0.02200 ± 0.1375	0.01944	0.6669	0.5064
10	MATERNAL WEIGHT	5.620±	5.380±	0.2319	0.6910	0.4912
11	USG FL/AC	0.3000 ± 1.474	0.4400± 1.215	0.1718	0.5182	0.6055
12	FETAL WEIGHT	2009.4± 383.02	2040.2± 323.42	45.739	0.4344	0.6650
13	S/D UMBILICAL ARTERY	-0.4558± 0.6315	-0.3580± 0.2963	0.04190	0.9913	0.3240
14	LIQUOR	-0.02000± 0.2466	-0.04000± 0.2828	0.04000	0.3769	0.7071

TABLE 4 : Comparison of Incidences of Pedal edema after treatment in patients

	Group-A	Group-A	Group-B	Group-B
Pedal edema	PATIENT No	%	PATIENT No	%
GR 0(absent)	45	90	41	92
GR 1(mild)	4	8	8	16
GR2(moderate)	1	2	1	2
GR 3(severe)	0	0	0	0

TABLE 5 : **Comparison of Incidences of hypertension after treatment in patients**

	Group-A	Group-A	Group-B	Group-B
Hypertension	PATIENT No	%	PATIENT No	%
GR 0(absent)	49	98	48	96
GR 1(mild)	1	2	2	4
GR2(moderate)	0	0	0	0
GR 3(severe)	0	0	0	0

Discussion:

Effect of *Garbhpal ras* on hemoglobin percentage: (Table 1,2,3)

It was observed that 32 patients (64%) in trial group showed increase in Hb%, 3 patients (6%) showed no change in Hb%, 15 patients (30%) showed fall in Hb%.
In control group 15 patients (30%) showed increase in Hb% and 35 patients (70%) showed fall in Hb%.
In spite of giving iron supplementation we found low haemoglobin count in patients during study period. This may indicate the impaired iron absorption leading to iron deficiency. Usually the demand of iron increases in 2nd and 3rd trimester. So Hb% falls in this period. When *Garphapalras* was administered in 50 patients of the trail group, 32 patients (64%) showed increased Hb% , means the drug either improves the iron absorption by correcting metabolism or gives direct supplementation in form of *Lohabhasma* or both ; and this effect is lacking in Placebo group where only 30% showed increase in Hb% and 70% showed fall in Hb% which was physiological.

Effect of *Garbhpal ras* on biochemical parameters of blood (Table 1,2,3)
Level of blood sugar was found within normal range in all groups. No incidence of hypo/ hyperglycemia was observed in any of the case (Table 1). Liver function (serum bilirubin, SGPT, serum albumin, serum protein) and renal function (serum creatinine)
were maintained during ante-natal period in trial group as well as control group
(Table 1 and 2). Normal levels of biochemical parameters till the end of treatment, show non-toxic nature of '*Garbhpal Ras*'.

Effect of *Garbhpal ras* on clinical parameters/ outcome of Pregnancy: (Table 1,2,3)
Pedal edema (Table 4)-The occurrence of pedal edema after treatment was 10% in trial group whereas 18% in control group. This suggest that incidence of pedal edema was less in trial group. Statistical analysis for padal edema shows that there is no difference in both the groups. **Maternal weight gain** - It was found that trial group patients show on an average 10.70% weight gain and control group patients show 10.67% weight gain which is statistically significant in both groups.
Blood pressure (Table 5) - Incidence of mild hypertension in trial group was 2% and in control group was 4% after completion of study which is statistically insignificant.
Incidence of Oligohydromnios and polyhydromnios -In trial group 94% patients have normal AFI and in control group 92% patients have normal AFI after completion of study. Two patients developed oligohydromnios in trial group and 1 patient in placebo group. One patient developed polyhydromnios in trial group and 2patients in placebo group. This is statistically insignificant.
Incidence of IUGR - In trial group was 8% and in control group was 6% fetus developed IUGR after completion of study. This is statistically insignificant**.**
Fetal weight gain – Results were extremely significant for both groups.

Effect of *Garbhpal ras* on ultrasonography parameters : (Table 1,2,3)

The change in Ratio of femur length and abdominal circumference [FL/AC] in both groups was statistically insignificant.

Amniotic Fluid Index [AFI] - This result is statistically non-significant in both groups.Umbilical Artery Doppler Ultrasound (S/D) is a powerful predictor of adverse perinatal outcomes in high risk pregnancies. In this study no patient in either group showed abnormal findings in the above investigation.

In trial group 4 patients (8%) developed IUGR diagnosed by ultrasound. In *Garbhapalras* contents following drugs control group 3 patients (6%) developed IUGR. Rest all patients showed normal fetal growth pattern.

Fetal weight assessment by ultrasound was extremely significant for both groups. We can find that this study is non-conclusive about the effect of *Garbhapal ras* on FL/AC, AFI, Umbilical Artery S/D. Large sample size studies may be helpful for deciding role of *Garbhapalras* in this.

About Drug efficacy

Drugs	Actions
Hingul	*Yogavahi, Rasayan*
Nagbbhasma,	*Balya* to Uterus.
Vangbhasma	*Balya* to reproductive organs
Trijatak	*Shukra-dhatuvardhak*
Trikatu, chavya	*Deepan, Pachan, Hrudya*
Dhanyak	*Deepan, Pachan*
Krushnajeerak	*Mutral, Pittashamak*
Draksha	*Dahashamak,*
Devadaru	*Garbhsthapak, Gabhashaybalya, Kledanashak*
Lohabhsma	*Raktadhatuvardhak, balya, Rasayan*
Vishnukranta	*Garbhasthapak, Vatashamak, Balya to Garbha and Garbhashaya.* Decreases irritation in nerves and brain. Haemostatic action

Garbhapalrasa has *deepan, pachak, kledaghna, rasayan* properties, *improves Jatharagni* and *Dhatvagni*. It helps in the formation of good quality of *Aahar rasa* in pregnancy. This helps to produce *Uttarottar 'Sara Dhatu and Upadhatu'* in *garbhini*. *Lohabhasma* is a rich source of iron. *Trikatu, trijatak, devadaru* helps in

improving metabolism. It helps to maintain good health and prevents occurrence of complications during pregnany.

All this leads to generation of *'Sara Dhatu* and *Upadhatu'* in foetus and its proper growth and development.

Conclusion:

Conclusions are drawn which are based on tables and graphs,statistical analysis and discussion done in previously.

In the present study *Garbhapalras* administration produce statistically significant increase in the Hemoglobin concentration of pregnant women. This shows its role in Iron metabolism in pregnancy. Normal haematological, biochemical parameters, maintained liver and renal function and maintained Ultrasonoghraphy parameters suggests safe use of *Garbhapal ras*.

Garbhapal ras in 125 mg does not produce hepatotoxicity or nephrotoxicity when given with milk anupana for 3 months. Incidences of intrauterine fetal death or other complications to the fetus were not found during study period. All above findings suggests that it is safe to use *Garbhapal ras* in pregnancy in 125 mg BD dose along with milk in second and third trimester.

Ethical committee permissions details:

Ethical committee permission was taken before conducting the study.

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Conflict of Interest: Non

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