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RANDOMISED CLINICAL CONTROLLED STUDY OF KASHMARYADI 'KSHEERPAN' AND 'TIL TAIL MATRA BASTI' IN MANAGEMENT OF GARBHASHOSH (IUGR)

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ABSTRACT
Asymmetric Intrauterine growth retardation (IUGR) is a major problem observed in pregnant women. There is need to study the reason for selection of the disease Garbhashosha (IUGR) and its importance. Analytical study of drug sample was done in the standard lab. About sixty numbers of patients were examined under the inclusion and exclusion criteria, clinical assessment and ultrasound based parametric assessment, investigation criteria & criteria of diagnosis were explained. Statistical tests applied to collected data and results have been drawn in this section. It is studied that the drug therapy has effective action on Garbhashosha. Kashmaryadi ksheerpan and Til Tail matrabasti is proved highly significant in increasing symphysis fundal height, abdominal girth and fetal weight.

KEYWORD: Kashmaryadi- ksheerpan, Til -tail matra basti, Garbhashosha (IUGR).

INTRODUCTION
Pregnancy is a very precious moment of women's life as it highlights the woman's amazing creative and nurturing powers while providing a bridge to the future. The best gift of Motherhood is undoubtedly power of regeneration, conception, successful pregnancy and birth of baby. All these are the blessing for every woman. Woman plays a very important role in producing, carrying, bearing fetus in womb, bringing up, maintaining, supporting, & nourishment of child. Conception & growing of fetus in mother's womb is one of the best miraculous processes happening in the world. This process is very complicated to understand. Many times various known and unknown factors can complicate this process creating life-threatening condition for mother and fetus. Antenatal period is said to be most delicate period as woman become more sensitive in all aspect. Ayurveda has described Antenatal care in the form of Garbhini Paricharya i.e. month wise dietary regime. Since the evolution of the life in the universe, women have been placed on extreme worship due to her power of 'Janani'. Many times various known and unknown factor can complicate this process creating a life threatening condition for mother and fetus. One of these conditions is Garbhshosha i.e. I.U.G.R.

Intrauterine growth restriction is said to be present in those babies whose birth weight is below the 10th percentile of the average for gestational age. Babies who have IUGR are more likely to have certain health problems (both during pregnancy and after birth). These problems faced by babies due to Garbhashosha are difficult to control. Usually IUGR is not due to maternal causes, neither genetic nor placental. Most frequently related conditions are like poverty, chronic malnutrition, placental insufficiency, drug abuse and under nutrition are most correctable causes of Garbhshosha i.e. IUGR in developing countries like India.

In modern medicine, treatment of Garbhshosha(I.U.G.R) is empirically directed towards weight gain of mother and fetus by rest, O_2 therapy, gluco-corticosteroids, nutrition with high protein diet, hydration, mechanical therapy and pharmacological therapy i.e. low dose aspirin, hyper alimentation in the form of trans amniotic, intragastric and intravenous routes. It is very clear form foresaid facts that treatment is cost effective, time consuming and with drastic side effects of drugs and steroids on pregnant mother. At present, there is no proven therapy in modern science for reversing growth restriction. All these facts highlighted that mother suffering from Garbhashosha(intra uterine growth restriction), has to face a lot of problems. Taking foresaid facts in mind thoughts triggered me that both Kashmaryadi ksheerpan and Til Tail Matra Basti if administered in combination may give more beneficial

effects. If this proves its efficacy it well be a great achievement through Ayurveda to the obstetrics science. Hence in a humble attempt to expand the concept of Garbhashosha according to Ayurveda and to yield a flourishing result to this world wide problem through Ayurveda, this has been selected for the study. Therefore present study entitled "Controlled Clinical Evaluation of Kasmaryadi 'Ksheerpan' and Til Tail 'Matra Basti' In Management of Garbhashosha (IUGR)" has been evaluated. The study outcome of this research paper may be helpful to the researcher in future.

MATERIALS AND METHODS

- **Study type**-Open randomized controlled study.
- **Ethical clearance**-clearance from ethical committee of our institute was taken.
- **Consent**-An informed written consent of all 60 patients included in study was taken in the language best understood by them. Their disease and line of treatment was explained to them.
- **Subject Recruitment**- Patients were selected from OPD and IPD of our institute.

Groups of management

1. **Group A:** This group was termed as 'Trial Group'

a) Number of patients: 30
b) Treatment: Kasmaryadi Ksheerpan and Til Tail Matra basti.
c) Dose: 80 ml Ksheerpan by oral route daily and Til Tail Matrabasti 50ml weakly ones.
d) Duration of treatment: 1 month.

2. **Group B:** This group was termed as, 'Controle Group'.

a) Number of patients: 30
b) Treatment: Inj. Alamine SN and Cap Alamine Fort.
c) Dose: Cap Alamine Fort orally twice daily and Inj. Alamine SN 200ml by intravenous routes, on every 4th day for five consecutive cycles.
d) Duration of treatment: 1month.

Inclusion Criteria

1) All the pregnant women with IUGR, having more than 28 weeks to 38 weeks of gestation.
2) Patients having age between 18-40 years
3) Patients having HB% >8 gm%

Exclusion Criteria

1) Patients with less than 28 weeks of gestation.
2) Multiple pregnancies.
3) Patients having HB% <8 gm%.
4) Patients having cyanotic heart disease.
5) Patients having STDs, HIV, etc.
6) Patients having diabetes mellitus.
7) Patients having PIH.

Preparation of Kashmaryadi siddha ksheerpaka for ksheerpan

Bharada churna of the all dravyas were taken 1.5gms of each along with 80ml ksheera and 320ml of water and ksheerpak was prepared.

- **Contents of ksheerpak for ksheerpan**

Ingredient	Quantity
Kashmari phala bharad churna	1.5gms
Yashtimadhu bharad churna	1.5gms
Sita	1.5gms
Cow milk	80ml
Water	320ml

Clinical examination

Complete systemic examination from the point of view of Garbhashosha was done to diagnose and assess the patient's disease condition. Patients undergoing study were examined clinically for every follow up and record was mentioned.

Criteria of Assessment

Patients having presenting complaints of Garbhashosha were assessed with respect to following points.
*Clinical parameters
*Ultrasound based Parameters

- **Parameters to be observed**

The diagnosis of Garbhashosha was done on the basis of clinical observations and also by ultrasonography based parameters and the clinical profile was mentioned. Readings was taken before and after completion of treatment.

i. Clinical Parameters: Abdominal girth in cm, Fundal height in cm.
ii. Ultrasound Parameters: AC, AFI, AFW.

Follow up

At 1st visit complete systemic examination was done with all required investigation and USG scan. Consent was taken and required treatments were started. Follow up of 7 day, 15 day and 1month was given. Symptomatic assessment was done on 1st month, record was maintained. At the end of 1st month of treatment all required investigations and USG scan were done. Efficacy of treatment was concluded with the help of clinical, and USG parameters mentioned above.

Analysis of data

The data collected from the CRF were then subjected to Demographic and statistical analysis. To assess the effect of therapy on clinical and USG parameters 'students paired t test' was applied to the data generated. Comparison between two groups was done by using 'Unpaired t test'. The 'chi square test' was applied to the total effect of therapy. The significance of data was analyzed at 5% level of significance. Thus the statistical analysis was done to find out the significance of the difference in the improvement.

RESULTS AND DISCUSSION

The study entitled "Controlled Clinical Evaluation of Kashmaryadi Ksheerpan and Til Tail Matra Basti In The Management Of Garbhashosha (IUGR)" was planned to evaluate effect of Kasmaryadi Ksheerpan and Til Tail Matra Basti in Garbhashosha. For that 30 patients were studied in the trial group in which patients were selected as per criteria of diagnosis to whom Kashmaryadi Ksheerpan And Til Tail Matra Basti was given as per the dose prescribed in materials methods. To compare the results of Kashmaryadi Ksheerpan And Til Tail Matra Basti a standard known effective drug Cap. Alamine and Inj. Alamine SN given to control group comprising 30 patients of Garbhashosha.

Prior to start of the study in both groups, patients selected for study were closely observed and detailed history of patients was evaluated as per proforma of Case Record Form. Ultrasonography scan and all routine investigation were carried out and these values were termed as before treatment. As well as the status of the patients was also recorded with respect to symptoms and signs found in the patients. After completion of duration, all the patients of this series from both groups were again explored for the investigations which were carried out before starting the treatment, all these values were recorded as after treatment values. The status of all parameters was also noted down after completion of treatment. Thus change in the status of parameters was recorded.

The history recorded on case record from, revealed the facts and findings, which are presented herewith in the tabular form. Some of them are highlighted with the help of graphical presentations.

Demographical data

Table no. 1: Table showing Age Wise Distribution of 60 pregnant Women with A symmetrical IUGR.

Sr.no.	Age Group (years)	Trial Group		Control Group		Total	
		No.of Pts	%	No.of Pts	%	No.of Pts	%
1	18-20	4	13.33	3	10	14	23.33
2	21-25	15	50	14	46.66	29	48.33
3	26-30	9	30	8	26.66	17	28.33
4	31-35	1	3.33	3	10	4	6.66
5	35-40	1	3.33	2	6.66	3	5

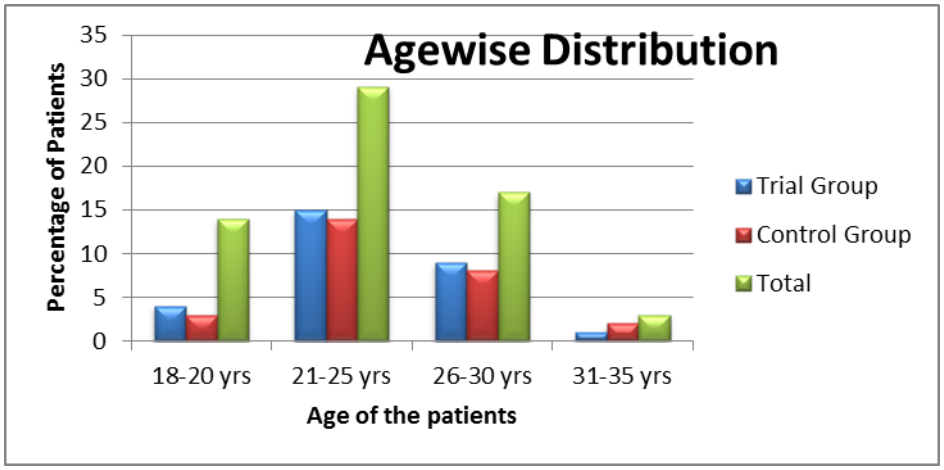

Table no. 2: Table showing occupation wise distribution of 60 patients of a Symmetrical IUGR.

Sr.no.	Occupation	Trial Group		Control Group		Total	
		No. of Pts	%	No. of Pts	%	No. of Pts	%
1	House wife	25	83.33	27	90	52	86.66
2	Labor	3	10	2	6.66	5	8.33
3	Service	2	6.66	1	3.33	3	5

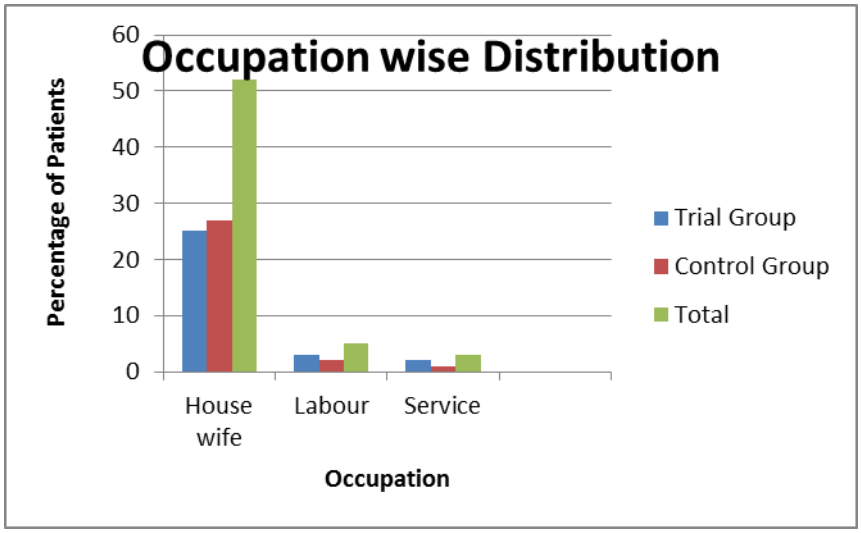

Table no. 3: Table showing gravid wise distribution of 60 Patients of a Symmetrical IUGR.

Sr.no	Gravida	Trial Group		Control Group		Total	
		No. of Pts	%	No. of Pts	%	No. of Pts	%
1	Primi	12	40	10	33.33	22	26.66
2	Second	10	33.33	9	30	19	31.66
3	Multi	8	26.66	11	36.66	19	31.66

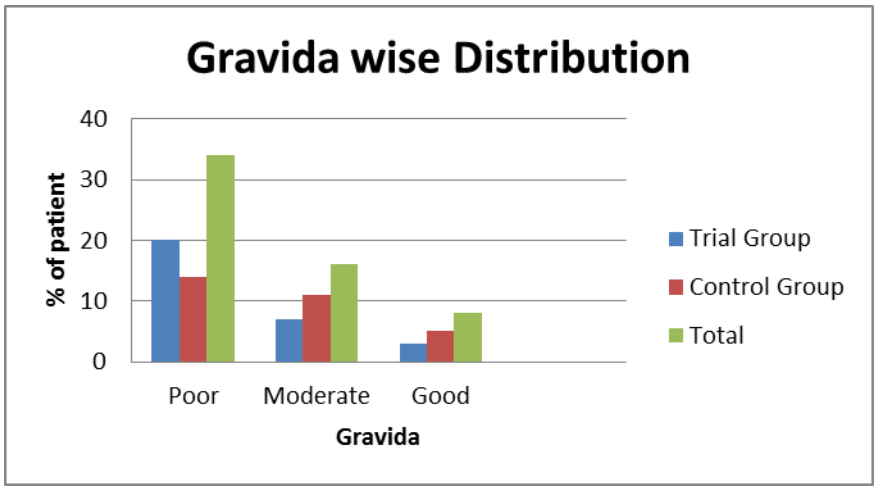

Table no. 4: Table showing Diet wise distribution of 60 Patients of a Symmetrical IUGR.

Sr.no.	Diet	Trial Group		Control Group		Total	
		No. Of Pts	%	No. Of Pts	%	No. Of Pts	%
1	Vegetarian	6	20	8	26.66	14	23.33
2	Mixed	24	80	22	73.33	46	76.66

Table No. 5: Table showing Liquor status at first visit of 60 Patients of a Symmetrical IUGR.

Sr.no.	Liquor	Trial Group		Control Group		Total	
		No. of Pts	%	No. of Pts	%	No. of Pts	%
1	Oligo	12	40	16	53.33	28	46.66
2	Adequate	18	60	14	46.66	32	53.33

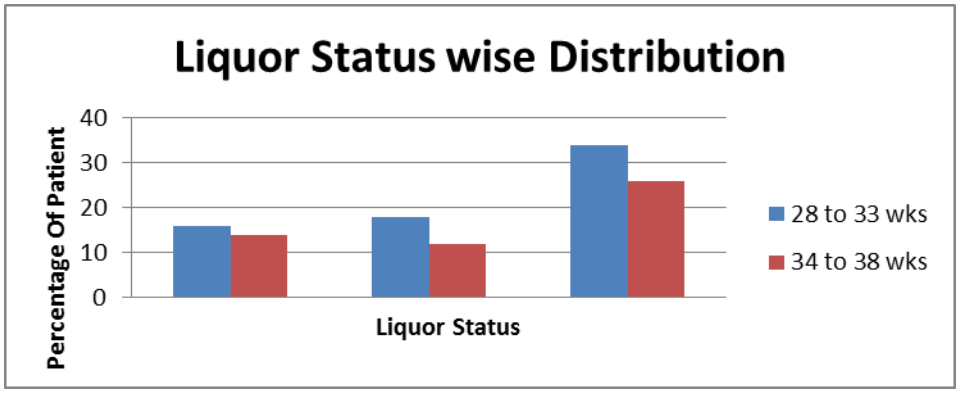

Table No. 6: Table showing distribution of period of gestation of 60 Patients of a Symmetrical IUGR.

Sr.no.	Period of gestation	Trial Group		Control Group		Total	
		No. of Pts	%	No. of Pts	%	No. of Pts	%
1	28 to 33 wks	16	53.33	18	60	34	56.66
2	34 to 38 wks	14	46.66	12	40	26	43.33

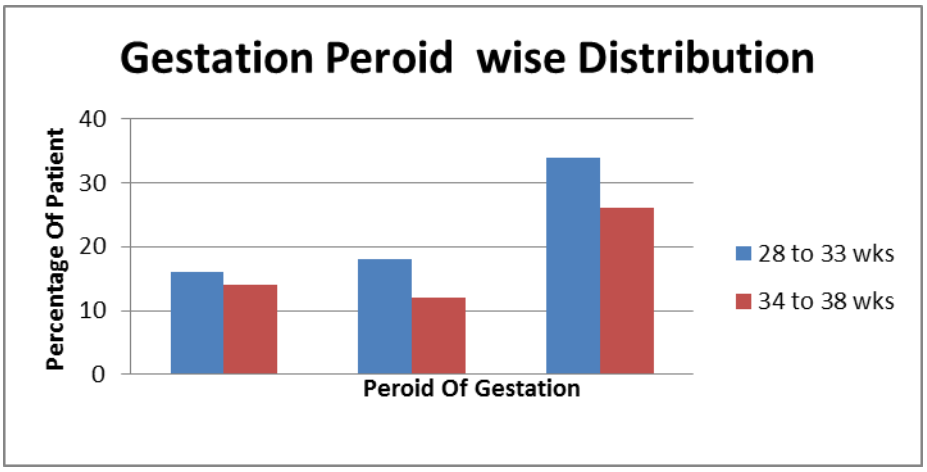

Table no. 7: Table showing effect on parameters of 30 patients of Garbhashosha of Trial group by paired 't'test.

Sr.no	Parameter	Mean + SD		Mean Of Diff+ SD	SE	T	P
		BT	AT				
1	FH	28.75+1.920	31.277+ 2.158	2.527+ 1.157	0.21	11.96	<0.0001
2	AG	83.797+3.155	87.300+ 3.084	3.503+ 2.053	0.37	9.34	<0.0001
3	AC	27.517+2.624	29.940+ 2.378	2.423+ 1.180	0.21	11.24	<0.0001
4	AFI	9.177+2.292	10.983+ 1.534	1.807+ 1.796	0.32	5.5	<0.0001
5	AFW	2049.13+459.1	2485.30 + 434.38	436.20+ 177.28	32.3	13.47	<0.0001

Table no. 8: Table showing effect on parameters of 30 patients of Garbhashosh of control group by paired't' test.

Sr.no.	Parameter	Mean + SD		Mean Of Diff + SD	SE	T	P
		BT	AT				
1	FH	28.067+ 2.333	29.677+ 2.603	1.610+ 0.803	0.146	10.97	<0.0001
2	AG	85.583+ 3.504	87.337+ 3.129	1.75+ 0.6907	0.126	13.90	<0.0001
3	AC	25.461+ 2.052	27.75+ 1.827	2.244+ 0.8412	0.153	14.60	<0.0001
4	AFI	7.553+ 1.838	10.367+ 1.273	2.813+ 1.408	0.257	10.94	<0.0001
5	AFW	1783.9+ 359.13	2150.6 + 355.13	366.70+ 132.82	24.25	15.12	<0.0001

Table no. 9: Table showing comparison between two groups by unpaired't' test.

Sr.no	Parameter	Mean of difference + SD		SE	T	P
		Trial group	Control Group			
1	FH	2.527+ 1.157	1.610+ 0.8036	0.257	3.564	<0.0001
2	AG	3.503+ 2.053	1.753+ 0.6907	0.395	4.288	<0.0001
3	AC	2.190+ 1.335	1.904+ 0.8944	0.92	0.979	0.1
4	AFI	1.807+ 1.796	2.813+ 1.408	0.417	2.416	<0.0001
5	AFW	436.20+ 177.28	366.70 + 132.82	40.44	1.718	<0.1

Table no. 10: Table showing Total effect of therapy on 60 patients of Garbhashosha.

Sr.no	Total effect of therapy	Trial Group		Control Group		Total effect of therapy	
		No. of Pts	%	No. of Pts	%	No. of Pts	%
1	Upashaya	27	90%	25	83.33%	52	86.66%
2	Anupashaya	3	10%	5	16.66%	8	13.33%

- **Plan of study**

We selected 60 patients of Garbhashosh (IUGR), having their written consent. These patients were divided into two groups. One group called Ttrial -30 patients, in which Kashmaryadi Ksheerpan and Til Tail Matra Basti was given, while in another group called control group-30 patients to whom Amino acid therapy was given for 1 month. All concerned symptoms and foresaid investigations were reported, after the completion of therapy in both the groups. The result and observations obtained are discussed here with as follows-

- **Effect of therapy**

1) Mean of difference of fundal height in trial group was 2.5 cm while in control group was 1.6 cm. This indicates that trial group therapy is more effective.
2) Mean of difference of abdominal girth in trial group was 3.5 cm and in control group was 1.7 cm. This indicates that trial group was more effective.
3) The mean of difference of abdominal circumference in trial group was 2.4 cm while in control group was 2.2 cm. This also indicates that trial group therapy is more effective.
4) The amniotic fluid index it was increased by 1.8 cm in trial group and 2.8 cm in control group that indicates control group therapy is more effective.
5) Mean of difference of approximate fetal weight in trial group was 436.2gm while in control group was 366.7gm. This indicates that trial group therapy is more effective.
6) From the foregoing, it can be deciphered that Trial group drugs were more effective in both fetal growth and abdominal circumference. Control group drugs have also shown better effect.
7) Thus from statistical analysis, one can comment that in IUGR, Kasmaryadi Ksheerpan and Til Tail Matra basti has better effect over Inj. Alamine.
8) Patients of trial group showed improvement in weakness, fatigue, general debility etc.
9) Birth weight significantly increased with Kasmaryadi Ksheerpan and Til Tail Matra basti, most of babies were fair in complexion and good muscle tone.
10) This shows that basti improve quality of life of mother along with fetus.

- **Total Effect of Therapy**

In case of trial group 25 patients (83.33%) got upashaya and 5 patients(16.66%) got Anupashaya. In case of control group 21 patients(70%) got upashaya and 9 patients(30%) got Anupashaya.

Comparison between two groups by chi-square test:
Comparison between two groups was statistically evaluated by Chi-square test. The value is 0.7041($p<0.05$) which was statistically insignificant which suggested that there is no significant difference between two groups with respect to total effect of therapy.
Yates correction=0.1442

CONCLUSION

1) Total 60 pregnant women were registered in present Clinical study. Maximum no. of patients (56.66%) were in the 28-33 weeks of gestation age.
2) Maximum patients (48.33) belong to 21-25 years age.
3) 53.33% patients used to have oligohydramnios.
4) Kasmaryadi Ksheerpan and Til Tail Matra basti is proved highly significant in increasing fundal height, abdominal girth, and fetal wt.

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