WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.084
Volume 10, Issue 13, 1650-1657. Research Article ISSN 2277– 7105

CONTROLLED CLINICAL EVALUATION OF VIDARYADI GANA SIDDHA KSHIRPAN AND KSHIRBASTI IN THE MANAGEMENT OF GARBHASHOSH [IUGR]

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Article Received on
05 Sept. 2021,

Revised on 26 Sept. 2021,
Accepted on 17 October 2021

DOI: 10.20959/wjpr202113-22107

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INTRODUCTION

Concept of fetal well being has gained importance in conventional science in recent era but this concept of **'supraja janana'** was a prime concern of Ayurveda since old era. Apart from prematurity, **intrauterine growth restriction** is a major public health problem in most of the developing countries. In Ayurvedic text, this today's severe and universal problem is stated shortly as Garbashosha. According to all Acharya's Kshaya or shosha is one of the Karma of Vata, Basti is the main treatement for Vata dosha it has been selected as the line of treatment. A principle of treatment of all dosh dhatujanyakshaya should be treated with dravyas having similar Yoni.Also Acharyas Kashapa gives preference to Kshir as is provides nutriment and stability to the fetus. Hence above subject is taken for study

KEYWORDS: Garbha shosha, vidaryadi Gana, kshir basti, khirpan, IUGR.

Aims and Objectives

To study the effect of Khirbasti and Kshirpan on Garbhshosh.

To evaluate the combined effect of Kshirbasti & Kshirpan on Garbhashosh.

MATERIALS AND METHOD

- **Study type** - Open randomized controlled study.

Groupes of management

- **Group A**: 'Trial Group'.

- **Number of patients**: 30
- **Treatment**: Vidaryadi Gana sidha kshirpan & kshirbasti.
- **Dose**: 80 ml kshirpan by oral route and 400 ml kshirbasti by transrectal route, daily.

Duration of Treatment: 15 days.

Vydaryadi gana kshirpakabasti consist of Bharad churna of, vidarikanda, Gokshur, Sariva, Yahtimadhu, Punarnava, Shalparni and sita each were taken 3 gms. Gokshir (cow milk) was taken 160ml and water 640ml added to it and ksheerpak done as per sharagdhara. Tiltail, cowghee, honey 80ml each added to sukhoshna (Lukewarm) kshirpak, was well churned using churning staff. Bastidharan kala is noted

Group B: 'Controle Group'.

- **Number of patients** : 30
- **Treatment**: Inj. Alamine SN and Cap Alamine Forte
- **Dose**: Cap Alamine Forte oraly twice daily and Inj. Alamine SN 200 ml by intravenous route, on every 4th day for five consecutive cycles.
- **Duration of Treatment**: 15 days.

Inclusion Criteria: All the pregnant women with IUGR, having more than 28 wks to 38 wks of gestation. 2) Patients having age between 18-40 yrs.) Patients having Hb% more than 8 gm%.

Exclusion Criteria: 1) Patients with less than 28 wks of gestation. 2) Multiple pregnancies, 3) Patients having Hb% less than 8gm%. 4) Patients having cyanotic heart disease. 5) Patients having STDs, HIV. 6) Patients having diabetes mellitus. 7) Patients having PIH **Diagnosis:** The diagnosis of Garbhashosh was done on the basis of clinical observations and also by ultrasonography based parameters and the clinical profile was mentained. Readings were taken before and after completion of treatment

Clinical Parameters: 1) Abdominal girth in cm 2) Fundal height in cm.

Ultrasound Parameters: AC, AFI,AFW,PI

Criteria of Assesment: Patients having presenting complaints of Garbhashosh were assessed with respect to following points

- Clinical Parameters

- Ultrasound based Parameters

Follow up

At 1st visit complete systemic examination was done with all required investigations and USG scan. Consent was taken and required treatment was started. Follow up of 7 days and 15 days was given. Symptomatic assesment was done on 15th day and record was maintained. At the end of 15th day 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 analysed at 5% level of significance.

Thus the statistical analysis was done to find out the significance of the difference in the improvement.

Total effect of therapy: The total effect of therapy was concluded on the basis of relief in percentage. All the patients were categarised in two categories, upashaya and unupashaya, according to relief experienced and the calculated relief from various clinical and USG parameters. It is as follows

1) **Upashaya** –Total relief and improvement in all parameters such as AFI, AFW, AC, PI, AG and FH has been considered in this category.
2) **Anupashaya** - Those patients presenting no improvement in their parameters has been catagorised as Anupashaya.

Table showing effect on parameters of 30 patients of Garbhashosh 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	0.211	11.96	<0.0001
2	AG	83.797± 3.155	87.300± 3.084	3.503± 2.053	0.374	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	2485.303± 434.38	436.20± 177.28	32.3	13.47	<0.0001
6	PI	7.061± 0.461	7.420± 0.348	0.358± 0.408	0.07	4.81	<0.0001

Effect of therapy on parameters of trial group: Effect of therapy on parameters was statistically evaluated in trial group by paired 't' test as follows,

1. Symphysis pubis to fundal height -The mean fundal height in trial group before starting the treatment was 28.750±1.920which was increased upto31.277± 2.158. increase in fundal height by 2.527±1.157was tested statistically by paired 't' test . 't' was11.962 which was highly significant, $p < 0.0001$. **2. Abdominal Girth** The mean Abdominal Girth in trial group before starting the treatment was 83.797± 3.155which was increased upto87.300±3.084 Increase in Abdominal Girth by3.503±2.053 was tested statistically by paired 't' test. 't was 9.347' which was highly significant, $p < 0.0001$. **3. Abdominal circumference** The mean Abdominal circumference in trial group before starting the treatment was27.517± 2.624 which was increased upto29.940± 2.378. Increase in Abdominal circumference by 2.423±1.180 was tested statistically by paired 't' test . 't' was 11.249 which was highly significant, $p < 0.0001$. **4. Amniotic fluid index** The mean Amniotic fluid index in trial group before starting the treatment was 9.177 ± 2.292 which was increased upto10.983± 1.534 increase in Amniotic fluid index by was1.807± 1.796 tested statistically by paired 't' test . 't' was 5.509 which was highly significant, $p < 0.0001$. **5. Aproximate fetel weight** The mean Aproximate fetel weight in trial group before starting the treatment was2049.130 ± 459.14 which was increased upto2485.303± 434.38 increase in Aproximate fetel weight by 436.20± 177.28 was tested statistically by paired 't' test . 't' was13.476 which was highly significant, $p < 0.0001$. **6. Ponderal index** The mean Ponderal index in trial group before starting the treatment was 7.061±0.461which was increased upto 7.420± 0.348 increase in Ponderal index by0.358± 0.408 was tested statistically by paired 't' test . 't' was4.810 which was highly significant, $p < 0.0001$.

Table showing effect on parameters of 30 patients of Garbhashosh of controle 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	0.1467	10.97	<0.0001
2	AG	85.583± 3.504	87.337± 3.129	1.75± 0.6907	0.1261	13.90	<0.0001
3	AC	25.461± 2.052	27.7.5± 1.827	2.244± 0.8412	0.1536	14.60	<0.0001
4	AFI	7.553± 1.838	10.367± 1.273	2.813± 1.408	0.2571	10.942	<0.0001
5	AFW	1783.9± 359.13	2150.6± 355.13	366.70± 132.82	24.250	15.122	<0.0001
6	PI	6.785± 0.500	7.239± 0.339	0.454 ± 0.339	0.0620	7.327	<0.0001

Effect of therapy on parameters of control group

Effect of therapy on parameters was statistically evaluated in control group by paired 't' test as follows,**1. symphysis pubis to fundal height -**The mean fundal height in control group before starting the treatment was 28.067± 2.333which was increased upto29.677± 2.603 increase in fundal height by 1.610± 0.803 was tested statistically by paired 't' test . 't ' was 10.97 which was highly significant, p < 0.0001**2. Abdominal Girth** The mean Abdominal Girth in control group before starting the treatment was 85.583± 3.504which was increased upto 87.337± 3.129. Increase in Abdominal Girth by1.75± 0.6907 was tested statistically by paired 't' test. 't' was 13.90which was highly significant, p < 0.0001**3. Abdominal circumference** The mean Abdominal circumference in control group before starting the treatment was25.461± 2.052 which was increased upto 27.7.5± 1.827 Increase in Abdominal circumference by2.244± 0.8412 was tested statistically by paired 't' test . 't' was14.60 which was highly significant, p < 0.0001

4. Amniotic fluid index: The mean Amniotic fluid index in control group before starting the treatment was 7.553± 1.838 which was increased upto10.367± 1.273 increase in Amniotic fluid index by2.813± 1.408 was tested statistically by paired 't' test . 't' was10.942 which was highly significant, p < 0.0001

5. Aproximate fetel weight The mean Aproximate fetel weight in control group before starting the treatment was 1783.9± 359.13which was increased upto2150.6± 355.13 increase in Aproximate fetel weight by366.70± 132.82 was tested statistically by paired 't' test . 't' was15.122 which was very highly significant, p < 0.001

6. Ponderal index The mean Ponderal index in control group before starting the treatment was 6.785 ± 0.5000 which was increased upto 7.239 ± 0.339 increase in Ponderal index by 0.454 ± 0.339 was tested statistically by paired 't' test . 't' was 7.327 which was highly significant, p< 0.0001the difference between two groups with respect to these characters only by Unpaired 't' test.

Table 21: Table showing comparison between two group 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±	1.904±	0.92	0.979	0.1

		1.335	0.8944			
4	AFI	1.807± 1.796	2.813±1.408	0.417	2.416	<0.001
5	AFW	436.20± 177.28	366.70± 132.82	40.44	1.718	<0.1
6	PI	0.3588± 0.4087	0.4546± 0.3398	0.009	0.986	0.1

Comparison between two groups was statistically evaluated by Unpaired 't' test

1. Symphysis pubis to fundal height -The mean of difference of trial group was 2.527± 1.157 which was compaired with that of mean of difference in control, it was 1.610± 0.8036. unpaired 't' was 3.564; $p < 0.0001$which suggested that difference of mean exhibited by trial group was highly significant.

2. Abdominal Girth The mean of difference of trial group was3.503± 2.053 which was compaired with that of mean of difference in control, it was 1.753± 0.6907. unpaired 't' was4.288; $p < 0.0001$which suggested that difference of mean exhibited by trial group was highly significant.

3. Abdominal circumference The mean of difference of trial group was 2.190±1.335 which was compaired with that of mean of difference in control, it was1.904±0.8944. Unpaired 't' was0.9792; p was 0.1 which suggested that difference of mean exhibited by trial group was significant.

4. Amniotic fluid index The mean of difference of trial group was 1.807± 1.796 which was compaired with that of mean of difference in control, it was 2.813±1.408 unpaired 't' was 2.416; p < o.oo1 which suggested that difference of mean exhibited by trial group was highly significant.

5. Aproximate fetel weight The mean of difference of trial group was 436.20± 177.28 which was compaired with that of mean of difference in control, it was366.70± 132.82. unpaired 't' was1.71; p < o.1 which suggested that difference of mean exhibited by trial group was highly significant

6. Ponderal index: The mean of difference of trial group was 0.3588± 0.4087 which was compaired with that of mean of difference in control, it was0.4546± 0.3398. unpaired 't' was0.9868; p < o.1 which suggested that difference of mean exhibited by trial group was highly significant.

Total effect of therapy Total effect of therapy has been evaluated in terms of upashaya and anupashaya.

Table 30: Table showing Total effect of therapy on 60 patients of Garbhashosh.

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

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

Comparison between two groups by chi squre 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

- Total 60 pregnant women were registered in present clinical study. Maximum no.of patients (56.66%) were in the 28-33weeks of gestation age
- Maximum patients (48.33%) belong to 21-15 years age
- 48.33% patients had Vata pitta Prakriti.
- In 65% patients Kshirbasti pratyagam Kala was more than 4-6 hours.
- 53.33% patients used to have oligohydramnios.
- Vidaryadi gana sidha khirbasti is proved highly significant in incrising symphysis fundal hight, abdominal girth, fetal wt.

RESULT

- Total effect of therapy has been evaluated in terms of Markedly Improved, Improved and Unchanged.
- In case of trial group 25 patients (83.33%) were got upashaya and 5 patients (16.66%) were got Anupashaya. In case of control group 21 patients (70%) were got upashaya and 9 patients (30%) were got Anupashaya.

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