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A Comparative Clinical Study of the Effect of Dadimadi Ghrita and Ferrous Sulphate in Management of Garbhini Pandu w.s.r. to Anaemia in Pregnancy

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ABSTRACT

Anaemia during pregnancy is a very grievous problem in many parts of the country. This may be due to illiteracy or ignorance of the common people. Garbhini pandu may lead to various different disorders also which can be life threatening as the during pregnancy the female body is in high demand of oxygen and nutrients for herself and also for the foetus. And anaemic condition in this stage can be proved to be fatal both for mother and the child. Iron supplementation during pregnancy is often administered but almost all preparations of iron if given by oral route produce gastritis, leading to epigastric burning, nausea and vomiting. Such iatrogenic problem gives rise to loss of appetite, which further reduces iron intake. Thus, it can be appreciated that therapy with modern iron preparation is troublesome for the patient and not well tolerated. Decrease in circulating blood quantity generalized weakness and lesser development of foetus are common problems in this condition.

Looking into the above-mentioned facts there is a need for treatment which can prevent complication of disease, safer, cost effective and easily available as well as reduce the recurrence effectively for which *Dadimadi ghrita (DG)* which has been advocated by Acharya *Charak* is taken for the study to evaluate its effect on *Garbhini pandu*. After study on 60 patients where *Dadimadi ghrita* was given in 30 patients and ferrous sulphate was given in 30 patients it was found that both the treatments were equally effective in relieving the sign and symptoms of Garbhini pandu like *nakha,*

netra twaka panduta, pindikodweshtana, Hrutspanda, ayasenshwas and klama and also statistically significant with p value<0.001. marked increase was also seen in haemoglobin percentage in both the groups.

Key words: *Garbhini pandu*, Anaemia, *Dadimadi ghrita*, Ferrous sulphate

INTRODUCTION

Anaemia is one of the most common disorder world-wide. Moreover, it is highly prevalent in Indian subcontinent. In the general population the causes are quite varied and it may lead to many other problems in the patient. However, when it is present along with pregnancy, it becomes quite hazardous. In our traditional system of medicine, ***Ayurveda***, anaemia is termed as '*Pandu Roga'* and its entity was known to the *Ayurvedacharyas* from the ancient times.

पाण्डुस्तुपीतभागार्धः केतकी धूलिसन्निभः (च.चि. 16)

पाण्डुत्वेनोपलक्षितोरोगः पाण्डुरोगः (च.चि. 16)

Anaemia when present in pregnancy has been termed as *Garbhini Pandu* in Ayurveda.[1,2] During pregnancy the demand of iron is much more increased because of foetus so in majority of cases the *Garbhini Pandu* is due to deficiency of Iron, which may develop because of variety of reasons. The most common reason for *Garbhini Pandu* is lack of iron in diet.[3,4] Persisting *Garbhini Pandu* during gestation period leads to many minor and even major complications, both in the mother and in the foetus as well. *Garbhini Pandu* is very much similar to Anaemia in Pregnancy in modern medicine which is highly prevalent disorder in pregnancy.[5]

In modern medical science, the treatment of anaemia in pregnancy is supplemental iron therapy (and Folic Acid) either orally or parenterally (in severe cases). Almost all preparations of iron if given by oral route produce gastritis, leading to epigastric burning, nausea and vomiting.[6] Such iatrogenic problem gives rise to loss of appetite, which further reduces iron intake. Thus, it can be appreciated that therapy with modern iron preparation is troublesome for the patient and not well tolerated.Decrease in circulating blood quantity generalized weakness and lesser development of foetus are common problems in this condition.

Looking into the above-mentioned facts there is a need for treatment which can prevent complication of disease, safer, cost effective and easily available as well as reduce the recurrence effectively. Ayurvedic scientists have claimed that the natural drug materials or approaches used according to the Ayurvedic system of medicine are not found to produce any resistance or side effects. *Dadimadi ghrita (DG)* which has been advocated by *Acharya Charak* is taken for the study to evaluate its effect on *Garbhini pandu*.[7]

MATERIAL AND METHODS

In Present clinical study total 60 patients were enrolled from OPD and IPD of Stri & Prasuti rog Department., based on the inclusion and exclusion criteria and divided in two groups. In one group test drug *Dadimadi Ghrita* was given and in the other group Ferrous Sulphate (FS) was given. Among total number of patients, 5 (five) patients dropped out from the study. So complete analysis (clinical) has been done on 55 patients.

Aim and Objectives:

- To Study the *Garbhini Pandu* in detail
- To Study the effect of *Dadimadi Ghrita* in *Garbhini Pandu*
- To compare the effect of *Dadimadi Ghrita* with Ferrous - Sulphate in Garbhini Pandu.

Study Setting: The present study was carried out in Major S.D. Singh P.G. Ayurvedic Medical College and hospital, Distt- Farrukhabad, (U.P.) 209601. The subjects were selected from the patients who reported in the outdoor of the Department of "P.G. Studies in Prasuti Tantra and Stri Roga". This study was conducted for a total period of sixteen months from 01st of January 2017 to 30th of April 2018.

Study Population

- Pregnant women of 21 – 35 years age group
- 2nd 3rd Trimester
- Hb% between 8 gm% to 10% gm Iron deficiency Anaemia

Inclusion Criteria:

1. Nakha-netra-tvak – pandutva (Faintness in colour of nails, eyes and skin
2. Pindikodveshatana (Pain in calf muscles)
3. Hritspanda (Increased heart rate)
4. Akshikutashotha (Swelling around eyes)
5. Klama (Fatigue)
6. Subjects having haemoglobin in between 8 gm % to 10 gm %

Exclusion Criteria:

A. The patients suffering from following conditions were excluded from study-

1. Liver cirrhosis
2. Oedema
3. Worms
4. Bleeding hemorrhoids
5. Tuberculosis
6. Blood cancer
7. Neurological disorders

B. Anaemia in pregnancy with other complications

C. Patients from 1st trimester of pregnancy

D. High risk pregnancies were rejected –

1. Primigravida with age more above than 35 years and age below 21
2. Patients with heart diseases, diabetes mellitus and hypertension
3. Pregnancy induced hypertension
4. Patients having bad obstetric history, e.g. recurrent abortion, intrauterine growth retardation.

Study design:

Group	Trial Group	Control Group
No of Patient	30	30
Drug	Dadimadi Ghrita	Tab Ferrous Sulphate
Dose	10 ml	100 ml
Sewankal	Twice a Day empty stomach	Twice a day after meal
Duration	2 months	2 months
Anupan	Warm water	Water
Followup	After 15 days	After 15 days

Study Period – 60 days for experimental group and 60 days for central group for individual. Follow up 15 days.

Method of Preparation

***Dadimadi Ghrita*:**[7]

Table no. 1- Ingredients and their useful parts

Sl no	Name	Hindi name	Useful part	Amount
1	Dadima [8]	*Punica granatum*	Dry Seed	192 gm
2	Dhanya [9]	*Coriandrum sativam*	Fruit	96 g
3	Chitrak[10]	*Plumbago zeylanica*	Root	48 g
4	Shringavera [11]	*Zingiber officinale*	Rhizome	48 g
5	Pippali [12]	*Piper nigrum*	Fruit	24 g
6	Ghrita [13]	Cow Ghee		960 g

- All the ingredients are taken of pharmacopeial quality. Wash, clean, dry the ingredients numbered from 2 to 5 of the formulation composition, then these are powdered separately and passed through sieve number 85 (*Kalka Dravyas*).
- Then these are *Kalka Dravyas* transferred to the wet grinder and grinded with sufficient quantity of water to prepare homogeneous blend (Kalka).
- *Dadima* seeds are cleared and crushed to prepare a paste. *Gau Ghrita* taken in a stainless-steel vessel and heated mildly to remove moisture if any. Then the ingredients of *kalka* and *Dadima* paste are added. The

renature is Stirred thoroughly while adding water. Then it is heated for 3 h with constant stirring maintaining the temperature between 500 and 900 during the first hour of heating. Then stop heating and allow to stand overnight.

- Start the heating next day and observe the boiling mixture for subsidence of froth and constantly check the *kalka* for formation of *varti (Madhyama Paka Lakshana*). Expose the *varti* to flame and confirm the absence of crackling sound indication absence of moisture.
- Stop heating when the *kalka* forms a *varti* and the froth subsides. Filter while hot (about 800) through a muslin cloth and allow to cool.
- Pack it in tightly closed glass containers to protect from light and moisture.

Description: A green-coloured, soft, low melting medicated fat, unctuous to touch with pleasant sweetish odour and ghee like taste.
Storage:Store in a cool place in tightly closed container, protect form light and moisture.

RESULT

Clinical Profile

The subjects were called every fortnight for their assessments. All the patients who were enrolled into the clinical trial were thoroughly examined on the day of their visit to the outdoor department of Prasuti Roga.The Results of the treatment were noted down on every visit and the data had been compiled but in the present article only the end results have been shown. This means the effect of the two treatments after 60 (sixty) days (2 months) have been shown.

Incidence of Symptoms of *Garbhini Pandu*

It has been observed that although all the patients were suffering from anaemia, *Pandutva* was clearly visible in 53 (96.36%) patients only. *Hritspanda* and *Ayasenshvasa* were found in 50 (90.91%) patients. Next common symptoms were *Klama* and *Pindikodveshatana* which were found in 48 (87.27%) patients each and least common symptom was *Akshikutashotha* which was present in 45 (81.82%) patients. This incidence of symptoms are given in table 2.

Table No. 2 - Showing Pattern of Symptoms of Pandutva

Symptom of Pandu	No. of subjects	%
Pandutva (faintness in colour in nails, eye and skin)	53	96.36
Ayasenshvasa (dyspnea on exertion)	50	90.91
Hritspanda (increased heart rate)	50	90.91
Klama (fatigue)	48	87.27
Pindikodveshatana (Pain in calf muscles)	48	87.27
Akshikutashotha (swelling around eyes)	45	81.82

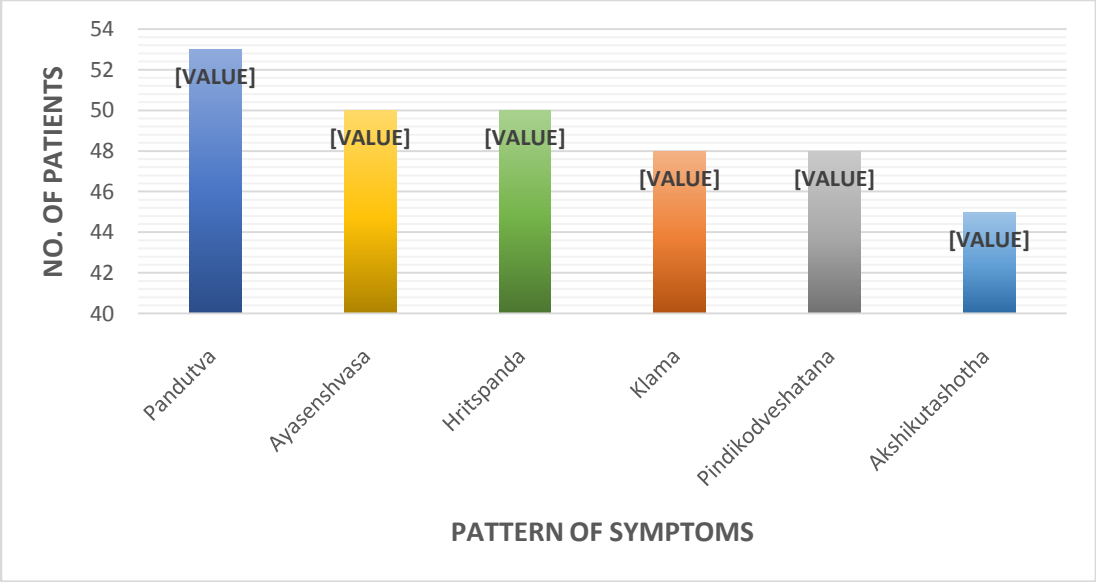

Figure 1:- Bar Diagram showing the incidence of symptoms in patients of *Garbhini Pandu* (Total 55 Patients)

1. **Effect of Drugs on Pulse Rate**

The pulse rate was found to be increased in 50 patients. When DG and FS was given to the patients this tachycardia was lessened in almost all the patients in proportionate manner. In maximum number of patients this decrease in *Hritspanda* was in 5-8 beat/minute and 9-12 beat/minute (table 3). This exhibits that out of 26 patients who received DG, pulse rate was significantly decreased in 17 subjects. Similarly, in the 24 patients who received FS, the tachycardia was significantly decreased in 16 patients. These results in DG and FS group are quite similar and comparable ($p>0.05$)

Table No. 3 - Showing comparison between the effect DG and FS on pulse rate

Reduction in pulse rate/minute	DG	FS
	No. of Subjects	No. of Subjects
No change	1	1
1 to 4	3	2
5 to 8 *	8	8
9 to 12 **	9	8
13 to 16 **	5	5
Total	**26**	**24**

*** p<0.05=Significant; ** p<0.01=Highly Significant**

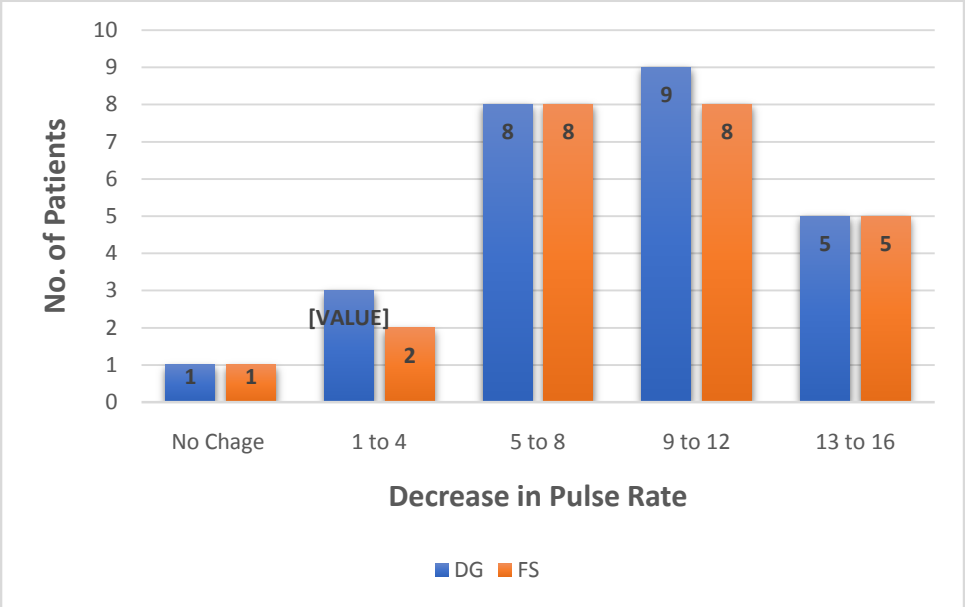

Figure 2: Bar Diagram showing the comparative decrease in pulse rate in patient's treated by DG and FS

2. Effect on Respiratory Rate

The effect of DG and FS on respiration has been shown in table 15. There was increase in respiration in patients of *Garbhini Pandu* In modern medical science, this increase in respiratory rate in termed as Tachypnoa and in Ayurved this tachypnea without exertion can be correlated to *Anayasen shwasa*. This symptom of *Anayasen shwasa* was present in 50 subjects of this study. This rise in respiratory rate was

due to less oxygen carrying capacity of blood in these patients. After treatment in both the groups it was found that respiratory rate was significantly reduced (3-6 per minute) in 19 patients treated with DG and in 18 patients treated with FS. These results in both the groups are comparable. The table 4 and figure 3 is showing the pattern of decrease in respiratory rate. However, it has been clearly evident that the benefit in tachypnoa *Anayasen shwasa* was almost parallel and comparable in both the groups DG treated and FS treated subjects.

Table No. 4: Reduction in Respiratory Rate

Reduction in RR per minute	**DG**	**FS**
	No. of Subjects	**No. of Subjects**
No change	2	2
1 to 3	5	6
4 to 6 *	7	7
7 to 9 **	8	6
10 to 12 **	4	3
Total	**26**	**24**

*** p<0.05=Significant; ** p<0.01=Highly Significant**

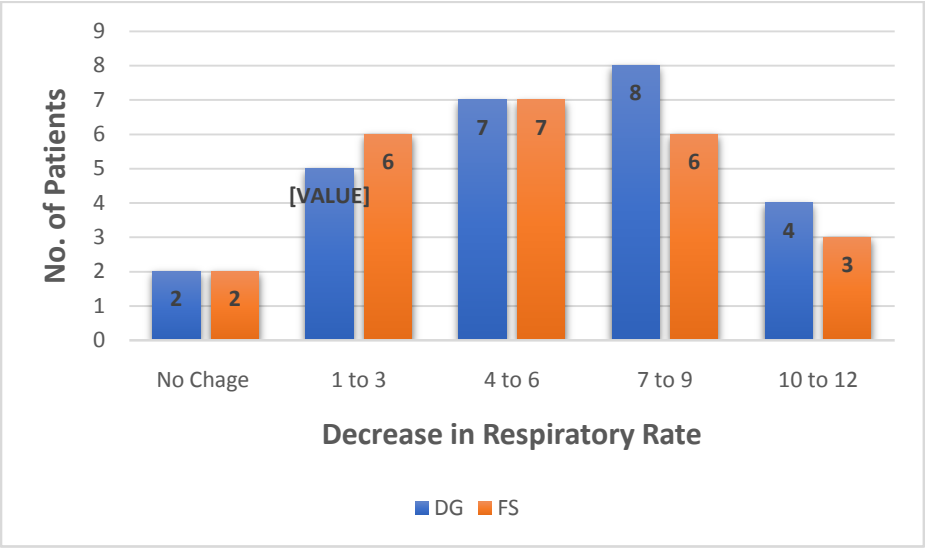

Figure 3: Bar Diagram showing the comparative decrease in respiratory rate *Anayasen shwasa* in patients treated by DG and FS

Effect on increase in Haemoglobin percentage

The haemoglobin of all the patients who were enrolled in the study was found to be decreased (Between 8gm% to 10gm%), thus the data of all 55 patients has been put to calculation and analysis. When DF and FS was given to the patients, haemoglobin level was increased in all the patients of both the groups. In few patients the rise in Hb% was between 1.0gm% to 1.5gm% (5 patients). In 45 patients the rise in Hb% was between 1.6gm% to 2.5gm%. Both DG and FS increased Hb% in comparable and almost parallel manner (Table 5). Only in one subject the rise in Hb% was more than 3gm% and this subject belonged to FS group.

Table No. 5: Effect on increase in Haemoglobin percentage

Difference in Hb%	**DG**	**FS**
	No. of Subjects	**No. of Subjects**
1.0 to 1.5 gm%	3	2
1.6 to 2.0 gm% *	11	10
2.1 to 2.5 gm% **	12	11
2.6 to 3.0 gm% **	2	3
>3.0 gm%	0	1
Total	**28**	**27**

*** p<0.05=Significant; ** p<0.01=Highly Significant**

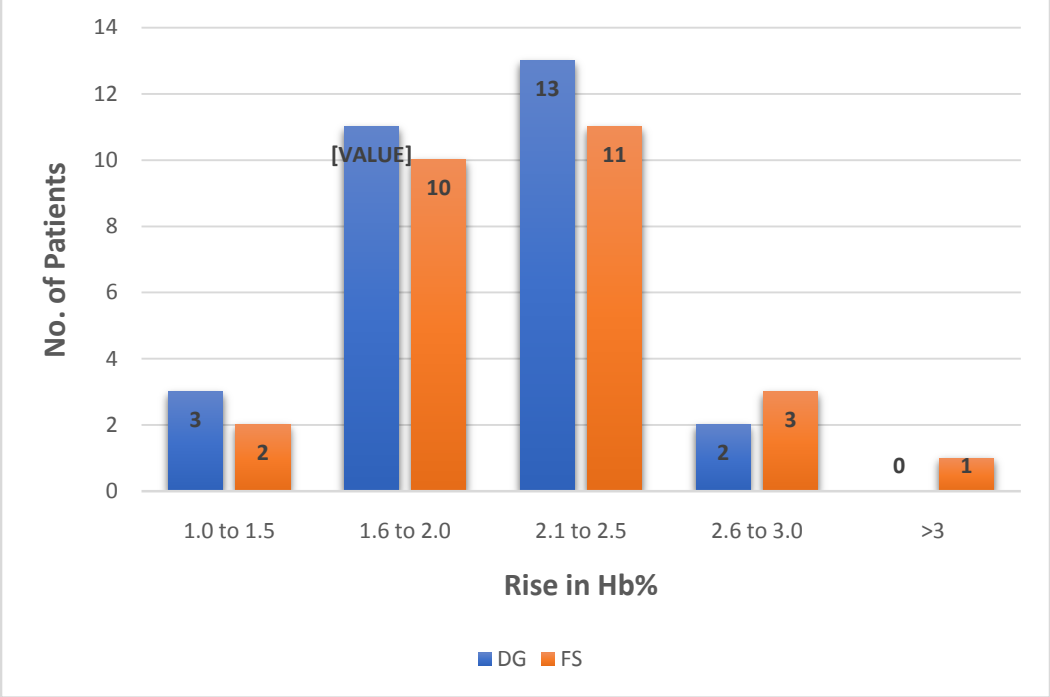

Figure 4: Bar Diagram showing rise in Hb% in patients of *Garbhini Pandu* after treatment with DG and FS

Total effect on *Garbhini Pandu*

Overall on *Garbhini Pandu*: the effect of DG and FS treatment has been shown in Table 6. It shows that both the treatments produced relief from 41% to 60% in 30 patients (14 and 16, respectively). In 11 patients (6 and 5, respectively) the relief obtained was w.e.f. 61 to 80%.

Table No. 6: Total effect on Garbhini pandu

% of Relief	DG	FS
	No. of Subjects	No. of Subjects
0 – 20%	2	3
21 – 40% *	6	3
41 – 60% **	14	16
61 – 80% **	6	5
Total	**28**	**27**

*** p<0.05=Significant; ** p<0.01=Highly Significant**

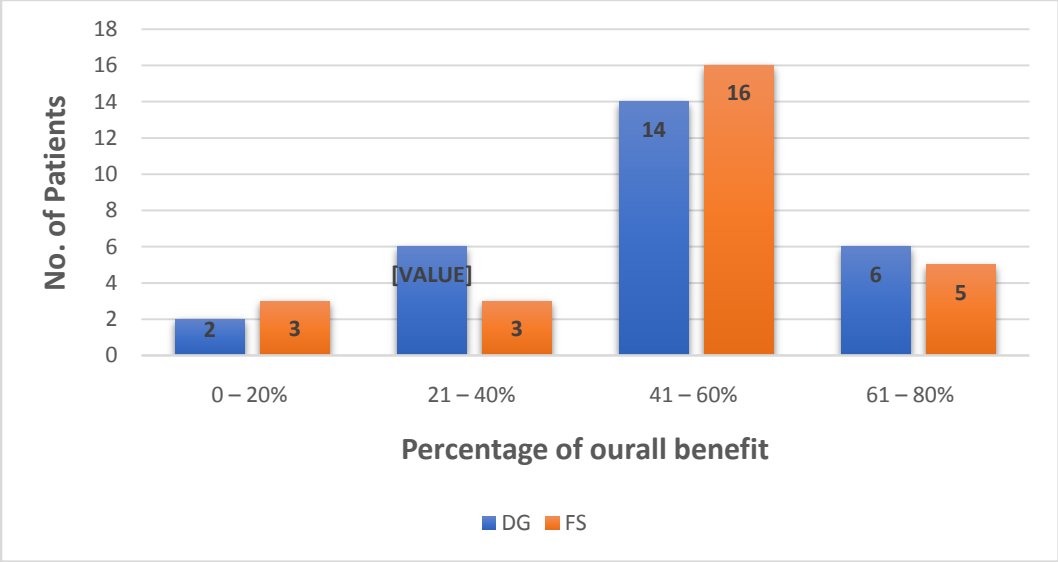

Figure 5: Bar Diagram showing overall improvement in patients of *Garbhini Pandu* by DG and FS

Side effects of the drug treatment

During this clinical trial the subjects were also asked to report any of the side effects, if they observed. During the visit of the patients also, they were enquired in respect of any side effects. The

patients who had been in the DG group did not develop any side effects. This means that DG did not elicit any side effect. It was well tolerated also by the subjects. On the other hand, some of the patients who received FS developed mild to moderate side effects. The common side effects were nausea, anorexia and epigastric irritation and pain. These side effects were controlled if the FS tablets were given after food and in few patients by co-administration of one of the proton pump inhibitors. However, none of the subjects required discontinuation of treatment.

DISCUSSION

***Samanya Lakshana* (General Symptoms):** General symptoms like *panduta* i.e. *Nakha-Netra-Twak Panduta, Pindikodweshtana, Hritspand, anayasenshwasa,Klama* etc were present. The classical symptom *Karnashweda* was not observed in this study. Most of these symptoms were present in all patients more or less dominantly. Some symptoms like *dourbalya*, *katishula*, *sarvangmarda*, *padashotha*, *agnimandya* were not present in each patient. This shows that in this project study all the patients selected were showing maximum symptoms. This ultimately helped to get clearer conclusion.

Discussion of effect of treatment by Dadimadi Ghrita& Ferrous Sulphate

Effect of treatment on Severity Index: After giving treatment of *Dadimadi Ghrita*, there is remarkable shift in severity grades. This shift is there because of improvement or complete reduction of *Nakha, netra, twaka panduta, Hrutspanda, pindikodweshtana, ayase shwas, klama.* This definitely suggests that given medicine has effect on *Garbhini Pandu*. *DadimadiGhrita* acts on the root of *Panduta* i.e. *Rakta* and *Pitta*. It improves the *Agni* and appetite and resulting in increased food intake.After giving treatment of severity index of *Garbhini Pandu* was as follows- Grade O or normal (all symptoms disappear), Grade 1 – mild (out of 5 symptoms 3 disappear), Grade II- Moderate degree (out of 5 symptoms 2 symptoms disappear but not affecting foetal growth) Grade III- Severe degree (all 5 symptoms are present having hazardous effects on mother and fetus). They were grade O-23, Grade I-24, Grade II-8, respectively.

After the use of treatments marked improvement was seen in the sign and symptoms of *garbhini pandu* like *nakha, netra twaka panduta, pindikodweshtana, Hrutspanda, ayasenshwas and klama* in both the groups. Haemoglobin was increased up to 1.5gm% in 5 patients, up 1gm% in 32 patients, more than 2 gm% in 11 patients, up 0.5 gm% in 04 patients, and no change is only in one patient. Hb% more than 2 gm% in 11 patients, 1.5 gm% in 52 patients, 1.0 gm% in 32 patients, 0.5 gm% in 04 patients and No change 01 patient.

Table no. 7 - Probable Mode of Action of Content Dadimadi Ghrita[14]

Dadima [15]	Dhanya [16]	Chitraka [17]	Shringabera [18]	Pippali [19]
Haemetinic Grahi Balvardhak Krimighna Ruchyavardahak Tridoshaghna Hridya Anti-Oxidant	Deepan Paachan Rechan Anuloman Rakhtwardhak Agniwardhak Krimighna	Deepan Pachan Rochan Panduhara Anuloman Vivandhara Digestive Antiinflammatory Anti – Oxidant Anti – Cancer Amapachaka	Deepan Pachan Rochan Grahi Tridoshbhara Krimighna Ruchya Anti-Bacterial Anti-Fungal Anti Diabetic Anti-Oxidant	Deepan Pachan Grahi Shodhahara Appetizer Agnimandhyahar

CONCLUSION

This present clinical trial was envisaged to evaluate the effect of *Dadimadi Ghrita* on the patients of *Garbhini Pandu* and to compare its efficacy with that of modern drug – Ferrous Sulphate as primary outcome. The semi-urban population of city/town area was taken in to consideration. Certain secondary outcomes were also observed during the study. The Ayurvedic test drug *Dadimadi Ghrita* was prepared according to the methodology described in the ancient literature.

By the analysis of the data obtained in this clinical trial, it may be concluded that *Dadimadi Ghrita* is almost equally effective in increasing the haemoglobin percentage and improving the *Pandutva* in *Garbhini*. Ferrous Sulphate, certainly, is helpful in improving the anaemia in pregnancy but at the same

time quite a few pregnant patients suffered with gastric irritation and nausea, thus there was decrease in appetite. Contrary to this *Dadimadi Ghrita* could be easily taken at empty stomach and it was helpful in improving the appetite also. Besides, the many ingredients present in this Ayurvedic preparation were found to improve overall health of the patients.

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