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A RANDOMIZED COMPARATIVE CLINICAL STUDY TO ASSESS EFFICACY OF *PUNARNAVA MANDURA* WITH AND WITHOUT *SHATAVARI AVALEHA* IN *GARBHINI PANDU*

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ABSTRACT

Background: Anaemia is one of the nutritional disorders in pregnancy. WHO estimates that even among the South Asian countries, India has highest prevalence of anaemia. About 80% of the maternal deaths due to anaemia is contributed by India alone. There is no direct reference of *Garbhini Pandu* (anaemia in pregnancy), however, many indirect references are available, in *Ayurvedic* texts,. *Acharya Charak*a explained about ***Bala varna hani*** of *Garbhini* in 6th month of pregnancy and in symptoms of 7th month *Acharya Chakrapani* has mentioned ***Shonita hinta***. All these symptoms are present in 2nd trimester of pregnancy and may be due to anaemia and can be considered as reference for *Garbhini Pandu.* Use of *Lauha* and *Mandura* (Iron oxide- Fe_2O_3) in the treatment of anaemia is evident from ancient times. *Mandura Bhasma* is excellent *Rakta Vardhak* (Hematinic), and best to be used in *Bala* (children) and *Garbhini* (Pregnant woman) instead of *Lauha Bhasma* due to its *Soumya guna* (Gentle).*Punarnava Mandura* is proved beneficial in Antenatal care by previous research works.and is commonly used for the management of all types of *Pandu.* In Group B, *Shatavari Avaleha* is selected with *Punarnava Mandura,* to evaluate its *Rasayana* effect in Pregnancy anaemia. **Objective:** To evaluate efficacy of *Punarnava Mandura* with and without *Shatavari Avaleha* in *Garbhini Pandu.* **Material and methods:** Pregnant women (n=30), clinically and pathologically diagnosed as anaemic, between 13th – 28th week of pregnancy, were registered for present clinical study from the OPD and IPD department of *Prasuti Tantra* and *Stri Roga,* of National Institute of Ayurveda (N.I.A.) Jaipur, after obtaining written voluntary informed consent from the patients and their attendants. *Punarnava Mandura* was given in the dose of 2 capsules of 500 mg, half an hour before meals with butter milk, twice daily in Group- A and in Group- B *Punarnava Mandura* was given in the dose of 2 capsules of 500 mg, half an hour before meals with butter milk, twice daily along with *Shatavari Avaleha* 5 gm twice daily with 1 glass of milk in morning and evening, for 2 months. The assessment was done on objective parameters .
Results: On all objective parameters Group - B has shown better results in terms of percentage relief as compared to group- A.
Discussion: The results may be attributed to *Rasayana* (Rejuvenating property), *Vata-Pitta*

Shamaka, Deepana (appetiser), *Balya and Garbhaposhaka* effects *of Shatavari Avaleha.*
Key words: Pregnancy anaemia, *Garbhini Pandu, Punarnava Mandura, Shatavari.*

INTRODUCTION:

Anaemia is one of the nutritional disorders in pregnancy. WHO estimates that, India has highest prevalence of anaemia in South Asia,. Anaemia either directly or indirectly contributes to 20% maternal deaths in third world countries[1]

Margaret Balfour was credited as the first to draw the attention on pregnancy anaemia in India.[2] The Indian Council of Medical Research estimated the prevalence of anaemia among pregnant women to be 88%.[3] These affect approximately 2 billion people, 80% of whom live in the developing countries.[4]

National family health survey (NFHS) 2, 3 and 4 graded anaemia according to WHO grading of anaemia: Pregnant woman with Hb level ≥11 gm/dl were graded as non anaemic: those with Hb levels between 10.0 – 10.9 gm/dl as mildly anaemic, with haemoglobin levels between 7.0- 9.9 gm/dl as moderate anaemia and Hb level below 7.0 g/dl as severely anaemic.[5]

Pandu is a *Varnoplakshita Vyadhi* where paleness is pathognomonic symptom (*Pratyatma Lakshna*). It has been described on the basis of its peculiar colour presentation as described by *Vachaspatya*- mixture of white and yellow colour which resembles with the pollen grains of *ketaki* flower.

Garbhavastha is only special physiological stage of womanhood. While mentioning *Garbhini Lakshana*, our *Acharyas* indirectly indicated toward the *Garbhini Pandu.*

*Acharya Charak*a in *Sharira Sthana*, while discussing *Masnumasik Garbha Vruddhi*, mentioned about *Bala- Varna hani*[6] of *garbhini* in 6th month of pregnancy, which means feeling of weakness and loss of complexion. *Shonita hinta* which means low blood volume is mentioned as symptoms in 7th month, according to *Acharya Chakrapani*. All these symptoms are present in 2nd trimester of pregnancy and may be due to anaemia and can be considered as reference for *Garbhini Pandu.*

In the context of *Rakta Gulma',*[7] *Acharya Kashyapa* has described *Pandu* as a symptom of *Garbhini*. *Acharya Harita* had described eight *Garbhopadrava, Vivarnatva* (Pallor) as one of them.[8] *'Vivaranatva'* is cardinal symptom in *Pandu Roga* (anaemia). Thus, this concept of *Garbhopadrava* (complications of pregnancy) in *Harita Samhita* can be taken as reference of *Garbhini Pandu* (Pregnancy anaemia).

In a nutshell, *Garbhini Pandu* is exclusively described in *Ayurvedic* texts under *Vyakta Garbha Lakshanas* (signs and symptoms of pregnancy),[9] *Garbhini Masanumasika Lakshanas*[10], *Raktagulma*[11] eight *Garbhopadravas,*[12] *Doshika Upvistaka Garbhini Lakshanas*[13] and *Arista Lakshanas* (fatal signs) of *Garbhini*[14].

In today's busy and hectic life, women are unable to follow *Ahara and Vihara* (diet and life style) mentioned in *Ayurvediya* texts during pregnancy. Due to *Apathyakar* (unwholesome) *Ahara Vihara*, abnormal *Rasa Dhatu* gets formed. It causes *Uttarottar* (Subsequent) *Vikrut Dhatu Utpatti* (Improper *Dhatu* formation) and all this leads in pathogenesis of *Garbhini Pandu.*

Different preparations of *Mandura*, used in the treatment of anaemia. *Mandura*

Bhasma is excellent *Rakta Vardhak* (hematinic), and best to be used in *Bala* and *Garbhini* instead of *Lauha Bhasma* due to its *Soumya guna* (Gentle property). Many recent researches have proved haematinic effect of *Mandura Bhasma*.[15]

Among the wide varieties of *Mandura Bhasma* preparations available in *Ayurvedic* classics for anaemic condition, *Punarnava Mandura* (*Ch. Chi.* 16/93-95) was selected for the present study on the basis of its *Pandughnata* (antianaemic), *Prinana* (nourishing) and *Raktaprasadana* (blood detoxifying) properties. *Shatavari Avaleha* have been selected in Group B with *Punarnava Mandura* to evaluate its *Rasayana* effect on pregnancy anaemia.

Classification of anaemia in pregnancy[16]-

A) Physiological anaemia of pregnancy

B) Pathological anaemia - It is of following types

I. Deficiency anaemia -

a) Iron deficiency

b) folic acid deficiency

c) Vitamin B12 deficiency

d) Protein deficiency

II. Hemorrhagic anaemia -

a) Acute hemorrhagic anaemia - following bleeding in early months of pregnancy or Ante partum haemorrhage.

b) Chronic hemorrhagic anaemia - hookworm infestation, bleeding piles etc.

III. Hereditary -

a) Thalassemias

b) Sickle cell haemoglobinopathies

c) Hereditary haemolytic anaemia

IV. Bone marrow insufficiencies

V. Anaemia of infection (malaria, tuberculosis etc.)

VI. Anaemia due to chronic disease or neoplasm.

MATERIAL AND METHODS:

Pregnant women (n=30), clinically and pathologically diagnosed as anaemic between 13th – 28th week of pregnancy, were registered for present clinical study, from the OPD and IPD of department of *Prasuti Tantra* and *Stri Roga*, of National Institute of Ayurveda (N.I.A.) Jaipur, after obtaining written voluntary informed consent from the patients. The study was started after getting approval by the Institutional Ethics Committee (No. IEC/ACA/2018/29; Date. 11/05/2018) and registering in clinical trial registry of India.

INCLUSION CRITERIA:

- A pregnant woman willing to participate in the trial aged between 20-35 years.
- Pregnant woman with haemoglobin percentage 7.0-10.00 gm/dl (moderate anaemia- due to iron deficiency), haematocrit less than 30%.
- Pregnant woman with anaemia between 13th to 28th weeks of pregnancy.

EXCLUSION CRITERIA:

- Anaemia other than iron deficiency anaemia.
- Patients having haemoglobin percentage less than 7.0 gm/dl.
- Patients suffering from systemic diseases like hypertension, diabetes, thyroid disorders, liver disorders, renal disorder, cardio-vascular disorders, cerebro-vascular disorders, tuberculosis etc.
- Patients suffering from pregnancy related complications such as pregnancy induced hypertension (PIH), pre-eclampsia, eclampsia, hyperemesis gravidarum, gestational diabetes etc.
- Pregnancy associated with jaundice, Rh-Incompatibility, ovarian tumor, abruptio placenta , and placenta previa.

Investigations-

Hematological: Hemoglobin (Hb)%, Haematocrit (HCT), total red blood corpuscles (TRBC), mean cell volume (MCV), Mean corpuscular hemoglobin (MCH), Mean corpuscular hemoglobin concentration (MCHC) and peripheral blood smear (PBS).

Specific markers of IDA: serum iron, serum ferritin and total iron binding capacity (TIBC) were carried out in all the patients before and after treatment.

Grouping and Dosage of drugs:

The selected patients were randomly divided by simple randomization in odd and even sequence, into two groups, A and B.

- Group A (*n* = 15): Two capsules of *Punarnava Mandura* (500 mg each) twice daily; half an hour before meals were administered with one cup of buttermilk, for consecutive 60 days
- Group B (*n* = 15): Two capsules of *Punarnava Mandura* (500 mg each) twice daily; half an hour before meals with one cup of buttermilk and *Shatavari Avaleha* (5 gm): twice daily: with one glass of milk in morning and evening were administered for consecutive 60 days.
- Both the trial drugs *Punarnava Mandura* and *Shatavari Avaleha* were prepared in Pharmacy of N.I.A., Jaipur by following classical guidelines.

Assessment criteria:

During the trial and follow up study the patients were assessed on the basis of objective parameters before and after the treatment.

Objective parameters:

Hematological parameters: Hb%, HCT, TRBC, MCV, MCH, MCHC, Serum iron, Serum ferritin and TIBC.

Statistical analysis:

The information gathered on the basis of observation made about various parameters were subjected to statistical analysis in terms of mean, standard deviation and standard error. For parametric data paired 't' test was used for inter and intra group comparison and results were calculated on the basis of p value. If p <0.001 - extremely significant, p <0.01- very significant, p < 0.05 - significant and p>0.05 as Insignificant.

Results

Effect of therapy on objective parameters:

On objective criteria, *Punarnava Mandura* in Group- A showed better results in terms of high percentage relief in improving MCV (4.21%)

On objective criteria, *Punarnava Mandura* showed extremely significant results (p< 0.01) in Hb%, HCT and TRBC while very significant results (p< 0.001) were obtained in MCHC and significant results (p< 0.05) were found in MCV and MCH. Non-significant results (p>0.05) were found in Serum iron, serum ferritin and TIBC. [Table no. 1]

Table no. 1: Effect of therapy on objective parameters in Group- A (n=15)

Variable	Mean		Mean diff.	% Change	SD±	SE±	T value	p value	Result
	B.T.	A.T.							
Hb%	9.047	10.00	-0.953	10.53	0.822	0.212	4.916	**0.0002**	**E.S.***

HCT	27.233	29.433	-2.200	08.07	2.194	0.566	5.026	**0.0002**	**E.S *** **
TRBC	3.717	4.092	-0.374	10.06	0.436	0.112	5.243	**0.0001**	**E.S *** **
MCV	79.487	82.840	-3.353	04.21	10.95	2.828	2.754	**0.0155**	**S***
MCH	26.720	27.780	-1.060	03.96	4.644	1.199	2.393	**0.0313**	**S***
MCHC	32.733	33.440	-0.706	02.15	1.208	0.311	3.400	**0.0043**	**V.S****
Serum Iron	48.056	52.953	-4.897	10.19	26.06	6.729	1.552	**0.1430**	**N.S#**
Serum ferritin	7.084	7.686	-0.602	08.49	5.025	1.297	0.636	**0.5347**	**N.S#**
TIBC	443.01	481.80	-38.78	08.75	91.96	23.74	1.565	**0.1399**	**N.S#**

On objective criteria, in Group- B, *Punarnava Mandura* showed better results with *Shatavari Avaleha* in terms of high percentage improvement in Hb% (11.14%), HCT (8.70%), TRBC (12.67%), MCH (4.21%), MCHC (3.38%), Serum iron (11.69%), serum ferritin (8.90%) and TIBC (15.90%).

On objective criteria, *Punarnava Mandura* with *Shatavari Avaleha* showed extremely significant results ($p< 0.01$) in Hb%, HCT and TRBC while very significant results ($p< 0.001$) were obtained in MCV and MCHC and significant results ($p< 0.05$) were found in MCH and TIBC. Non-significant results ($p>0.05$) were found in Serum iron and serum ferritin. [Table no. 2]

Table no. 2: Effect of therapy on objective parameters in Group-B (n=15)

Variable	Mean		Mean diff.	% Change	SD±	SE±	t value	p value	Result
	B.T.	A.T.							
Hb%	9.267	10.300	-1.033	11.14	0.656	0.169	6.298	**0.0001**	**E.S *** **
HCT	28.071	30.440	-2.443	08.70	1.954	0.512	4.862	**0.0003**	**E.S *** **
TRBC	3.441	3.877	-0.436	12.67	0.566	0.146	7.660	**0.0001**	**E.S *** **.**
MCV	79.813	82.813	-3.000	03.75	8.797	2.271	3.169	**0.0068**	**V.S ** **
MCH	26.573	27.693	-1.120	04.21	3.405	0.879	2.210	**0.0442**	**S***

MCHC	32.700	33.807	-1.107	03.38	1.157	0.299	3.631	**0.0027**	**V.S ****
Serum Iron.	64.040	56.553	7.487	11.69	32.048	8.27	1.754	**0.1013**	**N.S#**
Serum ferritin	23.199	25.263	-2.065	08.90	24.76	6.394	2.090	**0.0554**	**N.S#**
TIBC	434.39	503.49	- 69.107	15.90	108.18	27.93	2.555	**0.0229**	**S***

Intergroup comparison between Group-A and Group-B on all objective parameters by Paired 't' test shows p value, as per data >0.05, which means that, there is statistically no difference in both the therapies. Both therapies are equally effective. Except in Serum ferritin level, where it is statistically found to be quite significant (P<**0.05)** [Table no. 3]

Table no. 3: Effect of therapy on objective parameters in Group-A and Group-B (n=30)

Variable	Group	Mean diff.	SD±	SE±	t value	p value	Result
Hb%	Group- A	10.000	0.9681	0.2500	0.8500	**0.4096**	**N.S#**
	Group- B	10.300	0.7728	0.1995			
HCT	Group- A	29.433	2.086	0.5387	1.094	**0.2926**	**N.S#**
	Group- B	30.440	2.147	0.5544			
TRBC	Group- A	3.903	0.5427	0.1401	1.257	**0.2294**	**N.S#**
	Group- B	4.107	0.4367	0.1127			
MCV	Group- A	82.840	11.788	3.044	0.0071	**0.9944**	**N.S#**
	Group- B	82.813	8.784	2.268			
MCH	Group- A	27.780	4.873	1.258	0.0592	**0.9536**	**N.S#**
	Group- B	27.693	3.134	0.8091			
MCHC	Group- A	33.440	1.104	0.2850	0.9089	**0.3788**	**N.S#**
	Group- B	33.807	1.127	0.2911			
Serum Iron	Group- A	52.953	26.743	6.905	0.2967	**0.7710**	**N.S#**
	Group- B	56.553	29.190	7.537			
Serum Ferritin	Group- A	8.553	6.927	1.788	2.033	**0.0615**	**Q.S@**
	Group- B	23.813	25.377	6.552			
TIBC	Group- A	481.80	105.29	27.187	0.5240	**0.6085**	**N.S#**
	Group- B	503.49	112.16	28.959			

@Q. S. -- Quite significant

- This clinical study overall concluded that both the therapies are effective in treating *Garbhini Pandu*. *Punarnava Mandura* alone also showed good results but with *Shatavari Avaleha* due to its *Vata-Pitta hara* and *Rasayana* properties comparatively better results are obtained on all objective parameters of *Garbhini Pandu.*

DISCUSSION: According to *Acharya Kashyapa* like all other disorders, *Pandu* is also a common disease during pregnancy.[17] Fetus is nourished by the maternal *Rasa* and *Rakta*, in this way qualitative reduction of maternal blood during the pregnancy itself becomes a cause of *Garbhavasthajanya Pandu.*

According to *Ayurveda texts Garbhini Pandu* is described as a complication of *Garbha* and is mentioned indirectly in context with *Rakta Gulma, Upvishtaka Garbha* and *Garbhini Lakshanas* .

In pregnant woman *Rasavaha Srotasa* gets pressurized due to developing fetus. So, there is obstruction in *Rasavaha Srotasa* and formation of *Raktadi Dhatu* does not take place properly and thus resulting in *Pandu* (anaemia).

After 3rd month of pregnancy, *Dauhridavastha* is an important cause for the excessive desire of *Nidana Sevana* like excessive intake of *Amla* (sour) *Lavana* (salty) and *Katu* (pungent) *Rasa* (taste) or improper diet, *Diwaswapa* (day time sleep), *Vegavidharana*, which may efflict the *Manasika Bhavas* (*Bhaya, Shoka* etc) and results in *Garbhini Pandu*.

Probable mode of action:

Herbo- mineral formulations, upon interaction with digestive juices, adopt a colloidal form. and plays a role of catalytst for absorption of other nutrients and correcting a disease process.

Punarnava Mandura is herbomineral preparation which acts possibly by its effect on *Srotas*

(micro channels) and *Agni* (digestive enzyme) enhance the digestive capacity owing to *Deepana* (appetizer), *Pachana* (digestive). It helps to maintain efficient kidney and urinary functions with its diuretic and anti- inflammatory property.[18]

Drugs of *Punarnava Mandura* possess mainly *Katu, Tikta Rasa, Laghu, Ruksha* and *Tikshana Guna, Ushna Virya* and *Katu Vipaka.* It has ***Deepana, Pachana, Krimighana*** and *Stanya-Shodhana* effect.

Actions of main contents of Punarnava Mandura:

Punarnava works as *Rasayana,* it rejuvenates the body by cleansing it's with unique property of flushing out the mala (toxins) from the *Dhatus* (body tissues).

- *Mandura Bhasma* is *Soumya, Sookshma, Vrishya, Ruchikara, Deepana* and *Pitta prashmana.* It possesses significant haematinic and cytoprotective activity. [19]
- *Gomutra* works as *Rasayana* by its antioxidant property. It has been found to be a very good immune enhancer. Presence of erythropoietin Hormone and iron in *Go- Mutra* helps in Production of Red Blood Cells.[20]
- *Triphala* helps in relieving the problem of constipation, which is quite natural in pregnancy.
- *Amalaki* has potent *Rasayana* enhancing the essence of all the *Dhatus*. Ascorbic acid, present in *Amalaki* helps in the absorption of iron.[21] *Haritaki is Panduhara,*[22] and has ferric-reducing antioxidant activity,[23] cytoprotective[24] and

hepatoprotective effect. *Vibhitaki* has *Dhatuvardhaka*[25] property.

- *Trikatu* has thermogenic action which promotes *Agni* or digestive fire which burns the harmful toxins and revitalizes the metabolism. It enhances the bioavailability.
- Contents which possess ***Krimighana*** action are *Vidanga, Musta, Maricha, Haridra and Vibhitaka.* These contents attributes in antihelmintic property of *Punarnava Mandura*. Worm infestation especially hookworm infestation is one of the main cause of anaemia, which is associated with poor sanitation.
- *Punarnavadi Mandura* is administered with *Takra* (butter milk) as *Anupana.*Buttermilk is digestive due to the presence of probiotics, *Pandughna* and rich source of minerals and Vitamin $B_{12.}$ It is acidic in pH and contains lactic acid. Iron absorption is aided by decreased pH[26].

Probable mode of action of *Shatavari Avaleha*:

- *Shatavari* is *Madhura, Tikta* in *Rasa, Guru* and *Snigdha* in *Guna, Sheeta Virya* and *Madhura* in *Vipaka. It has* ***Vata-Pitta Shamaka, Rasayana,*** *Medhya, Chakshushya, Balya, Deepana,* ***Garbhaposhaka, Stanyajanana****, Shukrala* and ***Mutrala*** properties.

- *Rasayana* effect of *Shatavari* promotes nutrition by direct enrichment of the nutritional quality of rasa, through improving *Agni*, metabolism and by promoting the competence of *Srotas* i.e. microcirculatory channels in body. Its high folic-acid content prevents anaemia.
- *Shatavari Avaleha* contributes in maintaining pregnancy and relieving in *Aruchi, Chhardi, Trisha, Daurbalya, Bhrama, Shrama* etc symptoms associated with *Garbhini Pandu.* The results may be attributed to its ***Rasayana, Vata-Pitta Shamaka, Balya, Garbhaposhaka,*** and ***Mutrala*** effects.
- *Shatavari Avaleha* is given with *Dugdha* as *Anupana. Dugdha* is advisable to *Garbhini* for the *Garbha Pusti* in almost all the months of pregnancy. As, It fulfill almost all the requirements of mother and growing fetus. It is mentioned in *Pandu Rogi* by *Acharya Sushruta.*

The significant results obtained in all objective parameters, in Group-B could be attributed to these properties.

In both groups, where *Punarnava Mandura* is administered with and without *Shatavari Avaleha*, no any complications like, bleeding per vaginum, leaking or lower abdomen pain were developed during and after treatment in whole antenatal-period. Many physicians avoid using *Punarnava Mandura* during Pregnancy, due to presence of *Go-Mutra* in it. But its safety in Antenatal care is well established by previous studies and even in the present study.

CONCLUSION

This clinical study overall concluded that both the therapies are effective in treating *Garbhini Pandu*. *Punarnava Mandura* alone also showed very significant results but with *Shatavari Avaleha* due to its *Vata- Pitta Hara* and *Rasayana* Properties comparatively better results are obtained in all Objective parameter of *Garbhini Pandu.*

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