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A COMPARATIVE CLINICAL STUDY OF DHANVANTARA GUTIKA AND BALADI MOOLA GHANAVATI IN GARBHINI UDARSHOOLA IN SECOND TRIMESTER

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ABSTRACT

Women experience *Udarshoola* during *sagarbhavastha* due to various physical and physiological changes to accommodate the growing fetus. *Udarshoola* can be managed by regularising the *Vata karma* which is mainly causing the *Shoola*. The study aimed to evaluate the effect of *Dhanvantara Gutika* and *Baladi Moola Ghanavati* in *Garbhini Udarshoola*. Objective of the study was to compare the efficacy of the two aforesaid drugs. The study was a single blind randomized comparative clinical study with pre and post test design. 30 patients diagnosed with *Garbhini Udarshoola* fulfilling the criteria of inclusion were randomly allocated into two groups. *Dhanvantara gutika* (500 mg) with *Ushnodak* was administered in Group A and Group B *Baladi Moola Ghanavati*(250 mg) with *Dugdha* and *sharkara* were administered in *vyanodaan kala* for 7 days. Assessment was done on Day 2,4 and 7 of treatment for subjective and objective parameters. Results were decided after statistical analysis using Students paired and unpaired 't' test. In group A- 9 Patients and group B- 10 Patients got complete relief.*Garbhini Udarshoola* presented as a *Swatantra* as well as a *Paratantra vyadhi*. *Baladi moola ghanavati* proved to be more effective than *Dhanvantara gutika* in curing *Garbhini Udarshoola.*

KEYWORDS: *Ayurveda, Baladi Moola Ghanavati, Dhanvantara Gutika, Garbhini, Udarshoola.*

INTRODUCTION

In a questionnaire based study conducted in a tertiary care centre of South Asia (India) on 184 women, it revealed that 30.4% of the respondents report one or the other bowel problem during pregnancy as compared to only 10.9% before it. Constipation was the most common symptom (seen in 45 women, that is 24.5%).[1] Because of the fear about use of drugs during pregnancy, some pregnant women would rather suffer than treat their pain. Liberal use of analgesics and anatacids cannot be done during preganancy due to high risk of IUGR, perinatal death and hindrance in absorption of Iron.[2]

According to *Adhamalla*, commentator of *Sharangadhar Samhita, Makkalla* is *rakta- marutaja shool* and it is of two types -1. During *Garbhavastha* 2.During *Sutikavastha.*[2] *Acharya Sushrut* in *Sharira sthana* mentions about *Makkalla lakshanas* for '*Prajata'*. In *Nibandha sangraha* the commentary on *Sushrut Samhita*, *Acharya Dalhana* clarifies that these symptoms are similar in context to '*Aprajata'* too. *Makkalla shoola* is

located in *Adho-Nabhi, Parshwa, Basti* and *Bastishira.*[3] If *Garbhini* does *sevan* of *mithyaaahar-vihar* or suffers from any *roga*, it leads to *pushpa darshan* or *shoola.*[4] *Ativyayama, aayas, bharavahan* and *guru pravaran* leads to *kukshishoola.*[5] *Udarshoola* as a *lakshana* appears in many other conditions. *Sushrutacharya* mentions about pain in *Garbhashaya, Kati, Vankshan, Bastipradesh* as a *samanya lakshan* of *Garbhapata.*[6] *Acharya Sushrut* includes *Makkallashoola*as an *Upadrav*a of *Mudhagarbha.*[7] *Kukshishoola* appears as a *samanya lakshan* of *Garbhini* afflicted by *Jataharini.*[8] In *Kashyap Samhita, parshwashoola* and *yoni shoola* is enlisted as an *arishta lakshan* in *Garbhini.*[9] Hence, careful observation has to be done and the exact *hetu* which is leading to *udarshoola* along with its consequences has to be kept in mind while handling such conditions.

The study involves the use of two formulations from *Sahasrayogam* i.e *Dhanvantara gutika*[10] and *Baladi moola ghanavati*[11] having *vatanuloman* and *shoolahara* properties which will help in control of *Apaan vayu*

dominant in the *apaan kshetra* ultimately giving relief from pain.

AIM AND OBJECTIVES

Aim: To study about effect of *Dhanvantara gutika* & *Baladi moola ghanavati* in *Garbhini udarshoola*.

Objective: To evaluate the comparative effect of both, *Dhanvantara gutika* and *Baladi moola ghanavati* in vague abdominal pain in Second trimester.

MATERIALS AND METHODS

Ethical clearance: Ethical clearance was obtained from Institutional Ethical Committee of Parul Institute of Ayurved, Parul University, Vadodara-391760 having Ref.- PIA/IECHR/2017/20 dated 10-04-2017.

Clinical trial registration: The registration no. of the trial is CTRI/2018/04/013192.

Drug

Dhanvantara Gutika was procured from Vaidyaratnam Pharmacy and the required documents like Quality Analysis certificate and Lab Test certificate of the batch-17C0204 & 17C0434 which was used for the study was procured. The other drug of the study i.e *Balaadi Moola Ghanavati* containing *Bala, Jivanti, Ushira, Utpala* and *Sariva* was prepared as per guidelines and standard reference from classical texts in the GMP certified Pharmaceutical Unit of Parul Institute of Ayurved, Vadodara, Gujrat. Drug standardization and analysis was done in the Pharmaceutical laboratory of Parul Institute of Ayurved, Parul University, Vadodara, Gujarat.

Patients

Patients of *Garbhini udarshoola* (n=30) were selected from the outpatient department of *Prasuti Tantra evum Stree Roga* of Parul Ayurved Hospital as well as Parul Sewashram Hospital, Vadodara. After diagnosing the patient with *Garbhini udarshoola*, only those patients fulfiling the inclusion criteria were included in the study. Informed written consent was obtained from the patient prior to treatment.

Diagnostic criteria: Vague abdominal pain associated with any of the symptoms like *vibandha, aatopa, adhmaan, udgaar*, etc since 2 days or more.

Inclusion criteria: *Garbhini* belonging to 20-35 years of age, irrespective of parity were selected.*Garbhini* of 2nd trimester having *Udarshoola* were taken for the study.

Exclusion criteria: Acute abdominal pain related with pregnancy eg. ectopic pregnancy, Pregnancy induced complications like P.I.H, Patient suffering from acute appendicitis,peptic ulcer, and other Systemic illnesses.

Grouping

Minimum of 30 patients fulfilling the inclusion and exclusion criteria, irrespective of parity were selected for the study and divided into two groups for the study.

15 patients- Group A (*Dhanvantara gutika*); 15 patients- Group B (*Baladi Moola Ghanavati*)

Investigations

USG, CBC, Urine routine & microscopic analysis. These investigations were done only for the confirmation of normal ANC profile in order to include the patient for the trial.

Posology

- Group A- *DHANVANTARA GUTIKA-500mg*[12] *Vyanodaan kala* with *Ushnodak* for 7 days
- Group B- *BALADI MOOLA GHANAVATI-250mg Vyanodaan kala* with *Dugdha* and *sharkara* for 7 days.

Assessment criteria

Assessment was done on 2nd, 4th and 7th day of treatment.

Table No. 1: Subjective parameters.

Sr. No	Subjective parameters	Criteria	Grade
1.	*Udarashoola*	(VAS Scale) No pain Mild pain Moderate pain Unbearable pain	 0 1 2 3
2.	*Udaragaurav*	No gaurav Mild gaurav Moderate *gaurav* Severe *gaurav*	0 1 2 3
3.	*Aatopa*	No *aatopa* Occasional Frequently	0 1 2
4.	*Vibandha*	No constipation Occasional Frequently Daily	0 1 2 3

5.	*Udgar*	None	0
		Occasional	1
		Frequently	2

VAS Scale:Grade 0= score 0 of VAS scale, Grade 1= score 1-3 of VAS scale, Grade 2= score 4-6 of VAS scale, Grade 3= score 7-10 of VAS scale

Objective parameters
Abdominal circumference (cm).

OBSERVATIONS

Out the 30 patients registered for the trial, all of which completed the treatment. Observation was made on the demographic data obtained from the patients and the clinical data as well. Maximum patients belonged to 20-25 years of age (76.66%), from *sadharana desha* (90%), belonging to Hindu community (86.66%), having matriculation as their education qualification (50%) and were housewives (86.66%) from middle class (83.33%). Majority of the population had other (Unexplainatory) *swaroop* of *Udarshoola* (53.33%), which aggravated during the *ratri kala* (93.33%) especially *bhojan paschat* (56.66%). The associated complains were *adhmaan* (43.33%), *Aatopa* (16.66%), *Vibandha* (36.66%) and *Udgar* (16.66%). Maximum patients had *samyak nidra*, took tea as supplementary diet, had regular dietary habit and were taking *guru guna pradhan aahaar, katu rasa pradhan ahaar* and *niramish ahaar.*

No adverse effects were reported during the conduction of the trial by any of the patients during the entire period of the study.

Statistical analysis
The obtained data was statistically analysed in terms of mean, standard deviation and standard error using statistical software- 'Sigma stat 3.5'. Student's paired and unpaired 't' test was used for analysis. 'p' value <0.001 was considered statistically significant.

Table no. 2: Assessment of overall effect of therapy based on the percentage of relief.

Cured (complete relief from all symptoms)	Markedly improved	Moderately improved	Mildly improved	No change
100%	75-100%	50-75%	25-50%	Upto 25%

RESULTS

Table no. 3: Effect of therapy on subjective parameters.

Lakshana	Group	N	Mean BT	Mean AT	S.D	S.E	't' value	'p' value	% effect	Result
Udarshoola	GroupA	15	1.8	0.400	0.516	0.133	11	<0.005	81.11%	S
	GroupB	15	1.8	0.333	0.516	0.133	11	<0.005	84.44%	S
Udargaurav	GroupA	15	0.333	0.067	0.458	0.118	2.256	<0.005	87.5%	S
	GroupB	15	0.200	0.000	0.414	0.107	1.871	>0.005	100%	N.S
Aatopa	GroupA	15	0.200	0.000	0.414	0.107	1.871	>0.005	100%	N.S
	GroupB	15	0.067	0.067	0.000	0.000	0.000	>0.005	100%	N.S
Vibandha	GroupA	15	1.000	0.067	1.163	0.300	3.108	<0.005	92.86%	S
	GroupB	15	0.600	0.133	0.990	0.256	1.825	>0.005	77.78%	N.S
Udgar	GroupA	15	0.467	0.000	0.834	0.215	0.215	<0.005	100%	S

Table no. 4: Effect of therapy on objective parameter.
Result on Abdominal circumference

Abdominal circumference	N	Mean BT	Mean AT	S.D	S.E	't' value	'p' value	Result
Group A	15	85.47	84.64	0.468	0.121	6.838	<0.001	S
Group B	15	72.93	72.32	0.607	0.523	4.493	<0.001	S

Table no. 5: Comparative effect of therapies.

Parameters	N	Df	Group A	Group B	S.D	S.E	't' value	'p' value	Significant
Udarshoola	15	0	1.467	1.467	0.516	0.133	0	>0.005	N.S
Udargaurav	15	0.067	0.267	0.200	0.414	0.107	0.418	>0.005	N.S
Aatopa	15	0.133	0.200	0.067	0.258	0.067	1.058	>0.005	N.S
Vibandha	15	0.467	0.933	0.467	0.990	0.256	1.183	>0.005	N.S

Udgar	--	---	---	---	---	---	---	---	---
Abdominal Circumference	15	0.220	0.827	0.607	0.523	0.135	1.214	>0.005	N.S

DISCUSSION

With changing lifestyle and dietary habits and the stressful life these days it easily causes imbalance of *doshas* leading to disease formation. Regarding the gravity of the disease, although vague abdominal pain does not have much deleterious effect on the health of the mother or the fetus, care has to be taken and even the slightest of the alarming sign of severe gravity must not be ignored.

The aetiological factors relevant today can be compared to the *nidana* mentioned years ago by our *Acharyas*. Intake of *vatakara* items like *bhanta, kalay*, bakery items and *vihara* in the form of *vishamashana, prajagara, maithunsevan, bharavahan, atiaayas, yanasevana* (travelling) formed the major *nidana* which were encountered during the trial.

Probable mode of action of *Dhanvantara gutika*

Amongst the 12 drugs of *Dhanvantara gutika*, 10 drugs are having *Ushna virya* along with *vatashamak karma*. Ingredients like *Ela, Karpura* which are *gandha pradhan* indicate *prithvi pradhanya*. *Sthira guna* of *prithvi* opposes the *chala guna* of *vata*. Ingredients like *Ela, Abhaya, Jati, Devdaru* help in *vataanulomana* as well as to *normalize vimarga vata*. *Ela, Shunthi, Jati, Bruhati, Jiraka* help in *agnideepan karma*. *Jati, Bruhati* helps in *aampachan*. *Shunthi, Devdaru, Jiraka, Jati, Chinoshan* are said to possess *shoolahara* and *Vedanasthapana* property.

Probable mode of action of *Baladi moola ghanavati*
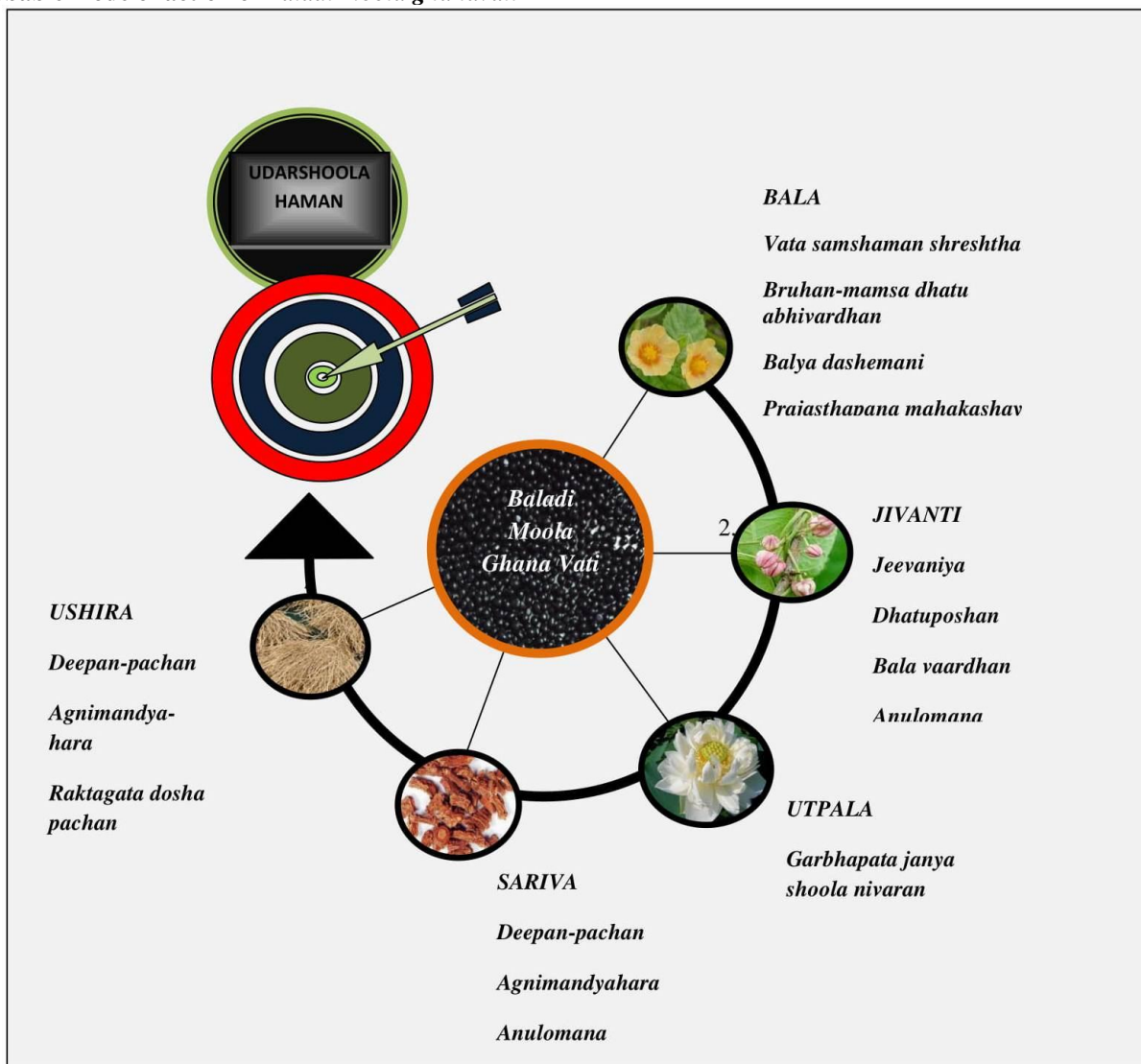
The table indicating the comparison between the group reveals the statistical analysis of subjective and objective parameters of group A *(Dhanvantara gutika)* and group B *(Baladi Moola Ghanavati).*Comparison could not be done for the parameter of *udgar* since there was no patient complaining of *udgar* in group B. There appears to be no statistical significance in the results of group A and group B.

OVERALL EFFECT OF THERAPY
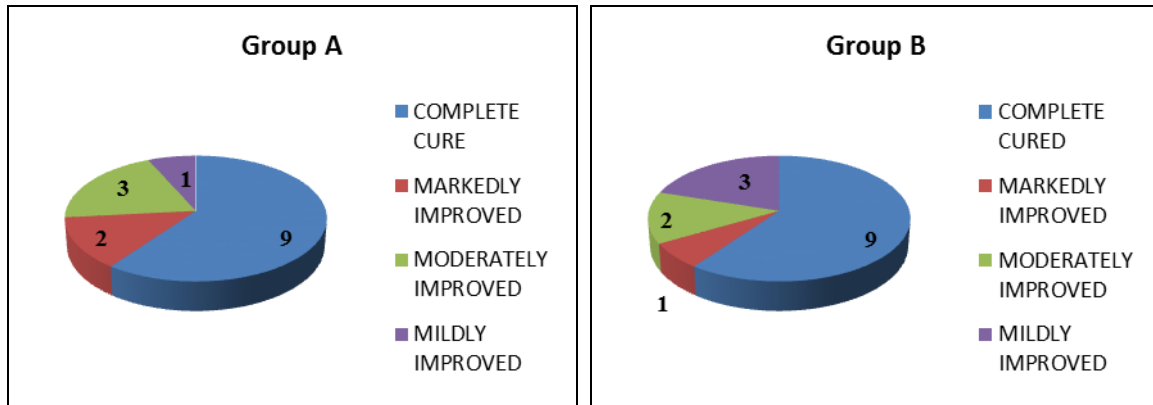
CONCLUSION

Dhanvantara gutika and *Baladi moola ghanvati* proved effective in curing *Garbhini udarshoola. Dhanvantara gutika* and *Baladi moola ghanavati* was effective in providing relief in the associated complains as well. *Baladi moola ghanavati* proved to be more effective than *Dhanvantara gutika* in curing *Udarshoola. Baladi moola ghanavati* is an effective, safe and economical alternative for the management of *Garbhini Udarshoola. Dhanvantara gutika* was found to be more effective in subsiding associated complaints like *vibandha, adhmaan and udgar.*

ACKNOWLEDGEMENT

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