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An open label single arm clinical study to evaluate the combined effect of Dashamoola Ksheera Basti and Rakta Chandana Yoga oral administration in Vandhyatwa w.s.r. to Female Infertility

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Infertility is a global crisis that affects millions across the world. Infertility is the failure to achieve conception by a couple of mature age, having normal coitus, during appropriate period of menstrual cycle, regularly at least for one year.[1] It affects approximately 12-15% of couples of reproductive age globally.[2] Increasing incidence of infertility demands more energetic Ayurvedic approaches. So, aiming at finding out the best method of treatment for Infertility, this study is taken up to evaluate the combined effect of Dashamoola Ksheera Niruha Basti and Rakthachandana Yoga oral administration on 20 patients of female infertility selected from OPD and IPD of Shree Dharmasthala Manjunatheshwara Ayurveda Hospital, Udupi and clinical assessment was done on the basis of subjective and objective criteria. Statistically and clinically significant results were obtained.

Keywords: Dashamoola Ksheera Basti, Rakta Chandana Yoga, Vandhyatwa, Female Infertility

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Introduction

Parenthood is often celebrated as a profound and joyous journey, with the arrival of a new life as one of the nature's most miraculous. Traditionally, marriage has been closely linked with the expectation of procreation and family life; therefore, infertility becomes a particularly complex issue that intertwines personal distress with societal expectations.

Infertility, when viewed from both modern and Ayurvedic perspectives, reveals distinct yet complementary insights. Infertility is defined as the inability to conceive after one year of unprotected sexual intercourse. Female infertility can be caused by various factors like- cervical, uterine, tubal and ovarian factors. Though the explanation of infertility is available in other Samhitas, particularly in the *Harita Samhita*, a detailed explanation of *Vandyatwa* (infertility) and its subtypes is provided. [3]

In classics, *Vandyatwa* is often considered a complication arising from untreated conditions such as *Yonivyapat* (gynaecological disorders), *Artavavyapat* (menstrual disorders), and *Asrigdhara* (abnormalities in menstruation), and is classified as one of the 80 *Vataja Nanatmaja Vikaras* (diseases caused by *Vata* imbalance).[4]

Vata Dosha plays a pivotal role in the pathology of all Yonivyapat and Artavavyapat. [5] Basti, being Ardha Chikitsa, [6] which is said to be Paramaushadha for treatment of Vata disorders, [7] tackles all the gynecological pathologies of Vata including Vandhyatwa. Sahacharadi Taila is selected for Anuvasna Basti.

As Sahachara is a potent Vatahara drug[8] and Taila does Yoni Vishodhana.[9] Dashamoola is best Vata Kaphahara. Ksheera is Amritopama.[10]

When Dashamoola is processed with Ksheera, it acts best on Tridosha. Dashamoola Ksheera Niruha Basti is thus preferred. Raktachandana is Vrishya[11] and Apamarga is Vatahara. So, in this clinical trial oral administration of Raktachandana with Apamarga Swarasa has been taken.

Materials and Methods

Ethical Clearance: Clearance from the Institutional Ethical Committee was obtained.

Sample source: A minimum of 20 subjects who have been unable to conceive and fulfilling the diagnostic criteria were selected for study from OPD and IPD of Sri Dharmasthala Manjunatheswara Ayurveda Hospital, Kuthpady, Udupi.

Consent: A written consent was taken from the patients before their participation in the trial.

Drug source: Sahacharadi Taila, Rakthachandana Churna and the drugs for Niruha Basti were procured from SDM Pharmacy, Udupi.

Apamarga (Achyranthes aspera Linn.) identified and collected from their natural habitat.

Inclusion Criteria:

- 1. Patients of Primary infertility and secondary infertility, aged between 19-40 years.
- 2. Patient who is in active marital life with partner having normal seminogram.
- 3. Patients who are fit for
- 4. Patients with Unexplained Infertility.

Exclusion Criteria:

- 1. Patients with Genital infections.
- 2. Patients with Bad obstetric history (Previous unfavorable fetal outcome in terms of 2 or more consecutive spontaneous abortions, early neonatal deaths, etc.)
- 3. Patients with premature ovarian failure.
- 4. Patients with Congenital anomalies of uterus.
- 5. Patients with surgical factors including uterine fibroids, cervical polyp, pin hole cervical os etc.
- 6. Patients suffering from genital tuberculosis.
- 7. Patients with hydrosalpinx and tubal block.
- 8. Patients with Sexually Transmitted Diseases such as HIV and HBsAg.
- 9. Any other systemic illness such as DM, HTN, Thyroid dysfunction.

Intervention:

- 1. Dashamoola Ksheera Basti and Sahacharadi Taila Anuvasana Basti in Yoga Basti course, after cessation of menstrual bleeding for 2 consecutive menstrual cycles.
- 2. Combination of *Raktachandana Churna* 5 grams and *Apamarga Swarasa* 10 ml, before food BD for 8 days, after cessation of menstrual bleeding for 2 consecutive menstrual cycles (No other interventions will be done till the follow-up of the subject)

Poorvakarma:

Preparation of the medicine:

Ingredients:

Preparation of *Ksheerapaka* - 125 gm of *Kashaya* drugs is taken. To this 1000 ml of water and 250 ml of *Godugdha* is added and boiled till it is reduced to 250 ml.

Madhu - 80 ml Saindhava Lavana - 5 gm Moorchita Tila Taila - 120 Ml Dashamoola Kalka - 40 gm Dashamoola Ksheerapaka - 250 ml Total - 480 ML

Preparation of the patient:

- Sthanika Abhyanga to abdomen and buttock with Murchitha Tila Taila with Ushna Jala
- Sthanika Swedana to abdomen and buttocks by Nadi Sweda
- Patient will be on empty stomach for Niruha Basti and consume food before the administration of Anuvasana Basti

Pradhana Karma:

Niruha and *Anusavasana Basti* were administered as per *Basti* guidelines.

Duration:

- Duration of treatment Two Consecutive cycles- 16 days
- Follow-up After 2 months
- Total duration of study 2 Months

Assessment Criteria:

Patient was evaluated before (0th day), at the end of the second course of Basti and oral medication and on the day of follow up, based on subjective and objective parameters.

Subjective Parameters:

Attainment of Suddha Artava Lakshanas.

Objective Parameters:

Conception evidenced by UPT and USG.

- Conceived
- Not conceived

Observation and Results

1. Colour of bleeding

Table 1: Showing the mean of Colour of bleeding.

BT Mean	Mean Diff D			%		Wilcoxon rank test					
						SD	SEM	Р	Z	Significance	
1.600	ΑT	1.150	0.45	28.125	вт	0.821	0.184	0.016	-2.460	S	
					ΑT	0.489	0.109	1.000	0.000	S	
	FU	1.150	0.45	28.125	FU	0.489	0.109	0.031	-2.251	S	

The initial mean score for Colour of bleeding was 1.600, which decreased to 1.150 after treatment and 1.150 after follow-up. This reflects a mean difference of 0.45, after treatment and follow-up, indicating improvements of 28.125%. Additionally, tests for statistical significance confirm that these results are statistically significant, with p-values of 0.016, demonstrating a definite therapeutic benefit of the treatment on Colour of bleeding.

2. CLOTS

Table 2: Showing the mean of clots

BT Mean	M	lean	DiffD	%		Wilcoxon rank test				
						SD	SEM	Р	Z	Significance
0.500	ΑT	0.150	0.35	23.3	вт	0.513	0.115	0.039	2.333	S
					ΑT	0.366	0.0819	0.002	-3.162	S
	FU	0.000	0.5	33.33	FU	0.000	0.000	0.002	-3.162	S

The initial mean score for Clots was 1.500, which decreased to 0.150 after treatment and further to 0.000 after follow-up. This reflects a mean difference of 0.35 and 0.5, respectively, after treatment and follow-up, indicating improvements of 23.3% and 33.33%. Additionally, tests for statistical significance confirm that these results are statistically significant, with p-values of 0.039 and 0.002, demonstrating a definite therapeutic benefit of the treatment on Clots of Menstrual bleeding.

3. Dysmenorrhea

Table 3: Showing the mean of dysmenorrhea

				_		-						
BT Mean	M	lean	DiffD	%		Wilcoxon rank test						
						SD	SEM	P	Z	Significance		
2.500	ΑT	1.350	1.15	46	ВТ	1.000	0.224	<0.001	-3.360	S		
					ΑТ	0.489	0.109	0.031	-2.449	S		
	FU	1.050	1.45	58	FU	0.224	0.0500	<0.001	-3.568	S		

The initial mean score for Dysmenorrhea was 2.500, which decreased to 0.1350 after treatment and further to 1.050 after follow-up.

This reflects mean difference of 1.15 & 1.45, respectively, after treatment & follow-up, indicating improvements of 46% & 58%. Additionally, tests for statistical significance confirm that these results are statistically significant, with p-values of <0.001, demonstrating definite therapeutic benefit of treatment on dysmenorrhea.

4. Dyspareunia

Table 4: Showing mean of Dyspareunia

BT Mean	1	4ean	DiffD	%		Wilcoxon rank test					
						SD	SEM	Р	Z	Significance	
0.350	ΑT	0.0500	0.3	85.71	вт	0.489	0.109	0.031	-2.449	S	
					ΑT	0.224	0.0500	1.000	-1.000	NS	
	FU	0.000	0.45	100	FU	0.000	0.000	0.016	-2.646	S	

Initial mean score for Regularity of cycle was 0.350, which decreased to 0.0500 after treatment & further to 0.000 after follow-up. This reflects mean difference of 0.3 & 0.45, respectively, after treatment & follow-up, indicating improvements of 85.71% & 100%. Additionally, tests for statistical significance confirm that these results are statistically sig., with p-values of 0.031 & 0.016

5. Shudharthava

Table 5: Showing mean of attainment of Shudarthava Lakshana

BT Mean	M	lean	DiffD	%		Wilcoxon rank test					
						SD	SEM	Р	Z	Significance	
0.900	ΑT	0.000	0.900	100	вт	0.308	0.144	<0.001	-4.243	S	
					ΑT	0.000	0.000	1.000	1.976	NS	
	FU	0.000	0.900	100	FU	0.000	0.000	<0.001	-4.243	S	

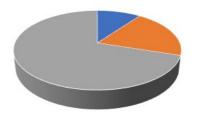
Initial mean score for Shuddha Artava Lakshana was 0.900, which decreased to 0.000 after treatment & further to 0.000 after follow-up. This reflects mean difference of 0.9, respectively, after treatment & follow-up, indicating improvements of 100%. Additionally, tests for statistical significance confirm that these results are statistically significant, with p-values of <0.001 demonstrating definite therapeutic benefit of treatment on Shuddha Artava Lakshana

Final Result

Table 6: Table showing Final result

Final Result	No. of Subjects	Percentage
rillai Result	No. of Subjects	Percentage
Conceived	4	20
Improved	14	70
No Relief	2	10
Total	20	100

No.of Subjects



No Relief
 Conceived
 Improved

Figure 1: Showing the Final Result

Out of 20 patients, 4 patients conceived. There was significant improvement found is attaining Shudharthava.

Discussion

Unexplained Infertility account for a significant portion of female infertility. As the patients included in the present study were of unexplained infertility, and notable effects on attaining *Shuddhartava Lakshana* were noted, which is very important for conception. While corelating to modern science, *Shuddhartava* ensures a well-nourished endometrial lining, making implantation more successful.

Ayurveda offers various treatment options for managing this condition (Vandhytwa), with Panchakarma being the primary treatment as it removes Srothorodha and maintains Tridosha Sathmyata. Basti, a unique procedure, serves multiple therapeutic purposes, including Shodhana, Balakara, Sangrahaniya, Vayasthapana and Shukra Vardhana. It is Paramoushadha for Vata predominant diseases, as Pakwaashaya is the main site of Vata. It is classified as Niruha and Anuvasana Basti. It stimulates the Enteric Nervous System to regulate the HPO axis function.

Dashamoola drugs are Vatakaphahara and when processed with Ksheera acts on Tridosha. Dashamoola drugs contain chemical constituents which regulate the menstrual cycle by estrogenic effects and enhance chances of conception by providing protective environment to reproductive cells by antioxidant effect. Raktachandana has Vrishya properties. The Chemical composition of Raktachandana have phytoestrogenic effects, Anti-inflammatory properties and does hormonal regulation. Apamarga has properties like Deepana, Kaphavatahara.

The Chemical composition of *Apamarga* is helpful in fertility as its chemical constituents possess the Antioxidant properties which support ovarian function and balance hormones. The gastrointestinal tract consists a complex enteric nervous system (ENS) extending from the esophagus to the anus, with the sigmoid, rectal, and anal regions being more richly innervated by parasympathetic fibers that stimulate defecation reflexes. Absorption occurs through the gastrointestinal mucosa via active transport and passive diffusion, with the rectum's dense blood and lymphatic vessels allowing lipidsoluble substances to be readily absorbed. The active ingredients in Basti formulations are mainly water-soluble, and the hyperosmotic nature of Niruha Basti enhances the uptake of harmful substances. The gut acts as a sensory organ with neural, immune, and sensory cells that provide feedback to local regulatory systems and communicate with the central nervous system (CNS). Basti stimulates the ENS, potentially impacting the CNS and restoring physiological balance while targeting inflammatory substances with its anti-inflammatory components. Ingredients honey and Saindhava generate action potentials, while the Kalka may induce colonic distention, triggering evacuatory reflexes and catecholamine release. Recent studies highlight the importance of gut-brain interactions in managing discomfort, as visceral afferent menstrual stimulation activates the HPA axis and autonomic nervous system, restoring neurotransmitter and hormone balance.

Also, Action of *Basti* in this study can be analyzed *Basti* action can be analyzed as; by fostering gutbrain communication, these interactions can alleviate symptoms associated with menstrual discomfort.

Hence, we can conclude the properties of Dashamoola drugs and Sahacharadi Taila along with the combination of Raktachandana Yoga collectively help in Artava Dushti and Yonidosha and thus help in Vandhyatwa.

Conclusion

In conclusion, this study effectively highlights the combined therapeutic impact of *Dashamoola Ksheera Basti* and *Rakta Chandana Yoga* in managing female infertility.

Vandhyatwa, as established, should not be considered an isolated condition but rather the result of various Yoni Vyapath and Arthava Dushti, predominantly influenced by Vatadushti. Hence, normalizing Vata Dosha emerges as the central focus in infertility management.

The clinical use of *Sahacharadi Taila*, administered as *Matra Basti*, proved significantly beneficial due to its *Vatahara* properties and established indications for *Yoniroga*. Additionally, the combination of *Dashamoola* (noted for its *Vatakaphahara* properties) and *Ksheera* (renowned as *Amritopama*) further enhanced therapeutic efficacy, emphasizing the relevance of *Dashamoola Ksheera Niruha Basti* as a preferred intervention.

Rakta Chandana (Vrishya) and Apamarga (Vatahara). kev components of the oral combination, demonstrated synergistic action in improving fertility parameters. The results revealed notable success, with four patients successfully conceiving, alongside substantial symptomatic relief in conditions such as dysmenorrhea, dyspareunia, and improvements in Shudharthava. Two patients achieved conception within the treatment duration, while two others conceived during the follow-up period.

Overall, this study underscores the efficacy of integrative Ayurvedic interventions in addressing female infertility, paving the way for further research to validate these findings and expand their clinical applicability.

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