

Research Article

Exploring the Role of Ardhhamatrika Basti in Anovulatory Female Infertility: A Clinical Evaluation

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Abstract

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Introduction: The difficulty to conceive or subfertility represents major social and psychological burden amongst couples. Anovulation, fallopian tube disease, pelvic adhesions, endometriosis, and unexplained infertility are the major causes of female infertility. Initial treatment for women with anovulatory infertility involves a sequential approach, moving from less to more resource-intensive therapies. Anovulation is dominant factor, which comprises 30-40% of female infertility factor. **Aim:** To evaluate the efficacy of *Ardhamatrika Basti* in the management of female Infertility with special reference to Anovulatory factor. **Methods & Materials:** The study was conducted on 18 female subjects of anovulation with primary or secondary infertility, fulfilling the inclusion criteria and diagnosed by Transvaginal sonography for 2 consecutive cycles. Patients received *Ardhamatrika Basti* (through rectal root, after cessation of menstruation) for 16 days till ovulation occurred. The observations and results were assessed by follicular study conducted from 8th-9th day of menstrual cycle till 20th day for three consecutive cycles. **Statistical Analysis:** The results were drawn after analysing nonparametric data statistically by means of Wilcoxon signed-rank test. **Results:** In the study, ovulation was achieved in 81.25 % of the patients including 25 % conceptions within follow up period. **Conclusion:** As a result, it has been concluded that *Ardhamatrika Basti* is effective treatment modality in infertility owing to anovulatory factor.

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Introduction

A condition of the female or male reproductive system is referred to as infertility when it results in the inability to conceive a clinical pregnancy following 12 months of regular, unprotected sexual intercourse activity (1). It is estimated to affect 15% of reproductive-aged couples worldwide (2). In the female reproductive system, infertility may be caused by fallopian tube disease, Anovulation, Uterine disorders, pelvic adhesions, disorders of endocrine system, and unexplained causes, etc. Anovulation is dominant factor, which comprises 30-40% of female infertility factor According to International Federation of Gynecology and Obstetrics (FIGO) manual (3).

Differentiation, separation and then expulsion are the function of *Vata*. So, Process of folliculogenesis and ovulation have influence

of *Vata Dosha*. *Vata Dosha* plays a significant role for normal physiological functions of reproductive system and also generation of pathological conditions of the same (4). So, in anovulation cases *Vata* may be disturbed and *Basti* is believed to be the prime treatment for the same (5). *Yapana Basti* is one of the type of the *Niruha Basti*, which is specifically indicated to infertile female also (6). Acharya Vrundmadhava have stated *Ardhamatrika Basti*(7). It is one type of *Yapana Basti* and having *Deepana* (local Appetizer), *Pachana*(digestive), *Brihana* (nourishing), *Sarvarogahara* (capacity to destroy all diseases), etc. Objective of this study is to evaluate the efficacy of *Ardhamatrika Basti* in the management of *Vandhyatva*(female Infertility) w.s.r. to Anovulation along with Menstrual Abnormalities. As taking into consideration, it has been plotted to evaluate effect of *Ardhamatrika Basti* (A special medicated enema) on Anovulatory factor.

Materials and Methods

Study Design and Setting: This study was single-arm, interventional prospective study trial was organized during years 2017–2020. The study had a due clearance from the Institutional Ethics Committee (IEC). IEC No.PGT/7/-A/Ethics/2018-19/2638 (Dated 18/12/2018). Written consent was taken from each patient prior to beginning of the study. The demographic profile, personal

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history, and history of past illness were recorded in the Clinical proforma. The Trail drug was given for 2 cycles. During the follow up, ovulation study and occurrence of conception were recorded.

Trial interventions: In present study, *Ardhamatrika Basti* was selected as trial drug. *Tila Taila*, *Saindhava*, *Madanphala Choorna* and *Dashmoola Kashaya* were acquired from Pharmacy of Gujarat Ayurved University, Jamnagar. Rest of raw drugs were purchased from local market of Jamnagar on 28/2/2019. The classical method of *Niruha Basti* preparation will be used for the preparation of *Ardhamatrika Basti*. Ingredients of *Ardhamatrika Basti* are given as per Table 1. *Basti* preparation was done as per classical *Basti* preparation method. With 480ml quantity of *Ardhamatrika Basti* was given through Rectal route for 16 days after cessation of menses for 2 consecutive cycles at morning 8:30am to 10:00am time.

Study Participants: Patients were chosen from the Out-Patient Department of Prasutitantra and Streeroga Department, PG Ayurveda Hospital, ITRA, Jamnagar who are fulfilling the criteria of diagnosis and inclusion criteria. They were enrolled for study, irrespective of their caste, religion etc.

Inclusion Criteria: Female patients of child bearing age from 20-40 years, Patients, who possess active married life minimum 1 year and suffering from Infertility with 2 or more consecutive anovulatory cycles diagnosed by Transvaginal sonography, Primary and secondary both types of infertile patients having anovulatory cycle or with unruptured follicle, Patient eligible for administration for *Basti*, Patient who were having any body mass index will be included for Study. Patients were included after 3 month of washout period of hormonal therapy.

Exclusion Criteria: Female patients of age less than 20 years and more than 40 years, Congenital deformities and infectious diseases of reproductive tract like tuberculosis, Sexually Transmitted Diseases and carcinoma, Patients with PCOS, Chronic systemic diseases like Diabetes, Hypertension, HIV, TB etc., Patient not eligible for *Basti*, Patient with Hormonal medication will be excluded for the study.

Laboratory Investigations: Before starting the course of treatment, every patient were examined by routine haematological examination {Haemoglobin%, Total WBC Count, Differential Blood Count, Pack Cell Volume (PCV), Erythrocyte Sedimentation Rate (ESR)} and Urine examination {Routine and microscopic} to rule out any type of general pathology. Also, Serum Follicular Stimulating Hormone, Serum Luteinizing Hormone, Serum Thyroid Stimulating Hormone and Serum Prolactin have been carried out before and after treatment.

Statistical estimation of results: Statistical analysis was performed using the Sigma Stat for Windows version 3.5 software (8). Baseline characteristics were reported as mean \pm standard deviation (SD) and frequency in percentage. Wilcoxon signed-rank test was used to the nonparametric statistical data for assessing the difference between before and after treatment. A value of $P < 0.05$ was marked as a statistically significant.

Criteria of Assessment: The result was evaluated on the basis of follicular study (ovulation study).

Objective Parameter: Follicular study was assessed by Trans Vaginal Sonography before and after treatment. According to size of follicle, special scoring method was followed. A special validated scoring pattern for objective parameters was used from

concluded Randomized trial. Scoring Pattern for objective parameter can be seen as per Table 2.

Subjective Parameter: A special proforma was prepared incorporating the associated complains related to anovulation like menstrual abnormalities. Scoring Pattern for Subjective criteria is mentioned in Table 3.

Observation and Results

Total 18 patients were enrolled in this study, among them 16 patients completed the total protocol of treatment and only 2 patients dropped out during treatment. Participant's flow chart has mentioned in Figure no 1.

The demographic data of this trial have shown that mean age of participants is 28.2 years. The majority of patients were housewives (82.35%) and literate (41.17%). 88.23% patients belonged to lower middle class and 64.70% patients belonged to joint family. 76.47% patients came from urban habitat. All (100%) patients were Hindu. 82.35% patients were vegetarian. 17.64% of patients were having BMI (18.5-24.9), 76.47% of patients with (25-30) BMI and 11.76 % of patients were having (>30) BMI.

In this study, primary infertility and secondary infertility had seen in 50%-50% of total patients. 100% of patients were having anovulatory cycles. 44.44% patients had 1-5 years chronicity. 72.22% patients had used hormonal treatment for infertility. 82.35% of patients were having irregular cycle of menstruation. 47.05% patients were having scanty menses. 23.53% had painful menses. 5.88% patients had duration of menstrual period of <2 days. 82.35% of patients were having >35 days interval of cycle. 41.17% patient's husbands were reported with undesirable semen report.

Analyzing the results, it was found that 13 patients (81.25%) had ovulated after treatment. Total 85.41% of relief was found. So, statistically highly Significant ($P = <0.001$) improvement was noted as placed in Table 4. While during 1st follow up month, 13 (81.25%) of patients got ovulated. In 2nd follow up month, 11 (68.75%) of patients had ovulation, as mentioned in Table 5. Seeing the Overall Effects of Therapies, normal Ovulation was seen in 81.25% of the patients. 6.25% were remaining unchanged as given data in Table 6. Effect of therapy on follicular size and growth described as per Table 7. While discussing effect of *Ardhamatrika Basti* on hormonal level, statistically significant changes were observed in S.PRL level ($P=0.009$) as given in Table 8.

Discussion

As a one of the world's oldest medical systems, Ayurveda also contributes treatment protocol for female infertility broadly. *Tridoshha*(three governing factors of body) are the root cause for each and every process or phenomenon occurs in our body. *Vata Dosha* is responsible for functions like differentiation, separation and then expulsion in all systems of body. So, Process of folliculogenesis and ovulation have influence of *Vata*. *Basti* is believed to be the prime treatment for *Vataja* diseases (9).

As per numerous clinical studies that are conducted throughout country, it was concluded that when *Basti* was given under classical criteria, maximum efficacy was observed. Support to this conclusion one Randomized clinical trial has been reported that *Madhutailika Basti* is a type of *Yapana Basti*, which is most effective to induce ovulation (10). Another study has stated that *Narayana Taila Matrabasti* is also highly significant to induce ovulation (11). Analyzing our observation, *Ardhamatrika Basti* is also effective for ovulation induction.

Ardhamatrika Basti is one type of *Yapana Basti* performs dual function of both *Anuvasana* and *Niruha*; hence these *Basti* are *Brihana* and *Srotoshodhaka* at a time (12). Anovulation is condition where, significant loss of the body elements for proper growth of follicle supervened by obvious *Vatapradhama Tridoshaprakopa*. Such conditions demand *Brihana* and *Tridosha Shaman*. *Yapana Basti* can achieve both the goals at a time.

Maximum drugs used in *Ardhamatrika Basti* like *Tila Taila* (oil of *Sesamum indicum* Linn.), *Madhu*, *Purana Guda*, *Masha Yusha* are *Ahara Dravya*. Hence, these are wholesome and do not act adversely. As an *Ahara Dravya*, their most importance function is to keep nourishment of All *Dhatus* and *Upadhatu*. *Artava*(Ovum) must be nourished by this *Basti* and as a result timely ovulation occurs. Phytoestrogenic property of ingredients of *Ardhamatrika Basti* like *Shatapushpa* (*Anethum sowa* Linn.), *Tila Taila* regulates neuropeptide Y activity, which in turn regulates the activity of gonadotropin secretion (13, 14, 15). *Masha Yusha* is aphrodisiac (16). *Dashamoola Kwatha* has Anti-inflammatory action (17). They are working indirectly through nourishment of all *Dhatus*. After LH Surge, secretion of steroids, prostaglandins, chemokines, and cytokines takes place, which are also mediators of inflammatory processes (18). It can be assumed that *Basti* ingredients as a synergistic and cumulative effect may help to disintegrate the pathogenesis of Anovulation. Timely recruitment and selection of follicle, proper folliculogenesis and ovulation occurs.

Also, during trial it has been observed that *Ardhamatrika Basti* is highly significant in cases of hyperprolactinemia, as mentioned in Table 6. It may be due to Phytoestrogenic property *Shatapushpa* and *Tila Taila*. It acts in both high oestrogenic and low oestrogenic condition. Thus, it corrects hypoestrogenic condition due to hyperprolactinemia. By virtue of *Deepana*, *Pachana*, *Srotoshodhana*, *Anulomana* properties, *Ardhamatrika Basti* leads to *Amapachana*, *Vatakaphashamana* and *Garbhashaya Shodhana* which may remove *Sanga* and *Avarana* leading to proper function of *Vayu* regulating function of *Beejakosha* and *Beejotsarga* (Ovulation) as well as corrects menstrual abnormalities. Hence, the growth and rupture of follicles were observed in *Ardhamatrika Basti* group. It nourishes the *Dhatu* which are vitiated due to *Vata Prakopa*.

Ardhamatrika Basti through rectum goes instantly into systemic circulation thus has faster absorption. The Enteric nervous system (ENS) is a collection of neurons in the gastrointestinal tract (GIT) that constitutes 'brain of gut' and can function independent of

CNS (19). It is well established that the ovarian cycle is regulated through the feedback of hormones on the neural tissue of CNS. *Ardhamatrika Basti* may have an effect on endogenous opioids within the ENS particularly endorphins ((β -endorphin). They are stimulated to have an effect on GnRH release and reduction of the release of follicle-stimulating hormone(FSH) and luteinising hormone(LH) to regularizing HPO axis regulating proper folliculogenesis and ovulation (20, 21).

It has also been seen that, no any complications, adverse effects, side effects are detected in any patients during this clinical trial. No any study has been done on efficacy of *Ardhamatrika Basti* on Anovulation. Other studies have been conducted on the clinical safety and efficacy of *Ardhamatrika Basti* suggests that clinical trials did not found any adverse drug reactions. Also, it is clinically effective and reliable in the management of *Janu Sandhigatavata*, *Amavata*, *Shukrakshaya* (22, 23, 24).

Limitations: However, this trial was conducted for 16 days after cessation of menstruation for 2 consecutive cycles only and it may require an extended duration of treatment to note ovulation. To evaluate the effect of *Ardhamatrika Basti* in relation to menses abnormalities, same trial can be planned with longer study duration.

Conclusion

Basti is the best treatment for *Vataja* disorders. Some components of *Basti* possess phytoestrogenic constituents also. So, in nut shell *Ardhamatrika Basti* may help to enhance quality of reproductive organs by local purification and to regularize hypothalamus-pituitary-ovarian axis. This corrected hormonal orchestra supports the proper folliculogenesis, regular ovulation and provide healthy atmosphere within uterus, which helps to achieve conception.

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Ethical Statement: Institutional Ethics Committee (IEC) approval was taken in accordance with the Declaration of Helsinki. Informed Written Consents have been received according to rule of Institutional Ethics Committee (IEC), ITRA, Jamnagar

Conflicts of interest: There are no conflicts of interest.

Table 1: Ingredients of *Ardhamatrika Basti*

<i>KwathaDravya</i>				
No	Drug (<i>Yavakuta</i>)	Latin Name	Part used	Quantity
1	<i>Bilva</i>	<i>Aegle marmelos</i> corr.	Stem bark	
2	<i>Shyonaka</i>	<i>Oroxylum indicum</i> vent.	Stem bark	
3	<i>Patala</i>	<i>Stereospermum</i>	Stem bark	
4	<i>Gambhari</i>	<i>Gmelina arborea</i> linn.	Stem bark	
5	<i>Agnimantha</i>	<i>Premna mucronata</i> Roxb.	Stem bark	
6	<i>Kantakari</i>	<i>Solanum surattense</i>	Whole plant	
7	<i>Brihati</i>	<i>Solanum indicum</i> linn.	Whole plant	
8	<i>Gokshura</i>	<i>Tribulus terrestris</i> linn.	Fruit	
9	<i>Shalaparni</i>	<i>Desmodium gangeticum</i>	Whole plant	
10	<i>Prushniparni</i>	<i>Uraria picta</i> Desv.	Whole plant	
				Total 192 ml

Kalka Dravyas				
11	<i>Shatapushpa</i>	<i>Anethum sowa</i> linn.	Seed	12gm
12	<i>Madanaphala</i>	<i>Randia dumetorum</i> lam.	Dry Fruit	1 dry fruit=10gm (Appr.)
13	<i>Madhu</i>	Honey		48g
14	<i>Saindhava</i>	Rock salt		12g
15	<i>TilaTaila</i>	<i>Sesamum indicum</i> linn.		96ml
16	<i>Purana Guda</i>	Jaggery		48g
17	<i>Masha Yusha</i>	<i>Phaseolus mungo</i> Linn.		96 ml

Table 2: Scoring pattern of follicle

Scoring Number	Size of follicle
3	<12 mm
2	12-19 mm
1	>19-23 mm
0	Ovulated

Table 3: Scoring Pattern for Subjective criteria

Subjective criteria	Score	Subjective criteria	Score
1. Interval between two cycles		3. Quantity of menstrual Blood	
21 to 35 days	0	4 or more than 4 pad use/cycle	0
>35-40 days	1	3 pad use/cycle	1
>40-45 days	2	2 pad use/cycle	2
>45 days	3	1 pad use/cycle	3
		Spotting bleeding without pads	4
2. Duration of menstrual cycle		4. Pain during Menses	
4-7 days	0	No Pain	0
3 days	1	Mild Pain	1
2 days	2	Moderate Pain	2
1 day	3	Severe Pain	3

Table 4: Effect of *Ardhamatrika Basti* in Follicular Size (Sign Rank Test)

N	Mean		Mean diff	% of Relief	W	Z	P	Significance
	B.T	A.T.						
16	2.5	0.43	2.06	85.41	-120.00	-3.520	<0.001	HS

(n=number of patients, HS- Highly significant)

Table 5: Follicular sizes in follow up period (n=16)

Size of Follicle(mm)	No. of Patients	1st month	No. of patients	2nd month
0-12	3	18.75	4	25.00
>12-19mm	0	0.00	1	6.25
>19-23	0	0.00	0	0.00
Ovulation	13	81.25	11	68.75

Table 6: Overall Effects of Therapy

Parameters	No. of patients	%
Conceived	4	25
Normal Ovulation	13	81.25
Markedly Improved	0	0.00
Moderately Improved	2	12.50
Unchanged	1	6.25

Table 7: Effect of *Ardhamatrika Basti* on Follicular Growth and Ovulation (n= 16)

Size of follicle (in mm.)	B.T.		D.T.(1st Cycle)		D.T.(2nd Cycle)		A.T.	
	No. of patients	%	No. of patients	%	No. of patients	%	No. of patients	%
0-12	18	100	4	25.00	2	12.50	2	12.50
>12-19	0	0	3	18.75	2	12.50	1	6.25
>19-23	0	0	0	0.00	0	0.00	0	0.00
Ovulation	0	0	11	68.75	12	75.00	13	81.25

Table 8: Effect of *Ardhamatrika Basti* on Hormonal Level

n	Investigation	Mean Score		% Relief	S.D. (±)	S.E. (±)	t'	P
		B.T.	A.T.					
16	S. FSH	6.407	5.836	8.92	4.062	1.173	0.448	0.635
16	S. LH	7.004	7.657	34.24	5.664	1.635	1.467	0.170
16	S.PRL	18.371	12.293	33.08	6.711	1.937	-0.749	0.009
16	S.TSH	1.740	2.655	52.54	3.849	1.111	-0.823	0.428

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