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ORIGINAL RESEARCH ARTICLE

ROLE OF MADHUTAILIKA BASTI IN INFERTILITY W.S.R. TO ANOVULATORY FACTOR

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Abstract:

Background: Anovulation is probably the major cause of female infertility which inevitably disrupts a woman's chances to conceive and affects personal as well as social life of a female. **Aims:** To study Infertility caused by anovulatory factor conceptually and to evaluate the clinical efficacy of the holistic Ayurvedic approach specifically a special mode of therapy i.e. Madhutailika Basti upon this factor. Madhutailika Basti is a type of Basti therapy which has least complications and can be easily applied in today's fast life. **Setting & Design:** Clinical study was conducted on patients of age group 19-40 years having complaint of failure to conceive for minimum one year with two consecutive anovulatory cycles in serial trans- vaginal sonography. **Methods & Materials:** Total 11 patients were registered, out of them 10 completed the treatment. Before starting treatment, Ampachana tablets were given for seven days to improve digestion after that bio-purification was done with castor oil mixed milk. Madhutailika Basti was given after cessation of menses for 15 days in two consecutive menstrual cycles. **Statistical Analysis Used:** The results were drawn after analysing the findings statistically by means of 't' tests. **Results:** In the study, ovulation was achieved in 70% of the patients including 20% conceptions within follow up period. **Conclusion:** As a result it was concluded that madhutailika Basti is effective treatment modality in infertility owing to anovulatory factor.

CTRI Registration: This Clinical trial is registered under CTRI (Clinical Trials Registry - India) vide number: CTRI/2012/10/003037

Key words: Beeja, Ovulation, Infertility caused by Anovulatory factor, Madhutailika Basti

Introduction:

Infertility primarily refers to the biological inability of a person to contribute to conception.¹ 12 months is the lowest reference limit for time to pregnancy (TTP) by the World Health Organization.² Among the causes of infertility contributed by female, Ovulatory dysfunction accounts 30-40% which includes Anovulation i.e. failure to produce a

mature ovum. Proper time of menstrual cycle and ovulation(Ritu), Healthy status of Reproductive organs(Kshetra), Nutritional Status of mother (Ambu) and Sperm & Ovum(Beeja) are considered as prime requisites for conception and healthy progeny as per ayurvedic classics. Abnormality of ovum (Vitiation of beeja) includes anovulation.³ Vata has prime importance in formation of ovum by virtues of its division &

providing structural differentiation to tissue properties.⁴ Vitiating of *Vata* can lead to Anovulation which is mentioned as amenorrhoea, anovulation, malformed ovum, cessation of ovulation in Ayurvedic classics.^{5, 6, 7, 8} Basti therapy (Medicated enema therapy) is propounded as best line of treatment for vitiated *Vata*,⁹ hence may help in Anovulation too. No such clinical trial on infertility caused by anovulatory factor in ayurvedic context using treatment protocol of Madhutailik Basti (medicated enema) has been undertaken in any of the Ayurvedic PG/research centres so far. Hence keeping in mind the strong relation between pathogenesis of anovulation with vatadosha and after analysing anovulation in Ayurvedic perspectives, this clinical study was conducted to evaluate the efficacy of madhutailik basti in infertility caused by anovulatory factor.

Aims and Objectives:

- To study infertility caused by anovulatory factor conceptually.
- To evaluate the clinical efficacy of the selected procedure on ovulation process and thus, to assess the role of *vata* in process of ovulation.

Materials and Methods: Patients attending the O.P.D. of S.R.P.T. Dept., I.P.G.T. & R. A. Jamnagar, having complaint of failure to conceive for minimum one year were selected for the study and were diagnosed on the basis of anovulation in serial trans-vaginal sonography for two consecutive cycles.

All the raw drugs were procured from pharmacy of the institute which were authenticated by Pharmacognosy laboratory of the institute. For preparation of madhutailika basti, classical methods described for preparation of basti were adapted.¹⁰

Preparation of Madhutailika Basti

S. No.	Content of madhutailik Basti	Matra
1.	Erandamool Kvath - 2 pala (96 ml)	2 pala(96 ml)
2.	Madhu - 1 pala (48 ml)	1 pala(48 ml)
3.	Tiltail - 1 pala (48 ml)	1 pala(48ml)
4.	Satapushpa Kalka - 1/2 pala (24 ml)	½ pala(24 ml)
5.	Saindhava - 1/4 pala (12 gm)	¼ pala(12 gm)

Ethics: Study was approved by Institutional Ethics Committee, wide letter no. PGT/7-A/Ethics/2011-12/2087 dated 5/9/2011 S. No. 44.

Inclusion criteria:

Married female patients of reproductive age group of Primary / Secondary Infertility having two consecutive anovulatory cycles were selected for the trial.

Exclusion criteria: Patients having age less than 19 years and more than 40 years, patients suffering from disorders of reproductive tract e.g. tuberculosis, carcinoma, congenital deformities; Sexually transmitted disease – VDRL (Venereal Disease Research Laboratory), HIV (Human immunodeficiency Virus) were excluded from the study.

Study Design:

Type of Study: This study was a randomised clinical study.

Registered and dropped out patients- Total 11 patients were registered for the study, out of them 1 patient left the treatment due to separation from her partner. 10 completed the treatment.

Treatment protocol:

Preparatory phase - In all the patients Tablet Aampachana [containing Haritaki (*Terminalia Chebula*), Sunthi(*Zingiber Officinale*), Maricha(*Piper Nigrum*), Pippali(*Piper Longum*), Hingu(*Foetida Nerifolia*), Saindhav(Rock Salt) etc.] was given for 7 days to stimulate appetite and after that bio

purification was done by giving mild laxative in the form of Caster oil 1 tsf in cup of milk for one day prior to basti therapy.

Duration of treatment:

After cessation of menses, Madhutailika Basti was given for 15 days for two consecutive menstrual cycles. To assess the efficacy of treatment, serial Trans Vaginal Sonography carried out during treatment as well after treatment for two months.

Procedure of Basti Therapy:

- Pre-operative: Massage with Bala oil on all around the pelvic area including sole of feet for 10 minutes then steam sudation was given.
- Operative: Freshly prepared Madhutailika Basti; 228 ml in volume was given through anal route in Left lateral position.
- Post-operative: Rest in supine position for at least 30 minutes followed by sudation.

Criteria for assessment:

- The efficacy of the therapy was assessed on the basis of follicular study by Trans Vaginal Sonography and/or on the basis of conception.
- To evaluate the overall effect of therapy, a special scoring method was adopted to assess the size of follicle as follow:

Scoring Pattern of Follicle:-

- 0 = 0-12 mm
- 1 = 12-19 mm
- 2 = 19-23mm-cystic
- 3 = Ovulated

(For this scoring method, serial TVS were carried out in two consecutive cycles)

Assessment of Overall effect of therapy:-

- Complete remission- If Ovulation occurs
- Markedly Improved – If Ovulation does not occur but improvement in the size of follicles up to fully maturation i.e.>19 mm.
- Moderately improved – If there is improvement in size of follicles i.e.12-19 mm
- Conceived (As a secondary outcome) - Number of patients who conceived I during the treatment or follow up period.

Statistical Estimation of results:

The obtained data was analysed for statistical significance by using paired 't' test.

Follow up study.

Follow up study was done for two cycles after completion of the treatment.

Observations & Results:

Total 10 patients completed the treatment. Observations and results have been shown under table no.1 to 4 & Chart no.1, 2 & 3.

Table 1: Effect of Madhutailika Basti on follicular growth and ovulation in 1st cycle

Size of follicle (in mm.)	B.T.		D.T.		A.T.	
	No. of patients	%	No. of patients	%	No. of patients	%
0-12	10	100	03	30	02	20
12-19	00	00	00	00	01	10
19-23-Cystic	00	00	00	00	00	00
Ovulation	00	00	07	70	07	70

Table 2: Effect of Madhutailika Basti on follicular growth and ovulation in 2nd cycle

Size of follicle (in mm.)	B.T.		D.T.		A.T.	
	No. of patients	%	No. of patients	%	No. of patients	%
0-12	10	100	02	20	03	30
12-19	00	00	02	20	00	00
19-23/Cystic	00	00	00	00	00	00
Ovulation	00	00	06	60	07	70

Table 3: Effect of Madhutailika Basti on haematological and urine investigations

'n'	Investigation	Mean Score		S.D. (±)	S.E. (±)	't'	P
		B.T.	A.T.				
10	Hb	11.32	11.20	0.618	0.195	0.61	>0.05
10	TLC	7640	8770	1583.28	500.68	-2.26	=0.05
10	N	60.60	63.50	9.32	2.95	-0.98	>0.05
10	L	33.10	31	8.48	2.68	0.78	>0.05
10	E	4.1	2.9	2.25	0.71	1.69	>0.05
10	M	2.20	2.60	0.97	0.31	-1.31	>0.05
10	ESR	14	29	18.36	5.81	-2.52	<0.05
10	PCV	34.92	34.61	1.58	0.50	0.62	>0.05
10	URINE PUS CELLS	0.90	0.70	1.033	0.33	0.61	>0.05
10	URINE EPI.CELLS	1.30	0.50	1.55	0.49	1.63	>0.05

Table 4: Effect of therapy on follicular size

N	Mean		X (AT-BT)	%	S.D.	S.E.	T	P
	B.T.	A.T.						
10	0.00	2.20	2.20	73.33	1.317	0.416	5.284	<0.001

Chart 1: Total effect of therapy on ovulation

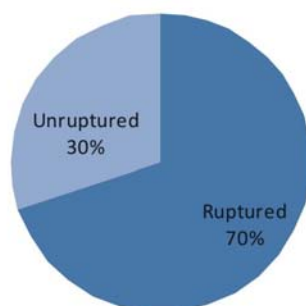


Chart 2: Total effect of therapy on conception

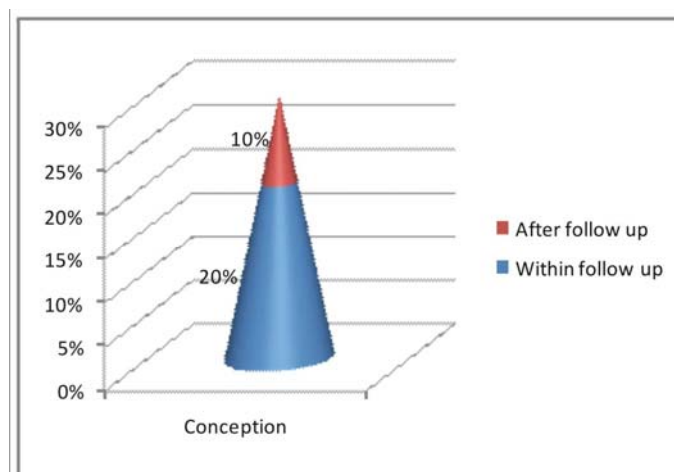
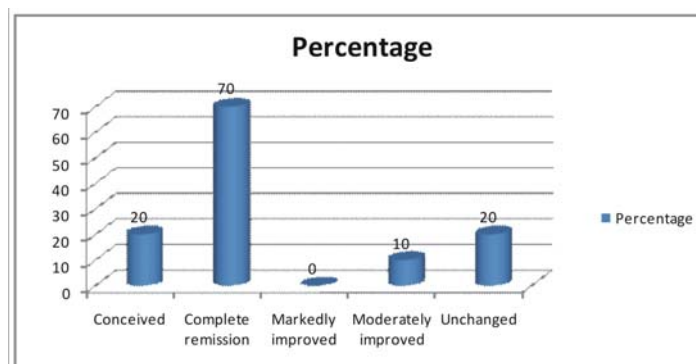


Chart 3: Overall effect of therapy



Discussion:

- Maximum 63.64% had primary infertility which indicates increasing incidence of infertility as a result of modern life style.
- 72.73% patients gave history of hormonal treatment. In modern medical science, so many therapies are developed, but they have unsatisfactory results, enormous expenses and lots of side effects like ovarian hyper- stimulation which direct people to turn towards Ayurveda.
- Body mass index was found below the normal limit in 18.18% and above the normal limit in 45.45% patients. Researches reveal that 6% of primary infertility in which ovulatory

dysfunction is present, 6% of results from being excessive underweight and another 6% from being excessively overweight.¹¹

- Improper dietary habits, and disturbed digestion were found in 45.45% patients. Which indicates that vitiation of digestive and metabolic fire and Doshic involvement results in to Anovulation.
- Worry/stress was present in 63.64% patients. Disturbed psychology lead to Vata –Pitta vitiation resulting in vitiation of Dosha, Dhatu and Mala. Ultimately hampers proper formation of Rasa Dhatu and its *Updhatu* Artava (Menstruation including ovum). The modern research reveals that stress disturbs the normal hormonal

regulation and it decreases the LH secretion, which ultimately leads to Anovulation.¹²

- Disturbed sleep pattern and day sleep were found in 63.64% and 72.73% patients respectively. Significant association is established between FSH levels and sleep duration in previous researches.¹³ Day sleep results in low digestive & metabolic process as a result creates disturbance in formation of its sub tissue Artava.
- 100% patients were having artava vaha srotodushti lakshana (Clinical features of vitiation of the menstrual channel) while Rasa Vaha and Rakta Vaha Srotodushti Lakshana were present in 90.91% patients.
- 70% of the patients started ovulating in both the cycles. Advantage of Basti was achieved even in the first cycle of treatment which was proved by finding of TVS during the treatment. In follow up period also, no relapse was found. This result was statistically highly significant ($P < 0.001$). Two patients i.e. 20% conceived within follow up period including one patient with primary infertility for 14 years and the other, having secondary infertility for 6 years. In addition to this, one more conception was achieved after follow up period that had started ovulating after completion of therapy.

Mode of action of Madhutailika Basti:

Basti normalizes the Apana Vata through both local and systemic effect as anal area is considered as root of body and site of Apana Vata is lower part of the body. Honey¹⁴ having Yogavahi property, increases potency of Basti. Saindhava by molecular, quick and smooth properties, reaches up to micro channels, breaks down morbid mala and liquefies Dosha. Sesamee oil^{15, 16} with smooth, heavy properties pacifies dry, rough properties of vata and increases permeability of cell membrane. Shatapushpa¹⁷ and Eranda Moola¹⁸

add appetizing, uterine purification, restoration of health property to this. By virtues of all these, Madhutailika Basti helps in amapachana and Vata Kapha Shamana which leads to removal of blockage from channels thus maintaining proper functioning of Vayu resulting in regulation of Ovarian function and finally ovulation.

According to modern science^{19,20}:

1. Madhutailika Basti through rectum reaches instantly into systemic circulation thus has faster absorption and quick results.
2. Enteric and nervous system controls the motility, exocrine and endocrine secretions and microcirculation of the G.I. tract. ENS(Enteric Nervous System) closely resembles the CNS(Central Nervous System).
3. Endogenous opioids are mainly present in G.I. tract and in brain (hypothalamus, pituitary). β endorphin has a role in regulation of normal menstrual cycle.

Ovarian cycle is regulated through the feedback of hormones on the neural tissue of CNS. The regulation of ovarian function occurs through Hypothalamic-Pituitary-Ovarian axis by autocrine, paracrine and endocrine mechanisms. Hypothalamus & Pituitary is under control of CNS; Ovaries is under control Parasympathetic. Intestine is richly supplied with nerves. Hence the theory of ENS emerges out.

ENS $\rightarrow$ Synergistic work as $\rightarrow$ CNS
(System Biology concept)

Madhutailika Basti enters into G.I tract which is considered as enteric nervous system. The essence of Basti dravya stimulates. Endogenous opioids which are usually present in G.I. tract. These endogenous opioids (β endorphin) may influence GnRH release and aids to regulate Hypothalamo-pituitary ovarian axis and thus regulates the ovarian cycle. Basti- stimulates- the ENS- generates the stimulatory signal for CNS - causes stimulation of Hypothalamus for GnRH

and the Pituitary for FSH & LH with the help of neurotransmitters.

Adverse Drug Reaction:

Conclusion:

Vata dosha plays major role in physiology as well as pathology of the pelvis including ovulation.²¹ This hypothesis was acceptable with the highly significant results of treatment i.e. Basti- the best treatment modality of vitiated Vata dosha. Madhutailika Basti a type

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