Published online in http://ijam.co.in ISSN No: 0976-5921

International Journal of Ayurvedic Medicine, Vol 15 (4), 2024; 917-922

Comparative evaluation of *Phalasarpi* (medicated ghee) oral administration (paan) versus intrauterine instillation (*uttarbasti*) in management of anovulatory cyclein fertility (vandhyatva)

Research Article

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Abstract

Anovulatory menstrual cycle is one of major cause of infertility found approximately 40% cases of female infertility. In today's fast-moving life, causes of infertility vary from faulty food habits, sedentary lifestyle, unstable mental state, depression etc. In contemporary science, ovulation induction is the most advised treatment apart from medications. However, not all causes of anovulation are amenable to treatment by ovulation induction. Thus, research into alternate approaches to treating anovulatory-based infertility is necessary. Ayurveda has included infertility under *Vandhayatva*. *Uttar basti* (intrauterine instillation of medicated drugs) and oral medications has been advised and practised since long for the treatment of *vandhatya* (infertility). *Phalasarpighrit*is used for the treatment of *vandhatya* (infertility) as advised by the Acharyas. Here, comparative study for the route of administration of the medicated ghee that is *Phalasarpi* Oral administration (*paan*) and *Uttarbasti* (intra uterine instillation) in infertility due to anovulatory cycle has been done. Methodology: - Two groups, A and B, were randomly selected from a total of sixty patients. Thirty patients from Group B received oral *Phalasarpi* (Medicated ghee) treatment, while thirty patients from Group A received *Phalasarpi* (Medicated ghee) intrauterine instillation treatment. Both groups were assessed using the Case Record Form and the results of the investigations. Observations and results were drawn accordingly. It was concluded that between these two, *Phalasarpi Uttarbasti* (intra uterine instillation) gives better results in increasing menstrual blood flow, endometrial thickness and timely ovulation, as it directly affects receptivity of hormones at local level as compared to the oral administration (*paan*).

Keywords: *Uttarbasti, Phalasarpi*, Infertility, *Vandhyatva,* Anovulatory cycle.

Introduction

Motherhood is an incredible honour and privilege that God has bestowed upon women. One of the most common health problems that married couples nowadays deal with is infertility.

Failure to conceive after a year or more of consistent, unprotected sexual activity is known as infertility. (1) Infertility has many negative effects, some of which are societal and others of which are personal. Around 12% marriages prove to be childless. (2) Among women in the reproductive age bracket, the prevalence of infertility would be almost 50%. Failure to ovulate is the major problem which is nearly 40% cases of female infertility. This can be attributed to anovulation or severe oligo-ovulation. (3)

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In Ayurveda unable to produce offspring is called *Vandhyatva.*(4)(5)(6)Ayurveda focused on four primary vital factors for fertility: *Rutu* (ovulation period), *Kshetra* (reproductive system), *Ambu* (uterine fluids), *Beeja* (healthy spermatozoa and ovum), as well as a healthy psychological state and normal *vata* function (one of the body's governing factors). Any one of these flaws could lead to infertility. A *beeja* (sperm and ovum) factor is the most important of these four in the pathophysiology of reproduction. (7)

Faulty food habits (*Mithya Ahar*) and Disturb lifestyle (*Mithya Vihar*) are the main etiological factor in derangement of *strotas* (System) in the form of *strotodushti*. *Acharya Sushruta*has considered *Artavahastrotas* separately and described the manifestations of *Artavahastrotodushti*. Derangement of *artavahastrotas* lead to *Vandhyatva*. In symptomatology of "*ArtavahaStrotoVidhaLakshane*" he mentioned '*Vandhyatva*'.(8)

Despite all other considerations, the reproduction is not possible without *beeja*, which is essential for the process. And here, *beeja* is understood to be the ovum, or *Antahpushpa*. As a result, anovulation is interpreted as *Beeja*'s absence. *Vata*, in particular *Apana Vayu* (the mechanism responsible for the correct evacuation of the

ovum), regulates the act of ovulation. Therefore, according to the Ayurvedic texts, Acharya Charaka recommended *Uttarbasti* in *Siddhisthana* to cure *Apana Vayu*, the primary element vitiating the reproductive system. (9) Also, *Phalasarpighrit* (medicated ghee) is indicated in *vandhatya* by the acharyas which can be administered by different routes i.e oral (paan) or intra uterine instillation (*uttarbasti*). In this study a comparative analysis of route of administration of *Phalasarpighrit* was done amongst *vandhyatva* patients specially those due to anovulatory cycles. The results of *Uttar Basti* were found to be more effective, which can serve as a treatment modality in place of ovulation induction method.

As an alternative to modern ovulation induction treatment the medicated *Ghrit* treatment of *Phalasarpi* was given via two different routes. (10) There is a lot of room for research to identify an Ayurvedic treatment for anovulatory-caused infertility that is safe, effective, and affordable for the greatest outcomes.

Aims and Objectives

- To evaluate the effects of intrauterine instillation (*Uttabashti*) and oral *Phalasarpi* (medicated *ghee)* in anovulatory cycle.
- To offer patients with infertility herbal, affordable, and superior alternative treatment.

Methodology

Trial type: A comparative clinical trial with ethical clearance from the institutional ethics council, in which patients were randomised into two groups.

Patients were randomly allocated into two groups by predetermined computer-generated random allocation plan.

Table 1

	GroupA	GroupB
Sample size	30	30
Drug used	*Phalasarpi*	*Phalasarpi*
Procedure done	*Phalasarpi Uttarbasti*	Oral administration
Route	Intrauterine	Orally
Period/Kaal	After cessation of menses/ *rutukala* Rutukal is the most appropriate period of *Beejotsarga* (Ovulatory phase) and *Garbhadharana.*considered 12 days by Acharya Sushruta and 16 days by Acharya Dalhan. Ref-Sushrut Sharirsthan 3/6,Ghanekar Tika,page no. 75,Volume	Whole month except during menstruation. (Due to digestive problems during menstrual cycle.) (Bernstein MT, Graff LA, Avery L, Palatnick C, Parnerowski K, Targownik LE. Gastrointestinal symptoms before and during menses in healthy women. BMC Womens Health. 2014 Jan 22;14:14. doi: 10.1186/1472-6874-14-14. PMID: 24450290; PMCID: PMC3901893.
Dose	5ml per day	1 Pala (40ml) once a day
Duration	5 days after cessation of menstrual bleeding for consecutive 3 cycle	90 days
Follow ups	After cessation of menses for consecutive 3 cycle	After cessation of menses for consecutive 3 cycle

Inclusion criteria

- Women in the 18–40 age range who report not being able to conceive after a year of sexually active marriage.
- Infertility due to -
  - Irregular menstrual cycle / scanty bleeding with an anovulatory cycle
  - Anovulatory cycle
  - PCOD with anovulatory cycle

Exclusion criteria

- Cervical tumor, Polyp, CA cervix,
- Uterine fibroids
- Congenital anomalies in female genital tract
- Tubercular Endometritis
- HIV,VDRL,HBsAg Positive Patients
- Any malignancy

Criteria / parameters for assessment of patient's result

Following are the chief criteria for the clinical assessment in this trial, based on findings of changes occurring in follicular study and menstrual cycle.

Subjective criteria

Menstrual Cycle Pain

Table no 2

Grade	Criteria
0	No pain(0 reading on VAS)
1	Mild(1 - 3 on VAS)
2	Moderate (4 - 7 on VAS)
3	Severe(8 - 10 on VAS)

Visual Analogue Scale

No Pain severe pain

0-----1-----2-----3-----4-----5-----6-----7-----8-----9-----10

Amount of Bleeding

Table 3

Grade	Amount of bleeding	
0	Spotting	
1	Scanty	1-2 pads/day
2	Moderate	2-3 pads/day
3	Excessive	4-5 pads/day

(Participants were asked to used same brand of sanitary pads and count the number and graded as mentioned in table 3).

Objective criteria
Follicular Size:

Table 4

Grade	Follicular size
0	<12mm
1	12-20mm
2	>20mm
3	Ovulated

Endometrial Thickness

Table 5

Grade	Endometrial thickness
0	<5mm
1	5-7mm
2	7-9mm
3	>9mm

Ovulation: Ovulated / anovulated after treatment.

Follicular size, endometrial thickness and ovulation were observed by follicular study i.e ultra sonography (TVS) of the participants which was done from day 10th of menstrual cycle.

Investigations

Following investigation were done, to rule out other disorders and to assess the prognosis of the patient's general condition.

- Haematological investigations
  - Blood group
  - HIV/ VDRL/ HbsAg
- USG pelvis
- Follicular study - A serial vaginal or abdominal sonography was done from 10th day of menstrual cycle, till after ovulation. According to size of follicle it was done on alternate day. Ovulation was presumed to have occurred when there is a sudden reduction in size or complete disappearance of the dominant follicle measuring 18 to 25 mm prior to its rupture and minimal fluid collection in Pouch of Douglas.
- All Routine haematological examinations will be carried out to assess the general health.

Trans vaginal sonography is basic and primary investigation for this study. It was done from day 10th day of menstrual cycle up to at least 22nd day of cycle to see ovulation or anovulation. For perfect diagnosis it was done in each and every patient before and after study.

Total effect of Treatment:

The overall effect will be graded into 5 types-

- Unchanged
- Improved
- Complete remission
- Conceived
- LAMA

Unchanged effect: No improvement means follicular size < 12mm

Improved results: There is no Ovulation but only improvement in the size ofovarian follicles means ≥ 12-20 mm

Complete remission: Timely ovulation with increase in the follicular size > 20mm

Conceived Patients: Patients conceived after the treatment.

LAMA (Left Against Medical Advice) refers to patients who left therapy before the recommended duration or who disobeyed instructions.

Drop outs: No drop outs were seen during the study.

Statistical analysis

Following the CRF, statistical and demographic analysis was performed on the data. The clinical parameters were subjected to the Wilcoxon Signed Rank test and the Paired "t" test. The 'Mann Whitney U test' was used to compare two groups. The overall impact of therapy was evaluated using the "Chi Square test." At the 5% level of significance, the data's significance was examined.

Observations and Results

Impact of treatment on patients' pain during menstruation in both groups

Table 6

Group		BT	%	AT	%
A	Painful	6	20	5	16.66
	Painless	24	80	25	83.33
B	Painful	8	26.66	8	26.66
	Painless	22	73.33	22	73.33

It was seen that in **Group A**, 6 (20%) patients out of 30 patients had dysmenorrhoea.

And after the treatment, it was seen that, 5 patients out of 30, (16.66%) had painless menstruation after treatment.

Out of 30 patients in **Group B**, 8 (26.66%) experienced dysmenorrhea.

Following the regimen, it was noted that the symptoms of menstruation pain remained unchanged.

Amount of bleeding

Following table is showing % wise relief obtained in the menstrual bleeding after giving the treatment.

Table 7

Group		BT	%	AT	%
A	Spotting	0	0	0	0
	Scanty	6	20	1	3.33
	Moderate	23	76.66	28	93.33
	Excessive	1	3.33	1	3.33
B	Spotting	2	6.66	2	6.66
	Scanty	4	13.33	1	3.33
	Moderate	22	73.33	25	83.33
	Excessive	2	6.66	2	6.66

It was observed that, in group A, out of 30 patients it was seen that, Before, treatment 6(20%) had

scanty menses, 23(76.66%) patients were having moderate menstrual bleeding and 1 (3.33%) patient was having excessive menses. After treatment it was seen that, 1 patient (3.33%) had scanty menses, and 28 (93.33%) patients had moderate menses and 1(3.33%) patient had excessive menses.

In group B, out of 30 patients it was seen that, Before, treatment 2(6.66%) patient had spotting during menstruation, 4 (13.33%) patients had scanty menses, 22 (73.33%) patients had moderate menses, and 2 (6.66%) patient had excessive menses. After treatment, it was seen that, 2(6.66%) patients had spotting menses, 1(3.33%) patient had scanty menses, 25(83.33%) patients had moderate menses and 2 (6.66%) patient had excessive menses.

Table 8: Endometrial thickness

Group	Endometrial Thickness	BT	%	AT	%
A	<5	2	6.66	0	0
	5-7	5	16.66	4	13.33
	7-9	10	33.33	9	30
	>9	13	43.33	17	56.66
B	<5	1	3.33	0	0
	5-7	3	10	2	6.66
	7-9	20	66.66	15	50
	>9	6	20	13	43.33

The percentage of patients with each endometrial thickness before and after each treatment cycle is displayed in the above table. Thus, it can be said that endometrial thickness is more increased in Group A in comparison to Group B after treatment.

Table 9: Follicular size

Group	Follicular Size	BT	%	AT	%
A	<12mm	15	50	0	0
	12-20	8	26.66	5	16.66
	>20mm	7	23.33	5	16.66
	Ovulated	0	0.00	20	66.66
B	<12mm	15	50	8	26.66
	12-20	10	33.33	7	23.33
	>20mm	5	16.66	6	20
	Ovulated	0	0	9	30

The percentage of patients in each group that had the appropriate follicular size before and after each treatment cycle is displayed in the above table. Both, the groups showed improvement in the follicle size. It was seen that ovulated follicles were more after treatment in the Group A (66.66%) as compared to Group B (30%).

Table 10: Ovulation

Group		BT	%	AT	%
A	Ovulated	0	0.00	20	66.66
	Anovulated	30	100	10	33.33
B	Ovulated	0	0.00	9	30
	Anovulated	30	100	21	70

The percentage of patients having ovulatory/ anovulatory cycles before and after treatment is displayed in the above table, with Group A exhibiting a somewhat greater improvement.

Statistical analysis (11):

Table 11: Statistical Analysis of Treatment Effects on Subjective and Objective Group A Parameters Utilizing the Wilcoxon matched-paired signed rank test

	Symptom		Mean	SD	SE	W	N	P
1	Menstrual cycle pain	BT	0.833	1.177	0.2149	-54	15	0.1354 Not significant
		AT	1.133	0.8193	0.1496			
		DIFF	-0.300	0.9154	0.1671			
2	Quantity of Bleeding	BT	1.833	0.4611	0.0841	-35	9	0.1641 Not Significant
		AT	2.00	0.2626	0.0479			
		DIFF	0.1667	0.5307	0.09689			
3	Endo. Thickness	BT	2.133	0.9371	0.1711	-36	8	0.0078 Significant
		AT	2.433	0.7270	0.1329			
		DIFF	-0.300	0.5350	0.0976			
4	Follicle Size	BT	0.733	0.8277	0.1511	-368	27	<0.0001 Extremely significant
		AT	2.500	0.7768	0.1481			
		DIFF	-1.767	1.235	0.2072			

Table 12: Statistical Analysis of Therapy's Impact on Group B's Subjective and Objective Parameters Using a paired signed rank Wilcoxon test

Sr.no	Symptom		Mean	SD	SE	W	n	P
1	Menstrual Pain	BT	1.133	1.042	0.1902	-11	10	0.6250 Not Significant
		AT	1.200	0.7611	0.1390			
		DIFF	-0.066	0.5833	0.1065			
2	Quantity of Bleeding	BT	1.800	0.6644	0.1213	-6.0	3	0.2500 Not significant
		AT	1.900	0.6074	0.1109			
		DIFF	-0.100	0.3051	0.0557			
3	Endometrial Thickness	BT	2.033	0.6687	0.1221	-55	10	0.002 Significant
		AT	2.367	0.6149	0.1123			
		DIFF	-0.333	0.4795	0.087			
4	Follicle Size	BT	0.6667	0.7581	0.1384	-210	20	<0.0001 Very Significant
		AT	1.533	1.196	0.2183			
		DIFF	-0.7931	1.320	0.2450			

From table 11&12 it can be observed that statistical analysis shows a significant difference on both endometrial thickness and follicular size both in Group A and Group B.

Table 13: Chi Square Test statistical examination of the therapy's impact on Groups A and B

Sr. No	Symptoms for both the groups	Chi Square Value	Degrees of freedom	P value
1	Menstrual pain	2.503	3	0.4747; Not significant
2	Menstrual bleeding	2.503	3	0.4747; Not significant
4	Follicle size	12.597	3	0.0056; Very significant
5	Endometrial Thickness	2.700	2	0.2592; Not Significant

As a result, group A has a higher percentage of patients experiencing ovulation following treatment than group B.

Discussion

Infertility remains a grave issue in perpetuation of progeny. Anovulation being one of the foremost reasons of infertility needs to be critically addressed. Our Ancient Acharyas have discussed *Vandhyatva* in a broad sense, covering both *Nidana* (causes) and *Chikitsa* (treatments). Nevertheless, modern science holds that there are etiological variables that contribute to infertility, which are not quite consistent with the Nidana indicated in Ayurveda. The therapeutic aspect is similarly unclear; while several treatment philosophies are presented in our Ayurvedic classics, it is not made apparent which kind of infertility these philosophies specifically target or which factors—such as *Rutu*, *Kshetra*, *Ambu*, and *Beeja*—they specifically work upon. Investigating each of these elements independently is imperative right now.

Uttarbasti with medicated oil and *ghrit* has been mentioned as a modality for the treatment of *vandhyatava*. This, study was primarily aimed to compare the effect of route of administration of *phalasarpi* ghrit through the Oral (Paan) and intra uterine instillation (*Uttar Basti*) methods in infertility (*vandhatyatva*) patients with special reference to anovulatory cycle. The parameters taken for the same were menstrual pain, regularity of menses, quantity menstrual bleeding, follicle size and endometrial thickness.

Mode of action:

In present study the same drugs were administered by two routes (1) Oral route (*Paan*) and (2) Intrauterine route (*Uttar Basti*).

Oral Route

a.) *Tridosha shamaka* property of drugs along with *Madhura Vipaka* causes *Vata Shamana*. b.) *Dipana* property acts as *Agnidipaka* correcting the *Agnimandya*. c.) The *Kashaya* and *Madhura Rasa*, *Shita virya* may increases the muscular strength of reproductive system (*Yoni*) When taken together, these medications give internal genital organs sustenance in the form of *bruhana* and *poshana*. Consequently, increase the blood supply to the follicles and regulate the function of ovulation through the *Tridosha shamaka* property. (12)

Intra Uterine Route

Warm ghee travels to the desired locations (all layers of the uterus, fallopian tubes, and ovary) via a network of *strotamsi* that are present throughout the system. The dispersal of ghee is improved by its mild temperature.

During the proliferative phase, both the vascularization flow index and the endometrial and sub-endometrial vascularization index rise. These changes peak three days before ovulation and up to five days after ovulation.

Therefore, a medication based on *sneha* that is injected into the uterus at this proliferative stage may be readily absorbed into the bloodstream.

The benefits of taking this path might be - (13,14)

- Easy administration of drug.
- Compared to oral or other methods, low systemic drug exposure and higher permeability.

- The "first-ovary pass effect," which is the potential for medications to be transferred to the ovary preferentially due to low enzymatic activity, may potentially help with drug delivery.

Discussion on the Clinical Observations

Although there was improvement in both groups for the subjective measures, such as menstrual pain and monthly bleeding, there was no statistically significant difference between the two groups. (Table no. – 6 and 7).

The objective criteria of endometrial thickness and follicular size (table no 8 and 9) on comparison showed more improvement in Group A in comparison with Group B in terms of both endometrial thickness and follicular size, which was observed on statical analysis too.

Also, on comparing the ovulatory and anovulatory cycles in both the groups, it was seen that the number of ovulatory cycles increased in group A after treatment with *phalasarpi* intra uterine instillation in comparison to the group B post treatment i.e. *phalasarpipaan* (Table no. 12 and 13). This can be attributed to the mode of action of *phalasarpi ghrit* via the intra uterine route.

Conclusion

The study concluded that both Phalasarpi *Uttar Basti* (intrauterine instillation) and its oral administration (Paan) help regularize irregular menstrual cycles, with 70% improvement in Group A and 63.33% in Group B, along with increased menstrual flow.

When comparing the two administration methods, Phalasarpi *Uttar Basti* (Group A) was found to be more effective in improving follicle size, achieving timely ovulation in 66.66% of patients, and increasing endometrial thickness in 56.66%.

In contrast, the oral administration (Group B) resulted in changes in follicle size and timely ovulation in 30% of participants, with a 43.33% improvement in endometrial thickness.

Therefore, *Phalasarpi* administered through the intrauterine route (*Uttar Basti*) offers a more effective, affordable, and herbal treatment option for managing anovulatory cycles compared to oral administration.

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