



## COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFECT OF 'PHALA GHRIT'- ORAL &UTTAR VASTIIN 'VANDHYATWA' W.S.R. TO FEMALE INFERTILITY

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### ABSTRACT :

Motherhood is the cherished desire deep down in the heart of every woman. The desire for offspring in every woman is as synonymous with motherhood as it adds a new meaning to her life and existence. Infertility has been long standing problem since ancient period but it is most burning issue nowadays because of improper lifestyle. Childlessness may be a tragedy to the married woman, and can be a cause of marital upset as well as of personal unhappiness and ill health. In *Ayurveda* Infertility is termed as *Vandhyatwa*. *Ayurveda* may give a promising hand to cure this disease. As the subject is discussed in *Ayurveda*, it becomes necessary to study, understand and prove them particularly in light of modern scientific parameters in the present era. So the field of research in the *Vandhyatwa* opens broad scope for a worker, hence this topic requires proper thought & orientation in implementation of *Ayurvedic* treatment of success in aimed target of attaining twinkle in the eye of childless women. In *Samprapti*, the main *Adhithana* of the *Vandhyatwa* is *Yoni*. *Vata Dosha* is the governing factor of the whole reproductive physiology therefore any vitiation in *Vata* will certainly affect the fertility. In *Ayurveda*, *Sneha* and *Vasti* said to be the best treatment for *Vata*. Hence *Uttar Vasti* is selected as procedure. Considering all these points, in present study the *Ghrita* preparation was selected for oral medicine and *Uttar Vasti*. Clinical study was completed on clinically diagnosed 30 patients of female infertility in P.G. department of Prasuti and Striroga, National Institute of Ayurveda at Jaipur (Raj.). The patients were divided into two groups of 15 patients each with the aim to see the effect of *Phala Ghrit*, to compare the efficacy of *Uttar Vasti* & oral therapy in female infertility.

**Key words:** *Vandhyatwa*, *Uttar Vasti*, *Phala Ghrit* Infertility.

**INTRODUCTION:** Motherhood is the cherished desire deep down in the heart of every woman. The desire for offspring in every woman is as synonymous with motherhood as it adds a new meaning to her life and existence. Infertility has been long standing problem since ancient period but it is most burning issue nowadays because of improper lifestyle. Childlessness may be a tragedy to the married woman, and can be a cause of marital upset as well as of personal unhappiness and ill health.

Infertility is defined as the inability of couple to achieve conception after 1 year of regular unprotected coitus.

### TYPES OF INFERTILITY<sup>1</sup>

1. **Primary infertility:** It denotes those patients who have never conceived.
2. **Secondary infertility:** It indicates previous pregnancy but failure to conceive subsequently within one or more years of regular unprotected intercourse.

Conception depends on the fertility potential of both male and female partner. Male

is directly responsible in about 30 - 40%, female in about 40 - 55 % and both are responsible in about 10 % and the remaining 10 % is unexplained.

In *Ayurveda* Infertility is termed as *Vandhyatwa*. *Acharya Sushruta* has described four essential factors to achieve conception<sup>ii</sup> i.e. *Rutu* i.e. fertile period, *Kshetra* i.e. female reproductive organs should be normal (healthy *Yoni*), *Ambu* i.e. proper nutrient fluid, *Beeja* i.e. Viable ovum & sperm. Presence of abnormality in any of the above said factors causes *Vandhyatwa*.

#### **AIMS AND OBJECTIVES:**

1. To study etiopathogenesis of *Vandhyatwa* as per the classical literature and modern texts.
2. To provide safe, cheapest & non-surgical treatment.
3. To evaluate the effect of *Phala Ghrit* in female infertility.
4. To compare the efficacy of *Uttar Vasti* & oral therapy in female infertility.

#### **Drug and Procedure Selection:**

In *Ayurveda* the word "*Yoni*" refers to female reproductive organs collectively. *Yoni* never gets spoilt without vitiation of *Vata*<sup>iii</sup>. *Vata Dosha* is the governing factor of the whole reproductive physiology. Female infertility is a *Yonigata Vikara* and pacification of vitiated *Vata* is the best cure for *Yonigata Vikaras*. In *Ayurveda*, *Sneha* and *Vasti* said to be the best treatment for *Vata*. In the context of *Uttar Vasti* *Acharya Charaka* has mentioned that once the *Vata* is controlled by *Uttar Vasti* female achieves conception quickly<sup>iv</sup>.

It is a procedure where the drugs are administered directly into the *Garbhashaya*. Therefore *Uttar Vasti* with *Sneha* will definitely act on *Yonigata Vikara* and hence on female infertility. Lots of work

has been done on *Uttar Vasti* with drugs described for infertility in *Ayurvedic* text. One of them is "*Phala Ghrit*" described in *Sharangdhara Samhita Madhyama Khanda* 9/80-87. It has been indicated as a useful medicine for *Vandhya*<sup>v</sup>. Taking reference from there, this *Ghrit* has been selected for *Uttar Vasti* and orally<sup>6</sup>.

#### **MATERIALS AND METHODS:**

##### **A. Conceptual Materials Methods**

Disease Review, Historical review and Modern review are compiled from various text.

##### **B. Clinical Materials Methods**

###### **Selection of the patients:**

- 1) The study was conducted on 34 clinically diagnosed & confirmed patients of infertility at PG department of *Prasuti* and *Striroga* unit of NIA, Jaipur (Rajasthan).
- 2) Patients were selected from OPD/IPD of NIA hospital, Jaipur & were examined thoroughly as per history sheet specially prepared for this clinical study.
- 3) Written consent was taken from the patients before starting trial.

###### **INCLUSION CRITERIA:**

1. All primary & secondary cases of infertility
2. Age group between 20 to 40 years
3. Male counterpart should be normal in all aspects

###### **EXCLUSION CRITERIA:**

1. Female less than 20 yrs and more than 40 years of age.
2. Surgical factors including fibroid uterus, cervical polyp, cervical stenosis.
3. Congenital anatomical defect.
4. Infertility due to abnormality in male partner.
5. Patient suffering from severe infection or chronic systemic diseases.

6. Infertility due to tubal & peritoneal factors.

7. Patient suffering from any malignancy.

## 2. Management of the Patients

During the treatment period, O.P.D. patients were advised to take *Pathyakara Ahara* while I.P.D. patients admitted for *Uttar Vasti* were given light diet and *Ushnodaka*.

### GROUPING:

**Group A:** *Uttar Vasti* with *Phala Ghrit*

Dose - 5 ml, intrauterine administration after 24 hrs of cessation of menses for 3 alternate days for 3 consecutive cycles.

*Uttar Vasti* started after 1 *Anuvasan Vasti* (*Dashmool oil*) and 1 *Niruha Vasti* (*Dashmool kwath*) in each cycle.

**Group B:** Oral Medication –*Phala Ghrit*

Dose – 5 ml twice a day orally with hot milk (200 ml) for 3 months

### Criteria for diagnosis

#### Investigation:

##### Before Treatment

Medical History & physical Examination  
Pelvic Examination to look for abnormalities or infection

1. **Blood test-** Hb%, TLC, DLC, ESR, HIV, VDRL, HBsAg, Mantoux test, RBS, TSH

2. **Urine test-** Routine & Microscopic

3. Pap Smear- if needed

4. X-ray chest PA view (if needed)

5. Special tests-

a. Semen Analysis

b. Cervical mucous (1) SpinnBarkeit ( 2) Fern Test

6. Post coital test

- USG-Uterus & Adnexae
- HSG
- Follicular study (if possible)
- Antisperm & Antibody Test (if needed)

##### After Treatment

1. Cervical mucous – Fern test & spinnbarkeit test

2. Follicular study (if needed)

3. Urine Pregnancy detection test (if needed)

### Follow Up Study:

Follow up was done fortnightly during trial & monthly up to two months after the completion of the trial.

**Criteria for assessment:** To facilitate the statistical analysis of the efficacy of therapy, scoring system was adopted on the basis of interval of menstrual cycle, duration of menstrual cycle, amount of blood loss during menses, pain during menses, dyspareunia, psychological stress, fern test on 22<sup>nd</sup> day, Spinnbarkeit test on 14<sup>th</sup> day, post coital test on 14<sup>th</sup> day, follicular study, endometrial thickness (on 14<sup>th</sup> day), Conception.

**Overall effect of treatment :** The score of individual symptoms were obtained before and after treatment and the total effect of therapy was assessed accordingly in terms of

- Conception.
- Increased in size of ovarian follicle
- Improvement in the character of cervical mucus
- Improvement in menstrual parameters
- Unchanged

**Presentation of data :** The data collected from the study was subjected to statistical analysis.

1) The first section deals with the general observations.

2) The second section deals with the effects of therapy evaluated statistically on the basis of improvement.

**Statistical Analysis:** Various observations made and results obtained were computed statistically using Wilcoxon matched-pairs

signed-ranks test in each group, Mann-Whitney test for the Inter-group comparison, Paired 't' test for the results of conception in each group to find out the significance of the values obtained and various conclusions were drawn accordingly. All the Results calculated by using Online InStat GraphPad software.

#### **OBSERVATIONS AND RESULTS:**

- Total 34 patients were registered under two trial groups to study efficacy of oral and intrauterine administration of trial drug *Phala Ghrit* in cases of female infertility. Out of 34, 04 patients were dropped out from the trial due to irregular follow up and non-compliance of treatment. So, data of 30 patients who have completed the trial was only analyzed to see the efficacy of trial drug and procedure.
- 50.00% patients were having both primary and secondary infertility each.
- Regarding associated symptoms, it was found that 6.66% patients had acne and 3.33% patients had hirsutism.
- 93.33% patients had no family history of infertility.
- Pertaining to menstrual history it was observed that in 90.00% patients had menarche onset between the ages of 12-15 yrs, 70.00% had regular menses, 60.00% patients had normal amount of blood loss, 76.66% had painful menses, and 80.00% patients were having 3-5 days of duration and 21 – 35 days of interval of menses each.
- Frequency of coitus was found 4-6 times/week in 60.00 % patients and 16.66 % patients were having pain during coitus.
- Pertaining to personal history it was found that 70.00% patients were having vegetarian diet, 70.00% with sound sleep, 76.66% patients with regular bowel

habit, 86.66% addicted to tea and 50.00% patients had normal BMI.

- All the patients were having normal secondary sexual characteristics like development of breast, pubic and axillary hair, vulva etc.
- On genital examination it was found that 3.33% had vaginitis, 10.00% had erosion, 30.00% had vaginal discharge, 93.33% patients were having nulliparous external os, 96.66% patients were having anteverted and anteflexed uterus, 20.00% patients had tenderness in fornices.
- 40.00% patients were having *Vata Kapha Prakriti*, 80.00% had *Madhyam Sara*, 56.66% had *Madhyam Samhanana*. 76.66% patients had *Madhyam Pramana*, 66.66 % patients had *Madhyam Satmya*, 76.66 % patients had *Madhyam Satva*. 90.00% patients had *Madhyam Ahara Shakti*. 56.66% patients had *Madhyam Vyayama Shakti*.
- All patients were included under *Madhyam avastha* on *Vaya Pariksha*.
- In the present study 46.66 % patients had infertility due to unexplained causes, 43.33% patients had anovulation (including PCOD in 20%) and 10% patients had infertility due to cervical factor.

#### **Effect of therapy on follicular study**

In Group A, before treatment, mean score was 2.33 and after treatment it was 1.26 with 45.73% relief showing statistically extremely significant result ( $p \leq 0.001$ ). In Group B, before treatment mean score was 1.80 and after treatment it was 1.06 with 40.73% relief showing statistically very significant result ( $p < 0.01$ ).

#### **Effect of therapy on endometrial thickness:**

In Group A, before treatment mean score was 0.73 and after treatment it was 0.20 with 72.72% relief showing sta-

tistically significant result ( $p < 0.05$ ). In Group B, before treatment mean score was 0.80 and after treatment it was 0.40 with 50.00% relief showing statistically significant result ( $p < 0.05$ ).

**Effect of therapy on fern test** : In Group A, before treatment mean score was 1.86 and after treatment it was 0.93 with 49.98% relief showing statistically very significant ( $p < 0.01$ ). In Group B, before treatment mean score was 2.13 which was 1.13 after treatment with 46.88% relief showing statistically very significant result ( $p < 0.01$ ).

**Effect of therapy on spinnbarkeit test:** In Group A, before treatment mean score was 1.40 and after treatment it was 0.66 with 52.37% relief showing statistically very significant result ( $p < 0.01$ ). In Group B, before treatment mean score was 0.86 and after treatment it was 0.33 with 61.53% relief showing statistically very significant result ( $p < 0.01$ ).

**Effect of therapy on Post coital test:** In Group A, before treatment mean score was 0.133 and after treatment it was 0.06 with 49.62% relief showing statistically not significant result ( $p > 0.05$ ). In Group B, before treatment mean score was 0.266 and after treatment it was 0.133 with 50.00% relief showing statistically not significant result ( $p > 0.05$ ).

**Effect of therapy on amount of menses**  
In Group A, initial mean score was 0.93 which was decreased up to 0.13 with 85.74% relief, and the result was statistically significant ( $p < 0.05$ ). In group B, initial mean was 0.60 which was decreased up to 0.26 with 44.45% relief showing the result statistically not significant ( $p > 0.05$ )

**Effect of therapy on interval of menses:**  
In Group A, initial mean score was 0.20 which was decreased up to 0.13 with

33.33% relief, and the result was statistically not significant ( $p > 0.05$ ). In group B, initial mean was 0.20 which was decreased up to 0.06 with 66.65% relief showing statistically not significant result ( $p > 0.05$ )

**Effect of therapy on duration of menses:**  
In Group A, initial mean was 0.33 which was decreased up to 0.06 with 80.01% relief, and the result was statistically not significant ( $p > 0.05$ ). In group B, initial mean was 0.33 which was decreased up to 0.13 with 60.00% relief showing statistically not significant result ( $p > 0.05$ )

**Effect of therapy on dysmenorrhoea:**  
In Group A, initial mean score was 1.20 which was reduced to 0.46 after treatment with relief of 61.08% showing statistically extremely significant result ( $P \leq 0.001$ ). In Group B, initial mean score was 0.73 which was reduced to 0.20 with relief of 72.75% showing statistically very significant result ( $P < 0.01$ ).

**Effect of therapy on dyspareunia:** In Group A, initial mean score was 0.26 which was reduced to 0.06 after treatment with the relief of 74.99% and the result was statistically not significant ( $p > 0.05$ ). In Group B, initial mean score was 0.20 which was reduced to 0.06 with relief of 66.65% showing statistically not significant result ( $p > 0.05$ ).

**Effect of therapy on stress:** In Group A, initial mean score was 1.93 which was reduced to 1.26 after treatment with the relief of 34.49% showing statistically very significant result ( $p < 0.01$ ). In Group B, initial mean score was 1.80 which was reduced to 1.06 with relief of 40.73% showing statistically very significant result ( $p < 0.01$ ).

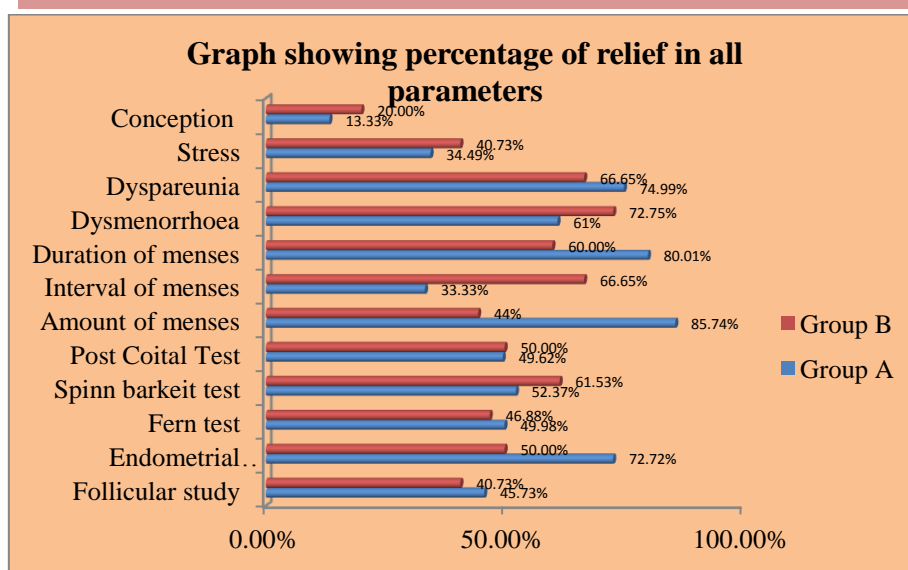
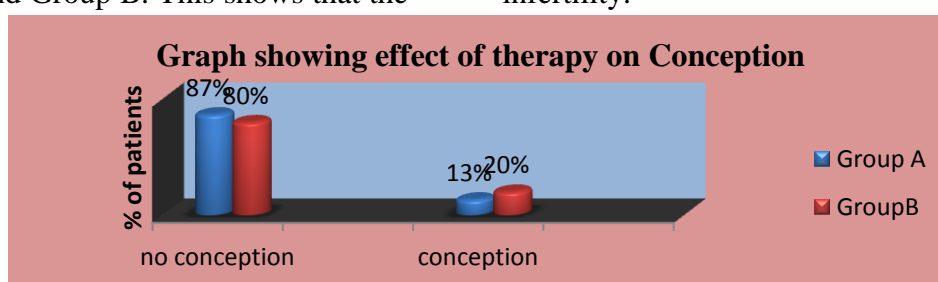
**Effect of therapy on specific factors:** Effect of therapy shows the post treatment conception in 4 cases of unex-



plained causes of infertility with an average improvement of 28.57% (14.28% and 42.85% improvement were seen in Group A and B cases respectively). Post treatment conception achieved in 01 case (PCOD related case) of anovulation related infertility with an average improvement of 7.69% (14.28% improvement were seen in Group A, while no improvement were seen in group B). In cervical factor, no post treatment conception were seen both in Group A and Group B. This shows that the

effect of therapy were more effective in unexplained infertility.

**Effect of therapy on conception:** In group A, out of 15 patients 2 patients conceived and in group B out of 15 patients 3 patients were conceived during or after treatment. In group A all 2 patients conceived were of primary infertility. In group B, all 3 patients conceived were of secondary infertility. This shows that effect of therapy was more effective in secondary infertility.



### AVERAGE % OF IMPROVEMENT IN BOTH SUBJECTIVE AND OBJECTIVE PARAMETERS IN BOTH GROUPS

S.No.	Parameters	Result in %	
		GroupA	GroupB
1.	Follicular Study	45.73%	40.73%
2.	Endometrial Thickness (On 14 <sup>th</sup> day)	72.72%	50.00%
3.	Fern test (On 22 <sup>nd</sup> day)	49.98%	46.88%
4.	SpinnBarkeit test (On 14 <sup>th</sup> day)	52.37%	61.53%
5.	Post coital test (On 14 <sup>th</sup> day)	49.62%	50.00%
6.	Amount of menses	85.74%	44.45%
7.	Interval of menses	33.33%	66.65%

8.	Duration of menses	80.01%	60.00%
9.	Dysmenorrhoea	61.08%	72.75%
10.	Dyspareunia	74.99%	66.65%
11.	Stress	34.49%	40.73%
	Average % of relief	58.18%	54.57%

**CONCLUSION:** In Group A, out of 15 patients 2 patients got conceived, showing 13.33% relief in infertility. In Group B, out of 15 patients 03 patients got conceived, showing 20.00% relief in infertility. Overall effectiveness of therapy in all studied 30 patients of infertility was 16.66%. Regarding conception Group B was better than Group A. In both groups no adverse effect was observed during trial and follow-up study. Thus it can be concluded that uttaravasti of phalaghrita compared with oral administration has insignificant difference in the treatment of infertility. Phalaghrita orally and uttarbasti has a significant effect on other localized complaints like menstrual disorder, lower abdominal pain, tenderness and dyspareunia. Further study on a large sample is needed to confirm the efficacy of the drug.

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