



Ayurveda Intervention in Endometrial Factor Infertility

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Introduction: Vandhyatva (Infertility) is neither a somatic problem nor a psychological problem but it is a psychosocial problem. Endometrial factor comes under the Umbrella of Kshetra, which is one of the important factors for conception i.e., Rutu, Kshetra, Ambu and Beeja.[1] Abnormal endometrium is the major cause of implantation failure.

Aim and Objective: The present study was carried out for the clinical evaluation of efficacy of Yoni Pichu of Phalakalyana Ghrita and Baladi Vati orally in female infertility w.s.r endometrial factor.

Materials and Methods: Single arm clinical trial among 32 diagnosed patients of endometrial factor infertility were treated with Phalakalyana Ghrita (20 ml) as Yoni Pichu for 8 days twice daily along with oral administration of Baladi Vati (500 mg tablet) twice daily. Assessment of results was done on the basis of Appelbaum's USSR by the tool of Transvaginal colour doppler sonography.

Results: Study shows statistically highly significant ($p > 0.001$) result in upgrading endometrial receptivity.

Conclusion: The total effect of therapy was very encouraging and highly significant to enhance the endometrial receptivity assessed on the basis of Appelbaum's USSR.

Keywords: Ayurveda, Appelbaum's USSR Score, Baladi Vati, Endometrial Receptivity, Phalakalyana Ghrita, Stree Vandhyatva, Yoni Pichu

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Introduction

The God has blessed the female with most valuable gift of motherhood. Mother is also called as "*Janani*" who gives birth to child. Infertility is defined as the inability to conceive after one year of unprotected intercourse.[2] Female factor is directly responsible in 40-55%.[3] Among various causes of infertility uterine factor as endometrial abnormalities play an important role in the causation of infertility. Decreased endometrial receptivity is the main cause of implantation failure, which contributes 23% among the various causes of repeated abortion.[4] IVF success rate was only 35%, rest 65% cases of IVF failed because of implantation failure in which decreased endometrial receptivity is commonest cause.[5] The latest techniques like In-Vitro Fertilization (IVF), Embryo Transfer (ET), and Gamete Intra Fallopian Transfer (GIFT) all become failed due to decreased endometrial receptivity. Thus, the need of the hour today is to enhance endometrial receptivity through indigenous medicines. Here a preliminary effort has been made to provide simple and effective management for decreased endometrial receptivity.

Aim and Objective

The present study was carried out for the clinical evaluation of efficacy of *Yoni Pichu* of *Phalakalyana Ghrita* and *Baladi Vati* orally in female infertility w.s.r. to endometrial factor.

Materials and Methods

Study Design: Interventional single arm clinical study

Sample Size: 30 Patients

Site: Patients attending the Outdoor Patients Department of Prasuti Tantra Evum Stree Roga, Parul Ayurved Hospital, Vadodara (Gujarat), fulfilling the criteria for selection was incorporated and enrolled using a special research proforma.

Ethical Clearance

Ethical clearance was obtained from the Institutional Ethics Committee. Ref. PU/PIA/IECHR/2021/318 (Dt. 29/01/2021)

CTRI Registration: Study was registered in CTRI as CTRI/2021/04/032549 (Dt.05/04/2021)

Criteria for Selection

Inclusion Criteria

1. Married women with in the age group between 20-35 years.
2. Women with regular menstrual cycle.
3. Women with either primary or secondary infertility.
4. Women with history of recurrent abortion due to uterine factors (implantation defect).
5. Infertility due to only endometrial factors.

Exclusion Criteria

1. Married women of age below 20 yrs and above 35 yrs.
2. Severe pelvic inflammatory disease, pelvic organ prolapses, ovarian tumors, cancer of cervix and uterus.
3. Patients with systemic disorders like pulmonary Koch's, Asthma, HTN, DM2, Thyroid dysfunction.
4. Other causes of female infertility like ovulatory dysfunction, tubal disease, cervical factors, pelvic endometriosis.

Investigations

- CBC, RBS
- T3, T4, TSH, FSH, LH
- Trans vaginal colour doppler sonography performed for diagnosis & assessment of result.

Assessment Parameters

According to Applebaum, certain sonographic qualities of the uterus are noted during the normal mid-cycle (day 10 - till ovulation). Table 1. These include:

- **Endometrial thickness** > 7 mm in greatest anterior-posterior (A-P) dimension (full thickness measured from the myometrial-endometrial junction to the endometrial-myometrial junction).
- **Triple-layered** ('5-line') endometrial appearance.
- **Homogeneous myometrial echogenicity.**
- **Uterine artery blood flow** < 3, as measured by pulsatility index (PI) on Doppler.
- **Blood flow within zone 3** (hypoechoic inner layer) of the endometrium on colour Doppler.
- **Myometrial blood flow** - internal to the arcuate vessels (seen on Gray-scale)

Table No: 1. Appelbaum's Uterine Scoring System for Reproduction

Parameter	Determination	Score
Endometrial Thickness(mm)	<7	0
	7-9	2
	10-14	3
	>14	1
Endometrial Layering	No layering	0
	Hazy 5-line appearance	1
	Distinct 5-line	3
Endometrial motion (no. of myometrial contractions in 2 minutes (real time))	<3	0
	>3	3
Myometrial echogenicity	Course in homogenous	1
	Relatively homogenous	2
Uterine artery Doppler flow (PI)	2.99-3.0	0
	2.49	1
	<2	2
Endometrial blood flow in zone 3	Absent	0
	Present, but sparse	2
	Present multifocally	5
Myometrial blood flow (gray scale)	Absent	0
	Present	2

Statistical estimation of results:

The obtained data was analyzed by using Data Analysis in SPSS (V23) for statistical significance. Friedman test, Wilcoxon Signed Rank Test with Bonferroni correction and paired 't' test were applied. The level of 'P' between 0.005 to 0.001 and $P < 0.001$ was considered as statistically significant and highly significant respectively. The level of significance was noted and interpreted accordingly.

- Insignificant $P > 0.005$
- Significant $P < 0.005$
- Highly Significant $P < 0.01$ & 0.001

Intervention

Drug and Procedure: Infertility due to endometrial factor was considered as *Dhatukshaya* (Poor nutrition condition) and *Vata* predominant *Tridoshaja* condition which is due to *Agnimandya* (metabolic dysfunction). *Vata* is causative factor for *Parmanu* (cell) *Sanyog* (union) & *Vibhag* (division), [6] so new cell regeneration from basal layer may be assumed by proper *Vata* function.

Timeline of Intervention:**Table 2: Treatment Protocol**

Oral administration of Baladi Vati (Anubhuta Yoga)Ingredients - Bala, Ashwagandha, Guduchi, YashtimadhuBhavana Dravya - Durva
Purvakarma - Deepana Pachana

Pitta is responsible for conversion of one *Dhatu* into another *Dhatu* in adequate amount by its *Pakti*[7] (metabolic transformation) property, hence it is responsible for production of adequate level of hormonal support by aromatization of androgen into estrogen. *Kapha* by its *Upachaya Guna* (nutritive function) responsible for proliferative and secretory changes in endometrium for further development of cells, these three *Dosha* contributed in different stages of receptive endometrium formation by their normal function. Any vitiation in three *Dosha* is collectively responsible for defective endometrial formation. The drug assumed as effective for healthy endometrial formation was considered to have *Tridoshaghna*, *Agnivardhaka*, *Balya*, *Rasayana*, *Brimhana* properties. *Phalakalyana Ghrita*[8] is - *Tridoshaghana*, *Garbhasthapaka*, *Anulomna*, *Deepana* and *Rasayana* properties. So, this formulation is selected for its evaluation as *Yoni Pichu*. *Panchakola Phanta*[9]- *Deepana Pachana* and *Vata Anulomana*. *Baladi Vati*[10] is *Balya*, *Prajasthapaka*, *Brimhana*, *Vyasthapaka*, *Jeevaniya* and *Vrishya* was selected for study.

Phalakalyana Ghrita and *Baladi Vati* both drug have phytoestrogenic[11,12] property.

Yoni Pichu[13]

Vaginal drug delivery possesses systemic as well as local action. The blood cells are abundant in vaginal wall. This vascularity of vaginal tissue is responsible for first uterine pass effect, or direct preferential vaginal to uterine transport. When drugs are absorbed in vagina, it passes to uterus by osmolarity of *Sneha*. The *Sneha* which remains in inner portion of vagina may show systemic effect by being absorbed and transported into inferior vena cava by vaginal, retro sigmoidal, vesical and uterine veins. *Yoni Pichu Kriya* is indicated in *Vataja* and *Pittaja Yonivyapada Chikitsa*. [14,15] *Vandhyatva* due to Endometrial factor is *Tridoshaja* condition that's why *Yoni Pichu* with *Phalakalyana Ghrita* was used in this clinical trial.

Follow-Up Study: Follow up study was conducted for two cycles (two consecutive months) after completion of the treatment.

Drug	Dose		Frequency	Duration
Panchakola Phanta	6 gm made in 100 ml		Twice a day	3 days
Pradhanakarma				
Drug	Dose	Anupana	Frequency	Duration
Baladi Vati	500 mg (1 tablet)	Godugdha	Twice a day	2 months (2 consecutive cycle)
Yoni Pichu with Phalakalyana Ghrita				
Purvakarma:				
Yoni Abhyanga with Goghrita				
Yoni Swedana with Sukhoshna Jala				
Pradhanakarma:				
Drug	Dose	Frequency	Duration	
Phalakalyana Ghrita	20 ml	Twice a day	5th day to 12th day of menses - 8 days (2 consecutive cycle)	

Observations and Results

The observations of the study are presented in Table no. 3 and 4. The effect of therapy is shown in Table no. 5. The Sonographic findings on endometrial thickness of patients before treatment and after treatment are given in Fig. 1. to Fig. 4. Study shows statistically highly significant ($p>0.001$) result in improving endometrial receptivity.

Table 3: Observations on Demographics and Previous treatment

Observation	No. of Patients	%
Age group 26-30 yrs	18	56.3%
Occupation as housewife	27	84.4%
History of abortion	9	28%
Primary Infertility	28	87.5%
Secondary Infertility	4	12.5%
Previous Treatment	No Treatment	16 50%
	Allopathic	14 43.7%
	Ayurvedic	2 6.2%

Table 4: Observations on Bowel Habits, Appetite, Dietary Habits, Rasa dominance, Agni, Sleep

Observation	No. of Patients	%
Bowel Habits - Irregular	12	37.5%
Appetite - Moderate	21	65.6%
Diet - Veg	19	59.4%
Rasa Dominancy in Diet	Lavana	13 40.6%
	Katu	10 31.2%
Dietary Habits	Vishamasana	20 62.5%
	Adhyasana	8 25%
Agni	Vishamagni	17 53.1%
	Agnimandhya	13 40.6%
Sleep	Disturbed	8 25%
	Divasvapna	14 43.7%

Table 5: Effect of Therapy on Appelbaum's Parameters

Parameter	N	Mean Score		% Improvement	P-Value
		BT	AT		
Endometrial Thickness	30	0.00	2.70	90%	0.000
Endometrial layering	30	1.20	2.60	46.66%	0.000
Myometrial Echogenicity	30	1.10	1.86	38%	0.001
Uterine Artery Doppler Flow (PI)	30	0.83	1.93	55%	0.000
Endometrial Blood Flow in Zone 3	30	2.40	4.70	46%	0.000
Myometrial Blood Flow (Gray Scale)	30	0.46	2.00	77%	0.000

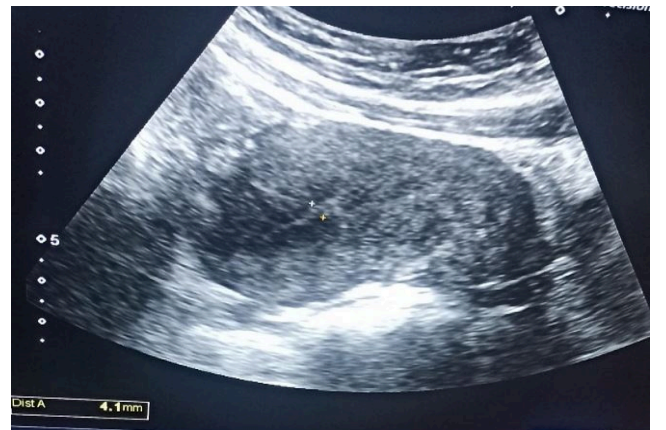


Fig. 1: BT Endometrial Thickness on TVS



Fig. 2: AT Endometrial Thickness on TVS

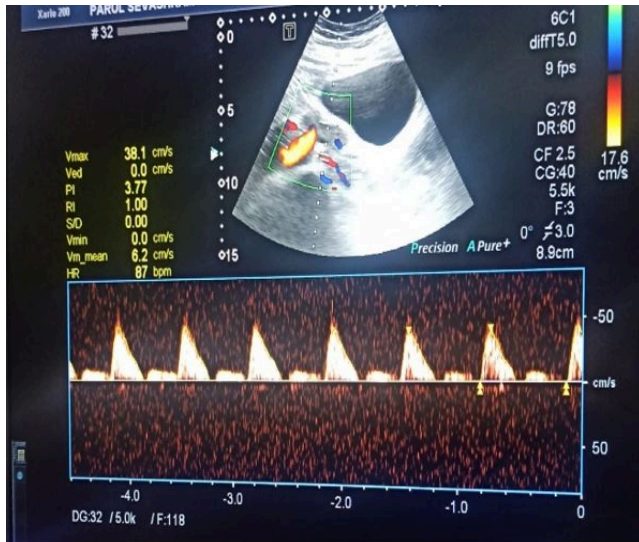


Fig. 3: Doppler BT

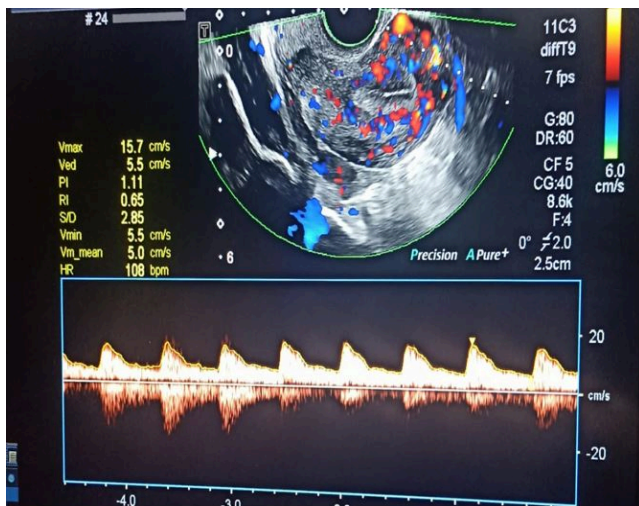


Fig. 4: Doppler AT

Discussion

Discussion on general observations

- Defective dietary habits (62.5%), *Vishamashana*, *Adhyashana* (25%) cause *Jatharagni Dushti* results in *Dhatvagni Dushti* leads to *Rasa Dhatu Dusti* and its *Updhatu Artavadushti*.
- Due to faulty dietary and life style most, digestive power was affected with *Mandaagni* (6%) and *Vishamagni* (53.1%).
- Excessive use of *Lavana Rasa* (40.6%), *Amla Rasa* (21.9%), *Katu Rasa* (31.2%) in routine diet became the *Aharaja Nidana* of *Pitta Dusti*. *Divaswapna* (43.75%) imparts *Agnimandya* which leads to *Rasa Dushti* and creates disturbance in formation of *Upadhatu Artava*.

- Disturbed sleep pattern (25%) due to stress - *Manasika Bhavas* lead to *Vata-Pitta Prakopa* which resulted in vitiation of *Dosha*, *Dhatu*, *Mala*. Ultimately it hampers the proper formation of *Rasa Dhatu* and its
- History of hormonal pills intake (43.7%) with clomiphene citrate for augmentation of ovulation, had anti- estrogenic effect.

Discussion on effect of therapy

Endometrial Thickness:

The *Brimhana* property of therapy is directly responsible to increased thickness of endometrium. *Phalakalyana Ghrita Yoni Pichu* gives nourishment to endometrium potentially by its *Brimhana* property through local action. *Baladi Vati* help in follicular growth, proper formation of endometrium by activation of epidermal growth factor and phytoestrogenic properties.

Endometrial Layering:

Layering in endometrium seems due to differences in compactness of tissues in functional & basal layer. A distinct five lines indicate compact & favourable endometrium for implantation. As proliferative activities are *Karma* of *Vata* & secretory function of *Kapha*. The *Ama Pachana* & *Vataanulomana* & *Brimhana* action of drugs are substantiable.

Myometrial Echogenicity:

Homogenous myometrium indicates healthy myometrium of uterus. Proper cell division is the action of proper functioning of *Vata*, *Yoni Pichu* with *Phalakalyana Ghrita* does *Snehana Karma* and gives nourishment to local tissue while *Baladi Vati* by its *Rasayana* property rejuvenates tissues. Uniform contractility of myometrium is significant for normal of endometrial regeneration and implantation in the *Kshetra* - i.e., *Garbhashaya*. Thus, the *Chala Guna* of *Vata* is pacified and regulated by *Sthiraguna* of drugs in *Yonipichu* and strengthening of the tissues of myometrium through *Snehana* activity of *Ghrita*.

Uterine Artery Doppler Flow:

Uterine arteries are arterial supply to uterus with pulsatile index <2, while if abnormal resistance found in uterine artery, then pulsatile index is raised. *Vata* is responsible for any type of *Gati* (velocity); contraction and relaxation are also the action of *Vata*,

Thus the drugs restoring the *Prakruta Karma* of *Vyana Vata*, *Rasadhatu Vikshepa* (circulatory redistribution) occurs normally, Pulsatile index of uterine artery is restored to normalcy. Both the drugs were effective for this parameter of uterine scoring.

Endometrial Blood Flow:

Blood circulation reaches in third zone of endometrium when all micro channels for circulation gets decontaminate and open, so that basal layer of endometrium begets proper nourishment to produce healthy cells of functional layer. *Yoni Pichu* purifies all micro channels and both drugs provide nourishment to cell by topical and systemic action.

Myometrial Blood Flow:

Enhanced arterial supply and venous drainage prove the improvement in circulation. The proper oxygenation of tissues and elimination of tissues oxidative biowastes thus provide favourable environment for epidermal growth factors and appropriate maturation of endometrium. It was evidenced from colour doppler study that both the drugs enhanced the myometrial blood flow.

Conclusion

Thus, the interventions were encouraging and highly significant in enhancing the endometrial receptivity assessed on the basis of Appelbaum's USSR.

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