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# A Clinical Study on *Uttar Basti* of *Bhrihat Shatavari Ghrita* and *Baladi Churna* in the management of Female Infertility w.s.r. to Endometrial Receptivity

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## ABSTRACT

**Introduction:** Endometrial factor comes under the umbrella of *Kshetra*, which is one of the important factor for conception described in *Ayurveda* i.e. *Rutu*, *Kshetra*, *Ambu*, *Beej*. Decreased endometrial factor is the major cause of implantation failure, Therefore the present study was carried out for the clinical evaluation of efficacy of *Uttar Basti* of *Bhrihat Shatavari Ghrita* and *Baladi Churna* in female infertility w.s.r endometrial factor. **Materials and methods:** A simple randomized clinical trial was conducted of total 28 registered patients in two groups i.e. First Group with *Bhrihat Shatavari Ghrita Uttar Basti* combined with *Baladi Churna* Oral and other Group *Baladi Churna* Oral. 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 ( $p > 0.001$ ) effect of therapies in the both groups but clinically Group A (*Bhrihat Shatavari Ghrita Uttar Basti* combined with *Baladi Churna* Oral) provided better result in upgrading endometrial receptivity comparatively. **Conclusion:** It can be concluded that *Bhrihat Shatavari Ghrita Uttar Basti* combined with *Baladi Churna* Oral overall can be a better choice in improving endometrial receptivity in cases of female infertility.

**Key words:** Appelbaum's USSR, *Baladi Churna*, *Bhrihat Shatavari Ghrita*, Endometrial Receptivity, Female infertility, *Uttar Basti*.

## INTRODUCTION

A womanhood is never considered complete without achievement of motherhood. Infertility is "a disease of the reproductive system defined as failure to achieve a conception after 12 months or more having

regular unprotected sexual intercourse."<sup>[1]</sup> Female factor is directly responsible in 40-55%.<sup>[2]</sup> 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.<sup>[3]</sup> IVF Success rate was only 35%, rest 65% cases of IVF failed because of implantation failure in which decreased endometrial receptivity is commonest cause of implantation failure.<sup>[4]</sup> Their latest techniques like In-Vitro Fertilization (IVF), Embryo Transfer (ET), and Gamete Intra Fallopian Transfer (GIFT) all become failed due to decreased endometrial receptivity. The whole world see towards us with sight of hope where, research works on endometrial factor was negligible in *Ayurveda* research field. Thus, the need of the hour today is in findings means to improve the implantation rates. Here a preliminary effort has been made to provide

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simple and effective management of decreased endometrial receptivity which can be practiced regularly for the achieving and preserving conception by increase implantation rates.

## OBJECTIVE

To evaluate the clinical efficacy of *Bhrihat Shatavari Ghrita Uttar Basti* and *Baladi Churna* to upgrade endometrial receptivity adopting Applebaum's scores for management of Female infertility.

## MATERIALS AND METHODS

### Source of Data

Patients attending the Outdoor Patients Department of *Stree Roga & Prasooti Tantra* fulfilling the criteria for selection was incorporated into the study. A special research performa was prepared. Total 28 patients were registered, out of them 21 patients completed the course of treatment.

### Ethics

Study started only after obtaining Ethical clearance from the Institutional Ethics Committee. Ref.PGT/7-A/Ethics/2012-13/1964 (dated 21/9/12)

### CTRI Registration

Study registered in CTRI as REF/2013/07/005300.

### Criteria for selection of cases

#### Inclusion criteria

Patient of child bearing age of 20 to 40 year with active marital life of 1 year, having endometrial thickness  $\leq 7$ mm, on the diagnostic basis of Trans vaginal sonography.

#### Exclusion criteria

Patients having age less than 19 years and more than 40 years, with any possibility of active pelvic infection, sexually transmitted disease or any debilitating systemic diseases were excluded from the study.

### Investigations

- Routine haematological and urine investigations were done before and after treatment.
- Serological tests for HIV (Human Immunodeficiency Virus), HBsAg (Australia antigen for hepatitis B) and VDRL (Venereal

Disease Research Laboratory) were carried out in all the patients before starting the course of treatment.

- Trans vaginal colour doppler sonography performed for diagnosis and assessment of result.

### Selection of drug

Infertility due to endometrial Factor has been considered as the *Vata* predominant *Tridoshaja* condition, with *Pitta* as being the next *Dosha*, as *Vata* was responsible for *Dhatu Vhuhana* and *Pravartan*,<sup>[5]</sup> and *Vata* is causative factor for *Parmanu* (cell) *Sanyog* (union) and *Vibhag* (division),<sup>[6]</sup> so new cell regeneration from basal layer may be assumed by proper *Vata* function. *Pitta* is responsible for conversion of one *Dhatu* into another *Dhatu* in adequate amount by its *Pakti* property,<sup>[7]</sup> hence it is responsible for production of adequate level of hormonal support by aromatization of androgen into estrogen. *Kapha* by its *Upachaya Guna* responsible for proliferative and secretory changes in endometrium for further development of cells, these three *Dosha* contributed in the different stages of receptive endometrium formation by their normal function. Any vitiation in the three *Dosha* was collectively responsible for the defective endometrial formation. The drug assumed as effective for healthy endometrial formation was considered to have *Tridoshaghna* properties mainly *Vatapittashamaka*. *Brihata Shatavari Ghrita* is mentioned by *Acharya Charaka* in management of *Yonivyapad* (not occurs without vitiation of *Vata*). So, this formulation was selected for its evaluation as *Uttar Basti*. *Baladi Churna*<sup>[8]</sup> mentioned by *Acharya Bhavaprakasha* containing medicine with *Balya*, *Punsavan* and *Vrishya* properties was selected for the study. *Uttar Basti* is a unique procedure to administration of drug directly into uterus given in *Ayurveda* for the treatment of *Vandhyatva*. The ingredients of *Baladi Churna* are 66.67% ingredients having *Vatapittashamak* property, while 33.33% have *Kaphapitta Shamaka* property.

That's why these formulations were selected for its evaluation as *Uttar Basti* and oral compound.

### Treatment protocol

In the present study, before starting the treatment *Deepana*, *Pachana* by *Amapachana Vati* - 2 tab B.D

with luke warm water for 3 days, from the hospital supply was given to the patients as *Deepana, Pachana* followed by *Koshtha Shuddhi* was done in all patients *Koshtha Shuddhi* with *Eranda Bristha Haritaki* with luke warm water before bed time for 2 days.

**Group-A** - Intra uterine *Uttar Basti* of 5 ml. *Brihat Shatavari Ghrita* was given for 6 days after the cessation of menses for two menstrual cycles along with *Baladi Churna* orally 3 gm. B.D. with milk before meal for 2 months.

**Group-B** - *Baladi Churna* orally 3 gm. B.D. with milk before meal for 2 months.

#### Method of Uttar Basti

##### Poorva Karma

- *Yoni Prakshalana* - by *Panchvalkala Kvatha* of antiseptic property.
- *Snehana* of Abdomen, back, thigh and legs by *Bala taila*.
- *Svedana* by *Nadi Sveda* on back and lower abdomen.

##### Pradhana Karma

Autoclaved posterior vaginal speculum, Anterior vaginal wall retractor, vulselum and *Uttarbasti* cannula with disposable syringe are required for *Uttarbasti* procedure. Patient was taken in dorsal lithotomy position on Operation theatre table. Part preparation was done by *Panchvalkala Kvatha*. Cervix was exposed with instruments than uterine sounding was done. Autoclaved lukewarm *Brihat Shatavari Ghrita* loaded in 5 ml disposable syringe. Drug administration was done slowly in uterine cavity by *Uttarbasti* cannula attached on disposable syringe. After drug administration tampon was placed in vaginal cavity.

##### Pashchat Karma

- Complete rest in head low position for at least 2 hours
- Abdominal hot fomentation with hot water bag
- Advised to take light diet and rest.

#### Method for Assessment

For the evaluation of result the Appelbaum's Uterine Scoring system for reproduction was adopted. (Table 1)

**Table 1: Appelbaum's uterine scoring system for reproduction (USSR)**

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 appearance	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

According to Applebaum, certain sonographic qualities of the uterus are noted during the normal mid-cycle (day 11- till ovulation). 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)

#### Statistical estimation of results

The obtained data was analyzed for statistically significance by using student 't' test. The level of 'P' between 0.05 to 0.01 and  $P < 0.001$  was considered as statistically significant and highly significant respectively. The level of significance was noted and interpreted accordingly. If the calculated 't' value was more than 0.05 ( $P > 0.05$ ) results were taken as insignificant.

- Insignificant  $P > 0.05$
- Significant  $P < 0.05$
- Highly Significant  $P < 0.01$  &  $0.001$

#### Follow up study

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

#### OBSERVATIONS AND RESULTS

The observations of the study are presented in Tables 2 to 4. The Sonographic findings on endometrial thickness of patients before treatment and after treatment are given in Figures 1-2. The effect of therapy is shown in Tables 5 to 7.

The results shows statistically insignificant difference between two therapy but clinically Group A show gross improvement of Appelbaum,s USSR over Group B.

**Table 2: Status of Patients.**

Total Registered	28
Completed	21

Drop out	07
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**Table 3: General observations on demographics and Manasika Bhava of 28 patients.**

Observations	Number of Patients	%
Age group 26-35 years	19	67.85%
Occupation as house wife	25	89.20%
History of Abortion	10	36%
Primary infertility	15	53.57%
Secondary infertility	12	42.85%
<i>Chinta</i>	27	96.40%
<i>Shoka</i>	11	39%

**Table 4: General observations on dietary habits, Rasa dominance of 15 patients.**

Observations	Number of Patients	%
<i>Vishamasan</i>	14	50%
<i>Adhyashan</i>	13	46.42%
<i>Vishamagni</i>	13	46.42%
<i>Mandagni</i>	13	46.42%
<i>Lavana</i>	24	86%
<i>Amla</i>	14	50%
<i>Katu</i>	16	57%
History of Hormonal treatment	23	82.14%

**Table 5: Effect of therapy on Appelbaum's USSR of Group-A (n=10)**

Parameter	Mean Score		% of relief	S.D. (±)	S.E. (±)	“t” (paired)	P
	B. T.	A. T.					
Endometrial Thickness	0.1	2.2	70%	0.875	0.276	7.58	p<0.001
Endometrial Layering	0.1	2	63.33%	1.1	0.348	5.545	p<0.001
Myometrial echogenicity	1	1.8	40%	0.42	0.133	5.45	p<0.001
Uterine Artery Doppler Flow	0.3	1.2	45%	0.567	0.179	5.01	p<0.001
Endometrial Blood Flow Zone 3	0.6	2.6	40%	0.816	0.258	7.74	p<0.001
Myometrial Blood Flow	0.4	2	80%	0.843	0.266	6	p<0.001

**Table 6: Effect of therapy on Appelbaum's USSR of Group-B (n=11)**

Parameter	Mean Score		% of relief	S.D. (±)	S.E. (±)	“t” (paired)	P
	B. T.	A. T.					
Endometrial Thickness	0.2	2.2	66.7%	0.471	0.14	13.41	p<0.001
Endometrial	0	1.8	60%	1.03	0.3	5.57	p<0.001

rial Layering	0				3		01
Myometrial echogenicity	1.2	1.7	25%	0.53	0.17	3	p<0.05
Uterine Artery Doppler Flow	0.4	1.5	55%	0.74	0.23	4.71	p<0.001
Endometrial Blood Flow Zone 3	0.8	3.5	54%	1.49	0.47	5.71	p<0.001
Myometrial Blood Flow	0.2	1.6	50%	0.97	0.31	4.58	p<0.001

**Table 7: Comparative effect of therapy between Group-A and Group-B Chi square test.**

Group	0-25%	26-50%	51-75%	76-100%	Chi square value	P
A	1	4	4	1	1.99	0.15
B	0	3	5	3		

## DISCUSSION

### Discussion on general observations

Maximum patients i.e. 67.85% were between the age group of 25 to 35 years. The findings are very close to the figures of most studies because it is the most favorable period of reproductive life. 89.21% patients were housewife. Due to responsibility of her kids, husband and other family members, female always ignore their disease so disease turned into chronic phase which leads to bad prognosis and fertility also hampered. 36% patients had history of abortion figures suggests that endometrium was not supportive for continuation of pregnancy. 53.57% patients had primary infertility and 42.85% had secondary infertility [Table 3]. Most of the patients had defective dietary habits i.e. 50% patients had

habit of *Vishamasan* and 46.42% had habit of *Adhyasan* cause *Jatharagni Dusti*, consequence in *Dhatvagni Dusti* leads to *Rasa Dhatu Dusti* and its *Updhatu Artava*. Due to faulty dietary and life style most digestive power affected i.e. 46.42% were suffering from *Mandaagni*, while rest 46.42% suffered by *Vishamagni*. [Table 4] 86.% patients use excessive *Lavana Rasa*, 50% patients *Amla*, 57 % *Katu Rasa* in routine diet became the *Aharaja Nidana* of *Pitta Dusti*. [Table 4] *Chinta* was present in 96.40% patients while and *Shoka* was found in 39% of patients[ Table 4]. *Manasika Bhavas* leads to *Vata-Pitta Prakopa* which again lead to vitiation of *Dosha, Dhatu, Mala*. Ultimately it hampers the proper formation of *Rasa Dhatu* and its *Upadhatu*. The modern research reveals that stress disturbs the normal hormonal regulation.<sup>[9]</sup>

In present study, 82.14% of patients had history of taking hormonal treatment. [Table 4] Among which most used Clomiphene citrate for induction of ovulation. A direct adverse effect of clomiphene citrate on endometrium has been presumed.<sup>[10]</sup> it is estrogen antagonist<sup>[11]</sup> that's why it inhibit the process of endometrium proliferation so, due exposure of clomiphene citrate endometrial receptivity decreases gradually. Therefore, after the presence of ovum conception not occur because of implantation failure.

#### Discussion on effect of therapy in both Groups

**1) Endometrial Thickness** - Group A and Group B both shows their effectiveness but clinically it was found that the endometrial thickness in most patients of group A was raised upto 10-12mm while in group B most results comes under zone of 7-9 mm. *Brinhana* property of therapy is directly responsible to increase thickness of endometrium, here in group A *Brihat Shatavari Ghrita Uttar Basti* gives nourishment to endometrium potently by its *Brinhana* property of *Ghrita* through local action and *Baladi Churna* works on *Dhatu Poshan* level.

Hence, Group A is more potent in raising endometrial thickness as compare to Group B due to synergetic effect of *Baladi Churna*.

**2) Endometrial layering** - Layering in the endometrium seems due to differences in

compactness of tissues in functional and basal layer, if distinct five lines appear in sonography it means that both layers of endometrium are perfectly compact and the tissue in both layers are healthy and properly arranged so that implantation can occur easily in it. As the division and arrangement is *Karma* of *Vata* and *Basti* is one of best treatment for *Vata Dosha*.

Here both treatment regimens are effective but Group-A shows better results over Group-B due to combined action of *Baladi Churna*.

**3) Myometrial echogenicity** - Homogenous myometrium means that muscular portion of uterine wall is normal. This uniformity can be disturbed when there are another cells grow in myometrial layer. Proper cell division is the action of proper functioning *Vata* that's why *Uttar Basti* of *Brihat Shatavari Ghrita* did *Shodhan Karma* of *Vata Dosha* and gives nourishment to local tissue while *Baladi Churna* by its *Rasayana* property *rejuvenates* tissues of uterus. Hence, combined effect of both drugs (Group A) is more effective over alone use of *Baladi Churna* (Group B).

**4) Uterine Artery Doppler Flow** - Uterine arteries provide blood to uterus. When blood flows normally in uterine artery it shows pulsatile index <2, while if abnormal resistance found in uterine artery than pulsatile index raised. Here, according to *Ayurveda Vata* is responsible for any type of *Gati* (velocity); contraction and relaxation is also action of *Vata*, So by purify *Vata Dosha* Pulsatile index of uterine artery can be ranging in normal zone. Clinically as well as statistically both groups are effective for this parameter of uterine scoring.

**5) Endometrial Blood flow in zone 3** - Blood circulation reaches in third zone of endometrium when all micro channels for circulation gets decontaminate and open, so that basal layer of endometrium get proper nourishment to produce healthy cells of functional layer.

*Uttar Basti* purifies all micro channels and both drugs gives nourishment to cell by topical and systemic level. So, both Groups are effective to upgrade endometrial blood flow in zone 3.

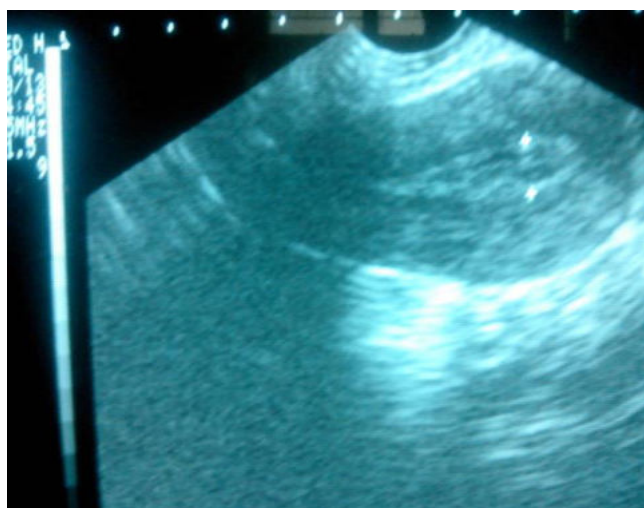
**6) Myometrial Blood Flow** - If blood flow found in myometrial, it means that muscles of uterus got proper nourishment for growth so they divide in their natural form and it also minimize the probability of formation of other abnormal growth in musculature of uterus. Both Groups are shows improvement in raising myometrial blood flow but Group A is more effective due to combined effect of oral regime.

This total effect of therapy was very encouraging and highly significant to increase endometrial receptivity assessed on the basis of Appelbaum's USSR. It shows that drugs have potently increased endometrial receptivity.

#### Trans vaginal colour Doppler findings



**Figure 1: Endometrial Thickness in B.T < 7 mm**



**Figure 2: Endometrial Thickness in A.T = 9mm with triple layer pattern**

#### CONCLUSION

In both the groups, effect of therapy was found highly significant but on comparison effect of therapy, significant difference was not observed statistically, which verifies our hypothesis that *VataPitta* are root factor for etiopathogenesis of decreased endometrial receptivity is accepted because drug has *VataPitta Shamaka* property and it has efficacy to improve conception rate by increasing endometrial receptivity. Combined therapy is more effective than alone use of *Baladi Churna* in which *Uttar Basti with Brihat Shatavari Ghrita* combined with *Baladi Churna* shows best result in comparison to alone use of *Baladi Churna* to increase endometrial receptivity.

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