

## “A Clinical Study To Evaluate The Efficacy Of Shatapushpa Tail Uttarbasti & Shatavari Tail Uttarbasti With Herbal Compound In The Treatment Of Anovulatory Cycle”

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**Abstract-** Infertility is major health problem. The rate of infertility is steadily increasing due to change in life style. High pollution, socioeconomic cause, enormous amount of stress. Among many causes of infertility the anovulation is very common problem in approximately 40% cases of female infertility. Majority of these cases could be treated either hormonal therapy or surgical intervention. This study will emphasize on careful holistic approach in management of anovulatory cycles. 60 patients were completed clinical trial. 30 patient in Group A treated with Shatapushpa Tail Uttarbasti with Herbal Compound and 30 patient Group in B treated with Shatavari Tail Uttarbasti with Herbal Compound for three month. The subjective and objective parameters were measured before and after treatment in each group. Group A and Group B showed induces timely ovulation, increase endometrial thickness and menstrual flow. But menstrual pain is insignificant in Group B.

**Key Words-** Shatapushpa & Shatavari Tail Uttarbasti, Herbal Compound, Anovulatory Cycle.

### I. Introduction-

Motherhood is described as the pleasing punishment to woman. God "The creator" has empowered every human being to reproduce itself. The function of reproduction is the noblest. God has given this magnanimous gift only to woman. The "DESIRE" of women for "CHILDREN" is sometimes stronger than self interest in beauty and figure, and may be stronger than the claims of career. The children cement a marriage. Infertility is becoming a major health problem, this infertility condition has deep impact on individuals physical and mental health and disturbs her family life. The treatment suggested in modern science is though effective, has lots of side effects.

Ayurveda is ancient medicine system which originated in India thousand of years ago. In Ayurveda we find this topic of infertility described under the heading of 'vandhyatva'. So this burning issue of the society is selected for the study. Ovarian factor are most common cause of infertility, contributing 25-35%.

In Ayurveda, to achieve pregnancy Sushruta has given four essential factors **rutu** (fertile period), **kshetra** (healthy reproductive organs), **ambu** (proper nutrient fluid), **beeja** (ovum/ sperm) in this four factor, one important factor is 'beeja', which directly related to ovulation process<sup>2</sup>. Defect in any one of them can cause vandhyatva.<sup>2</sup>

The saying, "as you sow, so shall you reap" signifies the importance of the seed. It is the seed which gives the fruit and so it is the **beeja which yields the garbha**. And the absence of this beeja in women is termed as anovulation.

Acharya Sushruta has mentioned the importance of Uttarbasti in Aartavadosha and Agney Gunatmak Dravyas act on ovulation.

Taking into consideration of infertility many women suffering from anovulatory cycles. It is present with irregular, frequent, scanty menses and infertility. Therefore this topic was selected for clinical study.

### II. Aims and Objectives-

#### Aims-

To find the effects of the drug on the ovulation (Beejotsarga).

#### Objectives-

- To study to propose the probable mechanism of action of the study drug on anovulatory cycles.
- To study in detail Ayurvedic and modern literature regarding Vandhyatva and study drug.
- To find the effect of the drug on endometrium (Garbhashayya)
- To study the complications if any during the course of treatment.

### III. Materials and Methods-

#### A. Materials -

##### Literature

All available Ayurvedic classics and modern available texts, magazines, journals, M.D. Dissertations, Research Papers and internet were referred for the complete review of the literature.

##### Material & Method-

Attending OPD Stri-rog & Prasutitantra, M.A. Podar Ayurved Medical Hospital, Detailed history of patient was taken covering high risk behaviors, Modes of transmission presenting complaint and physical examination. After a written informed consent, approval of institutional ethical committee was taken.

##### Inclusion Criteria-

- Married patients (Age group 20-40yrs)
- Infertility patient
- PCOD.
- Irregular menses / scanty menses due to anovulatory cycle
- Anovulatory cycle
- Delayed ovulation.

##### Exclusion Criteria-

- Unmarried patients
- Bleeding P/V
- Cervical tumour, polyp, Ca cervix
- Uterine fibroid
- Congenital anomalies in female genital tract
- Tubercular endometritis
- HIV/VDRL/HbsAg positive
- Malignant diseased patients and cytotoxic patients.

##### Discontinous Criteria-

- An acute or severe illness.
- Patient left against medical advice.

##### Grouping Of The Patient-

**Group A** - 30 patients of anovulatory cycle were given **Shatapushpa tail Uttarbasti with Herbal compound.**

**Group B** - 30 Patients with anovulatory cycle were given **Shatavari tail Uttarbasti with Herbal compound.**

**Dosage**- Intrauterine Uttarbasti 5cc for successive 5 days after cessation of menstruation, it was repeated for 3 months and oral herbal compound 2 gm (4 Tablet) were given in two times a day. Suggest for taking in morning empty stomach and in evening given two hours before taking meal with water.

**Drugs**- Shatapushpa (*Anthem sowa*), Shatavari (*Aspergus racemosus*), Trikatu (*Zingiber officinale*, *Piper longum*, *Piper nigrum*), Aswagandha (*Withania somnifera*), Jeerak (*cuminum cymium*), Kanchnar (*Bauhinia variegata*), Gudmar (*gymnema sylvestris*), Rason (*Alum sativum*).

Raw material were purchased directly from the market. The drugs were checked for the authenticity. Taila was prepared by standard method given in kashyapa samhita.

##### Investigations -

###### 1) Haematological investigations -

- CBC, ESR
- Blood group B.T., C.T.
- HIV/VDRL/HbsAg
- BSL F/PP
- Urine R/M

###### 2. USG pelvis

3. **Follicular study**- A serial vaginal or abdominal sonography was done from 10<sup>th</sup> day of menstrual cycle, till after ovulation.

**A) Subjective Criteria:-**

1) **Irregularity of menses –**

**Regular – Grade 0.**

**Irregular –Grade 1.**

2) **Quantity of Bleeding:-**

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

**B) Objective Criteria:-**

1) **Follicular Size -**

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

2) **Endometrial Thickness-**

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

**Total effect of Treatment-**

The overall effect will be graded into 5 types-

- Unchanged
- Improved
- Complete remission
- Conceived

**Unchanged** - No improvement .

**Improved** - Ovulation not occurred but only improvement in the size of follicles means  $\geq 12-20$  mm

**Complete remission** - ovulation occurred with the follicular size  $\geq 20$ mm

**Conceived** -The patient's husband otherwise normal was conceived after the treatment.

**Observations And Results-**

**Age wise distribution of patients –(Table 1)-**

Age group (in years)	No Of Pts.		Total (Out of 60 Patient)	%
	Group A	Group B		
20-25	1	2	3	5
26-30	9	11	20	33.3
31-35	16	15	31	51.6
36-40	4	2	6	10

Age group was divided into four groups,patient above the age of 20 yr taken up for study.3 patients out of 60 (5%)belonged to the age group of 20-25 yr. 20 patients out of 60 (33.3%) belong to age group of 26-30 yr.31 patients (51.6%) belonged to the age group of 31-35 yrs.&6 patients (10%)belonged to age group of 36-40 years.

**Distribution of patients by Type of infertility –(Table 2)**

Type of infertility	No Of Pts.		Total(Out of 60 Patient)	%
	Group A	Group B		
Primary	24	25	49	81.6
Secondary	6	5	11	18.3

Out of 60 patients observed 49 (81.6%) patients were having Primary infertility and 11 (18.3%) patients were of secondary infertility.

**Distribution of patients by Prakruti –(Table 4)**

Prakruti	No Of Pts.		Total(Out of 60 Patient)	%
	Group A	Group B		
Vata-Pitta	4	9	13	21.6
Vata-Kapha	11	5	16	26.6
Pitta-Vata	7	2	9	15
Pitta-Kapha	3	4	7	11.6
Kapha-Vata	2	6	8	13.3
Kapha-Pitta	3	4	7	11.6

Out of 60 patient observed 13 (21.6%) had Vata-Pitta prakruti, 16 patients (26.6%) had vat-kapha prakruti, 9 patients (15%) had pitta-vata prakruti, 7 patients (11.6%) had pitta-kapha prakruti, 8 patient (13.3%) had kapha-vata prakruti, 7 patients (11.6%) had kapha pitta prakruti.

This shows that anovulatory cycle is commonly seen in patient with vata-kapha and vata-pitta prakruti.

**Distribution of patients by causes of Anovulation -**

Anovulation	NO OF Pts.		TOTAL	%
	GROUP A	GROUP B		
PCOD	6	7	13	21.6
Delayed Ovulation	2	4	6	10
Unexplained	22	21	43	71.6

Out of 60 patients observed 13 (21.6%) patients were having PCOD, 6 patients (10%) patients were having delayed ovulation and cause of anovulation in 43(71.6%) patients was unexplainatory.

77% patients had not any history of major disease. 9% patients had history of hypertension. 62% of patients were kroot koshti and 38 % were mrudu koshti. the apan vayu dushti was found in 77% patients either by atipravrit or by apravriti. We observed that most of patients in habbit of Vishamashan 69%, Samshan is 49%, Ajeernashan 67% and almost all categories of Avidhi aahar was found in patients. Maximum number of patients were practicing the vatic ahara, but the paittik and shlaishmik ahara was also taken by the patients much amount. This shows all tridoshas can produce the disease in predominance of vata. pragvat sevan, vegasandharan, ati adhyayan, atishram, atyadhwa gaman and abhyang dwesha were prominent. These are main etiological factor which aggravate disease.

**Statistical Analysis-**

After statistical Analysis of effect of therapy on subjective & objective parameters Group A by Wilcoxon Signed rank test.

Sr.No.	Symptom		Mean	SD	SE	W	n	Z	P
1)	Follicular size.	BT	1.12	0.89				3.58	<0.0001 Extremely Significant.
		AT	2.42	1.11		-	-		
		DIFF	-1.30	1.44	0.26	303	27		
2)	Endometrial Thickness	BT	1.7	0.60	0.10			2.72	<0.01 Very significant
		AT	2.3	0.71	0.12	-	20		
		DIFF	-0.5	0.92	0.16	162			
3)	Menstual Flow	BT	1.21	0.62	0.11			2.66	0.01 Very significant.
		AT	1.66	0.72	0.14				
		DIFF	-0.47	0.72	0.13	132	19		
4)	Menstual pain	BT	1.86	0.85	0.15			2.74	<0.01 Very significant
		AT	1.29	0.64	0.12	170	22		
		DIFF	0.58	0.85	0.16				

After

statistical

Analysis of effect of therapy on subjective & objective parameters Group B by Wilcoxon Signed rank test.

**In Group A-**

Sr.No.	Symptom		Mean	SD	SE	W	n	Z	P
1)	Follicular size.	BT	1.1	0.87	0.16	-300	-	2.87	<0.0001 Extremely Significant.
		AT	2.4	1.1	0.22				
		DIFF	-1.3	0.76	0.16				
2)	Endometrial Thickness	BT	1.85	0.76	0.13	-158	22	2.57	<0.01 Very significant
		AT	2.39	0.84	0.15				
		DIFF	-5.32	0.93	0.17				
3)	Menstual Flow	BT	1.4	0.66	0.12	-165	21	2.87	40.00 Highly significant.
		AT	1.7	0.60	0.10				
		DIFF	-0.6	0.69	0.12				
4)	Menstual pain	BT	1.71	0.78	0.15	40	15	1.12	70.05 Not significant
		AT	1.51	0.75	0.13				
		DIFF	1.67	0.71	0.12				

At the end of treatment it was seen that 74.19% of patient had ovulated.5.59% of patients had conceived and endometrial thickness 54.37% of patient were increased.follicular size 14.01% of patient were increased.

Painless cycle were obtained in 76.67% of the patient.The menstrual flow is normal in 72.79% of patient.

**In group B-**

At the end of treatment it was seen that 73.89 % of patient had ovulated.9.29 % of patients had conceived and endometrial thickness 54.67% of patient were increased.follicular size 11.59% of patient were increased.

Painless cycle were obtained in 37.19% of the patient.The menstrual flow is normal in 52.09% of patient. Intergroup comparison of Group A with Group B(Man Whitney U test) showed statistically very significant result in improving menstrual pain in Group A than in Group B.But all other profile were found significant in both group.

**IV. Probable Mode Of Action Of Shatpushpa And Shatavari Tail-**

Vandyatva due to anovulation is vata-kapha pradhan vyadhi.In case of avaranatmak samprapti it is vata pitta pradhan vyadhi. In case of kshayatmak samprapti it is vikruti of vata dosha.(i.e.Apan vayu karmatah hani)occurs.Hence the treatment be vata kaphashamak,agnidipan,pachak and vatanulomaka and brihan.

The probable mechanism of the shatpushpa and shatavari tail is synergistic action between siddha tail of the uttarbasti.Uttarbasti is the procedure through which the drug is instilled into the uterus.Uterus is the mulasthan of artava vaha srotasa.The drug being directly instilled in the uterus gives direct access to the seat of strotovaigunya and dosha –dushya-sammurchana and hence acts on the vikrut vayu thereby disintegrating the samprapti.It may be also possible the drug given by the intra-uterine route may stimulate the receptor and corrects its function means Beejotsarga i.e.Ovulation.

Tikta rasa of shatapushpa causes rasraktashodhana,agnideepana and amapachan.Katurasa of it helps in rutupravartan,yonishukravishodhana.ushna virya of shatapushapa works as vatashamaka. Madhura rasa of shatapushapa acts as sthanik balya and pittashamana.

Tikta rasa of shatavari causes rasraktashodhana,agnideepana and amapachan.

Madhura rasa of shatapushapa acts as sthanik balya and pittashamana.

Shatapushpa and Shatavari is a phytoestrogen,it exerts both estrogenic and antiestrogenic activity.It acts in both high oestrogenic and low oestrogenic condition.Thus it increases the endometrial thickness.

**V. Probable Mode Of Action Of Herbal Compound-**

It also contains Shatpushpa (*Anthem sowa*), Shatavari (*Aspergus racemosus*), Trikatu (*Zingiber officinale,Piper longum,Piper nigrum*), Aswagandha(*Withania sonnifera*),Jeerak (*cuminum cymium*), Kanchnar (*Bauhinia variegata*),Gudmar (*gymnema sylvestris*),Rason(*Alum sativum*)increases the bioavailability of drug in body.

The combination of drug virtue of its kashaya rasa &laghu,ruksha guna and katu vipaka affect kapha dosha. In anovulatory cases kapha is associated as avarana on vata.the ushna guna of drug also regulate vata and ovulation occurs.The drug mean by of dipana,pachan and shaman of grathit kapha fight against agni dushti.the increased dhatvagni promote the formation poshakansh of dhatu and updhatu (aartava)and it also suppress the increased formation of mala.Being ushna guna of dravyas they act on the derangement reduces the sheeta guna of kapha dosha and being snigdha and picchila increases these guna of kapha three guna of kapha there by increasing endometrial thickness.

**VI. Conclusion-**

Both drug induces the ovulation & increases follicular size because Shatapushpa tail & Shatavari tail uttarbasti directly act on uterus HPO axis.

Shatapushpa and Shatavari both are contains natural phytoestrogen therefore its increases endometrial thickness & menstrual flow.

Menstruating flow is statistically significant in group A than in group B.

The formulation proves to be an Cost effective,Herbal,Safe treatment for anovulatory menstrual cycle.

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