

CLINICAL EVALUATION OF THE EFFECT OF *SHATPUSHPA KALPA* IN *STREE BANDHYATVA* W.S.R. TO FEMALE INFERTILITY

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ABSTRACT

Female infertility is the major disorder which has altered the mankind for lack of conception and reproductively. Stressful work, excess radiation, lack of biological food, genetic disorder, changing life style, has result the female infertility. In *Ayurveda* text like *Charaka Samhita*, *Sushruth Samhita*, *Ras Ratna Samuchya*, & *Haritt Samhita*, so many type of *Bandhyatva* had described. *Acharya Sushruta* described four essential factors for conception i.e. *Ritu*, *Kshetra*, *Ambu*, and *Beeja*. In present study all the factor is taken up for clinical drug trial. *Acharya Kashyapa* described *Shatpushpa* in a separate chapter called “*Shatapushpa Shatavari Kalpadhyaya*” as nectar for woman in various female disorders i.e. infertility. *Bandhyatva* occurred by *Vata* vitiation The selected drug is effective due to *Vata Shamaka Guna*.. *Shatapushpa* is the single drug of choice which is helpful in female reproductive disorders.

Keywords: *Bandhyatwa*, *Ritu*, *Kshetra*, *Ambu*, *Beeja*, *Shatpusha kalpa*

INTRODUCTION

The God has blessed the female with most valuable gift of motherhood mother is also called as “*Janani*” who give birth to child. A woman hood is never considered complete without achievement of motherhood. *Acharya Charaka* has mentioned that the woman is the Cause of origin of progeny¹ *Bandhyatva* (Infertility) is recognized since from *Vedic* period. The first systemic literature of health science *Ayurveda* has given detailed description in a classified manner.

Ritu (fertile period), *Kshetra* (Healthy uterus and female genital tract), *Ambu* (Nutritional fluid), *Beeja*

(high quality spermatozoa and high quality ovum) are essential factor for conception², also healthy psychological status, normal functioning of *Vata* (one of the governing factors of body according to *Ayurveda*) and *Shadbhava* (six factors- *matru*, *pitru*, *atma*, *satva*, *satmya*, *rasa*). Any abnormality in these factors would cause infertility.³

In *Ayurveda* *Acharya Sushruta* used term *Vandhya* in *Yoni vyapad*⁴ characterized by a specific feature, the *Nashtartava* & *Acharya Charaka* describe *Vandhya* under *Beejanshdushti*⁵

Acharya Sushruta has include *Bandhyatva* under the clinical feature of injury to *Artavaha Srotas* along with other symptoms i.e. dyspareunia and amenorrhoea.⁶ And *Kashyapa* described *Bandhyatva* in eighty type of *vata* disorder.⁷

Infertility is a social stigma and ceasing the opportunity to procreate. Infertility is defined as the inability to conceive a pregnancy after one year of unprotected intercourse. It can either be primary where no previous pregnancy has occurred or secondary where there has been a previous documented pregnancy. In recent years, prevalence of Infertility has dramatically increased up to estimated 10 %- 15% of couple of reproductive age. In which female is directly responsible in 40-55 % of cases.⁸

AIM AND OBJECTIVES

- To study the *Bandhyatva* in *Ayurveda* classics and infertility in Modern text books.
- To see the efficacy of *Shatpusha kalpa* in *Bandhyatva*.

MATERIAL AND METHOD-

Total 30 Patients Diagnosed with will be selected by simple randomized method for the study within a single group attending Prasuti Tantra and Streerogas O.P.D. of Rishikul Ayurveda collage and hospital, Haridwar.

PLAN OF STUDY-

1) CRITERIA FOR SELECTION OF PATIENTS:

A) INCLUSION CRITERIA

1. Married female patient with reproductive age (Age group 20-40).
2. Patient having complained of failure to conceive after 1 yr. of regular unprotected coitus.
3. Primary and secondary both type of infertile patient will be selected randomly.
4. Patient fulfilling the diagnostic criteria.

B) EXCLUSION CRITERIA

1. Abnormal semen analysis of male partner.
2. Patient suffering from acute and chronic medical and systemic diseases like Hypertension, T.B., Heart disease, Hypothyroidism, Hyperthyroidism, Patient having congenital anomalies of uterus i.e. Unicornuate uterus, Uterus didelphys, Bicornuate uterus, Septate uterus, arcuate uterus etc.

3. Patient having Pelvic diseases such as fibroids, benign/malignant tumours of ovary, STDs, PID, Endometriosis, cervicitis, Salpingitis etc.

C) DIAGNOSTIC CRITERIA- Diagnosis will be made on the basis of following criteria

1. Detailed history according to Performa, *Prakriti Parikshana* and general, systematic gynaecological examination.
2. Patient having proper developed Secondary sexual characters like breast fully developed hair distribution on axillary & pubis and normal hair growth.
3. On P/S examination patient having normal vaginal canal with no infection and lesion.
4. On P/V examination patient having position of uterus either AV or RV, normal size of uterus, mobility of uterus i.e. mobile and clear Fornices.

ASSESSMENT CRITERIA-

- 1-Duration of menstrual flow
- 2- Amount of menstrual blood loss.
- 3- Interval of menstrual cycles.
- 4- Pain during menstrual cycles

STUDY DESIGN: -

PERIOD OF STUDY: for three consecutive menstrual cycles and one cycle after Completion of treatment.

OBSERVATION: Observation will be carried out before, during & after the treatment. The patients will be observed at 15 days' interval for assessment of parameters for three consecutive cycles in which drug will be given.

Type of Study: Open trial.

PREPARATION OF SHATPUSHPA KALPA POWDER-

The drug *Shatpushpa* fruit in the form of *Churna* has classical references of *Kashyapa Samhita* in *Bandhyatva*, *Artva Kshya* (Hypomenorrhoea) and *Kashtartva* (Dysmenorrhoea) with *Anupana* of *Gau-Ghrita* (cow ghee). Manufacturing of the drug was completed in the pharmacy of Premnagar Ashram Haridwar, as per guidance and in presence of Research scholar. After proper identification, *Shatpushpa* fruit will be taken and powdered by the

help of mortar and pastel and then this powder was kept in air tight polybag for clinical trial.

Kalpa schedule used in the present study was as follows:

According to *Kashaypa* Hundred *Pala* powder of *Shatpushpa* should be stored in new earthen pot. After getting up in the morning (of previously taken meal), according to the capacity of patients 1/4 *Pala*, 1/2 *Pala* or 1 *Pala* of this powder should be licked with

Gau-Ghrita. After its digestion the patient should eat cooked rice mixed with milk. After using hundred *Pala* of *Shatpushpa Kalpa* the patient will conceive.

- Total 45 days increasing manner of dose - 2400gm
- Next 45 days decreasing manner of dose -2400gm
- So the 90 days' period of study total *Kalpa* dose - 4800gm {100 *Pala*}

SHATPUSHPA KALPA DOSE SCHEDULE

Increasing manner of dose-

DOSE	MINIMUM DOSE	DAYS	TOTAL DOSE
12 gm	6gm BD	5 days	60gm
24gm	12 gm BD	6days-11 days	144gm
36gm	18gm BD	6 Days-17 days	216gm
48 gm	24gmBD	6days-23 days	288gm
60gm	30gm BD	7days-30 days	420gm
72gm	36gm BD	7 days-37days	504gm
84 gm	42 gm BD	8 days- 45days	772gm

Decreasing manner of dose-

DOSE	MINIMUM DOSE	DAYS	TOTAL DOSE
84gm	42gm BD	8days-53 days	772gm
72gm	36gm BD	7days- 60days	504gm
60 gm	30gm BD	7 days- 67days	420gm
48gm	24gm BD	6 days-73days	288gm
36gm	18gm BD	6 days-79 days	216gm
24gm	12gmBD	6 days-85days	144gm
12gm	6gm BD	5 Days-90days	84gm

Duration –

This *Kalpa* schedule occupied a period of 90 days. During this period 4800grams of *Shatpushpa* powder was consumed by each patient.

Follow up - Evaluation will be done before treatment and after treatment.

OBSERVATION-

DEMOGRAPHY OF GENERAL PROFILE

The study shows that out of total 30 patients, maximum patients belonged to age group 26-30 years (40%), and Hindu religion (70%), educated up to secondary (47.5%), belong to middle class (57%) maximum patients were housewives (70%), had mixed diet (77%), *Mrudu kostha* (67%), *Mandagni*

(35%), *Vata-Kapha Prakruti* (40%), had normal psychological status and sound sleep (80%). The obstetrical history of parity, 36.6% was secondary infertility patients and 63.3% patients were nulliparous. In obstetrical history of abortion, 20% of patients were having history of abortion. This show the *Kshetra, Ambu*, is the main causative factor for fertility. On observation of menstrual history maximum 80% Patients were having irregular menstrual history. 60% patient were having Scanty bleeding during menses, and (50%.) patients were having menstrual interval >56 days. Maximum 60% patients required oral analgesics during menstruation.

Observation Recorded During and After Treatment on Different Parameters

Table 1: Observation of 30 patients based on interval of menstruation

Interval of Menstruation		Before Treatment		During treatment						After treatment	
No. of pt.		%		1 st cycle (no.Of Pt)	%	2 nd cycle (No. of pt.)	%	3 rd cycle (no. of pt.)	%	No. of pt.	%
(Grade 0) 30-35 days	4	13.3%		7	23.3%	15	50%	20	66.6%	25	83.3%
(Grade 1) 36-45 days	4	13.3%		5	16.6%	5	16.6%	4	13.3%	4	13.3%
(Grade 2) 46-55 days	7	23.3%		8	26.6%	8	26.6%	5	16.6%	1	3.3%
(Grade 3) >56 days	15	50%		10	33.3%	2	6.6%	1	3.3%	0	0%

Table 2: Observation of 30 patients based on duration of menstruation

Duration of Menstruation	Before treatment		During treatment						After Treatment	
	No.of.pt	%	1 st cycle (no. of pt.)	%	2 nd cycle (no. of pt.)	%	3 rd cycle (no.0f pt.)	%	N0.Of pt.	%
(Grade 0)3-5 days	5	16.6%	7	23.3%	12	40%	20	66.6%	25	83.3%
(Grade 1)2 days	7	23.3%	10	33.3%	12	40%	5	16.6%	5	16.6%
(Grade 2) 1 day	11	36.6%	8	26.6%	3	10%	5	16.6%	0	0%
(Grade3) Spotting only for1 day	7	23.3%	5	16.6%	3	10%	0	0%	0	0%

Table 3: Observation of 30 patients based on quantity of bleeding

Quantity of bleeding	Before treatment		During treatment						After Treatment	
	No. of pt.	%	1 st cycle (no. of pt.)	%	2 nd cycle (no. of pt.)	%	3 rd cycle (no.0f pt.)	%	N0. of pt.	%
(Grade 0)3-5 pad/day	10	33.3%	10	33.3%	17	56.6%	24	80%	25	83.3%
(Grade 1)2 pad/day	10	33.3%	11	36.6%	11	36.6%	5	16.6%	4	13.3%
(Grade 2) 1 pad/day	5	16.6%	4	13.3%	1	3.3%	1	3.3%	1	3.3%
(Grade3) No pad use Spotting only	5	16.6%	5	16.6%	1	3.3%	0	0%	0	0%

Table 4: Observation of 30 Patient Based on Pain Associated With Menstruation

Pain associated with menstruation	Before treatment		During treatment						After Treatment	
	No. of pt.	%	1 st cycle (no. of pt.)	%	2 nd cycle (no. of pt.)	%	3 rd cycle (no. of pt.)	%	N0. Of pt.	%
Grade 1) No pain	5	16.6 %	7	23.3%	12	40%	15	50%	22	73.3 %
(Grade 2) Bearable pain	7	23.3 %	9	30%	12	40%	12	40%	8	26.6 %
(Grade 3) Requirement of oral analgesics	18	60%	14	46.6%	6	20%	3	10%	0	0%

Table 5: Observation on Ovulation (Follicular Size)

Ovulation (follicular size)	Before treatment		After treatment	
	No. of pt.	%	No. of pt.	%
(Grade 0) Rupture of follicle(Ovulation	1	3.3%	19 out of 13 patients got pregnant.	63.35%
(Grade 1) 18-23mm	1	3.3%	7	23.3%
(Grade 2) 10-17mm	8	26.6%	2	6.6%
(Grade 3) <10mm	20	66.6%	2	6.6%

Table 6: Spinbarkeit test wise distribution of 30 patients of *Bandhyatva*

Spinbarkeit test	Before treatment		After treatment	
	No. of pt.	%	No. of pt.	%
(Grade 0) >9cm	3	10%	22	73.3%
(Grade 1) 5 to 9cm	12	40%	4	13.3%
(Grade 2) 1 to 4cm	11	36.6%%	4	13.3%
(Grade 3) <1cm	4	13.3%	0	0%

Table 7- Hysterosalpingography (HSG) wise distribution of *Bandhyatva* Patients.

Hysterosalpingography (HSG)	Before treatment		After treatment	
	No. of pt.	%	No. of pt.	%
Grade 0- both tube patent, free Spillage from both tubes.	12	40%	12	40%
Grade 1- Dye inserts bilaterally But there is spillage from Tube on delayed imaging	0	0%	0	6.6%
Grade 2- blockage present on Either side of fallopian Tube.	0	0%	0	23.3%
Grade 3- both tubes are blocked	2	6.6 %	2	6.6 %

Table 8: Observation of 30 Patient Based on Endometrial Thickness

Endometrial thickness	Before treatment		During treatment						After Treatment	
	No. of pt.	%	1 st cycle (no. of pt.)	%	2 nd cycle (no. of pt.)	%	3 rd cycle (no. of pt.)	%	N0. of pt.	%
(Grade0) >9mm	3	10%	5	16.6%	10	33.3%	15	50%	22	73.3%
(Grade 1) 8-7mm	12	40%	10	33.3%	8	26.6%	10	33.3%	8	26.6%
(Grade 2) 5-6mm	5	16.6%	10	33.3%	7	23.3%	3	10%	0	0%
(Grade 3) <5mm	5	16.6%	5	16.6%	5	16.6%	2	6.6%	0	0%

RESULTS: -**Statistical Analysis-**

- The information collected on the basis of observation was analysed by using appropriate

statistical test (Wilcoxon signed rank test) on subjective criteria to evaluate the significance at different level i.e. at 0.05, 0.01 and 0.001 levels.

- Paired 't' test was applied on Objective criteria.

Table 9: Effect of *Shatpushpa Kalpa* powder on subjective parameter-

SYMPTOMS	Mean		Mean DIFFERENCE	% RELIEF	W Value	P Value
	BT	AT				
1-Interval of menstruation	2.100	0.167	1.933	92.38%	351	<0.001
2-Duration of menstruation	1.533	0.167	1.36	88.71%	325	<0.001
3-Quantity of bleeding	1.167	0.200	0.96	82.26%	210	<0.001
4-Pain association with menstruation	2.433	1.267	1.166	68.2%	300	<0.001

Table 10: Effect of *Shatpushpa Kalpa* powder on Objective parameter-

TEST	Mean		Mean DIFFERENCE	% RELIEF	S.D.	S.E.	P Value	't' Value
	BT	AT						
1-Spinbarkeit test	5.307	8.427	3.120	58.79%	2.678	0.489	<0.001	6.38
2-Ovulation profile	10.680	20.047	9.367	87.70%	5.537	1.011	<0.001	9.266
3-Endometrium thickness	6.817	10.233	3.417	50.12%	1.875	0.342	<0.001	9.979
4-HSG	2	2	0.0	0%	0.00	0.00	0.00	0

DISCUSSION**Subjective Parameter Discussion (Effect of Drug on Interval of Menstruation)-**

Statistically analysing the effect of treatment on interval of menstrual cycle shows highly significant ($p < 0.001$) result. It may be due to *Amapachana*, *Srotoshodhana* and *Vata Shamaka* properties of *Shatpushpa Kalpa* because they have *Katu*, *Tikta Rasa*, *Laghu*, *Rukshna*, *Tikshna Guna*, *Ushna Virya* & *Katu Vipaka*. It also increases the *Agneya Guna* of *Pitta* which is responsible for *Artva* formation. And decrease the interval of menstruation. As we know *Artva* is *Agneya* enhance the formation of *Artva* & normalize the quantity & quality of *Artva*.

Effect of Drug on Pain during Menses-

Menstrual pain was improved by 68.2% which is statistically highly significant ($p < 0.001$). It relieves dysmenorrhoea due to inhibition of prostaglandin production and antispasmodic action.

Due to *Ushna Virya* it inhibits the *Sheeta Guna* of *Vatadosha* and *Tikshna*, *Laghu guna* inhibit the *Picchila Guna* of *Kapha*. Due to *Ushna* and *Tikshna Guna*, it acts as *Rajah pravartaka*. So It has good effect on *Rajorodha* & *Yonishoola*.

Effect of Drug on Duration of Menses-

Effect on duration of menstruation was improved by 88.71% which is statically highly significant ($p < 0.001$). *Shatpushpa* promote normal flow of menstrual blood, due to *Ushna* and *Tikshna Guna* it acts as production of *Artava*. *Artava* is an *Updhatus*, formed from *Rasa* within a month after proper metabolism of by its *Dhatwagni* and *Bhutagni*. It can be said that *Agneya Guna* of *Pitta* increases amount of *Artva*.

Effect of Drug on Quantity of Menstrual Bleeding-

Effect on quantity of bleeding was improved by 82.26% which is statistically highly significant ($p < 0.001$) due to *Ushna Guna* it normalizes vitiated *Vata* after normalize the *Vata* & *Kapha Dosha*, *Ushna guna* of *Shatpushpa* promote normal flow of menstrual blood.

Shatpushpa powder *Guna* of *Deepana*, *Pachna* and *Amadosahara*. So it regulates *Jatharagni*, *Dhatavagni* & *Bhutagni* which correct metabolism in formation of *Dhatus* & *Updhatus* (*Artva*).

Objective Parameter Discussion**(Effect of Drug on Follicular Study (Ovulation) -**

Effect on ovulation profile was improved by 82.26% Patients. Spinbarkeit test was positive in these

patients, which is statistically highly significant ($p < 0.001$).

This may be because Due to property of *Katu Rasa* and *Ruksha, Tikshna Guna*, it removes the obstruction in *srotas* by *Kapha Vata Shamaka, Amapachan Guna* of the drug, as obstruction is cleared, Proper functioning of *Apana Vata*, and normal *Rajah Pravritti* and effect of the phytoestrogenic property it increases the amount of cervical mucus.

Guna of *Shatpushpa* is *Ushna & Tikshna* it stimulates the *Artava srotas* and *Beejagranthi*. By the stimulation of *Beejagranthi* (ovary), Follicles size was increase and lead to ovulation.

Effect of Drug on Thickness of Endometrium In Follicular Study-Effect On Endometrium thickness was improved by 50.12% which is statistically highly significant ($p < 0.001$). It is experimented that it is a good uterine stimulant drug. It increased vascularity of endometrium, regeneration & proliferation of the endometrium.

Shatpushpa is a phytoestrogenic property. It acts in both high estrogenic & low estrogenic condition thus increases the endometrial thickness. *Kashyapa* described that its *Madhura, Brimhana, Balya & Rasayana* Properties, increase the thickness of endometrium and increase responsiveness of endometrium to bear conception.

Probable Mode of Action of Shatpushpa Powder-

There are many cause of female infertility but anovulation is the commonest cause of all. Patients with regular or irregular menstrual cycle suffer from anovulation and long term treatment with hormonal imbalance result from much untoward effect like weight gain.

Although drug *Shatpusha* is having *Ushna Virya, Vatanulomaka* and *Vata Shamaka* drug so especially it acts on *Vata Pradhan Kati Pradesh* and corrects the *Apana Vata dushti* which regulate the menstrual cycle. Due to *Katu Vipaka* it corrects the *Dhatvagni* and release the obstruction of nutrition of next *Dhatu*s and finally *Artava Upadhatu* also which gets nutrition from its mother *Dhatu* i.e. *Rasa Dhatu*.

Ovaries contain receptors which receive hormone under the influence of hypothalamus and pituitary gland. The drug seems to stimulate these receptors

which lead to enhance ovarian function and resulting in ovulatory cycles. *Shatpushpa* by virtue of phytoestrogenic property it increases endometrial thickness.

According to *Rasapanchaka* of *Shatpushpa Rasadhatu Vridhikara* and will remove *Ama* and will help in its proper functioning. Having *Madhura Rasa, Katu Vipaka* and *Ushna Virya* which is a rare quality found only in *Shatpushpa* so it has *Kapha Nashaka* property also and will clear all the channels by removing *Margavrodha* and due to *Ushna Guna* it normalizes vitiated *Vata* after normalize the *Vata & Kapha Dosha*, it increases vitality power of reproductive organ & prepare *Kshetra* for conception because *Samanya kapha* have an anabolic action on body.

By the *Rasa, Guna, Virya, Vipaka* and *karma* of *Shatpushpa* Powder, it clears the *Strotosanga* & stimulates the *Srotas*. It enters in the microchannel (*Srotasa*).

Thus making the proper function of *Dhatvagni* which regulated the menstrual cycle and ovulation occurs.

Effect of Shatpushpa Drug Based On Conception-

Overall this study concludes that the *Shatpusha kalpa* treatment in the management of female infertility is highly effective. The treatment modalities can also be helpful for management of oligomenorrhea, scanty menses and Anovulation. If we consider the factors of *Stri Bandhyatva* the drug is also seeming to be effective on *Kshetra* and *Ambu* i.e., endometrial receptivity and functional anatomical features of fallopian tubes.

CONCLUSION

- Dose of medicine depend on the status of *Agni-bala* of the patient.
- Due to hot potency of medicine it was not possible in few patients (of different status of *Agni-bala*) to give increased dose of *Shatpushpa Kalpa*, which resulted in negative effect to patient such as early menses, nausea, vomiting.
- *Stree Bandhyatva* is a *Vata Dosha* dominant disease and here as per *Ayurveda* science it is known that without the *Vata Dosha streerogas* will not be noticed.

- Female infertility due to ovarian factor contributes about 40% cases. Which include anovulation, failure of follicle development and release of ovum.
- Thus it is concluded that *Shatpusha* Powder in *Kalpa* method as an oral medicine shows better result in regularizing menstruation and normalizing the ovarian dysfunction.

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