

A comparative clinical study of *Shatapushpa churna* & *Pippalyadi churna* with *Ashwagandha ksheer paka* in 'Vandhyatwa' with special reference to female infertility

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Abstract

Childlessness may be a tragedy to the married women and can be a cause of marital upset as well as of personal unhappiness and ill health. In today's fast world due to lack of time, mode of life and increasing mental stress, infertility is emerging as a major disorder affecting the social and psychological aspect of the life of the masses. Looking into the *Samprapti* of the *Vandhyatwa*, it is a disease in which main vitiated *dosha* is *Vata*, *strotas* involved are *Artavavahastrotas* and the *adhithana* is *Yoni* i.e. female reproductive system. So our treatment should be aimed at *Vatashamaka*, *Yonidosahara*, *Srotoshodhaka*, *Rasayana* and *Garbhashthapana*. So in the present study, 30 clinically diagnosed patients from OPD/IPD of *Prasuti & StriRoga* Deptt., NIA, Jaipur were selected along with consideration of inclusion and exclusion criteria. Two groups of 15 patients each were formed. Group A was given *Shatapushpachurna* along with *Ashwagandha ksheer paka* and Group B was given *Pippalyadichurna* along with *Ashwagandha ksheer paka* for 90 days or 3 consecutive menstrual cycles. The study reveals that group A showed better results than the group B in all parameters but both were almost equally effective on conception.

Keywords: *Vandhyatwa*, Infertility, *Shatapushpa churna*, *Pippalyadi churna*, *Ashwagandha ksheer paka*

Introduction

In today's fast world due to lack of time, mode of life and increasing mental stress, infertility is emerging as a major disorder affecting the social and psychological aspect of the life of the masses.

¹. According to *Acharya Charaka*, *Garbha* is originated from mother, without mother there is no existence of *GARBHA*.

According to the definition of woman or *Stree*, one who lodges *GARBHA* is known as *Stree*. *Acharya Charaka* has mentioned that the woman is the origin of pregnancy

Infertility is defined as failure to conceive within one or more years of regular unprotected coitus.

Reproductive endocrinologists consider a couple to be infertile if²:

- ✓ The couple has not conceived after 12 months of unprotected intercourse if the female is under the age of 35.
- ✓ The couple has not conceived after 6 months of unprotected intercourse if the female is over the age of 35.
- ✓ The female is incapable of carrying a pregnancy to term.

According to *Acharya Sushruta* four main factors required for the proper conception are³: *Ritu* (Season or fertile period), *Kshetra* (Normal female reproductive organ, healthy yoni), *Ambu* (Nourishing factor) and *Beej* (Viable ovum & sperm). Abnormality in any of the above said factors cause '*Vandhyatwa*'.

In allopathic system, Hormonal therapy, In Vitro Fertilization (IVF), Embryo transfer (ET), Gamete Intra fallopian Transfer (GIFT) etc. so many therapies are developed, but they have unsatisfactory results, enormous expenses and lots of side effects like ovarian hyper stimulation, frequent abortion, multiple gestations and major long term possibility of ovarian cancer. Treatment of Female infertility is world's demand. In India most of the people are in economically low conditions so they want cheapest with safest treatment. *Ayurveda* may give a promising hand to cure this disease.

Acharya Kashyapa & Chakrapani has mentioned

*Shatapushpa*⁴ & *Pippalyadichurna*⁵ (combination of *Pippali*, *Shrugavara*, *Maricha* and *Nagakasara*) in context to *Vandhyatwa* respectively which have properties of *deepana*, *pachana*, *vatakaphashamak*, *srotoshodhaka*, *Yonidosahara* and *Garbhashthapana*. In *Gadanigraha Ashwagandha Ksheer paka*⁶ is mentioned in *Vandhyatwa* which has *Balya*, *Brimgana*, *Rasayana*, *Vrushya*, *Vatakaphashamaka* and *Garbhashthapaka*. So in present study the comparative study of *Shatapushpa churna* and *Pippalyadi churna* along with *Ashwagandha ksheer paka* (common in both groups) was taken.

Aims & objectives

- To study aetiopathogenesis of '*Vandhyatwa*' as per the classical literature and modern texts.
- To evaluate the effect of *Shatapushpachurna* along with *Ashwagandhaksheerpaka* in female infertility.
- To evaluate the effect of *Pippalyadichurna* along with *Ashwagandhaksheerpaka* in female infertility.
- To compare the efficacy of *Shatapushpachurna* and *pippalyadichurna*.

Material and methods

Selection of the patient:

- 33 Clinically diagnosed patients of infertility from OPD & IPD of NIA, Jaipur were selected. The study was completed on 30 clinically diagnosed subjects of infertility.
- Patients were examined thoroughly as per history sheet specially prepared for this clinical study.
- Written consent was taken from the patient before starting the trial.

PLAN OF STUDY:

1) CRITERIA FOR SELECTION OF PATIENT:

Inclusion criteria:

- Primary or secondary cases of infertility other than exclusion criteria.
- Age group between 20 to 40 years.
- Male counterpart should be normal in all aspects.
- At least one fallopian tube should be patent.

Exclusion criteria:

- Surgical factors including fibroid uterus, cervical polyp, cervical stenosis etc.
- Congenital anatomical defect.
- Patient suffering from severe infection.
- Chronic systemic diseases.
- Infertility due to tubal factors
- Infertility due to peritoneal factors.

Withdrawal criteria:

- During the course of trial if any serious condition occurs that require urgent treatment.
- Patient herself wants to withdraw from the clinical the trial.
- Irregular follow up.

2) INVESTIGATION:

Before Treatment

- Medical History & Physical Examination
 Pelvic Examination to look for abnormalities, or infection
 Blood test-Hb%, TLC, DLC, ESR, HIV, HBsAg, VDRL, MONTOUX TEST(if needed), RBS, T3, T4, TSH. LFT, RFT
 2. Urine test - Routine & Microscopic
 3. Cervical mucus (1) SpinnBarkeit2) Fern Test
 4. Post coital test
 5. USG-Uterus & Adnexa
 6. HSG
 7. Anti-sperm & Antibody Test (if needed)
 8. Pap smear- (if needed)
 9. Follicular study (if possible)
 10. Hormonal assays- S. FSH, S. LH, S. Progesterone, S. Prolactin (If possible)

After Treatment

1. Cervical mucus (1) SpinnBarkeit (2) Fern test
 2. Follicular study (If possible)
 3. Urine Pregnancy detection test
 4. USG- To Confirm Pregnancy

SCORING PATTERN –

1. Interval of menstrual cycle

- 21–35days - 0
- <21days - 1
- 36–45days - 2
- >45days - 3

Treatment Protocol:

	Group A	Group B
DRUG	<i>Shatapushpa churna</i>	<i>Pippalyadi churna</i>
DOSE	3 gm	3 gm
SAHAPANA	<i>Ghrita</i>	<i>Ghrita</i>
ROUTE	Oral	Oral
ANUPANA	<i>Ashwagandha Ksheer paka</i>	<i>Ashwagandha Ksheer paka</i>
DURATION	90 days in three consecutive menstrual cycles	90 days in three consecutive menstrual cycles

2. Duration of menstrual cycle

- 3–7days - 0
- >7days - 1
- 1-2days - 2
- <1days - 3

3. Amount of blood loss during menses

- Normal (2-3pads/day) - 0
- Moderately high (4-5 pads/day) - 1
- Excessive (More than 5 pads/day) - 2
- Scanty (Spotting to 1-2 pad/day) - 3

4. Pain during menses

- No pain - 0
- Mild - 1
- (Menses painful but daily activities not affected)
- Moderate - 2
- (Daily activities affected, need to take analgesic)
- Severe - 3
- (Pain continuous after administration of analgesic)

5. Dyspareunia

- Absent - 0

- Mild pain during coitus - 1
- Moderate pain during coitus - 2
- Severe pain – tries to avoid coitus - 3

- < 10 Motile sperm / HPF - 1
- > 10 Dead sperm / HPF - 2
- < 10 Dead sperm / HPF - 3

6. Psychological stress -A infertility related stress questionnaire was prepared to assess psychological stress

- No stress - 0
- Mild stress - 1
- Moderate stress - 2
- Severe stress - 3

7. Fern test on 22nd day

- No crystallization - 0
- Atypical Fern formation - 1
- Primary and secondary stem -2
- Tertiary and quarternary stem - 3

8. Spinnbarkeit test on 14th day

- > 8 cm - 0
- 5-8 cm - 1
- 1-4 cm - 2
- < 1 cm - 3

9. Post Coital test on 14th day

- > 10 Motile sperm/ HPF
- 0

10. Assessment of dominant follicle on USG (14th day)

- Ovulated - 0
- >20 mm and unrupture - 1
- 12 – 20 mm - 2
- <12 mm/ no dominant follicle-3

11. Assessment of endometrial thickness (on 14th day)

- ≥ 8 mm - 0
- 6 - 7.9 mm - 1
- 4 – 5.9 mm - 2
- <4 mm - 3

Follow Up Study –

After completion of trial follow up was done monthly upto two months.

Statistical Analysis:

Various observations made and results obtained were computed statistically using Wilcoxon matched-pairs signed-ranks test, Mann-Whitney test to find out the significance of the values obtained and various conclusions were drawn accordingly.

RESULT

EFFECT OF THERAPY ON OBJECTIVE PARAMETERS (GROUP A)

S.N	Parameter	N	Mean		Mean Diff.	%	S.D. (±)	S.E. (±)	‘W’	P	Result
			B.T.	A.T.							
1.	Dominant Follicle	15	2.13	0.73	1.40	65.63	0.98	0.25	78.00	<0.001	ES
2.	Endometrial thickness	15	0.60	0.13	0.46	76.66	0.51	0.13	28.00	<0.05	S
3.	Fern test	15	1.93	0.53	1.40	72.42	0.98	0.25	78.00	<0.001	ES
4.	Spinnbarkeit test	15	1.33	0.60	0.73	55.11	0.70	0.18	45.00	<0.01	VS
5.	Post coital test	15	0.13	0.06	0.06	49.93	0.25	0.06	1.00	>0.05	NS

EFFECT OF THERAPY ON OBJECTIVE PARAMETERS (GROUP B)

S.N	Parameter	N	Mean		Mean Diff.	%	S.D. (±)	S.E.(±)	‘W’	P	Result
			B.T.	A.T.							
1.	Follicular study	15	2.53	1.20	1.33	52.65	0.97	0.25	78.00	<0.001	ES
2.	Endometrial thickness	15	0.93	0.33	0.60	64.30	0.73	0.19	45.00	<0.05	S
3.	Fern test	15	2.13	0.86	1.26	59.39	0.88	0.22	91.00	<0.001	ES
4.	Spinnbarkeit test	15	1.53	0.80	0.73	47.71	0.59	0.15	55.00	<0.01	VS
5.	Post coital test	15	0.40	0.13	0.26	66.5	0.59	0.15	6.00	>0.05	S

EFFECT OF THERAPY ON SUBJECTIVE PARAMETERS (GROUP A)

S.N	Parameter	N	Mean		Mean Diff.	%	S.D(±)	S.E(±)	‘W’	P	Result
			B.T	A.T							
1.	Amount of menses	15	0.80	0.26	0.53	66.62	1.0	0.27	10.00	> 0.05	NS
2.	Interval of menses	15	0.26	0.13	0.13	50.00	0.35	0.09	3.00	>0.05	NS
3.	Duration of menses	15	0.40	0.06	0.33	83.25	0.72	0.18	6.00	>0.05	NS
4.	Dysmenorrhoea	15	1.53	0.60	0.93	60.78	0.70	0.18	66.00	<0.001	ES
5.	Dyspareunia	15	0.73	0.13	0.60	81.33	0.73	0.19	28.00	<0.05	S
6.	Stress	15	1.66	0.86	0.80	47.99	0.41	0.10	78.00	<0.001	ES

EFFECT OF THERAPY ON SUBJECTIVE PARAMETERS (GROUP B)

S. No.	Parameter	N	Mean		Mean Diff.	%	S.D. (±)	S.E. (±)	‘W’	P	Result
			B.T.	A.T.							
1.	Amount of menses	15	1.26	0.26	1.00	78.92	1.4	0.37	15.00	>0.05	NQS
2.	Interval of menses	15	1.60	0.733	0.86	54.64	0.99	0.25	36.00	<0.01	VS
3.	Duration of menses	15	0.80	0.20	0.60	75.00	0.91	0.23	15.00	>0.05	NQS
4.	Dysmenorrhoea	15	1.73	0.80	0.93	53.33	0.79	0.20	55.00	<0.01	VS
5.	Dyspareunia	15	1.06	0.26	0.80	74.97	0.77	0.20	45.00	<0.01	VS
6.	Stress	15	1.53	0.73	0.80	52.18	0.67	0.17	55.00	<0.01	VS

INTER GROUP COMPARISON IN SUBJECTIVE PARAMETERS

S. No.	Parameter	Mean		SD		SE		U	P	P value	Result
		G _A	G _B	G _A	G _B	G _A	G _B				
1.	Interval of menses	0.13	0.80	0.35	0.86	0.09	0.22	63.00	0.015	P<0.05	S
2.	Duration of menses	0.33	0.33	0.72	0.72	0.18	0.18	112.5	0.97	P>0.05	NS
3.	Amount of menses	0.53	0.10	1.06	1.46	0.27	0.37	100.00	0.53	P>0.05	NS
4.	Dysmenorrhoea	0.93	0.93	0.70	0.79	0.18	0.20	112.00	>0.99	P>0.05	NS
5.	Dyspareunia	0.60	0.80	0.73	0.77	0.19	0.20	96.00	0.47	P>0.05	NS
6.	Stress	0.80	0.80	0.41	0.67	0.10	0.17	109.50	0.90	P>0.05	NS

INTER GROUP COMPARISON IN OBJECTIVE PARAMETERS

S. No.	Parameter	Mean		SD		SE		U	P	P value	Result
		G _A	G _B	G _A	G _B	G _A	G _B				
7.	Fern test	1.40	1.20	0.98	0.86	0.25	0.22	96	0.48	P>0.05	NS
8.	Spinnbarkeit	0.73	0.73	0.70	0.59	0.18	0.15	110.5	0.94	P>0.05	NS
9.	PCT	0.066	0.266	0.25	0.59	0.06	0.15	97	0.29	P>0.05	NS
10.	Dominant follicle	1.40	1.33	0.98	0.97	0.25	0.25	107.5	0.84	P>0.05	NS
11.	Endometrial thickness	0.46	0.60	0.51	0.73	0.13	0.19	98	0.51	P>0.05	NS

In Inter Group comparison there is statistically not significant changes except interval of menses.

EFFECT OF THERAPY ON CONCEPTION

In Group A, during or after treatment 00.00% patients conceived. In Group B, during or after treatment 20.00% patients conceived.

S. No.	Group	Total no. of pts.	Effect based on conception		
			Conception	No conception	%relief
1.	Group A	15	03	12	20.00
2.	Group B	15	03	12	20.00

As a result of the clinical trial done on total 30 patients of infertility total 6 patients conceived i.e. 20.00% result.

DISCUSSION**SHATAPUSHPA CHURNA:**

- Due to *UshnaVirya* it inhibits the *SheetaGuna* of *Vatadosha* and *Tikshna*, *Laghuguna* inhibit the *PicchilaGuna* of *Kapha*. Due to *Ushna* and *TikshnaGuna* it acts as

Kaphavatashamaka and *Pittavardhaka*.

- Due to *Anulomana Karma*, it will cause "*DoshanamSanshosana*" and facilitate the free movement of *ApanaVayu* that in turn will help in its proper functioning. One of the main function of *Apanavayu* is the

production of *Artava*. It acts as *Rajah pravartaka* (emenagogue). So It has good effect on *Rajorodha & Yonishoola*.

- It relieves Dysmenorrhoea due to inhibition of prostaglandin production and antispasmodic action.
- Due to property of *Katu Rasa* and *Ruksha, Tikshna Guna*, it remove the obstruction in *Srotas* by *Lekhana karma*, it acts through provascularising the uterine musculature, along with it cures the *Upalepa* produced by *Kapha* in the *Artavavaha Srotas* and dilate the passage. *Kapha Vilaya* occurs in this way they help in *Srotoshodhana*. So it stimulates follicle and helps in ovulation. As obstruction is cleared, free flow of *Artava* occurs into lumen.
- *Shatpushpa Churna* possess *Deepana, Pachana* and *Amadoshahara* so it regulates *Jatharagni, Dhatavagni & Bhutagni* which correct metabolism at cellular level, which result in formation of *dhatu & upadhatu* (*Artava*).
- It is experimented that it is a good uterine stimulant drug. It increased vascularity of endometrium i.e. regeneration & proliferation of the endometrium. It's *smadhura, Brimhana, balya & Rasayana* increases the thickness of endometrium and increase responsiveness of endometrium to bear conception.
- Due to phytoestrogenic effect⁸, it increases amount of cervical mucus, spinnbarkeit, ferning, motility & density of sperms in cervical mucus

PIPPALYADI CHURNA:

- As mentioned earlier in conceptual part of study that in *Samprapti* of *Vandhyatwa, Agni Dushti* and *Ama* formation causes *Khavaigunya* in *Artavavaha Srotasa* which leads to

Vadhyatwa. The Oral drug *Pippalyadi Churna* possesses *Vatakaphashamana, Deepana, Pachana* and *Anulomana* properties.

- All drugs of *pippalyadi churna* having hepato-protective, which helps in proper metabolism of hormones, so improve the function of liver which ultimately helps in folliculogenesis and regulation of menstrual cycle.
- *Lagu & Tikshnaguna* of all contents decrease the *pichchilata* of *kapha*, viscosity of cervical mucus is decrease & length of spinnbarkeit test is increase.
- ⁹Antiserotonergic activity of *shunthi* helps to regularise the HPO axis because serotonin plays an inhibitory role in release of GnRH.
- Anti-oxidant drugs are supposed to remove free radicals which are similar to *Ama*.

GOGRITA AS SAHAPANA:

- *Ghrita* has one property *Samskaranuvartan* i.e. it can imbibe the properties of ingredients without losing its natural properties. It is *Yogavahi* so it carries active principles of the drugs to increase the potency of the compound drug. Drugs were given with the *Sahapana* of *Ghrita* which adds *Rasayana* property and also decreases *Tikshna Guna* of formulations.
- It has *Agnivardhak, Rochaka, ojovardhak & Vrishya* properties so that it regulates *Tridoshas* and help in proper formation of *dhatu* and *Upadhatu*.
- *Ghrita* contains beta-carotene and Vitamin E, which are anti-oxidants themselves. It also contains Cholesterol which provides the basic material for the production of sex hormone and anti-stress hormone. Saturated fats boost immune system.

ASHWAGANDHA KSHEER PAKA:

- *Anupana* is depends according to disease. *Ashwagandha* is directly indicated in *Vandhyatwa* in *Gadanigraha* and *Ksheer* has *Garbhadhankara* & directly indicated *inyoniroga* & *Garbhastrava*. *Ashwagandhaksheerpakais* given strength to reproductive organs, So it was given in both Group as *ananupana*.
- *Madhura* *rasa*, itself *PrithviJalaMahabhutaPradhana* and *Balya*, *Brimhana*, *Rasayana* properties are responsible for *Upachaya* thereby improves the endometrial thickness and helps in folliculogenesis.
- *Nidrajanana* & ¹⁰Antistress and CNS depressant activity of *ashwagandha* regulate the function of HPO axis because due to stress endogenous opioids are increase, which suppress both the dopamine and GnRH pathway leading to increase in prolactin secretions.
- *Shothahara* property or Anti-inflammatory action of withaferin may be helping in preparing the endometrium to receive products of conception & also helpful in dyspareunia, Pelvic inflammatory disease or vaginitis or cervicitis.
- *Ksheer* has *madhura*, *brimhana*, *balya*, *vajikar*, *rasayana* and *garbhadhankara* properties so it increase the efficacy of *ashwagandha*.

Conclusion

- ❖ *Shatapushpachurna* (Group A) showed better result in comparison to *pippalyadichurna* in Dominant follicle, endometrial thickness, fern test, spinnbarkeit test, duration of menses, dysmenorrhea and

- dyspareunia while *Pippalyadichurna* (Group B) showed better result in PCT, amount of menses, interval of menses and stress in comparison to *Shatapushpachurna*.
- ❖ Effect of therapy on specific factor of group A showed an average improvement of 50% of unexplained cases whereas Group B showed no improvement. In anovulation, 16.66% improvement showed in group A, while 30.00% improvement showed in group B. Thus *pippalyadichurna* is more effective in infertility due to anovulation.
- ❖ In Group A, during treatment 20.00% patients conceived and in Group B, during or after treatment (within 2 month) 20.00% patients conceived, thus *Shatapushpachurna* and *pippalyadichurna* both have almost equally effective on conception.
- ❖ In Inter Group comparison there is statistically not significant changes observed in subjective and objective parameters except Interval of menses which shows significant changes. This shows that *pippalyadichurna* has better effect on decreasing the interval between the period of menses specially in cases of oligomenorrhoea.
- ❖ It was found that, Average % of relief in subjective and objective parameters were 64.52% in 'Group A' and 61.78% in 'Group B'. It shows that overall effect of drug *Shatapushpachurna* was slightly more than *Pippalyadichurna*.
- ❖ Thus, Based on this study *Sathapushpachurna* and *Pippalyadichurna* along with *Ashwagandhaksheerpaka* can be recommended safely for the management of infertility with success.

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