

A Randomized Comparative Clinical Study to Evaluate the Effect of Dhataki Pushpadi Yoga and Baladi Churna Along with Ashwagandha Ghrita in Female Infertility

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Abstract

The cause of female infertility are multifaceted, and may extend to either of the partners or even both. Indeed, the root issues of infertility can be related to both sexes, approximately 50 percent of infertility is caused by female conditions, while approximately 40 percent is male related. 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 *artava vaha strotas* and the *adhithana* is *Yoni* i.e. female reproductive system. So our treatment should be aimed at *Vata shamaka*, *Yoni dosha hara*, *Srotoshodhaka*, *Rasayana Garbhakara* and *Vandana Saka*. In the present study, 30 clinically diagnosed patients from OPD/IPD of *Prasuti & Striroga* dept., NIA, Jaipur were selected randomly on multiple factors of infertility. Two groups of 15 patients each were formed. Group A was given *Dhataki pushpadi yoga* along with *Ashwagandha ghrita* and Group B was given *Baladi churna* along with *Ashwagandha ghrita* for 90 days or 3 consecutive menstrual cycles. The study reveals that group A showed better results than the group B in maximum parameters.

Keywords: Infertility, dhataki pushpadi yoga, baladi churna, ashwagandha ghrita.

Introduction

Infertility is a global issue for all over the world. Infertility does not threaten physical health but has a strong impact on psychological and social well-being of the couples. The factor responsible for infertility may be either male or female or both, but in male dominant society of India, female partner is generally blamed and she becomes the victim of social gossip, this gradually brings unhappiness in the female partner.

The American society for the study of infertility (1966) defines it "when pregnancy has not occurred after a year of coitus without contraception". Infertility is a relative term implying the failure to conceive, however sterility is an absolute term implying the inability to conceive.

Determining the root cause of infertility is a complex process and it involves a lot of research and investigations. Ranging from simple and visible problem of cyst, fibroid or hormonal imbalances to a very complex genetic disorder or even due to some occupational hazards like exposure to chemical substances or radioactive elements, it can be anything.

Two Types of Infertility are there

- i) Primary infertility
- ii) Secondary infertility

Primary infertility is infertility in a couple who have never had a child and secondary is failure to conceive following a previous pregnancy.

In *Ayurveda*, infertility is termed as *Vandhyatwa*. *Acharya Charaka* has mentioned that women are the only source of human progeny. Women are considered as one of the most essential factors for producing offspring ^[1].

According to *Acharya Sushruta* four main factors required for the proper conception are ^[2].

1. Ritu (Fertile period)
2. Kshetra (Healthy yoni)
3. Ambu (Nourishing factor)
4. Beej (Viable ovum & sperm)

Presence of any abnormality in any of the above said factors causes infertility.

In present study, comparative study of *Dhataki pushpadi yoga* ^[3] and *Baladi churna* along with *Ashwagandha Ghrita* ^[3] (common in both groups) was taken.

The ingredients of *Dhataki pushpadi yoga* are *Dhataki* and *Nilotpala*-having the properties like *stambhana*, *sandhaniya*, *madhur*, *balya*, *medhya* and *prajasthapna*. The *phalashruti* of *Dhataki pushpadi yoga* is "*Kshipram Garbhena Yujyate*" which is mentioned in *Gadanigraha*.

The ingredients of *Baladi churna* are *Bala*, *Atibala*, *Yasthimadhu*, *Sharkra*-having the properties like *balya*, *brimhana*, *vatahara*, *pittahara*, *prajasthapana*, *ojovardhaka*, *vrishtya*, *medhya* and overall effect of the drug according to *Vangasen* is "*Garbhaprada*".

Ashwagandha possess *vatashamaka*, *balya*, *vrishya*, *rasayana*, *vedanasthapana* properties and reduces stress, regulates hormones. Especially *ghrita* is very beneficial for the *sapta dhatu vardhana* including *ojas*, calms the mind so that ultimate goal of treating *vandhyatawa*, is to be solved i.e. having conception. In *Gadanigraha*, *Ashwagandha ghrita* is indicated for *Vandhya* i.e. "*Garbhsandhankam*."

Considering all these points, these all drugs have been selected for oral medicines in the present study.

Aims & Objectives

- To study aetiopathogenesis of 'Infertility' as per the classical literature and modern texts.
- To evaluate the efficacy of *Dhataki pushpadi yoga* along with *Ashwagandha ghrita* in female infertility.
- To evaluate the efficacy of *Baladi churna* along with *Ashwagandha ghrita* in female infertility.
- To compare the efficacy of *Dhataki pushpadi yoga* and *Baladi churna* along with *Ashwagandha ghrita* in female infertility.

Materials & Method

Selection of the Patients

37 Clinically diagnosed patients of Infertility from OPD & IPD of NIA, Jaipur will be selected. The study is completed on total 30 clinically diagnosed patients of infertility.

- Patient will be examined thoroughly as per clinical research proforma specially prepared for this clinical study.
- Voluntary Written informed consent is taken from the patient before starting the trial.

Plan of Study

Inclusion Criteria

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

Exclusion Criteria

- Surgical factors including, cervical stenosis, cervical polyp, fibroid uterus etc.

- Congenital anatomical defect.
- Patient suffering from severe infection and any systemic disorder.
- 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 trial.
- Noncompliance of the patient.

Investigations

Before Treatment

Medical History & Physical Examination

Pelvic Examination to look for abnormalities, or infection

- Blood test-Hb%, TLC, DLC, ESR, LFT-Total Serum Bilirubin, Serum Alkaline phosphate, SGOT, SGPT, RFT-Blood urea, Serum creatinine, HIV, HBsAg, VDRL, RBS. T3, T4, TSH
- Montoux test (if ESR is arised)
- Urine test-Routine & Microscopic
- Cervical mucus
 - Spinn Barkeit
 - Fern Test
- Post coital test
- USG-Uterus & Adnexa
- HSG
- Pap smear-(if in p/s finding cervical hypertrophy is present)
- Follicular study
- Hormonal assays-Serum Follicle stimulating hormone, Serum Luteinizing hormone, Serum Prolactin.

After Treatment

- Urine Pregnancy detection test
- USG-To Confirm Pregnancy
- Cervical mucus
 - Spinn Barkeit
 - Fern test

Scoring Pattern

Table 1: Table showing Scoring Pattern.

1	Interval of Menstrual Cycle	Score
	21-35 days	0
	<21 days	1
	36-45 days	2
	>45 days	3
2	Duration of menstrual cycle	
	3-7 days	0
	>7 days	1
	1-2 days	2
	< 1 days	3
3	Amount of menstrual cycle	
	Normal (2-3 pads/day)	0
	Moderately high (4-5 pads/day)	1
	Excessive (More than 5 pads/day)	2
	Scanty (spotting 1-2pads/day)	3
4	Pain during menses	

	No pain	0
	Mild (Menses painful but daily activities not affected)	1
	Moderate (Daily activities affected, need to take analgesic)	2
	Severe (Pain continuous after administration of analgesic)	3
5	Dyspareunia	
	Absent	0
	Mild pain during coitus	1
	Moderate pain during coitus	2
	Severe pain-tries to avoid coitus	3
6	Psychological stress questionnaire was prepared to assess psychological stress	
	No stress	0
	Mild stress	1
	Moderate	2
	Severe	3
7	Post Coital test on 14th day	
	>10 Motile sperm/HPF	0
	< 10 Motile sperm/HPF	1
	>10 Dead sperm/HPF	2
	<10 Dead sperm/HPF	3
8	Fern test on 22nd day	
	No crystallization	0
	Atypical fern formation	1
	Primary and secondary stem	2
	Tertiary and quaternary stem	3
9	Spinnbarkeit test on 14th day	
	> 8 cm	0
	4-8 cm	1
	1-4 cm	2
	< 1 cm	3
10	Dominant Follicle on USG on 14th day	
	Ovulated	0
	>20 mm but unruptured	1
	12-20 mm	2
	<12 mm/ no dominant follicle	3
11	Endometrial thickness (on 14th day)	
	≥ 8 mm	0
	6-8 mm	1
	4-6 mm	2
	<4 mm	3

Follow Up Study

After completion of trial follow up was done monthly up to two month.

Statistical Analysis

Various observations made and results obtained were computed statistically using Student's t-test, Wilcoxon

matched-pairs signed-ranks test, Mann-Whitney test by using Graphpad Prism 8 software to find out the significance of the values obtained and various conclusions were drawn accordingly.

Results

Table 2: Average Percentage of the improvement in both subjective and objective parameters in both groups

S. No.	Parameters	Results in Percentage	
		Group A	Group B
1.	Dominant Follicle (on 14 th day)	63.63	50.00
2.	Endometrial Thickness (on 14 th day)	59.08	45.77
3.	Fern test (on 22 nd day)	51.43	45.45
4.	Spinn Barkeit test (on 14 th day)	65.01	59.07
5.	Post coital test (on 14 th day)	39.99	39.99

6.	Amount of menses	58.84	49.99
7.	Interval of menses	33.32	49.98
8.	Duration of menses	33.32	33.32
9.	Dysmenorrhea	28.57	22.22
10.	Dyspareunia	28.57	22.22
11.	Stress	42.84	26.09

Table 3: Inter group statistical analysis comparison of objective parameters (n=30, G_A=15, G_B=15)

S. No.	Parameter	Mean		Standard Deviation		Standard Error		U	P	Result
		G _A	G _B	G _A	G _B	G _A	G _B			
7.	Fern test	1.13	1.20	1.35	1.32	0.35	0.34	108.00	0.85	NS***
8.	Spinnbarkeit	0.46	0.60	0.74	0.73	0.19	0.19	99.50	0.55	NS***
9.	PCT	0.20	0.20	0.41	0.41	0.10	0.10	112.50	0.97	NS***
10.	Dominant follicle	0.80	1.20	0.94	1.37	0.24	0.35	95.50	0.45	NS***
11.	Endometrial thickness	0.60	0.60	0.73	0.73	0.19	0.19	112.50	0.98	NS***

NS***-Non significant

Table 4: Inter group statistical analysis comparison of subjective parameters (n=30, G_A=15, G_B=15)

S. No.	Parameter	Mean		Standard Deviation		Standard Error		U	P	Result
		G _A	G _B	G _A	G _B	G _A	G _B			
1.	Interval of menses	0.26	0.13	0.70	0.51	0.18	0.13	105.00	0.57	NS***
2.	Duration of menses	0.26	0.26	0.70	0.70	0.18	0.18	112.50	0.97	NS***
3.	Amount of menses	0.46	0.33	0.83	0.81	0.21	0.21	98.500	0.46	NS***
4.	Dysmenorrhoea	1.00	0.93	0.53	0.45	0.13	0.11	106.00	0.73	NS***
5.	Dyspareunia	0.66	0.33	0.61	0.48	0.15	0.12	80.00	0.12	NS***
6.	Stress	1.06	1.13	0.70	0.83	0.18	0.21	106.00	0.78	NS***

NS***-Non significant

Table 5: Effect of therapy on conception

S. No.	Group	Total No. of pts.	Effect Based on Conception		
			Conception	No Conception	Percentage Relief
1.	Group A	15	08	07	53.33%
2.	Group B	15	06	09	40.00%

As a result of the clinical trial done on total 30 patients of infertility total 14 patients conceived i.e. 46.66% result.

Discussion

Group A

Dhataki Pushpadi Yoga: This is a compound formulation containing *Dhataki* and *Nilotpala*.

Dhataki

It is having *katu, kashya rasa, laghu, ruksha guna, sheeta virya, katu vipaka*.

It's *Yoni-srava-hara, Raktastambhana* properties due to *katu, kashya rasa and shita virya*.

It has *kaphapitta shamaka, Yoni-srava-hara, Stambhana, Garbhasthapana, Raktastambhana, Raktapitta-shamaka*, properties. *Dhatakipushpa* is having *Garbha sthapana* [4] property and is well described in cases of *Garbhasrava* to prevent *Garbhasrava*. It is having hepato-protective property, which helps in proper metabolism of hormones, so improve the function of liver which ultimately helps in folliculogenesis and regulation of menstrual cycle.

Nilotpala

It is having *madhura, tikta kashya rasa, laghu, snigdha, pichila guna, sheeta virya and madhura vipaka*. It is having

garbhasthapak, raktapittahara and asrigdharhar properties [5]. *N. stellata* demonstrated a broad spectrum of activity against phytopathogenic bacteria, antibacterial activity against *E. coli* also having an, antifungal, antiprotozoal and antiviral properties [6]. All of these properties help in reduction of vaginal discharges and maintain ph of vaginal flora. It is also having analgesic and anti-inflammatory activity and due to that relieves in dysmenorrhoea.

Ashwagandha Ghrita

It is a common drug in both the groups. It is a compound *ghrita* preparation containing *Ashwagandha* and *ghrita*, *Ashwagandha* is the main ingredient.

It is having *tikta, kashaya, madhura rasa, laghu, snigdha guna, ushna virya, madhura vipaka*, having *Balya, Brinhana, Rasayana, Atisukrala* [7] properties. Due to *madhura rasa & vipaka, ushna virya and snigdha guna* it act on *kshayajanya vataprakopa* and regulates *vatadosha*. Due to *tikta, katu rasa and ushna virya* it *pacifies kapha dosha*. *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, vaginitis or cervicitis. *Nidrajanana*, antistress and CNS depressant activity of *ashwagandha* regulate the function of HPO axis because due to stressendogenous opioids are increase, which suppress both the dopamine and GnRH pathway leading to increase in prolactin secretions [8].

Goghrita

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. *Ghrita* is

beneficial for *rasa dhatu*, *shukra dhatu* (reproductive elements) and *oja*. It also acts as *yonishodhaka*. *Ghritha* is *rasayana*, *medhya*, *agnivardhak*, *rochaka ojovardhak*, *vrishya* and *dhatupushhtikar* acts synergistically to pacify the principle *dosha vata* as well as balance the rest *doshas* by its *tridosha* balancing properties.

Group B

Baladi Churna: This is a compound drug comprising *Bala*, *Atibala*, *Yasthimadhu*, *Sharkra*.

Bala: It is having *madhura rasa*, *laghu*, *snigdha*, *pichila guna*, *sheeta virya* and *madhura vipaka*.

It has *Balya*, *Grahi*, *Vrsya*, *Ojo vardhaka*, *Stambhana*, *Brhmana*, *Sothahara*, *Rasayana* properties.

It is mentioned in *Prajasthapana mahakasaya* by *Acharya Charaka*. *Bala* as *brmhaniya*, a bulk promoting herb and as *balya* tonic and *prajasthapana* which promotes reproduction. It is also having antibacterial and anti-oxidant properties.

Atibala: It is having *madhura rasa*, *snigdha guna*, *sheeta virya* and *madhura vipaka*. It has *Balya*, *Brimhana*, *Dhatu vardhaka*, *Krimihara*, *Kledopshamana*, *Tridosahara*, *Rasayana* properties.

Yasthimadhu: It is having *madhura rasa*, *guru*, *snigdha guna*, *sheeta virya* *madhura vipaka*. It has *Balya*, *Vrishya*, *Raktaprasdana*, *Vatapittajit*, *Sukrala*, *Garbhakara*, *Vandhyanasaka*, *Putradam*, *Alparetas*, *Kheenaveerya* properties^[9].

Conclusion

- *Dhataki pushpadi yoga* (Group A) showed better result in comparison to *baladi churna* in dominant follicle, endometrial thickness, spinnbarkeit test, fern test, amount of menses, dysmenorrhea, dyspareunia and stress while *baladi churna* (Group B) showed better result in interval of menses, in comparison to *dhataki pushpadi yoga*. *Dhataki pushpadi yoga* and *baladi churna* are equally effected in duration of menses and PCT.
- In Group A, during or after treatment (within 2 month) 53.33% patients conceived and in Group B, during or after treatment (within 2 month) 40.00% patients conceived, thus *dhataki pushpadi yoga* is more effective on conception.
- In Inter Group comparison there is statistically not significant changes observed in subjective and objective parameters.

Thus, based on this study *dhataki pushpadi yoga* and *baladi churna* along with *ashwagandha ghritha* can be recommended safely for the management of infertility with success.

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