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A Clinical Study on the efficacy of *Ashvagandha Ksheerapaka* in *Stree Vandhyatva* w.s.r. to Anovulation

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ABSTRACT

Fertility is an existential necessity and as such has assumed over whelming importance from time immemorial. However, not all couples who desire a pregnancy will achieve one spontaneously and a proportion of couples will need medical help to resolve underlying fertility problems. Infertility has been recognized as a public health issue world wide by the World Health Organization. Infertility severely affects the couples psychologically, sexually and socially. Anovulation accounts for 25 - 40% of the female infertility. Ayurveda offers several potent combinations in such a condition. The aim of the present paper is to address this problem by studying the efficacy of *Ashvagandha Ksheerapaka* in the induction of ovulation.

Key words: *Ashvagandha Ksheerapaka, Vandhyatva,* Anovulation.

INTRODUCTION

Infertility is a condition in women's life which indicates inability to procreate. Conception depends on multiple factors, ovulation being one among them. A remarkable decline in human fertility is observed beyond the age of 30 years due to reduction in quality and number of healthy ovum. Anovulation is reported to be one of the major cause for female infertility ranging up to 25 - 40% of infertile women.[1] If the menstrual cycles followed by ovulation are related to an outside influence like nutrition or lifestyle, effective treatments will include regulating eating habits and moderating physical activities. Making changes to one's weight (gaining or losing weight) may also be enough to jump-start stalled ovulation. Sometimes internal imbalances are the reason and in such cases, medications are to be prescribed for fertility. These medications are designed to combat the cause of a woman's infertility. There are drugs designed to ripen the follicles, increase estrogen and help the ovaries release an egg.[2]

In Ayurveda, four *Garbha Sambhava Samagri* are enumerated as *Ritu, Kshetra, Ambu* and *Beeja*. Any abnormalities in any of these affect the formation and development of *Garbha*.

According to *Shabdakalpadhruma*, a women who has hindrance of any kind, in the normal process of conception is termed as *Vandhya*. Infertility according to Ayurveda is not only limited to non-achievement of conception but also includes failure to continue it till viability and birth of a healthy live child. In this *Pumbheeja* (*Shukra*) and *Streebheeja* (*Artava*) are very much important.[3] *Artavanasha* is due to *Avarana* in *Artavavaha Srotas*.[4] *Ashvagandha* is mentioned in

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the treatment of *Stree Vandhyatva*.[5] Studies on *Ashvagandha* shows significant increase in ovarian function and folliculogenesis.[6] This paper intends to describe the efficacy of *Ashvagandha Ksheerapaka* in *Stree Vandhyatva* w.s.r. to anovulation.

Materials and Methods

Total 30 women fulfilling the inclusion criteria were selected from outpatient and inpatient department of P.G. Studies in Prasuti Tantra and Stree Roga, S.D.M. College of Ayurveda and Hospital, Hassan in a single group and were studied. The drug *Ashvagandha Choorna* was obtained from the pharmacy of SDM Centre for Research in Ayurveda and Allied Sciences, Udupi for the present study. The Ethical Clearance for the study was obtained from Institutional ethical committee. The informed and written consent along with specially designed Case Proforma for the study was prepared.

Inclusion Criteria

1. Females of age group of 20 - 35 years.
2. Females with normally developed secondary sexual characters, ovary and uterus.
3. Women who are diagnosed with anovulatory cycles and single or multiple cyst in either of the ovaries.
4. Patients who were ready to sign in the informed consent form.

Exclusion Criteria

1. Known case of genetic abnormalities.
2. Known case of chronic systemic disorders (diabetes mellitus, hypertension, tuberculosis) and endocrinal disorders. (thyroid dysfunction).

Criteria for diagnosis

1. Female patients of primary and secondary infertility were assessed for Anovulation.
2. Anovulation was confirmed by USG - Follicular study.

Drug - *Ashvagandha Ksheerapaka* (Sharangadhara method 1:4:8 ratio) in a dose 100ml twice a day before food administered Orally.

Duration - Consecutive 3 cycle (from 5th day after cessation of menses till the commencement of next menstrual cycle)

Criteria for Assessment

Sonological Parameters - Follicular study was repeated after completion of oral intake of *Ashvagandha Ksheerapaka* for three menstrual cycles. Efficacy of therapy was assessed on the basis of size of follicles, endometrial thickness and signs of ovulation.

Patients were divided to following categories for assessment of follicle development and size.

- Grade 0 = < 12mm follicle
- Grade 1 = 12 - 19mm follicle
- Grade 2 = 19 - 23mm follicle
- Grade 3 = ovulation

Overall effect of treatment

1	Grade 3	Conceived	The patient conceived after the treatment.
2	Grade 2	Ovulated	Ovulation occurred
3	Grade 1	Improved	Ovulation not occurred but only improvement in the size of follicles i.e. 12-19 mm.
4	Grade 0	Unchanged	No change in the growth of the follicle

Follow up study was conducted every 15 days and also on 12th day of menstrual cycle for follicular study after completion of the treatment.

Observation

Total 30 subjects registered and all 30 patients completed the study. The data collected from the proforma was subjected to statistical methods using SPSS (version 16) with Friedman's test and Wilcoxon's signed rank test which were filled on the starting of the first day of the treatment. All patients in the present study were having proper development and proper fat distribution on pubis and vulva. Average vaginal discharge was observed in 76.7% of patients, while cervical erosion was found in 13.3% of patients.

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96.7% of patients were having nulliparous cervix. All of patients were having normal size uterus. 100% of patients had freely mobile uterus and fornices were clear.

After the treatment among 30 patients, in maximum 93.3% there was no change observed in the growth of the follicles, where as in 6.7%, there was slight improvement in follicular growth also the endometrial thickness, but it was not statistically significant.

RESULTS

Table 1: Showing USG - Follicular study reports of 30 patients.

Factors			No of patients	%
Right ovary	**BT**	< 12 mm follicle	19	63.3
		12-19mm follicle	10	33.3
		19-23mm follicle	01	3.3
		Ovulated	00	00
	AT	< 12 mm follicle	19	63.3
		12-19mm follicle	10	33.3
		19-23mm follicle	01	3.3
		Ovulated	00	00
Left ovary	**BT**	< 12 mm follicle	24	80.0
		12-19mm follicle	03	10.0
		19-23mm follicle	03	10.0
		Ovulated	00	00
	AT	< 12 mm follicle	22	73.3
		12-19mm follicle	05	16.7
		19-23mm follicle	03	10.0
		Ovulated	00	00
Endometrial thickness	**BT**	<6mm	10	33.3
		6-8mm	19	63.3
		>8mm	01	3.3
	AT	6mm	08	26.7
		6-8mm	22	73.3
		>8mm	00	00
Free fluid in POD	**BT**	Present	00	00
	AT	Absent	30	100

Among 30 patients before treatment 63.3% patients had <12mm follicular size, 33.3% patients had follicular size in between 12 - 19 and 3.3% had 19 - 23mm follicle size in right ovary, in left ovary 80% had <12mm follicular size, 10% each had 12 - 19mm and 19 - 23mm sized follicle with ET 6 - 8mm in 63.3%, <6mm in 33.3% and >8mm in 3.3% with no free fluid in POD. Whereas after treatment 63.3% patients had <12mm follicular size, 33.3% patients had follicular size in between 12 - 19mm and 3.3% had 19 - 23mm follicle size in right ovary, in left ovary 73.3% had <12mm follicular size, 16.7% had 12 - 19mm and 10.0% had 19 - 23mm sized follicle with ET 6-8mm in 73.3%, <6mm in 26.7% with no free fluid in POD.

Table 2: Showing Friedman Test

Parameter	N	X2(2)	Df	P value	Remarks
Right ovary	30	0.000	01	1.000	NS
Left ovary	30	1.000	01	0.317	NS
Endometrial thickness	30	0.077	01	0.782	NS
Free fluid in POD	30	-	01	-	NS

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Friedman's test shows that the trial drug is not giving statistically significant result in induction of ovulation.

Table 3: Showing Wilcoxon Signed Ranks Test.

Parameter	Negative ranks			Positive ranks			Ties	Total	Z value	P value	Remarks
	N	MR	SR	N	MR	SR					
RO BT-AT	4	4.50	18.00	4	4.50	18.00	22	30	0.000	1.000	NS
LO BT-AT	1	2.50	2.50	3	2.50	7.50	26	30	-1.000	0.317	NS
ET BT-AT	6	7.00	42.00	7	7.00	49.00	17	30	-0.277	0.782	NS
POD BT-AT	0	0.00	0.00	0	0.00	0.00	30	30	0.000	1.000	NS

Bonferroni correction - 0.01, N - No., MR - Mean Rank, SR - Sum of Ranks

Wilcoxon signed rank test shows that the trial drug is not giving statistically significant result in induction of ovulation.

Among 30 patients maximum 93.3% there was no change observed in the growth of the follicles where as in 6.7% there is slight improvement in follicular growth also the endometrial thickness. But this is not statistically significant.

CONCLUSION

The present work was designed to study the efficacy of *Ashvagandha Ksheerapaka* in *Stree Vandhyatva* on anovulation. The effect of *Ashvagandha Ksheerapaka* is not clinically and statistically significant on ovulation. Better result may be achieved after *Shodhana* along with the administration of other *Prajasthapanagana Dravya* or *Pumsavana Dravya* or other compound medicine. Anyhow, no adverse drug reaction (ADR) and side effects were reported in the present study and the drug in the prescribed dose and the method used for the procedures proved safe.

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