

CLINICAL STUDY OF GARBHASTHAPAK CAPSULE (INDIGENOUS COMPOUND FORMULATION) IN VANDHYATVA (INFERTILITY)

Seeni MK^{1*}, Mahendra Singh Meena², Sushila Sharma³

1. Assistant Professor, Dept. of Kriya sharira, Govt. Ayurveda Medical College, Nagercoil, Tamil Nadu, India.
2. Professor & Head, Dept. of Kriya sharira, National Institute of Ayurveda, Jaipur, Rajasthan, India.
3. Assistant Professor, Dept. of Prasoothi tantra, National Institute of Ayurveda, Jaipur, Rajasthan, India.

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Abstract

Infertility has been one of the unsolved major complaints of womanhood. The school of Ayurveda mentions a few principles about vandhyatva (infertility) and describes some measures to combat the same. In our classics, Acharyas have mentioned so many drugs for the treatment of Vandhyatva. Five aushadhi's (herbal drugs) namely – putrajivaka, srngataka, sveta brhati phala, ashwagandha and Shivalingi beeja which are having Garbhasthapak guna along with vatapittashamaka qualities were powdered and capsulized. In the present clinical study 14 patients of infertility were selected and administered with Garbhasthapak capsule 500 mg -2 BD for 3-5 months orally. Overall effect of therapy based on conception showed statistically insignificant (P<0.1) results. In the treatment group out of 14 patients 3 patients got conception. Out of 3 patients, 2 patients were secondary infertility. This shows that effect of therapy were more effective in secondary infertility.

Key words: Vandhyatva; Infertility; Garbhasthapak; Capsule.

*Address for correspondence:

Dr. Seeni MK, M.D., Ph.D. (Ayu),
Assistant Professor, Dept. of Kriya sharira,
Govt. Ayurveda Medical College,
Nagercoil, Tamil Nadu, India – 629 002
E-mail: drseeni1979@yahoo.co.in

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INTRODUCTION

Infertility is defined as a failure to conceive within one or more years of regular unprotected coitus. Mainly two types are described in modern science; as Sterility - means inability to conceive and Infertility - means failure to conceive. Types of infertility are two (1) Primary Infertility - denotes those patients who have never conceived. (2) Secondary infertility - indicates previous pregnancy but failure to conceive subsequently.

In Ayurveda, various references on Vandhyatva (infertility) are available. Vandhya word is used as a symptom rather than a disease in our classics. Failure to achieve pregnancy has been referred under various conditions that is coitus with an young or old diseased woman, coitus in abnormal posture etc and the need of four important factor for Garbhasthapani.^[1] After observing the description about Vandhyatva in Ayurveda, it can be concluded that the definition of infertility, sterility i.e. failure to conceive in modern science is a part of definition of Vandhyatva in Ayurveda. This means Ayurveda has much broader approach regarding this subject. The incidence of infertility is 10 percent in hospital statistics. In general population it is 2-5 %. In the male dominating society of India, for infertility the female partner is generally blamed and she becomes the victim of social gossip for her barrenness. This gradually brings forth unhappiness in the female partner, psychosomatic ill health and even suicide. Remarriage of the male partner is not permitted by the present Hindu law as was common in the past. For the literate society, infertility brings forth family unhappiness, marital disharmony which many end in divorce.

Conception depends on the fertility potential of both male and female partner. The male is directly responsible in about 30-40 %, the female in about 40-50 % and both are

responsible in about 10 % cases. The remaining 10 %, is unexplained inspite of through investigations with modern technical knowhow. Hence in the present clinical study of Vandhyatva (Infertility) a capsule was prepared with five ingredients namely – putrajivaka (*Putranjiva roxburghi* Wall.),^[2] srngataka (*Trapa natans* Linn),^[3] sveta brhati phala (*Solanaum torvum* Swartz),^[4] ashwagandha (*Withania somnifera* Dunal).^[5] and Shivalingi beeja (*Diplocyclos palmatus*)^{[6][7]} which are having Garbhasthapani guna along with vatapittashamaka qualities to prove its efficacy scientifically.

MATERIALS AND METHODS

Patients were selected from the Department of Prasuti and Stree Roga OPD and IPD of National Institute of Ayurveda, Jaipur, Rajasthan. Total 15 patients were registered, out of which 14 patients completed the study and 1 patient left against medical advice; patients were selected according to the following criteria.

Inclusion criteria

- Primary and secondary infertility
- Age group between 20 to 35 years.
- Partner's sperm report normal
- Unexplained infertility
- At least one side tube patient
- Antibody antisperm defect

Exclusion criteria

Following patients were excluded in present treatment.

- Physiological infertility
- Defect in male partner semen report
- Blockage of both tubes
- Mentally ill and non-co-operative patients
- Patients with congenital anatomical defect

Criteria for diagnosis

Every patient's history was taken according to description given in Ayurvedic and modern science considering the inclusion and exclusion criteria.

Vaginal examination was done by vaginal palpation and inserting vaginal speculum.

Laboratory investigations

Patient's husband semen analysis; Blood - Hb%, ESR, VDRL, Random blood sugar, blood group and Rh factor; Complete urine examination- Routine and microscopic; U.S.G (lower abdomen), H.S.G or S.S.G; Fern test and Post coital test; Antisperm and antibody test (If needed); T.S.H (If needed); Serum Prolactin Test (If necessary); TORCH (If necessary)

Plan of study

Total 14 patients of infertility w.s.r. to inclusion criteria were studied. Treatment Group: 14 patients were given Garbhashthapak capsule 500 mg -2 BD for 3-5 months along with milk.

Method of Detection of Physiological changes of Female Genital Organ

Method of detection of ovulation Cervical Mucus : The most helpful changes predictive of impending ovulation is that of cervical mucus under the influence of estrogen the mucus increases in amount in pre ovulatory estrogen dominated phase of the cycle under the influence of progesterone in amount changes in character and no longer dries in a ferning pattern.

Mid cycle mucus is the best clinical marker of ovulation and useful in timing of donor insemination cervical mucus can be tested by Spinn Barkeit, Fern Test etc.

Spinn Barkeit

Cover slip placed on a drop of cervical mucus is pulled apart ovulatory mucus shows a thread of at least 6 – 7 cm. before break. Thread fracture earlier when put under tension during luteal phase.

Fern Test

Fern test of cervical mucus is indirect evidence of ovulation showing palm leaf or fern like pattern of cervical mucus under microscopic when mucus is dried on a slide. This result from crystallization of sodium chloride with mucus due to estrogen effect.

Fern Pattern

Cervical mucus is collected from cervical canal by tuberculin syringe. Mucus is smeared on glass slide dried for 15 minutes and examined under low power of microscope. This fern status usually on 10th day and may disappear on 22 – 24th day. Non disappearance of fern on 22nd days shows indirect clue of Anovulatory cycle.

Ovarian follicular study by transvaginal sonography

Serial vaginal sonography is now practised - complete disappearance of the dominant follicle measuring 18 – 25 mm prior to its rupture. In this study, sonography was done since 10th day up to maximum 18 days according to condition of follicle.

Post coital test (PCT)

Usually on 14th day of menstrual cycle its varies on pt. following intercourse within 8 hrs (2 hrs preferable), mucus aspirated from cervix is placed on glass slide & examined under high power after placing cover slip , the test is positive if there are more than 5 motile sperm found in the mucus. Absence of any sperm signifies either aspermia or it shows

faulty intercourse. Presence of immotile sperms with normal sperm count in a good quality of cervical mucus signifies presence of immunological factors (sperm antibodies).

Prolactin test

Done in patient of any previous history of secretion / draining in nipple and also repeated for same patients after completion of treatment.

Anti sperm & anti body test (Immunologic test)

If marital history was more than 5 yrs with unexplained infertility anti sperm & anti body test (immunologic test) was carried out and repeated after the completion of the treatment.

Follow up study

After completion of treatment for one month follow up started and result was assessed in following parameters. **Note:** During treatment intercourse was advised on ovulation period mainly.

Criteria for assessment

Effect of treatment depend on-fern test, post coital test, menstrual bleeding-amount of loss & pain, interval of menstrual cycle, follicular study, most important in the basis of conception was determined. Thus score of individual symptoms were obtained before treatment and after treatment. The total effect of therapy was assessed in terms of Conception, Increased in size of follicle, Improvement in cervical mucus, quantity & quality of menstrual cycle and Unchanged. (Table 1)

RESULTS AND OBSERVATION

The study of age shows that maximum number of patients was found belonging to the age group of 26-30 age group (57%), followed by

31-35 age group (29%) and in 20-25 age group (14%). Majority of the patients were Hindu, followed by Muslim and Christian. The study of marital life in years status shows that maximum number of patients were having married life 5-8 years i.e. 50%, followed by 2-4 years i.e. 42.85%, whereas 7.14% were having 9-14 years of married life. The study of education status among the registered patients, were secondary educated and Under graduate were 35.71% followed by post graduate 14.28% where as 14.28% patients were primary educated. Maximum number of patients was housewives and service woman followed by labourers. This study reflects that maximum number of patients i.e. 57.14% were of middle class followed by Rich and poor class. In this study, 85.71 % patients were vegetarian while 14.28% patients were having mixed type of diet. Out of 14 patients, regular bowel habit was found in 28.57 %, while 71.42 % were having irregular bowel habit with Vibandha. Out of 14 patients, satisfactory sexual life was found in 78.57 %, while 21.42 % were having unsatisfactory sexual life. The present study shows that maximum number of patients was vata-pitta, followed by vata-kapha and pitta-kapha prakriti. All the patients were of madhyama sara i.e. 100 %. All of them were having Madhyama Samhanana i.e. 100 %. The study shows that 100 % of patients were having Madhyama Satva. Out of 14 patients reveals that 50 % were having Madhyama and Avara Vyayama Shakti respectively. Madhyama Ahara Shakti was observed in all the registered 28 patients. Considering the manasika bhavas, Anxiety was observed in all the patients i.e. 100 %, while Shoka was observed in 7.1 % of registered patients. Physical structure wise distribution shows the maximum number of patients i.e. 64.28 % were in average group, 7.14 % patients were in over weight group, 14.28 % of patients were in above -average group and 14.28 % of patients were in slim group. This study shows that maximum number of patients was found belonging to the primary infertility 64.28 % followed by

secondary infertility i.e. 35.71 %. Maximum patients were of regular menstrual history group followed by irregular menstrual history. The distribution of the patients according to the duration of menstrual period shows that 78.57 % were having 3-5 days duration while 14.28 % and 7.14 % of patients had 5-7 days and 2-3 days duration respectively. Interval of menstrual cycle was observed, 26-28 days in maximum patients i.e. 64.29 %, followed by 21.42% in 30-40 days and 14.28% in 28-30 days cycle respectively. In the observation of menstrual history, 42.86 % of patients were observed having scanty and moderate menses respectively, followed by excessive menses i.e. 21.42 %. Pain during menstruation, wise distribution shows that 57.14 % of patients were having painful menses and 42.86 % of patients were having painless menstruation. In regularity of menses, 71.42 % of patients were having regular menses, followed by irregular menses in 28.57 % of patients. In obstetrical history of parity, 35.71 % of patients were previous gravida and 64.28 % of patients were nulligravida. In obstetrical history of abortion, observed 28.57 % of patients were having history of abortion. The distribution of patients according to the position of the uterus shows that the maximum number of patients was having AVAF and minimum number of the patients was having RVERF position of the uterus. 92.86 % of patients were observed nothing abnormal detected in cervical examination while 7.14 % of patient were having cervical erosion. This study shows that no patients had tuberculosis or Discharge in breast/galactoria. 7.14 % of patients had ectopic pregnancy. The distribution of patients according to investigation shows that all the patients i.e. 100 %, were put under Fern test, post coital test (PCT) Ultrasonography (USG) and hysterosalpingography (HSG) or sono salingo graphy (SSG) while 57.14 % of patients were put to serum prolactin, 50 % of patients were put to TSH and 35.71 % of patients were put to Antisperm antibody test. In this series of associated disease in infertility the maximum number of patients i.e. 21.42 %

showed leucorrhoea, 14.29 % of patients showed one side tubal block, 7.14 % of patients were having polycystic ovarian disease (PCOD), 14.28 % of patients were observed immunological factors defect and no patients had thyroid disorder. In all patients before treatment and after treatment on 14th day fern test showed positive result. (Table 2)

In treatment group 42.86% of patients were having fern formation before treatment which reduced upto 28.57% i.e., No fern formation 57.14% of patients increased upto 71.43% of patients. In Treatment group 64.29% of patients were observed motile sperm and adequate in PCT before treatment which increased upto 92.86% of patients i.e., Dead sperms and poor 35.71% of patients were reduced upto 7.14% of patients respectively. In treatment group 42.86% and 21.43% of patients were having scanty and excessive amount of loss before treatment which reduced upto 0% after treatment, where as moderate 35.71% before treatment increased upto 100% after treatment. In treatment Group 57.14% of patients were having Kashtartva before treatment while after treatment only 14.29% had Kashtartva and 85.71% of patients has painless menstruation. In the Group 28.57% of patients had irregular menstruation before treatment while after treatment only 14.29% had irregular and 85.71% of patients had regular menstruation. In the Group 21.43% of patients had leucorrhoea before treatment while after treatment only 7.14% had leucorrhoea and 92.86% of patients had absent of leucorrhoea. In the Group before treatment size of follicle poor in 28.57% of patients, 28.57% of patients had inadequate size and 42.86% patients had adequate size. After treatment 50% of patients had adequate size, 42.86% had inadequate size and only 7.14% had poor size of follicular growth. Effect of oral Yoga based on conception after treatment 21.43 % of patients had conception and 78.57% of patients no conception.

Table 1: Scoring pattern

Sl.No.	Criteria	Symptoms	Scoring
1	Fern test on 22 nd day	No fern formation (No crystallization)	0
		Fern formation	1
2	Post coital test on 14 th day	Motile sperm & adequate	0
		Dead sperm & poor	1
3	Amount of blood loss in m/c	Scanty	-1
		Moderate	0
		Excessive	1
4	Pain	Painless	0
		Painful	1
5	Interval of menstrual cycle	Regular	0
		Irregular	1
6	Leucorrhoea	Absent	0
		Present	1
7	Follicular growth	Adequate (>20 mm)	0
		Inadequate (12-20mm)	1
		Poor (<12mm)	2

Table 2: Effect of treatment

Sl.No.	Test	B.T.		A.T.		
		No.	%	No.	%	
1	Fern test on 22 nd day	Fern formation	06	42.86	04	28.57
		No fern Formation	08	57.14	10	71.43
2	PCT on 14 th day	Motile sperm &adequate	09	64.29	13	92.86
		Dead sperm & poor	05	35.71	01	07.14
3	Amount of loss	Scanty	06	42.86	00	00
		Moderate	05	35.71	14	100
		Excessive	03	21.43	00	00
4	Pain	Painful	08	57.14	02	14.29
		Painless	06	42.86	12	85.71
5	Regularity	Irregular	04	28.57	02	14.29
		Regular	10	71.43	12	85.71
6	Leucorrhoea	Present	03	21.43	01	07.14
		Absent	11	78.57	13	92.86
7	Size of Follicle	Poor	04	28.57	01	07.14
		Adequate	06	42.86	07	50.00

Table 3: Statistical analysis

Treatment Group	n	Mean		Mean Diff.	% of change	S.D. (±)	S.E. (±)	't'	'p'	Result
		B.T.	A.T.							
Fern test on 22 nd day	06	1.00	0.67	0.33	33.33%	0.52	0.21	1.58	> 0.1	IS
PCT on 14 th day	05	1.00	0.20	0.80	80.00%	0.45	0.20	4.00	< 0.025	S
Amount of loss	09	-0.33	0	- 0.33	100.0%	1.00	0.33	1.00	> 0.1	IS
Pain	08	1.00	0.25	0.75	75.00%	0.46	0.16	4.58	< 0.005	HS
Regularity of menses	04	1.00	0.50	0.50	50.00%	0.58	0.29	1.73	> 0.1	IS
Leucorrhoea	03	1.00	0.33	0.67	66.67%	0.58	0.33	2.00	> 0.1	IS
Size of Follicle	08	1.50	1.00	0.50	33.33%	0.53	0.19	2.65	< 0.050	S
Based on conception	14	1.00	0.79	0.21	27.27%	0.43	0.11	1.88	> 0.1	IS

Statistically before treatment mean score was 1.00 and after treatment it was 0.67 with 33.33% relief showing statistically insignificant ($p > 0.1$) result. Before treatment mean score was 1.00 and after treatment it was 0.20 with 80% relief showing statistically significant ($p > 0.025$) results in both group. In the Group before treatment mean score was -0.33 and after treatment it was 0 with 100% relief showing statistically insignificant ($p > 0.1$) result. In the Group before treatment mean score was 1.00 and after treatment it was 0.25 with 75% relief showing statistically Highly significant ($p < 0.005$) result. In the Group before treatment mean score was 1.00 and after treatment it was 0.50 with 50% relief showing statistically insignificant ($p > 0.1$) result. In the Group before treatment mean score was 1.00 and after treatment it was 0.33 with 66.67% relief showing statistically insignificant ($p > 0.1$) result. In the Group before treatment mean score was 1.50 and after treatment it was 1.00 with 33.33% relief showing statistically significant ($p < 0.050$) result. In the Group before treatment mean score was 1.00 and after treatment it was 0.79 with 27.27% relief showing statistically insignificant ($p > 0.1$) result. (Table 3)

DISCUSSION

Ayurvedic literature provides ample information regarding the drugs to text infertility and offer ample scope for effective and economic treatment. Effect of therapy on pct in 14th day showed significant ($P < 0.025$) result on post coital test (PCT) on 14th day. The number of patients increased with positive result after treatment. It may be due to Madhura Rasa and Sheeta Virya of the drug used for treatment. It provides Kshetra in healthy and supportive for receiving the Shukra. Effect of Therapy on Amount of Menstrual Bleeding showed statistically insignificant ($P > 0.1$) on amount of loss of menstrual bleeding. Effect of therapy on kashtartava showed statistically highly significant ($P < 0.005$) results on pain in

menstrual cycle (Kashtartava). Thus, it can be said that oral drugs are providing relief in Kashtartava. Effect of therapy on regularity of menses showed statistically insignificant ($P > 0.1$) results on regularity of menstrual cycle. Effect of therapy on leucorrhoea showed statistically insignificant ($P > 0.1$) results. Effect of therapy on Follicular growth showed statistically significant ($P < 0.050$) results. This shows the positive effect of oral drugs in infertility. Overall Effect of Therapy Based on Conception showed statistically insignificant ($P < 0.1$) results. In the treatment group out of 14 patients 3 patients got conception. Out of 3 patients, 2 patients were secondary infertility. This shows that effect of therapy were more effective in secondary infertility.

Probable Mode of Action of Drugs

The drug used for oral yoga i.e. Garbhasthapak capsule are mostly having Garbhasthapana Guna (Conception promoting or fetus stabilizing). All these drugs are having Vatapittashamaka qualities, Prajasthapana i.e. promoting fertility, Sothahara, Dahasamaka and Apatyakara, as well as helping conception and development including stabilization of fetus in pregnancy. So by these qualities, it nourishes the body, it has also have regeneration capacity due to proper nutrition and Vatanulomana property it promotes fertility.^[8]

CONCLUSION

The treatment drug Garbhasthapak capsule administered orally were more effective in secondary infertility. Yet the study should be conducted in large sample size.

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