

## CLINICAL STUDY TO EVALUATE EFFECT OF BRAHMI GHRITA IN VANDHYATVA W.S.R. TO FEMALE INFERTILITY

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### ABSTRACT

A Clinical study was conducted on clinically diagnosed 10 patients of infertility in females in P.G. Department of *Prasuti* and *Striroga*, National Institute of Ayurveda at Jaipur (Raj.) Patients were given *Brahmi Ghrita* orally, significant results observed in follicular study, endometrium thickness, fern pattern, cervical mucous length, and in conception.

**KEYWORDS:** Vandhyatva, Brahmi Ghrita, female infertility.

### INTRODUCTION

Mother is the most sacred and beautiful word in the world. To become mother is the first right of a woman; she becomes complete and feels proud on giving birth to a new life, but the tragedy is that all women are not Mother. This is the reason why the question of fertility is most important for women. All hazards that hamper the capacity of fertility attract unique attention for cure. 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.

Reproductive endocrinologists, the doctors specializing in infertility, consider a couple to be infertile if.<sup>[1]</sup>

- 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 (declining egg quality of females over the age of 35).
- The female is incapable of carrying a pregnancy to term.

### TYPES OF INFERTILITY<sup>[2]</sup>

1. Primary infertility: It denotes those patients who have never conceived.
2. Secondary infertility: It indicates previous pregnancy but failure to conceive.

Conception depends on the fertility potential of both the Male and Female partners. Infertility is a problem of neither the male nor the female but both are equally responsible.

The contribution of both of them is as follows.<sup>[3]</sup>

Male	30%
Female	40%
Both	20%
Unexplained	10% (D. C. Dutta)

According to Ayurveda the four main factors required for the proper conception are *Ritu* (*Ritu Kal*), *Kshetra* (Fertile uterus), *Ambu* (Amniotic fluid), and *Beeja* (viable Ovum and Sperm). Absence or any abnormality in any of the above factors may cause *Vandhyatva*.<sup>[4]</sup>

Ayurveda may give a promising hand to cure this disease. As the subject matter discussed in Ayurveda, it becomes necessary to study, understand and prove them particularly in light of modern scientific parameters in the present era. So the field of research in the *Vandhyatva* opens broad scope for a worker, hence this topic requires proper thought and orientation in implementation of *Ayurvedic* treatment of success in aimed target of attaining twinkle in the eye of childless women. So keeping this aim in my mind, I thought to work on Female Infertility.

### Aims and Objectives

1. To provide safe, cheapest, non-surgical treatment .
2. To avoid the undue social and psychological stress due to infertility.
3. To evaluate the effect of *Brahmi Ghrita* in female infertility.

### Drug and Procedure Selection

In Ayurveda the word "*Yoni*" refers to reproductive organs collectively. Without *Vata yoni* never gets spoilt. *Vata dosha* is the governing factor of the whole reproductive physiology;

therefore any vitiation in *Vata* will certainly affect the normal phenomenon of fertility.<sup>[5]</sup> Female infertility is a *Yoni Gata Vikara* and pacification of vitiated *Vata* is the best cure of *Yoni gata vikaras*, and we know that the *Sneha* is the best treatment for *Vata*. A lot of research work has been done on many of them but some of them are still untouched, one of them is "***Brahmi Ghrita***" described in *Ashtang hridaya utara sthanam adhyaay 6 /23-25*. It has been indicated as a useful medicine for *Vandhya Stri* and for *Unmaad, Kushtha, Apasmara*.<sup>[6]</sup> Taking reference from there, this specific *Ghrita* has been selected for treatment.

Keeping all these views in mind a clinical study was planned to evaluate the efficacy of *Brahmi Ghrita* Orally. So to find a sure shot treatment of *Vandhyatva*, without any side effect, oral treatment is selected.

## MATERIALS AND METHODS

### A. Conceptual Materials Methods

Disease Review, Historical review and Modern review are compile from various text.

### B. Clinical Materials Methods

#### 1. Selection of Patients

The Study was conducted on 10 clinically diagnosed and confirmed patients of Infertility at P.G. Department of *Prasuti* and *Striroga* of N.I.A. Jaipur (Raj.). Patients were selected with consent, from O.P.D. / I.P.D. of NIA hospital, Jaipur and were examined thoroughly as per the case sheet specially prepared for this clinical study.

- (i) A special proforma was prepared incorporating all signs and symptoms based on both *Ayurvedic* and Modern description.
- (ii) A detailed clinical history was taken and complete physical examination of each patient was done on the basis of proforma.

#### Inclusion criteria

1. All primary and secondary cases of infertility.
2. Age group between 20 to 35 years.
3. Male counterpart should be normal in all aspects.
4. Duration of infertility less than 10 years.

#### Exclusion criteria

1. Infertility more than 10 years.

2. Female less than 20 years and more than 35 years of age.
3. Congenital anatomical defect.
4. Surgical cases of Infertility.
5. Infertility due to abnormality in male partner.
6. Infertility due to chronic systemic diseases.
7. Tubal blockage.

## 2. Management of the Patients

During the treatment period, patients were advised to take *Pathyakara Ahara*.

For clinical trial 10 patients selected.

Oral administration of *Brahmi Ghrita*

Dose - 5 ml twice a daily orally with milk (200 ml) for 3 months.

## 3. Criteria for Diagnosis - Criteria for diagnosis was based on.

### Investigation (Before Treatment)

Medical History and Physical Examination

Pelvic Examination to look for abnormalities, or infection.

1. **Blood test** - Hb%, TLC, DLC, ESR, VDRL, Montoux test, RBS/FBS (if needed)

2. **Urine test** - Routine and Microscopic

3. **Routine tests** –

1. X-ray chest PA view (if needed)
2. TSH, FSH, LH (if needed)
3. Pap smear (if needed)

### 4. special test for infertility.

1. Semen Analysis of male partner
2. Cervical mucous (1) Spinnbarket test ( 2) Fern Test
3. Post coital test
4. USG- Pelvis and Adenexa , Follicular study (if needed)
5. HSG or SSG
- 6 Antisperm and Antibody Test (if needed)

### Specific Investigations: (Before Treatment)

1. Cervical Mucus Study for Amount, Viscosity, Spinnbarkeit, Ferning and PCT.

2. Endometrium Biopsy (wherever required) to assess the nature of Endometrium. (if needed).
3. Hysterosalpingography- (wherever required) to rule out tubal patency.  
(In Proliferative phase- 2 days after the bleeding stops).
4. Transvaginal Sonography (for Follicular Size Study).
5. Laparoscopy (If required).

#### **Investigation (After Treatment)**

1. Cervical Mucus Study for Amount, Viscosity, Spinnbarkeit, Ferning and PCT.
2. Hormonal Study (After treatment if needed)
3. Transvaginal Sonography (D 10-D18 for Follicular Size Study)
4. Urine Pregnancy Test (Gravindex Test) - After 7<sup>th</sup> day of missed period.
5. USG- to see the improvement.

#### **5. Follow Up**

1. Follow up done monthly up to two months after the completion of Therapy.
2. Treatment completed / not completed.

#### **6. Result Assessment**

1. Subjective improvement- Feeling of well-being and relief in associated complaints.
2. Objective Improvement- Clinical recovery and Goal Achievement i.e. Conception.

#### **Follow Up Study**

After completion of trial follow up was done monthly upto two month and result assessed in following parameters.

Note – During treatment intercourse was advised during ovulation period mainly.

**Criteria for Assessment** - To facilitate the statistical analysis of the efficacy of therapy, four grade scoring system from 0 to 4 (zero to four) was adopted. Effect of treatment depends on four grade (from 0 to 4) scoring system of.

- Fern test
- Post coital test
- Menstrual bleeding –
- Amount of blood loss during menstruation
- Pain during menstrual bleeding

- Interval of menstrual cycle

Most importantly on the basis of conception.

### **Overall effect of treatment**

The score of individual symptoms were obtained before and after treatment. And the total effect of therapy was assessed accordingly in term of

- Conception.
- Increased in size of Ovarian follicle
- Improvement in the quantity and characters of cervical mucus
- Improvement in menstrual parameters.
- Improvement in leucorrhoea.
- Unchanged

### **Presentation of Data**

The data collected from the trial study was subjected to statistical analysis.

- 1) The first section deals with the general observations.
- 2) The second section deals with the effects of therapy evaluated statistically on the basis of improvement.

All values of qualitative variables are expressed as percentage and all values of quantitative variables are calculated as mean  $\pm$  S.D., S.E. t and P values were calculated by using paired 't' test. Inter-group comparison is done by Anova Test.

### **OBSERVATION AND RESULTS**

Out of 10 patients maximum 5 patient were belong to 20- 24 years age group.

A study of a population of French women from 1670 and 1789 shows that those who married at age 20–24 had 7.0 children on average and **3.7%** remained childless. Women who married at age 25–29 years had a mean of 5.7 children and **5.0%** remained childless. Women who married at 30–34 years had a mean of 4.0 children and **8.2%** remained childless.<sup>[7]</sup> Age related decline in female infertility can be attributed largely to progressive follicular depletion and a high incidence of abnormality in aging oocytes.<sup>[8]</sup>

### **AGE OF MENARCHE**

9 patients had their age of menarche between 12 to 15 year age.

This data shows normal pattern of menarche. The age of menarche is usually 10-16 year the average being 13.5 years in India. The age of menarche varies to some extent with family, race, Social class, family size, birth order, environment, diet and general health. Early and delayed menarche both leads to infertility due to hormonal imbalance.

- **MENSTRUAL HISTORY**

7 patients had regular menses, 6 patients had normal flow, 8 patients had painful menses and maximum 7 patients had 4-6 days flow days.

This data explains disturbance in function of *Vata* because *Apana Vayu* is responsible for proper *pravartana* of *artava*. The menstrual cycle and ovarian cycle are interdependent because they are controlled by Hypothalamus - pituitary-ovarian axis. i.e. under the control of hormones. Disturbed levels or functions of hormones affect the menstrual as well as ovarian cycle. So the patients having anovulatory cycles generally have the complaints of oligo menorrhoea or polymenorrhoea.

- **TYPE OF INFERTILITY**

6 patients had primary infertility.

It shows that these patients have much interest in *ayurvedic* treatment.

- **SEXUAL HISTORY**

7 patients had satisfactory sexual act with frequency of 1-3/wk.

Coital satisfaction involves the mental aspect and regulates the sexual hormonal levels and hence improves the fertility.

- **EFFECT OF THERAPY ON FOLLICULAR STUDY**

The follicular study in this work is done with USG per Abdomen. Follicular Study improve in 70.00% patient.

Follicular study	No follicle both side		Small follicle(s) and unruptured		follicle(s) size normal and unruptured		follicle(s) size normal and ruptured	
	BT	AT	BT	AT	BT	AT	BT	AT
No. Of Patient	1	0	1	1	7	2	1	7
%	10	00	10	10	70	20	10	70

- **THERAPY ON SIZE OF ENDOMETRIUM IN FOLLICULAR STUDY**

Endometrial size improved in 70.00% of patient.

Endometrium Size	≤ 4.9 mm		5- 7.9 mm		8-10.9 mm		≥ 11 mm	
	BT	AT	BT	AT	BT	AT	BT	AT
No. Of Patient	0	0	1	0	7	3	2	7
%	10	00	10	10	70	20	10	70

- **Effect on fern test**

On 14<sup>th</sup> day fern pattern formation in cervical mucus due to crystallization of Sodium chloride shows, the estrogenic effect in mid menstrual phase prior to ovulation. Positive fern pattern before and after treatment shows that drug have no effect on change in fern pattern in the view of physiological changes in infertility on the 14<sup>th</sup> day of menstrual cycle.

On 22<sup>nd</sup> day of cycle , in all the patient before treatment mean score was 0.7 which was 0.5 after the treatment with 28.75 % relief showing statistically not significant (P>0.1). According to modern concept disappearance of fern pattern on 22<sup>nd</sup> day shows presence of increased progesterone level after ovulation. Thus disappearance of ferning is presumptive evidence of ovulation.

According to *Ayurvedic* point of view fern pattern can be taken as the function of the proper *Agni*. So when there will be proper functioning of *Agni* there may be proper fern pattern.

**Effect of therapy on cervical mucus on 14<sup>th</sup> day in spinn barkeit test**

it is improved in 30.00 % of patient.

**Effect of therapy on post coital test in 14<sup>th</sup> day**

In 80.00% of patient of sperm was motile and adequate in amount.

**Effect of therapy on dysmenorrhoea**

60.00% of patients were having mild and 20.00 % were having moderate dysmenorrhoea before treatment while after treatment only 20.00% had mild dysmenorrhoea and 80.00% of patients has painless menstruation. oral drug is providing relief in dysmenorrhea. it is beneficial due to its *Vatanulomana* property.



### Effect of therapy based on conception

Out of 10 patients 5 patients got conception during or after treatment. Out of 5 patients conceived, 3 were Primary infertility, 2 were secondary infertility. This shows that effect of therapy were more effective in Primary infertility. Before treatment mean score was 0 and after treatment it was 0.5 with 50.00% relief showing statistically significant ( $P < 0.05$ ) result.

S. No.	Type of administration of drug	Total no. of pts.	Effect based on conception		
			conception	No. conception	%relief
1	orally	10	05	05	50.00

### DISCUSSION

Discussion is the process to re-examine the work done. To communicate the findings with the results, discussion is essential. Hence, it becomes very much important part of any scientific research. It can either support the hypothesis or it may revolutionize the concept totally.

#### • Probable Mode of Action of Oral Drug

- ✓ Main ingredients of *Brahmi Ghrita* are *Brahmi*, *Shankhapushpi*, *Saptala*, *Argvadha*, *pippali*, *marica*, *shunti*, *goghrita* etc.<sup>[9]</sup>
- ✓ These drugs are mainly having *Vatapittashamaka*, *Vrishya*, *Balya*, *Garbhasthapaka* properties.
- ✓ Majority of the drugs are having *Rasayana* property.

The primary constituents of *Bacoppa monniera* (*Brahmi*) are mainly Triterpenoid, saponins, believed to be responsible for its wide therapeutic actions. Apart from wound healing, the herb is recommended for the treatment of amenorrhea, diseases of the female genitourinary tract.<sup>[10]</sup> Saponin acts like natural steroids, thus it can regulate the hypothalamo - pituitary – ovarian axis and helps in ovulation.

This drug is also recognized for its efficacy in relieving acute pain and inflammation, through selective inhibition of cyclo-oxygenase-2 (COX-2) enzyme and consequent reduction in COX-2-mediated prostanoid mediators.<sup>[11]</sup> Significant reduction<sup>[11]</sup> in the activity of acetyl cholinesterase enzyme in all brain regions on feeding of *Brahmi* leaf powder was noted, this action of the drug establishes that it modulates the cholinergic function. These actions of the drug may be helping in preparing the endometrium to receive products of conception.<sup>[12]</sup>

Since *Brahmi* is good nervine tonic, in cases of infertility also it might have regulation the vitiated *Apanavayu* i.e. autonomic system governing the functions of pelvic organs, especially reproductive organs to function to their optimum levels in order to maintain normal follicular phase, ovulation and secretary phase. Due to its poly-pharmacological effects it might supported in all respects for conception.

✓ *Shankhpushpi* is *Vrishya*, *Tridosahara* specially *Vattapittahara*, also mentioned in *Medhya Rasayana*, so it helps to improve the system harmony.

The ethanolic extract of *Convolvulus plauricaulis* and its ethyl acetate and aqueous fractions were evaluated for their memory-enhancing properties.<sup>[13]</sup>

Methanolic extract of the whole plant produced alterations in the general behaviour pattern, reduction in spontaneous motor activity, hypothermia, potentiation of pentobarbitone-sleeping time, reduction in exploratory behavioural pattern, and suppression of aggressive behavior.<sup>[14]</sup> Nitrogen containing active principle of drug produced marked reduction in I-131 uptake, acetylcholine, suggesting its effect on various glands through neurohumors particularly acetylcholine.<sup>[15]</sup> These action shows that *Shankhpushpi* acts on hypothalamus and regulate various functions, so it might have acts on HPO axis and helps in ovulation.

Since *Shankhpushpi* is also a good nervine tonic, in cases of infertility also it might have regulation the vitiated *Apanavayu* i.e. autonomic system governing the functions of pelvic organs, especially reproductive organs to function to their optimum levels in order to maintain normal follicular phase, ovulation and secretary phase. Due to its poly-pharmacological effects it might supported in all respects for conception.

✓ *Pippali* has *Vrishya* (Aphrodisiac), *Agnideepana*, *Vaatanulomaka* properties, As the data shows that *Agnideepana* and *Vaatanulomana* properties might have support the proper function of receptor in the endometrium specially in ferning pattern.

✓ *Saptala*, *Danti*, *Trivrita*, *Argvadha* these drugs have the *Virechak Guna*, hence they regulate *Doshas* by *Samshodhana Karma*. The vitiation of *Vata* may be due to *Margavrodha* (*Avrita Apana Vayu*) with *Kapha Dosh*, The treatment should be *Agnideepaka*, *Vatanulomaka*, *Srotoshodhana* and *Pakvashaya Shuddikara*. Thus *Samshodhana karma* clear the GIT and regulates function of *Tridosha* specially *Avrita Apana Vayu*.

✓ *Goghrita* has *Rochana, Deepana, Rasayana, Vrishya* properties so it regulate *Tridoshas* and help to destruct the *Samprapti of Vandhyatva* .

There by gives proper feed back to the Hypothalamus, the governing body of H-P-O axis, By governing the H-P-O axis, it helps in the maintenance of Follicular growth, Ovulation and Corpus luteum regulates the vitiated *Dosha, Malas and Apanavayu*.

## CONCLUSION

The overall effect of therapies in female infertility shows that the administration of *Brahmi ghrita* orally is effective.

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