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CLINICAL STUDY OF KALYANAKA GHRIT IN VANDHYATWA W.S.R. TO OVARIAN FACTOR

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ABSTRACT

Infertility is emerging as a major disorder due to changing lifestyle and increasing stress affecting the social and psychological aspect of the women. Ovulatory cause accounts about 40% of infertility cases among women. In modern science, various treatment available for ovulation induction but all have unsatisfactory results and complications, thus, there is a great scope of research to find out safe, potent, less costly and effective remedy for the management of *Vandhyatwa*. In this clinical study, 15 patients were given *Kalyanaka Ghrit* orally with milk for 3 months. The study shows very significant result in follicular study, fern test, dyspareunia and 3 patients got conceived. No adverse effect was observed. Thus, *Kalyanaka Ghrit* can be recommended for the management of infertility.

KEYWORDS: *Vandhyatwa, Kalyanaka Ghrit,* Infertility.

INTRODUCTION

Infertility is emerging as a major disorder due to changing lifestyle and increasing stress affecting the social and psychological aspect of the women. It is defined as the inability of couple to achieve conception after one year of unprotected coitus. Ten to fifteen percent of marriages prove to be childless.[1] Conception depends on the fertility potential of both male and female partner. Male is directly responsible in 30 - 40%, female in 40 - 55% and both are responsible in 10% and remaining 10% is unexplained.[2]

Acharya Sushruta has described four essential factors to achieve conception i.e. *Rutu*, *Kshetra*, *Ambu*, *Beeja*.[3] Presence of abnormality in any of the factors cause *vandhyatwa*. Among these factors, *Beeja* (*Antahpushpa*) is the core stone of the female reproductive process. Thus anovulation can be included under *Beeja dushti*. Ovarian factor contributes 30-40% of infertility cases among women.[4]

In modern science, various treatment available for ovulation induction but all have unsatisfactory results and complications. So there is a great scope of research to find out safe, potent, less costly and effective remedy for the management of *Vandhyatwa*.

It is mentioned in our classics that *Yoni* never gets spoilt without vitiation of *Vata*.[5] Female infertility is a *yoni gata vikara* and pacification of vitiated *vata* is the best cure for *yoni gata vikaras*. In *Ayurveda*, *Sneha* said to be the best treatment for *Vata*. Due to "*Samskaranuvartan Guna*" *Ghrit* is the best *Sneha* among *Mahasneha*s.[6]

Considering all these points, *Kalyanaka Ghrit* indicated in *Vandhya*[7] have been selected from *Charaka Samhita Chikitsa sthana adhyaay* 9/35 – 42 for the present clinical study because in this *Ghrit* mainly drugs have *tridoshashamaka*, *Yonidoshahara*, *garbhasthapaka*, *Rasayana* and *Vrishya* actions.

AIMS AND OBJECTIVES

1. To study aetiopathogenesis of *Vandhyatwa* as per the classical literature and modern texts.
2. To avoid the undue social & psychological stress due to infertility.
3. To evaluate the efficacy of *Kalyanaka Ghrit* on ovulation.

MATERIAL AND METHODS

Selection of patients

Total 17 clinically diagnosed and confirmed patients of infertility were selected from OPD/IPD of NIA, Jaipur (Rajasthan) On the basis of inclusion and exclusion criteria after taking written informed consent.

Criteria for inclusion

1. All primary and secondary cases of infertility
2. Age group between 20-35 years
3. Male counterpart should be normal in all aspects
4. Infertility due to PCOD

Criteria for exclusion

1. Female less than 20 years and more than 35 years of age
2. Infertility due to abnormality in male partner
3. Surgical cases of infertility
4. Infertility due to tubal and peritoneal factors
5. Infertility due to uterine factors
6. Infertility due to cervical factors
7. Congenital anatomical defect
8. Infertility due to severe infection / chronic systemic diseases

Criteria for withdrawal

When the condition of patient deteriorated during trial or patient developed any complication and irregular follow up.

Laboratory investigation

Before treatment

a) **Blood test** - CBC, ESR, VDRL, HIV, HBsAg, Mantoux test, RBS

b) **Urine test** - Routine & Microscopic

c) **Special tests** - 1. Semen Analysis

2. USG – uterus & adnexa, Follicular study

3. X-ray chest PA view (if possible)

4. Cervical mucus (1) Spinnbarkeit (2) Fern test

5. Hormone assays - FSH, LH, PRL, TSH

6. Post coital test

7. HSG

8. Antisperm antibodies test (if possible)

9. Pap smear (if possible)

After treatment

a) Fern and Spinnbarkeit test

b) Urine Pregnancy test (after 7^{th} day of missed period)

c) USG - to confirm pregnancy

d) USG – Follicular study

Administration of drug

Selected patients were given *Kalyanaka Ghrit* orally 5 ml BD with milk for 3 months.

Follow up study

Follow up was done every 15 days during the trial and every month upto two months after completion of trial.

Criteria for assessment

Scoring pattern

1. **Interval of menstrual cycle**
   - 21 – 35 days - 0
   - 36 – 45 days - 1
   - 46 – 60 days - 2
   - > 60 days - 3

2. **Duration of menstrual cycle**
   - 3 – 5 days - 0
   - 1 – 2 days - 1
   - 6 – 7 days - 2
   - > 7 days - 3

3. **Amount of blood loss during menses**
   - Normal (2-3 Pads/day) - 0
   - Scanty (Spotting to 1 Pad/day) - 1
   - Moderate (4-5 Pads/day) - 2
   - Excessive (More than 5 Pads/day) - 3

4. **Pain during menses**
   - No Pain - 0
   - Mild - 1
   - Moderate - 2
   - Severe - 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 (Infertility related stress questionnaire)

- 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. Assessment of Follicular Study

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

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

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

Statistical Analysis

Various observation made and result 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.

P value

- P > 0.05 - Not significant or not quite significant
- P < 0.05 - Significant
- P < 0.01 - Very significant
- P < 0.001 - Extremely significant

OBSERVATION AND RESULT

Total 17 patients were registered for the present study. Out of them 02 patients were dropped out and study was completed on 15 patients.

Table 1: Effect of therapy on subjective parameters

S.N	Parameter	N	Mean		Mean Diff.	%	S.D. (±)	S.E. (±)	'W'	P	Result
			B.T.	A.T.							
1.	**Amount of menses**	**15**	0.6	0.2	0.4	66.66	0.63	0.16	15.00	>0.05	**NQS**
2.	**Interval of menses**	**15**	0.66	0.33	0.33	50	0.72	0.18	6.00	>0.05	**NS**
3.	**Duration of menses**	**15**	0.33	0.06	0.26	80.81	0.70	0.18	3.00	>0.05	**NS**
4.	**Dysmenorrhoea**	**15**	1.06	0.2	0.86	81.69	0.35	0.09	91.00	<0.001	**ES**
5.	**Dyspareunia**	**15**	1.06	0.26	0.8	75.47	0.77	0.20	45.00	<0.01	**VS**
6.	**Stress**	**15**	1.73	1.00	0.73	42.19	0.88	0.22	36.00	<0.01	**VS**

This study shows that extremely significant result was observed in dysmenorrhoea and very significant result were observed in dyspareunia and stress.

Table 2: Effect of therapy on objective parameters

S.N	Parameter	N	Mean		Mean Diff.	%	S.D. (±)	S.E.(±)	'W'	P	Result
			B.T.	A.T.							
1.	**Follicular study**	**15**	2.00	1.26	0.73	36.65	0.70	0.18	45.00	<0.01	**VS**
2.	**Endometrial thickness**	**15**	0.73	0.26	0.46	63.01	0.51	0.13	28.00	<0.05	**S**
3.	**Fern test**	**15**	1.73	1.06	0.66	38.49	0.72	0.18	36.00	<0.01	**VS**
4.	**Spinnbarkeit test**	**15**	1.26	0.73	0.53	42.06	0.51	0.13	36.00	<0.01	**VS**

This study shows that very significant result were observed in follicular study, fern test and spinnbarkeit test and significant result was observed in endometrial thickness.

Effect of therapy on conception – Total 3 patients got conceived i.e 20.00% result.

DISCUSSION

Acharya Sushruta has mentioned four essential factors to achieve the conception i.e. *Rutu, Kshetra, Ambu* and *Beeja*. Any abnormality in these four factors interferes with the process of healthy conception and can be causative factor of *Vandhyatwa*. *Vandhyatwa* has been described in eighty types of *Vata Vikaras.*[8] The main reasons for *Vata* vitiation are *Strotorodha, Dhatukshaya* and *Avarana.*

On the other hand, vitiated *Kapha* causes *Apakti* which leads to *Ama* formation which is responsible for *Strotorodha* which further vitiates *vata*. It also vitiates its *Ashraya Rasa Dhatu* and *Upadhatu Artava*. Thus *Vata* and *Kapha* are the prime cause for anovulation. For *Avrita Apana Vayu* with *Kapha Dosha,* the treatment should be *Strotoshodhaka, Agnideepaka, Vatanulomaka* and *Pakvashaya Shuddhikara*.

Sneha kalpana is the best treatment for the *Ruksha Vata dosha*. *Ghrit* is *Yogvahi, Agnideepaka, Rasayana, Vrishya, VataPitta shamaka* and overcomes vitiated *Kapha dosha* due to *Samskaranuvartana guna*.

- **Probable Mode of Action of *Kalyanaka Ghrit***

✓ Majority of the drugs are having *Tridoshashamaka, Dipana – Pachana, Vrishya, Rasayana, Yonidoshahara, Garbhasthapaka* properties.

✓ *Haridradaya, Sarivadaya, Ela, Talisa, Vidanga, Devadaru, Nirgundi, Amalaki* etc have *Dipana, Pachana* and *Amadoshanashak* properties so that it regulates *Jatharagni, Dhatvagni* and *Bhutagni* which corrects metabolism at cellular level, results in proper formation of *Dhatus* and *Upadhatus* (*Artava*) and *Strotoshodhan* by removing *Ama.*

✓ *Haritaki, Amalaki, Vibhitak, Visala, Danti* have the *Sara guna* and *Virechak* action so that they regulate *Doshas* by *Samshodhana Karma*. The vitiation of *Vata* may be due to *Margavrodha* (*Avrita Apana Vayu)* with *Kapha Dosha. Acharya Charaka* has mentioned *Triphala* and *Danti* for *virechana* in *Pakvashyagata Dosha*[9] and *Pakvashaya* is the main *sthana* of *vata dosha* so it regulates vitiated *vata* along with *Kapha* and *Pitta.* Thus *Samshodhana karma* clear the *strotas* and regulates function of *Tridosha* specially *Avrita Apana Vayu*.

✓ *Triphala, Elavaluka, Haridra, Daruharidra, Ela, Manjistha, Kustha* have *yonidoshahara* action i.e it alleviates local inflammation and infection and it is mentioned in our classics that conception only occurs in *shuddha yoni*.[10]

- ✓ *Sarivadaya, Shalaparni, Prishniparni, Dadima* etc drugs and *Ghrita* itself have *Madhura rasa, Prithvi Jala Mahabhuta Pradhana* and *Brihana* property which is responsible for *Upachaya* thereby improves the endometrial thickness.
- ✓ Essential oil and alcohol extract of Valeriana wallichii exerted good peripheral analgesic action via inhibition of PG synthesis on acetic acid induced writhing.[11] It also acts as antidepressant and increase norepinephrine and dopamine levels in fore brain.[12]
- ✓ Stigmasterol present in *Nirgundi* and *Kustha* is precursor of progesterone, acts as intermediate in the biosynthesis of androgens, estrogens and corticoids and possesses antioxidant, hypoglycaemic and thyroid inhibiting properties.[13]
- ✓ *Amalaki, Tagar, Ela, Dadima, Prishniparni, Chandana, Padmaka, Daruharidra* etc. drugs have antioxidant property which decrease oxidative stress.
- ✓ *Goghrita* has *Agnivardhak, Rochaka, Rasayana, Vrishya* properties so it regulate *Tridoshas* and help in proper formation of *Dhatus* and *Upadhatus.*
- ✓ According to modern science, *Ghrita* is lipophilic in nature, thus it diffuses rapidly across the cell membrane which is also composed of bimolecular lipid matrix and *Ghrita* can also cross blood brain barrier and acts on central nervous system i.e hypothalamus and pituitary gland and may correct hormonal imbalance. *Ghrita* contains the cholesterol which is responsible for the synthesis of steroid hormones i.e estrogen and progesterone.

CONCLUSION

Infertility is on the rise in today's era due to changed lifestyle and one of leading causes of marital upset, personal unhappiness and ill health. It is caused by derangement of *gati* of *Apanavayu*, due to the obstruction in the *Artavavahastrotas* and any deviation in the normalcy of *Beeja.* The principles of the management of infertility are: *Garbhasthapana* and *Vatanulomana.* In this study, 03 patients got conceived, showing 20.00% relief in infertility. No adverse effect was observed during trial and in follow-up study. Based on this study, *Kalyanaka Ghrit* can be recommended for the management of infertility.

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