INTERNATIONAL
AYURVEDIC MEDICAL
JOURNAL

IAMJ

International Ayurvedic Medical Journal (December, 2016 - January, 2017) 1(2) 195-201

CLINICAL STUDY OF KALYANAKA GHRIT UTTAR BASTI IN VANDHYATWA

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Published online: January, 2017

ABSTRACT

Infertility is the common global problem affecting the social and psychological aspect of the women and it is seen that one third of the infertile population seeking advice from the infertility clinics shows anovulation. In modern science, various treatments are available for ovulation induction but all have unsatisfactory results and complications, thus, there is a great scope of research to find out safe, potent and effective remedy for the management of *Vandhyatwa*. An open randomised clinical trial was conducted on 17 clinically diagnosed patients of *Vandhyatwa* and was given *Kalyanaka Ghrit Uttar basti* for 3 cycles. The study shows significant result in follicular study, endometrial thickness and dyspareunia, very significant result in fern and spinnbarkeit test, but no patient conceived during the trial and follow up. No adverse effect was observed. Thus, *Kalyanaka Ghrit* can be recommended for the management of anovulation.

Key words: *Vandhyatwa, Kalyanaka Ghrit,Uttar Basti,* Anovulation

INTRODUCTION

Infertility is emerging as a major disorder due to changing lifestyle and increasing stress affecting the social and psychological aspect of the women. Inability of couple to achieve conception after one year of unprotected coitus is defined as infertility. Ten to fifteen percent of marriages prove to be childless.[1]

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Acharya Sushruta has mentioned four essential factors to achieve conception i.e *Rutu, Kshetra, Ambu, Beeja.*[2]Presence of abnormality in any of the factors cause *Vandhyatwa*. Among these factors, *Beeja* (*Antahpushpa*) is the most important factor for the female reproduction and in absence of this factor *Garbha* cannot occur in spite of the proper *Rutu, Kshetra* and *Ambu.* Thus anovulation can be included under *Beeja Dushti.* Ovarian factor contributes 30-40% of infertility cases among women.[3]

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

It is mentioned in classics that *Yoni* never gets spoilt without vitiation of *Vata.*[4]*Vata Dosha* is the governing factor of the whole reproductive physiology therefore any vitiation in *Vata* causes anovulation and pacification of vitiated *Vata* results in proper formation of *Beeja* and *Beejotsarga*. In *Ayurveda, Sneha* said to be the best treatment for *Vata.* Due to "*Samskaranuvar-*

tan Guna" *Ghrit* is the best *Sneha* among *Mahasneha*s.[5]In the context of *Uttar Basti Acharya Charaka* has mentioned that once the *Vata* is controlled by *Uttar Basti* female achieves conception quickly[6]. Hence *Uttar Basti* was selected as a procedure.

Considering all these points, *Kalyanaka Ghrit* indicated in *Vandhya*[7] has 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 evaluate the efficacy of *Kalyanaka Ghrit Uttar Basti* 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 and cervical factors
6. Congenital anatomical defect
7. 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, HBs Ag, 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 7th day of missed period)
c) USG - to confirm pregnancy
d) USG – Follicular study

Administration of drug:

Selected patients were given *Kalyanaka Ghrit Uttar Basti* 5 ml after 24 hrs of cessation of menses for 3 alternate days for 3 consecutive cycles.

Follow up study:

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

Assessment criteria:

Subjective parameters -

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

2. Duration of menstrual flow	
o 3 – 5 days	0
o 1 – 2 days	1
o 6 – 7 days	2
o > 7 days	3

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

4. Pain during menses	
o No Pain	0
o Mild	1
o Moderate	2
o Severe	3

5. Dyspareunia	
o Absent	0
o Mild pain during coitus	1
o Moderate pain during coitus	2
o Severe pain – tries to avoid coitus	3

Objective parameters -

1. Fern test on 22nd day	
o No crystallization	0
o Atypical Fern formation	1
o Primary and secondary stem	2
o Tertiary and quarternary stem	3

2. Spinnbarkeit test on 14th day	
o > 8 cm	0
o 5-8 cm	1
o 1-4 cm	2
o < 1 cm	3

3. Assessment of Follicular Study	
o Ovulated	0
o >20 mm and unruptured	1
o 12 – 20 mm	2
o <12 mm/ no dominant follicle	3

4. Assessment of endometrial thickness on 14th day	
o ≥ 8 mm	0
o 6 - 7.9 mm	1
o 4 – 5.9 mm	2
o <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 dropped out and study was completed on 15 patients.

Table 1: Distribution of patients on the basis of subjective parameters

S.N.	Parameter		No. of pts.	%
1.	Amount of menses	Normal	8	53.33
		Scanty	6	40.00
		Excessive	1	6.66
2.	Interval of menses (days)	21-35	12	80.00
		36-45	3	20.00
3.	Duration of menses (days)	3-5	10	66.66
		1-2	2	13.33
		6-7	3	20.00
4.	Dysmenorrhoea		14	93.33
5.	Dyspareunia		7	46.66

Table 2: Ovarian factor wise distribution

Ovarian factor	No. of pts.	%
Anovulation	10	66.66
PCOD	4	26.66
LUFS	1	6.66

In this study 66.66% patients had anovulation, 26.66% patients had PCOD and 6.66% had luteinised unruptured follicular syndrome.

Table 3: 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	0.06	0.53	88.33	0.83	0.21	21.00	<0.05	S
2.	Interval of menses	15	0.2	0.066	0.133	66.5	0.35	0.09	3.00	>0.05	NS
3.	Duration of men-	15	0.53	0.33	0.2	37.73	0.56	0.14	3.00	>0.05	NS

	ses										
4.	Dysmenorrhoea	15	1.2	0.4	0.8	66.66	0.41	0.10	78.00	<0.001	ES
5.	Dyspareunia	15	0.8	0.2	0.6	75	0.82	0.21	21.00	<0.05	S

This study shows that extremely significant result was observed in dysmenorrhoea and significant results were observed in amount of menses and dyspareunia.

Table 4: 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	1.86	1.13	0.73	39.25	0.96	0.24	28.00	<0.05	S
2.	Endometrial thickness	15	0.53	0.13	0.40	75.47	0.50	0.13	21.00	<0.05	S
3.	Fern test	15	1.6	0.73	0.866	54.12	0.83	0.21	45.00	<0.01	VS
4.	Spinnbarkeit test	15	1.53	0.93	0.60	39.21	0.50	0.13	45.00	<0.01	VS

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

Effect of therapy on conception – No patient got conceived during the trial and follow up.

DISCUSSION

Acharya Sushruta has mentioned four essential factors to achieve the conception i.e. *Rutu*, *Kshetra*, *Ambu* and *Beeja*. Abnormality in any of the four factors causes *Vandhyatwa*. 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* is 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* and it is mentioned in classics that once the *Vata* is controlled by *Uttar Basti* female achieves conception quickly.

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*, *Dhat-vagni* 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* has the *Sara Guna* and *Virechak* action so that they regulate *Doshas* by *SamshodhanaKarma*. 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*[8] 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*.[9]

✓ *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.[10]

✓ 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.[11]

✓ *Ghrit* has *Yogvahi*, *Agnideepaka*, *Rasayana*, *Vrishya*,*VataPitta Shamaka* action and overcomes vitiated *Kapha Dosha* due to *Samskaranuvartana Guna*.

✓ 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. *Ghrita* contains the cholesterol which is responsible for the synthesis of steroid hormones i.e estrogen and progesterone.

✓ *Vatanulomaka* and *Strotoshodhana* effect of *Basti* is well known. *Uttarbasti* which is given in *Garbhashaya* stimulates the *Artavavaha Strotas* as well as the *Beejagranthi*. By the stimulation of ovary, the *Sanga* in the *Beejagranthi* is removed and *Vata* performs its two functions properly – *Vibhajana* i.e reduction division in oocyte and proliferation of granulosa cells and responsible for development of follicle along with *Kapha* and *Pravartana* i.e. rupture of follicle which leads to ovulation.

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 *Apana vayu*, due to the obstruction in the *Artavavaha strotas* and any deviation in the normalcy of *Beeja*. The principles of the management of infertility are: *Garbhasthapana* and *Vatanulomana*. In this study, 07 patients had ovulation showing 46.66% relief. 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 anovulation.

ACKNOWLEDGEMENTS

I sincerely convey my thanks with respect and gratitude to my honorable guide Prof. C.M. Jain and Dr. Sushila Sharma, Associate professor and HOD, Department of Prasuti and Striroga, NIA, Jaipur, whose inspiring teaching, valuable guidance, timely remarks and helpful suggestions throughout the preparation of this dissertation are beyond capacity of my words to reciprocate with thankfulness.

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How to cite this URL: *Khushbu Jain Et Al: Clinical Study Of Kalyanaka Ghrit Uttar Basti In Vandhyatwa*. International Ayurvedic Medical Journal {online} 2017 {cited December, 2016 - January, 2017} Available from: http://www.iamj.in/posts/images/upload/195_201.pdf