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Clinical Evaluation of *Uttar Basti* and some Herbo- Mineral Compounds in Female Infertility

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ABSTRACT:

Introduction: Infertility is an emerging health problem that has profound socioeconomic and health implication on both the individual and society. Ayurveda explained female infertility as *Vandhyatva* and mentioned *Garbha Sambhava Samagri* (proper union of four factors like fertile period, healthy reproductive system, nutrition and healthy ovum and sperm) and *Manasika Abhitapa* (psychological and emotional factors) as chief factors responsible for conception. The efficacy of *Uttar basti* of *Kalyanak Ghrita* with oral *Garbhadharak yog* with *anupana* of *Ashwagandha Ksheerpaka* mixed with *Kalyanak Ghrita* has encouraging effects for the management of primary cases of *Bandhyatva*.

Methods: In this trial, randomly categorized the patients of primary infertility and grouped them into A, B & C who were ineligible for fertility after the several years of unprotected intercourses. The Group A patients were treated with *Kalyanak Ghrita Uttarbasti*, 3 days alternatively in a month for consecutive three cycle. The Group B patients were treated with Oral *Garbhadharak Yoga* while Group C patients were treated with *Kalyanak Ghrita Uttarbasti and Oral Garbhadharak Yoga* for three months consecutively.

Result: Total 60 patients were investigated for *Bandhyatva* for present study. The effect of *Uttar basti* of *Kalyanak Ghrita* with oral *yog* (*Garbhadharak yog* with the *anupana* of *Ashwagandha Ksheerpaka* mixed with *Kalyanak Ghrita*) in Group C Patients Shows maximum relief in cervical mucus was 50.00%, Viscosity 65%, Spinnbarkeit formation 54.54%, cellularity 37.83% reduced Fern pattern on 22nd day was 48.27%, PCT 27.77%, Leucorrhoea 83.33%, Amount of blood loss 17.50%, Regularity 71.42%, Dysmenorrhoea 88.88%, and improvement in follicular growth was 54.16%.

Conclusion: In Group C, out of 20 patients 05 patients were conceived showing 25% relief in primary infertility. The overall effectiveness of therapy in all studied 60 patients of primary infertility was 15%. The statistical analysis data of the clinical research work done on all 60 patients of infertility shows the highly significant result ($p < 0.001$)

Key words: *Bandhyatva*, *Uttar basti*, *Anuvasan*, Conception.

INTRODUCTION

Infertility or *Bandhyatva* is the inability to naturally conceive a child or to carry a pregnancy to full term. The

couple has not conceived after 12 months of unprotected intercourse if the female is under the age of 35 or the couple has not conceived after 6 months of unprotected



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intercourse if the female is over the age of 35¹ Fertility is important physiological activity of the reproductive organ. Infertility cases are increasing due to stress, obesity lack of exercise, and environmental pollution. Unexplained infertility is earmarked to those couple who have undergone complete basic infertility work up and in whom no abnormality has been detected and still remains infertile. The main principle of the management of infertility is *garbhashthapaka (prajasthapana) and vatanulomaka* treatment. Female infertility is a *yonigata vikara* and pacification of vitiated *Vata* is the best cure of *Yonigata vikaras*, and *Sneha and Uttar basti* are the best treatment for *Vata*^{2,3} *Uttar basti* is a specialized form of *basti* treatment, where the drugs are administered directly in to the *garbhashaya*^{4,5} A clinical study was planned to evaluate the efficacy of *Kalyanak Ghrita Uttarbasti and Garbhadharak Yog* Orally, along with *anupana* of *Ashwagandha ksheer pak* mixed with *Kalyanaka Ghrita*. So without any side effect, this special combination of oral as well as *Panchakarma (Uttar basti)* treatment was selected^{3,6,7}

AIMS AND OBJECTIVES

The present study has been undertaken with the following aims and objectives.

- To evaluate the effects of *Kalyan Ghrita Uttar Basti* in Female Infertility.
- To evaluate the effect of *Garbhadharak Yog* Orally with *Anupana* of *Ashwagandha ksheer pak* mixed with *Kalyan Ghrita* in Female Infertility.
- To evaluate the effects of both *Uttar Basti* and Oral therapy on Female Infertility.

MATERIALS AND METHODS

Selection of Patients - The Study was conducted on 60 clinically diagnosed and confirmed patients of Primary Infertility at P.G. department of *Panchakarma* of N.I.A. Jaipur (Rajasthan) over a period of three years from January 2007 to September 2009. Patients were selected with written 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.

Inclusion criteria

1. All married female of age group between 18-45 years.
2. Duration of Infertility below 15 years.
3. All primary Cases of infertility.
4. Cases of Tubal Blockage without any Mechanical blockage / fibrosis.

5. Non-surgical cases of Infertility.
6. Male counterpart must be normal in all aspect.

Exclusion criteria

1. Infertility more than 15 years.
2. Female > 45 years of age.
3. All Congenital anomalies of female reproductive system.
4. Surgical Cases of Infertility.
5. Infertility due to abnormality in male counterpart.
6. Infertility due to severe infection / chronic disease.
7. Infertility due to long term use of steroids /antifungal medications.

Study Procedure- In Ayurveda the word "Yoni" refers to reproductive organs collectively. Without *vata yoni* never gets spoilt. "*Kalyanka Ghrita*" described in Charak Samhita in Ch.09 of *chikitsa sthana*. It has been indicated as a useful medicine for *Bandhya Stri and for Pumsavana*. The other Ayurvedic text such as *Yogaratanakara* and *Chakradutta* also describes the same properties of this *Ghrita*. Taking reference from there, this specific *Ghrita* has been selected for *Uttar Basti* (also used in *Anupana* of the oral medicine). In *Ras Tantra Sara and Siddha Prayog Samgraha* of *Krishna gopal Kaleda* Publication, "*Garbhadharak yog*" is indicated as an ultimate *yog* for the treatment of *Bandhyatva*. Keeping all these views in mind a clinical study was planned to evaluate the efficacy of *Kalyanak Ghrita Uttarbasti and Garbhadharak Yog* Orally, along with *anupana* of *Ashwagandha ksheer pak* mixed with *Kalyanaka Ghrita*. So, to find a sure shot treatment of *Bandhyatva*, without any side effect, this special combination of oral as well as *Panchakarma (Uttar basti)* treatment is selected.

Grouping of patients For clinical trial Selected 60 patients after the diagnosis, were randomly categorized in three groups of 20 each:

Statistical Analysis

Total 60 patients were investigated for *Bandhyatva* for present study. Many time more than one faulty factor was found in the same cases. All the patients had primary infertility of 2 to 15 years and most of them were coming after taking allopathic medicine. Observation of age wise distribution reveals that maximum numbers of patients i.e. 60% belonged to age group of 26-35 years followed by 16.66% patients to 21-25 years, 15% patients belonged to 36-40 year, 5.0% patients to <20 years, 3.34% patients belonged to 41-45 years of age group. Maximum patients were between 26-35years age groups because this is the age of marriage and 1-5years after marriage if there is no issue,

they start to consult doctors. Fertility rates are 4 to 8% lower in women aged 25-29, 15 to 19% Lower between ages 30-34, 26.46% lower in women aged 35-39. Age related decline in female infertility can be attributed largely to progressive follicular depletion and a high incidence of abnormality in aging oocytes. Majority of the patients i.e. 51.67% had marital life between 1-5 years; followed by 41.67% had between 06-10 years, and 06.66% patients had marital life between 11-15 years. Infertility is defined after one year of unprotected sexual relationship after marriage. After 2-3 yrs. of marriage couple starts worrying about issue and come to seek medical advice.

RESULTS

It is concluded from the observations that total 9 patients were conceived out of 60 cases as result of the above clinical study or 15% of patients conceived. Which are statistically highly significant ($p < 0.001$). The overall effects of therapies on physiological properties in infertility showed that the administration of Uttar Basti with oral drugs (Group C) was more effective to increase the factors towards fertility in comparison to Uttar Basti or oral drugs alone. *Uttar basti* with Oral Yoga (Group C) provided comparatively more relief in the cervical mucus amount, viscosity, Spinnbarkeit, cellularity, fern pattern, PCT, Dysmenorrhea, leucorrhea and also the follicular growth and ovulation than *Uttar basti* and oral therapy alone. *Uttar basti* alone (Group A) provided better effect on cervical mucus amount, viscosity, Spinnbarkeit, fern pattern, and also the follicular growth and ovulation as compare to Oral therapy alone (Group B). while all the three groups have the equal effect on amount and regularity of menstrual cycle.

DISCUSSION

Bandhyatva is most complicated problem of all gynecological complaints and the leading cause of marital upset, personal unhappiness and ill health. Term *bandhyatva* can be inferred here as the entire primary cases of infertility. *Vata dosha* is the governing factor of the whole reproductive physiology; therefore, any vitiation in vata will certainly affect the normal phenomenon of fertility. 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 and Basti are the best treatment for *Vata*, in this aspect, Basti is considered to be the best treatment for the present study and since the present study is related to *Yoni gata vikara* for which *Uttar*

basti is a specialized form of basti treatment, which imparts excellent qualities to the reproductive system. It is a procedure where the drugs are administered directly in to the *garbhashaya*. Therefore, *Uttar basti* with Sneha will definitely act on *yonigata vikara* and hence on female Infertility^{3,6,7} Infertility is produced by the vitiation of *Anulomagati of Apanavayu and Prakrutagati of Vyanavayu* along with *pachaka pitta and kledhaka kapha, sthanik, sanga and dusti* mainly with *poshanatmak dushti*. The main principle of the management of infertility are *garbhasthapaka (prajasthapana) and vatanulomaka* treatment.

CONCLUSION

The effect of *Uttar basti of Kalyanak Ghrita* with oral *yog (Garbhadharak yog with anupana of Ashwagandha Ksheerpaka* mixed with *Kalyanak Ghrita*) in Group C Patients Shows maximum relief in cervical mucus was 50.00%, Viscosity 65%, Spinnbarkeit formation 54.54%, cellularity 37.83% reduced fern pattern on 22nd day 48.27%, PCT 27.77%, Leucorrhea 83.33%, amount of blood loss 17.50%, Regularity 71.42%, Dysmenorrhea 88.88% & improvement in follicular growth was 54.16%. In Group A, out of 20 patients 01 patient conceived showing 5% relief in primary infertility. In Group B, out of 20 patients 03 patients were conceived showing 15% relief in primary infertility. In Group C, out of 20 patients 05 patients were conceived showing 25% relief in primary infertility. The overall effectiveness of therapy in all studied 60 patients of primary infertility was 15%. The statistical analysis data of the clinical research work done on all 60 patients of infertility shows the highly significant result ($p < 0.001$). The patients on Group C had provided the better improvement than the individual groups i.e. either *Uttar Basti* or Oral therapy indicates that the *Uttar basti of Kalyanak Ghrita* with oral *Garbhadharak yog* with the *anupana of Ashwagandha Ksheerpaka* mixed with *Kalyanak Ghrita* can be recommended for the management of primary cases of *Bandhyatva*.

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Tables: 1

Grouping of Patients for Clinical Trial			
Procedure	Group A	Group B	Group C
Treatment	<i>Uttarbasti</i> [Kalyanak Ghrita]	<i>Oral Yoga</i> [Garbhadharak Yoga]	<i>Uttarbasti with Oral Yoga</i> [Kalyanak Ghrita Uttarbasti plus Oral Garbhadharak Yoga]
Route	Intrauterine	Oral	Intrauterine Plus Oral
Kala	<i>Ritukala</i>	<i>Ritukala</i>	<i>Ritukala</i>
Dose	5ml	250 mg b.i.d [Capsule]	5 ml Plus 250 mg b.i.d [Capsule]
Anupana		<i>Aashvagandha Ksheera</i> <i>Pak mixed with 10ml</i> <i>Kalyanak Ghrita</i>	<i>Aashvagandha Ksheera Pak mixed</i> <i>with 10ml Kalyanak Ghrita</i>
Duration	Three days alternatively in a month for consecutive three cycle (after 4 th day of Menses).	Three months consecutively	Three months consecutively
Uttar Basti was started after 1 <i>Anuvasan (Dashmool Oil)</i> + 1 <i>Nirooha Basti (Dashmool Kwatha)</i>			

Tables: 2

The No. of patients with Faulty factor		
S.No.	Faulty factor	No. of patients
1	Cervical Factors	15
2	Anovulatory cycles.	11
3	Tubal blockage partially or both	11
4	Poly Cystic Ovarian Disease	8
5	Tubo-ovarian mass	05
6	Endometriosis	02
7	Unexplained causes	08
	Total	60

Tables: 3

Age wise distribution of patients		
S.No.	Age group	Percentage
1	Below 20 years	5%
2	21-25 years	16.66%
3	25-35 years	60%
4	36-40 years	15%
5	41-45 years	3.34%

Tables: 4

Marital life span		
S.No.	Marital life span	Percentage
1	Between 1-5 years	51.67%
2	06-10 years	41.67%
3	11-15 years	06.66%

Tables: 5

End Points and Assessment						
S. No.	Effect of therapy	Group A	Group B	Group C	Results	Remarks
1	Amount of cervical mucus	35.48%	17.24%	50%	In group-A and group C result was statistically highly significant (P<0.001). While in group B the result was statistically significant (P<0.02).	[local effect of ghrta has the tendency to increase the amount of cervical mucus]
2	Viscosity of cervical mucus	56.25%	28.00%	65%	In Group-A and Group-C result was statistically highly significant (P<0.001). While in Group-B it was nonsignificant (P<0.05).	Decreased in Viscosity of cervical mucus [positive sign for fertility].
3	Spinnbarkeit formation	41.37%	29.62%	54.54%	In Group A and B improvement in spinnbarkeit of cervical mucus was statistically significant (P<0.01), (P<0.02). While in group C the result was statistically highly significant (p<0.001).	More thready cervical mucus [positive sign for fertility].
4	Cellularity	No changes	No changes	37.83%	In Group C reduction in cellularity of cervical mucus was statistically highly significant (P<0.001).	
5	Fern test on 14 th day of cycle	No effect	No effect	No effect		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 th day of menstrual cycle.
6	Fern pattern on 22 nd day of cycle	65% cases of fern formation reduced to 55% after treatment	80% cases of fern formation reduced to 60% after treatment	95% cases of fern formation reduced to 55% after treatment	In Group A and C statistically highly significant results were seen on fern pattern (P <0.001). While In Group B this improvement was statistically significant (P < 0.01).	Disappearance of fern pattern on 22 nd day shows presence of increased progesterone level after ovulation. This improvement might be due to Agni Vardhaka (hormonal level) properties of both the therapy (Uttar Basti & oral).

7	Post coital test on 14 th day	Sperm counts and motility increased from 80% to 90%.	Sperm counts and motility increased from 75% to 80%.	Sperm counts and motility increased from 65% to 90%.	In Group A and B improvement was statistically non significant (P<0.10). While in group C statistically moderately significant (p<0.02).	" <i>samanyam vridhhi karanam</i> " <i>shukra and ghrita</i> having the same properties to simultaneously increases each other.
8	Menstrual bleeding & regularity	Irregular menses reduced 45% to 25%	Irregular menses reduced to 35% to 15%	Irregular menses reduced to 35% to 10%	Group A, B and C shows statistically significant (P<0.02)	
9	Dysmenorrhoea	Reduced 30% to 10%	Reduced 35% to 30%	Reduced 45% to 15%	Group A shows statistically significant (P<0.02). Group B shows statistically non significant (P<0.10). Group C shows statistically highly significant (P<0.001)	Uttar Basti does the <i>Garbhashaya shodhana</i> to promote the receptivity of the endometrium and patency of cervix. Uttar basti is having <i>vata shamak and vatanulomak</i> properties and thus helpful in <i>vata vikaras.i.e. Bandhyatva</i> .
10	Leucorrhoea	Reduced	Reduced	Reduced	Group A and B shows statistically non significant (P<0.10). Group C shows statistically significant (P<0.02).	<i>Vatapitta shamaka and vatanulomaka</i> properties of Uttar Basti with medicated ghrita. Oral medicine contains <i>jayaphal</i> which is having <i>stambhan</i> properties.
11	Follicular growth				Group A shows statistically non significant (P<0.05). Group B shows statistically significant (P<0.02). Group C result was statistically highly significant (p<0.001).	The size of the follicles were getting increased by the <i>Dipan, Pachan and dhativardhak guna</i> of the drug. <i>anupana ashvagandha ksheerpaka</i> mixed with <i>kalyana ghrita</i> is also having the <i>balya and brimhana guna</i> adding to the follicular growth activity of the oral drug.
12	Faulty factors	no improve ment seen	33.33% improve ment seen	50% improve ment seen		Uttar Basti with oral drugs was more effective to increase the factors towards fertility in comparison to Uttar Basti or oral drugs alone.

13	Conception	5.0% (1) patients conceived	15% (3) patients conceived	25%(5) patients conceived	Group A shows statistically non significant (P<0.10). Group B shows statistically non significant result (P<0.05). Group C result was statistically significant (p<0.02).	Cumulative effect of therapy was more effective in primary infertility
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Tables: 6

Effect of Therapy on Conception		
Groups	No of Patients	No of Patients Conceived
Group A	20	1
Group B	20	3
Group C	20	5

Graph: 1

