Research Article

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A CLINICAL STUDY OF KASHMARYADI GHRIT UTTAR BASTI IN FEMALE INFERTILITY

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ABSTRACT

Introduction-Infertility is defined as failure to conceive within one or more years of regular unprotected coitus. Women who are able to conceive but then have repeated miscarriages are also said to be infertile. Present study deals with both primary and secondary infertility. Aims and Objectives- To provide safe, cost effective and non-surgical treatment and to evaluate the effect of Kashmaryadi Ghrit Uttar basti in female infertility. Materials and methods- For present clinical study Kashmaryadi ghrit Uttar basti has been selected for the management of Infertility. Trial was conducted on 15 clinically diagnosed patients of infertility. The method adopted in present study was open randomized clinical trial. Result-Very significant results are observed in Follicular study, Endometrial thickness and Spinn Barkeit test. During or after treatment 13.33% patients conceived. Discussion and Conclusion- Clinical trial completed on total 15 patients of infertility out of which 2 patients conceived i.e. result was 13.33%. During and after the treatment no adverse effect or complications were produced. So this treatment is safe, economic, non-surgical and effective and can be recommended for the management of Vandhyatwa.

Keywords: Vandhyatwa, Kashmaryadi ghrit, Uttar basti.

INTRODUCTION

Infertility is defined as one year of unprotected intercourse without pregnancy. This condition may be further classified as primary infertility, in which no previous pregnancies have occurred, and secondary infertility, in which a prior pregnancy, although not necessarily a live birth, has occurred[1].Infertility cause great personal suffering & distress. In some societies the pressure to conceive is directed towards the woman, but conception depends on the fertility potential of both the male and female partners. The male is directly responsible in about 30-40%, the female in about 40-55% and both are responsible in about 10% cases. The remaining 10% is unexplained in spite of thorough investigations with modern technical knowhow.[2]

In Ayurveda infertility is termed as 'Vandhyatwa'. Acharya Charaka has clearly described the Nidanas of Vandhyatwa i.e. Yonidosha, Mansika-abhitapa, Shukra-artava dosha, Ahara-Vihara Dosha, Akalyoga (Coitus at improper time), Bala-kshaya which causes delay in achieving conception in Sapraja women as well as in Apraja.[3]

Acharya Sushruta has propounded four factors responsible for Garbhotpatti (Conception).[4] They are Ritu, Kshetra, Ambu & Beeja. Ritu means fertile period. Dalhana has more specified it, as Raja samay (ovulation period). Kshetra means Garbhashaya (all the reproductive organs). It should be in healthy and normal condition. Ambu means Rasa dhatu (proper nutrition-hormones & maternal nutrition both). Beeja means Artava-shukra (adequate and healthy ovum & spermatozoa). It is obvious that if any of these factors are altered, in any adverse way then, the process of conception will be definitely affected. According to modern science the main etiological factor is found in the female is about 40% of cases, about 35% of the husbands. In 10-20% of cases, a combination of factors operates and the rest have unexplained infertility[5]. In female, ovulatory factors are responsible for infertility in 27%, tubal/uterine factors in 22%, others 9% and unexplained cause in17% cases.[6]

AIMS AND OBJECTIVES- To provide safe, cost effective and non-surgical treatment and to evaluate the effect of Kashmaryadi Ghrit Uttar basti in female infertility.

MATERIALS AND METHODS

Selection of the patients- Total 18 clinically diagnosed patients of infertility from OPD & IPD of NIA, Jaipur were selected for the present clinical trial after taking informed consent. Out of which 15 patients were completed the course of treatment.

Method of Research: The method adopted in present study was open randomized clinical trial.

Drug: The drug Kashmaryadi Ghrit for the present study has been selected from Charak samhita chikitsa sthan 30/52-53 and it was prepared according to classic reference in the Pharmacy of National Institute of Ayurveda, Jaipur.

Criteria for selection of patients

Inclusion Criteria

1. All primary & secondary cases of infertility.
2. Age group between 20 to 40 years.
3. Male counterpart should be normal in all aspects.
4. Infertility due to PCOD.
5. Infertility due to cervical factors.
6. One fallopian tube must be patent.

Exclusive criteria

1. Surgical factors including fibroid uterus, cervical polyp, cervical stenosis etc.
2. Congenital anatomical defect.
3. Patient suffering from severe infection or chronic systemic diseases.
4. Infertility due to tubal factors (if both tubes are blocked).
5. Infertility due to peritoneal factors.

Withdrawal criteria

1. During the course of trial if any serious conditions or serious adverse effect develops which requires urgent treatment.
2. Patient herself wants to withdraw from the clinical trial.
3. Irregular follow up.

CRITERIA FOR DIAGNOSIS

Investigations

Before Treatment

- Medical history & physical examination
- Pelvic examination to look for abnormalities or infections
- Blood test- Hb %, TLC, DLC, ESR, HIV, HBsAg, VDRL, RBS, T3, T4, TSH
- Mantoux test (if needed)
- Urine test -Routine & Microscopic
- Cervical mucus (1) Spinn Barkeit (2) Fern Test
- Post coital test
- USG-Uterus & Adnexa
- HSG
- Antisperm & Antibody Test (if needed)
- Pap smear- if needed.
- Follicular study (if possible)
- Hormone assay- FSH, LH, Progesterone, Prolactin (If possible)

After Treatment

- Follicular study
- Cervical mucous – Fern test, Spinnbarkeit Test
- Urine pregnancy detection test. (After 7days of missed period)
- USG- To confirm pregnancy

Table 1: Ingredients of Kashmaryadi ghrit

Drug Name	Latin Name	Part used
Gambhari	*Gmelina arborea* Roxb	Phala(Fruit)
Haritaki	*Terminalia chebula* Retz.	Phala(Fruit)
Bibhitak	*Terminalia bellirica* Roxb.	Phala(Fruit)
Amalaki	*Emblica officinalis* Gaertn.	Phala(Fruit)
Draksha	*Vitis vinifera* Linn	Phala(Fruit)
Kasmard	*Cassia occidentalis* Linn	Phala(Fruit)
Parusak	*Grewia asiatica* Linn	Phala(Fruit)
Punarnava	*Boerhavia diffusa* Linn	Moola(Root)
Haridra	*Curcuma longa* Linn	Kand(Tuberous root)
Daru haridra	*Berberis aristata* DC	Moola(Root)
Kaknaasa	*Asclepias curassavica* Linn	Moola(Root)
Sahachar	*Barleria prionitis* Linn	Patra(Leaf)
Shatavari	*Asparagus racemosus* Willd.	Kand(Tuberous root)
Guduchi	*Tinospora cordifolia* Willd.	Kaand(Stem)
Goghrit		

Table 2: Administration of drug

Drug	Kashmaryadi ghrit
Dose and Route	5 ml Intrauterine administration after 24 hours of stopping menstrual cycle for 3 alternate days for 3 consecutive cycles. Uttar Basti was started after 1 Anuvasan Basti (Dashmool Oil) + 1 Niruha Basti (Dashmool kwath) + 1 Anuvasan Basti (Dashmool Oil) in each cycle
Duration	3 months

Follow up study

Follow up was done after each cycle during trial & up to two months after the completion of trial.

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 terms of

- Conception.
- Increased in size of ovarian follicle
- Improvement in the character of cervical mucus
- Improvement in menstrual parameters
- Unchanged

CRITERIA OF ASSESSMENT: The improvements in the parameters were assessed mainly on the basis of relief in the signs and symptoms of the disease. To assess the effect of therapy all the signs and symptoms were scored depending upon their severity. Scored as following gradings-0,1,2,3…

Statistical Analysis: Various observations made, and results obtained were computed statistically using Wilcoxon matched-pairs signed-ranks test, Paired 't'test for conception to find out the significance of the values obtained and various conclusions were drawn accordingly. All the results calculated by using Online InStatGraphPad software.

***P* value**

- $P > 0.05$ - Not significant or not quite significant
- $P < 0.05$ – Significant
- $P < 0.01$ - Very significant
- $P < 0.001$ - Highly significant

RESULTS AND DISCUSSION

Table 3: Effect of therapy on subjective parameters

Parameter	N	Mean		Mean Diff.	%	S.D. (±)	S.E. (±)	'W'	P	Result
		BT	AT							
Amount of menses	15	0.267	0.200	0.067	25.09	0.258	0.067	1	>0.05	N.S.
Interval of menses	15	0.266	0.133	0.133	50.00	0.516	0.133	1	>0.05	N.S.
Duration of menses	15	0.466	0.133	0.333	71.45	0.723	0.186	6	>0.05	N.S.
Dysmenorrhoea	15	0.733	0.133	0.600	81.85	0.50	0.13	45	<0.01	V.S.
Dyspareunia	15	0.733	0.133	0.60	81.85	0.632	0.163	36	<0.01	V.S.

On completion of trial Very significant results are found on Dysmenorrhoea and Dyspareunia.

Table 4: Effect of therapy on objective parameters

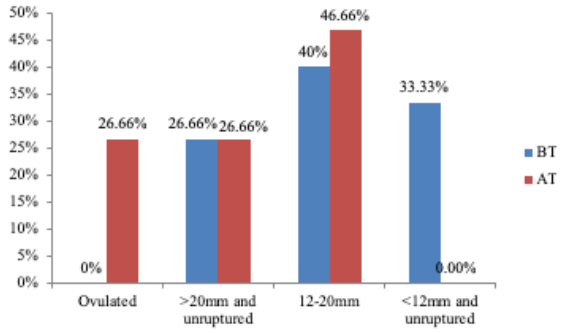
Parameter	N	Mean		Mean Diff.	%	S.D. (±)	S.E. (±)	'W'	P	Result
		BT	AT							
Follicular study	**15**	2.067	1.200	0.867	41.94	0.743	0.19	55	< 0.01	**VS**
Endometrial thickness	**15**	1.200	0.333	0.867	72.25	0.74	0.19	55	< 0.01	**VS**
Fern test	**15**	1.467	0.466	1.000	68.16	1.195	0.308	28	< 0.05	**S**
Spinnbarkeit test	**15**	1.400	0.600	0.800	57.14	0.676	0.175	55	< 0.01	**VS**
Post coital test	**15**	0.200	0.133	0.066	33.00	0.258	0.066	1	> 0.05	**NS**

On completion of trial Very significant results are found in Follicular study, Endometrial thickness and Spinnbarkeit test.

Table 5: Effect of therapy on conception

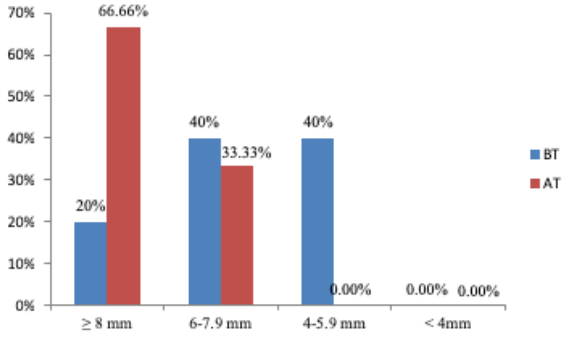
Total number of patients	Effect based on conception		
	Conception	No conception	%relief
15	02	13	13.33

During or after treatment 13.33% patients conceived.



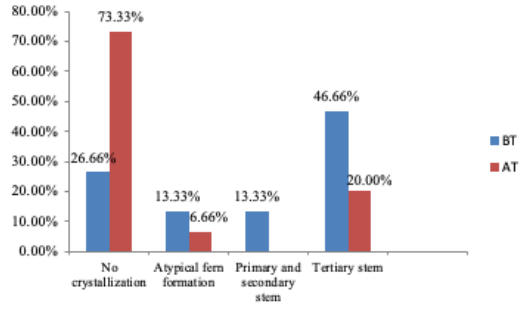
BT-Before treatment, AT-After treatment

Graph 1: Effect on follicular study



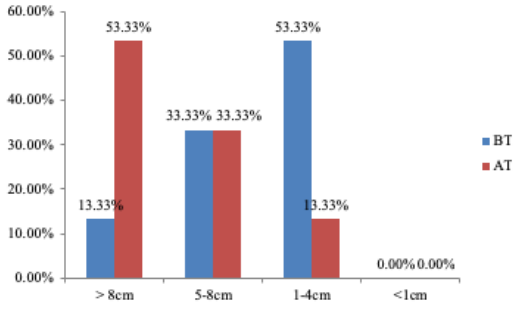
BT-Before treatment, AT-After treatment

Graph 2: Effect on Endometrial Thickness



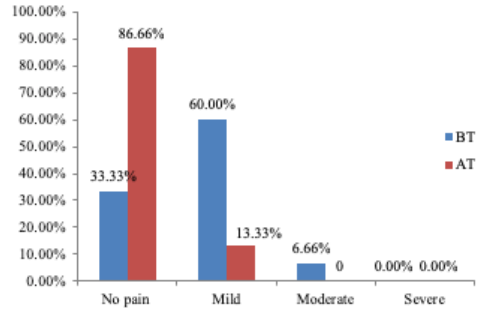
BT-Before treatment, AT-After treatment

Graph 3: Effect on Fern test



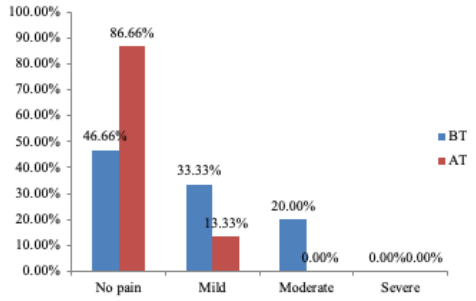
BT-Before treatment, AT-After treatment

Graph 4: Effect on Spinnbarkeit test



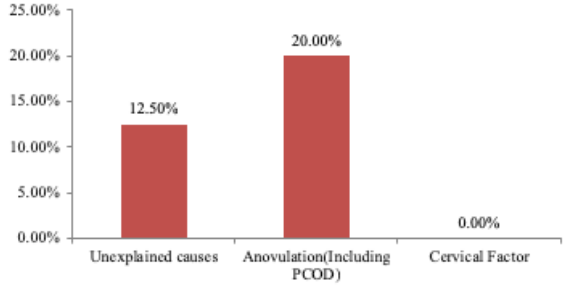
BT-Before treatment, AT-After treatment

Graph 5: Effect on Dysmenorrhoea

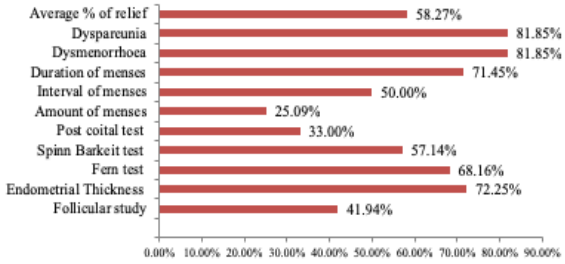


BT-Before treatment, AT-After treatment

Graph 6: Effect on Dyspareunia



Graph 7: Percentage of conception in specific factors



Graph 8: Average % improvement in both subjective and objective parameters

Vandhyatwa has not been described as a separate disease in Ayurvedic classics, but all the gynecological disorders are undertaken twenty Yonivyapad. The Yoni never gets diseased without vitiated Vata[8]. Vandhyatwa has also been described in eighty types of Vata Vikaras[9]. Margavarodha, Dhatukshaya, Avarana and Svanidana prakopa are the main reasons for Vata vitiation. For Avrita Apana Vayu with Kapha Dosha, the treatment should be Agnideepaka, Srotoshodhana, Vatanulomaka and Pakvashaya Shudhdhikara. In case of association of Avarana of Pitta Dosha Daha, Srava, Shosha etc occurs, which required Pittashamak, Sheeta and Brihana treatment. Sneha-kalpana is the best treatment for the Ruksha Vata Dosha. Ghrit is also said to be Yogavahi, Vata-Pitta Shamak, Brihana and with its Sanskaar-anuvartana guna it also overcomes the vitiated Kapha Dosha. Basti is the main treatment for the vitiated Vata and Uttar Basti is the specialized Basti especially for Yoni Vikaras i.e. Vandhyatwa. Acharya Charaka has states that once the Vata is controlled by Uttar Basti female achieve conception quickly.[10]Drug acts through its Rasa, Guna, Veerya, Vipaka and Prabhava. While considering Rasa, Veerya, Vipaka, Guna and Doshaghnata, the compound has maximum Kashaya and Tikta Rasa, Ushna Veerya, Madhura Vipaka and Tridoshaghna property. Gambhari[11], Triphala, Haridra-dvaya, Kasmard[12], Guduchi[11], Punarnava[12] etc. have Deepana, Pachana and Amadosha-nashak properties, so it regulates Agni, which corrects metabolism, results in proper formation of Dhatus and Upadhatus (Artava) and Srotoshodhana by removing Ama. Haritaki, Vibhitaki, Amalaki, Draksha, Gambhari, Parushak have the Sara guna[13] and Virechak action so that they regulate Doshas by Sanshodhana karma. The vitiation of Vata may be due to Margavarodha (Avrita Apana Vayu) with Kapha Dosha. Acharya Charaka has mentioned Triphala for Virechana in Pakvashyagata Dosha[14] and Pakvashaya is the main sthana of Vata Dosha so it regulates vitiated Vata along with Kapha and Pitta. Thus Sanshodhana karma clears the Srotas and regulates the function of Tridosha especially Avrita Apana Vayu. Draksha is indicated in Grabhashay-daurbalya[15]. Because of Madhur rasa and Sheet veerya it may increase the muscular strength of reproductive system. As mentioned in our classics that conception only occurs in Shuddha Yoni, Haridra, Daruharidra and Triphala possess Yonidoshahara action[16], it treats local inflammation and infection and Gambhari, Kasmard, Punarnava, Kaknasa, Sahachar, Haridra have Shothahara actions, and it cures inflammations. Gambhari, Draksha, Parushak, Kasmard, Sahachar, Shatavari etc. drugs and Ghrit itself have Madhura Rasa, Prithvi, Jala Mahabhuta Pradhanata and Brihana property which improve the endometrial thickness and prepare the endometrium for implantation. Madhura rasa increases secretion and decreases degeneration of cervical epithelial cells. Madhura rasa and Vipaka nourishes Rasa, Rakta, Mansa Dhatu and give them strength.[17]Shatavari nourishes the endometrium and prepares the reproductive organs for conception and prevents threatened abortion. Shatavari contains precursor of estrogen i.e. phyto-estrogens, which increases amount of cervical mucus, motility and density of sperms in cervical mucus.[18]Here, in this particular research work, Ghrit is used. Due to its Snehana and Jeevaniya properties, Ghrit nourishes local cells. Ghrit stimulates Sthanika Agni and reduces Ama. Due to its Sukshma guna it enters into small channels and corrects the Sangatmaka Srotodushti. Modern science states that Ghrit is lipophilic, thus it diffuses rapidly across the cell membrane. Ghrit can also cross blood brain barrier and acts on central nervous system i.e hypothalamus and pituitary gland and may correct hormonal imbalance. Ghrit contains cholesterol which is responsible for the synthesis of steroid hormones i.e. estrogen and progesterone.

CONCLUSION

Clinical trial completed on total 15 patients of infertility out of these 2 patients conceived i.e. result was 13.33%. During and after the treatment no adverse effect or complications were produced. So this treatment is safe, economic, non-surgical and effective and can be recommended for the management of

Vandhyatwa. Considering the time bound duration of study with small sample size and limited resources for conducting this clinical trial, drawing the precise conclusions would be premature so number of patients in large scale will be more valid in suggesting efficacy of the drug.

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