A CLINICAL STUDY OF KASHMARYADI GHРИT УТΤАР BASTI IN FEMALE INFERTILITY

Baranwal Deepika 1*, Dave Hetal H 2

1. M.S. Scholar, P.G. Department of Prasuti and Stree Roga, National Institute of Ayurveda, Jaipur, Rajasthan, India
2. Assistant Professor, P.G. Department of Prasuti and Stree Roga, National Institute of Ayurveda, Jaipur, Rajasthan, India

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*Corresponding author
E-mail: deepika.brnwl11@gmail.com

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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. 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. Yonidoshha, Mansika-abhitupa, Shukra-artava dosha, Ahara-Vihara Doshha, Akalyoga (Coitus at improper time), Bala-kshaya which causes delay in achieving conception in Sapraja women as well as in Apraja. 4

Acharya Sushruta has propounded four factors responsible for Garbhapathti (Conception). 4 They are Ritu, Kshetra, Ambu & Beeja. Ritu means fertile period. Dallhana 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 & spermatzoa). 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. In female, ovulatory factors are responsible for infertility in 27%, tubal/uterine factors in 22%, others 9% and unexplained cause in 17% cases.

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. Patien 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

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

Table 1: Ingredients of Kashmaryadi ghrit

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

Table 2: Administration of drug

<table>
<thead>
<tr>
<th>Drug</th>
<th>Kashmaryadi ghrit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose and Route</td>
<td>5 ml Intruterine administration after 24 hours of stopping menstrual cycle for 3 alternate days for 3 consecutive cycles. Utttar Basti was started after 1 Anuvasan Basti (Dashmool Oil) + 1 Nuruha Basti (Dashmool kwath) + 1 Anuvasan Basti (Dashmool Oil) in each cycle</td>
</tr>
<tr>
<td>Duration</td>
<td>3 months</td>
</tr>
</tbody>
</table>

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

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

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

Table 4: Effect of therapy on objective parameters

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

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

Table 5: Effect of therapy on conception

<table>
<thead>
<tr>
<th>Total number of patients</th>
<th>Effect based on conception</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Conception</td>
</tr>
<tr>
<td>15</td>
<td>02</td>
</tr>
</tbody>
</table>

During or after treatment 13.33% patients conceived.
Draksha is indicated in the function of Tridosha Vata Dosha Pakvashyagata Acharya Charaka Margavarodha (Avrita Apana Amalaki, Draksha, Gambhari, Srotoshodhana formation of Dhatus regulates Agni, maximum Kashaya and Tikta Rasa, Ushna Veerya, Madhura Veerya, Vipaka, Guna and Doshaghnata female achieve conception quickly. Charaka Basti overcomes the vitiated Kapha Dosha. Basti Shamak, Bri treatment. Sneha associati Vatanulomaka and Pakvashaya Shudhdhikara. In case of vitiation. For Avrita Apana Vayu Avarana and Svanidana prakopa without vitiated Vata undertaken twenty Yonivyapad Vandhyatwa. Thus especially for Yoni Vikaras has states that once the Vata Pachana and Amadosha -Dhatu Pitta Dosha Daha, Srava, Shosha etc. have the Sara and Ghrit itself have Madhura Rasa, Prithvi, Jala Mahabhuta Draksha, Parusha 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. Madhura 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 Yonisodhahara action, 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. 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. 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 Srotodushni. 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 infertility. 

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**Graph 7: Percentage of conception in specific factors**

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. Vandhyatwa has also been described in eighty types of Vata Viyakas. Margavarodha, Dhatuksheyam, Avarana and Svanidana prakopa are the main reasons for Vata vitiation. For Avrita Apana Vayu with Kapha Dosh, the treatment should be Agnideepaka, Srotoshodhana, Vanamulomaka and Pakvashaya Shuddhidikara. In case of association of Avarana of Pitta Dosa Daha, Srava, Shosha etc. which required Pittashamak, Sheeta and Brihana treatment. Sneha-kalpana is the best treatment for the Ruksha Vata Dosa. Ghrit is also said to be Yogavahi, Vata-Pitta Shamak, Brihana and with its Sanskar-anuvartana guna it also overcomes the vitiated Kapha Dosa. 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. Drug acts through its Rasa, properties, which corrects metabolism, results in proper formation of Dhatus and Upadhatu (Artava) and Srotoshodhana by removing Ama. Haritaki, Vibhitaki, Amalaki, Draksha, Gambhari, Parushak have the Sara guna and Virechana action so that they regulate Doshas by Sanshodhana karma. The vitiation of Vata may be due to Margavarodha (Avrita Apana Vayu) with Kapha Dosa. Acharya Charaka has mentioned Triphala for Virechana in Pakvashayagata Dosa and Pakvashaya is the main shtana of Vata Dosa 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. 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 Yonisodhahara action, 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. 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. 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 Srotodushni. 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**

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

Average % improvement in both subjective and objective parameters:
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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