CLINICAL STUDY TO EVALUATE THE EFFICACY OF KASHMARYADI GHRIT IN VANDHYATWA W.S.R. TO FEMALE INFERTILITY

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ABSTRACT
Motherhood is a boon to a women’s existence. This blessing from God is being interfered by the fast paced lifestyle of modern world affecting the female health adversely. As a result, infertility has been observed as an emerging health issue. 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. In present era Vandhyatwa has been one of the major clinical challenge which is yet to be resolved. Ayurveda may give a promising hand to cure this disease. So to find effective treatment of Vandhyatwa, without any side effect, Kashmaryadi ghrit oral treatment was selected. 15 patients were selected randomly for present clinical trial study. Highly significant results are observed in follicular study, Very significant results are shown on fern test and spinnbarkeit test. Based on the observations it can be concluded that Kashmaryadi ghrit is an effective drug for the management of female infertility.

Keywords: Vandhyatwa, Kashmaryadi ghrit

INTRODUCTION
Infertility is defined as a failure to conceive within one or more years of regular unprotected coitus. Primary infertility denotes those patients who have never conceived. Secondary infertility indicates previous pregnancy but failure to conceive subsequently¹. Infertility does not threaten physical health but has a strong impact on psychological and social well-being of the couples. Hence, infertility is of public health importance, especially in developing countries because of its high prevalence and its serious psychological, financial and social implications.

Conception depends on the fertility potential of both the male and female partner. 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.¹

In Ayurveda infertility is termed as ‘Vandhyatwa’ According to Acharya Susruta, four main factors required for the proper conception are:²

1. Ritu (Fertile period)
2. Kshetra (Healthy uterus)
3. Ambu (Proper nutrient fluid)
4. Beeja (Viable ovum & sperm)

Presence of any abnormality in any of the above said factors causes Infertility.

In modern science causes are-3
1. Male-25 %
2. Ovulatory—27 %
3. Tubal/Uterine—22%
4. Other—9%
5. Unexplained-17%

Nowadays acceptability of Ayurveda as mode of therapy and treatment for infertility is increasing and people endorsed their faith in this branch of medicine, which occupies its prominence in the naturally available herbs. Ayurveda may give a promising hand to cure this disease. As the subject matter discussed in Ayurveda, it becomes necessary to study, understand and prove them particularly in light of modern scientific parameters in the present era.

AIMS AND OBJECTIVES: To evaluate the effect of Kashmaryadi Ghrit orally in female infertility in order to search for a safe, affordable and non-surgical treatment for female infertility.

MATERIAL AND METHODS:
Selection of the patients- Total 17 clinically diagnosed patients of infertility from OPD & IPD of NIA, Jaipur were selected for the present clinical trial and informed consent was obtained. Out of which 15 patients 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 classical 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.

Exclusion 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
- Montoux 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:

<table>
<thead>
<tr>
<th>Drug name</th>
<th>Latin name</th>
<th>Parts used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gambhari</td>
<td>Gmelina arborea Roxb</td>
<td>Fruit</td>
</tr>
<tr>
<td>Haritaki</td>
<td>Terminalia Chebula Retz.</td>
<td>Fruit</td>
</tr>
<tr>
<td>Bibhitak</td>
<td>Terminalia bellirica Roxb.</td>
<td>Fruit</td>
</tr>
<tr>
<td>Amalaki</td>
<td>Emblica officinalis Gaertn.</td>
<td>Fruit</td>
</tr>
<tr>
<td>Draksha</td>
<td>Vitis vinifera Linn</td>
<td>Fruit</td>
</tr>
<tr>
<td>Kasmard</td>
<td>Cassia occidentalis Linn</td>
<td>Fruit</td>
</tr>
<tr>
<td>Parusak</td>
<td>Grewia asiatica Linn</td>
<td>Fruit</td>
</tr>
<tr>
<td>Punarnava</td>
<td>Boerhavia diffusa Linn</td>
<td>Mula (Root)</td>
</tr>
<tr>
<td>Haridra</td>
<td>Curcuma longa Linn</td>
<td>Kand</td>
</tr>
<tr>
<td>Daru haridra</td>
<td>Berberis aristata DC</td>
<td>Mula</td>
</tr>
<tr>
<td>Kaknaasa</td>
<td>Asclepias curassavica Linn</td>
<td>Mula</td>
</tr>
<tr>
<td>Sahachar</td>
<td>Barleria prionitis Linn</td>
<td>Patra(Leaf)</td>
</tr>
<tr>
<td>Shatavari</td>
<td>Asparagus racemosusWilld.</td>
<td>Kand</td>
</tr>
<tr>
<td>Guduchi</td>
<td>Tinospora cordifolia Willd.</td>
<td>Kand</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>Kashmamyadi ghrit</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOSE</td>
<td>5 ml twice a day with hot milk (200 ml)</td>
</tr>
<tr>
<td>ROUTE</td>
<td>Oral</td>
</tr>
<tr>
<td>DURATION</td>
<td>3months</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. 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 improvement 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 grading’s- 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-

Table 3: Effect of therapy on Subjective parameters--

<table>
<thead>
<tr>
<th>S.N.</th>
<th>Parameter</th>
<th>N</th>
<th>Mean</th>
<th>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>1</td>
<td>Amount of menses</td>
<td>15</td>
<td>0.533 0.266</td>
<td>0.266</td>
<td>49.9</td>
<td>0.704</td>
<td>0.182</td>
<td>3</td>
<td>&gt;0.05</td>
<td>N.S.</td>
</tr>
<tr>
<td>2</td>
<td>Interval of menses</td>
<td>15</td>
<td>0.467 0.067</td>
<td>0.400</td>
<td>85.65</td>
<td>0.507</td>
<td>0.131</td>
<td>21</td>
<td>&lt;0.05</td>
<td>S</td>
</tr>
<tr>
<td>3</td>
<td>Duration of menses</td>
<td>15</td>
<td>0.600 0.066</td>
<td>0.533</td>
<td>88.83</td>
<td>0.915</td>
<td>0.236</td>
<td>10</td>
<td>&gt;0.05</td>
<td>N.S.</td>
</tr>
<tr>
<td>4</td>
<td>Dysmenorrhoea</td>
<td>15</td>
<td>0.933 0.266</td>
<td>0.666</td>
<td>71.38</td>
<td>0.48</td>
<td>0.12</td>
<td>55</td>
<td>&lt;0.01</td>
<td>V.S.</td>
</tr>
<tr>
<td>5</td>
<td>Dyspareunia</td>
<td>15</td>
<td>0.666 0.200</td>
<td>0.466</td>
<td>69.96</td>
<td>0.639</td>
<td>0.165</td>
<td>21</td>
<td>&lt;0.05</td>
<td>S</td>
</tr>
</tbody>
</table>

Very significant results are shown in Dysmenorrhoea. Significant results are shown in Interval of menses and Dyspareunia.

Table 4: Effect of therapy on Objective parameters-

<table>
<thead>
<tr>
<th>S.N.</th>
<th>Parameter</th>
<th>N</th>
<th>Mean</th>
<th>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>1</td>
<td>Follicular study</td>
<td>15</td>
<td>1.867 0.933</td>
<td>0.933</td>
<td>49.97</td>
<td>0.704</td>
<td>0.18</td>
<td>66</td>
<td>≤0.001</td>
<td>HS</td>
</tr>
<tr>
<td>2</td>
<td>Endometrial thickness</td>
<td>15</td>
<td>1.000 0.467</td>
<td>0.533</td>
<td>53.30</td>
<td>0.74</td>
<td>0.19</td>
<td>21</td>
<td>&lt;0.05</td>
<td>S</td>
</tr>
<tr>
<td>3</td>
<td>Fern test</td>
<td>15</td>
<td>2.133 0.933</td>
<td>1.200</td>
<td>56.25</td>
<td>1.474</td>
<td>0.385</td>
<td>56</td>
<td>&lt;0.01</td>
<td>VS</td>
</tr>
<tr>
<td>4</td>
<td>Spinnbarkeit test</td>
<td>15</td>
<td>1.267 0.600</td>
<td>0.667</td>
<td>52.64</td>
<td>0.617</td>
<td>0.159</td>
<td>45</td>
<td>&lt;0.01</td>
<td>VS</td>
</tr>
<tr>
<td>5</td>
<td>Post coital test</td>
<td>15</td>
<td>0.266 0.200</td>
<td>0.066</td>
<td>24.81</td>
<td>0.258</td>
<td>0.066</td>
<td>1</td>
<td>&gt; 0.05</td>
<td>NS</td>
</tr>
</tbody>
</table>

Highly significant results are observed in follicular study. Very significant results are shown in Fern test and SB test. Significant results are shown on endometrial thickness.

Table 5: Effect of therapy on conception-

<table>
<thead>
<tr>
<th>Total no. of pts.</th>
<th>Conception</th>
<th>No conception</th>
<th>% relief</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>03</td>
<td>12</td>
<td>20.00</td>
</tr>
</tbody>
</table>

During or after treatment 20.00% patients conceived.

Graph 1: Effect on Follicular study-

(BT-Before treatment, AT-After treatment)
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**Graph 2:** Effect on Endometrial thickness

- Before treatment (BT): 26.6%
- After treatment (AT): 53.3%

**Graph 3:** Effect on Fern test-

- No crystallization (BT): 53.3%
- Atypical fern formation (BT): 26.6%
- Primary and secondary stem (BT): 46.6%
- Tertiary stem (BT): 33.3%

(BT-Before treatment, AT-After treatment)

**Graph 4:** Effect on Spinnbarkeit test-

- 0-8 mm (BT): 13.3%
- 8-14 mm (BT): 46.6%
- 1-4 mm (AT): 40%
- <1 mm (AT): 6.6%

(BT-Before treatment, AT-After treatment)
**DISCUSSION**

Probable Mode of Action of Kashmaryadi Ghrity-

- The contents of Kashmaryadi Ghrity are Gambhari, Triphala, Draksha, Kasmard, Parushak, Punarnava, Haridra-dvaya, Kaknaasa, Sahachar, Shatavari, Guduchi, Goghrit etc. Most of the drugs are Madhur, Tikta and Kashaya rasa pradhan, Ushna Veerya, Madhur Vipaka, Laghu and Ruksha guna pradhanaya.
- Gambhari is Garbhasthapak\(^5\), so helps in conception.
- Some drugs like Amalaki, Haritaki, Guduchi and Kaknasa are Rasayana drugs\(^5\). These drugs are beneficial for proper nourishment of all Dhatus and Upadhatus. By improving
strength of all dhatus including Rasa and its Upadhatu may be formation of Beeja is improved by proper nourishment.

- Gambhari, Triphala, Haridra-dvaya, Kasmard, Guduchi, Punarnava etc. have Deepana, Pachana properties so that it regulates Jatharagni, Dhatvagni and Bhutagni which corrects metabolism at cellular level, which results in proper formation of Dhatus and Upadhatu (Artava) and Srotoshodhana by removing Ama.

- 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 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 specially Avrita Apana Vayu.

- Draksha is indicated in Grbhashayadaurbalya. Because of Madhur rasa and Sheet veerya it may increase the muscular strength of reproductive system. Draksha is Soumanasyajanana and Acharya Charak said that Soumnasya garbhadharmanam.

- Triphala, Haridra, Daruharidra have Yonidoshahara action so that it pacify local inflammation and infection and it is mentioned in our classics that conception only occurs in Shuddha Yoni.

- Gambhari, Kasmard, Punarnava, Kaknasa, Sahachar, Haridra have Shothahara actions, it cures inflammations.

- Gambhari, Draksha, Parushak, Kasmard, Sahachar, Shatavari, etc. drugs and Ghrit itself have Madhura Rasa, Pritivi, Jala Mahabhuta Pradhanata and Brimhana property which is responsible for Upachaya thereby improves the endometrial thickness. Madhura rasa increases secretion and decreases degeneration of cervical epithelial cells. Madhura rasa and Vipaka nourishes Rasa, Rakta, Mamsa Dhatu and give them strength.

- Shatavari totally nourishes the female reproductive organs causing it to be very effective in enhancing the fertility. It nourishes the womb and ovum and prepares the reproductive organs for conception and prevents threatened miscarriages. Shatavari contains phyto-estrogens, the precursor of estrogen. Due to this effect increases amount of cervical mucus, motility and density of sperms in cervical mucus.

- The causative factor of infertility is mainly vitiation of Vata. Acharya Charak says that all the gynecological disorders are due to vitiation of Vata and maximum drugs of Kashmaryadi ghrit having Vatashamak and Vatanulomak action. By normalize Doshas it may ensure proper functioning of Dhatus.

- Ghrit has property of Samskaranuvartan i.e. it can imbibe the properties of ingredient without losing its natural properties. It is Yogavahi so it carries active principles of the drugs to increase the potency of the compound drug.

- Goghrit has Agnivardhak, Rochaka, Rasayana, Vrishya properties.

- In general, the blood cerebrospinal fluid and the blood brain barriers are highly permeable to water, carbon dioxide, oxygen, and most lipid soluble substances, and slightly permeable to electrolytes such as sodium chloride and potassium. The more lipophilic the drug is, the more likely it is to cross the 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.
Mode of Action of Kashmaryadi Ghrit- On Cervical Factor-

Laghu Guna→ ↓ Pichchhilata of Kapha → ↓Viscosity & Spinnbarkeit↑
Madhura Rasa → Anabolic action → ↑Secretory units→ ↑Amount

Deepana, Pachana, Anulomana → Proper function of receptor mechanism →Ferning

Sheeta and Mridu Guna pacifie the Ushna and Tikshna Guna of Pitta and decreases acidic mucous.

On Ovulation-

CONCLUSION

- As a result of the clinical trial done on total 15 patients of infertility total 3 patients conceived i.e. 20.00% result.
- No adverse effect or complications were produced with the use of this treatment. So this treatment is found to be safe, economic, nonsurgical and effective and can be recommended for the management of unexplained cases of Vandhyatwa.
- Considering the time bound duration of study with small sample size and limited resources for conducting this clinical trial, drawing concrete and 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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Source of Support: Nil
Conflict Of Interest: None Declared

How to cite this URL: Baranwal Deepika & Dave Hetal H: Clinical Study To Evaluate The Efficacy Of Kashmaryadi Ghrit In Vandhyatwa W.S.R. To Female Infertility. International Ayurvedic Medical Journal {online} 2018 {cited March, 2018} Available from: http://www.iamj.in/posts/images/upload/529_537.pdf