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.4 Infertility causes 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 knowledge.2

In Ayurveda infertility is termed as ‘Vandhyatwa’. Acharya Charak has clearly described the Nidanas of Vandhyatwa i.e. Yonidosha, Mansika-ahhitupa, 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.1

Acharya Sushruta has propounded four factors responsible for Garbhotpatti (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 Aartava-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

After Treatment
- Follicular study
- Cervical mucous – Fern test, Spinnbarkeit Test
- Urine pregnancy detection test. (After 7 days 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)|
| Parasak     | Grewia asiatica Linn           | Phala(Fruit)|
| Panarnava   | Boerhavia diffusa Linn         | Mool(Root) |
| Haridra     | Curcuma longa Linn             | Kand(Tuberous root) |
| Daru haridia| Berberis aristata DC           | Mool(Root) |
| Kaknaasa    | Asclepias curassavica Linn     | Mool(Root) |
| Sahachar    | Barleria prionitis Linn        | Patra(Leaf) |
| Shatavari   | Asparagus racemusus Willd.     | Kand(Tuberous root) |
| Guduchi     | Tinospora cordifolia Willd.    | Kaand(Stem) |
| Goghrit     |                                |            |

Table 2: Administration of drug

| Drug                | Kashmaryadi ghrit                  |
|---------------------|-----------------------------------|
| Dose and Route      | 5 ml Intruterine 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 BT | Mean AT | Mean Diff. | %   | S.D. (%) | S.E. (%) | 'W' | P    | Result |
|----------------------------|----|---------|---------|------------|-----|----------|----------|-----|------|--------|
| 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   | 0.600      | 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 BT | Mean AT | Mean Diff. | %   | S.D. (%) | S.E. (%) | 'W' | P    | Result |
|----------------------------|----|---------|---------|------------|-----|----------|----------|-----|------|--------|
| 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.

Graph 1: Effect on follicular study

Graph 2: Effect on Endometrial Thickness

Graph 3: Effect on Fern test

Graph 4: Effect on Spinnbarkeit test
Vandhyatwa has not been described as a separate disease in Ayurvedic classics, but all the gynecological disorders are undertaken twenty Yoniyapad. The Yoni never gets diseased without vitiated Vata. Vandhyatwa has also been described in eighty types of Vata Vikaras. Margavarodha, Dhatukshaya, Avarana and Svanidana prakopa are the main reasons for Vata vitiation. For Avrita Apana Vayu with Kapha Dosa, the treatment should be Agnidipaka, Srotoshodhana, Vatunolumaka and Pakvashaya Shuddhkara. In case of association of Avarana of Pitta Dosha Daha, Srava, Shosha etc occurs, which required Pittashamak, Sheeta and Brihanka treatment. Sneha-kalpaka is the best treatment for the Rukska Vata Dosha. Ghrit is also said to be Yogavahi, Vata-Pitta Shamak, Brihanka 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.16Drug acts through its Rasa, Vipaka nourishes the endometrium. Vandhyatwa is the best treatment for the Ruksha Rasa, Kasmard, Punarnava, Kaknasa, Sahachar, Haridra have Shothahara actions, and it cures inflammations. Gambhari, Draksha, Parushak, Kasmard, Sahachar, Shatavarti etc. drugs and Ghrit itself have Madhura Rasa, Prithvi, Jala Mahabhuta Guna, Veerya, Vipaka and Prabhava Guna, Veerya, Vipaka nourishes the endometrium 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 Jeevaniya properties, Ghrit nourishes local cells and prepare the endometrium for implantation. As the Ghrit itself has Madhura Rasa, Prithvi, Jala Mahabhuta Guna, Veerya, Vipaka and Prabhava Guna, Veerya, Vipaka nourishes the endometrium and prepare the endometrium for implantation. Ghrit is used to correct hormonal imbalances, 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 guna13 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 Dosa. Acharya Charaka has mentioned Triphala for Virechana in Pakvashyagata Dosa14 and Pakvashaya is the main shtag 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-daurbalya15. 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 action16, 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, Shatavarti etc. drugs and Ghrit itself have Madhura Rasa, Prithvi, Jala Mahabhuta Pradhanata and Brihanka 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 Jeevaniya properties. Ghrit nourishes local cells. Ghrit contains cholesterol which is responsible for the synthesis of steroid hormones i.e. progesterone and estrogen. As the Ghrit itself has Madhura Rasa, Prithvi, Jala Mahabhuta Guna, Veerya, Vipaka and Prabhava Guna, Veerya, Vipaka nourishes the endometrium and prepare the endometrium for implantation. 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. progesterone and estrogen.

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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Cite this article as:
Baranwal Deepika and Dave Hetal H. A clinical study of Kashmargadi ghiurt uttar basti in female infertility. Int. J. Res. Ayurveda Pharm. 2018;10(1):35-39. http://dx.doi.org/10.7897/2277-4343.10019

Source of support: Nil, Conflict of interest: None Declared

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