CLINICAL TRIAL OF PHALAGHRITA ON FEMALE INFERTILITY

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ABSTRACT: The present study was carried out in a sample of 30 numbers of female infertility cases with the use of phalagritam in the from of intra uterine insuffilation. After the treatment of three consecutive cycles an overall encouraging result was observed which will be represented in the full paper.

INTRODUCTION:

Stree bandhyatwa or female infertility a gynaecological disorder is not fatal, but hinders the of progeny. The aetiological factors include the defect in the union of sperm and ovum during fertile period. Defect in uterus, cervix and fallopian tube, defect in ovulation and defect in hormonal function. (Defect in Ritu. Kshera, Ambu and Beeja).

Thirty patients of infertility were taken for the present study after proper clinical and laboratory investigations, and the cause of infertility was traced out.

The trial drug phalaghrita was administered in the form of uttaravasti in each cycle (after cessation of menstrual bleeding ) for three successive cycles. The effectiveness was evaluated based upon the cause of infertility. It was revealed that phalagrita uttaravasti was having 46.67% effectiveness of its cause of female infertility irrespective of its cause.

MATERIALS & METHOD:
This is a controlled single blind clinical trial confined only to female infertility and its management. Thirty patients of female infertility including both primary and secondary were taken by multiphase random sampling method and screened according to the selection criteria.

Criteria for selection of cases:
Prior to trial consent was obtained form each patient and registered. The criteria applied for selection of cases were as follows. Married female patients within the age group of 20-30 yrs.

a) Subjective criteria
i) Pain in lower abdomen
ii) Tenderness in lower abdomen
iii) Back ache
iv) Head reelig
v) Head ache
vi) Weaknees
vii) Character, duration and interval of menstruation.

b) Objective criteria
i) Infertility (No conception)
ii) Ovulation negative
iii) Blockage of fallopian tubes.

Exclusion criteria: Patients with
i) Infertility of age below 20 years and above 35 years  
ii) Congential absence or deformities of uterus  
iii) Ovarian tumours  
iv) Cancer of cervix or uterus  
v) Tubectomy  
vi) Diabetes mellitus positive cases.  
vii) V.D.R.L. Positive cases.  
viii) Monutoux positive cases  
ix) Thyrotoxocosis  

Were excluded from the study.

Drug and Dose:
The trial drug phalaghrita described in sharangadhara was prepared by purifying (Murchhita) cow’s ghee with triphala, musta, haridra and lemon juice. Then the thirteen herbs such as Triphala, sahachara, saireyaka, Guduchi, Punarnava, Syonaka, Twak, Haridra, Daru haridra, Rasna, Meda and Satavari were put into that murchhita ghrita, after being cooked with four times cows milk and eight times water in ghrita paka vidhi. The prepared drug was standardized by physiochemical analysis.

The Trial drug phalaghrita is Ghee based herbal preparation. It is applied locally as an intrauterine insufflation or uttaravasti by a specially designed vasti yantra in the dose of 3-5 ml day for to total 9 days in three months. During the process of uttaravasti patients were watched carefully for occurrence of pain, discomfort or any other symptoms. Complete aseptic measures were adopted during the process.

ASSESSMENT:
Assessment was done in each month upto 3 consecutive cycles and after three months of follow up, the initial finding through questionnaire; clinical and pathological statements were compared with the result of progressive 1st month 2nd month, 3rd month and 6th month. The clinical assessment was made depending upon the changes in subjective and objective features such as

1. Fertility or Amenorrhea along with positive response in preg colour card test.  
2. Ovulation positive by premenstrual endometrial biopsy.  
3. Patency of fallopian tubes by hysterosalpingography  
4. Regulation and relief of associated symptom of menstruation  
5. 5. Abolishment of sexual problems in intercourse.  
6. Relief from associated symptoms like pain, tenderness in lower abdomen, head ache Head reeling, back ache and weakness.  

The clinical assessment of result was being done as cure 100% ,maximum improvement 75-99%, moderate improvement 50-74%, mild improvement 25-49% and no improvement < 25% free from signs like infertility, unovulator cycles and tubal blockage.

OBSERVATION:
Thirty number of patients having the complain of childlessness were taken after proper clinical and laboratory investigations. All these case were thoroughly examined to trace out the cause of infertility, and were noted in a specially designed case-sheet to follow up the progress during the treatment period.

The clinical observation from different aspects aspects approaching to the treatment for the entire patients had been represented showing the incidences statical analysis of effectiveness of trial
drug along with clinical assessment of result.

The incidence of infertility was observed that 50% case were within the age group of 26-30 yr and had the duration of infertility within 1-3 years regarding the age of marriage. Occupation and type of infertility 46.67% of cases had got married within the age of 21-25 yr. 70% patients were house wives and 70% patients were house wives and 70% cases were also of primary infertility, Uterine, cervical, Tubal, ovulatory and unexplained are being the causes of infertility, there were 50% cases with uterine cause, 40% with cervical cause, 30% tubal cause, 16.67 ovulatory cause, 6.67% unexplained cause.

Regarding the clinical sign and symptoms 73.33% of patients had weakness 53.33% had pain in lower abdomen 43.33% had tenderness in lower abdomen and back ache 40% of patients had head reeling 36.67% of patients were having head ache dysmenorrhoea and dryness in vagina 30% patients had menorrhagia and burning sensation in vagina. 20% patients had oligmenorrhoea and dyspareunia.

After treatment of three months it was evident that the clinical sign and symptoms indifferent patients which were in severe to mild degree were relieved abosolutly 100% indicating the highly effectiveness of the trial drug. Depending upon the cause of infertility and its percentage of improvement before and after treatment 46.67% of patients experienced amenorrhoea 60% of patients reported ovulatory cycles and 50% get relieved from tubal blockage. Out of the study the clinical assessment as a hole signify the effectiveness of the trial drug that favourable results were obtained in 60% of cases out of which 43.33 % cases were cured, 10% were in moderate improvement and 6.67% were in mild improvement.

The clinical pathological and radiological findings on every point have statistically analysed and configurated with pairedt test inorder to prove its significance in scientific manner.

Observations regarding the effectiveness of trial drug to infertility, its investigations and associated sign and symptoms was carries out by comparing the mean+-S.D value of each response before and after treatment. Finally the drug was found significantly effective in tubal blockage. And infertility with a P-value <0.05 and highly significant in all other associated sign and symptoms with a P- value of <0.01.

DISCUSSION:
Base pm the observation and result every aspects related to the management of infertility was discussed scientifically.

Bandhyatwa being a vatic disorder demands vasti karma with local snehana (soothing effect) and tarpana (nourishment of endometrium). So uttara vasti with phalaghrita was selected and administered keeping in view the above factors and textual hypothisis.

Endometrial biopsy was done to ensure ovulation. Form endometirum biopsy 5 patients (16.67%). Were reported non secretory endometrium before treatment. After treatment one cycle one patient had conceived with an evidence of ovulation.
Hystero salpingography was done to evaluate the effect of trial drug on blockage of fallopian tube. From H.S.G. 9(30%) patient were found with tube blockage. Out of them 3 patients had blockage on both the tubes and 6 had unilateral blockage. After treatment of one cycle 8.33% of patients were reported with conception and after the treatment of 3rd cycle 50% of cases were reported with patient fallopian tube. Out of the total cases of blacked fallopian tubes 6 patients became pregnant by the end of treatment schedule Dr. Cherny et al 1998 reported 29% pregnancy when an oil based contrast dye was used durante H.S.G., compared to 13% pregnancy rate with water soluble dye. Which suggests the opening of blocked tube with oil based dye. Phalaghritam being an oily preparation used therapeutically for the treatment of infertility. It is assumed that it might have opened the fallopian tube.

Though proper scientific hypothesis could not be traced out, three out of five number of unovulatory case showed ovulation after the treatment with phalaghrita. As regards the other symptoms associated with infertility, like irregular menstruation lower abdominal pain and tenderness, dyspareunia; a remarkable improvement has been observed in the present study.

CONCLUSION:
Thus it can be concluded that uttaravasti of phalaghrita is definitely an effective one in the treatment of infertility. It has also a significant effect on other localize complaints like menstrual disorder, lower abdominal pain, tenderness and dysparenia. Further study on a large sample is needed to confirm the efficacy of the drug.

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TABLE NO -1 : PHYSIO-CHEMICAL ANALYSIS OF PHALAGHRITA

| No. | Property          | Description       | No. of patients | Percentage |
|-----|-------------------|-------------------|-----------------|------------|
| 1   | Colour            | Greenish Yellow   | 7.7             |            |
| 2   | Smell             | Fragrant          | 8.6             |            |
| 3   | Touch             | Greasy            | 9.7             |            |
| 4   | Taste             | Astringent        | 10.7            |            |
| 5   | Loss on during at 110oC | 0.43% w/w | 11.7             |            |
| 6   | Volatile oil      | 0.34% w/w         | 12.7            |            |

| No. | Property          | Description       | No. of patients | Percentage |
|-----|-------------------|-------------------|-----------------|------------|
| 7   | Refractive index at 40o | 1.453            |                 |            |
| 8   | Ash value         | 0.03% w/w         |                 |            |
| 9   | Acid value        | 1.99              |                 |            |
| 10  | Saponification value | 223.40          |                 |            |
| 11  | Iodine            | 38.41             |                 |            |
| 12  | Total fat         | 97.43             |                 |            |

TABLE NO -2 : Showing the causes of infertility =30

| Case of infertility | No. of patients | Total | Percentage |
|---------------------|-----------------|-------|------------|
|                     | Primary         |       |            |
| Uterine             | 11 (36.67%)     | 15    | 50%        |
| Cervical            | 10 (33.33%)     | 12    | 40%        |
| Tubal               | 5 (16.67%)      | 9     | 30%        |
| Ovulatory           | 5 (16.67%)      | 5     | 16.67%     |
| Unexplained         | 13.33%          | 2     | 6.67%      |
|                     | Secondary       |       |            |

| Case of infertility | No. of patients | Total | Percentage |
|---------------------|-----------------|-------|------------|
|                     | Primary         |       |            |
| Uterine             | 4 (13.33%)      |       |            |
| Cervical            | 2 (6.67%)       |       |            |
| Tubal               | 4 (13.33%)      |       |            |
| Ovulatory           | 0               |       |            |
| Unexplained         | 1 (3.33%)       |       |            |

TABLE NO. -3 : Showing the clinical assessment of result N= 30

| Clinical Assessment | AT(1) | AT(2) | AT(3) |
|---------------------|-------|-------|-------|
|                     | No. of Pt. | %  | No. of Pt. | %  | No. of Pt. | %  |
| Cured               | -    | -    | -    | -    | 13 | 43.33 |
| Maximum Improvement | -    | -    | -    | -    | -  | -    |
| Moderate Improvement| 1    | 3.33 | 5    | 16.67| 3  | 10    |
| Mild Improvement    | -    | -    | 1    | 3.33 | 2  | 667   |
| No. improvement     | 29   | 96.67| 24   | 24   | 12 | 40    |