A CLINICAL STUDY OF APAMARGA MULA IN VANDHYATWA W.S.R TO ANOVULATION
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ABSTRACT
Anovulation is one of the common gynecological problems faced in daily practice. The most common cause of infertility is ovulatory disorder characterized by anovulation or by infrequent and or irregular ovulation. Ovulation failure is not only headache of this era but also was a problem in the ancient period.

40 patients were selected by simple randomized method & being diagnosed with anovulatory cycles according to inclusion & exclusion criteria & were given Apamarga mula churna 6gm in divided dose for three consecutive cycles. Entire patients were assessed clinically, pathologically & sonographically before treatment & after treatment. The result is 50% cured, 42.5% improved & 7.5% showed no change. Most of the patients ovulated and many of them relieved of menstrual symptoms like oligomenorrhoea. Thus Apamarga mula was found effective in Vandhyatwa w.s.r Anovulation.

KEY WORDS: Anovulation, Vandhyatva, Apamarga mula churna

INTRODUCTION: Acharya Manu has stated that, प्रजन्तारथम् स्त्रीः सृष्टया। Infertility was attached with a lot of social stigma during the period of Charaka. Infertile couples were considered as shade less, branchless, fruitless waste tree or like a lamp in a picture or portrait which will not emit any light or brightness. Vandhyatva (female infertility) is a common problem in clinical practice, and diagnostic assessment is important for making the right treatment decisions.
In *Ayurvedic* classics, all the gynaecological disorders are included under twenty *yonivypadas*. *Vandhyatwa* is one among the *yonivypada*. All the four factors namely *Rutu, Kshetra, Ambu* and *Beeja* are of prime importance for conception according to *Acharya Sushruta*. Here the *beija* is taken as *Antahapushpa* i.e ovum. So anovulation can be included under *Beeja dushti*. According to FIGO manual ovarian factor contributes to 15-25% of female infertility. So it is the second common cause of infertility. Ovulatory cause is an important subset in infertility among women, accounting for about 40% of cases (Infertility of Leon Sperrof et.al). Anovulation or inability to produce fertile ovum is an important cause among women with infertility. Ovulation refers to the physical act of rupture of the follicle with the extrusion of the oocyte. When the follicle does not rupture ovulation fails and it is called anovulation. There can be anovulation or severe oligo ovulation. In the latter case even though ovulation does occur, its relative infrequency decreases the woman’s chance of pregnancy. Over the years there has been a significant increase in infertility and childlessness. In conventional medicine there are treatments like clomiphene citrate for ovulation induction, but most of them have side effects. Assisted reproductive techniques are only provided in private centers and are very expensive. There are many advanced therapies of ART such as hormonal therapy, IVF, ET, GIFT etc. but they have unsatisfactory results involving enormous expenses and lots of side-effects like ovarian hyper stimulation, frequent abortion, multiple gestations and major long term possibility of ovarian cancer etc. Ayurveda is a proven age old science of life and it has its own natural scientific approach regarding to line of treatment. Lots of causes of *Vandhyatva* are given in *Ayurvedic* text including *Nastabeesjata* or Anovulation. Nowadays people have accepted *Ayurveda* and endorsed their faith in this branch of medicine, which occupies its prominence in the naturally available herbs. These untouched therapies and medicinal concepts are lying idle in *Samhitas* and
wanting to be tapped in today’s highly scientific world of medicine. It is our meaningful effort coupled with lots of innovative ideas to aim towards uncovering this medicinal concept towards Anovulation. God willing this may prove to be an accepted concept in the coming years. Mandagni is said to be the cause of formation of ama and subsequently vyadhi (Anovulation). Due to ama, rasa dushti (poshanatmakadushti) can cause Anovulation. The vitiated apanavayu and kapha when get mix can cause avaranatmakadusti causing Anovulation. The vitiated Vata along with Pitta causes the artavakshaya i.e. kshayatmakadusti causing Anovulation. So, this compelled us to think that the drug which is fruitful for Agnimandya i.e deepana and pachana drugs may also be useful for anovulation. Keeping this hypothesis in mind and the reference of Gada Nigraha, we planned to carry out some research.

**AIM AND OBJECTIVES:**

1. To study the disease *Stree Vandhyatwa* in detail.
2. To assess the impact and consequences of *Apamarga mula churna* orally on *Stree Vandhyatva*

**DRUG REVIEW:**

*Apamarga mula churna* is administered orally in the dose of 6gm in divided dose with *ksheera* for 15 days (from 5th day of menses up to 19th day) for 3 consecutive cycles, assessment done after each cycle.

**Apamarga**

- **Botanical name**: Acharynthus aspera
- **Family**: Amaranthaceae
- **Genus**: Achyranthes
- **Species**: Aspera

**Ayurvedic Properties**

- **Rasa**: Katu, Tikta
- **Guna**: -, Ruksha, Teekshana
- **Veerya**: - Ushna
- **Vipaka**: - Katu
- **Doshaghanata**: Kaphavatashamaka, kaphapittasamashodhaka

**Part Used**: Mula

**MATERIAL AND METHODS**

**SELECTION OF PATIENTS:**

It is a Single Blind clinical study. 40 patients will be selected on the basis of simple randomized sampling method as per inclusion criteria. Separate charts and case sheets will
be prepared as per norms of the selection criteria. Research will be conducted under the supervision of guide.

**CRITERIA FOR SELECTION OF PATIENTS:**

**INCLUSION CRITERIA:**
1. Married woman, Age group between 20-35 years.
2. Primary and secondary infertile patients with Anovulatory cycles.
3. Anovulatory cycles with or without PCOD.

**EXCLUSION CRITERIA:**
1. Systemic diseases like TB, DM, hyperthyroidism and hyperprolactinaemia, STDs, HIV, HBsAg.
2. Congenital anomalies of reproductive organs.
4. Menorrhagia, metrorrhagia, DUB

**STUDY DESIGN/ MANAGEMENT OF PATIENTS:**
For the present clinical study, 40 patients will be selected on the basis of simple randomized sampling method according to inclusion criteria under a single group.

**Medicine:** *Apamarga mula churna*

**Route:** Orally

*Anupana: Ksheera*

Follow up: Patient was asked to come for follicular study on 12th, 14th, 16th, 18th & 20th day of cycle or till ovulation every month for 3 cycles. And progress is noted on the basis of assessment criteria before and after treatment on every follow up in a specially prepared case sheet. Evaluation of symptoms will be done before treatment after 1st cycle, 2nd cycle and 3rd cycle.

**ASSESSMENT CRITERIA:**

**Objective parameters:**
- Follicular study.

**ASSESSMENT SCALE**
- Fertility will be assessed by absence of menstruation or amenorrhea followed by positive U.P.T.

**CLINICAL ASSESSMENT SCORING METHOD:**
The changes observed in the signs and symptoms were assessed by adopting suitable scoring method and the objective signs by using appropriate clinical tools. The details of scoring pattern adopted for assessment of subjective and objective parameters is as follows:

**Scoring Pattern of Follicle**
- Score 0 = No dominant follicle
Score 1 = Follicle size up to 10 mm
Score 2 = Follicle size ranging from 11-15mm
Score 3 = Follicle size ranging from 16-20mm
Score 4 = Follicle size ranging from 21-30mm
Score 5 = Rupture of follicle (For this scoring method, consecutive three cycles serial TVS were carried out to diagnose anovulation.)

OVER ALL EFFECT OF TREATMENT ON ANOVULATION

The overall effect was graded into 5 types. No response to Therapy 0%
Mild response to therapy 1 – 25%
Moderate response to therapy 25.1% - 50%
Fair response to therapy 50.1% - 75%
Good response to therapy 75.1% - 100%

OBSERVATIONS

For current project work of *Apamarga mula churna* oral treatment package in total 40 patients suffering from *Vandhyatwa* with special reference to Anovulation, fulfilling the both inclusion and exclusion criteria were registered. The observations and the results of the therapy statistically analyzed by following methods.

A) Descriptive observational Statistical Analysis.
B) Assessment of the effect of *Apamarga mula* oral medication in the patients of *Vandhyatwa*, by adapting paired ‘t’ test.

EFFECT ON OBJECTIVE PARAMETER:

**Effect of *Apamarga mula churna* on Follicular Study:**

<table>
<thead>
<tr>
<th>Follow up</th>
<th>BT (Mean)</th>
<th>AT (Mean)</th>
<th>SD</th>
<th>SE</th>
<th>t' Value</th>
<th>P Value</th>
<th>Effect %</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>0.65</td>
<td>1.125</td>
<td>0.7906</td>
<td>0.1250</td>
<td>3.427</td>
<td>0.001</td>
<td>65%</td>
<td>S</td>
</tr>
<tr>
<td>II</td>
<td>0.65</td>
<td>1.750</td>
<td>1.056</td>
<td>0.1670</td>
<td>5.628</td>
<td>0.000</td>
<td>67.5%</td>
<td>HS</td>
</tr>
<tr>
<td>III</td>
<td>0.65</td>
<td>2.650</td>
<td>1.61</td>
<td>0.2546</td>
<td>7.673</td>
<td>0.000</td>
<td>70%</td>
<td>HS</td>
</tr>
</tbody>
</table>

The patients showed increase in the follicular growth during, after treatment and after follow up i.e. 1.125, 1.75 and 2.650 respectively with comparison to initial mean score i.e.0.65. The average percentage was 65% in immediate after treatment.
and 67.5%, and 70% in immediate after follow up. On statistical analysis it was found to be highly significant at the level of $P < 0.000$.

### Graph No.1
Graphical Analysis Based on effect of *Apamarga mula churna* on Follicular study

<table>
<thead>
<tr>
<th>Parameters</th>
<th>No. of pts</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cured</td>
<td>20</td>
<td>50</td>
</tr>
<tr>
<td>Improved</td>
<td>17</td>
<td>42.5</td>
</tr>
<tr>
<td>Unchanged</td>
<td>03</td>
<td>7.5</td>
</tr>
</tbody>
</table>

The assessment of the role of Apamarga mula churna in Vandhyatva w.s.r. to anovulation was among 40 patients of anovulatory cycles and infertile 20(50%) patients cured, 17(42.5%) patients had shown improvement and remaining 3(20%) patients it was unchanged.

### Graph No.2.
Graphical Analysis Based on Total Effect of Apamarga mula Churna in Vandhyatwa w.s.r. to Anovulation.
DISCUSSION:

PROBABLE MODE OF ACTION OF DRUG

The conducted study would not be complete without knowing the pharmacodynamics and pharmacokinetics of the constituent drugs of the formulations that have been used. Drug which is used internally or externally effects through its Rasa, Guna, Virya, Vipaka and Prabhava. Evaluation of action of drugs depends on above points. According to Ayurvedic Classics vitiation of Tridosha is a basic factor in any disease. According to Ayurvedic point of view action of drug on disease depends upon interaction between Tridosha and Drug's rasa panchaka.

Properties of Apamarga mula Churna

The drug used is Apamarga mula churna which contains Katu & tikta rasa, Laghu, ruksha, Tikshna,& Sara guna, Ushna vireya, and Katu vipaka. It can be said that due to Laghu guna it is easily absorbable and it can enter every part of the cells easily. Ushna Virya involved in conversion of androgen to estrogen in graffian follicle.Ushnatwa helps in maturing of follicle by its function of paka karma.

This is the probable mode of action of drug because Acharya Charka said that-dravya can act by its rasa, guna, vireya, vipaka and prabhava.

CONCLUSION:

Infertility is a condition where the couple does not conceive after one or more years of regular & unprotected intercourse.Though the defect in process of fertilization lies in both partners, the female is responsible to 30% of cases. Commonly the lacuna in female reflects as irregular & scanty menstruation which is suggestive of Anovulation, thus contributes 20% cases.It can be concluded that Apamarga mula churna shows significant results in managing anovulation. No untoward effects were observed in patients.The method of treatment applied was simple, economical and required no hospitalization and could be done at OPD level.After treatment it was found that most of the patients had ovulation, & many patients relived of menstrual symptoms like oligomenorrhoea. However efficacy of the drug may be fully established with a large sample size in further research.
Apamarga mula churna is effective in the Management of vandhyatwa in anovulation.

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