OPEN LABEL, SINGLE CENTRE, PROSPECTIVE STUDY TO ASSESS THE EFFICACY OF RAJAHPRAVARTINI VATI IN THE TREATMENT OF PCOS

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ABSTRACT

Initially PCOS was related to infertility only but now it starts with puberty & ends with menopause. The most debilitating underlying disorder which causes Menstrual irregularities, acne, obesity is PCOS, which is not only a reproductive endocrinopathy, but also a metabolic syndrome. As per Ayurveda it is a disease caused by artavavahastrotas dushti may be correlated with udara, vidradhi etc. There are number of formulation which can be used in the symptoms of PCOS. Modern prescriptions for Delayed Menstruation are temporary in effect. Thus there is a need for an effective long lasting medicine. “Rajahpravartini is the prescribed vati” formulation for Menstrual Disorders. Thus, the present study is planned for 30 patients to study action of “Rajahpravartinivati on treatment of PCOS with special reference to Ovulation study. Observation of study shows total three month treatment gives satisfactory result.

Keywords: Rajahpravartini, PCOS

INTRODUCTION

Diseases pertaining to the reproductive system of the women are becoming increasingly common because of modern ways of lifestyle. Modern women are forced to face higher level of stress as they are not only home makers, but are also working women. First and foremost to show systemic abnormal functioning under increased stress is Endocrine system, which in turn effects the menstrual cycle. Thus menstrual abnormalities are becoming increasingly common among working women.

Polycystic ovarian syndrome¹ (PCOS) is a heterogeneous disorder characterized by menstrual irregularities, clinical and/or biochemical hyperandrogenism and hyperinsulinemia.
secondary to reduced insulin sensitivity⁸ and is the most common endocrinopathy in women, affecting 5–10%.

PCOS can be study as anukta vyadhi. PCOS has been defined by number of groups. The first was by the National Institute of Health (NIH) ON APRIL 1990, Which laid down three criteria i) hyper androgenesism, or hyper androgenemia ii) oligo ovulation & iii)exclusion of other known disorder. According to Ayurveda Acharya Sushruta² has described vandhya (suut 38/10) a type of yonivyapada whose symptom is amenorrhea or oligomenorrhea. Similarly, Acharya Charaka³ has mentioned Arajask ayonivyapada indicating amenorrhea. As per Ayurveda arta vakshaya involves vata pitta kapha dushti, rasaraktamedashukra dhatu dushti & artavahsrotasa.

Kapha predominance manifests as increased weight, sub-fertility, hirsutism, diabetic tendencies. Pitta predominance manifest as hair loss, acne, painful menses. Vata predominance causes dysmenorrheal, scanty menses, irregular menses.

Etiopathogenesis - according to ayurveda Kashyapa mentioned pushpaghni & revati having some resemblance with symptoms of PCOS in revati kalpa adhaya³. The term jatiharini is responsible for female infertility; this concept of jatiharini is explained in kalpa sthan of kashyap samhita. In Charak Chikitsa 30/7/8 due to improper diet & life style disturb the ovulatory function.

AIM:
1. To assess the effect of Rajahpravartini Vati in the treatment of patients having PCOS.
2. To determine the effect of Rajahpravartini Vati on Ovulation process in patients having PCOS with the help of USG for Follicular study.

OBJECTIVE:
1. To assess the effect of Rajahpravartini Vati in minimizing the symptoms in patients of PCOS.

Materials and methods:

Source of Data:
a) Source of drug - Genuine raw materials will be collected from authentic sources.
b) Place of work
- Preparation of the test drug done in Department of Bhaishjya Kalpana, Shree Saptashrungi Ayurved Mahavidyalaya and Hospital, Kamal Nagar, Hirawadi, Nashik
- Experimental study conducted in Shree Saptashrungi Ayurved Mahavidyalaya and Hospital, Kamal Nagar, Hirawadi, Nashik

INCLUSION CRITERIA:
- Patient willing to give voluntarily free written informed consent.
- Female patient having age group between 18 yrs to 35 yrs.
- Patient diagnosed with known case of PCOS.
- Patient having anovulatory cycle diagnosed by USG
- Patient having Dysmenorrhoea.
EXCLUSION CRITERIA:

- Hypersensitivity or idiosyncratic reaction to any drugs or herbal products.
- Congenital deformities of reproductive system.
- History of allergic conditions.
- History of autoimmune disorders e.g. systemic lupus erythematosus, Haemolytic anemia, RA.
- History of psychiatric disorders.
- Intake of any medication within 14 days before start of the study.
- Subjects who are scheduled to undergo hospitalization for surgery during the study period.
- Presence of clinically significant abnormal laboratory results during screening.
- Pregnancy or breastfeeding.
- Females of childbearing age potential not using medically accepted contraceptive measures, as judged by the investigator.
- Use of any recreational drugs or a history of drug addiction.
- Participation in a clinical study of any investigational product 1 month prior to visit 1 or during the study.

Material & Methods

Material –
Tankanamhingumkasisamkanyasaramsaman- saam| Kumariswarasenevchanakpramitavati|| Rajorodhamkashtarajavedanashatadudbhava |Rajapravartinivatitrnamvinshyet || Bhai. Rat.57/584

Table No. 1-

<table>
<thead>
<tr>
<th>Contain</th>
<th>Latin name</th>
<th>rasa</th>
<th>Vipak</th>
<th>Virya</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tankan</td>
<td>Borax</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Lekhan, chedan, Strotoshodhankaphagan</td>
</tr>
<tr>
<td>Hingu</td>
<td>Ferula narthex</td>
<td>Katu</td>
<td>Katu</td>
<td>Ushana</td>
<td>Vedanashapak, anulaman, Vatakaphashamak</td>
</tr>
<tr>
<td>Kasis</td>
<td>Ferrous sulphate</td>
<td>Amlatktakashaya</td>
<td>-</td>
<td>Ushana</td>
<td>Raktavardhak, raja pravartak</td>
</tr>
<tr>
<td>Kanyasara</td>
<td>Aloe veratourex</td>
<td>Katu, tikta</td>
<td>Katu</td>
<td>Shita</td>
<td>Garbhashayashodhak, Artavjanan</td>
</tr>
</tbody>
</table>

Preparation of “Rajahpravartinivati”. ShuddhaHingu, ShuddhaKaseesa, Shuddha-Tankan and Kanyasara is to be taken in equal quantity. All the ingredients are processed in Kumariswarasa (Aloe vera Linn) for 3 days and 3 ratti (375mg) weighing vati will be prepared.

STUDY DURATION:

This is 18 months study, in which patients will be studied for 15 months & 3 months for data analysis.

First 15 months – SSAM, Nasik for clinical assessment & follow-up will be taken of each patient. Data Analysis – In next 3 months data collection & analysis will be done.

- Scoring Pattern of Follicles : -
  0 - < 12 mm
  1 - 12 – 20 mm
  2 - > 20mm
  3 - Ovulated.
Observations

Table No: 2

Age wise distribution of 30 pt. shows maximum prevalence of PCOS in **Age group: 21-30** As PCOS is having predominance in adolescence & pubertal age.

Table No: 3:

**Residence wise distribution** shows PCOS is common in city, as PCOS has relation to lifestyle changes.

Table No: 4

**Akruti wise distribution** shows that out of 30 pt. 17 pt. madhyakriti & 12 pt. are of sthula. deha-prakruti wise distribution shows dominance of PCOS in vatapitta-prakruti followed by pitta kaph prakruti.

Table No: 5

**Prakruti wise distribution** of Patients
Occupation & working history of 30 pt. shows sedentary lifestyle is having symptoms of PCOS.

### Results of Difference between LMP:

#### Table No: 7

<table>
<thead>
<tr>
<th></th>
<th>Difference between LMP 1 &amp; 2</th>
<th>Difference between LMP 2 &amp; 3 treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>43.66</td>
<td>47.166</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>16.416</td>
<td>30.131</td>
</tr>
<tr>
<td>Standard Error</td>
<td>2.997</td>
<td>5.501</td>
</tr>
<tr>
<td>P value</td>
<td>&gt;0.1</td>
<td>&gt;0.1</td>
</tr>
</tbody>
</table>

The two tailed P value is 0.5785 i.e. Not significant t = with 58 degree of freedom

Insignificant result of difference between LMP shows regular ovulation, which manifest significant result in amenorrhea which is cardinal symptom of PCOS.

### Ovulation Results:

Trans-abdominal ultra sound is completely reliable in assessing the size and number of follicles for the prediction of pre ovulatory events however, trans-vaginal scanning with its superior evaluation is useful, so it is done for the evaluation of Ovary. For ovulation USG follicle study was done for 3 months of each patients and ovulation is observed.

#### Table No: 8

<table>
<thead>
<tr>
<th></th>
<th>Once Ovulation</th>
<th>Twice Ovulation</th>
<th>Thrice Ovulation</th>
<th>Other result- Hemorrhagic cyst</th>
<th>Un-ovulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>5</td>
<td>9</td>
<td>5</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td>Out of</td>
<td>90</td>
<td>90</td>
<td>90</td>
<td>90</td>
<td>90</td>
</tr>
<tr>
<td>%</td>
<td>5.555555556</td>
<td>10</td>
<td>5.555555556</td>
<td>1.1111111</td>
<td>10</td>
</tr>
</tbody>
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#### Table No: 9

<table>
<thead>
<tr>
<th></th>
<th>First time Ovulation</th>
<th>Second time Ovulation</th>
<th>Third time Ovulation</th>
<th>Other result- Hemorrhagic cyst</th>
<th>Un-ovulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of pt.</td>
<td>10</td>
<td>12</td>
<td>18</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td>Out of</td>
<td>30</td>
<td>30</td>
<td>30</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>%</td>
<td>33.333333</td>
<td>40</td>
<td>60</td>
<td>3.333333</td>
<td>30</td>
</tr>
</tbody>
</table>
It suggests that patients need to continue treatment for at least three months for regular ovulations.

Repeated Measures Analysis of Variance
The P value is 0.0116, considered significant. Variation among column means is significantly greater than expected by chance.

**ANOVA Comparisons Test for Follicle Size every month total duration three month**

If the value of q is greater than 3.408 then the P value is less than 0.05.

**Mean**

Comparison Difference P value

<table>
<thead>
<tr>
<th>Column A vs Column B</th>
<th>0.37932.199nsP&gt;0.05</th>
</tr>
</thead>
<tbody>
<tr>
<td>Column A vs Column C</td>
<td>0.75864.398**P&lt;0.01</td>
</tr>
<tr>
<td>Column B vs Column C</td>
<td>0.37932.199nsP&gt;0.05</td>
</tr>
</tbody>
</table>

**Mean95% Confidence Interval**

Difference From To

<table>
<thead>
<tr>
<th>Column A - Column B</th>
<th>-0.3793 -0.96710.2085</th>
</tr>
</thead>
<tbody>
<tr>
<td>Column A - Column C</td>
<td>-0.7586-1.346 -0.1708</td>
</tr>
<tr>
<td>Column B - Column C</td>
<td>-0.3793 -0.96710.2085</td>
</tr>
</tbody>
</table>

Intermediate calculations. ANOVA Table:

- **Source of Degrees of Sum of Mean Variation freedom squares square**
  - Treatment (between columns) 28.3454.172
  - Individual (between rows) 2887.2643.117
  - Random (residual) 5648.3220.8629

**Total 86143.93**

F = 4.835=Menstrual Treatment

Assumption test: Was the matching effective?

This test uses a second value of F and a different P value.

F = 3.612= (Menstrual Treatment)

The P value is < 0.0001, considered extremely significant. Effective matching (or blocking) results in significant variation among means. With these data, the matching appears to be effective.

**DISCUSSION**

1. The function of Reproduction is the noblest and should be the most reverent of all human power. God has given his Magnanimous gift only to the woman therefore he made Mother. Woman is considered as one of the greatest human race.

Women health care is not at all a new concept in the field of Ayurveda.

The subject has been emphasized since the problem related to **Artava Vikaras** is of much importance. Menstrual disorder is the common gynecological compliant. Ratio of Menstrual disorder (20-30%) is rising as a precursor of infertility. In Ayurvedic context as far as the ailment 'Alpartava' is concerned it is not coded as an individual disease. But there are many diseases, in which it is described as a symptom. Hence it should be included as **anukta vyadhi**.

2. **Rajahpravartinivati** is one of the best formulations utilized in the treatment of menstrual disorder.

Main ingredient of **rajhpravartini vati** are hingu, kasis, tankan & kanyasar i.e. kumari. Hingu act as vatanulomak, vedanshamak which may give relief in dysmenorea. **Kasis** is having property of **raktavardhak & atravija-**
nan. Tankan is of alkaline in nature which is having lekhan, strotovishodhan property, which may give result in amenorrhea, ovarian cyst & increased ovarian volume.

Aloevera (kanyasara) is also having stimulant activity on uterus.

3. This study point out that sedentary work, irregular diet habits, absence of exercise shows more prevalence of PCOS.

4. 21-30 Yrs. age group, patients in developed city are more prone to PCOS.

5. Statistically insignificant result of T-test in difference between LMP shows regular ovulation.

6. ANOVA comparison test for follicle size and ovulation suggest significantly greater than expected by at chance as P value is 0.0116.

Table No: 10

<table>
<thead>
<tr>
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<th>Third time Ovulation</th>
<th>Other result- Hemorrhagic cyst</th>
</tr>
</thead>
<tbody>
<tr>
<td>18%</td>
<td>20%</td>
<td>36%</td>
<td>24%</td>
</tr>
</tbody>
</table>

This research study observation shows significant result in ovulation by ultrasound study. Also decreased interval between menstrual cycles shows regularity in menstruation.

RESULT-
Open label, Single centre, Prospective study of Rajahpravartini Vati in the treatment of PCOS shows significant result in the ovulation by ANNOVA TEST. The statistical test suggests that overall result of treatment are satisfactory, ovulation study by USG suggest three month treatment duration is needed for regulation of menstrual cycle.

CONCLUSION

Observation of study shows total three month treatment gives satisfactory result.

REFERENCES


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7. Polysistic Ovary Syndrome: and Ayurvedic perspective vaidya Atreya Smith www.atrey.com

Details of Table:

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Rajahpravartinivati contains &amp; Property</td>
</tr>
<tr>
<td>2</td>
<td>Age wise distribution of 30 patients</td>
</tr>
<tr>
<td>3</td>
<td>Residence wise distribution of 30 patients</td>
</tr>
<tr>
<td>4</td>
<td>Akruti wise distribution of 30 patients</td>
</tr>
<tr>
<td>5</td>
<td>Prakruti wise distribution of 30 patients</td>
</tr>
<tr>
<td>6</td>
<td>Occupation wise distribution of 30 patients</td>
</tr>
<tr>
<td>7</td>
<td>Results of Difference between LMP</td>
</tr>
<tr>
<td>8</td>
<td>Ovulation Result (a)</td>
</tr>
<tr>
<td>9</td>
<td>Ovulation Result (b)</td>
</tr>
<tr>
<td>10</td>
<td>Pie Diagram of Ovulation</td>
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</table>

Source of Support: Nil
Conflict Of Interest: None Declared

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