ROLE OF LAVANBHASKAR CHURNA, SAJJI KSHARA AND NAVSADAR IN THE MANAGEMENT OF (BEEJKOTH) GRANTHI WITH SPECIAL REFERENCE TO PCOS

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ABSTRACT
PCOS is a relatively common endocrine disorder affecting women of reproductive age group; insulin resistance and hyperinsulinemia being one of important causes. It has also been studied that PCOS consequently results in infertility and the only treatment is Surgery and Hormone replacement therapy. There is no direct reference involving the detail clinical spectrum of PCOD in our ancient texts of Ayurveda; instead the symptoms have been explained as a part of various diseased conditions. The present study was carried out with a plan to clinically evaluate efficacy of Ayurvedic treatment regimen on PCOS. In the present study total 60 patients were registered in two groups. In the first group, a combination of three drugs namely Lavanbhaskar churna, Sajji kshara and Navsadar were given where as the second group was administered a placebo drug. Of 60 patients registered, only 36 completed the research study (30 patients in Group A and 06 patients in Group B). All the patients were assessed before and after treatment based on subjective parameters like Interval and Duration of menstruation, Dysmenorrhea, Obesity and Objective parameters like Follicular size, Hormonal profile. The results were statistically evaluated using unpaired T test. Comparatively, trial drug of group A has a beneficial effect on the symptoms of PCOS and showed significant results than group B. Thus it can be concluded that Combination of Lavan Bhaskar Churna, Sajjikshar and Navsadar can be used in the management of PCOS.

Keywords: Ayurvedic, Dysmenorrhea ,Hormone replacement therapy.

INTRODUCTION
Female being the root cause of progeny, utmost care should be given to protect her from any ailments that affect her motherhood but PCOS is one of the conditions affecting this unique capacity of woman. The disorder is probably the most common hormonal abnormality in women of reproductive age and certainly a leading cause of infertility. PCOS-Poly Cystic Ovarian Syndrome also known as Poly Cystic Ovarian Disease -as the name suggest, is a collection of signs and symptoms related to ovarian dysfunction. It was originally described by Stien and Levental in 1935, so called as “Stien-Levental
Syndrome”. It is a heterogeneous disorder characterized by menstrual irregularities, clinical and biochemical Hyperandrogenism and hyperinsulinemia, which ultimately leads to infertility\(^1\). PCOD is a common cause of infrequent & irregular periods affecting as many as 10% of women in their reproductive age\(^2\). The disorder accounts for 30% of all infertility cases with 73% of women suffering from PCOS. PCOS is a familial condition and appears to have its origin during adolescence mainly associated with increased weight gain during puberty. In Ayurvedic classics there is not a complete description of such disease menstrual irregularities are described under the broad heading of *Ashtoartavadushti*\(^3\), while the description of infertility due to anovulation is scattered as *Pushpopaghata*\(^4\) and *Abeejatva*\(^5\). *Pushpaghni Jataharini* is mentioned in *Kashyapa Samhita*, *Revati Kalpadhyaya* bears similitude to the symptom of Hyperandrogenism. But features of metabolic dysfunction and polycystic ovarian morphology are not evident from any depiction. PCOS is not a completely curable disease. In modern science, PCOS is treated by hormonal therapy along with symptomatic treatment which in long term is associated with many side effects. Moreover it may also fail in preventing the long term consequences of PCOS. The last alternative is surgery; Partial oophorectomy or drilling of the ovaries. In Ayurvedic literature, so far no standard Ayurvedic drug has been established for the management of PCOS. Thus, it is necessary to modulate a well accepted Ayurvedic approach towards the disease and formulate the principles of management. If the treatment is planned well by means of scientific research and applying the *doshic* status, it can make wonders in the curability of complex symptoms of PCOS. As this disease is manifested due to mixed etiological factors and presents with complex symptomatology, the treatment should also be broad spectrum. In view of this, *Lavanbhaskar churna*\(^6\), *Sajji Kshara* and *Navsadar* were selected as a trial drugs. As trial drugs have not been established as standard drugs for PCOS, the effect of it should only be assessed by comparing it with no drug group that is a Placebo. So in order to find out a therapeutically efficacious, safer, cost effective and an easily available drug for the management of PCOS an attempt has been made to evaluate the efficacy of these drugs by means of a comparative study with a placebo drug.

**Aim and objectives**

1. To find out the aetiopathogenesis of PCOS in Ayurveda parlances.
2. To evaluate the efficacy of both the selected drugs on menstrual irregularities & anovulation caused by PCOD.

**Materials and methods**

The whole study was carried out in the following manner.

**Conceptual study**

In this phase, a critical review of Ayurvedic and Modern literatures regarding the subject was carried out. Different Ayurvedic and modern texts, research papers and journals were consulted for the conceptual part for latest information.

**Clinical study**

Patients attending the OPD of Stri Roga & Prasooti Tantra of Post graduate institute of V.Y. D. S Ayurvedic Mahavidyalaya Khurja fulfilling the criteria for the selection were selected .A detailed history regarding menstrual history, obstetric history, family history, past medication, clinical findings pertaining to *Dosha, Dushya, Agni, Srotas* etc. along with vaginal and speculum examination to assess any sign of infection or any disease related to menstrual irregularity or infertility were filled up in specially prepared Performa.

1. **Study design**

Present study was designed as a randomized clinical trial.

2. **Sample size:**
Total 60 patients (30 in each Group) were registered fulfilling all the inclusion criteria.

3. Selection Criteria

A. Inclusion criteria: Patients fulfilling at least two of following three criteria:\n- Oligomenorrhoea / or Anovulation
- Hyperandrogenism (clinical /or bio-chemical)
- Bilateral or unilateral PCO - diagnosed by USG.

B. Exclusion criteria:
- Patients having any other disease causing Oligomenorrhoea and Anovulation.
- Any organic lesions of reproductive tract like TB, carcinoma and congenital deformities or any other pelvic pathology.
- Patients suffering from adrenal hyperplasia, severe insulin resistance, androgen secreting neoplasm, thyroid abnormalities, Cushing syndrome, and cardiac diseases were excluded.

4. Criteria for diagnosis:
Patients were selected on the basis of their clinical presentation particularly related to menstruation and hirsutism and on the basis of Ultrasonography (USG) with the report of unilateral or bilateral PCO and or anovulation. Hormonal assessment was carried out only to support the diagnosis, not as diagnostic criteria.

To assess the effects of therapies, a special scoring and gradation method based on subjective and objective parameters was adopted as follows:

Subjective Parameters
- Interval of menstruation.
- Duration of menstruation.
- Pain associated with menstruation.
- Obesity (on the basis of BMI).

Objective Parameters
- Follicular size.
- Hormonal profile including S. FSH and S.LH.
- C.B.C.

4. Selection of drug
- Group A: Lavanbhaskar Churna, Sajji kshara and Navsadar orally were given.
- Group B: Patients were treated with Placebo drug.

5. Posology

Group A:
- Lavanbhaskar churna orally 2g B.D for two months.
- Sajjikshar orally 1.5 g B.D for two months.
- Navsadar churna orally 1.5 gm B.D for two months.

Group B:
- Roasted wheat orally 500 mg B.D. after meals for 2 months.

6. Follow up
After completion of the treatment the patients of both the groups had been examined for follow up at the interval of one cycle to record whether the improvement provided by the therapy is sustained or otherwise, depending upon cooperation from patients after completion of treatment. Any new complaint or complication emerged during follow up related to study was also noted.

Results
The present study entitled ‘Role of Lavanbhaskar churna, Sajji kshara and Navsadar in the management of Beejkoth granthi with special reference to PCOS’ was conducted in Post graduate institute of Vaidya Yagya Dutt Sharma Ayurvedic Mahavidyalaya Khurja, Bulandshshar, U P. The study was designed with an aim to evaluate the effect of these three drugs mainly on menstrual irregularities and anovulation caused by PCOS. Of 60 patients registered in two groups only 36 completed the study (30 in group A and 6 in group B). In group A, improvement in irregular (delayed) menses was highly significant while insignificant result was observed in duration of menses, significant growth was found in follicular size while ovulation was found only in 2 patients. Also in this group, reduction in weight was highly significant. In group B (placebo), no any significant or marked effect was found in any of the symptoms of PCOS. Comparatively both A & B group showed mostly
similar effect on menstrual irregularities and follicular growth.

Comparative Statistical results
Table 1: Effect of therapy on Menstrual cycle Interval

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Mean B.T</th>
<th>X (BT-AT)</th>
<th>%</th>
<th>S.D</th>
<th>S.E</th>
<th>T</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>30</td>
<td>2.40</td>
<td>0.53</td>
<td>32.43</td>
<td>0.73</td>
<td>0.13</td>
<td>4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>B</td>
<td>06</td>
<td>0.83</td>
<td>-0.16</td>
<td>120.00</td>
<td>0.40</td>
<td>0.16</td>
<td>1</td>
<td>&lt;0.363</td>
</tr>
</tbody>
</table>

After treatment in group A, interval of menstruation decreased up to ≤ 35 days in 20.00% of patients; up to 36-45 days in 20.00% of patients; up to 46-55 days in 13.33 patients while it was found same (≥ 56 days) in 46.66% patients. While in group B, it decreased up to ≤ 35 days in 50% of patients; up to 36-45 days, up to 46-55 days and remained same (≥ 56 days) in 16.66% patients respectively.

In group A result is statistically highly significant, while in group B result is statistically insignificant.

Table 2: Effect of therapy on Duration of Menses

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Mean B.T</th>
<th>X (BT-AT)</th>
<th>%</th>
<th>S.D</th>
<th>S.E</th>
<th>T</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>14</td>
<td>1.00</td>
<td>0.16</td>
<td>12.50</td>
<td>0.46</td>
<td>0.08</td>
<td>1.9</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>B</td>
<td>06</td>
<td>1.00</td>
<td>0.16</td>
<td>25</td>
<td>0.46</td>
<td>0.08</td>
<td>1.9</td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>

In group A, though normal duration of 3-5 days was found in maximum patients (88.88%), after treatment the duration of menses increased upto 5 days in maximum (70%) of patients while in group B it remains almost same. Statistically the effect of therapy on duration of menses is insignificant in two groups. This result was found because most of the patients in all two groups were having duration of 5 days.

Table 3: Effect of therapy on Pain associated with Menses

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Mean B.T</th>
<th>X (BT-AT)</th>
<th>%</th>
<th>S.D</th>
<th>S.E</th>
<th>T</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>30</td>
<td>0.60</td>
<td>0.60</td>
<td>62.50</td>
<td>0.85</td>
<td>0.15</td>
<td>3.84</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>B</td>
<td>06</td>
<td>0.33</td>
<td>0.00</td>
<td>00.00</td>
<td>0</td>
<td>0</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

In group A, bearable pain during menstruation was found in 04 patients while need of oral analgesics was found in 07patients. After treatment 100.00% had no pain and 0% patients had bearable pain during menses. In group B, bearable pain during menses was found in 02 patients. After treatment it remained same. Effect of therapy on pain associated with menstruation is statistically highly significant in group A (<0.001); while no change was found in group B.

Table 4: Effect of therapy on Obesity

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Mean B.T</th>
<th>X (BT-AT)</th>
<th>%</th>
<th>S.D</th>
<th>S.E</th>
<th>T</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>30</td>
<td>0.40</td>
<td>-0.10</td>
<td>10.00</td>
<td>0.30</td>
<td>0.05</td>
<td>1.7</td>
<td>&lt;0.08</td>
</tr>
<tr>
<td>B</td>
<td>06</td>
<td>0.00</td>
<td>0.00</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
Effect of therapy on obesity particularly on the basis of BMI shows that there is no marked reduction in obesity in any patient of the two groups. Result is statistically insignificant in group A while it remains same or even reduced in group B.

Table 5: Effect of therapy on follicular size & ovulation

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Mean</th>
<th>X</th>
<th>%</th>
<th>S.D</th>
<th>S.E</th>
<th>T</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B.T</td>
<td>A.T</td>
<td>(BT-AT)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>14</td>
<td>0.10</td>
<td>0.46</td>
<td>-0.36</td>
<td>100</td>
<td>0.55</td>
<td>0.10</td>
<td>3.61</td>
</tr>
<tr>
<td>B</td>
<td>06</td>
<td>0.16</td>
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<td>0.00</td>
<td>0.00</td>
<td>0</td>
<td>0</td>
<td>-</td>
</tr>
</tbody>
</table>

Effect of therapy on Hematological parameters.
The Hb% result was found to be statistically significant after comparing before and after treatment. In group A, Statistically TLC result is insignificant while it is statistically significant in Neutrophils, Lymphocytes and Eosinophils. In case of Monocyte, result is statistically significant whereas result is statistically insignificant in Basophil and in ESR.

In group B changes of all the hematological parameters before and after treatment were insignificant.

Comparative effect of therapy
For the data analysis of parameters, the un-paired “t-test” is applied for inter group comparison.

Table 6: Comparative Total Effect of Therapy between Group A & B

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Group</th>
<th>N</th>
<th>Mean</th>
<th>SD+/-</th>
<th>SE+/-</th>
<th>DF</th>
<th>T+/-</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interval of menstruation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>A</td>
<td>30</td>
<td>1.87</td>
<td>1.22</td>
<td>0.22</td>
<td></td>
<td>34</td>
<td>1.5751</td>
<td>&lt;0.1245</td>
</tr>
<tr>
<td>B</td>
<td>06</td>
<td>1.00</td>
<td>1.26</td>
<td>0.52</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of menstruation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>30</td>
<td>0.83</td>
<td>0.53</td>
<td>0.10</td>
<td></td>
<td>34</td>
<td>0.0000</td>
<td>&lt;1.0000</td>
</tr>
<tr>
<td>B</td>
<td>06</td>
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<td>0.75</td>
<td>0.31</td>
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<tr>
<td>Obesity</td>
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<tr>
<td>A</td>
<td>30</td>
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<td>0.78</td>
<td>0.14</td>
<td></td>
<td>34</td>
<td>1.5584</td>
<td>&lt;0.1284</td>
</tr>
<tr>
<td>B</td>
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<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain with menstruation</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>A</td>
<td>30</td>
<td>0.47</td>
<td>0.82</td>
<td>0.15</td>
<td></td>
<td>34</td>
<td>0.8682</td>
<td>&lt;0.3914</td>
</tr>
<tr>
<td>B</td>
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<td>0.17</td>
<td>0.41</td>
<td>0.17</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Follicular growth</td>
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<td></td>
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<tr>
<td>A</td>
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<td>0.00</td>
<td>0.00</td>
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<td></td>
<td>34</td>
<td>3.7639</td>
<td>&lt;0.0006</td>
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<td>0.33</td>
<td>0.52</td>
<td>0.21</td>
<td></td>
<td></td>
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</tbody>
</table>

DISCUSSION

Today, PCOS commonly occurs during reproductive age of woman and accounts for being a major cause of infertility. The disorder is associated with a wide spectrum of presenting features including menstrual irregularities, anovulation, infertility, obesity, hirsutism and insulin resistance. Not all people who suffer from polycystic ovary syndrome will have all of these symptoms. Symptoms differ from woman to woman depending upon the level of severity. In PCOS, hormonal imbalance affects the development of follicular growth at various stages of maturation causing an arrest and atresia of the follicle. The retained follicle forms into a cyst and with each ovarian cycle a new cyst is formed leading to multiple ovarian cysts. PCOS can also be understood well on the basis of Ayurvedic concepts. PCOS occurs primarily due to the imbalance state of
doshas especially vata and kapha. This dosha vaishmya is linked to the symptoms of PCOS. The deranged vata vitiates the mamsa, shonita and meda mixed with kapha; they produce a circular, raised and knotted inflammatory swelling called granthi which can be compared with a cyst. Due to Srotorodha and suppression of Agneya Guna of pitta by the vitiated Kapha, the process of Beejanirmana cannot be completed (arrested maturation of follicles). Apana Vata, could not function normally for Beejotsarga and Artava Pravritti. This pathology is responsible for Anartava as well as Vandhyatva due to anovulation.

Role of Ama along with Dhatvagnimandya in the Samprapti has also been found. Here, multiple small cysts found in the periphery of ovaries can be taken as Ama. When production of androgens from these undeveloped or immature cysts becomes high and they circulate as free or unbound in the blood circulation, they produce all the symptoms. When Dhatvagni of a particular Dhatu is diminished, the formation and utilization of that Dhatu becomes incomplete and Ama is produced. This type of pathology can be seen in PCOD i.e. formation of Beeja is not been completed, hence the process of Beeja Nirmana renders at the level of follicular stage and becomes cysts. These cysts can be taken as Ama produced in Artavavaha Srotas due to Dhatvagnimandya. These cysts produce androgens which are not converted into estrogens and thus prevent ovulation. So, this Ama is responsible for all symptoms of PCOD.

Mode of action of drugs

The approach towards Ayurvedic treatment for PCOS includes vata kaphahara chikitsa, Sroto shodhan, ama pachan along with management of agnimandya at both dhatwagni and jatharagni levels.

In this disease, Because of Vata kapha dosha vriddhi and Pitta Kshaya the physiological process of menstruation gets disturbed resulting in Anartava. So Vata kaphahara dravya along with property with kshara may be effective for treatment.

Lavanbhaskar churna is Vata, Kapha nashak, Gulma niharaka and Vata shoool nashak. It aids in digestion and help in Sroto Shuddhi. The properties of Dipana and Pachana elevate the jatharagni, dhatwagni as well as artvagni. Sajjikshar is indicated in Vata-Kaphaja Artava Dushti. Sajjikshar and Navsadar are tikshan ushna guna pradhana kshara and will help in vimplapan of Granthi. Navsadar is tridosha shamak especially Kapha dosha hara. It is Ushna virya, Snigda, laghu, Pachaka and Jatharagni Pradeepak Where as Sajji kshara is Tikshan, Katu, Ushna .Pachaka and Vayu nashak and Udara roga nashak12. The given treatment may work to improve hormone utilization and regulates overall hormone balance.

CONCLUSION

The world of medical science is climbing new steps day by day but this newer disease like AIDS, Malignancies, PCOS etc. are arising every day for which there is no direct correlation in Ayurvedic classics. It is a health problem that affects a woman’s menstrual cycle, fertility, sex hormones production, insulin production, and physical appearance. Likewise the etiology and diagnosis remains controversial. No direct correlating condition was found in classical text books. It is found only under the broad heading of “Yoni Vyapada”. So, it is the need of time to postulate management of the disease by Ayurvedic norms. It is proved statistically to be effective in regularizing menstruation, achieving considerable reduction in body weight, substantial growth of follicles and thus ovulation and through these achievements it may prevent long term consequences of PCOS. No doubt, the above treatment protocol may be helpful but there is need for further study in management of PCOS in future.
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