Clinical Evaluation of Tamra Yoga in Rajo Kshaya

With special reference to PCOD

Rugmini R.K, Sridurga C.H, Suneela P

Abstract

**Background:** Polycystic Ovarian Disease (PCOD) is one of the most common endocrinological disorder affecting women of reproductive age in the recent times. Based on clinical features, this disease can be correlated with the condition Rajo Kshaya (Oligomenorrhea or Amenorrhea) mentioned in Ayurveda. Tamra Yoga is one of the special formulations found in Rasa Tantra Sara va Siddha Prayoga Sangraha - Prathama Khanda – Bhasma Prakarana. **Aims:** To evaluate the effectiveness of Tamra Yoga in the treatment of Rajo Kshaya w. s. t to PCOD. **Materials & Methods:** A total of 32 patients having signs and symptoms of PCOD were selected for the non-randomized, non-group, open labeled clinical trial. Tamra Yoga was administered in a dose of 655 mg two times a day after meals with hot water for 45 days. Follow-up was done after a period of 45 days. Evaluation was done totally grounded on the variations in the clinical features of PCOD and observations made by ultrasound. Results were analyzed statistically using ANOVA test. **Results:** Statistically highly significant relief (P<0.001) was seen in Interval and Duration of menstruation, Quantity of menstrual bleeding, Pain associated having signs and symptoms of PCOD were selected for PCOD. **Conclusion:** This study substantiates the efficacy of Tamra Yoga in the management of PCOD.

**Keywords:** PCOD, Tamra Yoga, Rajo Kshaya, Oligomenorrhea, Amenorrhea, Randomized Clinical Trial.

INTRODUCTION

Polycystic Ovarian Disease is one of the most common endocrinological disorder affecting women of reproductive age group. More than 10 million cases of PCOD were registered per year in India [1]. Approximately 2.2 to 26% of women of reproductive age are suffering from this disease [2]. It is a multifactorial, heterogeneous disorder characterized by excessive androgen production by the ovaries mainly. This excess androgen production interferes with the reproductive, endocrine, and metabolic functions.

Clinical features of PCOD include menstrual abnormalities like Oligomenorrhea, anovulation, hyperandrogenism (Clinical and / or biochemical), hirsutism, acne, Acanthosis nigricans, elevated plasma LH, obesity and polycystic ovaries. Diagnosis is usually made by the combination of clinical, ultrasonographic and biochemical parameters [3].

There is no direct reference describing the clinical condition of PCOD in classical texts of Ayurveda, instead the symptoms were explained as a part of various diseased conditions. Oligomenorrhea or Amenorrhea is one of the major clinical features witnessed in the patients of PCOD. The same clinical feature is termed as Artava Kshaya / Rajo Kshaya in Ayurveda.

*Tamra Yoga* is one of the significant preparations mentioned in in Rasa Tantra Sara va Siddha Prayoga Sangraha - Prathama Khanda – Bhasma Prakarana [4]. It contains 1 part of Tamra Bhasma and 4 parts of Chincha Kshara, Hingu (Ferula assafoetida Linn), Yoshimatsu (Glycyrrhiza glabra Linn), Trikatu and Sauvarchala Lavana (Unauqa Sodium Chloride) each. Altogether the *dravyas* used in the formulation possess various therapeutic properties which are useful in the management of PCOD. Hence, with an intention to find the effectiveness of *Tamra Yoga* on Rajo Kshaya w.s.t to PCOD, this drug has been selected.
MATERIALS & METHODS

The preparation of Tamra Yoga was carried out in the department of Rasa Shastra and Bhaishajya Kalpana, TTD’S S.V. Ayurvedic College and Sri Srinivasa Ayurveda Pharmacy, Tirupathi. The pharmacological procedures adopted in this study are Shodhana, Marana, Bhavana, Anrnutikarana, Hinga bharjana, Kshara nirmana, Churna nirmana and preparation of capsules of Tamra Yoga. Parada Shodhana was done by Mardana with (Sarjua Kshara, Yava Kshara, Tankana) Kshara traya for three days [3]. Gandhuka Shodhana was performed using cow’s milk by Pata method [4]. Equal quantities of Shodhitha Parada and Gandhuka were taken and made into Kaijali [5]. Tamra Patras was subjected to Samanya shodhana by Nirvapā in Tulika, Tokra, Aroanala, Gomutra, and Kulattha Kvaṭha for seven times [8]. Visesha shodhana was done by Dola yantra in Gomutra for three hours [9]. Equal quantities of Kaijali and Shodhitha Tamra Patras were triturated in a Khālwa yantra using Nimbu Swarasa. Chakrikas were prepared in a Sharava and subjected to Sharava samputikarana. This was subjected to Laghu puta and the total procedure was repeated for 18 times [10]. Then Tamra Bhasma having all Bhasma lakshnas have been attained. Then the obtained Tamra Bhasma was triturated with Kumari Swarasa and subjected to Anrnutikarana procedure by Laghu puta for 7 times [11]. Chincha phala twak was converted to ash by heating in a mesh placed over hearth. To the ash obtained four parts of water was added and kept overnight. Then the supernatant water collected was heated in a moderate flame to obtain Chincha Kshara [12]. Raw drugs of Sauvarchala lavana, Yashtimadhu, Trikatu and Hinga were made into fine powder. Then one part of Tamra Bhasma (30mg) and 4 parts each of Chincha Kshara, Sauvarchala lavana churna, Trikatu churna, Yashtimadhu churna, and Hinga churna (125mg x 5) were mixed together to prepare Tamra Yoga and the homogenous mixture were filled in capsules of 655mg [13].

A total of 32 patients with signs and symptoms of PCOD fulfilling the criteria for the selection have been selected from OPD of Department of Prasuti Tantra and Stree Roga and Department of Rasa Shastra and Bhaishajya Kalpana. The study has been initiated once getting approval from institutional ethics committee (IEC/SVAYC/RS/15/51) dated 26-3-2015. Informed written consent has been received from each patient before onset of treatment.

Inclusion criteria

- Patients suffering from Rajo Kshaya (Oligomenorrhoea/ Amenorrhoea) whose Ultra Sono Gram (USG) reports indicating the presence of Polycystic Ovaries were taken for the study.

- Patients who were in Reproductive Age group only were selected.

- Patients having any other symptoms than the mentioned above were not included under the Exclusion Criteria.

Exclusion criteria

- Patients having gross structural abnormalities of uterus and appendages.

- Those having primary amenorrhea by PCOD.

- Patients having Rajo Kshaya in conditions other than PCOD were not considered.

- Those suffering from malignancies of any kind, congenital deformities and chronic systemic diseases like T.B, Hypertension or any other pelvic pathology.

- Those suffering from adrenal hyperplasia, Cushing’s syndrome, Cardiac diseases, STD’s and HIV.

Investigations

Routine haematological examinations like haemoglobin percentage (Hb%), total leucocyte count (TLC), differential leucocytes count (DLC), erythrocyte sedimentation rate (E.S.R), fasting blood sugar (F.B.S) and post prandial blood sugar (P.P.B.S), thyroid profile, routine and microscopic urine examination. Special investigations like Ultra Sono Gram (USG); if necessary, hormonal Assays like Serum Estrogen, Follicle Stimulating Hormone (FSH), Luteinizing Hormone (LH), and Serum Testosterone were performed.

Posology

- Internal Therapy: Tamra Yoga

- Dose: 655 mg

- Kala: Twice a day after meals

- Anupana: Hot Water

Follow-up: All the patients were reviewed after every 15 days for a total period of 45 days.

Diet: Patients were advised to take normal diet and to avoid abhishyandi aghara, non-vegetarian, spicy, sour, fried food and over eating.

Statistical Analysis: ANOVA test was done for Statistical assessment of the data by using Graph Pad instat software – USA.

General observation

Several demographic parameters viz. age, marital status, religion, nature of work etc. along with specific features of Prakriti, Satva, Ahara shakti etc. were analysed in the present clinical trial.

Criteria for Assessment

Valuation was entirely cantered on the changes in the clinical features and observations made by ultrasound. To measure the intensity of the clinical features present before and after the treatment, a score index was designed for all signs and symptoms with grades.

Interval of menstruation

<table>
<thead>
<tr>
<th>Grade</th>
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<td>Grade</td>
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<table>
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<tr>
<th>Gap between two cycles</th>
<th>Grade</th>
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<tbody>
<tr>
<td>28-30 days</td>
<td>0</td>
</tr>
<tr>
<td>30-60 days</td>
<td>1</td>
</tr>
<tr>
<td>60-90 days</td>
<td>2</td>
</tr>
<tr>
<td>≥ 120 days</td>
<td>3</td>
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Duration of menstruation

<table>
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<tr>
<th>Grade</th>
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<td>Grade</td>
<td>Grade</td>
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<table>
<thead>
<tr>
<th>No. of Days</th>
<th>Grade</th>
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<tbody>
<tr>
<td>4-5 days</td>
<td>0</td>
</tr>
<tr>
<td>2-3 days</td>
<td>1</td>
</tr>
<tr>
<td>1 day</td>
<td>2</td>
</tr>
<tr>
<td>Spotted</td>
<td>3</td>
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Quantity of menstrual bleeding

<table>
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<th>No. of Pads</th>
<th>Grade</th>
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</tr>
<tr>
<td>Symptoms</td>
<td>Grade</td>
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<tr>
<td>--------------------------------</td>
<td>-------</td>
</tr>
<tr>
<td>Sthoulya</td>
<td>+/-</td>
</tr>
<tr>
<td>Karshya</td>
<td>+/-</td>
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</tbody>
</table>
work and socio-economic status of maximum patients (53.33%) was middle class.

Maximum patients (66.66%) came up with the chief complaint of irregularity in menstruation. 70% of patients took allopathic treatment for the same. 93.33% of patients did not have any family history. 43.33% of patients were consuming junk food, 40% of patients were following Sunashana, 43.33% of patients had mandagni and 53.33% had normal sleep. 53.33% of patients had constipation, 60% of patients faced some kind of emotional stress in their life. 43.33% of patients had Vata-Kaphaprakriti, 70% patients had madhyamanasatwa, 66.66% of patients had madhyamaaharashakti, 46.66% of patients had madhyamavyayamashakti and 83.33% of patients did not have the habit of doing exercise.

Out of 16 married patients only one patient had narrow vagina. 33.33% of patients had irregularity of menstruation since menarche and 23.33% had irregularity more than 2 years. Maximum patients (40%) had been diagnosed as PCOD by USG scan more than a year. 63.33% of patients had a habit of diwaswapna (day sleep), 33.33% of patients had a habit of ratrijagaranaand 30% of patients had a habit of vegadharana. Maximum patients i.e. 30% had Chinta, 23.33% of patients had Udvega and 20% of patients had Shoka. 6.67% of patients showed features of Sthoulya viz. Dourbalya (weakness) and Swedhabadha (sweating) and features of Gulma viz. Agnimandya (loss of appetite) was seen in 43.33% of patients, 3.33% of patients had Aruchi (anorexia), Udgar (belchings) and Chardi (vomitings).

### RESULTS

#### Table 1: Quantity of ingredients for each Tamra Yoga of 655 mg

<table>
<thead>
<tr>
<th>S. No</th>
<th>Name of content</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Tamra Bhasma</td>
<td>30 mg</td>
</tr>
<tr>
<td>2</td>
<td>Yashtimadhu</td>
<td>125 mg</td>
</tr>
<tr>
<td>3</td>
<td>Trikatu</td>
<td>125 mg</td>
</tr>
<tr>
<td>4</td>
<td>Chincha Kshara</td>
<td>125 mg</td>
</tr>
<tr>
<td>5</td>
<td>Bharjitha Hingu</td>
<td>125 mg</td>
</tr>
<tr>
<td>6</td>
<td>Sauvarchala Lavana</td>
<td>125 mg</td>
</tr>
</tbody>
</table>

#### Table 2: Effect on Symptoms of Sthoulya and Gulma

<table>
<thead>
<tr>
<th>S. No</th>
<th>Symptoms of Sthoulya &amp; Gulma</th>
<th>B. T</th>
<th>A. T</th>
<th>Follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Dourbalya</td>
<td>+</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>Swedhabadha</td>
<td>+</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>3</td>
<td>Agnimandya</td>
<td>+</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>4</td>
<td>Aruchi</td>
<td>+</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>5</td>
<td>Udgar</td>
<td>+</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>6</td>
<td>Chardi</td>
<td>+</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

*B. T: Before Treatment, †A. T: After Treatment

- Statistically highly significant relief (P<0.001) was seen after treatment and after follow up in these parameters

  a) Interval of menstruation
  b) Duration of menstruation
  c) Quantity of menstrual bleeding
  d) Pain associated with menstrual bleeding
  e) Right Ovarian volume
  f) Left Ovarian volume
  g) Number of follicles.

- Statistically highly significant relief (P<0.01) was seen after treatment & follow up in:

  a) Patients with Acne.
  b) It was found to be Statistically insignificant (P>0.05) for Obesity (on the basis of BMI) and manasikabhamas.
  c) No patient reported with the complaint of Acanthosis nigricans and Hirsutism.
  d) Marked improvement was seen in the Symptoms of Sthoulya and Gulma.
Graph 1: Showing Mean effect of Tamra Yoga on parameters in 30 patients

Complete Assessment of therapeutic effect

The treatment had revealed complete remission in 6.66% of patients, marked improvement in 53.33% of patients, mild improvement in 30% of patients and no improvement in 10% of patients.

Table 3: Showing overall assessment of Clinical trial

<table>
<thead>
<tr>
<th>Result</th>
<th>No. of Patients</th>
<th>% Of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete remission</td>
<td>02</td>
<td>6.66%</td>
</tr>
<tr>
<td>Marked Improvement</td>
<td>16</td>
<td>53.33%</td>
</tr>
<tr>
<td>Mild Improvement</td>
<td>09</td>
<td>30%</td>
</tr>
<tr>
<td>No improvement</td>
<td>03</td>
<td>10%</td>
</tr>
</tbody>
</table>

Graph 2: Showing overall assessment of Clinical trial
Figure 1: Showing USG of Clinical Study Patient before trial

Figure 2: Showing USG of Clinical Study Patient After trial
Figure 3: Showing USG of Clinical Study Patient Before trial

Figure 4: Showing USG of Clinical Study Patient After trial
DISCUSSION

The word “Stree” indicates the reproductive capacity of women. “Stree” implies the source of progeny, greatest care has to be given to guard her from any ailments that affect her motherhood. PCOD is one of the main conditions now-a-days distressing this exceptional capacity of woman.

In the present study, prevalence of PCOD was found to be more in the age group 21-30 years (60%), followed by 20% from the age group 16-20 years. This is the maximum transformation period in the life and during this period lot of physical, social and psychological changes takes place. Maximum patients belonged to the urban habit; the line between urban and rural areas was totally erased during recent years. The diet habits and psychological behaviour have almost become equal in people of both these areas. All the patients registered (100%) were educated. Because of high competition and corporate pattern of education system from higher secondary level, students were exposed to high amount of stress in their life. Most of the patients in the study belonged to middle class (53.33%) followed by rich people (33.33%). This indicates that PCOD is a Santarpananjanyavyadya. Moreover, the people of these two groups are also exposed to more stress which could also be a cause in the development of PCOD. 46.66% of patients were accustomed to sedentary work, whereas 21.67% of subjects were sedentary habit. 53.33% of patients had irregularity in menstrual cycle more than 2 years. The chronicity beyond 2 years (menstrual cycle since menarche and 23.33% had irregularity in menstrual cycle, which shows the awareness of the women about their menstrual cycle. Majority patients had mandagni (43.33%) followed by samagni (36.66%). Classics stated that mandagni is the sole reason for the occurrence of all diseases [3]. Whereas in patients with samagni, it can be said that Panchakagni might not be necessarily impaired in PCOD cases. 53.33% were having normal sleep, while 14 patients (46.66%) were having disturbed sleep. Though the maximum normal sleep pattern was seen in this distribution, sleeping for long hours (10-11 hours), remaining awake during night time and sleeping during day time was seen in majority of patients. Sleep is awake during night time and sleeping during day time was seen in majority of patients. Hence this study showed statistically insignificant result in this parameter. No complications or side effects were seen in the patients during or after the treatment.

Effect of Tamra Yoga on parameters

Effect on Interval of menstruation: Highly significant relief may be due to clearance of srotovarodha or sanga leading to Vataaunulomana.

Effect on Duration of menstruation: This significant relief may be due to proper functioning of Apanavata.

Effect on Quantity of menstrual bleeding: This significant relief may be due to decrease in Kapha Vaigunya and Apanavata anuloma which leads to proper formation of Artava. It is expelled out in the form of menstrual bleeding when there is a failure of fertilization.

Effect on Pain associated with menstrual bleeding: This significant relief may be due to anuloma of vata leading to decrease in the pain.

Effect on Obesity (on the basis of BMI): Features of Obesity were not seen in majority of patients. Hence this study showed statistically insignificant result in this parameter.

Effect on Acne: This significant relief may be due to decrease of kleda, medasand kapha.

Effect on Right and Left ovarian volume, Number of follicles: This significant relief may be due to improvement in the function of samana.
and vyanavata, clearance of srotorodha leading to regression of Gula
(cysts). This simultaneously causes normalcy of Kapha resulting in
reduction of Right and Left ovarian volume and number of follicles.

CONCLUSION

Tamra Yoga showed significant results on the parameters of Polycystic
Ovarian Disease. Basing on the results obtained from the present clinical
study, we can conclude that Tamra Yoga is very safe and effective in the
management of Raja Kshaya w. s. r to PCOD. However the observations
can be reevaluated through well-designed clinical trials involving larger
sample size and long duration of the study.

Conflict of Interest

None declared.

Financial Support

None declared.

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