



Research Article

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Clinical Evaluation of *Tamra Yoga* in *Rajo Kshaya*

With special reference to PCOD

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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* (*Oligomenorrhoea* or *Amenorrhoea*) 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. r 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 with menstrual bleeding, Right and Left Ovarian volume, Number of follicles and in Acne. **Conclusion:** This study substantiates the efficacy of *Tamra Yoga* in the management of PCOD.

Keywords: PCOD, *Tamra Yoga*, *Rajo Kshaya*, *Oligomenorrhoea*, *Amenorrhoea*, 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 *Oligomenorrhoea*, 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. *Oligomenorrhoea* or *Amenorrhoea* 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 *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 asafoetida* Linn), *Yoshimatsu* (*Glycyrrhiza glabra* Linn), *Trikatu* and *Sauvachala Lavana* (*Unaqua 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.r to PCOD, this drug has been selected.

MATERIALS & METHODS

The preparation of *Tamra Yoga* was carried out in 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*, *Amrutikarana*, *Hingu bharjana*, *Kshara nirmana*, *Churna nirmana* and preparation of capsules of *Tamra Yoga*. *Parada Shodhana* was done by *Mardana* with (*Sarja Kshara*, *Yava Kshara*, *Tankana*) *Kshara traya* for three days [5]. *Gandhaka Shodhana* was performed using cow's milk by *Putra* method [6]. Equal quantities of *Shodhitha Parada* and *Gandhaka* were taken and made into *Kajjali* [7]. *Tamra Patras* was subjected to *Samanya shodhana* by *Nirvapa* in *Taila*, *Takra*, *Aranala*, *Gomutra*, and *Kulattha Kwatha* for seven times [8]. *Visesha shodhana* was done by *Dola yantra* in *Gomutra* for three hours [9]. Equal quantities of *Kajjali* and *Shodhitha Tamra Patras* were triturated in a *Khalwa 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 *Amrutikarana 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 *Hingu* 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 *Hingu 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 amenorrhoea 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 leukocyte count (TLC), differential leukocytes 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
- Duration of Drug intake: 45 days.

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 ahara*, 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 centered 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

Gap between two cycles	Grade
28-30 days	0
30-60 days	1
60-90 days	2
≥ 120 days	3

Duration of menstruation

No. of Days	Grade
4-5 days	0
2-3 days	1
1 day	2
Spotting	3

Quantity of menstrual bleeding

No. of Pads	Grade
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2-3 Pads/ day	0	Karshya	+/-
1 Pad/ day	1	Chardhi	+/-
< 1 Pad/ day	2		
Appears	3	Obesity (on the basis of BMI)	Grade
Pain associated with menstruation	Grade	20-25 kg/m ²	0
No pain	0	25-30 kg/m ²	1
Bearable pain	1	30-40 kg/m ²	2
Requirement of oral analgesics	2	more than 40 kg/m ²	3
Requirement of injectable analgesics	3	<i>ManasikaBhavas</i>	Grade
Acanthosis Nigricans	Grade	Chinta ,Shoka , Bhaya, Krodha, Dainya, Udvega	
Normal	0	Normal	0
Mild	1	Mild	1
Moderate	2	Moderate	2
Severe	3	Severe	3
Acne	Grade	<i>Ovarian Volume</i>	
No Acne	0	Right and Left Ovary	Grade
Only on face (on & off)	1	< 10 cc	0
Persistent acne on face	2	10-14 cc	1
Spreading of acne to neck,		14-18 cc	2
chest and back	3	>18	3
Hirsutism: (Ferriman- Gallwey score)	Grade	Number of Follicles	Grade
Normal	0	<6 in no.	0
Mild coverage	1	6-8 in no.	1
Moderate coverage	2	8-10 in no.	2
Complete light coverage	3	>10 in no.	3
Heavy coverage	4		
Symptoms of <i>Sthoulya</i>	Grade	Criteria for Therapy Overall Effect: Overall effect of the therapy was measured based on the following criteria- Complete remission (76%-100%), marked improvement (51-75%), mild improvement (26%-50%), no improvement (<25%).	
Dourbalya	+/-	Statistical Analysis	
Dourgandhya	+/-	ANOVA Test with Tukey-Kramer multiple comparison tests was applied at the level of 0.05, 0.01, and 0.001 of P value for more effectiveness of therapy. The results were interpreted as- insignificant (p>0.05), significant (p<0.05), highly significant (p<0.01, p<0.001), extremely significant (p<0.0001).	
Swedhabadha	+/-	Observation	
Atimatrakshudha	+/-	Overall, 32 patients with signs and symptoms of PCOD were recorded. Of them 30 patients finished the treatment course. Two patients discontinued due to unknown reasons. In the current study, maximum patients (70%) were from the age group 21-30 years, 90% belonged to Hindu religion. Among them 53.33% were married with normal marital life. Maximum patients (66.66%) were from urban habitat. All the patients 100% were educated; maximum patients (46.66%) were house wives, while maximum patients (46.66%) were engaged with sedentary	
Atipipasa	+/-		
Symptoms of <i>Gulma</i>	Grade		
Agnimandya	+/-		
Aruchi	+/-		
Shula	+/-		
Udgara	+/-		

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 *Samashana*, 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-Kaphaprakruti*, 70% patients had *madhyamasatwa*, 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 *ratrijagarana* and 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), *Udgara* (belchings) and *Chardi* (vomiting).

RESULTS

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

S. No	Name of content	Quantity
1	Tamra Bhasma	30 mg
2	Yashtimadhu	125 mg
3	Trikatu	125 mg
4	Chincha Kshara	125 mg
5	Bharjitha Hingu	125 mg
6	Sauvarchala Lavana	125 mg

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

S. No.	Symptoms of <i>Sthoulya</i> & <i>Gulma</i>	B. T	A. T	Follow up
1	Dourbalya	+	-	-
2	Swedhabadha	+	-	+
3	Agnimandya	+	-	-
4	Aruchi	+	-	-
5	Udgara	+	-	-
6	Chardi	+	-	-

*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

- Interval of menstruation
- Duration of menstruation
- Quantity of menstrual bleeding
- Pain associated with menstrual bleeding
- Right Ovarian volume
- Left Ovarian volume
- Number of follicles.

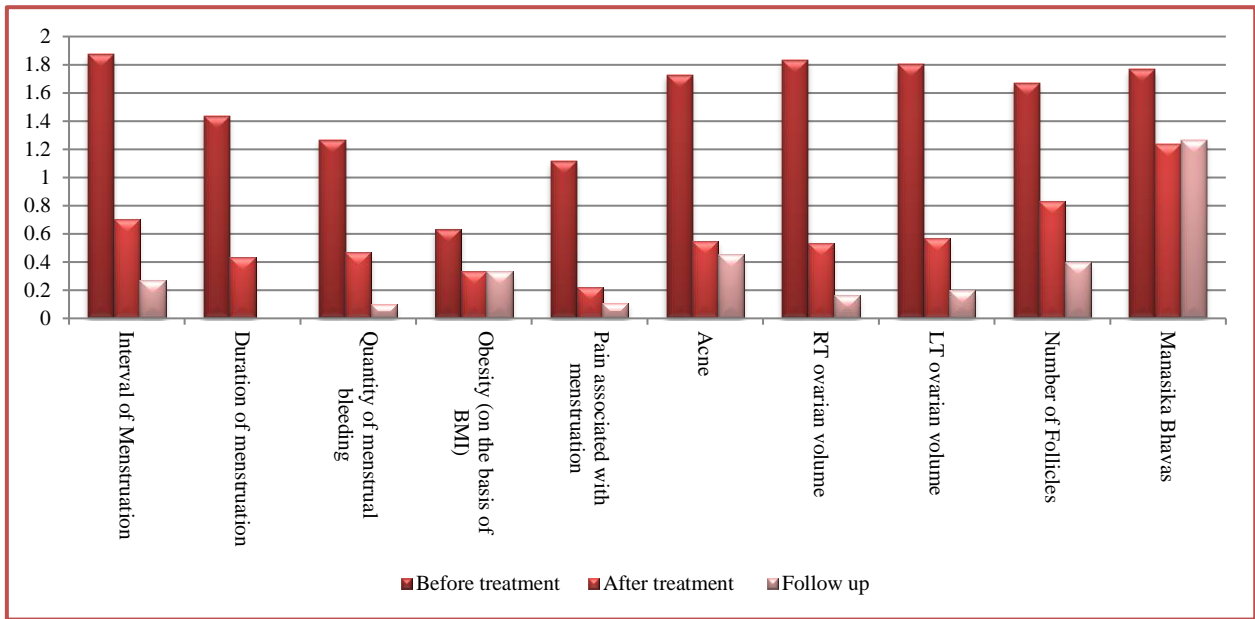
- Statistically highly significant relief ($P < 0.01$) was seen after treatment & follow up in:-

- Patients with Acne.

- It was found to be Statistically insignificant ($P > 0.05$) for Obesity (on the basis of BMI) and *manasikabhavas*.

- No patient reported with the complaint of *Acanthosis nigricans* and *Hirsutism*.

- Marked improvement was seen in the Symptoms of *Sthoulya* and *Gulma*.



Graph 1: Showing Mean effect of *Tamra Yoga* on parameters in 30 patients

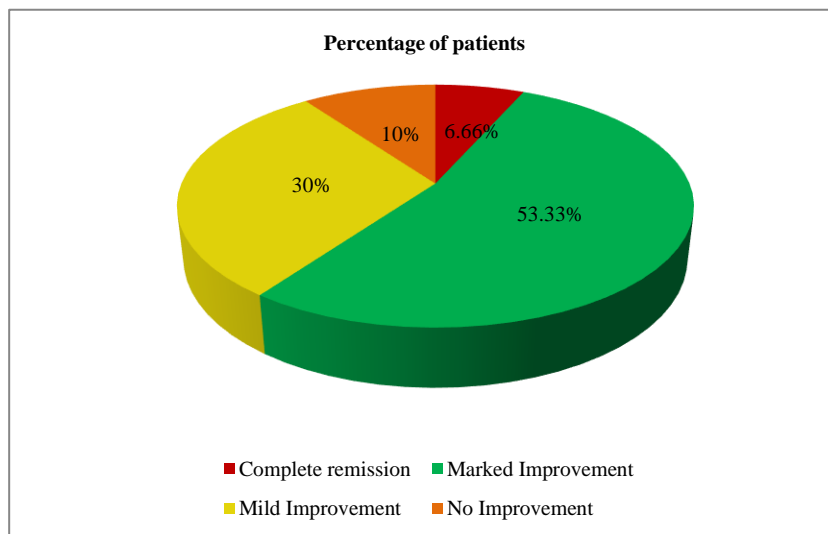
Complete Assessment of therapeutic effect

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

Result	No. of Patients	% Of Patients
Complete remission	02	6.66%
Marked Improvement	16	53.33%
Mild Improvement	9	30%
No improvement	03	10%



Graph 2: Showing overall assessment of Clinical trial

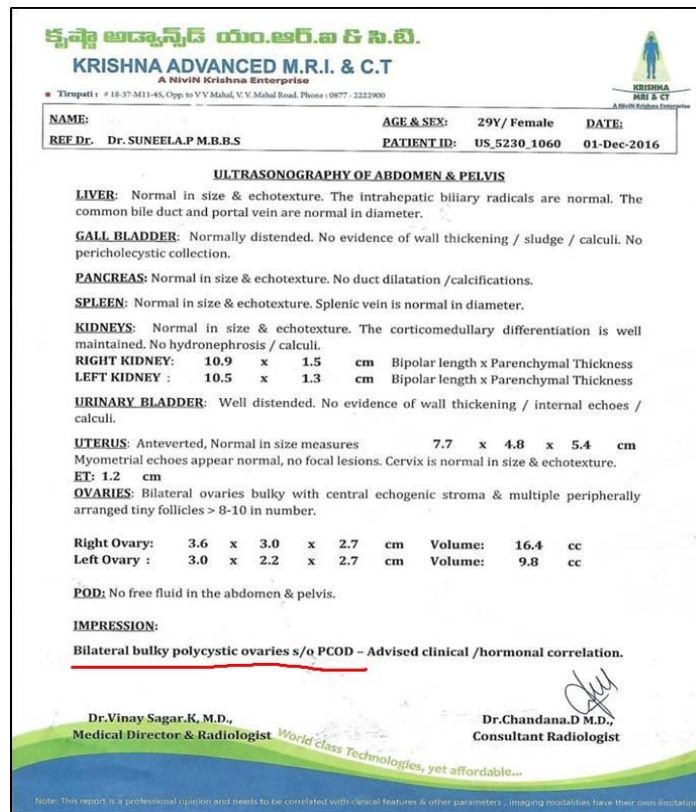


Figure 1: Showing USG of Clinical Study Patient before trail

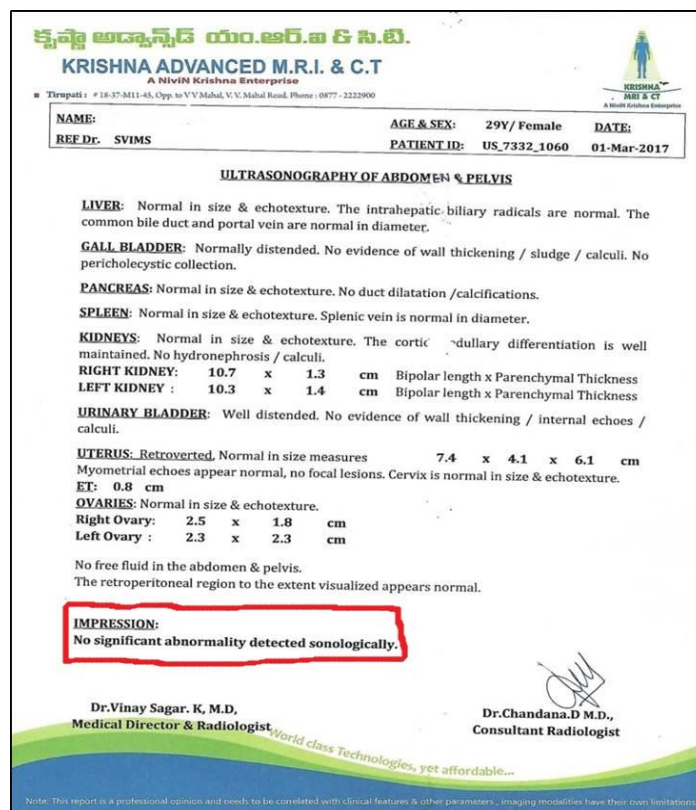


Figure 2: Showing USG of Clinical Study Patient After trail

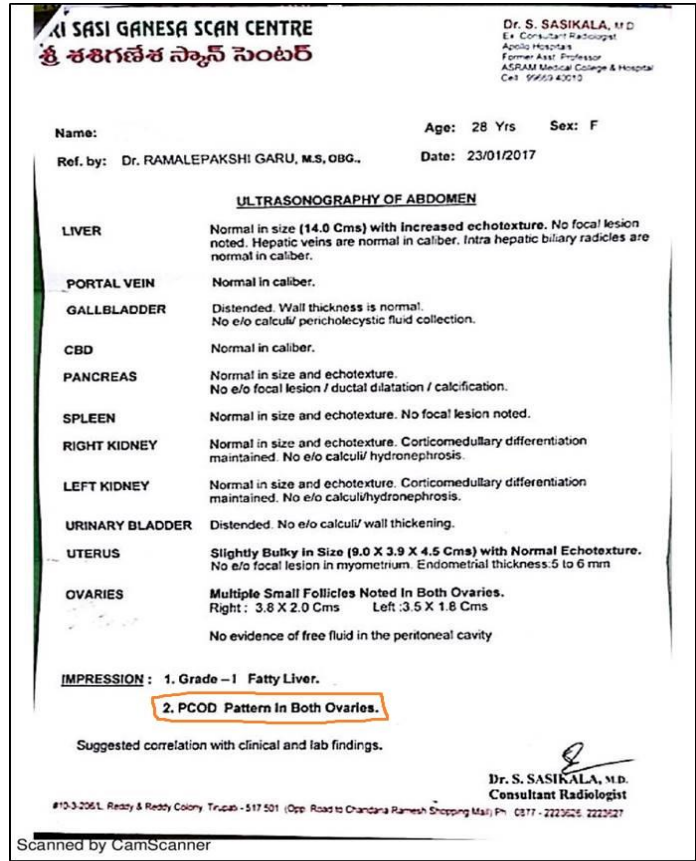


Figure 3: Showing USG of Clinical Study Patient Before trail

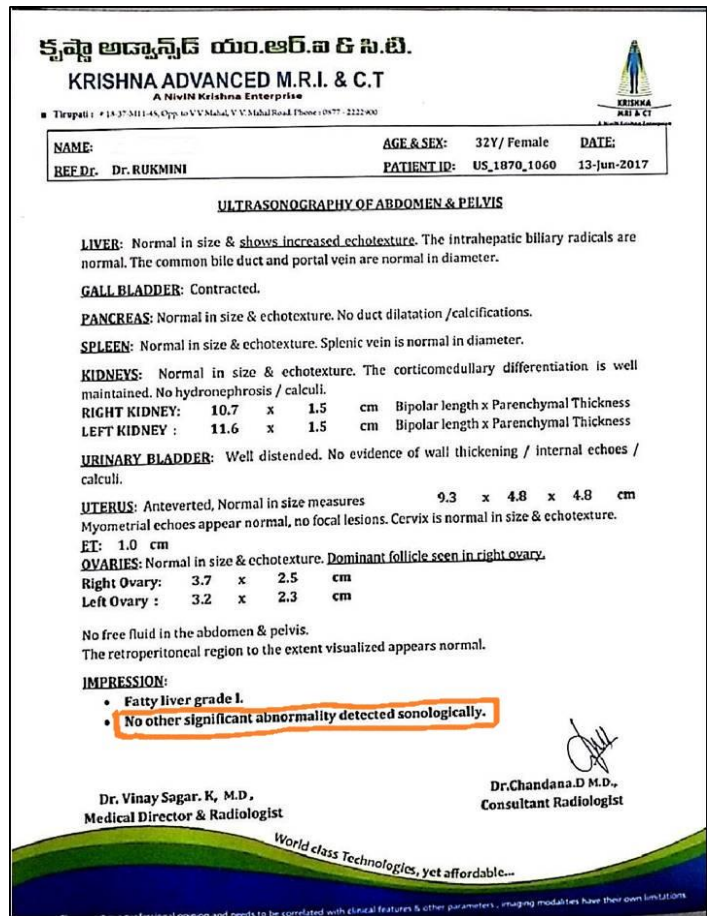


Figure 4: Showing USG of Clinical Study Patient After trail

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 habitat; 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 *Santarpanajanyavyadhi*. 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 and 43.33% to moderate work. *Asyasukha*, *swapnasukha*, *avyayama* are considered as *nidana* for *Kapha vrudhhi*, *Medo vrudhhi* and *srotoavarodha*, which is seen in the samprapti of PCOD [14]. Highest percentage (66.66%) reported the complaint of irregular menstruation which shows the awareness of the women about their menstrual cycle pattern. 43.33% had a habit of consuming junk foods and 30% had a habit of consuming homemade heavy diet. A research study conducted to know the role of diet in the treatment of PCOD suggested that, eucaloric Low CHO diet, low in carbohydrate (43%) and cholesterol, rich in fiber, and constituted of 45% fat (18% monounsaturated fat and <8% saturated fat), increased the metabolic power of women with PCOD within 16 days [15]. 12 patients (40%) were following *samashana*, 11 patients (36.66%) were following *vishamasana*, 05 patients (16.66%) were following *adhyashana*, 02 patients (6.66%) were following *anashana*. All these dietetic habits are abnormal and all the women in the present study have some kind of abnormal dietetic habits. This history strongly attributes the relation between PCOD and abnormal dietetic habits.

Maximum patients had *mandagni* (43.33%) followed by *samagni* (36.66%). Classics stated that *mandagni* is the sole reason for the occurrence of all diseases [16]. Whereas in patients with *samagni*, it can be said that *Pachakagni* 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 also intricately connected to various hormonal and metabolic processes in the body and is important in maintaining metabolic homeostasis. In research conducted to know the role of sleep on metabolism proved that, persons indulging in sleep for more than 8 hours were more prone to develop metabolic disorders [17]. 53.33% had constipation which indicates the vitiation of *Apanavata* in these patients. In the present study, 60% of patients had emotional stress. A stress response includes a release of a variety of stress hormones (primarily cortisol), increased sympathetic activity and decreased serotonin levels in the central nervous system which in turn lead to inadequate pulsatile secretion of GnRH from hypothalamus. Many studies proved the relation of psychological distress and development of PCOD [18]. Maximum patients belonged to *vatakapha prakruti*. PCOD mainly involves the vitiation of *Vata* and *Kapha doshas*. Hence the predominance of the patient with *Vata Kapha prakruti* signifies the predilection of the patient towards this disease. 33.33% had irregularity in menstrual cycle since menarche and 23.33% had irregularity in menstrual cycle more than 2 years. The chronicity beyond 2 years (*i.e.*, 56.66%) indicates the *yapyatwa* of the disease. 19 patients (63.33%) had a habit of *diwaswapna*, 10 patients (33.33%) had a habit of *ratrija garana* and 9 patients (30%) had a habit of *vegadharana*. *Diwaswapna* leads to *Kapha dushhti* [19]. *ratrija garana* and *Vegadharana* are the main causes for *vata dushhti* [20]. These are considered as the main *nidana* of PCOD, which were seen in the patients. To understand the pathology of the PCOD, it is

compared with pathological condition and symptoms of *Sthoulyaand Gulma*. *Dourbalya* and *Swedhabhadha* were noticed only in 2 patients (6.67%), it indicates that the disease PCOD in these patients has not progressed to a level where *medovahasrotas* involvement is found. Clinical features of *Gulma* were not found significantly in these patients. The clinical feature of *Rakta Gulma* discussed in the classical texts *viz.*, appearance of *Gulma* externally (*i.e.*, per abdomen) was diagnosed by USG as cysts (in PCOD), but not per abdomen.

Probable mode of action of *Tamra Yoga*

Contents of *Tamra Yoga* are *Tamra Bhasma*, *Yashtimadhu*, *Trikatu*, *Hingu*, *Chincha Kshara* and *Sauvarchala lavana*. *TamraBhasma* has *tikta*, *kashaya*, *katu rasa*, *ushnavirya* and *kapha-pitta hara*, *lekhana*, *laghu*, *saraka*, *deepana*, *urdhwaadhashodhaka* properties [21]. By these properties it helps in alleviating *Kaphavrudhhi*, *medovrudhhi*, *srotoavarodha*, *agnimandya*, *avarana* etc. conditions, which are the pathological changes seen in PCOD. Copper shows an vital role in reproduction. It acts at the level of hypothalamus through neural activity modulation, GnRH granules modification stability and neurohormone release modulation [22]. *Kajjali* enhances the bio availability of active principles to body tissues [23]. *Chincha Kshara* possesses *shulaand agnimandyanasha* properties [24]. *Hingu* has *katu rasa*, *tikshnaguna*, *saraguna*, *deepana*, *pachana*, *vataanulomana*, *artavajanaka*, *kaphanissaraka* properties [25]. Recent research studies have proven that *Ferula asafoetida* has neuroprotective, anti-spasmodic, hepato-protective, anti-hyperlipidemic, anti-diabetic and antioxidant activities [26]. *Sauvarchala Lavanahas Katu*, *kshara* *rasa*, *vishadaguna*, *ushnavirya*, *rochana*, *bhedaka*, *deepanaand pachana* properties [27]. *Yashtimadhu* has *madhura rasa*, *Swarya*, *Keshya*, *Shukrala*, *Varnya*, *Vranapaha*, *Sthanyavardhaka*, *Balya* and *Rasayana* properties [28]. Research studies on *Glycyrrhizag labrasha* showed significant activity in the hormonal regulation of androgens, regulation of LH to FSH ratio and decrease of serum testosterone levels in women with PCOD [29]. *Trikatu* is having *kapha-medoghna*, *mehakusthahara*, *twakdosahara*, *Gulma*, *Peenasahara* and *agnideepana* properties [30].

With regard to the pathology of the disease, *Ushnavirya*, *Tikshnaguna*, *Kaphahara*, *Vatahara*, *Deepana*, *Pachana*, *Lekhana*, *Sroroshodhana*, *Vataanulomanaand Artavajanana* properties of *Tamra Yoga* normalizes vitiation of *Vata* and *Kapha*; reduces excess *kapha & meda*, removes *srotoavarodha sanga* and creates normal functioning of *Apana Vata* in course of *Rajovahasrotas*.

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 *srotoavarodha* or *sanga* leading to *Vataanulomana*.

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 anulomana* 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 *anulomana* 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 *Gulma* (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 *Rajo Kshaya* w. s. r to PCOD. However the observations can be revalidated 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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