



### Clinical Evaluation of *Soodhagavaayu Pattai Legiyam* for the Management of Sinaipainerkatti (PCOS)

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#### ABSTRACT

Polycystic ovary syndrome (PCOS) is a common diagnosis in women presenting with anovulatory infertility, and it affects 5–10% of women of reproductive age. Symptoms of PCOS related to ovulation manifest as amenorrhoea or oligomenorrhoea. Polycystic ovaries are enlarged and contain a large number of immature follicles. There are also metabolic disorder associated with PCOS such as insulin resistance and hyperinsulinemia in women. Conventional therapy on PCOS management fails to offers expected clinical outcomes and further majority of the treatment aimed at symptomatic cure of which the reoccurrence rate is very high. Siddha system of medicine works behind the principle component on healing and rejuvenation. It was evident that occurrence of PCOS is due to several etiological factors. Siddha formulations normally possess multiple bioactive components which acts on inflammatory pathway, hormonal balancing, hypoglycaemic factors etc. The main objective of the present investigation is to clinically validate the potential of siddha formulation Soodhagavayu Pattai Legiyam against PCOS in women's attending Out-patient/ In-patient department of the Ayothidass Pandithar Hospital, National Institute of Siddha, Chennai, Tamil Nadu, India. Clinical study comprises of 10 patients with Sinaipaineerkatti (PCOS) were subjected to siddha therapy Legiyam (SPL) at the dose of 4-6gms and subsequent in-depth evaluation. Treatment with siddha formulation SPL showcase significant reversal of PCOS complications evidenced with decrement in ovaries size advocated by radiological examination. Data's also emphasise that there is a pronounced decrease in the level of oligo / amenorrhoea by 70%. Observation also documented the percentage declination in dysmenorrhoea (70%), hirsutism (80) and leucorrhoea (90%). It was concluded based on the data's of the present clinical investigation is that the siddha formulation *Soodhagavayu Pattai Legiyam* offers significant clinical improvement from the PCOS complication, hence it may be clinically recommended for the management of PCOS disease in near future.

**KEY WORDS:** PCOS, Sinaipaineerkatti, Siddha, Soodhagavayu Pattai Legiyam, Dysmenorrhoea, Hirsutism, Leucorrhoea

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## 1. Introduction

PCOS, also known as polycystic ovarian syndrome, is a very common condition that is caused by a combination of endocrine and metabolic dysfunction. It is estimated that between 4% and 18% of all reproductive-aged women around the world are affected by it [1,2]. Hyperandrogenism and ovarian abnormalities are two of the hallmarks of polycystic ovary syndrome (PCOS), which is caused by a disruption in the hypothalamic-pituitary-ovarian axis [3,4]. Clinically speaking, hyperandrogenism and insulin resistance are the primary factors responsible for reproductive and metabolic problems in women who have PCOS [5]. The exact cause of polycystic ovary syndrome (PCOS) has not been identified; nevertheless, it is believed that environmental, genetic, and hormonal variables all have a role in its development [6].

In PCOS condition it has been postulated that hyperandrogenism, persistent low-grade inflammatory disease, and insulin resistance are key contributors to the pathogenesis of these diseases [7,8]. It has been proven that circulating and molecular indices of pro-inflammatory and oxidative stress are significantly related with circulating androgens [9]. These findings provide credence to the theory that hyperandrogenism causes inflammation, which in turn leads to hyperglycemia. On the other hand, carbohydrate consumption leads to inflammation, which in turn encourages an increase in the ovary's overall androgen synthesis [10,11]. An increase in the biosynthesis of the cytochrome P450 17 superfamily has been linked to increased levels of excessive androgen production in the ovary (CYP17). The multipurpose enzyme known as cytochrome P450 number 19 (CYP19) is responsible for the conversion of androgens to estrogens [12]. cytochrome P450 aromatase and nicotinic adenine dinucleotide phosphate cytochrome reductase are the two components that make up this enzyme. This enzyme first changes pregnenolone and progesterone into 17-hydroxypregnenolone and 17-hydroxyprogesterone, respectively, before proceeding to change them into dehydroepiandrosterone and androstenedione [13]. The treatment of polycystic ovary syndrome (PCOS) is condition-specific [14]. Weight loss [15], oral contraceptive pills, cyclic

progesterin,[16] spironolactone, and finasteride are some of the treatments that are utilized to alleviate the symptoms caused by androgen increase [17]. In addition to the benefits of using oral contraceptives, there is also the potential for an increase in adverse consequences associated to IR, the heart, and the endocrine system [18,19]. Metformin can cause a number of unpleasant side effects, including diarrhoea, abdominal bloating and pain, loss of appetite, a taste similar to metal, a lack of vitamin B12, and lactic acidosis [20-23]. There are several conditions that can be treated, including polycystic ovary syndrome (PCOS), and complementary and alternative medicine is one of the most prevalent approaches [24]. In the past 10 years, there has been an increase in the use of complementary medicine that ranges from approximately 26% to 91%. Complementary medicine encompasses a wide range of practices, including acupuncture, herbal medicines, and reflexology [25]. Many individuals are now turning to these items as a treatment for a wide variety of health issues in a variety of national healthcare settings [26]. The usage of herbal medicines and phytonutrients or nutraceuticals is continuing to rise fast across the world. The main objective of the present investigation is to clinically validate the potential of siddha formulation Soodhagavayu Pattai Legiyam against PCOS in women's attending Out-patient/ In-patient department of the Ayothidass Pandithar Hospital, National Institute of Siddha, Chennai, Tamil Nadu, India.

## 2. Materials and Methods

### 2.1. Ingredients of the Trial Drug

Name of the formulation: *Soodhaga Vayu Pattai Legiyam*

List of Ingredients

1. Jathikaai (*Myristica fragrans*): 1 varagan (4 grams)
2. Kirambu (*Syzygium aromaticum*): 1 varagan (4 grams)
3. Parangipattai (*Smilax china*): 1 varagan (4 grams)
4. Chitrathai (*Alpinia galanga*): 1 varagan (4 grams)
5. Chukku (*Zingiber officinale*): 1 varagan (4 grams)
6. Arisi Thippili (*Piper longum*): 1 varagan (4 grams)
7. Milagu (*Piper nigrum*): -1 varagan (4 grams)
8. Lavangapattai (*Cinnamomum verum*): 1 varagan (4 grams)
9. Lavangapathiri (*Cinnamomum tamala*): 1 varagan (4 grams)
10. Elarasi (*Electaria cardomomum*): 1 varagan (4 grams)
11. Kichilikizhangu (*Curcuma zedoaria*): 1 varagan (4 grams)
12. Narseeragam (*Cuminum cyminum*): 1 varagan (4 grams)
13. Sadamanjil (*Nardostachys grandiflora*): 1 varagan (4 grams)
14. Narivilapattai (*Feronialimonia*): 1 varagan (4 grams)
15. Sathakuppai (*Anethum graveolens*): 1 varagan (4 grams)

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- 16.Pungamverpattai(*Pongamiapinnata*): 1varagan(4grams)
- 17.Ayilpattai(*Chukrasiatabularis*): 1varagan(4 grams)
- 18.Kumizhathipattai(*Gmelinaarborea*): 1varagan(4 grams)
- 19.Sarkarai : 6 palam(192 grams)
- 20.Honey: QS

## 2.2. Source of Trail drug

The required drugs will be purchased from a well reputed country shop and raw drugs are authenticated by the medicinal botanist of NIS. The medicine will be prepared in Gunapadam lab of National Institute of Siddha after proper purification. The prepared medicine will also be authenticated by the concerned Head of the Dept for its completeness. All the ingredients mentioned in the formulations purified as per the direction described in the siddha literature.

## 2.3. Method of preparation

The required quantity of the purified drugs are taken and grinded into fine powder. Gradually honey is added and grinded well with the powder for 1 hour until the required consistency obtained.

## 2.4. Dose and Administration [27]

Dosage : 1-11/2 VARAGAN (4 – 6g)  
Total Duration : 3 Months  
Diet : Whole grains, wheat, fresh fruit, lots of vegetables, legumes and nuts.  
Physical Exercise: Brisk walking in morning and evening for 40 mins.

## 2.5. Study design

Clinical study comprises of 10 patients with the condition called Sinaipaineerkatti (PCOS) were subjected to siddha therapy Soodhagavayu Pattai Legiyam (SPL) at the dose of 4-6gms and subsequent in-depth evaluation. The entire study was conducted on Out-patient/ In-patient department of the Ayothidass Pandithar Hospital, National Institute of Siddha, Chennai, Tamil Nadu, India. Institutional ethical committee clearance was obtained for this study by mentioning the stipulated time point of the observation (3 months).IEC NO:NIS/IEC/2019/P-7. Further this clinical study were registered in Clinical Trials Registry- India with the number CTRI/2019/06/019571. All the study participants were comprehensively explained about the objectives of this study before requesting them for their voluntary participation in this study.

Participants were also explained that completion and submission of the data's would be taken as consent to participate in this study. Data were dealt with the high level of anonymity and confidentiality.

## 2.6. Inclusion Criteria

The following were considered as the inclusion criteria's of the present clinical study which includes

- 1.Age: 18-35 years.
- 2.Patients who are having the clinical symptoms of Oligomenorrhoea (or) Amenorrhoea (or) obesity or infertility with polycystic changes in ovaries.
- 3.Imbalance in the hormones.
- 4.USG pelvis showing polycystic ovaries with the volume of 10-15cm<sup>3</sup>
- 5.Patient willing to participate in trial and signing in consent form

## 2.7. Exclusion Criteria

The following were considered as the exclusion criteria's of the present clinical study which includes

- 1.Existence of Specific disease- Ovarian cancer, H/O thyroid dysfunction, Fibroid uterus
- 2.Condition -Pregnancy and lactation
- 3.Clinical condition - Patient with any serious illness

## 2.8. Study withdrawal Criteria

The following are the withdrawal criteria of the present clinical investigation

- 1.Intolerance to the drug and development of adverse reactions during the drug trial.
- 2.Poor patient compliance & defaulters
- 3.Patients turned unwilling to continue in the course of clinical trial

## 2.9. Clinical assessment

Clinical efficacy of the siddha formulation SPL will be evaluated based on the clinical examination of the patients subjected to the therapy with the assessment scale on before and after treatment. The key point of assessment included the timely occurrence of menstrual Cycle, BMI measurement, USG Pelvis-Ovaries Size (Cm) examination, assessment on Oligo / Amenorrhoea, Dysmenorrhoea, Hirsutism, Leucorrhoea.

### 3. Results

#### 3.1. Clinical assessment on severity assessment of PCOS complication among study participants

Radiological examination of the ovaries demonstrate considerable increase in size of the ovaries evidenced with existence of PCOS condition. Further 100% of the study population signifies the prevalence of oligo / amenorrhoea and 80% reported with dysmenorrhoea. In addition to this 40% of the study population exhibit the complications of both hirsutism and leucorrhoea as shown in Table 1.

#### 3.2. Effect of siddha formulation SPL in ameliorating PCOS complication in study participants

Treatment with siddha formulation SPL showcase significant reversal of PCOS complications evidenced with decrement in ovaries size advocated by radiological examination. Data's also emphasise that there is a pronounced decrease in the level of oligo / amenorrhoea by 70%. Observation also documented the percentage declination in dysmenorrhoea (70%), hirsutism (80) and leucorrhoea (90%) as shown in Table 2.

### 4. Discussion

PCOS is one of the endocrine conditions that affects women at an alarmingly high rate . Insulin resistance and hypofunctions in the hypothalamic-pituitary axis are the root causes of polycystic ovary syndrome (PCOS) [28]. The illness can cause an increase in androgens, which can lead to obesity; it can also cause insulin resistance, which can lead to type 2 diabetes; and it can cause oxidative stress [29,30]. In women, changes to their antioxidant systems may cause pathological effects such as polycystic ovary syndrome (PCOS) and a disruption in their ovarian steroid production [31]. In these people, there is a decrease in the synthesis of gonadotropin, which is accompanied by an increase in the secretion of luteinizing hormone (LH) in comparison to follicle-stimulating hormone (FSH) [32]. PCOS can be treated with a variety of pharmaceutical therapies; however, the majority of these treatments are very temporary in their effects. In light of the bad effects that these medications can cause, it is absolutely necessary to locate and give alternative treatments [33].

Weight gain is usually associated with an exacerbation of symptoms, while weight loss usually improves the symptoms and endocrine and metabolic disturbances [34]. Many of the PCOS patients were identified by increased serum level of luteinizing hormone (LH) and normal or decreased serum level of follicle stimulating hormone (FSH) [35]. This is explained by an increased pulse frequency of the hypothalamic gonadotropin-releasing hormone [36]. Radiological examination of the ovaries demonstrate considerable increase in size of the ovaries evidenced with existence of PCOS condition. Further 100% of the study population signifies the prevalence of oligo / amenorrhoea and 80% reported with dysmenorrhoea. In addition to this 40% of the study population exhibit the complications of both hirsutism and leucorrhoea Siddha system of medicine works behind the principle component on healing and rejuvenation. It was evident that occurrence of PCOS is due to several etiological factors. Siddha formulations normally possess multiple bioactive components which acts on inflammatory pathway, hormonal balancing, hypoglycemic factors etc. Further herbal medicine usage by women has increased over the past decade [37,38]. Herbal remedies are known to contain active constituents with physiological effects on female endocrinology and have been shown to be positively associated with reduced incidence of breast, bone, and cardiovascular diseases [39]. Treatment with siddha formulation SPL showcase significant reversal of PCOS complications evidenced with decrement in ovaries size advocated by radiological examination. Data's also emphasise that there is a pronounced decrease in the level of oligo / amenorrhoea by 70%. Observation also documented the percentage declination in dysmenorrhoea (70%), hirsutism (80) and leucorrhoea (90%).

### 5. Conclusion

Traditional herbal remedies are becoming more common in replacing established medications for the treatment of PCOS. It was concluded based on the data's of the present clinical investigation is that the siddha formulation Soodhagavayu Pattai Legiyam offers significant clinical improvement from the PCOS complication, hence it may be clinically recommended for the management of PCOS disease in near future.

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**Table 1: Clinical assessment on severity assessment of PCOS complication among study participants before treatment.**

Case no.	Age	Menstrual cycle	BMI	USG pelvis- ovaries size (cm)	Oligo/ Amenorrh oea	Dysmenor rhoea	Hirsutism	Leucorrh oea
1	26 years	2/40-50 days	26.8	Left -3.7×1.6×2 Right- 3×2.1×1.8 Imp: Polycystic ovaries	Present	Present	Absent	Absent
2	29 years	9/35 days	28	Left- 3.3×2.9×2.3 Right- 3.4×2.5×2.2 Imp: Polycystic ovaries	Present	Present	Present	Present
3	31 years	3/60-70 days	31.5	Left- 4.6×2.9×2.8 Right- 4.3×2.8×3.4 Imp: Polycystic ovaries	Present	Present	Absent	Present
4	21 years	3/35 days	29.4	Left- 4.5×2.6×2.9 Right- 3.6×2.6×3.5 Imp: Polycystic ovaries	Present	Present	Absent	Absent
5	27 years	20/60-90 days	31.2	Left-4.2×3.4×1.8 Right- 3.7×3.4×2.3 Imp: Polycystic ovaries	Present	Present	Absent	Present
6	29 years	3/40-45 days	24.4	Left- 4.2×2×2.4 Right- 4.1×1.6×1.9 Imp: Polycystic ovaries	Present	Absent	Present	Absent
7	21 years	11/90 days	25	Left- 4.3×2.7×2.5 Right- 3.9×3×2 Imp: Polycystic ovaries	Present	Present	Present	Absent
8	30 years	8/60-90 days	30.5	Left- 4.1×3.6×2 Right- 3.7×3.6×3 Imp: Polycystic ovaries	Present	Present	Present	Present
9	23 years	3/60 days	25	Left- 4.6×2.1×2 Right - 4.8×1.6×2 Imp: Polycystic ovaries	Present	Present	Absent	Absent
10	20 years	3/90-180 days	23	Left- 3.6×3.2×2.4 Right- 3.6×2.7×1.9 Imp: Polycystic ovaries	Present	Absent	Absent	Absent

**Table 2: Effect of siddha formulation SPL in ameliorating PCOS complication in study participants**

Case no.	Age	Menstrual cycle	BMI	USG pelvis- ovaries size (cm)	Oligo/ Amenorrh oea	Dysmenor rhoea	Hirsutism	Leucorrh oea
1	26 years	3/30 days	26	Left - 2.7×1.8×1.5 Right- 3×2×1.6 Imp: Normal ovaries	Absent	Absent	Absent	Absent
2	29 years	3/28 days	26.5	Left- 3.3×2.5×2.3 Right- 3.4×2.8×2 Imp: Polycystic ovaries	Absent	Absent	Present	Absent
3	31 years	3/40 days	30	Left- 3.5×2.7×2.4 Right- 3.2×2.7×3 Imp: Polycystic ovaries	Present	Absent	Absent	Absent
4	21 years	3/30 days	29	Left- 3.5×2.2×3.2 Right- 3×2×3.5 Imp: Polycystic ovaries	Absent	Present	Absent	Absent
5	27 years	5/30 days	30	Left- 3×2.5×1.8 Right- 3.2×3×2.3 Imp: Normal ovaries	Absent	Present	Absent	Absent
6	29 years	3/28 days	24	Left- 3.5×2×1.6 Right- 3×2.3×1.8 Imp: Normal ovaries	Absent	Absent	Reduced	Absent
7	21 years	2/25 days	25	Left- 3.1×1.7×3 Right- 3×2.2×2.4 Imp: Small immature peripheral follicles	Absent	Present	Reduced	Absent
8	30 years	3/30-40 days	30	Left- 3.3×2.7×2.3 Right- 3.6×2.9×2.5 Imp: Polycystic ovaries	Present	Absent	Present	Present
9	23 years	3/35 days	24	Left- 3.1×1.8×2 Right- 3.3×1.8×1.5 Imp: Polycystic ovaries	Present	Absent	Absent	Absent
10	20 years	3/40 days	22.5	Left- 3×2.5×2 Right- 2.8×2.5×1.8 Imp: Normal ovaries	Present	Absent	Absent	Absent