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CLINICAL EVALUATION OF *SOOTHGA VAYU LEGIYAM* AND *VEEZHI ENNAI* IN THE MANAGEMENT OF *GARPA VAYU* (POLYSYSTIC OVARIAN SYNDROME)

Pratheepa.C[1], Nalinisofia. H[2], Vetha merlin kumari. H[3], Mohan.S[4]

[1]Asst.Medical officer, Govt. Hospital,Arumanai, Kanyakumari District.

[2]Lecturer, [3] Associate Professor, [4]Professor &HOD Dept.of Maruthuvam, National Institute of Siddha, Chennai, Tamilnadu, Corresponding author: dr.h.nalinisofia@gmail.com

ABSTRACT

Background: Garpavaayu is a uterine disorder characterized by abdominal discomfort, dysmenorrhoea, low back ache, constipation, amenorrhoea, and heaviness of thigh. These symptoms of *Garpavaayu* may be correlated with Polycystic Ovarian Disease of modern science.The classical Siddha literature *Pararasasekaram* cites that any imbalance in three humours may inhibit the release of ovum from the ovaries. This may be related to the subfertility due to ovulatory factors. Polycystic ovarian disease is the most common gynaecological disorder which is characterized by irregular menstrual cycle, obese, ultimately leads to infertility. The disease which were challenging to the medical world were often treated well by Siddha system of medicine. Hence the formulations *soothagavaayu leghium* and *veezhiennei* indicated for *Garpavaayu* were subjected to clinical study to confirm their efficacy scientifically. **Objective:** To evaluate the therapeutic efficacy of *soothagavaayu leghium* and *veezhiennei* in the treatment of *Garpavaayu* (Poly cystic ovarian disease). **Method:** Clinical trial was conducted in accordance with standard study protocol approved in IEC and registered in CTRI. *Garpavaayu* patients were screened by standard pre tested questionnaire. Patient recruitment was made based on the inclusion and exclusion criteria. The study drugs *soothagavaayu leghium* and *veezhiennei* were administered orally as per the dosage and duration mentioned in the approved protocol. The baseline data, clinical assessment in each visit and laboratory investigations before and after treatment were recorded in the case report form. The data of inter menstrual period score, Duration of bleeding score and body mass index before treatment and at the end of the treatment were analyzed by comparing the two point of data (before and after treatment) paired t' test was employed to study the efficacy of treatment. **Results:** The statistical analysis revealed that there has been a significant reduction in IMP assessment score after treatment indicating the improvement i.e., regular menstrual

cycle in patients. And also a significant reduction in DOB assessment score after treatment. **Conclusion:** The clinical trial showed that the study drugs *soothagavaayuleghium* and *veezhiennei* has significant therapeutic effect in *Garpavaayu* patients.

Key words:*Siddha, Garpavaayu, soothagavaayu leghium, veezhiennei,* Polycystic Ovarian Disease.

INTRODUCTION

Reproductive health is defined as the ability of women to live through the reproductive years and beyond with reproductive choice, dignity and successful child bearing and to be free of gynecological disease and risk. Polycystic ovarian disease is the most common gynecological disorder which is characterized by irregular menstrual cycle, obese, ultimately leads to infertility. The incidence appears to increase due to change in life style and stress. Its prevalence in India ranges from 2.2 to 26% with the age of 18 – 45 years i.e., it affect women in her entire fertile period. Polycystic ovarian disease (PCOD) is the most common gynecological endocrinopathy with ovarian expression of metabolic disturbances. The incidence appears to be increase due to change in life style and stress. The principle features are obesity, chronic non ovulation, irregular menstruation, excess of androgenic hormones. It is one of the leading causes for subfertility. The disease begins soon after puberty but may manifest during reproductive period. Women with PCOS are at increased risk of reproductive problems including infertility, endometrial cancer, late menopause, and also metabolic disturbances including insulin resistance, type II diabetes mellitus, cardiovascular disease, dyslipidemia. PCOS is a common female endocrine disorder with prevalence ranging from 2.2% to 26%. Most reports have studied adult women with age ranged from 18 to 45 years. PCOS occurs in 5% to 10% of women, making it one of the most common endocrine disorders. PCOS is a heterogeneous endocrine disorder that affects about 1 in15 women worldwide. The prevalence of polycystic ovaries in Indian sub-continent Asian women was 52 %. Polycystic morphology seen in ultrasound is approximately 22% of women. Hirsutism is a common problem in India as elsewhere in the world. Idiopathic hirsutism is 38.7%, PCOS 37.3%. In India nearly 40% of women are affected by PCOS, among them only 60% come to hospitals for treatment, when they recognize that they have got infertility.

PCOS is a heterogeneous disorder of uncertain etiology such as

1. Genetic cause: There is strong evidence that it is a genetic disease. Although specific gene associated with the condition have not yet been identified.

2. Hormonal imbalance: An imbalance in the release of the luteinizing hormone (LH) and the follicle stimulating hormone (FSH)fromthepituitaryhasbeenimplicated.

The LH / FSH ratio is altered and the secretion of LH is higher than that of FSH resulting in increased androgen, testosterone and dehydroepiandrosterone (DHEA) productions.

3. Insulin resistance: It is not solely a consequence of increased visceral obesity. Rather, obesity and hormonal abnormalities are thought to make additive contributions to insulin resistance. Functional insulin resistance is considered as consequence of defects in insulin-mediated glucose transport and signaling in adipocytes and myocyte. This may be the result of dysregulation in adipokine production and signaling from adipose tissues but the mechanism is incompletely understood.

4. Intrauterine exposures: Exposure to testosterone in utero may predispose to the later development of PCOS.

5. Environment / lifestyle factors: Several lifestyle factors and environmental exposures have been associated with more severe PCOS phenotype.

6. Obesity: Although obesity is not believed to cause PCOS, it is known to exacerbate the symptoms of the disease.

The principle features of PCOS includes,

1. Irregular menstrual periods:

PCOS mostly produce oligomenorrhoea (few menstrual periods) or amenorrhoea (no menstrual periods) but other types of menstrual disorders may also occur.

2. Central obesity: BMI > 30kg/cm^2, waist line.35”

3. Reproductive manifestation

Subfertility or infertility this generally results directly from chronic an ovulation.

4. Clinical hyperandrogenism:

The most common signs are acne and hirsuitism (male pattern of hair growth on face, chest, stomach or back) but it may produce hypermenorrhoea (very frequent menstrual periods), androgenic alopecia (Male-pattern baldness or thinning hair) or other symptoms. Approximately three-quarters of patients with PCOS (by the diagnostic criteria of NIH/NICHD 1990) have evidence of hyperandrogemia.

5. Acanthosisnigricans:

It is due to insulin resistance (IR) characterized by thick pigmented skin over the nape of neck, inner thigh and axilla. HAIR-AN syndrome has been coined to describe the constellation symptoms of hyper androgenism, insulin resistance and acanthosisnigricans.

6. Metabolicsyndrome:

It is a cluster of endocrine disturbances like IR, dyslipidemia, obesity, hypertension, type 2 diabetes mellitus, atherosclerosis and endothelial dysfunction. PCOS women have an 11 fold higher risk of having above metabolic syndromes compared to age matched controls. Homocysteine levels are higher in women with PCOS.

7. Psychologicalproblems:

It includes reduced quality of life, poor self-esteem, depression, anxiety. As per the text *Pararasasekeram, Garparogam*is classified into 9 types. *Garpavaayu* is one among them. The symptoms of *garpavaayu* are abdominal discomfort, dysmenorrhoea, low back ache, constipation, amenorrhoea, and heaviness of thigh. These symptoms of *Garpavaayu* may be correlated with Polycystic Ovarian Disease of modern science.The classical Siddha literature *Pararasasekaram* cites that any imbalance in three humours may inhibit the release of ovum from the ovaries. This may be related to the subfertility due to ovulatory factors.

Siddha formulations not only treat this disease but also strengthen the Uterus, Ovaries and correct the Hormonal imbalance without any undesirable effects. In ancient text there are many single herbal medicines, polyherbal and herbomineral formulations are indicated for *GarpaVaayu.* So there is a need to evaluate a classical Siddha formulation ***"Soothagavaayuleghium"*** mentioned in *Brahmamunivaidhyasoothiram* - Part II and ***"Veezhiennei"*** mentioned in *VaidhyaSarasangiragam* for the treatment of *Garpavaayu* (Polycystic ovarian disease).

Rationale:

- Plumbagin from the root of *Plumbagozeylanica.L*possesses reversible antifertility activity without adverse toxicity in female rats.
- *Cuminumcyminum.L* has oestrogenic activity
- *Anethumgraveolens.L*used either as a regulatory agent of the menstrual cycle for women with irregular cycles or as an antifertility agent.
- Hexane extract of the seeds of *Nigella sativa L* shows significant antifertility activity

- *Appalakaram*(Sodium carbonate) is used in dysmenorrhoea

The ingredients present in this formulations have potent hypoglycemic, anti hyperlipidemic and antioxidant effects. This formulation may treat this disease and also strengthen the uterus, ovaries and correct hormonal imbalance without any undesirable effects.

OBJECTIVE:

To evaluate the therapeutic efficacy of *Soothagavaayu leghium* and *Veezhiennei* (Internal medicines) in the treatment of *Garpavayu* (Polycystic ovarian disease)

METHOD:

The clinical study was conducted at OPD of Ayothidoss Pandithar Hospital, National Institute of Siddha, Chennai, Tamilnadu (from 2012-2014) with the approval of the Institutional Ethical Committee (IEC NO: NIS/IEC/12-13/02). Before initiating the clinical trial, it was registered in Clinical trial registry of India (CTRI number –CTRI/2014/01/004282). The raw drugs were authenticated by the Assistant professor of medicinal botany and the trial drug was prepared by the investigator in the *Gunapadam* laboratory of National Institute of Siddha.

Study Design:

Study type: An Open Clinical trial

Study Place: Ayothidoss Pandithar Hospital (OPD), National Institute of Siddha, Tambaram sanatorium, Chennai-47.

Study Period : 12 months

Sample size : 40 patients

Treatment

1. Drug **:***Veezhiennei* (for purgation)

Ref:Vaidhya saara sangiragam, P.no-41

Poem ref: Agasthiyar Vaithiyam-600 Pg.no-128

Dosage : ¼ *saer* (70 ml) single dose before food

Duration : first 3 days / cycle

Total duration of drug administration: 9 days (3 cycles)

2**.** Drug **:** *Soothagavaayuleghium*

Ref: Brahmamunivaidhya soothiram,part-2,P.no-21&22

Dosage : *Kottaipakkalavu* (6gm) twice a day after food

Duration : 15 days /cycle

Total duration of drug administration: 45 days (3 cycles)

Inclusion criteria:

- Age: 19-35 years female
- Patient having the symptoms of irregular menstruation
- Oligomenorrhoea (or) Amenorrhoea (or) Dysmenorrhoea
- Patient willing to take USG pelvis
- Patient willing to undergo routine blood investigation.
- USG pelvis showing polycystic ovaries
- Patient willing to undergo purgation as a preparatory part of treatment
- Patient willing to participate in trial and signing in consent form

Exclusion Criteria:

- H/O hypertension
- H/O diabetes mellitus
- H/O cardiac disease
- Pregnancy and lactation
- H/O thyroid dysfunction
- H/O recent hormone therapy (Past one year)

Withdrawal Criteria:

- Intolerance to the drug and development of adverse reactions during the drug trial.
- Poor patient compliance & defaulters
- Patients turned unwilling to continue in the course of clinical trial
- Patient will not take medication regularly

Study Enrolment:

Patient reporting at the NIS, OPD with clinical features of Amenorrhoea, Oligomenorrhoea, obesity, Irregular menstruation, infertility were chosen for enrolment based on the inclusion criteria. The patients who were enrolled and informed about the trial drug, possible outcomes and the objectives of the study in their own language and the terms understandable to them and the informed consent obtained from them in the consent form.

Conduct of the Study

On the first day purgation was given with *Veezhiennei* 70 ml in the early morning for three days to balance the deranged humours. Following purgation from 4^{th} day onwards drug holiday was observed for 6 days. Then from 10^{th} day onwards the trial drug *Soothagavayuleghium* administered for 15 days. The trial drug was issued by the investigator in the OPD of *Maruthuvam*, NIS, Chennai. The patients were asked to have a regular treatment in the OP

department once in 15 days. In each visit the clinical assessment were recorded in the prescribed Proforma. The laboratory investigations carried out before and after treatment and recorded in the prescribed format. At the end of the trial the patients were advised to come for follow up for 2 months for observation.

Data collection:

After enrolling the patient in the study, a separate file maintained for each patient and all forms were filed in that file. Study No. and Patient No. were entered on the top of file for easy identification. Whenever the study patient visits OPD during the study period, the respective patient's file will be taken and necessary recordings will be made at the assessment form or other suitable forms. The screening forms will be filed separately. All the baseline data were recorded in the first visit of the study. Clinical assessments were recorded each visit. Laboratory investigations were recorded before the trial drug administration and at the end of the study. The Data recording process were monitored by the Guide (HOD, Dept. of *Maruthuvam*) . If any AE/SAE/SUSARoccurred it was recorded and immediately informed to the members of the Pharmacovigilance department of NIS. No modification in the results is permitted for unbiased reports.

Adverse effect/serious effect management:

If any of the patient in this study developed any adverse reaction (acute abdominal pain, nausea, vomiting) he/she were referred to the pharmacovigilance department of NIS. The members of this department were assessing the adverse event and recorded in the prescribed adverse reaction form. For any AE the investigator has given the proper management in NIS OPD with free of cost.

Data analysis

The data collected from the study were entered into MS Excel and manually cross-checked the correctness of the data entry. The data of inter menstrual period score, Duration of bleeding score and body mass index before treatment and at the end of the treatment were analyzed by comparing the two point of data (before and after treatment) paired t' test was employed to study the efficacy of treatment.

Outcome of the study

Primary outcome was assessed by the improvement in the score of irregular menstruation (Intermenstrual period& duration of bleeding) before and after treatment

Duration of bleeding

Duration	Grade	Score
3-5 days	Nil	0
1-2 / 6-7 days	Mild	1
1 / 8-9 days	Moderate	2
Spotting / > 9days	Severe	3

Bleeding 1 or above days are considered as bleeding throughout the day., Spotting is considered as bleeding just 2 0r 3 drops.

Intermenstrual period

Duration	Grade	Score
28 days	Nil	0
28-45 days	Mild	1
45-60 days	Moderate	2
Above 60 days	Severe	3

Secondary outcome was assessed by the Changes in the polycystic swellings of the ovaries in USG pelvis and reduction in clinical symptoms.

RESULTS AND DISCUSSION:

Among 40 cases, 22 cases were in the age group of 21-25 years, 9 cases in the age group of 26-30 years, 5 cases were in the age group of 31-35 years and 4 cases were in the age group of 19-20years.

Marital status:

Among the 40 patients selected, 23 cases (57%) were married and 17 (43%) cases were single.

Parity:

Among the 23 married cases, 65% (15 cases) were Nulliparous, 26% (6 cases) were Multiparous and 2 (9%) cases were seeking for second child.

Diet pattern:

Among 40 patients, 33 (83%) cases were non vegetarian, and 7 (17%) cases were vegetarian.

Case distribution

All the 40 patients had PCOS. In this 23 (17 single and 8 married women) i.e. 58% were diagnosed as PCOS only, 15 cases (15 married women ie., 37%) were PCOS with *Maladu* (1º infertility) and 2 cases were PCOS with *kathalimaladu*(seeking for second child ie., 5%).

Table: 1 Body built of PCOS patients

BODY BUILT **Based on BMI**	**NUMBER OF CASES**	**PERCENTAGE**
Obese (>30)	12	30%
Over weight (25-30)	9	22%
Normal weight (21-25)	**16**	**40%**
Under weight (Below 20)	3	8%
Total	40	100

Among the 40 cases, 12 (30%) cases were obese, 16 (40%) cases were of normal weight, 3 (8%) cases were under weight and 9 (22%) cases come under over weight.

Occupational distribution

Among the 40 patients the incidence were more in non-working ie., 20 (50 %) cases, next in working 12 (30%) cases and finally in student category 8 (20%) cases.

Positive family history for the disease

Positive familial history was seen in only 2 (5%) of patients and the other 38 (95%) cases had no relevant family histories.

Duration of infertility (Nulliparous)

The chronicity of illness ie., infertility before treatment was in 9 (60%) cases between the time intervals of 1-2 years. 2 (13%) cases were between 2-3 years interval and 4 (27%) were between 3-5 years.

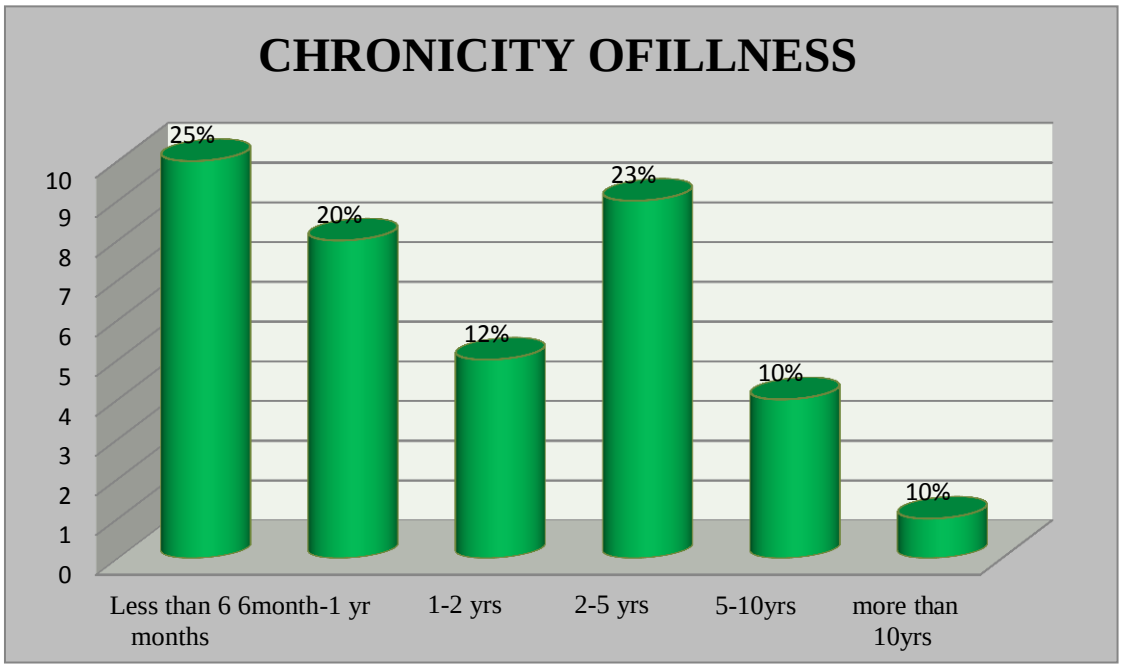
Treatment history other than siddha: (For treating infertility)

Among the 17 patients, 6 (35%) cases underwent IUI followed by ovulation induction, 6 (35%) cases have not taken any treatment and 5 (30%) cases underwent only ovulation induction.

(For irregular menstruation)

Among the 23 patients, 15 (65%) cases not taken any treatment, 6 (26%) cases underwent menstruation induction and 2 (9%) cases were under oral hypoglycaemic drug.

Figure: 1 Chronicity of illness: a) Irregular menstruation:



Among 40 patients, 8 cases (20%) the duration of illness was between 6months – 1 yr, 10 (25%) cases was less than 6 months, 5(12%)cases were between 1-2 years, 9 (23%) cases the duration was between 2-5 yrs, 4 (10%) cases between 5-10 yrs and 4 (10%) cases the duration was more than 10 years.

Clinical symptoms before treatment:

Out of the 40 cases, all 40 (100%) cases had irregular menstrual cycle (IMP or Duration of bleeding). Weight gain was found in 21 (53%) cases, constipation was seen in 3 (8%) cases, infertility in 15 (38%) cases, 10 (25%) cases had amenorrhoea, 7 (18%) cases had hirsuitism, 15 (38%) cases had dysmenorrhoea and 8 (20%) cases had oligomenorrhoea.

Outcome measurements:

Out of 40 cases, 5 cases with drawn from the study due to long term absence. So the outcome was assessed in 35 cases before and after treatment.

Table :2 **Inter menstrual period assessment score**

GRADE			EFORE		FTER					
Length of cycle			Cases	%	1C cases	%	2C cases	%	3C Cases	%
0	28 days	Nil	2	6%	5	15%	10	29%	**15**	**44%**
1	28-45 days	Mild	9	26%	12	35%	12	35%	10	29%
2	45-60 days	moderate	8	23%	7	21%	3	10%	8	24%
3	**bove 60 days**	**Severe**	**16**	**45%**	10	29%	9	26%	1	3%
TOTAL			35	100%	34	100%	34	40	34	100%

1C- first cycle; 2C-second cycle; 3C-third cycle, One get conceived during treatment.

Intermenstrual periods were found to be normal in 2 patients and severe in 16 cases before treatment. At the end of the treatment it was found normal in 15 (44%) number of cases and the severity was present only in 1 (3%)case.

Table: 2.Duration of bleeding

GRADE			BEFORE		AFTER					
			cases	%	1C cases	%	2C cases	%	3C cases	%
0	3-5 days	Nil	10	29%	20	58%	18	54%	**23**	**67%**
1	**1-2/ 6-7 days**	**Mild**	**21**	**60%**	10	29%	7	20%	4	12%
2	1/ 8-9 days	Moderate	0	0%	1	3%	0	Nil	7	21%
3	Spotting / >9days	Severe	4	11%	3	10%	9	26%	0	0%
TOTAL			35	100%	34	100%	34	100%	34	100%

1C- first cycle; 2C-second cycle; 3C-third cycle, One get conceived during treatment.

Duration of bleeding was found to be normal in 10 (29%) patients and severe in 4 (11%) cases before treatment. At the end of the treatment it was found normal in 23 (67%) cases and the severity was present in none of the cases.

Table: 3 Improvement in IMP score per patient:

SCORE			AT IMP			
			0	1	2	3
BT IMP	0	2	2	0	0	0
	1	9	8	0	0	0
	2	8	1	7	0	0
	3	16	4	3	8	1
Total		35	15	10	8	1

Among 35 cases, 16 cases in grade 3 (severe) get reduced to 1case in grade 3, 8 cases in grade 2, 3 cases in grade 1 and 4 cases in grade 0.

Table: 4 Improvement in DOB scores per patient:

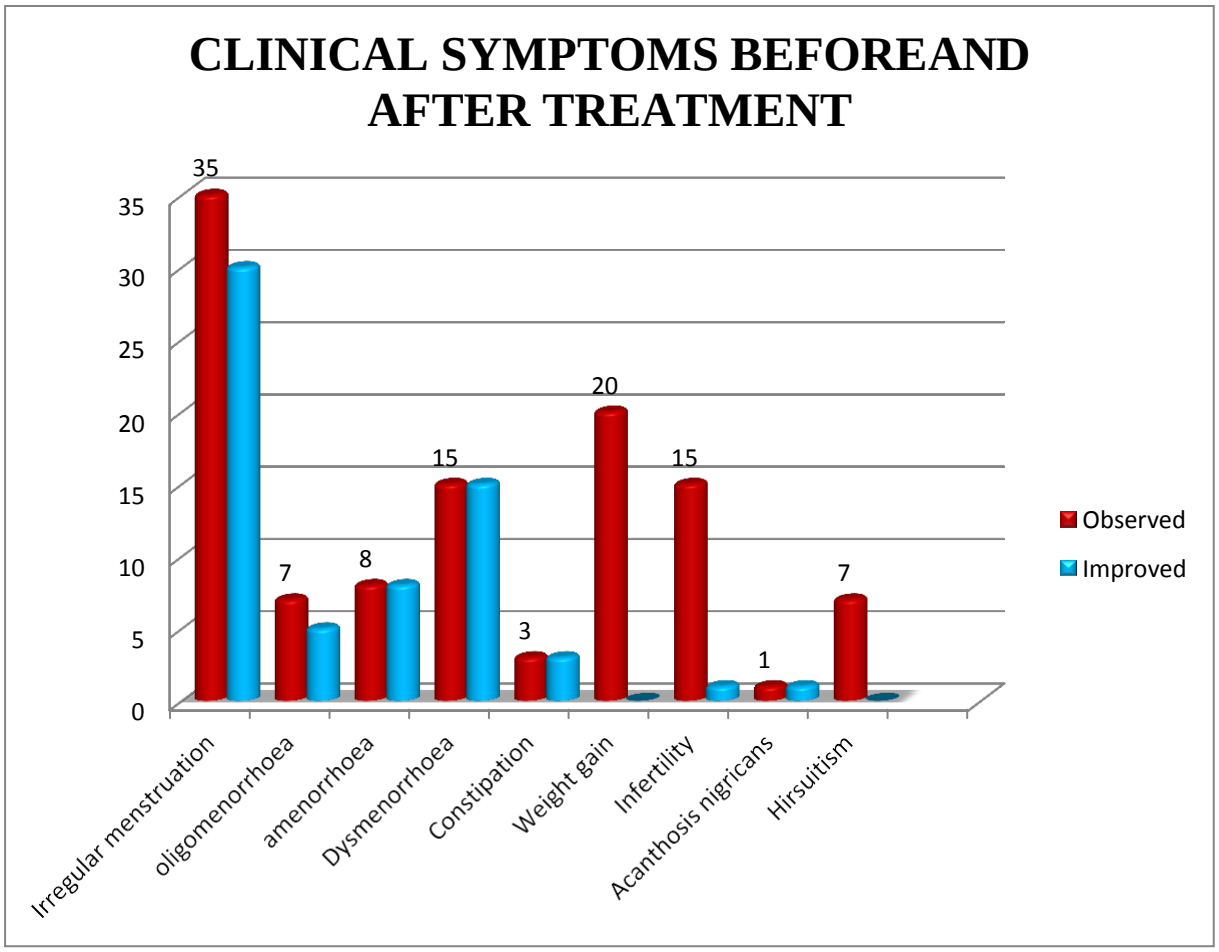
SCORE			AT DOB			
			0	1	2	3
BT DOB	0	10	10	0	0	0
	1	21	13	2	5	0
	2	0	0	0	0	0
	3	4	0	2	2	0
Total		35	23	4	7	0

Among 35 cases, 21 cases in grade 1 (mild) after treatment 13 cases comes under grade 0 (Nil), 2 cases comes under grade 1 and 5 cases comes under grade 2.

Changes in USG abdomen aftertreatment:

Among 35 cases that had completed the treatment, 13 patients were taken USG before and after treatment. All 13 cases showed polycystic changes in both ovaries Out of which, 4 patients (31%) showed complete clearance of cyst after treatment. Moderate changes seen in 1 (7%) case. No significant improvement was seen in the remaining (62%) cases**.**

Figure: 2 Clinical symptoms before and after treatment:



Out of the 35 cases, all the 35 cases the menstrual cycle was irregular (IMP or Duration of bleeding) before treatment. Secondly, weight gain was found in (67.5%) large number of patients before treatment. After treatment there was a considerable reduction in all symptoms particularly irregular menstruation, oligomenorrhoea, Dysmenorrhoea and amenorrhoea. After treatment there was a complete relief in the symptom like constipation. There were no significant changes in the body weight. Out of 15 infertility patients with PCOS one patient got conceived.

STATISTICAL ANALYSIS:

Table: 4 Intermenstrual period (IMP) score before and aftertreatment

IMP	MEAN ± SD	t VALUE	p VALUE
Before treatment	**2.117 ± 0.977**	**9.33**	**P < 0.0001**
After treatment	**0.852 ± 0.892**		

The statistical analysis revealed that there has been a significant reduction in IMP assessment score after treatment indicating the improvement ie., regular menstrual cycle in patients.

Table: 5 Duration of bleeding (DOB) score before and after treatment

DOB	MEAN ± SD	t VALUE	p VALUE
Before treatment	**0.941 ± 0.885**	**2.92**	**P <0.001**
After treatment	**0.529 ± 0.825**		

The statistical analysis revealed that there has been a significant reduction in DOB assessment score after treatment.

Table: 6 Body mass index before and aftertreatment

BMI	MEAN ± SD	t VALUE	p VALUE
Before treatment	**27.5 ± 6.27**	**0.9468**	**P <0.3506**
After treatment	**27.4 ± 5.99**		

There was no significant reduction in BMI after treatment statistically.

DISCUSSION

Advancement in the modern technology has enabled our present day society to exist in a world where the consent of hard work even moderate work is absolute and in fashionable. The physical inactivity, sedentary life style, food habits, environment pollution have caused so many diseases which also leads to menstrual abnormalities and causes *Garpavaayu.*

Garpavaayu is a disease characterized by abdominal discomfort, dysmenorrhoea, low back ache, constipation, amenorrhea, and heaviness of thigh. It may be correlated with Polycystic Ovarian

Disease of modern science.

The main aim of the study is to document the effective siddha medicines *Soothagavaayuleghium* and *Veezhiennei* (Internal medicines) in the management of *Garpavaayu* (Polycystic ovarian disease)

In this study the prevalence of the disease was found to be higher in 22 cases (55%) in the age group of 21-25 years. Many women who have PCOS are very frustrated with their lives and ignore the symptoms and do not try to treat themselves until it is too late. Among the 40 patients selected, prevalence of the disease was found to be higher in married females i.e. 23 cases (57%) and 17 (43%) cases are single. PCOS is a very common disorder that many women first learn about while seeking the cause of theirinfertility.

Out of 23 cases, 65% (15 cases) were found to be Nulliparous, 9% (2 cases) for PCOD and for second child and 26% (6 cases) were inMultiparous. PCOS is a very common disorder that many women first learn about while seeking the cause of theirinfertility. In this study most of the patients i.e. 33 (83%) were observed to be non-vegetarians.

All the 40 patients had PCOS. Among them 23 cases (17 single and 8 married women) ie., 58% were diagnosed as PCOS only, 15 cases (15 married women i.e., 37%) were PCOS with *Maladu* (1º infertility) and 2 cases were PCOS with *kathalimaladu* (seeking for second child i.e.,5%). Among the 40 cases, 12 (30%) cases were obese and 16 (40%) cases were of normal body built and 9 (22%) cases were found to be overweight. In this study most of the subjects are overweight. Obesity, particularly the abdominal phenotype, may be partly responsible for insulin resistance and associated hyperinsulinemia in women with PCOS. Therefore, obesity-related hyperinsulinemia may play a key role in favoring hyperandrogenism in these women. These obviously emphasize the role of obesity in the pathophysiology of PCOS.

Among the 40 patients the incidence were more in non-working i.e., 20 (50 %) cases.

In this study most of the patients are non-working i.e., house wives. The incidence appears to be increase due to change in life style and stress. House wives are distressed by both physical aspects and psychological aspects. Among the 40 cases observed, Positive familial history was seen in only 2 (5%) of patients and the other 38 (95%) cases has no family history for the incidence of the disease. In this study only minor group had familial history. Studies have shown that there is strong evidence it is a genetic disease. Family history might allow risk stratification of PCOS

women, which is important considering the high prevalence of PCOS.

Outcome measures:

a. Intermenstrual period assessment score

Out of 40 cases, 5 cases with drawn from the study due to long term absence. So the outcome was given for 35 cases before and after treatment.

Among 35 cases,

The outcome was normal (28 days cycle) in 15 cases. In 10 (29%) cases there was 28-45 days cycle.

In 8 (24%) cases there was 45-60 days cycle after treatment. In 1 (3%) of cases there was above 60 days cycle.

b. Improvement in duration of bleeding score

Among 35 cases,

21 cases from grade 1 showed improvement as 13 cases in grade 0, 2 cases in grade 1 and 5 cases in grade 2 and one got conceived.

Observation with reference to other Clinical symptoms:

Out of the 35 cases, 100% of cases showed improvement in irregular menstrual cycle (IMP or Duration of bleeding) after treatment. After treatment there were a considerable reduction in all symptoms particularly oligomenorrhoea, Dysmenorrhoea and amenorrhoea. There was a complete relief in the symptom like constipation. No significant changes were found in body weight. One got conceived during course of treatment.

Assessment through USGabdomen

Out of the 35 cases, 13 patients took USG before and after treatment. All 13 cases show polycystic changes in both ovaries, Out of which 4 patients (31%) showed complete clearance of cyst after treatment & Moderate changes was seen in 1 (7%) case. In 9 (62%) cases there were no significant changes**..**

Assessment of the effectiveness of drug:

The effectiveness of the drug was assessed by the improvement of the patients from irregular menstruation, which is measured using assessment score. The test drug is statistically significant ($p>0.0001$) and hence the formulation was effective in the treatment of *Garpavaayu*

During the study period, there was no adverse event reported except one patient got conceived and hence she was withdrawn from thestudy. During the study period out of 40 cases 5 cases were withdrawn from the study due to long termabsence. In this study out of 35 cases, the therapeutic efficacy of the trial drug by showing, regular menstrual cycle ie., 28 days intermenstrual period in 15 (44%) cases and duration of bleeding (3-5 days) in 23 (67%) ofcases. USG report shows complete clearance of cyst in 4 (31%) cases out of 13patients. Follicular study also confirms ovulation in 2 cases aftertreatment. As per the Siddha Literature and recent research articles, the ingredients of the trial drugs was found to have anti- oxidant, anti- diabetic, anti- hypercholesterolemia properties owing to the diseasemanifestations. Statistical analysis showed significant changes in the Intermenstrual period score and Duration of bleeding phase score before and aftertreatment.

CONCLUSION

No adverse drug reactions were noticed during the course oftreatment. Expenditure of the trial drug is cost effective, easy to prepare and much effective in *Garpavaayu.* As per the Siddha Literature and recent research articles, the ingredients of the trial drugs was found to have anti-oxidant, anti- diabetic, anti- hypercholesterolemia properties which may act on Garpavayu (Polycystic ovarian syndrome). Furthermore pharmacological studies on insulin resistance, dyslipidemia, ovulation induction required to strengthen the effectiveness of clinical study. Because of the encouraging clinical and laboratory results, the study may be undertaken with these medicines for a long period in a large number of cases for the treatment of *Garpavaayu.*

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