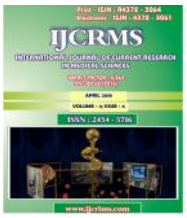
International Journal of Current Research in Medical Sciences
ISSN: 2454-5716
P-ISJN: A4372-3064, E -ISJN: A4372-3061
www.ijcrims.com



Original Research Article **Volume 4, Issue 4 -2018**

DOI: http://dx.doi.org/10.22192/ijcrms.2018.04.04.002

A pilot study evaluating the therapeutic efficacy of Madhumega Kudineeer a Siddha herbal formulation in the management of Sinaipaineerkatti (Polycystic Ovarian Syndrome).

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Abstract

Objective: To determine the effect of Madhumega kudineer, a Siddha herbal formulation in Sinaipaineerkatti (PCOS) patients.
Method: The pilot study was conducted at the Ayothidoss Pandithar Hospital, National Institute of Siddha, Tambaram Sanatorium, Chennai-47. Ten patients were recruited in the study those meeting with inclusion and exclusion criteria. They were treated with 60 ml of Madhumega kudineer twice a day for 90 days. All the patients were taken Ultra sonogram pelvis before and after treatment.
Result: Out of ten patients 9 patients (90%) had regular menstrual cycle, 8 patients (80%) had reduction in BMI, 4 patients (40%) have normal sonographic study and other (60%) patients had considerable reduction in size of both the ovaries. Hirsutism reduced in 2 patients out of 4 patients.
Conclusion: Madhumega kudineer has shown good effectiveness in the treatment of Sinaipaineerkatti (PCOS) and also did not cause any adverse reaction to any patients.

Keywords: Sinaipaineerkatti, Soothaga Vaayu, Polycystic ovarian syndrome, Lifestyle disorder, Madhumega kudineer, Siddha medicine, PCOD.

1. Introduction

Polycystic Ovary Syndrome is one of the most common endocrinopathy affecting women. In 1935 Irving F. Stein and Michael L. Leventhal described a symptom complex due to anovulation. Oligomenorrhea, hirsutism and obesity together with enlarged polycystic ovary (PCO) were the diagnostic criteria of PCOS. It is now accepted that this problem is arising from persistent anovulation with a spectrum of aetiologies and clinical manifestations.[1]

There is no universally accepted definition of PCOS. It is a complex clinical presentation and is traditionally thought of as a triad of oligomenorrhea, hirsutism and obesity, and is now recognized as a heterogeneous disorder that results in increased production of androgens, principally from the ovary, and is associated with insulin resistance.

PCOS may present with amenorrhea, infertility, features of hyperandrogenemia (HA), signs of metabolic disturbances like insulin resistance, and dyslipidaemia. The apparent underlying reason is persistent anovulation over a prolonged period. Different endocrinopathies can lead to anovulation and the subsequent emergence of polycystic ovaries.

PCOS is a complex endocrine disorder with 3.4% prevalence in the population of the reproductive age women. In India, its prevalence ranges from 2.2 to 26% with age group of 18 to 45 years. In PCOS, approximately 30% of women have normal menstrual cycle; some has amenorrhoea and oligo menorrhoea.

PCOS is characterized by fluid filled sac like structures in the ovary and is termed as Sinaipaineerkattti. The clinical features of PCOS have already been described in the Siddha literatures such as “YUGI MUNI VAITHIYA KAAVIYAM” AND “THIRUMOOLAR KARUKIDAI VAITHIYAM” etc. Siddhar Thiruvalluvar also called as Thiruvalluva Nayanaar in his Siddha Medical Monograph “Gnanvettiyaan-1500” has discussed about female reproductive problems like Infertility, PCOS and Fibroids etc. in detail. The following verses from the above literature explain the clinical features of PCOS,

சூதகத்தில் வாய்வதுபோய்ச் சொக்குங் காலைச்
சுருதியெனும் வன்னிபித்தந் துணையாய்ச் சேரும்
மாதவிடாய் நாகமதும் வஸ்துக்கட்டும்
மாதாந்தம் கட்டினதால் மாது தேகம்
ஊதுஉடல் சரீரமெல்லாங் கருப்பை துந்து
உதிரநீர் சூசிகா வாய்வுந்த் தோன்றி
வாதனையால் வயிறுடம்பு பெருத்து ஊதி
மகத்தான அடிமூலம் வாதஞ்சேர்ந்தே.

ஞானவெட்டியான்-1500

விளக்கம்:

பெண்களுக்கு சூதகத்தில் போய் வாயு தங்குங் காலத்தில் அப்போது அக்கினியான பித்தமும் துணையாய்க் கூடும். மாதவிடாயான நாதமானது கட்டிப்போகும். அப்படி அது கட்டினதால் சரீரம் ஊதும். உதிரங் கூட்டி நீர் நோக்கும், அதனால் சூசிகவாயு தோன்றும், அப்போது மூலத்தில் வாயு சேரும்.

In siddha system, the treatment is by adopting internal and external medicine, food, healthy life style, yogam and asanas. PCOS may be due to deranged vatham and kabam with dietary changes and lifestyle modification. According to Panchaboodham and Mukkutram theory bitter and astringent taste influences vatham and neutralizes pitham, kabam. Hence plants which are bitter and astringent taste may be administered for the treatment of PCOS as it is pathology of Kabavatham. PCOS may be termed as Sinaipaineerkatti, Soothagavaayu, Susigaavaayu.

As there is a common practice of using Insulin Sensitizing Drug (ISD) in the treatment of PCOS, Madhumega kudineer is selected for the study considering the above phenomenon. The description of the ingredients of Madhumega kudineer is as follows.

Plant Names	Botanical Names	Taste
Keelkaai nelli	*Phyllanthus amarus*	Astringent, bitter, sweet, sour taste
Nelli	*Emblica officinalis*	Astringent.
Karivembbu	*Murraya koenigii*	Pungent.
Kadukkaai	*Terminalia chebula*	Astringent, bitter, sweet, sour
Naaval	*Eugenia jambola*	Astringent.
Seendhil	*Tinospora cordifolia*	Bitter.
Korai	*Cyperus rotundus*	Astringent.

Method of preparation for Madhumega Kudineer

The purified raw drugs are taken and coarsely grinded. Then it is mixed with 240 ml of water and boiled to one fourth and filtered.

2. Method

This study was conducted in Sool and Magalir Maruthuvam outpatient department of Ayothidoss Pandithar Hospital attached to National Institute of Siddha, Tambaram sanatorium, Chennai-47 with standard protocol which is approved by Institutional Ethical Committee of National Institute of Siddha (NIS/IEC/10/2016-17/29-20.5.2016). The trial has been registered in clinical trial registry India (CTRI/2017/07/008965). Before enrolment into the study the informed consent was obtained from the patients.

3. Conduct of the study

A total of 10 patients between 18 to 35 years of age with clinical features of amenorrhoea, oligo menorrhoea, obesity, hirsutism, irregular menstrual cycle with polycystic changes in USG findings are chosen for enrolment based on inclusion criteria. Patients who are all selected under the criteria are treated with MADHUMEGA KUDINEER 60 ml twice a day for 90 days. At each visit once in 10 days symptoms were clearly noted for clinical assessment. The patients were asked to follow the dietary regimen and lifestyle modification during the treatment and follow up period.

USG pelvis and necessary investigations were performed for all the patients two times that is before starting the treatment and after completion of the treatment.

4. Study outcome:

Study outcome was defined as Regular menstrual cycle, Reduction in BMI, Changes in the polycystic appearance of the ovaries in USG pelvis and correction of other associated symptoms such as infertility etc.,

5. Results

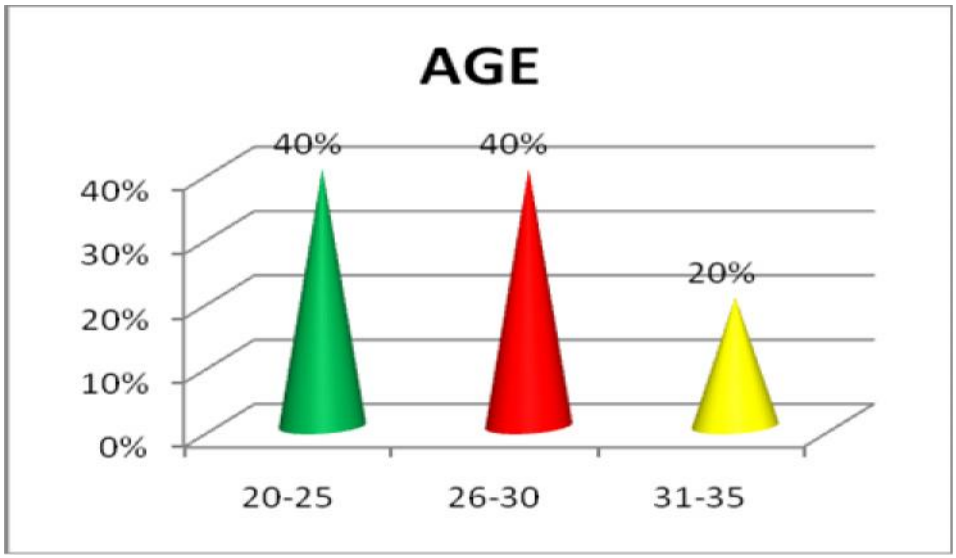
In the present study, ten women presenting with oligo/amenorrhea combined with the presence of bilateral polycystic ovaries were selected. All these ten patients were presented with oligomenorrhoea, six of these patients were reported with obesity, whereas four showed signs of hirsutism. Only two women presents with both obesity and hirsutism. These findings imply that polycystic ovary (PCO) is diagnosed by morphology in women with oligo/amenorrhoea, not all the features which are believed to be associated with PCOS need to be present.The occurrence of considerable heterogeneity in clinical symptoms and endocrine features associated with PCOS implies that some women with PCO on ultrasound scan may even exhibit none of the other features of PCOS. In this study diverse presentation of PCOS was observed.

After treatment,

- Out of 10 patients 9 patients had regular menstrual cycle.
- Out of 10 patients 8 patients had reduction in BMI (from 0.2 - 2) (Table 2).
- USG pelvis revealed that
  - 4 patients have no evidence of polycystic ovaries.
  - In other 6 patients there is reduction in the size of the both ovaries after treatment (Tables 4 & 5).
- Clinical symptoms such as dysmenorrhoea, leucorrhoea, oligo menorrhoea, were relieved during treatment (Table 3).
- Out of 10 patients 4 were prone with hirsutism and after treatment it was reduced in 2 patients.
- There were no adverse events reported during the study and no recurrence of polycystic ovaries for the 4 patients who exhibits no evidence of polycystic ovaries after treatment in USG pelvis, during the follow-up period of 6 months.

Table 1: Age wise distribution:

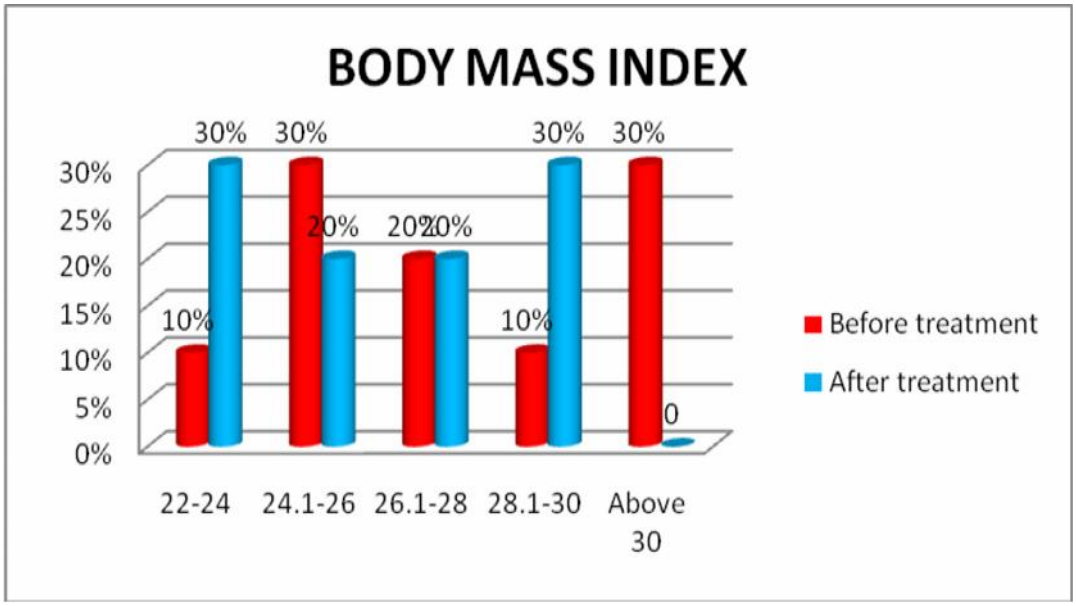
Sl.no	Age	No. of patients	Percentage
1	20-25	4	40%
2	25-30	4	40%
3	30-35	2	20%



Bar diagram 1

Table 2: Assessment of body Mass Index

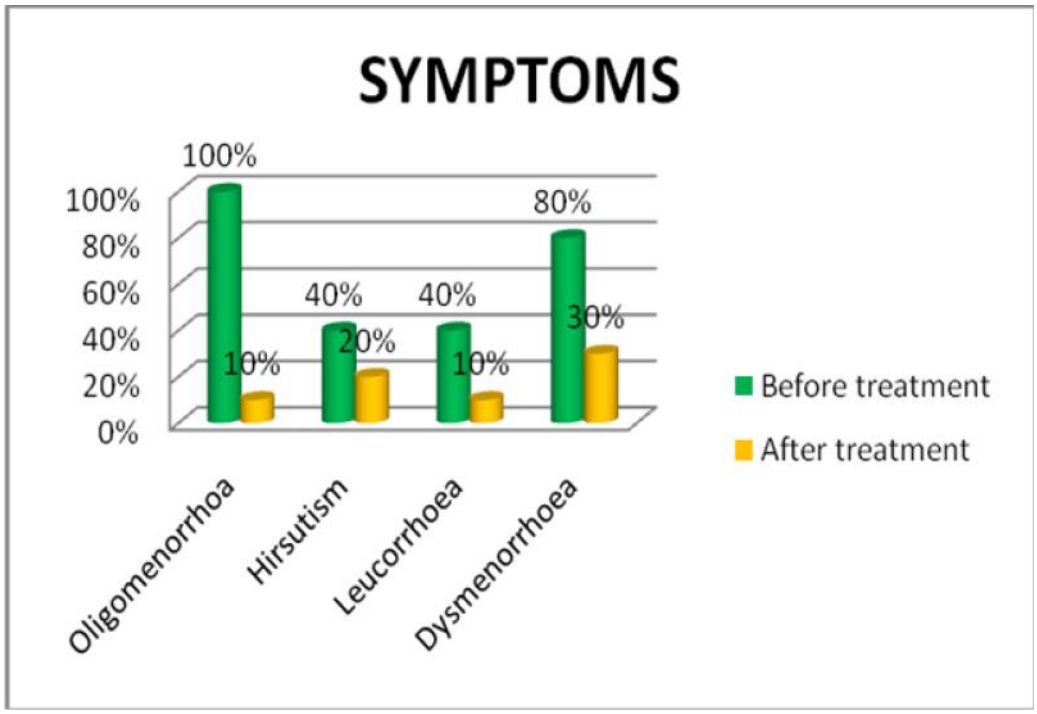
Sl.no	BMI	Before treatment	After treatment
1	22-24	10%	30%
2	24.1-26	30%	20%
3	26.1-28	20%	20%
4	28.1-30	10%	30%
5	Above 30	30%	0



Bar diagram 2

Table 3: Prognosis in symptoms:

Sl.no	Symptoms	Before treatment	After treatment
1	Oligomenorrhoa	100%	10%
2	Hirsutism	40%	20%
3	Leucorrhoea	40%	10%
4	Dysmenorrhoea	80%	30%



Bar diagram 3

Table 4:- Patient details:

Case no.,	*Age/ sex*	*Menstrual cycle*	*Body mass index*	*USG pelvis- ovaries size (cm)*	*Other symptoms*			
					Oligo/ Amenorrhoea	*Dysmenorrhoea*	*Hirsutism*	*Leucorrhoea*
1	26/F	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/F	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/F	3/60-70 days	31.6	Left- 4.6×2.9×2.8 Right- 4.3×2.8×3.4 Imp: Polycystic ovaries	Present	Present	Absent	Present
4	21/F	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/F	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/F	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/F	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/F	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/F	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/F	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 5:- Treatment outcome:

Case no.,	*Age/ sex*	*Menstrual cycle*	*Body mass index*	*USG pelvis- ovaries size (cm)*	*Other symptoms*			
					Oligo / Amenorrhoea	*Dysmenorrhoea*	*Hirsutism*	*Leucorrhoea*
1	26/F	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/F	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/F	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/F	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/F	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/F	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/F	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/F	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/F	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/F	3/40 days	22.5	Left- 3×2.5×2 Right- 2.8×2.5×1.8 Imp: Normal ovaries	Present	Absent	Absent	Absent

6. Discussion

Sinaipaineerkatti (PCOS) is a reproductive endocrinological disorder, and we treated with Madhumega kudineer by selecting the patients randomly. By the outcome of the above results there is a significant improvement in menstrual regularity, reduction in body weight, reduction in the size of the ovaries and also patients relieves from the associate symptoms like hirsutism, dysmenorrhoea and leucorrhoea.

Menstrual irregularity is corrected in 9 patients out of 10, for it may be changed to normal physiological function which means by administration of Madhumega kudineer it may correct the ovulation and decreases the androgen level in women which is the major cause for menstrual irregularity.

BMI is reduced in 80% of patients by taking Madhumega kudineer with lifestyle changes. Obesity in PCOS is mainly due to Insulin resistance. The drug Madhumega kudineer has the capacity to reduce the BMI of the patients which in turn reduces the obesity. Reduction in BMI may be due to the drug increasing the insulin response to glucose.

In 40% of cases polycystic ovaries have returned to normal ovarian size. It is because while taking Madhumega kudineer there may be a reduction in androgen level or immature follicles in ovaries.

There is reduction in size of ovaries in 60% of cases which may results in normal conception.

Hirsutism is reduced in 2 patients out of 4 patients (50%) which may be due to regulation of the hormones like testosterone or DHEA-S.

Finally from the above results and discussion Madhumega kudineer may have an ability to regular the menstruation, reducing the circulating androgen levels, reducing the circulating insulin level, restoring ovulation, and in reducing BMI (from 0.2 - 2).

7. Conclusion

The study was started to ensure the clinical efficacy of Madhumega kudineer in the treatment of Sinaipaineerkatti (PCOS). Moreover there is no adverse reaction throughout the study. The results of this pilot study suggest that Madhumega kudineer may be effective and safe in the treatment of Sinaipaineerkatti (Polycystic ovaries).

Further open clinical trial is needed to find out its action at hormone level. Also whether there is single or combined action in correcting the androgen level, FSH, Insulin resistance or ovulation.

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How to cite this article:
R.Vinodini, R.Vasuki, A.M. Amala Hazel, M. Meenakshi Sundaram, V. Banumathy.. (2018). A pilot study evaluating the therapeutic efficacy of Madhumega Kudineeer a siddha herbal formulation in the management of Sinai Pai Neerkatti (Polycystic Ovarian Syndrome). Int. J. Curr. Res. Med. Sci. 4(4): 10-18.
DOI: http://dx.doi.org/10.22192/ijcrms.2018.04.04.002