

CLINICAL EVALUATION ON EFFECT OF *SOOTHAGATHADAI KUDINEER* IN *SOOTHAGA THADAI* (SECONDARY AMENORRHOEA) - A CASE SERIES

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ABSTRACT

Nowadays Menstrual abnormalities are very common in women of reproductive age, due to lifestyle changes, lack of exercise, and unhealthy eating habits. Of these menstrual disorders, amenorrhoea is a common clinical presentation and it shows the abnormalities of the hypothalamic-pituitary ovarian axis. Here we have chosen *Soothaga thadai kudineer* from *Sigicharathnadeepam*, a sastric Siddha medicine for treating secondary amenorrhea.(absence of menstruation for three months or more in a women)since it causes more physical and psychological problems to affected women. The objective of this pilot

study was to determine the efficacy of *Soothaga thadai kudineer*, a Siddha herbal formulation in *Soothaga thadai* (Secondary Amenorrhoea) patients. It was conducted at Ayothidoss Pandithar Hospital, National Institute of Siddha, Tambaram Sanatorium, Chennai-47. Ten patients were recruited in this study in the age group of 20 -35 with the matching inclusion and exclusion criteria. All the patients were treated with 325 ml of *Soothaga thadai kudineer* once a day for 3 days and three months follow up. The assessment criteria were the amount and duration of menstrual bleeding, the interval of the menstrual cycle, and associated symptoms before trial, after trial, and after follow up. The trial drug was found to be effective

in improving the amount of menstrual bleeding from scanty to moderate and duration of bleeding from short to moderate level 70 % of patients got regular menstrual cycle for three consecutive cycles and 20% of patients observed reduction in BMI. thus *Soothaga thadai kudineer* has shown good effectiveness in the treatment of *Soothaga thadai* (Secondary Amenorrhoea) and did not show any adverse reaction to any of the patients.

KEYWORDS: *Soothaga thadai*, Secondary Amenorrhoea, *Soothaga thadai kudineer*, Siddha Medicine.

INTRODUCTION

Amenorrhoea means absence of menstruation in a woman of reproductive age. It is a symptom of ovarian and reproductive dysfunction due to disorder of Hypothalamic Pituitary Ovarian Axis. There are two types of amenorrhoea primary and secondary. Primary amenorrhoea is defined as failure of onset of menstruation by on the age of 16 yrs (Before puberty) whereas Secondary amenorrhoea is defined as absence of menstruation for three months or more in a women (2-3%). Here we are going to do trial for secondary amenorrhoea. It may be due to physiological (pregnancy, lactation, menopause) or Pathological. The causes of secondary amenorrhoea are Uterine 5%, Ovarian 40%, Pituitary 19%, Thyroid, Hypothalamic dysfunction 35%, Nutritional, Others (Diabetes, TB, Anaemia, Malnutrition and Physical stress).^[1]

In Siddha system of medicinal system, diet and lifestyle play a major role in health and in curing disease. Women are more suffered from uterine disorder among this amenorrhoea is considered as one of the cause for infertility. Around 37-45% of women are suffered from amenorrhoea. As per Siddha literature, a woman who is having a menstrual cycle regularly but due to certain factors if menstruation is absent for three months or more it is termed as soothaga thadai. In T.V. Sambasivam Pillai book *Soothaga thadai* is defined as Obstruction of menstruation when it should be normally present is termed as *Soothaga bandham*. So *Soothaga bandham* is also called *Soothaga thadai*.^[2]

In the textbook of *Sigicharathnadeepam*, a sastric Siddha medicine named *Soothaga thadai kudineer* authored by *Kannusamy Pillai* have been indicated for *Soothaga thadai*. It consists of herbs like *chithiramoola vaer*, *karunjeeragam*, *sathakuppai*^[3] These herbs are stimulating and emmenagogic^[4], which means that they stimulate the secretion of hormones that help maintain proper menstrual cycles in women. Arginine is one of the essential amino acids

present in the sathakkuppai. Healthy menstrual flows are maintained by the proper blood circulation to the uterus. Since l-arginine helps increase the production of nitric oxide, which is an important agent in the female reproductive processes, such as ovulation and implantation, it can increase circulation and menstrual flow.^[5]

OBJECTIVE OF THE STUDY

To clinically evaluate the effect of *Soothaga thadai kudineer* in *Soothaga thadai* (Secondary amenorrhoea) by administrating the drug orally for three days and clinically assessing whether attaining menstruation or not and observed for three consecutive cycles.

MATERIALS AND METHOD

Ingredients of *Soothaga thadai kudineer*.^[3]

S.NO	PLANT NAME	BOTANICAL NAME
1	Omum	<i>Trachyspermum ammi</i>
2	Moongil ilai	<i>Bambusa arundinaceae</i>
3	Mavilingapattai	<i>Crataeva religiosa</i>
4	Parangisakkai	<i>Smilax china</i>
5	Chukku	<i>Zingiber officinale</i>
6	Thippili	<i>Piper longum</i>
7	Chithiramoola vaer, vaer pattai	<i>Plumbago indica</i>
8	Karunjeeragam	<i>Nigella sativa</i>
9	Sathakuppai	<i>Anethum sowa</i>

Method of preparation of *Soothaga thadai kudineer*

The above mentioned ingredients are taken in equal quantity of 4.2 gram (1 *varagan*) and crush into small pieces. Add 650 ml (1/2 *padi*) quantity of water to it. Boil the mixture until it reduces to 325 ml (1/4 *padi*).^[3]

Dose: 325 ml once in a day.

CONDUCT OF THE STUDY

IEC Approval – NIS/IEC/10/2016-17/31-20.05.2016

Type of study – Interventional Study

Study period – 12 Months

Sample size – 10 Patients

Selection of patients-Women of age group between 20-35 years who are having the clinical symptoms of absence of menstruation for three months to six months, Obesity, hirsutism, irregular menstruation with polycystic changes chosen for enrolment based on inclusion criteria. The study was conducted in Sool and Magalir Maruthuvam Out patient department

of Ayothidoss Pandithar Hospital, National Institute of Siddha, Tambaram Sanatorium, Chennai-47 with standard protocol.

Exclusion criteria

- Patients with Primary amenorrhoea.
- Lactating mother.
- Patients with gross structural abnormalities of uterus, thyroid disease.
- Patients taking steroid medications or under long term medication for chronic illness.
- Subjects who are not willing.

Collection of data

The data was collected according to case proforma. The patient's details (name, age, socio economic status, education status) and history of personal, present and past history, menstrual history, obstetric history, treatment history were collected. General and systemic examination were done to rule out any systemic or structural abnormalities.

Investigations

- Haematological examination, Abdominal ultrasonography done before study to find out any ovarian or uterine pathology for amenorrhoea, Hormonal assay (FSH, LH and Prolactin) done before study to find out hormonal imbalance.

Assessment criteria

To know the effect of drug first it is assessed by whether attaining menstruation or not.

Then the characterization of menstruation is assessed by

1. Amount of blood loss is measured by number of pads used by the patient with area of soaking

Scanty-1-2 pads,

Moderate- 2-4 pads,

Excessive - above 4 pads

2. Duration of menstruation is assessed by

Short- 1-2 days,

Moderate- 3-5 days,

Excess- above 5 days

3. During observation of three consecutive cycles Interval of Menstruation is assessed by

Frequent- below 21 days,

Normal- 21-35 days,

Delayed- above 35 days

4. Clots present or not

Associated symptoms

Anaemia, Body weight, General body weakness, Pain during menstruation, Abdominal distension, Appetite, Hyper pigmentation of skin were also assessed.

Treatment procedure

Patients who are all selected under the inclusion criteria are treated with *Soothaga thadai kudineer*. Before enrolment into the study the informed consent was obtained from the patients. *Soothaga thadai kudineer* were given 325 ml once a day morning for 3 days. At the end of the trial the patients were advised to come for followup for 3 months for observation. during follow up no drug were administred.

Ethical consideration - Every patient was selected after getting an informed consent from them. Before starting study consent from the authorities was also obtained.

OBSERVATION AND RESULTS

In this study, All ten patients were presented with absence of menstruation for 3-5 months, Out of these five patients reported with obesity, two patients were reported with hirsutism and having irregular menstruation cycle with polycystic ovaries.

After Treatment

- After intake of soothaga thadai kudineer, 50% of the patients were attained menstruation with moderate flow of bleeding for three to five days.
- About 20% of the patients were in scanty flow of bleeding for two to three days
- Another 20% of the patients had spotting(one patient had spotting for four days, another patient had spotting for one day)
- Remaining 10% of the patients had not attained menstruation.

So After Treatment 70% of the patients were attained menstruation, 20% of the patients had spotting and remaining 10% of the patients was not attained menstruation.

Observed for three consecutive cycles

- 50% of the patients had regular menstruation with normal flow of bleeding for three to five days for three consecutive cycles.

- 20% of the patients was not attained menstruation for three consecutive cycles.
- 10% of the patients was not attained menstruation for first trial so, Soothaga thadai kudineer is given again after two months from the date of first trial. After intake of kudineer patient had regular menstrual cycle for next two months with normal flow of bleeding.
- 10% of the patients was attained menstruation for two consecutive cycles with scanty flow of bleeding for three days.
- 10% of the patients had spotting for one cycle and had normal of bleeding for another cycle for two days.

There was no any adverse reactions during this study and have a good result. Throughout this study average absence of menstruation for 3-5 months have more good result.

Table 1: Age wise distribution.

About 60% of patients is between 20-25 years of age, 30% of the patients is 26-30 years of age, 10% of the patient is 31-35 years of age(fig-1)

Table 1: Bar diagram 1: Age distribution.

S.no	Age	No of Patients	Percentage
1	20-25	6	60%
2	26-30	3	30%
3	31-35	1	10%

Age distribution of Patients

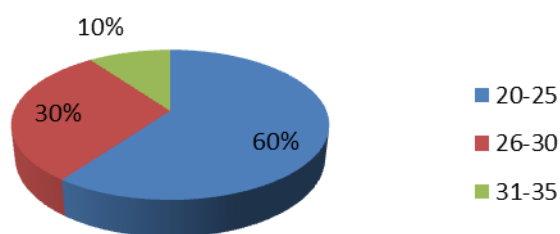


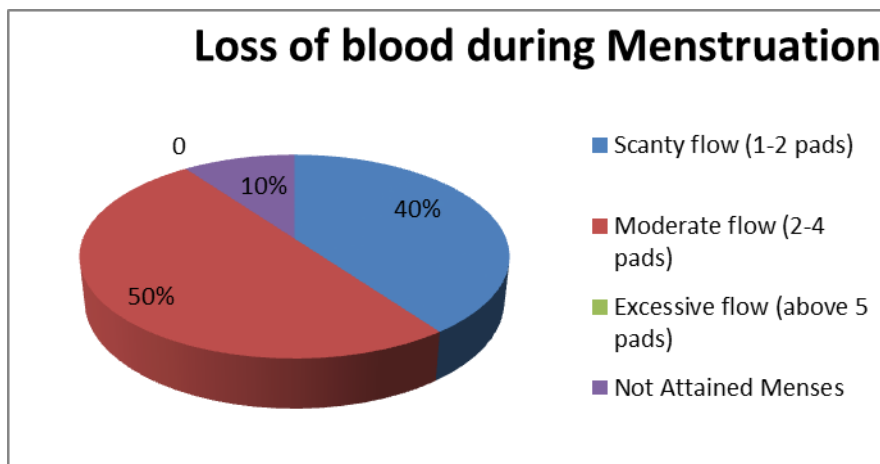
Fig-1.

Table 2: Loss of Blood during Menstruation

About 40% of the patients were in scanty bleeding, whereas 50% of the patients were in moderate bleeding, 10 % of the patients was not attained menstruation(fig-2).

Table 2: Bar diagram 2: Loss of blood during Menstruation.

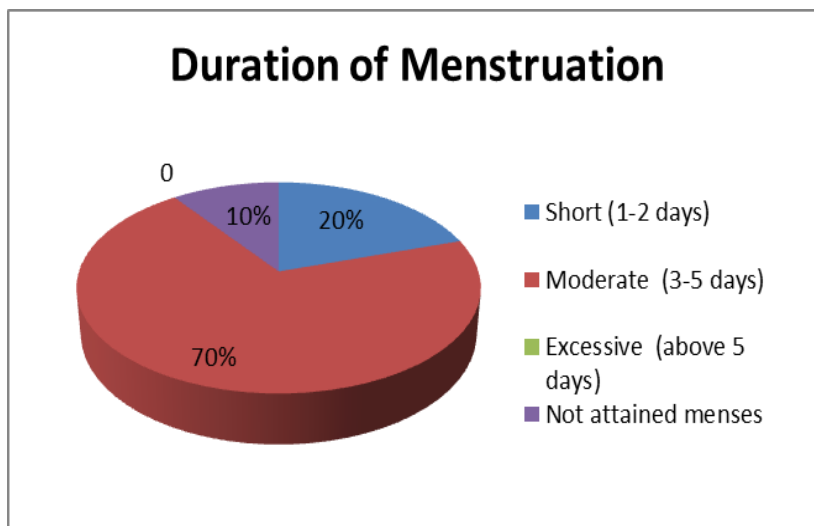
Loss of Blood	No of Patients	Percentage
Scanty flow (1-2 pads)	4	40%
Moderate flow (2-4 pads)	5	50%
Excessive flow (above 5 pads)	-	-
Not Attained Menses	1	10%

**“Fig-2”.****Table 3: Duration of Menstruation**

After treatment about 20% of the patients were attained for short duration (1-2 days), 70% of the patients were attained for moderate duration(3-5 days), 10% of the patients not attained menstruation(fig-3).

Table 3: Bar diagram 3: Duration of Menstruation.

Duration	No of Patients	Percentage
Short (1-2 days)	2	20%
Moderate (3-5 days)	7	70%
Excessive (above 5 days)	-	-
Not attained menses	1	10%



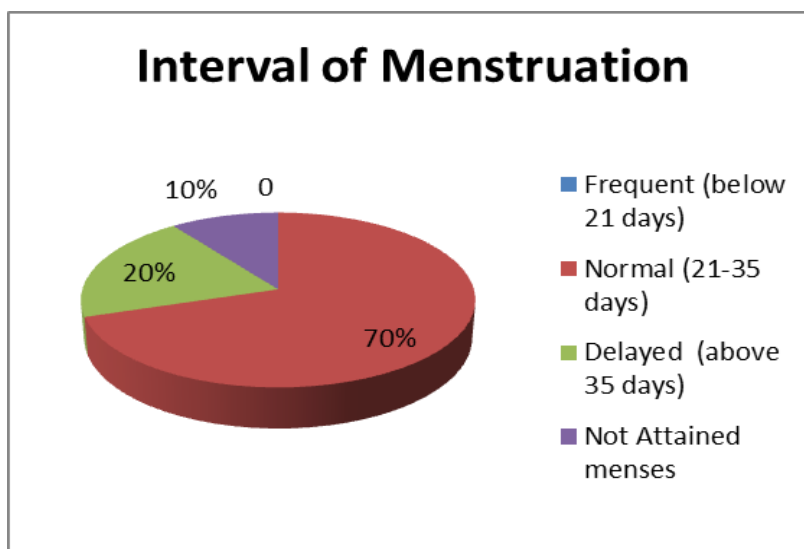
“Fig-3”.

Table 4: Interval of Menstruation (Observation- Consecutive cycles)

After treatment patient is observed for three consecutive cycles without intake of drug, in this period about 70% of the patients were attaining menstruation normally (21-35 days) by every month, 20% of the patients were in delayed menstruation (above 35 days), 10% of the patients not attained menstruation(fig-4).

Table 4: Bar diagram 4: Interval of Menstruation.

Duration	No of Patients	Percentage
Frequent (below 21 days)	-	-
Normal (21-35 days)	7	70%
Delayed (above 35 days)	2	20%
Not Attained menses	1	10%



“Fig-4”.

DISCUSSION

Patients from 20-35 years of age with complaints of an absence of menstruation for 3 months and above also had hyperpigmentation, central obesity, hirsutism. Ultrasound was done to find out ovarian or uterine pathology for amenorrhoea around 50 % of patients had the polycystic appearance of ovaries, whereas in hormonal assay before and after the study no significant hormonal imbalance was seen. Considering Naadi and prakriti most of the patients seem to be vathakapam and they had a very sedentary lifestyle and had junk foods which may lead to vitiation of kapham and polycystic ovarian disease are included in this study by selecting a patient randomly. Considering dosha predominance in patients most of them were vatha kapha prakriti. Psychological stress and anxiety may cause vatham vitiation. All leads to Soothaga thadai which in turn added to the pathogenesis of disease. Patients were treated with Soothaga thadai kudineer for three days once a day. After treatment, out of ten patients, 70% of cases attained menstruation and had a regular menstrual cycle for three consecutive cycles whereas 20% patients had spotting remaining five patients had a normal flow of menstruation for three days. 10% of patients have not attained menstruation after taking kudineer and we repeated for another month they got their menstruation. After follow up for three consecutive cycles without the intake of medicine. 20% of the cases were not attained menstruation. this medicine helped to induced menstruation but unable to regularize it. 20% of patients BMI has reduced to normal range.

The effect of the medicine by attaining menstruation was observed for three cycles consequently. The amount and duration of bleeding improved from scanty to moderate flow in most of the patients. The interval of the cycle seems to be regular in 70% of the patients.

Thus it can be concluded that Soothaga thadai kudineer may have an ability to inducing menstruation and but unable to regularize the menstrual cycle. this drug is found more effective with strict diet control, exercise, and yoga.

CONCLUSION

- Soothaga thadai kudineer was found to be effective in inducing menstruation, scanty to moderate flow, and short to moderate duration.
- The study drug was found to be more effective in amenorrhoea is satisfied by up to 70 %. Moreover, there is no adverse effect in this study.
- 20 % of patients BMI has reduced to normal range

- It has shown good effectiveness and safe in the treatment of soothaga thadai (secondary amenorrhoea).
- A further open clinical trial is needed to find out its action at the hormone level. Hence the pilot study is taken for further research on large scale.

REFERENCES

1. V.G. Padubidri and S.N. Daftary- Shaw's Textbook of Gynaecology- 16th edition- Elsevier India, 2014.
2. T.v. Sambasivam pillai- Tamil - English dictionary part 2- Department of Indian Medicine and Homeopathy, Chennai, March 1998; 106.
3. C. Kannusamy pillai - Sigicha ratna deepam- B.Rathina nayagar & sons, Chennai, 2007; 79.
4. Vaidhiya Rathanam Ka.Sa. Murugesu Mudhaliyar-Gunapadam-Mooligai vaguppu - Published by Indian system of Medicine and Homeopathy.
5. S. P. Kopperundevi, K. Arunachalam. Siddha Herbal Drugs on Treating Menstrual Disorders –A Review. *Int. J. Curr. Res. Med. Sci.*, 2019; 5(7): 10-12.