

Research Article

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A pilot study on the efficacy of ‘Sotrupperu Chendooram’ for the management of Primary dysmenorrhoea (Aga Soothagavali).

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Abstract

Keywords

Dysmenorrhea,
Sotrupperu Chendooram,
Pulipaani Vaithiyam,
Aga Soodhagavali

Objective: The present pilot study was designed to evaluate the effect of *Sotrupperu Chendooram* a Traditional Siddha medicine in *Aga Soothaga Vali*(Primary Dysmenorrhoea) patients.

Method: This study was conducted at the National Institute of Siddha, Tambaram, Chennai, India. The investigator recruited 10 patients with an inclusion and exclusion criteria. The patients were treated with 488 mg *Agasthiarkuzhambu* with lemon juice on the first day. For the next three days the patients were given 4.2 grams of Sotrupperu chenduram in Vellaipoonduthylam once daily in the morning Dietary regimen was advised for the patients. Study outcome was studied based on the improvement in the reduction of pain score in Numerical pain scale, clinical improvement and prevention of recurrence of Spasmodic dysmenorrhoeal pain for at least 3 months.

Results: Clinical symptoms such as spasmodic dysmenorrhoeal pain, nausea headache, vomiting, and diarrhoea were relieved during the treatment. There were no adverse events reported during the study and no recurrence of pain was noticed in 4 patients who were completely cured, during the follow up period of up to 3 months were reported and in all the other patients the pain was reduced.

Conclusion: Results suggest that the trial drug *Sotrupperu Chendooram* is effective and safe for the management of *Aga Soothaga Vali*(Primary Dysmenorrhoea) and in alleviating recurrences.

Introduction

Siddha system of medicine is an integrated part of Indian system which is very potent and unique in its own right, by providing healing of the body, mind and soul. Siddha system propounded by the Siddhars is an all inclusive versatile system which defines health as a perfect state of Physical, Psychological, and Social and Spiritual well being of an individual. Siddha medicine contributes much to the health care of human beings.

Dysmenorrhoea literally means painful menstruation . But a more realistic and practical definition includes cases of painful menstruation of sufficient magnitude so as to incapacitate day to day activities. It affects more than 50% of menstruating women. In fact, it's the leading cause of lost time from school and work among women of childbearing age. Approximately 10–15% of females experience monthly menstrual pain severe enough to stop normal daily functions at work, home, or school.³Dysmenorrhoea may involve sharp, intermittent pain or dull, aching pain.

It is classified as primary and secondary dysmenorrhoea. The primary dysmenorrhoea is one where there is no identifiable pelvic pathology. Increased prostaglandin secretion intensifies uterine contractions, apparently causing mild to severe spasmodic cramping pain in the lower abdomen, which radiates to the sacrum and inner thighs. The cramping abdominal pain peaks a few hours before menses. Patients may also experience nausea and vomiting, fatigue, diarrhoea, and a headache. Secondary dysmenorrhoea is normally considered to be menstruation associated pain occurring in the presence of pelvic pathology.

Modern medications used may include NSAIDs and opioid analgesics, as well as oral contraceptives (OCs). NSAIDs are contraindicated in patients with renal insufficiency, peptic ulcer disease, gastritis, bleeding diatheses, or aspirin hypersensitivity. OCs are not approved by the FDA for this indication⁴. Surgical interruption of the pelvic nerve pathways can be used in women who do not respond to medical treatment but, as yet, there is no strong evidence of long-term efficacy of this method^{5,6,7}. Emerging documents suggest many women are seeking for alternatives to conventional medicine including herbal medicine. Modern medical science has set its quest with traditional medicines for its cost effective and safe medication. With increased quality of life along with life expectancy and lifestyle modifications, the utilization of Siddha medicine is gaining significance among the public day by day. Siddha system also aims in both the treatment and prevention of the disease.

The drug *Sotruppu Chendooram*⁸ is indicated exclusively for dysmenorrhoea (soothagavali). The reference taken from *Pulipanni Vaithiyam 500* mentions that this medicine is a very good relief for dysmenorrhoeal pain. More over Soothagavali is due to alteration of vaathahumor. According to siddha philosophy “Viresanathalvaathamthazhum” which means vaathahumor can be neutralized by administration of purgatives or laxatives. Moreover it is also mentioned in our siddha literature to prescribe laxatives with salt preparations for dysmenorrhoea. In the present study, the Siddha formulation *Sotruppu Chendooram* was evaluated for its efficacy and safety in *Aga Soothagavali* (primary dysmenorrhea) patients in a scientific manner.

Method

This pilot study was conducted in *Ayothidoss Pandithar* Hospital in the OPD of Sool and Magalir Maruthuvam, National Institute of Siddha, Tambaram Sanatorium, Chennai-47 in accordance with standard protocol after obtaining the approval of the Institutional Ethical Committee (IEC) (NIS/IEC/8-14/34-26-08-2014). Before enrollment into the study the informed consent was obtained from the patients.

Conduct of Trial

A total of 10 female nulliparous patients between 11 and 25 years of age with symptoms of Spasmodic dysmenorrhoeal pain ranging from 4-10 according to Numerical Rating Pain Scale were treated with the trial drug as follows. On the first day of menstruation the patients were given 488 mg Agasthiarkuzhambu with lemon juice in the morning. From day II to day IV day the patients were given 4.2 grams of Sotruppuchenduramin Vellaipoonduthylam once daily in the morning. On day V the patients were advised to have oil bath. Fried salt and tamarind heated in flame can be added on this day. Raw rice and Green dhal kanji without salt was advised throughout the treatment period. The patients were asked to follow the following lifestyle modifications during the treatment and follow-up period.

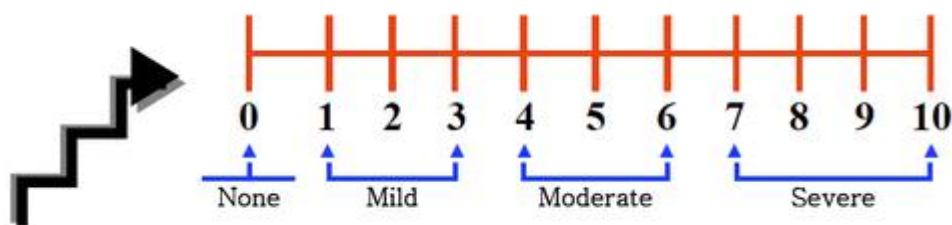
1. Lying on the back, supporting your knees with a pillow
2. Holding a heating pad or hot water bottle on the abdomen or lower back
3. Taking a warm bath
4. Gently massaging the abdomen
5. Doing mild exercises like stretching, walking, or biking – exercise may improve blood flow and reduce pelvic pain
6. Avoid strenuous exercise as it has been shown to alleviate symptoms of dysmenorrhea⁹
7. Getting plenty of rest and avoiding stressful situations as the period approaches.

Study Outcome

Study outcome was studied based on the improvement in the reduction of pain score in Numerical pain scale, clinical improvement and prevention of recurrence of Spasmodic dysmenorrhoeal pain for at least 3 months.

Results were observed with respect to the following criteria

Numerical Rating Pain Scale



Treatment outcome based on Numerical Pain Score

S.NO	AGE	Pain scale Before treatment	Pain scale After treatment	% of relief in pain	Pain scale during the 3 months follow up		
1	14	4	0	100 %	0	0	0
2	14	5	0	100%	0	0	0
3	20	6	1	83%	1	0	0
4	15	5	1	80%	1	1	1
5	26	6	1	83%	1	1	1
6	21	5	1	80%	0	0	1
7	18	6	2	66%	2	2	1
8	21	6	1	83%	0	1	1
9	23	7	2	71%	2	2	2
10	24	5	1	80%	0	0	0

Results

Clinical symptoms such as spasmodic dysmenorrheal pain, nausea headache, vomiting, and diarrhoea were relieved during the treatment. There were no adverse events reported during the study and no recurrence of pain was noticed in 4 patients who were completely cured, during the follow up period of up to 3 months were reported and in all the other patients the pain was reduced.

Discussion

The simple and highly efficient drug which has been mentioned in Siddha literature for the management of dysmenorrhea was used for the trial. Dysmenorrhea affects more than 50% of menstruating women. In

fact, it's the leading cause of lost time from school and work among women of childbearing age. Approximately 10–15% of females experience monthly menstrual pain severe enough to stop normal daily functions at work, home, or school³. A total number of 33 cases was screened and 10 cases was recruited and given treatment in the OPD and IPD of Sool and Magalir Maruthuvam OPD. After completion of the study, the patients were advised to visit the OPD of Soolmagalir Maruthuvam for 3 month for follow-up. The results obtained provide promising good result. Among 10 cases, 2% shows excellent improvement and 8 % shows good improvement. These results were based completely on the clinical improvements.

In the other hand, on the statistical data,

Treatment	Mean ± Std Dev	95% of C.I	Significance (t, p)
Before (10)	5.5± 0.84	4.89 to 6.10	27.0000 P 1.0000
After (10)	01 ± 0.66	0.52 to 1.4	

The mean and standard deviation of clinical symptoms score of dysmenorrhea before and after treatment were 5.5± 0.84 and 01 ± 0.66 respectively, which is statistically significant. The reduction of clinical

symptoms after the treatment is significant (p 1.0000).The reduction in the symptom is 82% at the end of the treatment.

Hence the efficacy of the trial drug Sotruppu Chendooram in the management of Agasoodhagavali(Primary dysmenorrhoeal) ,which is observed clinically and statistically is found to be fabulous.

Conclusion

Women are prone to many pains in their life time such as menstrual pain, labour pain etc. Siddha formulations described in traditional texts for the management of dysmenorrhoea are comparatively economical and also clinically effective. The observation both clinically and statistically made during the clinical study explores that the trail drug Sotruppu chendooram, was clinically effective in the management of Aga Soodhagavali. This has inturn, provided a golden opportunity for a new drug established in the management of Aga Soodhagavali.

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