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**Clinical evaluation of Siddha drug Sanga Dravagam
(internal) in the treatment of Aga Soodhagavali
(Primary Dysmenorrhoea)**

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Abstract

Background: Siddha system of medicine is contributing much to the women's healthcare. Siddhars clearly defined diseases of female genital tract in different terminologies such as Garpa vayu, Soodhagakatti, Garpa Vippuruthi, Soodhagasoolai etc., in their poems. According to the siddha text of Magalir Maruthuvam Soodhagavali can be correlated to dysmenorrhea. **Objectives:** The Main objectives of this study is to evaluate the therapeutic efficacy of siddha drug "Sanga Dravagam" (Internal medicine) in the treatment of **Agasoothaga vali** (Dysmenorrhea). The Secondary objectives of this study is to analyses the effect of other associated factors like Age, Life style, habits and to study the effect of the medicine on prostaglandin. **Methods:** In Clinical studies, out of 30 children only 10 children were included in inclusion criteria and received a Sanga dravagam with Sombu kudineer as internal for three days during menstruation. The duration of the study is three consecutive menstrual cycle. The improvement was seen in pain numerating Scale. **Results and discussion:** Based on these results, the Clinical study indicating the internal medicine had superior action as far as improvement in dysmenorrhea is considered. It has a definite action as well as clinical efficacy on symptoms in dysmenorrhoea seen in regular OPD and IPD. The effects of Internal and external therapies may be due individual drugs multipronged action. Further study is required for scientific validation to prove its clinical efficacy in multicentre clinical study.

Keywords: Siddha, Sanga dravagam, Sombu theeneer, Aga Soodhagavali, Dysmenorrhea

1. Introduction

Siddha system of medicine is contributing much to the women's healthcare. Siddhars clearly defined diseases of female genital tract in different terminologies such as Garpa vayu, Soodhagakatti, Garpa Vippuruthi, Soodhagasoolai etc., in their poems. According to the siddha text of Magalir Maruthuvam Soodhagavali can be correlated to dysmenorrhea. Dysmenorrhoea literally means painful menstruation. Practically it affects day to day activities. It affects more than 50% of menstruating women; in fact, it's the leading cause of absence from school, and affects work among women of childbearing age.

Dysmenorrhea 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, diarrhea, and a headache. The trail drug Sanga Dravagam is indicated

widely for all spasmodic pains and in particular for dysmenorrhoea (Soothagavali). The reference taken from **Gunapadam Thadhu Jeeva Vaguppu page no52 & Theraiyar Karisal 300 pg no 82** mention that this medicine is a very good relief for abdominal pain especially dysmenorrhea. More over Soothagavali is due to alteration of Vaatha humour. According to Siddha Philosophy "Viresanathal Vaatham thaazhum" which means Vaathahumour 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. So the author shows keen interest in selecting a preparation involving salty ingredients for the treatment of dysmenorrhoea. Many patients with the complaint of dysmenorrhoea come to our Sool & Magalir OPD in NIS. The trial drug Sanga Dravagam gives a good relief in complaints of dysmenorrhoea in our OPD patients.

2. Aim and Objectives

- To study the therapeutic efficacy of siddha drug "**Sanga Dravagam**" (Internal medicine) in the treatment of **Agasoothaga vali** (Dysmenorrhoea)
- To study the effect of other associated factors like Age, Life style, habits.
- To study the effect of the medicine on prostaglandin.

3. Materials and Methods

3.1 Preparation of experimental formulations:

It is pilot study conducted in Kuzhandhai Maruthuvam department, NIS. Sanga dravagam as internal were identified for this study. Raw drugs to prepare the products were purchased from the well reputed country shop in Tambaram. The raw materials have got authentication from the department of Medicinal Botany, National institute of Siddha, Chennai. After process the medicine was proper purification and prepared in Gunapadam lab of NIS. The Prepared medicine was stored in glass container authenticated by the concerned guide for its completeness.

3.2 Sangadravagam:

Salt petre (vediyuppu)	- 12 parts
Rocksalt (induppu)	- 8 parts
Common salt (sotruppu)	- 4 parts
Sal ammoniac (navacharam)	- 10 parts
Green vitreol(annabhedhi)	- 1 parts
Blue vitriol (thurusu)	- 1 parts
Common alum (padikaram)	- 1parts
Salt from alkalaine earth (pooneeru)	- 3parts
Borax (venkaaram)	-4 parts

Process

Powder the drugs separately and mix. Charge in a glazed earthen still and distill. The condensate is acidic and should be collected in porcelain, enameled or glass containers.

Indications

Ascitis, enlargement of liver and spleen, colic and spasmodic pain in the abdomen and chest.

Dosage: 5-8 drops twice a day after food for 3days[during menstruation]

Adjuvant: Sombu theeneer

Duration: 3 consecutive menstrual cycles of the study population

3.3. Clinical studies

The Present study was a interventional, open clinical, out-patient and In-patient based, Single Arm trail conducted in the department of Kuzhandai Maruthuvam (Paediatric), National Institute of Siddha, Chennai. It was conducted during 2016 to Oct 2017 after obtains approval from Institutional Ethics Committee NIS/IEC/2016/-17/28, 20.05.2016. After getting the approval from committee, registration done in CTRI and number is CTRI/2017/06/008900. The first 30 patients with dysmenorrhoea were screened during this period. The age group of 15-25 years who were diagnosed with dysmenorrhoea were identified and included in the study. Other type of dysmenorrhoea along with Dysfunctional uterine bleeding and Presence of any associated severe systemic illness. 10 patients satisfied the inclusion criteria and were willing to participate in the study, signed the informed consent. The parents of children who were enrolled was informed about the study, trail drug, possible outcomes and the objectives of the study in the language and terms understandable for them.

All the 10 patients, under OPD and IPD treatment received Sanga dravagam with Sombu theeneer as internal 5-8 drops twice a day after food for 3days[during menstruation]. The duration is 3 consecutive menstrual cycles of the study population. Experimental formulations were assigned to each subject and regular study drug reconciliation was performed to document the drug assigned, consumed and remaining are logged on the drug reconciliation form with sign and date.

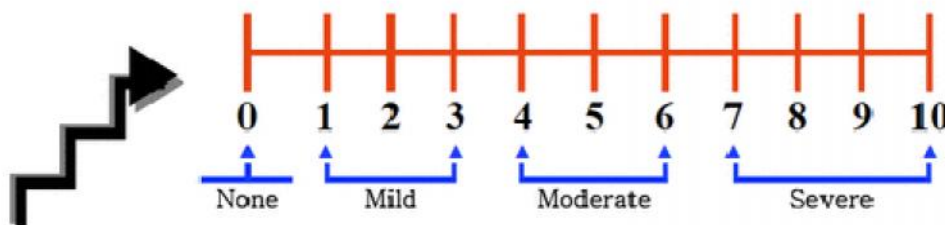
Data collection forms

- Form 1 Screening and selection proforma
- Form 2 Consent form
- Form 3 Case report proforma
- Form 4 Patient's information sheet
- Form 5 Drug compliance
- Form 6 Withdrawal form
- Form 7 Adverse reaction form
- Form 8 Pharmacovigilance form
- Form 9 Dietary advice form

4. Results and Discussion

Numerical Rating Pain Scale for Menstruation

The outcome will be assessed on the basis of reduction of pain which will be calculated using Numerical Rating Pain Scale.



Significant outcome - Reduction of pain from 4-10 to 0.
 Good outcome - Reduction of pain from 7-10 to 1 – 3.
 Moderate outcome - Reduction of pain from 4-6 to 1–3 and from 7-10 to 4-6.
 Poor/Nil - No reduction in pain scale number or clearance of associated symptoms.

The outcome before treatment will be assessed by the principal investigator and the outcome after treatment will be assessed by one of the trained faculty of NIS to fill up the assessment form.

Before and after treatment:

S.no	Date	Op No/ Ip No	Age/Sex	Before treatment	After treatment
1	16/11/2016	I 26757	20/F	Moderate	No pain
2	30/12/2016	H 12245	18/f	Severe	No pain
3	17/01/2017	I 52029	25/f	Severe	Mild pain
4	03/02/2017	I 58775	23/f	Moderate	No pain
5	01/02/2017	H 94668	20/f	Moderate	No pain
6	20/03/2017	I 83099	17/f	Severe	No pain
7	18/02/2017	I 57106	25/f	Severe	No pain
8	21/12/2016	I 77724	19/f	Severe	Mild Pain
9	10/04/2017	I 82476	17/f	Moderate	No pain
10	19/03/2017	H 80642	22/f	Severe	No pain

Results of efficacy of Sangdravagam for Dysmenorrhoea

S.NO	Results	Number of patients/10	Percentage
1	Significant outcome	8	80%
2	Good outcome	2	20%
3	Moderate outcome	0	0%
4	Poor outcome	0	0%


Based on this result, the Clinical study indicating the internal medicine had superior action as far as improvement in dysmenorrhea is considered. It has a definite action as well as clinical efficacy on symptoms in dysmenorrhoea seen in regular OPD and IPD. The effects of Internal medicines may be due individual drugs multipronged action.

5. Conclusion

In general, based on the results of this study, were found to be improvement in all the cases. No adverse effects were noticed during the treatment. Further follow up of these patients showed good recovery and fine improvement. The preparation of the medicine is simple as well as economical. Further study is required for scientific validation to prove its clinical efficacy in multicentre clinical study.

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