Evaluate the Effectiveness of *sphaeranthus indicus linn* on the Management of Constipation

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Abstract Constipation is the most common gastrointestinal complaint all over the world. There are various systems of medicines have several therapeutic index, among these herbal medicines are much effective with less side effect. *Sphaeranthus indicus* is a common herb having many traditional claims including constipation. However, the laxative property of *S. indicus* has not been confirmed through the clinical trial yet. There for the present study deals with the effectiveness of *S. indicus* on constipation. This study is a quasi-experimental study to determine the internal administration of *S. indicus Choornam* in the management of patient with constipation. Also deal with identify aggravating and reliving factors of the constipation, identify the side effects of *S. indicus* and determine the association factor between the constipation and Food habits, Life style and Hereditary. In present study, ten patients with constipation, according to the inclusive and exclusive criteria were selected and treated with *S. indicus Choornam* 2 gram orally, three times a day for 40 days. Evaluation visit were made at base line and 3rd, 6th, 10th, 15th, 20th, 25th, 30th and 40th days. After the final assessment the patients were observed on 50th and 60th days to determine the recurrence of disease. Clinical study showed statistically significant improvement on parameters like hard stool, incomplete evacuation, Excessive staining, Lower abdomen fullness and Gas collection (<0.001). The study also showed that statistically highly significant result in overall effect. According to this study laxative activity of the *S. indicus* has been proved through this clinical trial.

Keywords Constipation; Sphaeranthus Indicus; Hard Stool; Incomplete Evacuation; Excessive Staining; Lower Abdomen Fullness and Gas Collection

1. Introduction

This study deals with the internal administration of *Sphaeranthus indicus Choornam* in the management of patients with constipation. Constipation is a condition in which an individual experiences uncomfortable. It is the most common gastrointestinal complaint all over the world resulting in over two million reported cases annually (Rawat et al., 2012).
A consensus definition used in research (The Rome II criteria) defines constipation as having two or more of the following for at least 12 weeks: infrequent passage of stools (< 3/week), straining > 25% of time, passage of hard stools, incomplete evacuation and sensation of anorectal blockage (Kumar & Klark, 2006).

WHO reported that more than 80% of world populations specially in developing in develop countries dependent on herbal medicine (Clearinghouse, 2007).

Siddha medicinal plants have demonstrated remarkable biological effectiveness. According to Siddha medicine herbal treatment is the basic choice of treatment. If treatment with plants are not of effective gradual use of metals and minerals are suggested (Rajeswari, 1983).

Hence in order to find out a new drug for constipation from herbal origin the plant *Sphaeranthus indicus* Linn has been selected. *Sphaeranthus indicus* Linn is one of the medicinal plant belongs to family *Asteraceae*. The plant is commonly known as “Kottaikaranthal” in Tamil. It is an annual spreading herb. All the parts of the plant have medicinal uses. In folk medicine, the plant is reportedly used in treating epileptic convulsions, mental illnesses and hemicranias (Kirtikar & Basu, 1987).

### 1.1 Background and Justification of the Study

Siddha Medicine means medicine that is perfect. Siddha medicine revitalizes and rejuvenates the organ which is causing disease. This brings back normal functioning of the organs. It also maintains *Vath*ta, *Pit*ha and *Kapha*, thus maintaining the healthy state of body. Since no artificial chemicals are involved it doesn't cause any side effect (Uthamaroyan, 2005). Indigenous systems treat constipation as a problem arising due to the vitiation of the *vata dosha*. In fact, all people with the *vata prakrithi* have this problem to some extent or the other. From the Siddha point of view, dietary bad habits are the main cause of constipation. There are various systems of medicines have several therapeutic index among these herbal medicines are much effective with less side effect. (www.siddhavaidyam.com)

The extracts of *Sphaeranthus indicus* possess a wide range of pharmacological activities including anti-diabetic, Antimicrobial, Anti-bacterial, hepatoprotective, Analgesic and Antipyretic activities. But laxative action still not proved scientifically. There for this study deals with laxative property of whole plant of *S. indicus* on constipation.

### 2. Objective of the Research

To determine the effectiveness of *Sphaeranthus indicus* on constipation

### 3. Methodology

This is a quasi-experimental study in this study, Constipation patients, according to the inclusive criteria and exclusive criteria were selected at the Rural Ayurveda Hospital, Kopalapuram. The selected patients treated with selected drug.

### 3.1. Study Area

This is an institutional based study. The study was conducted at the Rural Ayurveda Hospital, Kopalapuram.
The selection of institution was based on the following criteria:

1. This hospital has necessary facilities for research work.
2. Both indoor and outdoor patients are available
3. The number of Out Patient Department (OPD) patients is higher than other Hospitals.

Accessibility of the rural Ayurveda Hospital, Kopalapuram.

3.1. Study Design

Quasi experimental study: Constipation patients, according to the inclusive criteria, were selected at the Rural Ayurveda Hospital, Kopalapuram. All the selected patients were interviewed by the researcher on their first visit to the OPD. They were assured that all information obtained from them would be strictly confidential. The purpose of the trial was explained to the patients and those who volunteered signed in the ‘informed consent’ form to enroll in the trial. Drugs were administrated for forty days with eight intervention treatment arms.

3.2. Selection of Patients

Ten Patients of between 18 to 70 years of age, both sexes presenting with the signs and symptoms of constipation were selected randomly based on randomization schedule from Out patients Department of the Rural Ayurveda Hospital, Kopalapurm, Trincomalee. They were assured that all information obtained from them would be strictly confidential. These patients were subjected to a detailed clinical examination based on proforma specially prepared for this study. Diagnosis was made on the basis of the history and physical examination.

Inclusion Criteria

1) Age- patients were selected between age group of 18-70 year
2) Both Sex
3) Sign & symptoms of constipation based on history taking
   Include two or three of the following
   i. Hard stool
   ii. Excessive staining
   iii. Incomplete evacuation
   iv. Lower abdomen fullness
   v. Gas collection
4) Those give the consent

Exclusion Criteria

1) Below 18 years
2) Above the 70 years
3) Patients who used any drug for various diseases

Individuals suffering from any other systemic disease – Diabetes, Hypertension, Rectal Prolapse, Anal stenosis, Anal fissure, Piles, Rectocele.
4. Preparation of Medicine

**Collection of plant**

The fresh Plant of *S. indicus* was collected from the Thambala in Polonnaruwa district in the month of January.

**Authentication of plant**

The plant of *S. indicus* was taxonomically authenticated by Kunapadam division, Unit of Siddha Medicine, Trincomalee Campus, EUSL.

**Purification of plant**

The Plant of *S. indicus* cleaned and washed with water and dried in shade. Then cut in to small pieces then boiled in cow’s milk and allowed to dry in shade.

**Preparation of Chooranum**

The Plant of *S. indicus* was dried out under the Sun shade then bruised, well strained through fine meshes of sieve. This powder was stored in dry and air tight glass bottle for further studies.

5. Instrument

Interviewer administrated questionnaire were used to collect the data (Annexure 1). Questionnaire was formulated based on the specific objective.

5.1. Data collection

According to inclusive criteria patient were selected at Konesapuri area during February 15 to May 15, 2015. The purpose of trial was explained to the patient to get their consent a selected patient was interviewed by the researcher on their first visit to the OPD. The patient were subjected to a detailed clinical examination based on proforma specially prepared this study. Diagnosis will be made on the basis of history and clinical examination.

6. Treatment

The all selected patients were treated with *Sphaeranthus indicus* Chooranam, 2 gram orally, three times a day for 40 days

6.1. Side effects

Observed for any side effects after the treatment by the researcher.

6.2. Clinical assessment

Considering the symptoms of constipation as given in modern science the assessments were made. Full detailed history and physical examination of the patients were recorded into specially prepared proforma for *Malakattu*. Diagnosis was made on the basis of history and basic physical examination evaluation visit were made at base line and 3rd, 6th, 10th, 15th, 20th, 25th, 30th and 40th days.
After the final assessment the patients were observed on 50th and 60th days to determine the recurrence of disease.

Effectiveness of treatment was evaluated on the basis of change in the sign and symptoms of constipation. Hard stool, Excessive straining, incomplete evacuation, lower abdomen fullness, gas Collection were considered as a primary efficacy variables and they were analyzed by score as different between the first day of the treatment and after the treatment.

6.3. Data analysis

The data was analyzed using the Statistical Package for Social Sciences (SPSS) version 16. Dependent variables and independent variables are used to Evaluate the effectiveness of *Sphaeranthus indicus linn* on the management of constipation of each variable is separately analyzed. Following statistical techniques are used to analysis the study.

7. Results and Discussion

Table 1: Effect of Therapy on Hard Stool

<table>
<thead>
<tr>
<th>Days</th>
<th>Mean</th>
<th>Std. deviation</th>
<th>Std. error mean</th>
<th>Paired “t”</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before treatment</td>
<td>3.30</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>3rd day</td>
<td>2.00</td>
<td>.483</td>
<td>.153</td>
<td>8.510</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>6th day</td>
<td>1.50</td>
<td>.632</td>
<td>.200</td>
<td>9.000</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>10th day</td>
<td>1.30</td>
<td>.471</td>
<td>.149</td>
<td>13.416</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>15th day</td>
<td>1.10</td>
<td>.422</td>
<td>.133</td>
<td>16.500</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>20th day</td>
<td>1.00</td>
<td>.483</td>
<td>.153</td>
<td>15.057</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>25th day</td>
<td>1.00</td>
<td>.483</td>
<td>.153</td>
<td>15.057</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>30th day</td>
<td>1.00</td>
<td>.483</td>
<td>.153</td>
<td>15.057</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>40th day</td>
<td>1.00</td>
<td>.483</td>
<td>.153</td>
<td>15.057</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

100% of selected patients were show hard stool. Initial mean value of hard stool was 3.30 and 20th day it reduced into 1, it means hard stool never occur following to 20th day of treatment and also statistically highly significant improvement (p<0.001) in hard stool was observed. It clearly denoted that the medicine was effective on hard stool.

Table 2: Effect of Therapy on Excessive Straining

<table>
<thead>
<tr>
<th>Days</th>
<th>Mean</th>
<th>Std. deviation</th>
<th>Std. error mean</th>
<th>Paired “t”</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before treatment</td>
<td>2.40</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>3rd day</td>
<td>1.80</td>
<td>.516</td>
<td>.163</td>
<td>3.674</td>
<td>.005</td>
</tr>
<tr>
<td>6th day</td>
<td>1.60</td>
<td>.422</td>
<td>.133</td>
<td>6.000</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>10th day</td>
<td>1.30</td>
<td>.738</td>
<td>.233</td>
<td>4.714</td>
<td>.001</td>
</tr>
<tr>
<td>15th day</td>
<td>1.00</td>
<td>.516</td>
<td>.163</td>
<td>8.573</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>20th day</td>
<td>1.00</td>
<td>.516</td>
<td>.163</td>
<td>8.573</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>25th day</td>
<td>1.00</td>
<td>.516</td>
<td>.163</td>
<td>8.573</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>30th day</td>
<td>1.00</td>
<td>.516</td>
<td>.163</td>
<td>8.573</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>40th day</td>
<td>1.00</td>
<td>.516</td>
<td>.163</td>
<td>8.573</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
100% of selected patients were show Excessive staining. Initial mean value of Excessive staining was 2.40 and 15\textsuperscript{th} day it reduced into 1, it means Excessive staining never occur following to 15\textsuperscript{th} day treatment. The study showed that statistically highly significant result with ‘p’ value (p<0.001). It clearly denoted that the medicine was effective on Excessive staining.

Table 3: Effect of Therapy on Incomplete Evacuation

<table>
<thead>
<tr>
<th>Days</th>
<th>Mean</th>
<th>Std. deviation</th>
<th>Std. error mean</th>
<th>Paired &quot;t&quot;</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before treatment</td>
<td>2.70</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>3\textsuperscript{rd} day</td>
<td>1.70</td>
<td>.667</td>
<td>.211</td>
<td>4.743</td>
<td>.001</td>
</tr>
<tr>
<td>6\textsuperscript{th} day</td>
<td>1.50</td>
<td>.632</td>
<td>.200</td>
<td>6.000</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>10\textsuperscript{th} day</td>
<td>1.20</td>
<td>.527</td>
<td>.167</td>
<td>9.000</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>15\textsuperscript{th} day</td>
<td>1.00</td>
<td>.483</td>
<td>.153</td>
<td>11.129</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>20\textsuperscript{th} day</td>
<td>1.00</td>
<td>.483</td>
<td>.153</td>
<td>11.129</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>25\textsuperscript{th} day</td>
<td>1.00</td>
<td>.483</td>
<td>.153</td>
<td>11.129</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>30\textsuperscript{th} day</td>
<td>1.00</td>
<td>.483</td>
<td>.153</td>
<td>11.129</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>40\textsuperscript{th} day</td>
<td>1.00</td>
<td>.483</td>
<td>.153</td>
<td>11.129</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

100% of selected patients were show incomplete evacuation. Clinical study showed that Initial mean value of incomplete evacuation was 2.70 and 15\textsuperscript{th} day it reduced into 1, it means incomplete evacuation never occur following to 15\textsuperscript{th} day treatment and also statistically highly significant result with ‘p’ value (p<0.001). It clearly denoted that the medicine was effective on incomplete evacuation.

Table 4: Effect of Therapy on Lower Abdomen Fullness

<table>
<thead>
<tr>
<th>Days</th>
<th>Mean</th>
<th>Std. deviation</th>
<th>Std. error mean</th>
<th>Paired &quot;t&quot;</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before treatment</td>
<td>2.40</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>3\textsuperscript{rd} day</td>
<td>1.60</td>
<td>.7817</td>
<td>.2606</td>
<td>3.411</td>
<td>.009</td>
</tr>
<tr>
<td>6\textsuperscript{th} day</td>
<td>1.20</td>
<td>1.0000</td>
<td>.3333</td>
<td>4.000</td>
<td>.004</td>
</tr>
<tr>
<td>10\textsuperscript{th} day</td>
<td>1.10</td>
<td>1.0138</td>
<td>.3379</td>
<td>4.274</td>
<td>.003</td>
</tr>
<tr>
<td>15\textsuperscript{th} day</td>
<td>1.00</td>
<td>1.0138</td>
<td>.3379</td>
<td>4.603</td>
<td>.002</td>
</tr>
<tr>
<td>20\textsuperscript{th} day</td>
<td>1.00</td>
<td>1.0138</td>
<td>.3379</td>
<td>4.603</td>
<td>.002</td>
</tr>
<tr>
<td>25\textsuperscript{th} day</td>
<td>1.00</td>
<td>1.0138</td>
<td>.3379</td>
<td>4.603</td>
<td>.002</td>
</tr>
<tr>
<td>30\textsuperscript{th} day</td>
<td>1.00</td>
<td>1.0138</td>
<td>.3379</td>
<td>4.603</td>
<td>.002</td>
</tr>
<tr>
<td>40\textsuperscript{th} day</td>
<td>1.00</td>
<td>1.0138</td>
<td>.3379</td>
<td>4.603</td>
<td>.002</td>
</tr>
</tbody>
</table>

70% of selected patients were show Lower abdomen fullness. Initial mean value of Lower abdomen fullness was 2.40 and end of 15\textsuperscript{th} day it reduced into 1, it means Lower abdomen fullness never occur following to15\textsuperscript{th} day treatment. ‘P’ value is 0.002 there for statistically significant improvement was observed. It clearly denoted that the medicine was effective on Lower abdomen fullness.

Table 5: Effect of Therapy on Gas Collection

<table>
<thead>
<tr>
<th>Days</th>
<th>Mean</th>
<th>Std. deviation</th>
<th>Std. error mean</th>
<th>Paired &quot;t&quot;</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before treatment</td>
<td>2.70</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>3\textsuperscript{rd} day</td>
<td>1.70</td>
<td>.675</td>
<td>.213</td>
<td>6.091</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>6\textsuperscript{th} day</td>
<td>1.50</td>
<td>.949</td>
<td>.300</td>
<td>5.667</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
90% of selected patients were show Gas collection. Initial mean value of Gas collection was 2.70 and 15\textsuperscript{th} day it completely reduced into 1, it means Gas collection never occur following to 15\textsuperscript{th} day of treatment. The study showed that statistically highly significant result with ‘p’ value (p<0.001). It clearly denoted that the medicine was effective on Gas collection.

<table>
<thead>
<tr>
<th>Day</th>
<th>Mean</th>
<th>SD</th>
<th>N</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>10\textsuperscript{th}</td>
<td>1.20</td>
<td>.949</td>
<td>.300</td>
<td>5.667</td>
</tr>
<tr>
<td>15\textsuperscript{th}</td>
<td>1.00</td>
<td>.949</td>
<td>.300</td>
<td>5.667</td>
</tr>
<tr>
<td>20\textsuperscript{th}</td>
<td>1.00</td>
<td>.949</td>
<td>.300</td>
<td>5.667</td>
</tr>
<tr>
<td>25\textsuperscript{th}</td>
<td>1.00</td>
<td>.949</td>
<td>.300</td>
<td>5.667</td>
</tr>
<tr>
<td>30\textsuperscript{th}</td>
<td>1.00</td>
<td>.949</td>
<td>.300</td>
<td>5.667</td>
</tr>
<tr>
<td>40\textsuperscript{th}</td>
<td>1.00</td>
<td>.949</td>
<td>.300</td>
<td>5.667</td>
</tr>
</tbody>
</table>

Initial Comparative Mean value was 2.70 and 20\textsuperscript{th} day it completely reduced into 1, it means Constipation never occur following to 20\textsuperscript{th} day of treatment. The study also showed that statistically highly significant result with ‘p’ value (p<0.001) in overall effect (Table 1-5). It clearly denoted that the medicine was significant effect on Constipation.

Based on the findings the patients were not complained the symptoms of constipation after the treatment 50\textsuperscript{th} and 60\textsuperscript{th} day. This indicates there was no recurrent after the treatment.

Effectiveness is explained on the basis of Rasa, Veeriya, Vipaka, action and properties of selected plant. According to Siddha, dietary and lifestyle reasons may initially lead to derangement of Vatha or Pitha causing indigestion, bloated abdomen, gassiness etc. to treat constipation, drugs acting on both Vātha and pitha should be selected.

The plant S. indicus has bitter taste. Bitter taste has got Deepana (facilitate digestion), Pachana (augment digestion) properties. So it helps to digest the food particles.

The plant is ushna veeriyam and pungent vipakam. Ushna Veerya which helps in pacification of aggravated Vātha. The bitter taste increases the Dhatuvagni (cell metabolism) as result indigestion will be set off.

Above explanations has been supported by the results obtained from this study.
8. Conclusion

On the basis of results and the findings of this study, the following conclusion can be arrived; *Sphaeranthus indicus* can be used as an effective internal administration for constipation and no strict side effect was detected.

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