A CLINICAL EVALUATION OF SEENTHIL KUDINEER A SIDDHADRUGIN
THE TREATMENT OF KATTUMANTHAM (DYSPEPSIA)

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1. INTRODUCTION

The Siddha system of medicine is one of the ancient systems contemporaneous with those of the submerged lands, Egyptian, Chinese and Grecian medicine. The unique nature of this system is continuous service to humanity for more than 5000 years in combating disease and in maintaining its physical, mental and moral health.

Siddha system was developed by Siddhars. Siddhars are super human being. According to them physical body plays an important role in our life. It becomes our duty to keep it pure and perfect by regulating energy forces exiting in every individual, supplying necessary fuel to achieve proper balance, which is health and avoid imbalance which is illness.

The future of human society depends on the ability of children to achieve their optimal physical growth and psychological development. Early childhood development is considered to be most important phase in child’s life which determine the quality of health well being, learning and behaviour across the life span, particularly during toddler stage. It is the time between infancy and childhood where a child learns and grows in many ways. It is a period of great opportunity but also easily prone to many disease, So proper child care should be taken.

Kuzhanthai Maruthuvam is one among the treasures of siddha system exclusively dealing with disease which affects children. It is the collection of abundant medicine that pacifies the deranged humor paving way for healthy childhood thus laying a concrete pillar for healthy society. Children between age 1 to 3 are easily prone to disease due to dietary habit of mother or of the child, if the baby has started consuming solid foods.

These days working women may find difficult to maintain good feeding frequency so as to fulfill the child’s need as they are not available to feed often when the child requires, which leads to supplementary foods and increased the chance of indigestion. Other than this the altered food habits of the mothers also causes indigestion. Hence much care is really essential to prevent as well as to cure digestion problems in children.

Mantham is one of the diseases mentioned in Balavagadam and it is classified into 21 types. It illustrate that when mother feeds baby after having foods like mangoes, jack fruit and oily foods etc, may affect child’s health mentally and physically.

As per siddha literature kattu mantham is one among the 21 types of mantham. It is common in children between the ages of 1 to 3 years.
According to T.V.Sambasivampillai Tamil-English dictionary, kattumantham is a disease in children arising from constipation. It is marked by indigestion, stomach pain, cough, fever, yawning, perspiration etc. It may be correlated with dyspepsia in modern science.

Functional dyspepsia is defined as persistent or recurrent pain or discomfort centered in the abdomen, without evidence or organic disease. It is a functional disease in which the gastrointestinal organ primarily the oesophagus, stomach, small intestine & colon function abnormally. The primary symptom of dyspepsia are upper abdominal pain, abdominal bloating, early satiety and these symptoms are most often provoked by eating.

The incidence of dyspepsia in children above one year is 85% in pediatric population. In the Out patient department of Ayodhidoss Pandithar hospital, National Institute of Siddha around 1500 patients is visiting every day for treatment for various ailments. Among them, 3 - 5% of patients is in pediatric group and is mostly affected by common digestive problem. As no objective structural or pathophysiological measure exist to assess outcome one has to rely on the subjective reporting of symptoms by the patients and their impact on normal daily activities to decide whether a treatment intervention is of benefit or not.

In Balavagadam, there is a Sastric Siddha formulation seenthil kudineer for KattuMantham(dyspepsia) which is also mentioned in Gunapadam mooligai vaguppu. The main ingredients of the seenthil kudineer are seenthil, sukku ,sivathai which are known for their stomachic, carminative, laxative action. It is said to be cost effective also but efficacy of this medicine is not yet scientifically validated Hence, I have selected Seenthilkudineer for my clinical trial.
2. AIMS AND OBJECTIVES:

Primary Aim and Objectives:

To evaluate the efficacy of seeshtil kudineer for the management of kattu mantham in Children under the following preclinical and clinical parameters

- Physico-chemical Analysis, Carminative studies, Chemical analysis of trial drug
- Clinical studies

Secondary objectives:

- To collect and review the ideas mentioned in the ancient Siddha literature about the disease kattu mantham.
- To explore Definition, Etiology, Clinical features, Diagnosis, Investigations and treatment of kattu mantham as laid down from various siddha literature.
- To make the correlative study of the siddha and modern aspect of this disease.
SIDDHA ASPECT

பாதுகாப்பாக்கள்

பாதுகாப்பாக்கள், அவர்கள், அவர்கள் மற்றும் பல்வேறு பிள்ளைகள் குறிப்பிட்டு போக்கும் வருமானங்களை குறிப்பிட்டுக் கொள்ளும் விளைவையை தேவைப்படுத்துகூடாது.

முறை

மருத முறையில் பாதுகாப்பாக்கள் சாலாம்போன். மருத முறையானது ஏனையும் விளைவையை தேவைப்படுத்துகூடாது. அவர்கள் விளைவை தேவைப்படுத்தியுள்ளனர், புராணங்கள், தொகுதிகள், வாதகுதிகள் மற்றும் வாதகுதிகள் அதிகம் வாதகுதிகளை மருத முறையின் முக்கியமற்று விளைவையை தேவைப்படுத்துகூடாது.


சிறப்பு வகையான புகழ்பூனை:

சிறப்பு வகையான புகழ்பூண்டும், சுமார் புகழ்பூண்டும், புகழ்பூண்டும், முக்கியமற்று முதல்வரமானம் விளைவை தேவைப்படுத்தியுள்ளனர்.

அவர்களின் உடலுக்கு உள்ளன விளைவு உயிராக்கள் மற்றும் உயிராக்கள் உயிரிட்டுக் கொள்ளக்கூடாது விளைவையை தேவைப்படுத்தியுள்ளனர்.

முதல் பதவிகளின் பின்னர்

- பொது நோய்களின் பம்பது, பொது சாலா விளைவை அதிகமாகக் குறிப்பிட்டு கொள்ள வேண்டும்.
- முக்கியமான புராணங்கள், முக்கியமான வாதங்கள், முக்கியமான வாதகுதிகள், முக்கியமான வாதங்கள், வாதங்கள், வாதகுதிகள், வாதங்கள் விளைவை தேவைப்படுத்தியுள்ளனர். முக்கியமான வாதங்கள், வாதங்கள், வாதங்கள் விளைவை தேவைப்படுத்தியுள்ளனர். முக்கியமான வாதங்கள், வாதங்கள், வாதங்கள் விளைவை தேவைப்படுத்தியுள்ளனர்.
1. வசையார்கள்
2. அயன்பொய்கள்
3. வுடால் பருவம்
4. சிற்று பருவம்
5. பெரும் பருவம்
6. பாம்பில்லை பருவம்
7. கையாள பருவம்
8. பூங்கா பருவம்
9. பக்து பருவம்
10. மூடி பருவம்
11. பொன்ற பருவம்
12. கது பருவம்
13. துள்ளத்து பருவம்
14. குறுகிய பருவம்
15. குழல் பாதுகாக்க
16. கலந்துசெல்வது பாதுகாக்க
17. அம்மை பாதுகாக்க
18. இருதல் பாதுகாக்க
19. முன்னைய பாதுகாக்க
20. கலக்கு பாதுகாக்க
21. நேர்கல் பாதுகாக்க

இந்த கலந்துசெல்வு முறை வரும் 10 முறை குறுகிப்பிட்டுணரும். 

1. இ.பெண் பாதுகாக்க
2. அம்மை பாதுகாக்க
3. அம்மை பாதுகாக்க
4. இந்த பாதுகாக்க
5. இ.சோன் பாதுகாக்க
6. அர்த்தம் பாதுகாக்க
7. வரம் பாதுகாக்க
8. சுருக்கத்திய பாதுகாக்க
9. உத்தரம் பாதுகாக்க
10. ஐ.சோன் பாதுகாக்க

லசையும் பாதுகாக்கும் மலர்வாய்ப்புகளை முதல் அடுத்தவை பாதுகாக்கும் முறையில் அடுத்தவை

1. வெள்ளி பாதுகாக்க
2. இ.அம்மை பாதுகாக்க
3. இ.சோன் பாதுகாக்க
4. இ.அம்மை பாதுகாக்க
5. இ.சோன் பாதுகாக்க
6. இ.அம்மை பாதுகாக்க
7. இ.சோன் பாதுகாக்க
8. இ.அம்மை பாதுகாக்க

குறுகிப்பிட்டுணரும் முறையிலிருந்து 21 முறை குறுகிப்பிட்டுணரும்.
1. நெறிவாச் மாற்றம்
2. பொி மாற்றம்
3. அர் மாற்றம்
4. விசு மாற்றம்
5. அரு மாற்றம்
6. சாட் மாற்றம்
7. புரி மாற்றம்
8. கைலோ மாற்றம்

மூன்று குவி நாளில் மாற்றம் 13 வருடத்தில் புதிதகம்பிரிந்தது.

(தாய் புரி மாற்றத்து)

"தாய் புரி மாற்றத்து பிற்கும் தொடர்ந்து சில கமலம் மாற்றம்
வாராய்பாணத்கை மாற்றம் வரி மாற்றம் பிரிவு மாற்றம்
சுற்று மாற்றம் மாற்றம் வலிய மாற்றம் வளடை மாற்றம் பிள்ளை
நாயகிய் மிதவாகம் வள்ளி லண் அருகில் பறுபறு பன்னாடாலே"
Definition:
Indigested food in the stomach causes abdominal distension and manifests as Mantha Noi with vomiting and diarrhoea.

The above verse states that Mantham occurs in children due to the diet taken by the mother and the child, which causes indigestion and other related diseases. According to the Pilai Pini Maruthuvan text, Mantham occurs from the age of 3 months to 12 years in children particularly while child having breast milk (Exclusive Breast Feeding). Then weaning period during which both milk and solid foods were given and later stage where the child given solid foods (late weaning period).

During the period of exclusive breast feeding if the mother takes food which is not digestable in large amounts. The child becomes affected by Mantham Noi due to the intake of mother’s devitalized milk. The psychological feelings of the mother also affects the quality of milk given to the child.
During the weaning period, due to the diet taken by both the mother and the child, causes Mantha Noi. The psychosomatic feelings of mother like hunger, poverty, anger, fear, desire affects the efficacy of the milk fed to the child in this period.

During the late weaning period, the disease occurs mainly due to the improper food habits of children like taking not easily digestable foods, taking cleanless foods, taking irregular meal and taking imbalanced diet. Malnourished children are also affected by Mantham.

In Pillai Pini Maruthuvam part 2 (Types 43)

1. Adai Mantham
2. Atcha Akkara Mantham
3. Azhal Mantham
4. Allu Mantham
5. Eluppu Mantham
6. Uppal Mantham
7. Uppu Mantham
8. Ulai Mnatham
9. Oothu Mantham
10. Eri Mantham
11. Iya Mantham
12. Kattu Mantham
13. Kana Mantham
14. Karppa Mantham
15. Kanai Mantham
16. Kal Mantham
17. Kazhi Mantham
18. Sakthi Mantham
19. Sanni Mantham
20. Sanni Bhatha Mantham
21. Sura Mantham
22. Suzhi Mantham
23. Seriya Mantham
24. Thalai Mantham
25. Thittu Mantham
26. Neer kana Mantham
27. Thulai Mantham
28. Neer Mantham
29. Pal Mantham
30. Pul Mantham
31. Bethi Mantham
32. Pei Mantham
33. Por Mantham
34. Maladi Mantham
35. Mukku Mantham
36. Valippu Mantham
37. Vali Mantham
38. Varatchi Mantham
39. Vanthi Mantham
40. Val Mantham
41. Vida Mantham
42. Thoda Mantham
43. Veekka Manthamare described.

43 மாதாள் மானுடன் விற்பாண்டகங்கள் காட்சிப்படுத்துகிறது.

பிரிவான 10 மானுடன் போன்றவை மூன்று காட்சிப்படுத்தப்படுகின்றது.

அமைவிட முக்கியமானது மானுடன் விற்பாண்டகங்கள்:

✦ குருக்காளி ஒளி மூடிய செப்புக்கள்
✦ புற்றுக்கள் செய்யப்படும் செப்புக்கள்
✦ கிராமத்தில் விவசாயம் செய்யப்படும் செப்புக்கள்
✦ குருக்காளி செய்து விளங்கும் செप்புக்களை
✦ புற்றுக்களை போர்ட் மாதாளும் துளிய காட்சிகள்
• நூற்றன்று மாண்கள் வருகின்றது
• அமைக்கும் மாந்திர ஊர்கள்
• புனித மீது கடல்
• மேற்கு முழுமை ஆடல்
• குழுமம் பண்பாடுகள், வருடமான மாந்திர தொடர்வு, லலஸ்கர் மாந்திர மாந்திர பண்பாடுகளை
• என்று காண்பது குறிப்பிட்டால் தொடர்பு காணல்

கி.பி. போர்க்கு குறிப்பிட்டம்

"கவர்ந்த பண்பாடுகள் மாந்திரங்கள்
குறிப்பிட்டு பண்பாடுகளை செலவிக்கேற்கும்
முன் தொடக்க மறியுமல்
2. குறிப்பிட்டு பண்பாடுகளை
முன்னோடு பண்பாடுகளை தொடங்கும்
தொடர் வருடங்கள் பின்னர்
மறுவாது பின்னர்
குறிப்பிட்டு பண்பாடுகளை" 

-பொர்க்கு

குறிப்பிட்டம்

1. முன் வரும் குறிப்பிட்டம்
2. குறிப்பிட்டு பண்பாடுகளை
3. பின்னர் வரும்
4. குறிப்பிட்டம்
5. உடலின்
6. குறிப்பிட்டம்
A. Vali:

Site of vadham in body: திகழ்வு வாக்கில்

Abaanan, faces idakalai, below the umblical region, spermatic cord, pelvic bones, skin, nerve plexus, joints, hair follicle, muscle, alimentary tract, bones, ear and thighs.

விளக்கம்:

"அதிகீனம் வாக் பாதி மலர்நிலை" - கிருஷ்ணன்

"நீர்கதைக் வாக்கில் கிளையிலடை நடனம்

நாமிக் சிலைகள் நீர்வை அனையம்" - புரி போன்றை.

விலைநோக்கம் பலசம், நான்கு கிருட்டும் வாக்கிலகையாக்கல் மற்றும் வரகான வாக்காக

பாக்கித்தலத்தை ஆண்டுகள் (படை 139)
Vadham consists of 10 types

1. Praanan: (Uyirkaal)
   This controls knowledge, mind and five sense organs, which are useful for breathing and digestion.

2. Abaaban: (Keezh nokkung kaal)
   This is responsible for all down ward movement such as passing urine, stools, semen, and menstrual flow. Abaanan vayu is affected in Kattu mantham due to constipation.

3. Samaanan: (Nadukkaal)
   This aids in proper digestion and controls other vayus. In Kattu mantham, this vayu is altered leading to poor appetite and cannot control the other vayus.

4. Viyaanan: (Paravukaal)
   This is responsible for all movements of all parts of the body and distribution of saaram. This vayu is affected in Kattu mantham because of decreased activity due to symptoms like constipation.

5. Uthaanan: (Mel Nokkung kaal)
   Responsible for all upward movements such as vomiting and nausea. It distributes the saaram equally to all tissues. It is affected in Kattu mantham because unequal distribution of saaram and presence of cough.

6. Naagan:
   Responsible for opening and closure of eye lids.

7. Koorman:
   Responsible for vision and yawning.

8. Kirukaran:
   This is responsible for salivation, nasal secretion, sneeze, cough and maintains the appetite. In Kattu mantham, this vayu is affected due to presence of cough and poor appetite.

9. Devathatthan:
   This is responsible for tiredness (Lazziness), anger and emotional expression. This vayu is deranged in Kattu mantham because some patient had tiredness.

10. Dhananjeyan:
    It produces swelling of the body after death. It escapes on the third day after death bursting out of the cranium.

The above information is from the text in page 142-149.
ii. Azhal:
Sites of pitham in body:
Pinkalai, praanavayu, urinary bladder, moolakkini, heart, head, umblical region, stomach, sweat, saliva, blood, saaram, eyes and skin.

“இயல்கீழ் பிரமல் வூடாம் குன்றாகத்தில்” - தைவலூர்

“வாரலூர் பிரமல் குன்றாகத்தில் ஏற்படும் வேளா

சுருக்கால் காண்கள், ரோஜ் காண்போல்” - புதுப்பிள்ளை

எல்லாமல்லாமல் பிரமல், காண்கள் தூற்றாம் பிரமல் குன்றாகத்தில்.

இதன் முக்கியத்துவம் காண்போல்(பகுதி.153)

Pitham consists of 5 types
1. Anal pitham:
   It promotes appetite and helps in digestion. In Kattu mantham, it as affected due to presence of poor appetite.

2. Ranjagam:
   It gives colour to the blood. In Kattu mantham, some children are anaemic.

3. Saadhagam:
   It is important for day today activities with the help of mind and brain.

4. Praasagam:
   It gives complexion to skin.

5. Aalosagam:
   It brightens eyes and responsible for clear vision.

iii. Iyam:
Sites of Kabam in body:
Kabam (or) kapham is located in sammana vayu suzhumunai, sperm, head, tongue, uvula, fat, bone marrow, blood, nose, chest, nerve, bone, brain, large intestine, eyes, and joints and also present in throat, stomach and pancreas.

- இயல் முக்கியத்துவம் காண்போல் (பகுதி.155-157)

- இயல் முக்கியத்துவம் காண்போல் (பகுதி.158)
Kabam consists of five types

1. Avalambagam:
   It lies in the lungs. It controls the heart and other four kabams. In Kattu mantham, it is deranged due to presence of cough.

2. Kilethagam:
   It lies in the stomach and gives moisture to food material and also helps for digestion. In this disease, it is affected because of the poor appetite present in children.

3. Pothagam:
   It lies in tongue and responsible for taste sensation.

4. Tharpagam:
   It is present in the head and responsible for coolness of both eyes.

5. Santheegam:
   It is present in joints. Responsible for lubrication and free movements of joints.

PINIYARI MURAIMAI: (DIAGNOSIS)

Piniyari muraimai is a method of diagnosing a disease. The way of diagnosis is very important to the physician who deal the disease, because of that only he or she can pont out the cause of disease.

Siddha system has a very unique method for diagnosis. This is based upon three principles.

1. Poriyaal arithal (Inspection)
2. Pulanaal arithal (Palpation)
3. Vinaathal (Interrogation)
I. Poriyaal arithal:

Porigal means the five sense organs. These are eyes, ears, nose, tongue and skin. Poriyaal arithal is examining the five sense organs of the patient by the five sense organs of the physician.

In kattu mantham,

<table>
<thead>
<tr>
<th>Sense Organ</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mei (skin)</td>
<td>Normal</td>
</tr>
<tr>
<td>Vaai (Tongue)</td>
<td>Normal</td>
</tr>
<tr>
<td>Kann (Eye)</td>
<td>Normal</td>
</tr>
<tr>
<td>Mookku (Nose)</td>
<td>Normal</td>
</tr>
<tr>
<td>Sevi (Ear)</td>
<td>Normal</td>
</tr>
</tbody>
</table>

II. Pulanaal arithal:

Pulan means sense of perception from the five sense organs. That means understanding by the sense objects.

In Kattumantham,

<table>
<thead>
<tr>
<th>Sense Organ</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ooru (sensation)</td>
<td>Normal</td>
</tr>
<tr>
<td>Oosai (sound)</td>
<td>Normal</td>
</tr>
<tr>
<td>Oli (vision)</td>
<td>Normal</td>
</tr>
<tr>
<td>Suvai (Taste)</td>
<td>Normal</td>
</tr>
<tr>
<td>Naatram (smell)</td>
<td>Normal</td>
</tr>
</tbody>
</table>

III. Vinaathal:

Vinaathal means the physician should know about the patient's name, age, occupation, family history, socio-economic status, diet and habits, complaints, relevant to disease in the family by asking questions.

Ezhu udar kattugal and Ennvagai thervugal also used for diagnosing a disease in Siddha system

Ezhu udar kattugal:

1. Saaram
2. Senneer
3. Oonn
4. Kozhuppu
5. Enbu
6. Moolai
7. Sukkilam/suronitham

When the seven udar kattugal increase or decrease from the normal level, the normal functions of the body will be affected.

**In kattu mantham.**

a. Saaram : Deranged due to poor appetite causing tiredness.
b. Senneer : Deranged in some patient with nutritional anaemia.
c. Oonn : Normal
d. Kozhuppu : Normal
e. Enbu : Normal
f. Moolai : Normal.
g. Sukkilam/ Suronitham : Normal

The diagnostic value of Enn vagai thervugal is specific to siddha system of medicine.

**Enn vagai thervugal are:**

1. Naadi (Uyir thathu)
2. Sparisam (Touch feel sensation)
3. Naa (Tongue)
4. Niram (Colour of the skin)
5. Mozhi (Quality and character of speech)
6. Vizhi (Eye)
7. Malam (Stools)
8. Moothiram (Urine)
Naadi (Uyir thathu) :

Envagai ther vugal is the basic diagnostic principles and the uniqueness of the siddha system of medicine. The following lines are said about this.

"நாதி வாய்வியல் கத்தையுடைய
தாரையல் தலமையுடைய"

-தஞ்ச வருந்தக்கலன் கலவைன (ப.சோல.483)

Otherwise known as uyir thathu, is the principle method for diagnosis in siddha system. The naadi indicates the status of the body thathus and whether the body is normal or abnormal. It is responsible for existence of life in the physical body. It is said in literatures as  நாதி வாய்வியல் கத்தையுடைய காரணமல்லாமல் மனித மனித உணர்ச்சி "நாதி வாய்வியல் கத்தையுடைய"

"நாதி வாய்வியல் கத்தையுடைய
தாரையல் தலமையல் பெருக்கியுடைய"

- கொலம் கொலம் (கலவைன் 270)

In childrens the naadi nadai is not clearly seen. This is indicated by following lines,

"நாதி வாய்வியல் கத்தையுடைய
தாரையல் தலமையல் பெருக்கியுடைய காரணமல்லாமல் மனித உணர்ச்சி
நாதி வாய்வியல் கத்தையுடைய
தாரையல் தலமையல் பெருக்கியுடைய"

- கொலம் (கலவைன் 171).

b) Sparisam: (Touch feel sensation)

Identify the heat or coldness of the body, pain and skin nature (soft or hard)

In kattu mantham,

- It may be hot due to fever.
- It may be cold due to sweating.
c) **Naa: (Tongue)**

It is noted for colour of the tongue local lesion (ulceration, redness), coating deposition of tongue and dryness of the tongue.

d) **Niram: (Colour of skin)**

Colour of skin, conjunctiva, teeth, tongue, nail bud and hair are note. In Kattu mantham, Conjunctiva, nail bud may be pale due to nutritional anaemia.

e) **Mozhi : (Quality and character of speech)**

Observation of speech and voice. This is said in Agasthiar vallathi as

“அக்ஸ்டியுர் வலலுதார் மூழ்கும்”

In Kattu mantham normal voice is present.

f) **Vizhi : (Eye)**

By this examination, colour of eye (redness, pallor) protrusion, tears, excreta of eye, disease of eyes are noted.

In Kattu mantham, the eyes of Some patients have pallor of lower eyelid due to nutritional anaemia.

g) **Malam : (stools)**

Consistency of stool will be like hard pellets like, foul smell, decreased frequency of defeacation, constipation, lesser quantity of stool are noted.

In Kattu mantham, patient have hard pellets like stools and decreased frequency of passing stools.

h) **Moothiram : (Urine)**

Colour of urine (yellow, black, white copper colour, mixed colour. Then smell of urine (smell of fire, honey, sweet odours, fruity odour) frothy or not, decreasesd frequency of urination and quantity of urine are noted.

In Kattu mantham, there will be normal straw yellow colour of urine with decreased frequency of urine.
Neer nira kuri and Nei kuri:

This urine examination is unique in Siddha system of Medicine

Collection of sample urine:-

The patient must take well cooked food in the previous day. Food intake should be taken at correct time and avoid excessive intake. The urine is collected on the dawn of the next day in a pure glass container and closed immediately to prevent contamination. This specimen must be examined with in one and half hours from the collection.

A drop of gingelly oil is dropped on a wide glass vessel containing the urine to be tested which is kept under sunlight in a calm place. The derangement of three dhoshas can be diagnosed by the mode of spread of gingelly oil on the surface of urine.

In Kattumantham the results of nei kuri is snake like oil floating on urine in some patients and ring like structure on urine in some patients.
MARUTHUVAAM:

The treatment in siddha medicine is aimed at keeping the Mukkutram in the state of equilibrium.

i.e,

- Highly vitiated vatham to normal level
- Vitiated pitham to normal level
- Vitiated kabam due to vitiated vatham to normal level.
- To strengthen the seven udar kattugal and maintains the normal level.

Keeping in mind the need for bringing out an effective therapy for Kattu mantham with the Seenthil kudineer.

**Line of treatment:**

Siddha treatment is not only for to cure the disease but also teaches prevention and rejuvenation concepts.

Saint Thiruvalluvar says about the duty of a physician as follows

```
“தூய்மயங்க் தூய்மயங்கு நான் பின்னன் குறிக்கதை
நான் பின்னன் குறிக்கதை”– சோககுகள்
```

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“இருக்கார் நான் இருக்கார் நான் நான் கிளிக்கினை
கிளிக்கினை கிளிக்கினை”– சோககுகள்.
```

From the above verse, it is essential to know the etiology, the nature of patients, severity of the illness, the seasons and the time of occurrence the disease must be observed clearly.

**Line of treatment is as follows:**

1. Kaappu (prevention)
2. Neekkam (Treatment)
3. Niraivu (Restoration)
1. Kaappu: (prevention)

Prevention is the main aim of siddha system. Siddhars have described general preventive measures and special measures.

Especially in Balavagadam, special preventive measures said for prevention of disease of the child. It starts from the conception and goes on the child grows up in intrauterine life and after delivery, ie diet of pregnant women, her habits, medicine to take in every month of pregnancy, her psychological conditions and surroundings.

2. Neekkam: (Treatment)

The aim of treatment is based on

- To bring the three thodams into normal equilibrium state.
- To treat the patients according to the symptoms by internal medicine Seenthil kudineer

i. Anupanam in Siddha system:

“அனுபனம் வகித்து பதில் மாற்றம்,
நிலையம் செய்ய கண்டல் தூரமும் – மிகுயும்
பொருளின் மறு பாதுகாப்பு செலுத்து வழியில் பார்வையால் மேலும்
அமைத்து மாற்றம்ச்சலம்”

- தேவராஜ தேவராஜ

Siddha system considers anupanam as an important. It is otherwise known as “Thunai marunthu”, it can be translated as vehicle, adjuvant and supporting to drug therapy. Without anupanam, success in the treatment is mostly not possible.

ii. Pathiyam:

During the course of treatment, the patients were advised to follow certain restrictions regarding diet and physical activities.

This type of medical advice termed as pathiyam. Importance of pathiyam is said by Siddhars Theraiyar as follows,
The patient with Kattu mantham is advised to avoid spicy and hot food, contaminated water, junk foods.

3. Niraivu: (Restoration)

- Reassurance of disease recovery was given to all patients.
- All the patients are advised to prepare for lifestyle changes that provides a disease free life.

Diet:

Siddhars advise the diet regimens for Kattu mantham patients. They are explained below:

"கத்து மான்றத் தவறு போன்றவற்றை பிட்டமையான காத்தவை
அறிந்த காத்தவை மத்தியக்கட்டுருமுறை காத்தவை பிட்டத்துறை
மான்றத் தவறு போன்றவற்றை பிட்டமையான காத்தவை
அறிந்த போன்றவற்றை பிட்டமையான காத்தவை பிட்டத்துறை.

- புராணத்தில் காத்தவை விளக்கம்.

"இதிகாசம் கொலைஏற்றவர்கள் போராட்டக் காத்தவை
பிட்டமையான தவறு போன்றவற்றை - புராணப்
உருவத்தை காத்தவை போன்றவற்றை பிட்டமையான பிட்டத்துறை
பிட்டமையான பிட்டத்துறை.

- புராணத்தில் காத்தவை விளக்கம்.
கல்பக்கிளக்கு:-

• குக்கிகி
• பும்புமூல
• கோசை
• கன்மன்றகுக்கிகிகி
• குக்கிக்காம்ப
• பிறகுக
• மாயைப்புக்கசை
• புருணைந்தக
• பாகை
• புகைக்கி

இன்னால்கி பார்வுககால்:-

• புகைக்கி பார்வுக
• பார்வுககிகி

குரஞ்சுகா:-

• மாயைப்புக்கசைகா
• குமக்காப்பாலை
• பாகை
• புருணைந்தக
• புகைக்கிகி பார்வுக
• பகுக்கை காலனவுன்றதாலை சகாலை தேர்வுக்கு புகைக்கிகி பார்வுககா.
MODERN ASPECTS

GASTROINTESTINAL TRACT:

The GI tract is the pathway where food passes from the mouth, through the esophagus, stomach, small and large intestine within where the nutrients are extracted for the needs of the body. The residue then passes to the rectum where it is evacuated.

ANATOMY OF THE GASTROINTESTINAL TRACT:

1. The Esophagus:

The first part of the pathway of GIT is the esophagus, which guides food from the mouth, where it is prepared by chewing, down to the stomach where it is stored.

2. The Stomach:

The stomach is both a storage space, holding as much as a quart and a half of ingested food, and a secretory organ that produces the gastric acid necessary for digestion. However, the stomach does not absorb food. When food enters the stomach from the esophagus it remains for a short period while it is mixed with gastric acid. The stomach then by involuntary muscle contractions (peristalsis) empties the food gradually into the duodenum, the first part of the small intestine.

3. The small Intestine:

The small intestine consists of three parts: the duodenum, the jejunum and the ileum. In these three parts, certain digestive secretions are mixed with food, and the nutrients are absorbed into the blood stream.
The Duodenum:

The duodenum treats the food it receives with bile from the liver and enzymes from the pancreas. It also adds liquid duodenal fluid that comes from the wall of the duodenum itself. The food, bile, enzymes and liquids brought together in the duodenum are then passed into the jejunum.

II. The Jejunum:

The jejunum or second portion of the small intestine is approximately 10 feet long. It lies immediately behind the duodenum and continues the process of digestion, breaking down food into essential elements.

III. The Ileum:

The ileum or third portion of the small intestine, like the jejunum, is about 10 feet long. It is here that a major part of the absorption of food products and liquids occurs. Waste products of the digestive process are passed from the small intestine or terminal ileum, into the large intestine, also known as the colon.

4. Large Intestine (colon):

The colon moves waste products through about four feet by the continuing process of undulating motions or peristalsis, which is common to all parts of the gastrointestinal tract. The primary function of the colon is to store waste products of digestion prior to evacuation. The colon absorbs small amounts of water and electrolytes.

COMMON GASTROINTESTINAL TRACT DISORDER:

Functional gastrointestinal disorders are common in children. Our brain and our GI tracts are closely connected (the “mind-body connection”). Functional GI conditions are due to a combination of extra sensitivity of the GI tract, with changes in the motility or movement of the digestive system.

Functional gastrointestinal disorders is specifically manifested as abdomen pain, vomiting, early satity, abdominal distention, constipation.
FUNCTIONAL DYSPAESSIA

Definition

Functional dyspepsia is defined as persistant or recurrent pain or discomfort centered in the abdomen, without evidence of organic disease. It is a functional disease in which the gastrointestinal organ primarily the oesophagus, stomach, small intestine & colon function abnormally. The primary symptom of dyspepsia are upper abdominal pain, abdominal bloating, early satiety and these symptoms are most often provoked by eating.

Description

A functional GI disorder refers to a condition where the primary abnormality is an alteration in the way the body works (altered function), rather than an identifiable structural or biochemical cause. Gastrointestinal motility is defined by the movements of the digestive system, and the transit of the contents within it. When nerves or muscles in any portion of the digestive tract do not function normally, symptoms only persist. The disturbed motility present in functional dyspepsia leads to amplified sensation in the upper gut (visceral hyperalgesia).

Causes:

- Some foods like potatoes, chickpeas and other legumes, lentils, foods with lots of spices and oils donot get properly digested within body, they can cause dyspepsia
- Some psychological causes like child with temper trandum who donot take food wholeheartedly.
- Microorganisms that live within the lining of stomach can cause irritation which can interfere with the digestion process

Symptoms

Functional Dyspepsia is due to uncoordinated and uneven emptying of the upper digestive tract, The vast majority of patients experience more than one symptom.

- Pain in belly
- Fullness and bloating of abdomen
- An inability to finish meals
- Heartburn,
- sour taste in the mouth,
- Excessive burping, nausea,
- Sometimes vomiting.
- Characteristically, these complaints are sporadic, poorly localized, and without consistent aggravating or relieving factors,
- Constipation and various foods or additives in the diet can worsen functional pain.

**PATHOPHYSIOLOGY**

Functional dyspepsia is usually defined as chronic or intermittent upper abdominal symptoms for which no organic cause can be found. Division of functional dyspepsia into subgroups such as reflux-like, ulcer-like, dysmotility-like and non-specific dyspepsia has been proposed, but lack a scientific basis.

The major pathophysiological mechanism responsible for functional dyspepsia include psychosocial factors and alteration in motility and visceral sensation. Approximately 50% of patients with functional dyspepsia have motor disorders, such as impaired fundic relaxation, antral dilation and hypomotility.

Patients typically present with gastric hypersensitivity resulting from abnormal afferent function. The role of helicobacter pylori in functional dyspepsia is difficult to define. Impaired gastric and intestinal reflexes have also been observed in functional dyspepsia. In recent years other avenues of pathophysiology are also showing some interest in functional dyspepsia. Although both evidence are not sufficient to a significant genetic contribution to functional dyspepsia. Some evidence suggest an interaction between polymorphisms of genes responsible for components of the immune response and Helicobacter pylori infection among some patients with functional dyspepsia.

**DIAGNOSTIC TESTS**

There are no specific diagnostic markers for functional dyspepsia. As with many other conditions, a thorough and detailed history taken by a physician is the most important component of the assessment and often leads to the correct diagnosis. The history needs to include dietary, psychological, and social factors.

A history may disclose a relationship between symptoms and food, activity, or stressors. It is often helpful for the child and parents to maintain a symptom diary detailing the time, location, intensity and character of the pain or discomfort, time and content of the meals, daily activities, and stool pattern.
Considerable diversity of opinion remains among physicians regarding the extent of diagnostic tests to perform in a child who seems to have a symptom constellation pointing towards a functional cause of the dyspepsia.

- The diagnostic procedure needs to be individualized, according to the information obtained during the history taking and the physical examination. An upper gastrointestinal endoscopy is not mandatory.
- Urine evaluation and blood evaluation to screen for other disease are usually necessary.
- Endoscopy allows the discovery of ulcerations or significant inflammation in the upper gastrointestinal tract.
- If the endoscopy is normal, then it may be helpful to monitor for acid reflux (back flow of stomach contents into the esophagus).
- Abdominal ultrasonography does not appear to be helpful in children.
- Upper gastrointestinal x-rays with small bowel follow-through are useful to exclude physical causes such as malrotation [incorrect position of the intestine in the abdomen], terminal ileitis [Crohn’s Disease], and other obstructive or inflammatory lesions.
- Gastro duodenal manometry is a feasible and useful diagnostic tool in the clinical investigation of children.

**TREATMENT**:

The management of dyspepsia revolves around a structural or functional cause. If a structural cause is found, the treatment can be specific to the underlying cause. For functional dyspepsia, the aim is to provide symptomatic relief.

- Reduction or avoidance of spicy, fatty, or caffeine-containing food or drink may help if associated with symptom onset.
- Medications such as H2-blockers [reduce amount of acid produced in the stomach], proton pump inhibitors [limit amount of acid produced]
- Prokinetic agents such as metoclopramide, domperidone, cisapride or erythromycin [increase gastrointestinal motility], have been used with some success.
- There remains a proportion of children who may have a behavioral or psychological base to their complaint. For them, treatments such as
- Environmental modification,
- Relaxation techniques,
Psychotherapy,
Stress reduction,
Hypnotherapy, or biofeedback have been used with variable success.

PROGNOSIS
Functional dyspepsia may come and go and symptoms could present with increased severity for several weeks or months and then decrease or disappear entirely for some time.

PREVENTION
- To avoid or reduce heavy foods like cheese, yogurt, ice cream, peanut butter and bananas. Heavy foods overload the digestive system and cause problems like digestion, constipation, congestion and allergies.
- As much as possible children should eat real food, not highly-processed food with lots of additives.
- Sodas and high-fructose corn syrup can harm digestion. Many children don’t tolerate dairy, gluten or food additives.

DIFFERENTIAL DIAGNOSIS
Other disorders can have symptoms that may be similar to or overlap with gastrointestinal functional or motility disorders in children. Significantly, these disorders have features that a doctor can identify, which distinguish them from functional gastrointestinal or motility disorders.

1. Hirschsprung’s Disease

Definition
Children with Hirschsprung’s disease are missing the nerve cells (ganglion cells) within the wall of their colon or rectum. These cells are responsible for the normal wave-like motion of the bowel (peristalsis). When they are missing the stool stops and an obstruction occurs. The length of affected bowel varies. The most common transition point is in the upper rectum or the sigmoid colon.

Hirschsprung’s disease is a congenital disease. That means a person is born with it. The disease may also be hereditary, which means a parent can pass it to a child.
Symptoms

Symptoms usually begin within a few days after birth. But some people don't develop them until childhood or even adulthood.

In infants, the primary symptom is not passing meconium, an infant's first bowel movement, within the first 24 to 48 hours of life. Other symptoms include:

- Vomiting and abdominal distention as a newborn
- Chronic constipation
- More rarely diarrhea, fever, and distention (symptoms associated with enterocolitis – inflammation of the small intestine and colon).

Symptoms in older children include passing small watery stools, diarrhea, and a lack of appetite.

Diagnosis

The diagnosis is made by a combination of barium x-rays and rectal biopsy. In a lower GI series, x-rays are used to measure the width of the colon and rectum. Rectal biopsy involves removing a piece of rectal tissue to learn whether the nerve cells that control intestinal muscle contractions are present. Rectal manometry, a test that involves recording pressure changes within the colon and rectum, is sometimes performed.

Treatment

The treatment of Hirschsprung's disease is primarily surgical. The goal of surgery is to remove the abnormal bowel and attach the normal bowel to the anus just above the sphincter.

Irritable bowel syndrome

Definition

Irritable bowel syndrome is a disturbance of bowel function that includes symptoms of abdominal pain or discomfort and altered bowel habit (change in frequency or consistency) – chronic or recurrent diarrhea, constipation, or both in alternation. IBS comprises a group of functional bowel disorders.

"Irritable Bowel" refers to a disturbance in the regulation of bowel function that results in unusual nerve sensitivity and muscle activity.
Symptoms

The symptoms of IBS include abdominal pain or discomfort and changes in bowel habits. To meet the definition of IBS, the pain or discomfort should be associated with two of the following three symptoms:

- Start with bowel movements that occur more or less often than usual
- Start with stool that appears looser and more watery or harder and more lumpy than usual
- Improve with a bowel movement

Symptoms may often occur after eating a meal. To meet the definition of IBS, symptoms must occur at least once per week for at least 2 months.
DRUG REVIEW

1. CHUKKU - குரு

Botanical Name : Zingiber officinale
English Name : Dried Ginger
Family : Zingiberaceae
Part used : Rhizome

ORGANOLEPTIC CHARACTER

Suvai : Karppu
Thanmai : Veppam
Pirivu : Kaarppu

“காரிப்புத்துறைநிலை மரியாதைப் பயன்படுத்தல்
துணை விளையாட்டு பாதுகாப்பு - மலரை
துணை மருத்துவ பாதுகாப்பு வல்லுனர்
துணை இலட்சுமைக்கு குரு”

(Antimicrobial Antioxidant)

ACTIONS:

- Stimulant
- Carminative
- Stomachic

CHEMICAL CONSTITUENTS:

- Camphene
- Phellandrene
- Zingiberine
- Cineol and Borneol
- Gingerol
- An Oleoresin-Gingerin
- Resins and starch
- β-Sesquiphellandrene
- Gingerdiols, Gingerdiacetates.

*Ref: Indian Herbal Pharmacopoeia*

**Articles on Zingiber officinale:**

*Zingiber officinale* natural gold:

It is consumed worldwide as a spice and flavoring agent and is attributed to have many medicinal properties. The British Herbal Compendium reported its action as carminative, anti-emetic, spasmolytic, peripheral circulatory stimulant and anti-inflammatory. The oil of ginger is a mixture of constituents, consisting of monoterpenes (phellandrene, camphene, cineole, citral, and borneol) and sesquiterpenes (zingiberene, zingiberol, zingiberenol, β-bisabolene, sesquiphellandrene, and others). Aldehydes and alcohols are also present.

**Effect on gastrointestinal tract:** Some active components of ginger are reported to stimulate digestion, absorption, relieve constipation and flatulence by increasing muscular activity in the digestive tract. It is also significantly reduced the nausea and vomiting.

*International Journal of Pharma and Bio Sciences*


**Overview of pharmacodynamic data regarding the herbal substance(s)/preparation(s) including data on relevant constituents Gastrointestinal motility:**

Gastrointestinal motility of *zingiber officinalis* in a placebo-controlled, double-blind, cross-over study in 12 male volunteers, Micklefield et al. [1999] reported that inter-digestive antral motility of the stomach during phase III of the migrating motor complex and the motor response to a test meal in the corpus measured by stationary manometry were stimulated by ginger (200 mg of ginger rhizome extract) in both the fasting and postprandial states. However, a randomised, placebo-controlled, cross-over study by Phillips et al. [1993] did not observe an impact on gastric emptying rate in 16 healthy volunteers using the oral paracetamol absorption technique (without an accompanying nutrient load) after 1 g (2 capsules) of powdered ginger, suggesting that ginger, although increasing motility, may not affect the gastric emptying rate.

2. KADUKUROHINI - கோதுகுரோகினி

**Botanical Name**: Picorrhiza scrophulariflora  
**English Name**: Black Hellebore  
**Family**: Scrophulariaceae  
**Part used**: Root

**ORGANOLEPTIC CHARACTER**

- **Suvai**: Kaippu, karppu  
- **Thanmai**: Veppam  
- **Pirivu**: Karppu

**CHEMICAL CONSTITUENTS:**

- Iridoid glycosides,  
- Picroside I  
- Kutkoside

**Ref**: Indian Herbal Pharmacopoeia

**ACTIONS:**

- Cathartic  
- Antiperiodic  
- Anthelmentic
Articles on Picorrhiza kurroa:

International journal of pharmaceutical research and biopharmaceutical research

Bitter Glycoside of Picorrhiza

In general, bitters are the edible natural products mostly consumed before any normal meals to stimulate as well as enhance the appetite. However, the bitter glycosidase a class do possess almost similar activities like the bitters such as: digestive, stomachic and febrifuge. Therapeutically, the bitters have been found to exert their stimulant effects on the gustatory (i.e. related to the sense of taste) nerves located in the mouth and ultimately give rise to an improved gastric juice secretion in the stomach. The bitter glycosides have been found not confined to the same chemical class, but the most important ones amongst them essentially possess the pyran cyclopentane ring. A number of bitter glycosides isolated from natural plants have been put into actual therapeutic practice, namely: Picrorrhiza, Gentian and Chirata


3. KALIPAKKY—அற்குறுக்கு

<table>
<thead>
<tr>
<th>Botanical Name</th>
<th>Areca catechu</th>
</tr>
</thead>
<tbody>
<tr>
<td>English Name</td>
<td>Areca nut boiled tender</td>
</tr>
<tr>
<td>Family</td>
<td>Fabaeceae</td>
</tr>
<tr>
<td>Part used</td>
<td>Seeds</td>
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</table>

ORGANOLEPTIC CHARACTER

<table>
<thead>
<tr>
<th>Suvai</th>
<th>Thuvarpu</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thanma</td>
<td>Veppam</td>
</tr>
<tr>
<td>Pirivu</td>
<td>Karppu</td>
</tr>
</tbody>
</table>
CHEMICAL CONSTITUENTS:

- Tannins
- Catechin
- Catechu tannic acid
- Flavonoids
- Flavonols-quercitrin
- Quercitin

Ref: Indian Herbal Pharmacopoeia

ACTIONS

- Astringent
- Stimulant

Articles on Areca catechu:

*Areca catechu: A comprehensive pharmacological Study:*

The main constituents of the areca nut are carbohydrate, fats, fibre, polyphenol including flavonoids and tannins, alkaloids and minerals (IARC, 2004). The fatty acid constituents of the A. catechu nut oil are; lauric 19.5, myristic 46.2, palmitic 12.7, stearic 1.6, decanoic 0.3, oleic 6.2, linoleic 5.4, dodecenoic 0.3, tetradecenoic 0.6 and hexadecenoic 7.2%. The chief component glycerides are 56% of fully saturated (trimyristin, dimyristins and lauromyristopalmitin); 30% monounsaturated disaturated (mainly hexadeceno-lauromyristins) and 14% of diunsaturated-monomosaturated (oleolinoleo-glycerides, mostly oleolinoleopalmitin).
Areca is used for treatment of a mental disorder called schizophrenia and an eye disorder called glaucoma; it is also as a mild stimulant; and as a digestive aid. Some people used areca as a recreational drug because it speeds up the central nervous system.

http://www.journalcra.com/article/areca-catechu-comprehensive pharmacological

4. SEENTHIL

Botanical Name : *Tinospora cordifolia*
English Name : Heart leaved moon seed, tinospora, Gulanchatinospora
Family : Menispermaceae
part used : Stem

ORGANOLEPTIC CHARACTER

Suvai : Kaippu
Thanmai : Veppam
Pirivu : Kaarppu

CHEMICAL CONSTITUENTS:

- Berberine
- Cordifolioside,
- Asesqueterpene,
- Choline tinosporicacid
- Cordioside

Ref: *Indian Herbal Pharmacopoeia*

ACTIONS:

- Stomachic
- Mild diuretic
- Antioxidant
- Antispasmodic
Articles on *Tinospora cordifolia*:

**Chemistry and medicinal properties of *Tinospora cordifolia* (guduchi):**

The stem of *Tinospora cordifolia* is one of the constituents of several ayurvedic preparations used in general debility, dyspepsia, fever and urinary diseases. The stem is bitter, stomachic, diuretic, stimulates bile secretion, causes constipation, allays thirst, burning sensation, vomiting, enriches the blood and cures jaundice. The extract of its stem is useful in skin diseases. The root and stem of *T. cordifolia* are prescribed in combination with other drugs as an anti-dote to snake bite and scorpion sting. Dry barks of *T. cordifolia* have anti-spasmodic, antipyretic, anti-allergic, anti-inflammatory and anti-leprotic properties.


5. **KATRALAI-காற்பற்பை:**

- **Botanical Name**: *Aloe barbadensis*
- **English Name**: Indian Aloe, Curacao aloe
- **Family**: Liliaceae
- **Part used**: Pulp, milk

**ORGANOLEPTIC CHARACTER**

- **Suvai**: Sirukaippu
- **Thanmai**: Thatppam
- **Pirivu**: Inipu

**CHEMICAL CONSTITUENTS:**

- Glycosides
- Anthracenederivative
- Hydroxyanthraquinonederivatives
- Aloin

*Ref: Indian Herbal Pharmacopoeia*

**ACTIONS:**

Purgative
**ARTICLES ON ALOE BARBADENSIS:**

**Evaluation of the Nutritional and Metabolic Effects of Aloe vera**

**Laxative**

*Aloe vera* latex is commonly used in the treatment of constipation (de Witte 1993). The laxative effect of the anthraquinone glycosides found in *Aloe vera* latex is well established (Ulbricht et al. 2008). In a double-blind, randomized, controlled trial of 28 healthy adults, aloin was reported to have a laxative effect compared to a placebo that was stronger than the stimulant laxative phenolphthalein (Chapman and Pittelli 1974). In subjects with chronic constipation, a novel preparation containing *Aloe vera*, celandine, and psyllium was found to improve a range of constipation indicators (bowel movement frequency, consistency of stools, and laxative dependence) in a 28-day double-blind trial; however, the effect of *Aloe vera* alone was not investigated in this study (Odes and Madar 1991).

*Herbal Medicine: Biomolecular and Clinical Aspects. 2nd edition*

http://www.ncbi.nlm.nih.gov/books/NBK92765/

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6. **KADUKAI- காடுகை**

| Botanical Name | : Terminalia chebula |
| English Name   | : Chebulin myrobalan |
| Family         | : Combretaceae      |
| Part used      | : Dried matured fruit. |
ORGANOLEPTIC CHARACTER

Suvaï : Sirukaippu
Thanmai : Thatpam
Pirivu : Inipu

CHEMICAL CONSTITUENTS:

- Tannin
- Gallic acid
- Chebulic acid

Ref: Indian Herbal Pharmacopoeia

ACTUALS:

- Laxative
- Purgative
- Alternative

Articles On Terminalia chebula:

Haritaki A Boon To Herbalism – A Review

Terminalia chebula (Haritaki) is one of the important herbal drug used for treating many diseases including some varieties of cancer. It is rich in chemical constituents. Many pharmacological investigations have been carried out based on its chemical constituents. It contains high phenolic content, especially hydrolyzable tannins, anthraquinone, flavonol, carbohydrates, glucose and sorbitol, chebulic acid, chebulinic acid, ellagic acid, gallic acid, chebulagic acid etc.

Scholars Academic Journal of Biosciences (SAJB)

Comparative laxative evaluation for andrographis paniculata and Terminalia chebula in experimental animal model

Main objective of this study was the Comparative laxative activity evaluation for A. Paniculata & T. chebula in experimental animal model. Our experiment showed that both the extracts of A. paniculata and T. chebula ability to increase the laxative activity in constipation condition. The property of the herbal extract was determined by in vivo, its effect on faecal output in rats and the results were shown when compared with standard drug Bisacodyl.


7. Sivathai - ஸிவாதை

Botanical Name : Operculina Turpethum
English Name : Turtheth root
Family : Convolvulaceae
Parts used : Root

ORGANOLEPTIC CHARACTER

Suvaï : Kaippu
Thanma : veppam
Pirivu : Karppu

பாரம் கலவம்

அமலிகைக்குறிக் கிலிக

“ஒருப்ப பலம்ப சிறுமிகுத் துப்புப்பித்திகங்கால்
பாம்பிச்சுவர் குருகுணிகள் கூறியன் - பிள்ளைகாலச்சு
பௌர்ண குருகுணிகள் குமில்ப் பள்ளிக்கூறு
துப்பில் கிளைதள்ளத்து குளி”

(அமலம்புல் குருகுணிகள்)
CHEMICAL CONSTITUENTS:
➢ Turpethin resin 4 to 10%,
➢ Glucoside,
➢ Turpethin

Ref: Indian Herbal Pharmacopoeia

ACTIONS:
➢ Purgative
➢ Immuno modulatory
➢ Anti oxidant

Articles on Operculina turpethum:

Non-opiodergic like mechanism for antinociceptive analgesic and antipyretic activity of ethanolic root extract of operculina turpethum in swiss albino mice

The root extract of Operculina turpethum has been used as an anti inflammatory, purgative, hepato-protective agent and antipyretic.

International Journal of Pharma and Bio Sciences


Thus Sivathai having anti-inflammatory and anti pyretic action is helpful in the treatment of Kattu mantham.
MATERIALS AND METHODS

Kattu Mantham is one of the common functional GIT disorder in children. In our NIS OPD, 3-5% of cases are approaching Kuzhandhai Maruthuvam department daily with the Symptoms of Kattu Mantham. Hence it was proposed to study about the disease. A Protocol was prepared and submitted before IEC of National Institute of Siddha. The IEC approval was obtained No:NIS/IEC/18-14/20-18-26-08-2014. The trial was registered in Clinical trial Registry of India with Reg.No.CTRI/2016/04/006818. After obtaining approval from the committee, the clinical study on Kattu mantham (Dyspepsia) in children with drug Seenthil kudineer and carried out as per the protocol.

In vitro Carminative activity were conducted in Satya bama university, Chennai and physico chemical activity studies of Seenthil kudineer were done at CRI, Arumbakkam.

After finishing the In vitro Carminative activity studies, 40 cases were selected from the OPD & IPD of Kuzhandhai Maruthuvam Department, National Institute of Siddha. They were treated with the trial drug with Seenthilkudineer and observed for prognosis clinically.

PREPARATION OF SEENTHIL KUDINEER:

COLLECTION OF RAW DRUGS

The required drugs were purchased from a reputed raw drug shop at kanda swamy kovil street paris.

AUTHENTICATION

Raw drugs were authenticated by the Medicinal Botanist in National Institute of Siddha, Chennai. The test drug Seenthil kudineer was prepared at Gunapadam lab, National Institute of Siddha, Chennai-47.

Purification Method:

- Chukku - To soak in chunnambu thelineer for 3 hours dried and to peel off outer skin
- Seenthil - To peel off the outer skin.
- Sivathai - To remove veins, boil in milk, dried it in sunlight
• Kadugurookini - To soak in neem leaves juice for three hours and dried it in sunlight.

• Kadukai - To remove inner seeds.

• Kalipakku - Soak in water and dried in sunlight.

• Katralai sarugu - Remove thornes and dried it in sunlight.

Sikicha Rathina Deepam

Preparation of the Seenthil kudineer:

Ingredients:

Tinospora cordifolia (seenthil thandu) - 4 grams

Araca catechu (kali pakku) - 4 grams

Operculina terpethum (sivathai) - 4 grams

Terminalia chebula (kadukkai) - 4 grams

Zingiber officinalis (sukku) - 4 grams

Picrorhiza scrophulariiflora (kadukurokini) - 4 grams

Aloe barbadence (katralai sarugu) - 4 grams

Ref : Balavagadam (pg 93)

Method of preparation:

Above mentioned drugs were purified by purification method mentioned below. All purified drugs are coarsely powdered and kept in a clean glass container.

Method of preparing Kudineer:

Above mentioned decoction powder (26 gms) was taken and mixed with 80 ml of water and boiled until one eigth of decoction.
**Dosage**: 10 ml b.i.d

**Drug Storage:**

Prepared medicine in coarse powder form will be stored in clean and dry container.

**Dispensing:**

Prepared medicine of 52 gms will be given as coarse powder form in separate air lock covers.

**PHYSICO CHEMICAL ANALYSIS**

The physicochemical analysis of the test drug Seenthil kudineer was carried out as per WHO guidelines (Anonymous 1998). The test procedures were done at Siddha Central Research Institute (CRI), Arumbakkam Chennai. Since the form of the drug is in powder the parameters such as Loss on Drying at 105°C, Total ash, Acid insoluble ash, Water soluble Extractive, Alcohol Soluble Extrative, pH was done using Quality control methods for medicinal plants materials.

**Loss on drying of the sample at 105°C**

4g of test drug was weighed in a previously weighed 100ml beaker and heated in an oven at 105°C for 5 hours. Cooled in a dessicator and weighed. Repeated the procedure till constant weight was obtained. The percentage loss in weight of the test drug was calculated by the following formula.

**Calculation:**

\[
\text{Percentage of loss on drying at 105°C} = \frac{\text{Loss in weight of test drug}}{\text{Weight of test drug taken}} \times 100
\]

**Ash content**

a. **Total ash content**

4g of test drug was weighed accurately in a previously ignited and tared silica dish. The material was evenly spread and ignited in a muffle furnace at 600°C until it became white indicating the absence of carbon. The dish was cooled in a dessicator and weighed. As carbon free ash cannot be obtained in this manner, the dish was cooled and the residue
moistened with sufficient quantity of water. Dried on a water bath and then ignited in the electric furnace to get the constant weight. Cooled the dish in a dessicator and then weighed. The percentage of total ash of air-dried materials was calculated as per the formula given below.

**Calculation:**

\[
\text{Percentage of total ash} = \frac{\text{Weight of the ash}}{\text{Weight of test drug taken}} \times 100
\]

b. **Acid-insoluble ash**

The total ash of the test drug was found out as described above. To the dish containing the total ash was added 45 ml of 1: 5 hydrochloric acid in three portions of 13 ml each time. Boiled gently for 5 minutes and filtered. Collected the insoluble matter on an ashless filter paper (Whatman No.41) and washed with distilled water until the residue was free from acid. Transferred the filter paper containing the insoluble mater to the original dish. Dried and ignited to the constant weight. Cooled the dish in a dessicator, and then weighed. Calculated the percentage of acid-insoluble of the air-dried material by the given following formula.

**Calculation:**

\[
\text{Percentage of acid-insoluble ash} = \frac{\text{Weight of the acid-insoluble residue}}{\text{Weight of test drug taken}} \times 100
\]

**Extractive of the test drug**

a. **Water-soluble extractive of the test drug**

4 g of the test drug was weighed accurately in a glass stoppered flask. Added 100 ml of distilled water and shakened occasionally for 6 hours and then allowed to stand for 18 hours. Filtered rapidly taking care not to lose any solvent and pipetted out 25 ml of the filtrate in a preweighed 100 ml beaker and evaporated to dryness on a water bath. Kept in an air oven at 105°C for 6 hours. Cooled in a dessicator and weighed. Repeated the experiment twice, and taken the average value. The percentage of water soluble extractive was calculated by the formula given below.
Calculation:

\[
\text{Percentage of water soluble extract} = \frac{\text{Weight of the extract}}{\text{Weight of sample taken}} \times 100
\]

b. Alcohol-soluble extractive of the sample

4 g of the sample was weighed accurately in a glass stoppered flask. Added 100 ml of distilled alcohol (approximately 95%) and shaken occasionally for 6 hours and then allowed to stand for 18 hours. Filtered rapidly taking care not to lose any solvent and pipetted out 25 ml of the filtrate in a preweighed 100 ml beaker and evaporated to dryness on a water bath.

Kept in an air oven at 105ºC for 6 hours and cooled in a dessicator and weighed. Repeated the experiment twice, and taken the average value. The percentage of alcohol soluble extractive was calculated by the formula given below.

Calculation:

\[
\text{Percentage of alcohol soluble extract} = \frac{\text{Weight of the extract}}{\text{Weight of sample taken}} \times 100
\]

i. Determination of pH

The pH of the Seenthil kudineer was estimated as per the method prescribed in the Indian standard (IS) -6940(1982). The procedure was done at NIS, Chennai 47.

One gram of the testdrug was taken into a 100ml graduated cylinder containing about 50 ml of water. The cylinder was shaken vigorously for two minutes and the suspension was allowed to settle for hour at 25ºC to 27ºC, then 25 ml of the clear aqueous solution was transferred in to a 50 ml beaker and tested for pH using digital pH meter.
5.1.2 Pharmacological activity

**In-vitro Carminative Activity**

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<thead>
<tr>
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<th>PSA/30/16-17</th>
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</thead>
<tbody>
<tr>
<td>Institute</td>
<td>National Institute of Siddha, Chennai, Tamil Nadu, India</td>
</tr>
<tr>
<td>Sample Name</td>
<td>SeenthilKudineer</td>
</tr>
<tr>
<td>Sample ID</td>
<td>SK</td>
</tr>
</tbody>
</table>

**Preparation of Seenthil Kudineer Decoction**

Decoction of the raw sample was prepared by extracting the crude drug with distilled water by using soxhlet extraction setup. The decoction thus collected will be used for the following estimation.

**In-vitro Carminative activity acid-base titration technique**

In-vitro carminative activity of the SeenthilKudineer was evaluated by modified method of Swapnil Sharma et al. About 5, 10, 20 and 40 ml of the SK decoction were placed in conical flask fitted with air-tight nozzle, to this 100 ml of distill water was added.

About 100 ml of NaOH (1M, previously standardized to oxalic acid) was poured into a plastic container fitted with aeration tubing system that was connected directly to the
reaction vessel containing varying volume of test sample (SK). The flask was agitated manually for the next 45 mins and was allowed to stand for overnight. The carbon dioxide gas evolved from the reaction vessel was allowed to pass into a plastic container containing excess sodium hydroxide where it was absorbed and converted into equivalent amount of sodium carbonate. The resulting mixture consisting of excess sodium hydroxide and sodium carbonate was titrated with standard HCl using phenolphthalein as indicator to get first endpoint and in continuation to this the second endpoint was enumerated using methyl orange as indicator. The difference in milliliters between the first & second endpoints was used to calculate the carbon dioxide content per gram of sample.

Vol. of titrant x molarity of std. acid x mol. Wt. of CO2 = mass of CO2 in gm

Molarity of the Acid is 0.0829M

Mol. Wt. of CO2 is 44.01 g/mol

Triplicate 1

<table>
<thead>
<tr>
<th>Volume of Test Sample</th>
<th>Difference in Titration value (ml)</th>
<th>Mass of CO2 in gm</th>
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</thead>
<tbody>
<tr>
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<td>6.56</td>
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<tr>
<td>10</td>
<td>2.4</td>
<td>8.75</td>
</tr>
<tr>
<td>20</td>
<td>3.6</td>
<td>13.13</td>
</tr>
<tr>
<td>40</td>
<td>4.6</td>
<td>16.78</td>
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Triplicate 2

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<th>Mass of CO2 in gm</th>
</tr>
</thead>
<tbody>
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</tr>
<tr>
<td>10</td>
<td>2.2</td>
<td>8.02</td>
</tr>
<tr>
<td>20</td>
<td>3.3</td>
<td>12.03</td>
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<tr>
<td>40</td>
<td>4.5</td>
<td>16.41</td>
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Triplicate 3

<table>
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<th>Difference in Titration value (ml)</th>
<th>Mass of CO2 in gm</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
<td>40</td>
<td>4.2</td>
<td>15.32</td>
</tr>
</tbody>
</table>
Reaction Setup

Evolvement of Carbon dioxide from the reaction mixture
5.1.3 Biochemical analysis

Biochemical Analysis of Seenthil kudineer was done at the Biochemistry lab at National Institute of Siddha, Chennai by the method of Kolkate.

Preparation of Extract:

5ml of sample was taken in a 250ml clean beaker and added with 50ml of distilled water. Then it is boiled well for about 10 minutes. Then it is cooled and filtered in a 100ml volumetric flask and made up to 100ml with distilled water. This preparation is used for the qualitative analysis of acidic/basic radicals and biochemical constituents in it.

Procedure:

Test for Silicate

A 2ml of the sample was shaken well with distilled water.

Action of Heat:

A 2ml of the sample was taken in a dry test tube and heated gently at first and then strong.

Action of Heat:

A 2ml of the sample was taken in a dry test tube and heated gently at first and then strong.
Ash Test:

A filter paper was soaked into a mixture of extract and dil. cobalt nitrate solution and introduced into the Bunsen flame and ignited

I. Test for Acid Radicals

Test for Sulphate:

2ml of the above prepared extract was taken in a test tube to this added 2ml of 4% dil ammonium oxalate solution

Test for chloride:

2ml of the above prepared extracts was added with 2ml of dil.HCl is added until the effervescence ceases off.

Test for Phosphate:

2ml of the extract were treated with 2ml of dil.ammonium molybdate solution and 2ml of con.HNo3.

Test for carbonate:

2ml of the extract was treated with 2ml of dil. magnesium sulphate solution.

Test for Nitrate:

1gm of the extract was heated with copper turning and concentrated H₂SO₄ and viewed the test tube vertically down.

II. Test for Basic radicals

Test for lead:

2ml of the extract was added with 2ml of dil.potassium iodine solution.

Test for copper:

One pinch (25mg) of extract was made into paste with con. HCl in a watch glass and introduced into the non-luminous part of the flame.
**Test for Aluminium:**

To the 2ml of extract dil.sodium hydroxide was added in 5 drops to excess.

**Test for Iron:**

a. To the 2ml of extract add 2ml of dil.ammonium solution

b. To the 2ml of extract 2ml of thiocyanate solution and 2ml of con HNo3 is added.

**Test for Zinc:**

To 2ml of the extract dil.sodium hydroxide solution was added in 5 drops to excess and dil.ammonium chloride was added.

**Test for Calcium:**

To 2ml of the extract was added with 2ml of 4% dil.ammonium oxalate solution

**Test for Magnesium:**

To 2ml of extract dil.sodium hydroxide solution was added in drops to excess.

**Test for Ammonium:**

To 2ml of extract 1 ml of Nessler's reagent and excess of dil.sodium hydroxide solution are added.

**Test for Potassium:**

A pinch (25mg) of extract was treated of with 2ml of dil.sodium nitrite solution and then treated with 2ml of dil.cobalt nitrate in 30% dil.glacial acetic acid.

**Test for Sodium:**

2 pinches (50mg) of the extract is made into paste by using HCl and introduced into the blue flame of Bunsen burner.

**Test for Mercury:**

2ml of the extract was treated with 2ml of dil.sodium hydroxide solution.
Test for Arsenic:

2ml of the extract was treated with 2ml of dil. sodium hydroxide solution

III. Miscellaneous

Test for Starch:

2ml of extract was treated with weak dil. Iodine solution.

Test For Reducing Sugar:

5ml of Benedict's qualitative solution was taken in a test tube and allowed to boil for 2 minutes and added 8 to 10 drops of the extract and again boil it for 2 minutes. The colour changes are noted.

Test for the Alkaloids:

a) 2ml of the extract was treated with 2ml of dil. potassium Iodide solution.

b) 2ml of the extract was treated with 2ml of dil. picric acid.

c) 2ml of the extract was treated with 2ml of dil. phosphotungstic acid.

Test for Tannic Acid:

2ml of extract was treated with 2ml of dil. ferric chloride solution.

Test for Unsaturated Compound:

To the 2ml of extract 2ml of dil. potassium permanganate solution was added.

Test for Amino Acid:

2 drops of the extract was placed on a filter paper and dried well. 20ml of Burette reagent is added.

Test for Type of Compound:

2ml of the extract was treated with 2ml of dil. ferric chloride solution.
5.2 CLINICAL STUDIES:

Population and Sample:

The population consists of paediatric patients attending the OPD of AyothidossPandithar Hospital, National Institute of Siddha, Chennai-47.

The sample consists of 1-3 years age group fulfilling any 3 of the inclusion criteria and none of the exclusion criteria.

Sample size: 40 Patients

Study place: OPD & IPD of Ayothidoss pandithar hospital,
National Institute of Siddha,
Tambaram sanatorium,
Chennai – 46.

Inclusion criteria:
Age 1 to 3 years
Sex: Both male and female children.
Children with minimum 3 clinical symptoms such as
1. Indigestion
2. Stomach pain
3. Cough
4. Fever
5. Yawning
6. Prespiration
7. Constipation

Exclusion criteria:
1. Irritable Bowel Syndrome
2. Childhood Asthma
3. High temp >102°F
4. Severe cough
5. Intolerable stomach pain
Withdrawl criteria:

1. Occurrence of any adverse effect
2. Poor patient compliance & defaulters.
3. Patient turned unwilling to continue in the course of clinical trial.
4. Exacerbation of symptoms

Study design : An Open clinical trial.
Study duration : 12 Months
Dosage of drugs : 10ml (bid)
Name of the trial drug : Seenthil kudineer

A.CLINICAL ASSESSMENT

Clinical assessment were done with reduction of following symptoms

- Indigestion
- Stomach pain
- Cough
- Fever
- Constipation

B.SIDDHA METHOD OF ASSESSMENT

- Nilam
- Kaalam
- Uyirthathukkal
- Udalthathukkal
- Envagaithervugal

Study Enrollment:

1. In this study, patients reporting at the NIS OPD with the three or more clinical symptoms will be examined clinically for enrolling in this study based on the inclusion and exclusion criteria.

2. The patients who are to be enrolled would be informed (Form VI) about the study, experimental medicine, possible outcomes and the objectives of the study in the language and terms understandable to them and to their informants.
3. After ascertaining the patient and informant willingness, informed consent would be obtained in writing from them in the consent form (Form II).

4. All these patients will be given unique registration card in which patients’ Registration number of the study, Address, Phone number and Doctors phonenumber etc. will be given, so as to report easily communication for the sake of the patient.

5. Complete clinical history, complaints and duration, examination findings-- all would be recorded in the prescribed Proforma in the history and clinical assessment forms (form IV) separately. Screening Form- I will be filled up; Form III will be used for recording the patients’ history, clinical examination of symptoms and signs respectively.

6. Patient would be advised to take the trial drug and appropriate dietary advice (Form X) would be given according to the patients’ perfect understanding.

**Conduct of the Study:**

The trial drug “SeenthilKudineer” is given for 1 day. For OP patients before and after treatment the clinical assessment will be done and prognosis is noted on 3rd day. For IP patients the drug is provided and prognosis is noted and clinical assessment will be done on 1st day itself.

**Data Managment:**

After enrolling the patient in the study, a separate file for each patient will be opened and all forms will be filed in the file. When study patient visits OPD during the study period, the respective patient file will be taken and necessary recordings will be made at the assessment form or other suitable form. The screening forms will be filed separately.

The Data recordings will be monitored for completion and adverse event by HOD and data logical recording and completeness will be monitored by statistician (Sr.Research Officer (Statistics)). All forms will be further scrutinized in presence of Investigator by Sr.Research Officer (Statistics) for logical errors and incompleteness of data before entering onto computer to avoid any bias. No modification in the results is permitted for unbiased report.
Any missed data found in during the study, it will be collected from the patient, but the time related data will not be recorded retrospectively. All collected data will be entered using MS Access software onto computer. Investigator will be trained to enter the patient data and cross checked by SRO.

**Adverse Effect/Serious Effect Management:**

If the trial patient develops any adverse reaction, he/she would be immediately withdrawn from the trial and proper management will be given in OPD of National Institute of Siddha and the same will be reported to regional pharmacovigilance center.

**Ethical Issues:**

1. No other external or internal medicines will be used.

2. The data collected from the patient’s informant will be recorded. The patient’s informant will be informed about the diagnosis, treatment and follow-up.

3. After the consent of the patient’s informant (through consent form), patient will be enrolled in the study.

4. Informed consent will be obtained from the patient’s informant explaining in the understandable language to the patient’s informant.

5. Treatment would be provided free of cost.

6. In conditions of treatment failure, adverse reactions, patients will be given alternative treatment at the National Institute of Siddha with full care.

**Data Collection Forms:**

- Form I: Screening & Selection Proforma
- Form II: Consent Form
- Form III: History Proforma
- Form IV: Assessment Form
- Form V: Drug compliance
- Form VI: Patient information sheet
- Form VII: Withdrawal
- Form VIII: Adverse reaction
- Form IX: Pharmaco vigilance
- Form X: Dietary form
6. RESULTS AND OBSERVATIONS

Preclinical studies:
Physicochemical analysis of Seenthil kudineer

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Parameters</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Loss on Drying at 105°C</td>
<td>10.27%</td>
</tr>
<tr>
<td>2</td>
<td>Total Ash</td>
<td>4.92%</td>
</tr>
<tr>
<td>3</td>
<td>Acid insoluble Ash</td>
<td>0.53%</td>
</tr>
<tr>
<td>4</td>
<td>Water soluble Extractive</td>
<td>20.55%</td>
</tr>
<tr>
<td>5</td>
<td>Alcohol Soluble Extrative</td>
<td>15.20%</td>
</tr>
<tr>
<td>6</td>
<td>pH</td>
<td>4.70</td>
</tr>
</tbody>
</table>

Biochemical analysis of Seenthil Kudineer

Results of Acid radicals studies

<table>
<thead>
<tr>
<th>S.NO</th>
<th>Parameter</th>
<th>Observation</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Test for Sulphate</td>
<td>Cloudy appearance Present</td>
<td>Positive</td>
</tr>
<tr>
<td>2</td>
<td>Test for Chloride</td>
<td>-</td>
<td>Negative</td>
</tr>
<tr>
<td>3</td>
<td>Test For Phosphate</td>
<td>-</td>
<td>Negative</td>
</tr>
<tr>
<td>4</td>
<td>Test For Carbonate</td>
<td>-</td>
<td>Negative</td>
</tr>
<tr>
<td>5</td>
<td>Test For Nitrate</td>
<td>-</td>
<td>Negative</td>
</tr>
<tr>
<td>6</td>
<td>Test for Sulphide</td>
<td>-</td>
<td>Negative</td>
</tr>
<tr>
<td>7</td>
<td>Test For Fluoride &amp;oxalate</td>
<td>-</td>
<td>Negative</td>
</tr>
<tr>
<td>8</td>
<td>Test For Nitrite</td>
<td>-</td>
<td>Negative</td>
</tr>
<tr>
<td>9</td>
<td>Test For Borax</td>
<td>-</td>
<td>Negative</td>
</tr>
</tbody>
</table>

Interpretation

The acidic radicals test shows the presence of Sulphate.
Results of basic radicals studies:

<table>
<thead>
<tr>
<th>S.NO</th>
<th>Parameter</th>
<th>Observation</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Test for Lead</td>
<td>-</td>
<td>Negative</td>
</tr>
<tr>
<td>2</td>
<td>Test for Copper</td>
<td>-</td>
<td>Negative</td>
</tr>
<tr>
<td>3</td>
<td>Test For Aluminium</td>
<td>Brown precipitate is formed</td>
<td>Positive</td>
</tr>
<tr>
<td>4</td>
<td>Test For Iron</td>
<td>-</td>
<td>Negative</td>
</tr>
<tr>
<td>5</td>
<td>Test For Zinc</td>
<td>White precipitate is formed</td>
<td>Positive</td>
</tr>
<tr>
<td>6</td>
<td>Test for Calcium</td>
<td>Cloudy appearance and white precipitate present</td>
<td>Positive</td>
</tr>
<tr>
<td>7</td>
<td>Test For Magnesium</td>
<td>White precipitate obtained</td>
<td>Positive</td>
</tr>
<tr>
<td>8</td>
<td>Test For Ammonium</td>
<td>-</td>
<td>Negative</td>
</tr>
<tr>
<td>9</td>
<td>Test For Potassium</td>
<td>-</td>
<td>Negative</td>
</tr>
<tr>
<td>10</td>
<td>Test For Sodium</td>
<td>-</td>
<td>Negative</td>
</tr>
<tr>
<td>11</td>
<td>Test For Mercury</td>
<td>-</td>
<td>Negative</td>
</tr>
<tr>
<td>12</td>
<td>Test For Arsenic</td>
<td>-</td>
<td>Negative</td>
</tr>
</tbody>
</table>

**Interpretation**

The basic radical test shows the presence of calcium, Aluminium, Zinc, Magnesium, and absence of heavy metals such as lead, Iron, arsenic and mercury.
Miscellaneous:

<table>
<thead>
<tr>
<th>S.NO</th>
<th>Parameter</th>
<th>Observation</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Test for Starch</td>
<td></td>
<td>Negative</td>
</tr>
<tr>
<td>2</td>
<td>Test for Reducing sugars</td>
<td></td>
<td>Negative</td>
</tr>
<tr>
<td>3</td>
<td>Test For Alkaloids</td>
<td>Yellow colour developed</td>
<td>Positive</td>
</tr>
<tr>
<td>4</td>
<td>Test For Tannic acid</td>
<td>Blue-black precipitate obtained</td>
<td>Positive</td>
</tr>
<tr>
<td>5</td>
<td>Test for unsaturated compounds</td>
<td></td>
<td>Negative</td>
</tr>
<tr>
<td>6</td>
<td>Test for Amino acid</td>
<td></td>
<td>Negative</td>
</tr>
<tr>
<td>7</td>
<td>Test For Type of compounds</td>
<td>Blue colour developed</td>
<td>Phenol cresol and hydroquinone are present</td>
</tr>
</tbody>
</table>

**Interpretation**

The Miscellaneous test shows the presence of **Alkaloids, Tannic acid, Phenol cresol and hydroquinone**

**In-vitro carminative Activity**

**Result Analysis**

The carminative profiling of the test sample SeenthilKudineer was evaluated on basis of the amount of cabondioxide evolved from the reaction mixture with varying volume of SK. The amount of cabondioxide \(\text{g}\) produced by the 5ml of the sample SK was found to be \((6.68 \pm 0.55)\), for 10 ml of sample it was \((8.51 \pm 0.42)\), 20 ml of sample it was \((12.53 \pm 0.53)\) and 40 ml of sample it was \((16.17 \pm 0.75)\).
<table>
<thead>
<tr>
<th>Volume of Test Sample</th>
<th>Difference in Titration value (ml)</th>
<th>Mass of CO2 in gm</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>1.8</td>
<td>6.689 ± 0.55</td>
</tr>
<tr>
<td>10</td>
<td>2.3</td>
<td>8.513 ± 0.42</td>
</tr>
<tr>
<td>20</td>
<td>3.4</td>
<td>12.53 ± 0.53</td>
</tr>
<tr>
<td>40</td>
<td>4.4</td>
<td>16.17 ± 0.75</td>
</tr>
</tbody>
</table>

Each value represents the mean ± SD. N=3

Clinical Studies

40 Patients with confirmed diagnosis of with satisfying the inclusion criteria were enrolled after obtaining written informed consent and were to receive Seenthil kudineer with dosage of 10 ml bid for 1 day

Results were observed with respect to the following criteria:

1. Age
2. Sex
3. Parent’s Socio Economic Status
4. Diet
5. Nilam
6. Paruvakaalam
7. Uyirthathukkal
8. Ezhudalkattugal
9. Envagaithervugal
10. Neikuri
11. Clinical features
### Table 1. Distributions of patients with Kattu Mantham according to Age

<table>
<thead>
<tr>
<th>S.NO</th>
<th>AGE</th>
<th>NO.OF.CASES</th>
<th>PERCENTAGE %</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>1-2 Years</td>
<td>22</td>
<td>55</td>
</tr>
<tr>
<td>2.</td>
<td>2-3 Years</td>
<td>18</td>
<td>45</td>
</tr>
</tbody>
</table>

**Inference:**

Out of 40 patients, 55% of cases were within 1-2 years, 45% of cases were within 2-3 years. (Table 1)
Table 2. Distributions of patients with Kattu mantham according to Gender

<table>
<thead>
<tr>
<th>S.No</th>
<th>Sex</th>
<th>No of Cases</th>
<th>Percentage%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Male Child</td>
<td>25</td>
<td>62.5</td>
</tr>
<tr>
<td>2.</td>
<td>Female Child</td>
<td>15</td>
<td>37.5</td>
</tr>
</tbody>
</table>

Inference:

Out of 40 patients 62.5% were male children and 37.5% were female children. (Table 2)
Table 3. Distribution of patients with Kattu mantham according to socio-economic status

<table>
<thead>
<tr>
<th>S.No</th>
<th>Socio-economic Status</th>
<th>No of Cases</th>
<th>Percentage %</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>High Income group</td>
<td>5</td>
<td>12.5</td>
</tr>
<tr>
<td>2.</td>
<td>Middle Income group</td>
<td>32</td>
<td>80</td>
</tr>
<tr>
<td>3.</td>
<td>Poor Income group</td>
<td>3</td>
<td>7.5</td>
</tr>
</tbody>
</table>

**Inference:**

About 7.5% patients were under lower income group, 80% patients were under middle income group and 12.5% patients were under high income group. The highest incidence occurred in middle income group. (Table 3).
Table 4. Distribution of patients with Kattu mantham according to Diet reference

<table>
<thead>
<tr>
<th>S.NO</th>
<th>FOOD HABITS</th>
<th>NO OF CASES</th>
<th>PERCENTAGE %</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Vegetarian</td>
<td>3</td>
<td>7.5</td>
</tr>
<tr>
<td>2.</td>
<td>Non-Vegetarian</td>
<td>37</td>
<td>92.5</td>
</tr>
</tbody>
</table>

Inference:

According to diet, Vegetarian 7.5%, Mixed 92.5% were noted. (Table 4)
Table 5. Distribution of patients with Kattu mantham according to Nilam

<table>
<thead>
<tr>
<th>Nilam</th>
<th>No of cases</th>
<th>Percentage %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kurinji</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Mullai</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Marutham</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Neithal</td>
<td>38</td>
<td>95</td>
</tr>
<tr>
<td>Paalai</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Inference:

Among 40 patients, 95% were from Neithal land, 5% from Marutham land, 0% from Mullai land, and 0% from Kurinji land. (Table 5)
Table 6. Distribution of patients with Kattu mantham according to Paruvakalam

<table>
<thead>
<tr>
<th>S.No</th>
<th>Paruvakaalam</th>
<th>No. of cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Karkaalam (Avani – puratasi)</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>2.</td>
<td>Koothirkaalam (Iyppasi – karthikai)</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>3.</td>
<td>Munpani (Markazhi – Thai)</td>
<td>11</td>
<td>27.5</td>
</tr>
<tr>
<td>4.</td>
<td>Pin pani (Masi – Panguni)</td>
<td>26</td>
<td>65</td>
</tr>
<tr>
<td>5.</td>
<td>Elavenil (Chitirai, Vaigasi)</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>6.</td>
<td>Mudhuvenil (Aani, Aadi)</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Inference:

According to paruva kaalam, high incidence of cases 65% were reported in Pinpanikalam, 27.5% cases were reported in Munpani kalam, 2.5% cases were reported in elavenil kaalam and 2.5% were from Karkalam, 2.5% from karkalam and 2.5% from koothirkalam. (Table 6)
Table 7a. Distribution of patients with Kattu mantham according to derangement of Vatham

<table>
<thead>
<tr>
<th>SNO</th>
<th>VATHAM</th>
<th>NO OF CASES</th>
<th>PERCENTAGE %</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Piranan</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2.</td>
<td>Abanan</td>
<td>40</td>
<td>100</td>
</tr>
<tr>
<td>3.</td>
<td>Viyanan</td>
<td>40</td>
<td>100</td>
</tr>
<tr>
<td>4.</td>
<td>Uthanan</td>
<td>28</td>
<td>70</td>
</tr>
<tr>
<td>5.</td>
<td>Samanam</td>
<td>40</td>
<td>100</td>
</tr>
<tr>
<td>6.</td>
<td>Nagan</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>7.</td>
<td>Koorman</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>8.</td>
<td>Kirukaran</td>
<td>40</td>
<td>100</td>
</tr>
<tr>
<td>9.</td>
<td>Devathathan</td>
<td>40</td>
<td>100</td>
</tr>
<tr>
<td>10.</td>
<td>Thananjeyan</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Inference:

According to vatham, derangement of Pranan was 0%, Abanan was 100%, Viyanan was 100%, Uthanan was 70% samaanam was affected 100% and Kirukaran was deranged in 100% and devathathan was 100% (Table 7a).
Table 7b. Distribution of patients with Kattumantham according to derangement of Pitham

<table>
<thead>
<tr>
<th>S.No</th>
<th>Types of pitham</th>
<th>No.of Cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Analapitham</td>
<td>40</td>
<td>100</td>
</tr>
<tr>
<td>2.</td>
<td>Ranjagam</td>
<td>4</td>
<td>10</td>
</tr>
<tr>
<td>3.</td>
<td>Saathagam</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>4.</td>
<td>Prasagam</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>5.</td>
<td>Alosagam</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Inference:

According to Pitham, derangement of Analapitham was 100% and Ranjagam was 10% (Table 7b).
Table 7c. Distribution of patients with kattu mantham according to dearrangement of Kabam

<table>
<thead>
<tr>
<th>S.No</th>
<th>Types of Kabham</th>
<th>No.of Cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Avalambagam</td>
<td>40</td>
<td>100</td>
</tr>
<tr>
<td>2.</td>
<td>Kilethagam</td>
<td>40</td>
<td>100</td>
</tr>
<tr>
<td>3.</td>
<td>Pothagam</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>4.</td>
<td>Tharpagam</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>5.</td>
<td>Santhigam</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Inference:** According to Kabam, derangement of Avalambagam was deranged in 100% of cases and Kilethagam was affected in 100% cases (Table 7c).
Table 8. Distribution of patients with Kattu mantham according to derangement of Ezhu Udarkattugal

<table>
<thead>
<tr>
<th>S.No</th>
<th>Udarkattugal</th>
<th>No. of Cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Saaram</td>
<td>40</td>
<td>100</td>
</tr>
<tr>
<td>2.</td>
<td>Senneer</td>
<td>4</td>
<td>10</td>
</tr>
<tr>
<td>3.</td>
<td>Oon</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>4.</td>
<td>Kozhuppu</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>5.</td>
<td>Enbu</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>6.</td>
<td>Moolai</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>7.</td>
<td>Sukkilam / Suronitham</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**EZHU UDARKATTUKAL**

**Inference:**
Saram was affected in 100% of cases and Seneer was affected 10% (Table 8).
Table 9. Distribution of patients with Kattu mantham according to derangement of Enn vagai thervugal

<table>
<thead>
<tr>
<th>S.No</th>
<th>Enn Vagai Thervugal</th>
<th>Percentage%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Naa</td>
<td>10</td>
</tr>
<tr>
<td>2</td>
<td>Niram</td>
<td>10</td>
</tr>
<tr>
<td>3</td>
<td>Mozhi</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>Vizhi</td>
<td>10</td>
</tr>
<tr>
<td>5</td>
<td>Sparisam</td>
<td>15</td>
</tr>
<tr>
<td>6</td>
<td>Malam</td>
<td>100</td>
</tr>
<tr>
<td>7</td>
<td>Moothiram</td>
<td>10</td>
</tr>
<tr>
<td>8</td>
<td>Naadi</td>
<td>100</td>
</tr>
</tbody>
</table>

Inference:

Out of 40 cases Malam was affected in 100% of cases, Sparism was affected in 15% of cases, Naa and Vizhi was affected in 10% of the cases. (Table 9).

Inference (Naadi):

In Naadi, Vathapitham was observed in 50% of cases, Pithavatham was observed in 50% of cases.
Table 10. Distribution of patients with Kattu mantham according to observation of Neikuri analysis

<table>
<thead>
<tr>
<th>S.No</th>
<th>Character of urine</th>
<th>Neikuri Reference</th>
<th>No. of Cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Spreads like snake</td>
<td>Vatha Neer</td>
<td>20</td>
<td>50</td>
</tr>
<tr>
<td>2.</td>
<td>Spreads like ring</td>
<td>Pitha Neer</td>
<td>17</td>
<td>42.5</td>
</tr>
<tr>
<td>3.</td>
<td>Static as pearl</td>
<td>Kaba Neer</td>
<td>3</td>
<td>7.5</td>
</tr>
</tbody>
</table>

Inference

According to Neikuri, Vatha neer was observed in 50% of cases, Pitha neer was observed in 42.5% of cases, Kaba neer was observed in 7.5% of cases. (Table 10)
Table – 15 Distribution of clinical symptoms of Kattu mantham

<table>
<thead>
<tr>
<th>S.No</th>
<th>Signs and Symptoms</th>
<th>No.of cases (out of 40)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Constipation</td>
<td>40</td>
<td>100</td>
</tr>
<tr>
<td>2</td>
<td>Indigestion</td>
<td>28</td>
<td>70</td>
</tr>
<tr>
<td>3</td>
<td>Abdomen pain</td>
<td>30</td>
<td>75</td>
</tr>
<tr>
<td>4</td>
<td>Fever</td>
<td>6</td>
<td>15</td>
</tr>
<tr>
<td>5</td>
<td>Yawning</td>
<td>14</td>
<td>35</td>
</tr>
<tr>
<td>6</td>
<td>Cough</td>
<td>28</td>
<td>70</td>
</tr>
</tbody>
</table>

**Inference**

Among the 40 cases, 100% of the patients have constipation, 75% have abdomen pain, 70% have Indigestion, 15% have fever, 70% have cough and 35% have yawning.
Table 16 Results.

Table 11. Distribution of patients with Kattu mantham according treatment results obtained

<table>
<thead>
<tr>
<th>Clinical Features</th>
<th>Before Treatment</th>
<th>Percentage (%)</th>
<th>After treatment</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constipation</td>
<td>40</td>
<td>100</td>
<td>15</td>
<td>37.5</td>
</tr>
<tr>
<td>Indigestion</td>
<td>28</td>
<td>70</td>
<td>10</td>
<td>25</td>
</tr>
<tr>
<td>Fever</td>
<td>6</td>
<td>15</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Abdomen pain</td>
<td>75</td>
<td>30</td>
<td>8</td>
<td>20</td>
</tr>
<tr>
<td>Cough</td>
<td>28</td>
<td>70</td>
<td>8</td>
<td>20</td>
</tr>
<tr>
<td>Yawning</td>
<td>14</td>
<td>35</td>
<td>4</td>
<td>10</td>
</tr>
</tbody>
</table>

Inference:

Out of the 40 cases, the signs and symptoms like constipation 100%, indigestion 70%, fever 15%, abdominal pain 30%, cough 70%, yawning 35% were reduced into 37.5%, 25%, 5%, 20%, 20%, 10% respectively. These results were based on the clinical improvements observed.
For clinical studies

Statistical analysis:

All collected data were entered into MS Excel software using different columns as variables and rows as patients. STATA software was used to perform statistical analysis. Basic descriptive statistics include frequency distributions and cross-tabulations were performed. Bar diagram, Pie charts were used to describe the value of different variables for pictorial representation. The quantity variables were expressed as Mean and standard deviation and qualitative data as percentage. A probability value of less than 0.05 was considered to indicate as statistical significance. Paired ‘t’ test was performed for determining the significance between before and after treatment.

Clinical Symptoms score before and after treatment

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Mean ± Std Dev</th>
<th>95% of C.I</th>
<th>Significance (t, p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before (40)</td>
<td>0.533</td>
<td>4.479</td>
<td>t-value=23.9075</td>
</tr>
<tr>
<td>After (40)</td>
<td>0.952</td>
<td>1.320</td>
<td>p&lt;0.001</td>
</tr>
</tbody>
</table>

The mean and standard deviation of Before and After treatment were 0.533 and 0.952 respectively. Which is statistically significant t-value =23.9075 p value p<0.0001

The reduction of clinical symptoms after the treatment is significant . The reduction in the symptoms is 65 % from the start of the treatment.
7. DISCUSSION

Kattumantham is a Functional Dyspepsia. It is defined as persistant or recurrent pain or discomfort centered in the abdomen, without evidence or organic disease. Functional dyspepsia is the most commonest health problem encountered in primary care worldwide, present about 80% of paediatric population.

Preclinical studies

- Biochemical analysis

  The Biochemical analysis of trial medicines showed presence of calcium, magnesium, aluminium, sulphate, zinc, alkaloids phenol, hydro quinine and tannic acid.

  Presence of tannic acid – drug containing tannins possess anti ulcer activity, it reduce symptoms of dyspepsia.

  Presence of calcium – calcium ions significantly increase the drug release, it enhance the drug to absorb well.

Physicochemical analysis:

  Physico-chemical analysis was done as preliminary evaluation of Seenthil kudineer. The method of measuring the moisture content in solid or semi-solid materials is loss on drying at 105°C was found to be it falls in between the limit range (1-20%). The method of measuring the moisture content in solid materials is loss on drying (LOD). Low moisture content is always desirable for higher stability of drugs. In Seenthil kudineer showed Loss of drying at 105°C was found to be 10.27% it falls in between the limit range (1-20%). So the moisture content shows the good stability of the drug Seenthil kudineer.

  The ash value represents the purity of the drugs. The total ash includes both physiological ash, which is derived from the organic matter, and non physiological ash which is the residue of the extraneous matters like sand/soil, inorganic materials. The non physiological ash is represented by acid soluble ash. The total ash in Seenthil kudineer found to be 4.92% and the acid insoluble ash to be 0.53%. The both ash value were under limits.

  The extractive values helps to indicate the nature of chemical constituents present in the drug. The water soluble substance is polar in nature and the alcohol has the ability to dissolve non-polar substance. The water soluble extract value of Seenthil kudineer is 20.55%.
and the Alcohol soluble extractive is 15.20 % its shows the possibility of water soluble constituents such as tannins, sugars, plant acids and mucilage, and alcohol soluble substance such as tannins, resins, and alkaloids to be present in the drug. As the drug Seenthil kudineer having more water soluble constituents than alcohol soluble, it would be non polar. So the trial drug shows good absorption & intracellular distribution without possible of accumulation inside the cells. The good water solubility may rapid the drug absorption and action.

Strongly acidic nature of the drug can cause the harmful effects to the body. so the screening for the pH is important for the drug. It represents the chemical nature of the drug and the site of absorption of non polar drug. The pH of Seenthil kudineer is found to be 4.70 that is weakly acidic and safe in pH. The weakly acidic drugs are rapidly absorbed from stomach. So the trial drug Seenthil kudineer can act rapidly on oral administration.

**In vitro carminative activity of Seenthil kudineer**

In-vitro carminative activity of the Seenthil Kudineer was evaluated by modified method of Swapnil Sharma et al clearly indicates the test drug Seenthil kudineer (SK) The carminative profiling of the test sample Seenthil Kudineer was evaluated on basis of the amount of carbon dioxide evolved from the reaction mixture with varying volume of SK. The maximum amount of carbon dioxide {g} produced by the 20ml of the sample SK was found to be (12.53 ± 0.53) and 40 ml of sample it was (16.17 ± 0.75).

**CLINICAL REVIEW**

- **Age:**
  
  In the present study, Out of 40 patients, 62.5% of cases were within 1-2 years, 37% were within 2-3 years.

- **Sex:**
  
  Out of 40 patients 62.5% patients were male children and 37.5% patients were female children. Male children affected more than female children.

- **Socio-economic status:**
  
  About 7.5% patients were under lower income group, 80% patients were under middle income group and 12.5% patients were under high income group. The highest incidence occurred in middle income group.
- **Seasonal variation:**
  According to Paruvakalam high incidence of cases 65% were reported in pin pani kaalam and 2.5% were reported in elavenil kaalam and 27.5% were reported in Munpani kaalam 2.5% in kar kalam and 2.5% in koothir kalam.

- **Food habits:**
  According to food habits 7.5% had vegetarian diet 92.5% had mixed diet The highest incidence of cases was observed in mixed diet

- **Nilam:**
Among 40 patients, 95% were from Neithal land, 5% from Marutham land.

- **Vali (Vatham)**
  Due to the derangement of vatha the following symptoms occur. Abanan was affected in 100% of cases and cause constipation. Viyanan was affected in 100% of cases. Samanan was affected in 100% cases and cause poor appetite. Uthanan was affected in 70% of cases and cause cough, Kirukaran was affected in 100% and cause cough and Poor appetite and devathathan was affected in 100% and cause general body weakness.

- **Azhal (Pitham)**
  Due to the derangement of Pitham the following symptoms occur. Analapitham was affected in 100% of cases and cause poor appetite and ranjagam was affected in 10% of cases and cause anemia.

- **Iyyam (Kabam)**
  Deranged avalbagam was in 100% of cases, Klethagam was affected 100% of cases cause poor appetite.

- **Ezhu udarkattugal**
  In Ezhu udal kattukal, Saram was affected 100% and due to Cough, Poor appetite. Senneer was affected in 10% of cases due to anemia.

- **Envagai thervugal**
  According to this study Malam was affected in 100% of cases. niram was affected in 10% of cases
Vizhi was affected 10% of cases
Moothiram was affected 10% of cases
Sparisam was affected in 15% of cases (Low grade fever)

- **Naadi:**

  Vathapitham was observed in 50% of cases
  Pithavatham was observed in 50% of cases

  According to naadi, high Distribution observed in vali Azhal, Azhal vali naadi. In siddha literature, the character of vali Azhal is due to poor appetite, indigestion and nausea.

- **Neerkuri**

  Regarding moothiram, neerkuri showed straw coloured urine in all cases.

- **Neikuri**

  In the present study, 50% of patient had vatha neikuri, 42.5% was observed as pitta neikuri and 7.5% was observed as Kaba neikuri. According to this neikuri, vatham was dominately affected.

**Clinical features:**

The clinical feature of kattumantham may be correlate with general clinical manifestations of Dyspepsia. In accordance with the clinical features of kattumantham Among the 40 cases, 100% of the patients have constipation, 75% have abdomen pain, 70% have indigestion and 70% have cough, 15% have fever and 35% have yawning.

**Improvement in clinical features:**

Regarding the symptoms, Out of the 40 cases, the signs and symptoms like constipation 100%, indigestion 70%, fever 15%, abdominal pain 30%, cough 70%, yawing 35% were reduced into 37.5%, 25%, 5%, 20%, 20%, 10% reduced respectively. These results were based on the clinical improvements observed.

The mean and standard deviation of Seenthil kudineer before and after treatment were 0.533 and 0.952 respectively. Which is statistically significant t-value = 23.9075 p value p<0.0001.

The reduction of clinical symptoms after the treatment is significant. The reduction in the symptoms is 65% from the start of the treatment.
8. SUMMARY

- The disease Kattu mantham was taken for the clinical study with Seenthil kudineer after scrutinizing by the Screening committee of National Institute of Siddha.
- The Clinical studies were carried out after obtaining proper permission from approval IEC of National Institute of Siddha (No:NIS/IEC/18-14/18-26-08-2014).
- The trial registered in Clinical trial Registry of India with Reg .No.CTRI/2016/04/006818 was obtained.
- The Authentication of ingredients of the trial drug was done obtained from Medicinal Botanist, National Institute of Siddha, Chennai.
- Purification of raw drugs and preparation of trial drug was done at Gunapadam Laboratory, Department of Gunapadam, NIS Chennai.
- Biochemical Qualitative analysis of trial drug was done in Biochemistry laboratory, Department of Biochemistry, National Institute of Siddha, Chennai.
- Physicochemical analysis of Seenthil kudineer was done in CRI Arumbakkam,Chennai.
- In- vitro carminative Activity of trial drug was done in Satya Bama University,Chennai.
- All the 40 patients, were treated in OPD of Kuzhandhai Maruthuvam department at Ayothidoss Pandithar Hospital of National Institute of Siddha.
- The patients with Kattu mantham were recruited based on Inclusion and Exclusion criteria and a detailed study was done. Separate proforma was maintained for each patient along with progress chart to monitor the prognosis.
- The mean and standard deviation of Seenthil kudineer before and after treatment were 0.533 and 0.952 respectively. Which is statistically significant t-value =23.9075 p value p<0.0001
- The result shows 65% reduction in the clinical symptoms of patients after treatment and thus proves the efficacy of the medicine.
- The physicochemical analysis showed the trial drug is in appropriate consistency for trial study.
- The patients have not complained of any adverse effects or difficulties during the course of treatment. Thus the drug is found to be safe and effective in the management of Kattu mantham.
- The clinical efficacy of the drug was analyzed statistically on all the symptoms mentioned in the assessment criteria. The observation made during the clinical study showed that the trail drug Seenthil kudineer was clinically effective.
9. CONCLUSION

The Siddha system of medicines has certainty with safer medications to treat children.

The present study indicates the purity and stability of the Seenthil kudineer. The result of In-vitro Carminative Activity of Seenthil kudineer possess promising Carminative property.

The trial drug Seenthilkudineer is treated to the children of age group, 1-3 years who are all diagnosed to have kattu mantham. The ingredients of Seenthilkudineer are feasible and these compounds may serve as potentially useful drug at lower cost since most of them had carminative, laxative activity which controls kattu mantham.

Clinical results were found to be significant. Good improvement was found in 65% of cases.

The present clinical study has established that Seenthilkudineer is having good result in reducing the majority of the symptoms of kattumantham. This has in turn provided a further research and opportunity for new drug established in the management of Kattu Mantham. Because of the encouraging result of above study, the drug Seenthil kudineer may be taken for larger study in treatment of Kattumantham.
10. Bibliography

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- Sigiccha rathna deepam
- Dr. K. Na. Kuppusamy - Siddha Maruthuvam Podhu
- Dr. M. Shanmugavelu - Nooi Nadal Noi Mudhal Nadal Thiratu – Part(1)
- Dr. A. Sundarrasan - Pillaippini; Maruthuvam
- Siddha Maruthuvanga Surkkam
- Arumuga pillai- Seeveratchamirtham
- Batch Solvent Extraction Pmcid: Pmc4027291
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- Thirukkural
- Indian Medicinal Plants - Kiritikar and Basu
- The Wealth of India
- Thotra Kirama Aracheium Siddha Maruthuva Varalarum
- Gunapadam Thaathu Vaguppu, Dr.R.Thiyaga rajan
- Robinson’s pathology.
- Kannusamy parambarai vaithiyam

**Web Sites**

- http://imsear.li.mahidol.ac.th/handle/123456789/144976
- International Journal Of Science And Research (Ijsr)
CLINICAL EVALUATION OF SEENTHIL KUDINEER A SIDDHA DRUG IN THE TREATMENT OF KATTUMANTHAM (DYSPESIA) IN CHILDREN.

**SCREENING FORM - I**

1. S.L No:  
2. OP/IP No:  
3. Name:  
4. Age:  
5. Gender:  
6. Date of Enrollment:  
7. Date of completion:  
8. Informant:  
9. Reliability:  

**INCLUSION CRITERIA:**

<table>
<thead>
<tr>
<th><strong>YES</strong></th>
<th><strong>NO</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age: between 1 - 3 years</td>
<td></td>
</tr>
<tr>
<td>Constipation</td>
<td></td>
</tr>
<tr>
<td>Indigestion</td>
<td></td>
</tr>
<tr>
<td>Abdomen pain</td>
<td></td>
</tr>
<tr>
<td>Fever (below 102°F)</td>
<td></td>
</tr>
<tr>
<td>Cough</td>
<td></td>
</tr>
<tr>
<td>Yawning</td>
<td></td>
</tr>
</tbody>
</table>

**EXCLUSION CRITERIA**

- High temp > 102°F
- Botulism
- Hirsch sprung disease
- Irritable bowel syndrome
- Severe vomiting

**ADMITTED IN STUDY**

<table>
<thead>
<tr>
<th><strong>IF YES</strong></th>
<th><strong>OPD</strong></th>
<th><strong>IPD</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>SL NO OF THE PATIENT</strong></th>
<th><strong>O____</strong></th>
<th><strong>I____</strong></th>
</tr>
</thead>
</table>

Signature of Lecturer:  
Signature of HOD:  
Signature of Principal Investigator:
CONSENT FORM –II

CERTIFICATE BY INVESTIGATOR

I certify that I have disclosed all the details about the study in the terms readily understood by the parent/guardian

Signature __________________

Date ___________________

Name __________ _________

CONSENT BY PARENT

I have been informed to my satisfaction, by the attending physician, the purpose of the clinical trial, and the nature of drug treatment and follow-up including the laboratory investigations to be performed to monitor and safeguard my son/daughter body functions.

I am aware of my right to opt my son/daughter out of the trial at any time during the course of the trial without having to give the reasons for doing so.

I, exercising my free power of choice, hereby give my consent to include my son/daughter as a subject in the clinical trial of ‘seenthil kudineer’ for the treatment of kattu mantham

Date : Signature __________________

Name __________________

Date : Signature of witness Name ____________
செய்திக் குறிப்பிட்டு முடிவு பெற்றது

அவ்வாறு தொடர்ந்து முடிவை எட்டுத்தல்-47

நம்பிக்கை முக்கியாகத்

சீரமை ஆல்லான விளக்கங்கள் வழங்கும் காலம் பயணிகள் மதிக்கி அறிவு

பூட்டல் பட்டை முடிவை விளக்கும் காலத்தில் பயணிகள்.


c:

c:

தொடர்ந்து வார்த்தை 

சீரமை ஆல்லான விளக்கங்கள் வழங்கும் காலம் பயணிகள் மதிக்கி அறிவு

பூட்டல் பட்டை முடிவை விளக்கும் காலத்தில் பயணிகள்.


c:

c:

தொடர்ந்து வார்த்தை 

சீரமை ஆல்லான விளக்கங்கள் வழங்கும் காலம் பயணிகள் மதிக்கி அறிவு

பூட்டல் பட்டை முடிவை விளக்கும் காலத்தில் பயணிகள்.


c:

c:

தொடர்ந்து வார்த்தை 

சீரமை ஆல்லான விளக்கங்கள் வழங்கும் காலம் பயணிகள் மதிக்கி அறிவு

பூட்டல் பட்டை முடிவை விளக்கும் காலத்தில் பயணிகள்.


c:

c:

தொடர்ந்து வார்த்தை 

சீரமை ஆல்லான விளக்கங்கள் வழங்கும் காலம் பயணிகள் மதிக்கி அறிவு

பூட்டல் பட்டை முடிவை விளக்கும் காலத்தில் பயணிகள்.
### Form III- CASE REPORT FORM

#### 1. HISTORY TAKING

**Demographic data**

<table>
<thead>
<tr>
<th>SL No :</th>
<th>OP/IP No.</th>
<th>Visit Date : (<strong>/</strong>/____)</th>
</tr>
</thead>
<tbody>
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</tr>
<tr>
<td>Age :</td>
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</tr>
<tr>
<td>Gender</td>
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<td>Female ☐</td>
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<tr>
<td></td>
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<td>Father/ Mother /Guardian Name :</td>
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<td>Fathers Monthly Income :</td>
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<td>Religion :</td>
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<td>Socioeconomic Status :</td>
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</tr>
<tr>
<td>Patient Informant :</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Postal Address**

| Contact No. | |
|-------------| |
1. COMPLAINTS AND DURATION:

2. PRESENT ILLNESS:

3. HISTORY OF PAST ILLNESS:

4. FAMILY HISTORY:
Any Hereditary/Familial Disease  Yes  No
If Yes, Details

5. IMMUNIZATION HISTORY:
Immunization complete  Incomplete Complete but time lag

6. FOOD HABITS:

7. GENERAL EXAMINATION:
1. Pallor  YES  NO
2. Jaundice  YES  NO
3. Cyanosis  YES  NO
4. Clubbing  YES  NO
5. Pedal oedema  YES  NO
6. Lymph adenopathy  YES  NO
8. VITAL SIGNS:
1. Pulse rate / min -
2. Heart rate / min -
3. Respiratory Rate / min -
4. Temperature -

ANTHROPOMETRY:
- Height -
- Weight -

CLINICAL EXAMINATION:

ALIMENTARY SYSTEM

A) INSPECTION:
- Shape of the Abdomen: Distended / Scaphoid
- Scars: Present / Absent
- Umbilicus: Inverted / Everted
- Visible veins: Present / Absent
- Peristaltic waves: Present / Absent

b) PALPATION:
- Tenderness: Present / Absent
- Palpable mass: Present / Absent
- Enlargement: Present / Absent

c) PERCUSSION:
- Shifting dullness: Present / Absent
- Fluid Thrill: Present / Absent

d) AUSCULTATION:
- Bowel sounds: Absent/ Normal / Increased / decreased
Other systems:

- Cardio vascular system : Normal ◐ Affected ◐
- Gastro intestinal system : Normal ◐ Affected ◐
- Musculo skeletal system : Normal ◐ Affected ◐
- Central nervous system : Normal ◐ Affected ◐
- Endocrine system : Normal ◐ Affected ◐

**SIDDHA ASSESSMENT**

**Nilam:-**
Kurinji ◐ Mullai ◐ Marutham ◐ Neithal ◐ Paalai ◐

**Kaala Iyalbu:-**
Kaarkalam ◐ Koothirkaalam ◐ Munpanikaalam ◐
Pinpanikaalam ◐ Illavenirkaalam ◐ Muthuvenirkaalam ◐

**Yaakai:-**
Vatham ◐ Vatha Pitham ◐ Vatha Kabam ◐
Pitham ◐ Pitha vatham ◐ Pitha Kabam ◐
Kabam ◐ Kaba Vatham ◐ Kaba Pitham ◐

**Gunam**
Sathuvam ◐ Rasatham ◐ Thamasam ◐

**Pori / Pulangal**

<table>
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<tr>
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<td>◐</td>
<td>◐</td>
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<tr>
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93
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**Kanmendhirium / Kanmavidayam**

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**Uyir Thathukkal**

**Vatham:**

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<th>Naadi:</th>
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<tr>
<td>Date : ___________________</td>
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Signature of the Investigator:

Signature of the Lecturer:

Signature of the HOD:
FORM IV – CLINICAL ASSESSMENT FORM

CLINICAL EVALUATION OF SEENTHIL KUDINEER A SIDDHA DRUG IN THE TREATMENT OF KATTUMANTHAM (DYSPEPSIA) IN CHILDREN.

1. S.l. No: 2. OP/ IP No: 3. Name:
4. Age: 5. Gender: 6. Date of Enrollment:

<table>
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<th>SL.NO.</th>
<th>Clinical Features</th>
<th>1ST DAY</th>
<th>2ND DAY</th>
<th>3RD DAY</th>
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<tr>
<td>1</td>
<td>Constipation</td>
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<tr>
<td>2</td>
<td>Consistency</td>
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<tr>
<td>3</td>
<td>Abdominal Pain</td>
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<tr>
<td>4</td>
<td>Fever</td>
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</tr>
<tr>
<td>5</td>
<td>Indigestion</td>
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<td></td>
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</tr>
<tr>
<td>6</td>
<td>Cough</td>
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<tr>
<td>7</td>
<td>Yawning</td>
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</tbody>
</table>

Signature of the Investigator:

Signature of the Lecturer:
Signature of the HOD:
A CLINICAL EVALUATION OF SEENTHIL KUDINEER FOR KATTU MANTHAM IN CHILDREN

FORM V – DRUG COMPLIANCE

1. S.I. No:  
2. OP/ IP No :  
3. Name:  
4. Age:  
5. Gender :  
6. Date of Enrollment:  
7. Date of completion:  
8. Informant :  
9. Reliability:  

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<th>NAME OF THE DRUG</th>
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<tr>
<td>ADMINISTRATION</td>
<td>PER ORAL</td>
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<tr>
<td>DOSE &amp; DURATION</td>
<td>10ml (BD) FOR 1 DAY</td>
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<tr>
<td>NO. OF DRUG POCKET GIVEN</td>
<td>56 GMS</td>
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<td>NO. OF DRUG POCKET RETURNED</td>
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<th>EVENING</th>
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<td>DAY 1</td>
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Date:  
Station:  

Signature of Principal Investigator:
FORM VI PATIENT INFORMATION SHEET

Name of Principal Investigator : __________________________
Name of the institute : National Institute of Siddha,
Tamaram Sanatorium,
Chennai-47.

INFORMATION SHEET FOR PATIENTS PARTICIPATING IN THE OPEN
CLINICAL TRIAL.

I, ________________________________________ Studying as PG Scholar at
National Institute of Siddha, Tamaram Sanatorium is doing a trial on the study “KATTU
MANTHAM”. I will maintain confidentiality of your comments and data obtained. There
will be no risk of disclosing your identity and no physical, psychological or professional risk
is involved by taking part in this study. Taking part in this study is voluntary. No
compensation will be paid to you for taking part in this study.

You can choose not to take part. However, taking part in the study may be of benefit to
the community, as it may help us to understand the problem of defaulters and potential
solutions.

If you agree your child to be a participant in this study, he/she will be included in the
study primarily by signing the consent form and then you will be given the internal medicine
SEENTHIL KUDINEER[10ml-twice a day].

The information I am collecting in this study will remain between you and the
principal investigator (myself).

If you wish to find out more about this study before taking part, you can contact
myself Dr.P.MIRUNALENI, PG Scholar 8122978302. You can also contact the Member-
secretary of Ethics committee, National Institute Siddha, Chennai 600047, Tel no : 91-44-
22380789, for rights and participation in the study.
குறிப்பிடும்

கட்டணம் புகழ்பூண்டப்படுத்தப்பட்ட குழு பெயரில் (சிற்றொல் குறிகள்) பரிசைப்படுத்தும் குத்துமடிப்புக் குறி விளக்கங்கள் தேவாரமல்லாது பல்லியைக் குறித்து பயணம்.

துணையுருவு அனுமானகள் விளக்கு : பி. பிரியாசாத்யரி

தினசரியுறுதியானது விளக்கு : இரண்டு குறிக்குறி பிழைகாண்டு பிழைக்

குறிப்பிட்டு வணக்கம் விளக்கங்கள்-47

தொலைவு குறிக்குறி பிணைப்பானும் பழமையான வணக்கம் செய்யப்படும் ஆனந்தங்கள் தெளிவாகப் பூச்சிக்கூடு, குறிக்குறி விளக்கங்கள் இந்த தொடர்பில், பெரும்பாலும் ஐந்து வருடங்கள் வருகை

தொடர் பாதுகாப்புக்கான குறிப்பிட்டு அனுமானத்தை அவசரமாக வாய்ப்பாட்டு வணக்கம் செய்யாமல் அவசரப்படும் வருவயதை இரண்டு பிழைக் குறிக்குறி பிழைக்குறி மற்றும் வருவயதை பிழைக்குறி மற்றும் வருவயதை பிழைக்குறி

இரு ஆனந்தங்கள் புகழ்பூண்டு துணையுருவுகள் எளிய வழி பாதையில் பெற்றுள்ள வருத்துப் பாதையில் இரண்டு குறிக்குறி பிணைப்பானும் பெரும்பாலும் தொடரியில் வருவயதை மற்றும் வருவயதை பிழைக்குறி

இரு ஆனந்தங்கள் புகழ்பூண்டு துணையுருவுகள் எளிய வழி பாதையில் பெற்றுள்ள வருத்துப் பாதையில் இரண்டு குறிக்குறி பிணைப்பானும் பெரும்பாலும் தொடரியில் வருவயதை மற்றும் வருவயதை பிழைக்குறி

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பதிக்கு இறுதியாக IEC (இரண்டு பிழைக்குறி) செய்யும் புகழ்பூண்டு
A CLINICAL EVALUATION OF SEENTHIL KUDINEER FOR KATTU MANTHAM IN CHILDREN.

FORM VII    WITHDRAWL FORM

1. S.l. No:  
2. OP/ IP No :  
3. Name:  
4. Age:  
5. Gender:  
6. Date of Enrollment:  
7. Date of completion:  
8. Informant:  
9. Reliability:  

Date of trial commencement :  
Date of withdrawal from trial :  
Reason(s) for withdrawal : Yes/ No  
Long absence at reporting : Yes/ No  
Irregular treatment : Yes/ No  
Shift of locality : Yes/ No  
Complication adverse reactions if any : Yes/ No  
Exacerbation of symptoms : Yes/ No  
Patient not willing to continue : Yes/ No  

Date:  
Signature of Principal Investigator
### Form VIII - Adverse Reaction

1. **S.l. No:**
2. **OP/ IP No:**
3. **Name:**
4. **Age:**
5. **Gender:**
6. **Date of Enrollment:**
7. **Date of completion:**
8. **Informant:**
9. **Reliability:**

<table>
<thead>
<tr>
<th>Name</th>
<th>Age</th>
<th>Gender</th>
<th>OPD/ IPD No</th>
<th>Registration No</th>
<th>Date of trial commencement</th>
<th>Date of withdrawal from trial</th>
<th>Description of adverse reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Date:**

Signature of Principal Investigator
1. Patient / consumer identification (please complete or tick boxes below as appropriate)

NATIONAL PHARMACOVIGILANCE PROGRAMME FOR SIDDHA DRUGS

**Reporting Form for Suspected Adverse Reactions to Siddha Drugs**

**Please note:**

i. All consumers / patients and reporters information will remain confidential.

ii. It is requested to report all suspected reactions to the concerned, even if it does not have complete data, as soon as possible.

Peripheral Center code: 

State: 

<table>
<thead>
<tr>
<th>Name</th>
<th>Father name</th>
<th>Patient / Record No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Occupation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Address</th>
<th>Date of Birth / Age:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Village / Town</td>
<td>Sex: Male / Female</td>
</tr>
<tr>
<td>Post / Via</td>
<td>Weight:</td>
</tr>
<tr>
<td>District / State</td>
<td>Degam:</td>
</tr>
</tbody>
</table>

2. Description of the suspected Adverse Reactions (please complete boxes below)

<table>
<thead>
<tr>
<th>Date and time of initial observation</th>
<th>Season:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Description of reaction</th>
<th>Geographical area:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

103
3. List of all medicines / Formulations including drugs of other systems used by the patient during the reporting period:

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Daily dose</th>
<th>Route of administration &amp; Vehicle – Adjuvant</th>
<th>Date</th>
<th>Diagnosis for which medicine taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>Siddha</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any other system of medicines</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. Brief details of the Siddha Medicine which seems to be toxic :

<table>
<thead>
<tr>
<th>Details</th>
<th>Drug – 1</th>
<th>Drug – 2</th>
<th>Drug - 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Name of the medicine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) Manufacturing unit and batch No. and date</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) Expiry date</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d) Purchased and obtained from</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e) Composition of the formulation / Part of the drug used</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
b) Dietary Restrictions if any

c) Whether the drug is consumed under Institutionally qualified medical supervision or used as self medication.

d) Any other relevant information.

5. Treatment provided for adverse reaction:

6. The result of the adverse reaction / side effect / untoward effects (please complete the boxes below)

<table>
<thead>
<tr>
<th>Recovered:</th>
<th>Not recovered:</th>
<th>Unknown:</th>
<th>Fatal:</th>
<th>If Fatal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe: Yes / No.</td>
<td>Reaction abated after drug stopped or dose reduced:</td>
<td>Reaction reappeared after re introduction:</td>
<td>Date of death:</td>
<td></td>
</tr>
</tbody>
</table>

Was the patient admitted to hospital? If yes, give name and address of hospital

7. Any laboratory investigations done to evaluate other possibilities? If Yes specify:

8. Whether the patient is suffering with any chronic disorders?

Hepatic Renal Cardiac Diabetes Malnutrition

Any Others
9. H/O previous allergies / Drug reactions:

10. Other illness (please describe):

11. Identification of the reporter:

<table>
<thead>
<tr>
<th>Type (please tick): Nurse / Doctor / Pharmacist / Health worker / Patient / Attendant / Manufacturer / Distributor / Supplier / Any others (please specify)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Name:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Address:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Telephone / E–mail if any:</th>
</tr>
</thead>
</table>

Signature of the reporter: Date:

Please send the completed form to:

Name & address of the RRC-ASU / PPC-ASU

The Director

National Institute of Siddha,
(Pharmacovigilance Regional Centre For Siddha dicine),
Tambaram Sanatorium, Chennai-600 047.

(O) 044-22381314 Fax : 044 – 22381314

Website : [www.nischennai.org](http://www.nischennai.org)

Email: niscennaisiddha@yahoo.co.in
This filled-in ADR report may be sent within one month of observation /occurrence of ADR

Who Can Report?

⇒ Any Health care professionals like Siddha Doctors / Nurses / Siddha Pharmacists / Patients etc.

What to Report?

⇒ All reactions, Drug interactions,

Confidentiality

⇒ The patient’s identity will be held in strict confidence and protected to the fullest extent.
⇒ Submission of report will be taken up for remedial measures only not for legal claim
A CLINICAL EVALUATION OF SEENTHIL KUDINEER FOR KATTU MANTHAM IN CHILDREN

FORM IX-DIETARY ADVICE FORM

<table>
<thead>
<tr>
<th>✓ THINGS TO TAKE</th>
<th>✗ THINGS TO AVOID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fruits-Fig, Papaya, Guava, Grapes, Bananas, apples, orange, dates</td>
<td>Refrigerated items</td>
</tr>
<tr>
<td>All greens eg-palak</td>
<td>Tin and canned foods</td>
</tr>
<tr>
<td>Fresh vegetable soups</td>
<td>Cream containing biscuits and cakes</td>
</tr>
<tr>
<td>Boiled water</td>
<td>Junk and fast foods</td>
</tr>
<tr>
<td>Fiber rich foods eg- whole-grain breads and cereals, almonds, legumes</td>
<td>White sugar</td>
</tr>
<tr>
<td>Use palm candy instead of white sugar</td>
<td></td>
</tr>
</tbody>
</table>
CERTIFICATE

Address of Ethics Committee: National Institute of Siddha, Tambaram Sanatorium, Chennai-600047, Tamil Nadu, India

Principal Investigator: Dr. P. Mirunaleni, P. G. Student, Kuzhandhai Maruthuvam

Protocol title: A clinical evaluation of Seenthil kudineer a Siddha drug for Kattumantham (Dyspepsia) in children

Documents filed

- 1) Protocol
- 2) Data Collection forms
- 3) Patient Information Sheet
- 4) Consent form
- 5) SAE (Pharmacovigilance)

Clinical trial Protocol (others – Specify) Yes

Informed consent documents Yes

Any other documents -

Date of IEC approval & its number NIS/IEC/8-14/20 - 26-08-2014

We approve the trial to be conducted in its presented form.
The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information / informed consent.

Chairman

Member Secretary
NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 600047
CERTIFICATE OF BOTANICAL AUTHENTICITY

Certified that the following plant drugs used in the Siddha formulation “Seenthil kudineer” (Internal) for the treatment of Kattumantham (Dyspepsia) taken up for Post Graduation Dissertation studies by Dr.P.Mirunaleni, M.D.(S), II year, Department of Kuzhandhai Maruthuvam, 2015, are identified and authenticated through Visual inspection, Experience, Education & Training, Organoleptic characters, Morphology, Micromorphology and Taxonomical methods as

*Tinospora cordifolia* (Willd.) Meirs (Menispermaceae), Stem
*Areca catechu* Linn. (Areaceae), Nut
*Operculina turpethum* (Linn.) Silova Manso (Convolvulaceae), Root
*Terminalia chebula* Retz. (Combretaceae), Fruit
*Zingiber officinale* Rosc. (Zingiberaceae), Rhizome
*Picrorhiza kurroa* Royle ex Benth. (Scrophulariaceae), Root
*Aloe barbadensis* Mill. (Liliaceae), Dried leaf

Certificate No: NISMB1892015

Date: 27-08-2015

Authorized Signatory
Siddha Central Research Institute
(Central Council for Research in Siddha, Ministry of AYUSH, Govt. of India)
Arumbakkam, Chennai – 600106
[Ph: 044-26214925, 26214809, Fax: 26214809, Email: crisiddha@gmail.com, Web: www.siddhacouncil.com]

01.03.2016

Name of the student: Dr. P. Mirunaleni, II Year Kuzhandai Maruthuvam,
National Institute of Siddha, Chennai-47.

<table>
<thead>
<tr>
<th>S.No</th>
<th>Parameter</th>
<th>Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Loss on Drying at 105°C</td>
<td>10.27 %</td>
</tr>
<tr>
<td>2.</td>
<td>Total Ash</td>
<td>4.92 %</td>
</tr>
<tr>
<td>3.</td>
<td>Acid insoluble Ash</td>
<td>0.53 %</td>
</tr>
<tr>
<td>4.</td>
<td>Water Soluble Extractive</td>
<td>20.55 %</td>
</tr>
<tr>
<td>5.</td>
<td>Alcohol Soluble Extractive</td>
<td>15.20 %</td>
</tr>
<tr>
<td>6.</td>
<td>pH</td>
<td>4.70</td>
</tr>
</tbody>
</table>

(R. Shakila)
Research Officer (Chemistry)

(Dr. P. Sathiyarajswaran)
Assistant Director (Scientist 2) l/c
**FULL DETAILS (Read-only) -> Click Here to Create PDF for Current Dataset of Trial**

<table>
<thead>
<tr>
<th><strong>CTRI No</strong></th>
<th>CTRI/2016/04/006818 [Registered on: 12/04/2016] Trial Registered Retrospectively</th>
</tr>
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<tbody>
<tr>
<td><strong>Acknowledgement Number</strong></td>
<td>REF/2015/08/009557</td>
</tr>
<tr>
<td><strong>Last Modified On:</strong></td>
<td>13/06/2016</td>
</tr>
<tr>
<td><strong>Post Graduate Thesis</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Type of Trial</strong></td>
<td>Interventional</td>
</tr>
<tr>
<td><strong>Type of Study</strong></td>
<td>Siddha</td>
</tr>
<tr>
<td><strong>Study Design</strong></td>
<td>Single Arm Trial</td>
</tr>
<tr>
<td><strong>Public Title of Study</strong></td>
<td>Clinical trial for dyspepsia in children</td>
</tr>
<tr>
<td><strong>Scientific Title of Study</strong></td>
<td>CLINICAL EVALUATION OF SEENTHIL KUDINEER FOR KATTU MANTHAM (DYSPEPSIA) IN CHILDREN.</td>
</tr>
<tr>
<td><strong>Acronym</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Secondary IDs if Any</strong></td>
<td><strong>Secondary ID</strong></td>
</tr>
<tr>
<td></td>
<td>NIL</td>
</tr>
</tbody>
</table>

**Details of Principal Investigator or overall Trial Coordinator (multi-center study)**

| **Name** | Dr PMirunaleni |
| **Designation** | PG Scholar |
| **Affiliation** | National Institute of Siddha |
| **Address** | National Institute of Siddha Tambaram sanatorium Chennai-47 National Institute of Siddha Tambaram sanatorium Chennai-47 Chennai TAMIL NADU 600047 India |
| **Phone** | 8122978302 |
| **Fax** |  |
| **Email** | mirunalenibsms@gmail.com |

**Details Contact Person Scientific Query Clarification(s) with Reply**

| **Name** | Dr PMirunaleni |
| **Designation** | PG Scholar |
| **Affiliation** | National Institute of Siddha |
| Modification(s) | National Institute of Siddha Tamaram sanatorium Chennai-47  
| Address | National Institute of Siddha Tamaram sanatorium Chennai-47  
| Phone | 8122978302  
| Fax |  
| Email | mirunalenibsms@gmail.com |

| Details Contact Person | Name | DrAAmalaHazel MDs  
| Designation | Lecturer  
| Affiliation | National Institute of Siddha Tamaram sanatorium Chennai-47  
| Address | Chennai  
| Type of Sponsor | Research institution and hospital |

| Source of Monetary or Material Support | Self |

| Primary Sponsor | Name | National Institute of Siddha  
| Address | National Institute of Siddha Tamaram sanatorium Chennai-47  
| Details of Secondary Sponsor | NIL  
| Countries of Recruitment | India |

| Sites of Study | Name of Principal Investigator | NIL  
| Site Address | NIL  
| No of Sites | 1  
| Phone/Fax/Email |  

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<table>
<thead>
<tr>
<th>Details of Ethics Committee</th>
<th>Clarification(s) with Reply Modification(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of Ethics Committees= 1</td>
<td></td>
</tr>
<tr>
<td>Name of Committee</td>
<td>Approval Status</td>
</tr>
<tr>
<td>Institutional Ethics Committee</td>
<td>Approved</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Regulatory Clearance Status from DCGI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Status</td>
</tr>
<tr>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Health Condition / Problems Studied</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Type</td>
</tr>
<tr>
<td>Patients</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Intervention / Comparator Agent Clarification(s) with Reply Modification(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
</tr>
<tr>
<td>Comparator Agent</td>
</tr>
<tr>
<td>Intervention</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age From</td>
</tr>
<tr>
<td>Age To</td>
</tr>
<tr>
<td>Gender</td>
</tr>
<tr>
<td>Details</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
</tr>
<tr>
<td>-------------------</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

| Method of Generating Random Sequence |  |
| Method of Concealment                |  |
| Blinding/Masking                     |  |

<table>
<thead>
<tr>
<th>Primary Outcome</th>
<th>Outcome</th>
<th>TimePoints</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Relief from the symptoms</td>
<td>2 days</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Secondary Outcome</th>
<th>Outcome</th>
<th>TimePoints</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>any toxicity of the drug</td>
<td>14 days</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Target Sample Size</th>
<th>Total Sample Size=&quot;40&quot;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Size from India=&quot;40&quot;</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Phase of Trial</th>
<th>Phase 2</th>
</tr>
</thead>
</table>

| Date of First Enrollment (India) | 15/09/2015 |
| Clarification(s) with Reply Modification(s) |  |
| Date of First Enrollment (Global) | No Date Specified |

| Estimated Duration of Trial | Years="1" |
|                            | Months="0" |
|                            | Days="0" |

| Recruitment Status of Trial (Global) Modification(s) | Not Applicable |
| Recruitent Status of Trial (India) | Open to Recruitment |

<table>
<thead>
<tr>
<th>Publication Details</th>
<th>After the study</th>
</tr>
</thead>
</table>

| Brief Summary | My trial drug contains Tinospora cardifolia (seenthil |
thandu), Araca catechu (kali pakku), Operculina terpethum (sivathai), Terminalia chebula (kadukkai), Zingiber officinalis (sukku), Picrorhiza scrophulariiflora (kadukurokini), Aloe barbadence (katralai sarugu). It is given to children below 3 years orally twice a day in decoction form for a day to relieve constipation.
Ingredients of Seenthil Kudineer

Fig 1 Zingiber officinalis

Fig 2 Picrorhiza scrophulariiflora

Fig 3 Araca catechu

Fig 4 Tinospora cardifolia
Fig 5 - Terminalia chebula

Fig 6 - Aloe barbadence (katralai sarugu)

Fig 7 - Operculina terpethum

Fig 8 - Seenthil kudineer