A CLINICAL STUDY ON

RATTHA MOOLAM

(BLEEDING PILES)

WITH THE EVALUATION OF SIDDHA DRUG

MOOLAROGA CHOORANAM

Dissertation Submitted by

Dr. B. ANBARASAN (Reg No: 321411101)

Under the Guidance of

Prof. Dr. N. ANBU, M.D(S)

Submitted to

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

In partial fulfillment of the requirements
For the award of the degree of

SIDDHA MARUTHUVA PERARIGNAR

DOCTOR OF MEDICINE (SIDDHA)

BRANCH I – MARUTHUVAM

POST GRADUATE DEPARTMENT OF MARUTHUVAM

THE GOVERNMENT SIDDHA MEDICAL COLLEGE

CHENNAI – 106

OCTOBER – 2017

CERTIFICATE

This is to certify that the dissertation entitled "**A CLINICAL STUDY ON RATTHA MOOLAM WITH THE EVALUATION OF SIDDHA DRUG MOOLAROGA CHOORANAM"** is a bonafide work done by **Dr. B. ANBARASAN**, Government Siddha Medical College, Chennai – 600 106 in partial fulfillment of the University rules and regulations for award of **SIDDHA MARUTHUVA PERARIGNAR** under my guidance and supervision during the academic year 2014 – 2017.

Name & Signature of the Guide

Name & Signature of the HOD

Name & Signature of the Principal

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CONTENTS

INTRODUCTION

INTRODUCTION

Plants have been using by humans since the age of primitive man. The primitive man had several opportunities to study the Plants, Minerals, Animal sources in several aspects which they used to overcome diseases and lead a healthy life.[1] Usage of medicinal plants was disappeared in recent past and nowadays it regains its importance among the population. India is blessed with rich flora, which can be harnessed to treat diseases through right knowledge. Herbs are the main source for traditional medicines along with metals and minerals.

There are many traditional medicines exist in the world that uses plant and animal sources for preparing medicines, among which Siddha medicine is unique. The word Siddha means "S***iddhi***" namely ***spiritual power***. All siddhars had this power. The traditional Siddha system of medicine is based on 96 thathuvas [or] principles. It includes mainly ***Tridosas*** & ***Panchabhutha*** theory. According to Siddha system of medicine, health is defined as the state of physical, psychological, social and spiritual component of a human being which has been given in *Thirumanthiram* as

"One that cures physical ailment is medicine
One that cures psychological ailment is medicine
One that prevents ailment is medicine and
One that prevents immortality is medicine"

-Thirumoolar

As per siddha system physical health of human body is maintained by the three basic vital humours namely**:**

1. Vatham
2. Pitham
3. Kabam

They are called as *uyirthathukal* when these vital humours get vitiated by the life style modifications and then they are called as kutrams and that leads to the diseases.

In siddha system of medicine the disease of human beings are classified into 4448 types on the basics of Mukkutram theory. The word Haemorrhoids is derived from Greek word '*Haimorrhoidesphlebes*' which means 'Bleeding veins'.

In Siddha system of Medicine Bleeding Piles may be compared with RatthaMoolam. Sage Yugi classified Moola Noi into 21 types. Bleeding Piles is one among them.

Now- a- days people neglect symptoms like constipation, which later on may produce, Haemorrhoids, prolapse and fissure-in-ano.

In India, the Prevalence is 4.2–7.9% and approximately 40,723,288 people are reported to have hemorrhoids.[2] One million new cases are reported annually. Currentstatistics suggest nearly half of the world's population experiences some form of hemorrhoids especially when they reach the golden age of fifty.

Moola noi (Haemorrhoids) is one among the 4448 diseases. Rattha moolam is one among the 21 types of Moola noi which is mentioned in Yugi vaithiya chinthamani. Rattha moolam is compared with 1st degree internal haemorrhoids in modern aspect.

Increased risk of being overweight, pregnancy, aging, lifestyle modification, lack of physical activities, sedentary occupation heredity and food habits are the factors of Hemorrhoids. People above 50 years of age are commonly affected.

In our Siddha system, Siddhars tells us plenty of drugs and preventive measures. In that, I took one of the medicines, ***MOOLAROGA CHOORANAM*** stated by Pulipani, in the text book ***"PULIPANI VAITHIYAM 500"***

In Ratthamoolam cardinal complaint is bleeding per rectum. Bleeding or Haemorrhage is one such condition, which has to be treated promptly with utmost care, and requires a pragmatic approach. Any failure to treat unbridled bleeding can lead to dangerous and often fatal consequences. The Siddha medicines have immense potential to cure diseases with minimal or no adverse effects. In this way, peoples with Bleeding haemorrhoids can be cured without adverse reactions through Siddha drug. So, I preferred to select Ratthamoolam as my dissertation topic.

The drug ***Moolaroga Chooranam***, indicates that it cures all types of **Moola Noi**. I hope this drug will definitely help to cure the **RATTHA MOOLAM** [BLEEDING PILES].

AIM

AND

OBJECTIVES

AIM AND OBJECTIVES

AIM:

The purpose of this study is to evaluate the safety and efficacy of Siddha herbal formulation "MOOLAROGA CHOORANAM" in the treatment of Rattha Moolam.

OBJECTIVES:

- Collection of various Siddha literatures of the study.
- Herbal identification and authentication of the trial drug.
- To prepare the trial drug "MOOLAROGA CHOORANAM" as per Standard operating procedure drug preparation.
- To study the evaluation of Siddha trial drug “MOOLAROGA CHOORANAM” for Rathamoolam.
- To evaluate the Biochemical, Physico-chemical analysis of the trial drug.
- To evaluate the safety profile like Acute toxicity , Sub acute toxicity of the trial drug in animal models as per OECD guidelines
- To correlate the Siddha aspects of Rathamoolam to Bleeding piles of modern medicine with respect to causes, pathology, and clinical features.
- To gather the Siddha diagnostic parameters by Mukutram, Udal thathukkal, Uyir thathukkal and En vakai thervugal.
- To use modern parameters to confirm the disease.
- To make a clinical observation about the disease in relation of age, sex, occupation, Socio-economic status.
- To subject all patients are to thorough investigation before and after treatment.
- To find out the statistical analysis and efficacy of the drug through clinical study.

REVIEW OF LITERATURE

SIDDHA ASPECT

REVIEW OF LITERATURE

SIDDHA ASPECT

In Siddha literature view they are 4,448 disease, classified by our Siddhars. Moolam is one of the disease. In Yugi munivar apepect he says twenty one types of Moola Noi, in text book of Yugi Vaidhiya Chinthamani. RATTHAA MOOLAM is one among them. According to Siddhar therayar

"அனில பித்த தொந்தமலாது மூலம் வராது"

In siddha aspect disease are diagnosed on basis of mukkuttram, In Moola Noi, Vadham and Pittham kuttrams are elevated.

RATTHAA MOOLAM

IYAL [DEFINITION]

Ratthaamoolam is a disease characterized by inflammation on one are more veins [Kaar kuruthi kuzhal] of sigmoid colon to rectum. It produces burning sensation, itching in the anus Bulging of veins during constipation, so that difficult to passing stools, rupture the veins and produce blood with stools.

VERU PEYAR [SYNONYM]

Kuruthi moolam

NOI VARUM VALI

According to ***Yugi Vaithiya Chinthamani,*** the causes of Moola Noi are,

"தந்தையா மதிகமாங் குளிரினாலும்
தரியாத வழற்சிவாற் கிரந்தியாலும்
புத்தையாம் பொருந்தாத உஷ்ணத்தாலும்
புணர்ச்சியாற் கோபத்தாற் சலிப்பினாலும்
கத்தையாம் வெகுகாரம் வேண்டலாலும்
கடினமா முப்பாலும் காரத்தாலும்
மொத்தையாம் வெகுதனங்கள் போனதாலும்
மூலம்வந்துற் புத்திமுனையுந்தானே"

“முனையாக மூத்தோரை வைதலாலும்
மோசங்கள் பண்ணியே கற்பழித்தும்
நினையாக நினைவிலொன்று வாக்கிலொன்றும்
நேர்ந்தபடி சொல்லுகின்ற நிட்டூரர்க்கும்
பனையாகப் பரதேசி பந்து வானோர்
பசித்திருக்க உண்டதோர் பாதகர்க்கும்
தனையாகச் சமாதானந் தவிற்க்கின்றோர்க்கும்
சண்டாளமூலம் வந்து சனிக்குந் தானே”[3]

- **யூகி வைத்திய சிந்தாமணி 800.**

- Due to heat
- Due to sexual extravagance
- Due to spicy & sour foods
- Due to selfishness & angry
- Due to mental illness

According to Thirumoolar Karukkidai Vaithiyam,

“காயத்தில் மூல ரோகங்
கண்டிடும் விதங்கள் கேளாய்
பாயொத்த பசியில் லாமை
பட்டினி கிடக்கில் வாய்வு
மாயத்தி லிருத்திக் கொண்டு
மலவரை யடக்கும் போது
ஓயத்த குண்டலிக்கு
ளூட்புகும் வாயு தானே”[4]

- **திருமூலர் கருக்கிடை வைத்தியம்**

- Loss of appetite
- Fasting
- Constipation

According to A***gathiyar paripooranam400*** Moola Noi occurs due to old ***Sins .***

"நீங்காத மூலநோய் கன்மத்தாலே
நிலைகெட்ட அபானத்தில் நெருப்போமீறி
வாக்காலே யபானத்தின் வாசல் தன்னில்
வந்து முலைமேகத்தால் சூட்டால் காணும்
தாக்கோ லாலடைத்தாற்போல் வாயுநின்ற
தன்மையுள்ள மலமதனை வரட்டித் தீய்ந்துப்
பேய்க்கொலம் பண்ணுமடா மூல ரோகம்
புலத்தியனே பழவினைகளின் நங்கேளே"[5]

- **அகத்தியர் பரிபூரணம் 400**

MURKURIGUNANGAL [SIGNS]

- Loss of appetite
- Indigestion
- Thirst sensation
- Weakness
- Anger
- Constipation

NOI ENN[TYPES]

According to Yugi muni,

"சனிப்பான மூலத்தின் பெயரே தெறால்
சமரசமாம் நீர்மூலஞ் செண்டுமூலம்
முனிப்பான முலை மூலம் சிற்று மூலம்
மூர்க்கமாம் வறண்டுமூலம்ரத்தமூலம்
தினிப்பான சீமூலம் ஆழிமூலம்
திணியான தமரகமா மூலத்தோடு
வனிப்பான வதமொடு பித்தமூலம்
வகையான சேத்துமத்தின் மூலமாமே
வகையாகுந் தொந்தமா மூலத்தோடு
வளர்கின்ற வினைமூலம் மேகமூலம்
பகையகும் பவுத்திரமா மூலத்தோடு
படர்கிரந்தி மூலமொடு குதையாமூலம்

புகையாகும் புறமூலஞ் சுருக்குமூலம்
பொருகின்ற சவ்வாகு மூலத்தோடு
துகையாகு மூலந்தானிருத் தொன்றும்
சூட்சமா யிதனுடைய சுரபங்களே"[6]

- யூகி வைத்திய சிந்தாமணி 800.

1. Chendu moolam
2. Mulai moolam
3. Varal moolam
4. **Ratthaa moolam**
5. Seezh moolam
6. Neer moolam
7. Aazhli moolam
8. Thamaraga moolam
9. Vali moolam
10. Azhal moolam
11. Aiya moolam
12. Thontha moolam
13. Vinai moolam
14. Mega moolam
15. Pavuthira moolam
16. Kirathi moolam
17. Siru moolam
18. Kutha moolam
19. Pura moolam
20. Churukku moolam
21. Chavvu moolam

Among the 21 types, 9 types are incurable & other 12 types are curable, Raththamoolam is a curable Moola Noi.

THEERUM [CURABLE]

1. Neer moolam
2. Peru moolam
3. Varal moolam
4. Vali moolam
5. Azhal moolam
6. Mega moolam
7. Kuzhli moolam
8. **Kuruthi moolam**
9. Pura moolam
10. Chavvu moolam
11. Churukku moolam
12. Kiranthi moolam

Moola Noi is classified by various type of authors, Some of the types are below.

In the text of ***Agathiyar paripooranam 400, Agathiyar*** describes 9 types of Moola Noi.

1. Ul moolam
2. Pura moolam
3. ***Ratthaa moolam***
4. Seezh moolam
5. Mulai moolam
6. Moola paandu
7. Vali moolam
8. Azhal moolam
9. Aiya moolam

In ***Agathiyar 2000,*** Moola Noi is classified into 10 types.

1. Ul moolam
2. Pura moolam
3. Vaadha kiraani
4. Pittha kiraani
5. Sileththuma moolam

6. Vadha piththa moolam
7. Pittha sileththuma moolam
8. Vatha siltthuma moolam
9. Kadukku moolam
10. **Sivappu moolam [Ratthaa moolam]**

POTHU KURIKUNAGAL [SYMPTOMS]

According to Yugi Vaithiya Chinthamani, the symptoms are

"சேதியாய் தொப்புள்தனில் வலித்து நொந்து
சிறுகுதிர் போற்பீறிட்டு ரத்தம் வீழும்
மேதியாய் மேனிவற்றி வெளுத்துப் போகும்
மிகக் கைகாலசந்துமே சோபை யாகும்
மாதியாய் மார்பிளக்கும் தலநோ வுண்டாம்
மயக்கந்தான் மிகுதியாய்த் தள்ளிப் போடும்
நாதியாய் கன்னிரண்டு மஞ்சள் போலாகும்
நலியு மிரத்த மூலத்தின் நண்புதானே"

- **யூகி வைத்திய சிந்தாமணி 800.**

- Pain around the umbilicus
- Bleeding during defecation
- Anaemia
- Pain in the limbs
- Giddiness

According to text book of Aathmaratchamirtham,

இரத்தமூலக்குணம்

"தொப்பூளைச்சுற்றி வயிறுவலித்து நொந்து ரத்தம்வீழும்
உள்ளும் மலஞ்சிக்கும் அடிவயிரையும் கைப்பையும் புளிப்பையும்
மிகவிரும்பும் அன்னஞ்செல்லாது உடல்வெளுத்து அபான
னூவித்தெரியும் வெப்புத்தோன்றும்"

- ஆத்மரட்சாமிர்தம் என்னும் வைத்தியசார சங்கிரகம்

- Pain in the umbilicus
- Constipation
- Enhance bitter & sour
- Loss of appetite
- Anaemia

இரத்தமூலப்பாண்டுக் குணம்

"பித்தம் உடம்பெங்கும் பாய்வதால் தேகம்வெளுத்தூஊதும் அந்த
பித்தம் உருண்டுதிரண்டு வயிற்றில்தங்கி பிதிர்போல்விளும் தொப்பு
ளைச்சுற்றி வலிகாணும் மேல்மூச்சுஇளைப்புக்காணும் அடிவயிரு இரையு
மலஞ்சிக்கும் அன்னஞ்செல்லாது கைப்பையும் புளிப்பையும் மிகவி
ரும்பும்யிதை ரத்தமூலபாண்டென்று சொல்லப்படும்"[7]

- **ஆத்மரட்சாமிர்தம் என்னும் வைத்தியசார சங்கிரகம்**

- Anaemia
- Excess of gas in the abdomen
- Loss of appetite
- Enhance bitter & sour

According to Thirumoolar Karukkidai Vaithiyam,

"இறுகுஞ்சீழ்மூல மெழுமண்டலம் போல
மறுக்காணம் கொண்டு வருகுஞ்சீழ்மூலம்
உருக்கியவயுவா லுதிரமும் தான் கூடி
நறுக்கி விழுக்காட்டும் தான் ரத்தமூலமே"[8]

- **திருமூலர் கருக்கிடை வைத்தியம்**

According to ***Agathiyar Guna Vagadam Nool*** **[9]**

"தானான ரத்தமூலம் சொல்லக்கேளு
தனியான உள்மூலந் தன்னில் நின்று
தேனாக வருகின்ற ரத்தமப்பா
தெளிவாக நாளத்தில் நின்று காணும்

ஊனான நாடிதனில் இருந்து எழும்
உள்ளபடி தோன்றுமடா ரத்தந் தானும்

மானான இது தீரவகையைக் கேளு
மக்களுக்கு சொல்லுகிறேன் மகிழ்ந்து கேளே
கேளடா ரத்தந்தான் நிதமாயப்பா
கெணிதமுடன் நாள்தோறும் கண்டாலுந்தான்
நாளடா துர்பலமா யிருந்தாலுந் தான்
நலமான தலைவலியு மடைந்தாலுந் தான்"[9]

- **அகத்தியர் குணவாகடம்**

- Bleeding per rectum through rectal vein
- Curable disease by treatment
- Bleeding for longer duration causes headache.

According to ***Thanvanthiri Vaithiyam***

"தொப்பூளும் வலித்து நொந்து துலங்கிட ரத்தம் வீழ்ந்து
அப்போது தந்தமூல மறியவே வெளியில் தள்ளுந்
தப்பரு மேனிவற்றித் தளர்வுடன் துயரந் தோன்று
மிப்படி குணவிரத்த மூலமென் றியம்பலாமே"[10]

- **தன்வந்திரி வைத்தியம்**

- Pain in the umbilicus
- Bleeding per rectum
- Protrusion of pile mass

According to ***Agathiyar Aayulvedham 1200***

"எச்சவாய்க்குள் தானரிக்கு மிதற்குமரித்தான் மலமிரத்தம்
வச்சக்கூட்டில் வீழாமகிழ்ந்தே நரம்புதான்சிறந்து
அச்சமறவே ரத்தவீளு மதுவாங் குறிகளவன்றி
நிச்சமுனிவர் மானிடர்க்கு நிகழ்த்துங் குறிகளிதுவாமே"[11]

- **அகத்தியர் ஆயுள்வேதம்1200**

- Burning sensation in the anus
- Constipation
- Bleeding per rectum

According to ***Theran Segarappa***,

"மலமிறுகித் தழையுஞ் சுவேத மையின்
வகைமையென குழற்கடைத்த தாமரைப்போல்
பலமிதமா யொருவேளை யபானஞ் சுற்றிப்
பதும முகிழ் விரியமைதிப் பிரசம் போலஸ்
சலசலெனப் பொசி குருதித்தில்லை பொங்கத்
தள்ளாடி வசமழியத் தளர்வுண்டாக்கி
நிலவரமற் றிடவஞரை யுஞற்று மையா
நீசத்துவ மூலகுண நிலைமை தானே"[12]

- **தேரன் சேகரப்பா**

- Hard consistency & white coloured faeces
- Constipation
- Bleeding per rectum

MUKKUTRA VERUBADU

Keelvaai kanal increased, due to the food habits. So it stimulates the vadha and pitha kuttram.

" வாயு புகுந்து மலத்தோ டபானத்தைத்
தேயு கூட்டித் திரட்டிச் சுருக்கிடும்"

NAADI

"வாதமெனும் நாடியது தோன்றில்
சீதமந்தமொடு வயிறுபொருமல் தரட்சிவாய்வு
சீதமுறுங் கிராணி மகோதரம் நீராமை
திரள்வாய்வு சூலை வலிகடுப்புத் தீரை
நீதமுறுங் கிருமிகுன்மம் அண்ட வாதம்
நிலையும்நீர்க் கிரிச்சரங்கள் தந்து மேகம்
பேதகமா முதரப்பிணி **மூல ரோகம்**
பேசவெகு பிணிகளுமே பொருளதாமே"

- **சதக நாடி**

“பொருளான வாதத்தில் பித்தஞ் சேர்ந்து
பொருந்து குணங்களா முஷ்ணவாயு சத்தி
செரியாமை புளித்தேப்பம் பொருமல் நீரிற்
சிவப்புமலம் பிடித்தலுருந் தாது நட்டம்
கருவான தேகமதி லுளைச்சல் சோம்பல்
கைகால் தறிப்புநாக் கசக்கு மன்னம்
பரிவான ஊண்குறைதல் ருசிகே டாதல்
பலநோயும் வருத்திவைக்கும் பாங்குதானே”

- **சதக நாடி**

“சிறப்பான பித்தத்தில் வாத நாடி
சேரிலுறு தாதுநட்டமுதர பீடை
உரைப்பாகச் செரியாமை குன்மஞ் சூலை
உற்றசுரங்கிராணி வயிற்றிரைச்சல்
அறைப்பாண ஓங்காரபுறநீர்க் கோர்வை
ஆயச மிரக்கமொடு மயக்கமூர்ச்சை
முறைக்காய்வு விஷவீக்கம் **மூல வாய்வு**
முரடான நோய்பலவும் முடுகும் பண்பே”

- **சதக நாடி**

“மூவரு மந்தமானால் முளைத்திடும் மூலமெல்லாம்”

- **குணவாகட நாடி**

THINAI

Geographically, the living country has been divided into five distinct physical regions, namely:-

- Kurunchi – Hilly regions
- Mullai - Forest regions
- Marutham – Fertile regions
- Neithal - Sea regions
- Palai – Sandy regions

Each regions has got its own characteristic features which influence the inhabitants, mental, physical, economic, occupational and cultural activities. In each regions on basis of its peculiar physical and climatic features some ailments are endemic. The preventive and curative measures for these ailments are stated in the medical literature.

KALAM (Seasons)

With reference to the position of the sun in the orbit, the year is divided into six seasons. They are,

- Kaar kalam – Aavani and Purattasi (August 17 to October 16)
- Koothir kalam – Ippasi and Karthigai (October 17 to December 15)
- Munpani kalam – Markazhi and Thai(December 16 (2016) to February 12 (2017)
- Pinpani kalam – Maasi and Panguni (February 13 to April 13, 2017)
- Elavenin kalam – Chithirai and Vaigasi (April 14 to June 14)
- Muduvenir kalam – Aani and Aadi (June 15 to August 16)

In every season there will be some changes in the land, water, plants, animals, and human beings, which will modify the physiology and rendering them more susceptible to certain specific disease which are common in these seasons.

The Siddhars had good knowledge about those changes and advised certain measures in the form of diet, purgative exercises, etc, to avoid the onset of such ailment.[13]

UYIR THATHU:

Knowledge of three Uyir thathus and seven Udal kattugal will be helpful to do detailed study on the disease.

VATHAM:

The term vatham denotes vayu, dryness, pain and flatulence.

Location of Vatham:

Vatham located in the abanan, face, idakalai, spermatic cord, pelvic bone, skin, nerves, joints, hairs and muscles. It's mathirai is 1.

TYPES OF VATHAM:

It is divided into 10 types;

1. PRANAN (Uyir Kaal)

It is responsible for respiration and digestion. In Ratthaa moolam some patients affected respiratory illness due to anaemic.

2. ABANAN (Keezhnokku Kaal)

It lies below the umbilicus responsible for the downward expulsion of stools, urine and constriction of anal sphinchters. In ***Ratthaa moolam*** many patients having constipation, itching and burning sensation in anus,bleeding per rectum, some patiohaving pile mass due to defect of this vaayu.

3.**VIYANAN (Paravu Kaal)**

It is responsible for Nourishment of whole body.

4.UTHANAN (Melnokku Kaal)

It is responsible for Speech, expelling vomitus, hic-cough

5.SAMANAN (Nadu Kaal)

It is responsible for the balancing of the vayus: absorption of nutrient's and balance of the body. In Ratthaa moolam some patients are affected.

6.NAGAN:

It is responsible for the movement for eyelids.

7.KOORMAN:

It is responsible for the sight, closing of eyelids, yawning and closure of mouth.

8.KIRUKARAN:

It is responsible for the secretion of mouth and nose, appetite, sneezing, cough. In ***Ratthaa moolam*** some of patients affected loss of appetite.

9.DEVATHATHAN:

It is responsible for aggravating of the emotional disturbances anger, etc.In Ratthaa moolam some patients are affected due to Insomnia.

10. THANAJAYAN:

It escapes from the head on the third day after death.[14]

TYPES OF PITHAM

It is the thermal life force of the body. It's mathirai ½.

Location Of Pitham:

Pitham is located in Pirana Vayu, blood , moolakini, heart, umbilical region, abdomen, sweating, saliva, eyes and skin.

Functions Of Pitham:

Pitham controls digestion, temperature, vision, appetite, thirst, taste and strength of the body. It is responsible for the formation of red or yellow colour in the body and heat especially during digestion. It is also responsible for giddiness, increase of blood, discolouration of stools, urine, anger, memory and bitter and sour taste.

TYPES OF PITHAM

1. **ANALA PITHAM**

   This is responsible for digestion of food. It located in stomach and intestine. In Ratthaa moolam some patients are affected.

2. **RANJAGA PITHAM**

   It is responsible for the colour and contents of blood. In ***Ratthaa moolam*** patients are affect in anaemia due to bleeding while daefecation.

3. **SAATHAGAM :**

   It lies in the heart. It is responsible for the action after thinking.In Ratthaa moolam all patients are affected.

4. **PRASAGAM:**

   It is responsible for the complexion of skin. In ***Ratthaa moolam*** patient having pale skin due to anaemic.

5. **AALOSAGAM**

   It is responsible for the vision.[15]

KABAM:

It is responsible for the stream line functions of the body and maintains body's defence mechanism intact. It is mathirai ¼.

Location Of Kabam:

Kapham is located in samana vayu, sperm, head, tongue, uvula, fat, bone marrow, blood, nose, chest, nerve, bone, brain, eyes, and joint and it provides the material for the structure of every cell of the body.

Functions Of Kabam:

Generally it acts as a distructive factor in the body. When Kaphem is in normal condition, it maintains heart function, taste, coolness of eyes, lubricates and aids free movements of the joints.

TYPES OF KABAM

1. **AVALAMBAGAM**

   It causes diseases of the respiratory system when it is affected thereby indirectly affecting the other Iyyams.

2. **KILETHAGAM**

   Appetite and digestion may not be normal when it is affected. In ***Ratthaa moolam*** some patients affected due to loss of appetite.

3. **POTHAGAM**

   It is present in the tongue and gives and taste.

4. THARPAGAM

Memory and perception of sense may be affected when this is deranged.

5. SATHIGAM

It is present in the joints and helps free movements. Some patients have mobility of joints is affected due to drying up of the synovial fluid.[16]

SEVEN UDAL THATHUKKAL:

There are seven primary body tissues which constitute the entire human body and all the organs of the various system.

1. SAARAM:

Saaram the end product of digestive process. It provides strength to the body and mind.

2. SENEER:

The saram after absorption is converted into seneer. It is provides for knowledge, strength and health complexion. In Ratthaa moolam patients have anaemia due to blood loss.

3. OON:

It gives figure and shape to the body. It is responsible for the movement of the body.

4. KOZHUPPU:

It provides lubrication to organs and thus facilitates their function.

5. ENBU:

Gives shape to the body, helps locomotion and protects vital organs.

6. MOOLAI (**MACHAI**)

Present in the bone and it gives strength, maintains the normal condition of the bone.

7. SUKKILAM OR (SURONITHAM)

Responsible for reproduction.[17]

PINIYARI MURAIMAI:

The method adopted to find out a disease in Siddha is known as Piniyari muraimai.

It is based on the following principles.

- Poriyal Arithal
- Pulanal Arithal
- Vinavuthal

"**Pori**" is the five organs of perception namely,

- Nose
- Eyes
- Tongue
- Ears
- Skin.

"***Pulan***" are the actions using Pori. They are *Sense, Smell, Taste, Vision,* and *Auditory* respectively.

Poriyalarithal and Pulanal Arithal, go hand in hand with the concept to examine the patients " Pori " and " Pulan" with that of the " Patients" Pori and Physician "Pulan".

"Vinavuthal" is a method of inquiring the detail of either the patients problem that made him to approach the physician from his own or his / her attendents who accompany them.

Along with, above mentioned principles is also carried out inspection in modern medicine. Besides, Thottuparthal (palpation) and Thattiparthal (percussion) are also used to diagnose a patient.

The primi method adopted to diagnose the disease is by means of " Envagai Thervugal " (Elight types of investigation), Envagai Thervugal of Physician instruments and can be understood by the following versus.

நாடி ஸ்பரிசம் நா நிறம் மொழி விழி

மலம் மூத்திரம் மிவை மருத்துவராயுதம்

Eight fold system of clinical assessments:

Siddhars have given eight diagnostic methodological tools. They are

1. Naadi
2. Sparisam
3. Naa
4. Niram
5. Mozhi
6. Vizhi
7. Malam
8. Moothiram

In ***Ratthaa moolam*** Naa, and vizhi keel affected due to anaemia, Malam affected due to constipation.

SPARISAM:

By sparisam, the temperature of skin (thatpam- cold or veppam – heat), smoothness, roughness, sweating, dryness, hard patches, swelling, abnormal growth of organs and tenderness can be felt.

- In Ratthaa moolam sparisam not affected.

NAA:

Signs and symptoms in the tongue are noted here. Colour salivary secretion, ulcers, coating, inflammation, taste changes, deviation and its nature are generally noted.

- In Ratthaa moolam, the naa is affected due to anaemia.

NIRAM:

The colour of the skin is noted here.

- In Ratthaa moolam,, Niram is affected, in case of severe anaemia.

MOZHI:

Character of the speech is noted, mainly uraththa oli (high pitched), thazhndha oli (low pitched), or resembles the sound of any instrument.

- In Ratthaa moolam, mozhi is not affected.

VIZHI:

Character of the eye is noted. Colour, warm, burning sensation, irritation, visual perception are generally noted.

MALAM:

The stools are examined for quantity, hardening (malakattu), loose motion (bedhi), colour and smell.

- In Ratthaa moolam, Malam was affected in all patients due to constipation.

MOOTHIRAM

NEERKURI (Urine examination)

Urine examination is good diagnosis method compare to naadi and Envagai thervugal. Theraiyar mention below as.

"அருந்து மாறி ரதமும் அவிரோதமதாய்
அக்கல் அலர்தல் அகாலவூன் தவிர்தழற்
குற்றளவருந்தி உறங்கி வைகறை
ஆடிக்கலசத் தாவியே காதுபெய்
தொருமுகூர்த்தக் கலைக்குட்படு நீரின்
நிறக்குறி நெய்குறி நிருமித்தல் கடனே."

- Noi Nadal Noi Muthal Nadal Thirattu

The early morning urine sample is collected and sample should be examined within one and half hours.

SIRUNEERIN POTHU GUNAM:

“வந்த நீர்க்கரி எடை மணம் நுரை எஞ்சலென
றைந்தியலுளவை யறைகுது முறையே.”

- Noi Nadal Noi Muthal Nadal Thirattu

The urine is examined for its Niram (colour), Eadai (Specific gravity), Nurai (Froth), Natram (Smell), Enjal (Deposits).

NIRA THOGAI

“பீதம் செம்மைபைங் கருமை வெண்மையென்
றோதைங் கொழுமையை யொத்துகு நீரே”[18]

- Noi Nadal Noi Muthal Nadal Thirattu

1. Yellow
2. Red
3. Green
4. Black
5. White

Urine may be any colour mentioned above.

EADAI (SPECIFIC GRAVITY)

“மிகத் தடிப்பும் மிகத் தேறலும் இன்றெனில்
சுகத்தைத் தரும் மெய்ச் சுபாவ நீர் நன்றே.”

- Noi Nadal Noi Muthal Nadal Thirattu

NAATRAM (SMELL)

“ஒதமணத்தோ டவவோத மொத்தி றங்கும்
சீதளஞ் கம்மிய தேகிகளுக்கே
காணிதில சீழுற் கலந்திழி மணமுறின்[19]
……

- Noi Nadal Noi Muthal Nadal Thirattu

NURAI (FROTH)

“பந்தமெய்ப் பசையிளகப்படும் பருவத்
தந்தர்ப் பூதமாய் அனில மூத்திரத்தில்
சம்பந்தப்படும் ததிநுரைப் புனலே”[20]

- Noi Nadal Noi Muthal Nadal Thirattu

ENJAL (DEPOSITS)

"நார்த்தி நீர்ப்பால் போல
நனவுற்ரங் கிழியு மானால்
மாரற்ப முற்ற நீரி
லடி மண்டிக் கிடந்த தானால்
பாரிந்த மெழுகு மாங்காய்
பற்றிய கல்வி னாலே
சீருற்ற செய்கை யென்று
தெரிவுறச் செப்ப லாமே."[21]

- Noi Nadal Noi Muthal Nadal Thirattu

- In Ratthaa moolam, There are no abnormal changes present in Neerkuri.

NEIKURI

The early morning urine of the patient is analyzed by dropping a drop of gingely oil on the surface of the urine sample. The accumulation, formations, changes, and dispersal under the sunlight without any external disturbances of the urine sample can be noted.

The urine kept on the kidney tray in sun light, on non wind condition, should be examined by dropping a drop of gingili oil gently with rod. If oil spread like snake, it indicates valineer, a ring indicates azhal neer and float like a pearl indicates iyya neer and sinks in urine indicates mukkutram.

"அரவென நீண்டினஃதே வாதம்
ஆழி போற் பரவின் அஃதே பித்தம்
முத்தொத்து நிற்கின் மொழிவதென் கபமே."[22]

- Noi Nadal Noi Muthal Nadal Thirattu

- Vatha neer – The oil spreads like snake
- Pitha neer – The oil spreads like ring
- Kabha neer – The oil spreads like pearl

- If the oil spreads gradually, it indicates good prognosis
- If the oil spreads fast or gets mixed completely with urine or sinks in urine, it suggests bad prognosis.

Ratthaa moolam, is due to derangement of vatham and pitham,

The Neikuri is pitha neer or vatha neer.

LINE OF TREATMENT

Purgatives are given as initial measures.

In Moola Noi, vadham is affected, So purgatives are administered on the previous day of medicine.

- Then administration of internal medicine.
- Avoid long duration of sitting
- Avoid spicy food

DIET REGIMEN FOR MOOLA NOI

- Karunai kilangu
- Vilangu meen
- Thuthi keerai
- Thaali keerai
- Pasalai keerai
- Vendhaya keerai
- Karunaikizhangu
- Saenaikizhangu
- Vendaikkai
- Atthikkai
- Kovaikkai
- Green vegetables
- Pork
- Snail
- Butter milk
- Butter
- Ghee

- Fiber content food
- Oat bran, Rice bran
- Fruits.
- Drink plenty of water.

MODERN ASPECT

MODERN ASPECT

ANATOMY OF THE RECTUM

DEFINITION:

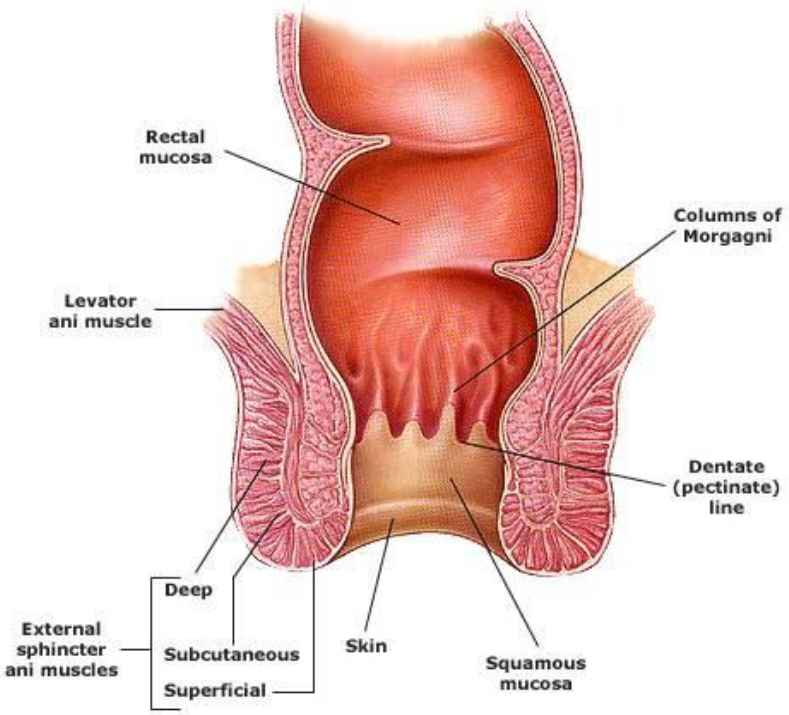
The rectum is the distal part of the large gut. It is placed between the sigmoid colon and anal canal. Distention of the rectum causes the desire to defaecate.

SITUATION

The rectum is situated in posterior part of the lesser pelvis, In front of the lower three pieces of the sacrum and coccyx.

DISTRIBUTION

The rectum is 12 cm in length, and it is Intraperitoneal at its proximal and anterior end, and is extra peritoneal at its distal and posterior end. The epithelial lining or mucosa of the rectum is of a simple columnar mucous secreting variety.[23]



PHYSIOLOGY

FUNCTIONAL PART OF RECTUM

Rectum has two functional parts. The upper part related to hindgut lies aboue middle fold of the rectum.It acts as a faecal reservoir which can freely distend anteriorly. The lower part of peritoneum lies below the middle fold it is empty in normal individuals, But may contain faeces in case of chronic constipation.

DAEFECATION REFLEX

The mass movements drive the faeces in to the sigmoid or pelvic colon.in the sigmoid colon the faeces is stored.The desire of daefecation when some of faeces enters rectum due to the mass movements.The desire of daefecation is elicited by an increase in the intrarectal pressure to about 20 to 25cm H_20.The process of daefecation the contraction of the rectum and relaxation of the internal and external anal sphincter.[24]

ANATOMY OF ANAL CANAL

DEFINITION

The Anal canal is the terminal part of the large intestine.

SITUATION

It lies in the anal triangle of peritoneum inbetween the the right and left ischiorectal fossae.

DISTRIBUTION

The anal canal is 3.8cm long.It extent from the ano-rectal junction to the anus. The dentate line is a imaginary line near the midpoint of the anal canal. This location lies, where the anal crypts are found.

ANORECTAL RING

This is a muscular ring present in the ano-rectal junction. It is formed by the pubo rectalis, deep external sphincter and internal sphincter.It is easily felt by a finger in the anal canal.[25]

PHYSIOLOGY OF THE ANAL CANAL

The proximal end of the anal canal is the point at which the columnar epithelium of the rectum becomes a transitional epithelium. This epithelium transitions to a stratified squamous variety at the dentate line. The distal most end of the anal canal is the anal verge which is the point where the stratified squamous epithelium becomes true skin marked by the presence of hair follicles and sweat glands. Anal glands secrete mucus that empty into the anal crypts by way of anal ducts.

BLOOD SUPPLY

The blood supply to the anorectal region is rich. The terminal branch of the inferior mesenteric artery is the superior hemorrhoidal (rectal) artery. The superior hemorrhoidal artery branches into right and left branches; the right branch further divides into anterior and posterior branches. The classic hemorrhoidal plexes are then located at the left later, right anterolateral, and right posterolateral locations. The middle hemorrhoidal (rectal) arteries are direct branches from the internal iliac arteries. The inferior hemorrhoidal (rectal) arteries are branches off the pudendal arteries which also arise from the internal iliac arteries.

The superior, middle, and inferior hemorrhoidal arteries complete the rich arterial supply to the anorectal region.

VENOUS DRINAGE

The venous drainage of the anorectal region consists of superior hemorrhoidal veins draining into the portal venous system (by way of the inferior mesenteric vein) and the middle and inferior hemorrhoidal veins draining into the caval system (by way of the internal iliac veins)

NERVE SUPPLY

The rectum is supplied by sympathetic[$L_{1,}L_2$] Parasympathetic[$S_{2,}S_{3,}S_4$] Superior rectal and inferior hypogastric plexuses.Pain sensation are carried by both of them.[26]

HAEMORRHOIDS

In greek-Haima = blood, Rhoos = flowing Syn. Piles in Latin-Pila = ball

Varicosities of the anal canal are known as haemorrhoids. It may be internal or external depending upon the position of the varicosity. If it is above the Hilton's line it is called 'internal haemorrhoid' and if it is below the Hilton's line it is called 'external haemorrhoids'. So internal haemorrhoid is covered with mucus membrane and external haemorrhoid is covered with skin.[27]

The veins which form internal haemorriods become engorged as anal lining descends and is gripped by the anal spincters. The two varieties may coexist and the condition is called intero-external Haemorrhoids.

Dilatation of the vein at the anal verge is sometimes seen in persons of secondary life particularly during staining. Peri anal hematoma or thrombosed external haemorroid-A small in the peri anal subcutaneous tissue can be seen superficial to ani muscle. This condition is due to back pressure on the anal venule consequent upon straining a stool, coughing or lifting heavy weight.

AETIOLOGY:

Hereditary - It often seen in members of the same family due to weakness of vein walls since birth.

Morphological -. In quadrupeds, gravity aid or at any rate does not retard,

return of venous blood from the rectum.

Anatomical - Absence of venous valves and lack of muscular or fascial support of the hemorrhoidal plexus.

Extreme looseness of the submucus connective tissue rendering the effect of gravity particularly harmful in thesitting and standing postures.

The passage of the tributaries of the superior hemorrhoidal vein directly through muscular wall of the rectum abouth 7 ½ cm above the anus causing intermittent constriction of the veins at the point.

The plexiform anastamoses just within the anus between inferior and middle and the superior hemorrhoidal tributaries so that the former, although connected with the systemic circulation, are subject to dilatation as result of portal junction.

The communication of superior haemorrhoidal vein with the inferior mesenteric vein and thus with portal system, which is subject to periodic physiologic congestion and to frequent pathologic obstructions.

The relation of the inferior hemorrhoidal veins and of the terminal branches of the inferior mesenteric veins to the fecal contents of the sigmoid and rectum, exposing them to frequent pressure.

Excisting causes – Once dilatation of the venous plexusbas well as partial prolapsed would occur with each bowel movement it would stretch the mucosal suspensory ligament.

Diet - Low roughage 'western' diet, consuming spicy foods etc.

PATHOLOGY:

Through Protoscopy the internal hemorrhoids are well visualized and can be divided in to three parts,

Pedicle – Lie just above the anorectal ring, covered with pale pink mucosa and through superior rectal vein can be seen.

Body of internal haemorriod – After the pedicle, it distally ends at the dentate line. It is covered by red or purple mucous membrane.

Associate external Haemorroid – It lies between the dentate line and the anal margin and it is covered by skin. Each primary internal haemorroid contains main three terminal divisions of superior rectal artery & vein, In lithotomy position it's ***left lateral*** [**3**'Oclock] ***right lateral*** [**7**'Oclock] ***right posterior*****[11**'Oclock][28]

CLINICAL FEATURES:

BLEEDING

It is the earlist symptom of haemorrhoids. It is bright red in colour, painless and occurs during daefecation [**a splash in pan**].It may continuously or intermittently thus for months or years. In this condition that bleeds but does not prolapsed outside the anal region.

PROLAPSE

It is a lateral symptom. According to prolapsed Hemorrhoids can be divided into four types.

FIRST DEGREE

First degree haemorrhoids are those in which hypertrophy of the internal haemorrhoidal plexus remains entirely within the anal canal as the mucosal suspensory ligaments remain intact. Patients in this stage usually present with Rectal bleeding and discomfort or irritation. Bleeding is bright red and occurs during daefecation as Splash in the pan. It may continue for months or years.

SECOND DEGREE

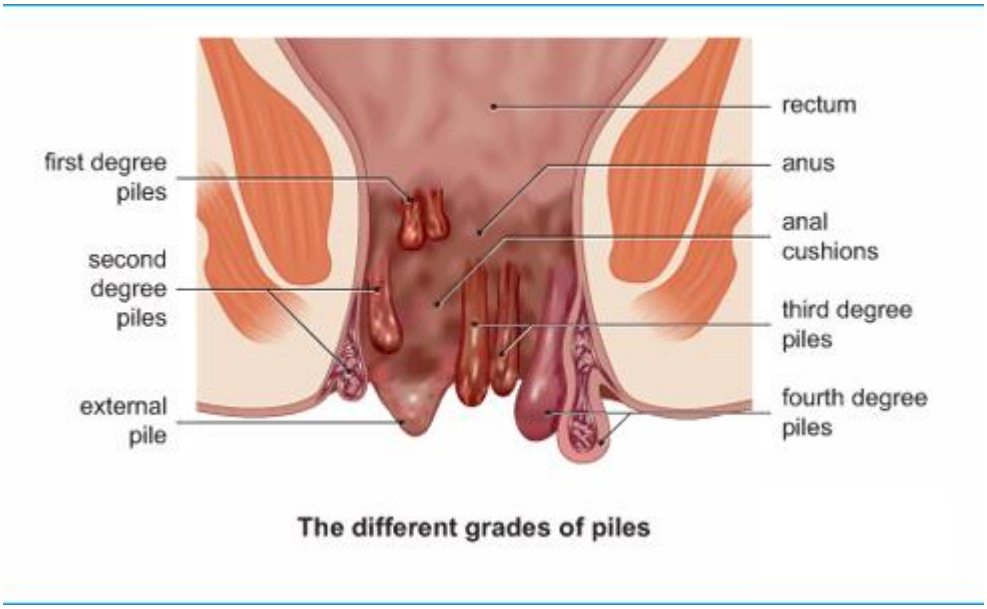
Haemorrhoids occur when with further hypertrophy, the mucosal suspensory ligaments become lax and piles will descend, so that they prolapsed during daefecation. But spontaneous reduction takes place afterwards. There may be a small skin tag. Some mucosal discharge, soreness and irritation.

THIRD DEGREE

Haemorrhoids, they remain prolapsed after daefecation and require replacement. This often descends spontaneously or on exercise. The mucosas overlaying such haemorrhoids undergo squamous metaplasia. Mucosal discharge and pruritis ani become troublesome and anaemia become obvious, secondary haemorrhoids occur between the three primary ones, the most common being the mid posterior portion. There may be a large skin tag.[27]

FOURTH DEGREE

The Haemorrhoids that are permanently prolapsed.



The different grades of piles

PAIN

It is not characteristic of Haemorroid unless there is associated thrombosis or fissure in ano.

MUCOUS DISCHARGE

It is a particular symptom of prolapsed Haemorrhoids.

ANAEMIA

Is often seen in long standing causes of Haemorrhoids.

DIAGNOSIS

In the begining with a physical examination to find out any swollen veins that may be causing external hemorrhoids. During this physical examination. Procedures such as a colonoscopy, anoscopy, sigmoidoscopy, or proctoscopy will used any possible abnormalities. In case of internal hemorrhoids, an endoscopy is used to examine inside the anus.

DIFFERENTIAL DIAGNOSIS

- Anal fissure
- Ano-rectal abscess
- Fistula
- Rectal prolapsed
- Pruritis
- Rectal polyps [29]

COMPLICATIONS:

- Thrombosis
- Fissure in ano
- Pyelophlebitis
- Fibrosis[30]

TRIAL DRUG

TRIAL DRUG REVIEW

Drug Name: Moolaroga chooranam

Reference: Pulipani vaithiyam 500

Preparation:

மூலரோக சூரணம்

“போமேநீ மூலமென்ற ரோகந்தீரப்
பூட்டுகிறேன் மருந்தொன்று சொல்லக்கேளு
ஆமேநீ தூதுவளை மூலத்தொடு
அடைவான ம்ருட்கிழங்கு கருணைமூலம்
தாமேநீ பிரண்டைவேர் நல்லவாரை
தயவான காட்டுடைய கருணைமூலம்
வாமேநீ மிலகருணை மூலந்தாணும்
வளமான அறுகினுடக் கிழங்குதானே

தானென்ற நீர்ப்பூண்டு கிழங்கு மூலி
தயவாக உரலிலிட்டுத் தூளாய் செய்து
கோனென்ற பொடியெள்ளாம் சமனாய் சேர்த்துக்
கொடுப்பாயே விரற்கடைதான் தேனிற் கொள்ள
நானென்ற நாற்பது நாள் கொள்ளும்போது
நடுங்கி மூலமெல்லாம் ஓடும்பாரு
வானென்ற போகருட கடாட்சத்தாலே
வளமான புலிப்பாணி விளம்பினேனே”[31]

- **புலிப்பாணி வைத்தியம் 500**

INGREDIENTS:

ROOTS OF THE FOLLOWING PLANTS:

- Thoothuvalai (*Solanum trilobatum*)
- Marul kizhangu (*Sansevieria roxburghiana*)
- Karunai kizhangu *(Amorphophallus paeoniifolius)*
- Pirandai *(Cissus quadrangularis)*
- Nilavaarai (Cassia senna)
- Kaatu karunai *(Amorphophallus sylvatus)*
- Arugan kattai *(Cynodon dactylon)*
- Neermulli *(Hygrophila auriculata)*
- Milagaranai *(Toddalia asiatica)*

All the ingredients are taken in equal ratio.

All the ingredients are purified, powdered and stored in an air tight container.

REFERENCE **:** PULIPPAANI VAITHIYAM 500

DOSE **:** 1 Gram, Twice a day

ADJUVANT **:** Honey

DURATION **:** 48 Days

PROPERTIES OF TRIAL DRUGS:

1. THOOTHUVALAI

Botanical name	**:**	*Solanum trilobatum*
Family	**:**	Solanaceae
Taste	**:**	Bitter, Pungent
Thanmai	**:**	Veppam
Pirivu	**:**	Kaarppu

Phytochemicals:

- Sobatum
- B- solamarine
- Solasodine
- Solaine
- Glycol alkaloid
- Diosogenin
- Saponin
- Tannin[32]

Action :

- Stimulant
- Anti inflammatory
- Expectorant
- Tonic

Gunam:

“தூதுபத்திரி யூன்சுவை யாக்கும்பூ
தாது வைத்தழைப் பித்திடும் காயது
வாத பித்தக பத்தையு மாற்றுவோர்
ஓதும் வல்லிபன் நோயுமொழிக்குமே” [33]

- **குணபாடம் மூலிகை வகுப்பு**

2. MARUL KIZHANGU

Botanical name	**:**	*Sansevieria roxburghiana*
Family	**:**	Liliaceae
Taste	**:**	Pungent, Sweet
Thanmai	**:**	Veppam
Pirivu	**:**	Kaarppu

Phytochemicals:

- Sansivierine
- Palmitic acid
- Phthalate
- Delta undecalactone
- N- hexadecanoic acid
- Pentadecanone
- Methyl hexadecanoate[34]

Action:

- Purgative
- Tonic
- Stimulant

Gunam:

"தொண்டைக்கட் டையந் தொலையும் மகோதரமும்
பண்டைப்பல் வீக்கம் பறக்குங்காண்- கெண்டைவிழி
மானே! மருள்கிழங்கால் மாறு **மூலங்களெலாந்**
தானே பசியெழும்புந் தான்" [35]

- **குணபாடம் மூலிகை வகுப்பு**

3. KARUNAI KIZHANGU

Botanical name	**:**	*Amorphophallus Paeonifolius*
Family	**:**	Araceae
Taste	**:**	Pungent
Thanmai	**:**	Veppam
Pirivu	**:**	Kaarppu

Phytochemicals:

- Alkaloids
- Flavanoids
- Fats
- Fixed oils
- Tannins
- Phenols
- Carbohydrates
- Proteins and amino acids
- Sterol
- Terpenoid [36]

Action:

- Stimulant
- Astringent

Gunam:

"சத்தகு **தாங்குரத்தை** துட்கபம் மேதையதி
கத்தை விலக்குங் கறியமைக்கிற்-பத்தியமாஞ்
சீரணத்தை யங்கொடிய தீபனத்தை யுங்கொடுக்குஞ்
சூரணத்தின் தண்டெனவே சொல்" [37]

- **குணபாடம் மூலிகை வகுப்பு**

4. PIRANDAI

Botanical name	**:**	*Cissus quadrangularis*
Family	**:**	Vitaceae
Taste	**:**	Pungent
Thanmai	**:**	Veppam
Pirivu	**:**	Kaarppu

Phytochemicals:

- Quarcetin
- Quadrangularin
- α and β amyrins
- Kaempferol
- Resveratrol
- Pallidol
- Piceatanon
- Perthinocissi
- Carotene
- Vitamin C[38]

Action:

- Alterative
- Emmenagogue
- Stomachic

Gunam:

"பிரண்டையைநெய் யால்வறுத்துப் பின்னரைத்து மாதே!
வெருண்டிடா தேற்று விழுங்கில்-அரண்டுவரும்
மூலத் தினவடங்கும் **மூலவி ரத்தமறும்**
ஞாலத்தி னுள்ளே நவில்" [39]

- **குணபாடம் மூலிகை வகுப்பு**

5. NILAVAARAI

Botanical name	**:**	*Cassia sennna*
Family	**:**	Cesalpinoideae
Taste	**:**	Bitter
Thanmai	**:**	Veppam
Pirivu	**:**	Kaarppu

Phytochemicals:

- Sennaside A
- Sennaside B[40]

Action:

- Purgative
- Laxative

Gunam:

"நிலாவாரை யிங்குணந்தான் நீகேள் மயிலே!

பல**மூல வாயு**வெப்பு பாவைச்-சிலகிரந்தி

பொல்லாத குன்மம் பொருமுமலக் கட்டுமுதல்

எல்லா மகற்றுமென எண்"[41]

- **குணபாடம் மூலிகை வகுப்பு**

6. KAATTU KARUNAI

Botanical name	**:**	*Amorphophallus sylvatus*
Family	**:**	Araceae
Taste	**:**	Bitter
Thanmai	**:**	Veppam
Pirivu	**:**	Kaarppu

Action:

- Stomachic
- Rubefacient

Phytochemicals:

- Alkaloids
- Tannins
- Steroids
- Flavanoids
- Glycosides
- Volatile oil
- Sterol
- Flavanoids
- Saponins
- Phenol compound[42]

Gunam

"மேகமணு காது வெகுதீ பணமாகுந்
தேகமதில் **மூலமுளை** சேராதே-போகாச்
சுரதோடம் போங்கரப்பான் றோன்றும் வனத்திற்
பரவுகரு ணைக்கிழங்காற் பார்" [43]

- **குணபாடம் மூலிகை வகுப்பு**

7. ARUGANKATTAI

Botanical name	**:**	*Cynodon dactylon*
Family	**:**	Poaceae
Taste	**:**	Sweet
Thanmai	**:**	Thatpam
Pirivu	**:**	Inippu

Chemical constituents:

- Linolenic acid
- Hexadecanoic acid
- Benzofuran
- Levoglucosenone
- Cinnamic acid
- Tumerone
- Vanillic acid
- Syringic acid
- Hexanediamide
- Pantolactone [44]

Action:

- Styptic
- Astringent
- Emolient
- Diuretic

Gunam:

"அறுகம்புல் வாதபித்த ஐயமோ டீளை
சிறுக அறுக்குமின்னுஞ் செப்ப-அறுவுதரும்
கண்ணோ யொடுதலைநோய் கண்புகையி ரத்தபித்தம்
உண்ணோ யொழிக்கு முரை" [45]

- **குணபாடம் மூலிகை வகுப்பு**

8. NEERMULLI

Botanical name	**:**	*Hygrophila auriculata*
Family	**:**	Acanthaceae
Taste	**:**	Sweet, Light bitter
Thanmai	**:**	Thatpam
Pirivu	**:**	Inippu

Chemical constituents:

- Asteracanthine
- Asteracanthicine
- Hentricontyle acetate
- Stigmasterol
- Lupeol
- Hentricotane
- Betulin
- Luteolin
- Glucuronide
- Apigenin[46]

Action:

- Refrigerant
- Diuretic
- Demulcent

Gunam:

"பாண்டு குளுப்பையறும் பாரிலுறு நீரேற்றம்
மாண்டுவிடும் நீர்க்கட்டு மாறுங்கான்- பூண்டதொரு
வீக்கமெல்லாம் நீராய் விடுமேநீர் முள்ளிக்குத்
தாக்கு மயில்விழியால்! சாற்று".[47]

– பதார்த குண சிந்தாமணி

9. MILAGARANAI

Botanical name	**:**	*Toddalia asiatica*
Family	**:**	Rutaceae
Taste	**:**	Astringent
Thanmai	**:**	Thatpam
Pirivu	**:**	Kaarppu

Chemical constituents:

- Toddalenol
- Toddalosin
- Toddalenone
- Oxyavicine
- Bergapten
- Luvangetin
- Diosmin
- Diosmetin
- Norbraylin
- Robustine
- Dictamine[48]

Action:

- Stimulant
- Tonic
- Diaphoretic
- Antiperiodic

Gunam:

"ஐயம் கற்றும் அசீரணவா தம்போக்குஞ்
செயயப்பித்த சூலைகளை தீர்குங்காண்-பையவரும்
ஈளை இருமல் இரைப்புப்பு சந்தொலைக்கும்
நாளு மிளகரணை நன்று" [49]

- **குணபாடம் மூலிகை வகுப்பு**

INGREDIENTS OF TRIAL DRUG

Thuthuvalai ver

Thoothuvalai plant

Nilavarai ver

Nilavarai

Pirandai ver

Pirandai

Neermulli root

Neermulli plant

Milagaranai ver

Milagaranai plant

Arugan kattai

Marul

Karunai

Kattukarunai

MOOLAROGA CHOORANAM

MATERIALS AND METHODS

MATERIALS & METHODS

STUDY DESIGN:

A clinical trial on RATTHA MOOLAM was conducted at the OPD section of POST GRADUATE, POTHU MARUTHUVAM DEPARTMENT attached to ARIGNAR ANNA HOSPITAL OF INDIAN MEDICINE, Chennai-106, during the period 2015- 2017.

A Study was approved by Institutional Ethics Committee(IEC) and the approval number is GSMC-CH-ME-4/2015/002. The study was registered in Clinical trials Registry,India (CTRI) and the CTRI number is CTRI/2017/05/008568.

POPULATION AND SAMPLE:

The sample consists of all patients satisfying the inclusion and exclusion criteria mentioned below. Population consists of *Rattha moolam* patients attending the OPD of Arignar Anna Hospital, Arumbakkam, Chennai-106.

SAMPLE SIZE:

The trial size was 40 patients.

INCLUSION CRITERIA:

- Age 20 to 60 years
- Patients with appropriate symptoms like, bleeding during defecation, Constipation,
- Loss of appetite
- Giddiness, tiredness
- Patients who are all willing to give blood samples at subsequent visit are involved in this study.

EXCLUSION CRITERIA (CLINICAL HISTORY):

- Pregnant and lactating women
- External haemorrhoids
- Fissure in ano
- Second degree haemorrhoids

- Fistula
- Hypertension
- Diabetes mellitus
- CA Rectum

WITHDRAWAL CRITERIA:

- Intolerance to the drug and development of any serious adverse effects during the trial (If ADR is reported the patient was to be directed to RPC)
- Patients turned unwilling to continue in the course of clinical trial
- Poor compliance.
- Any other acute illness which need rescue medication.

DURATION OF TREATMENT:

48 days.

EVALUATION OF CLINICAL PARAMETERS:

The history includes past, personal, family, occupation, dietary habits, seasonal history, and associated history.

CLINICAL INVESTIGATIONS:

BLOOD:

TC, DC, ESR, Hb , Sugar, Urea,

Serum Creatinine, Cholesterol, Bleeding time, Clotting time.

URINE:

Albumin, Sugar, Deposit

MOTION:

Occult blood, ova, cyst

SPECIFIC INVESTIGATIONS

Proctoscopy

SIDDHA ASSESSMENTS:

- Envagai thervugal
- Neerkuri
- Neikkuri

A case sheet format was prepared on the basis of the Siddha methodology ex: Envagai thervvugal, Mukkutram, Nilam, Kaalam, Udal thathukkal, including Neerkuri and Neikuri. Individual case sheet was maintained for each patient at outpatient department.

RESULTS

AND

OBSERVATIONS

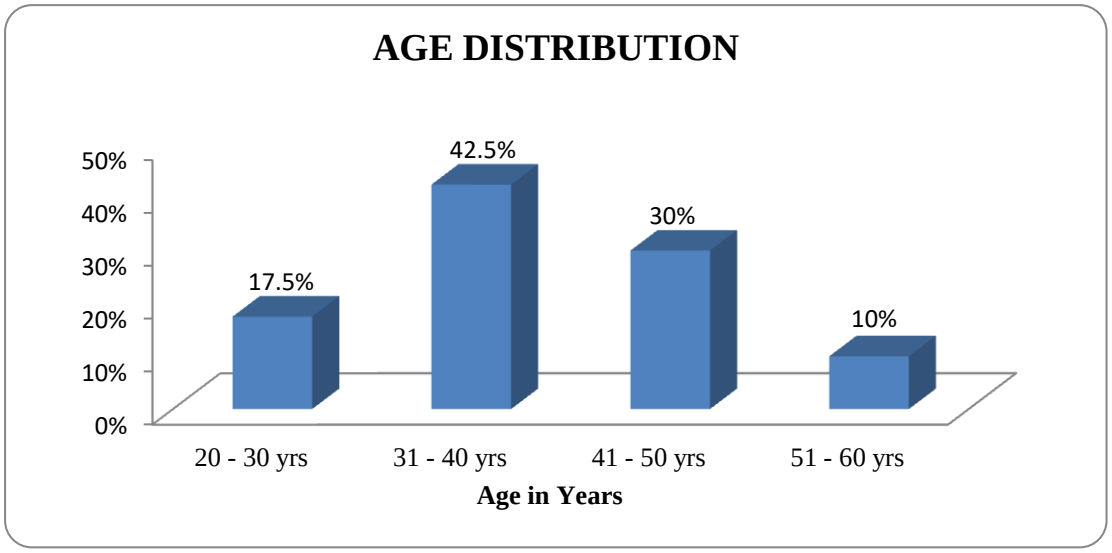
RESULTS AND OBSERVATIONS

The study on Ratthamoolam was carried out in 40 patients in the Department of Pothu Maruthuvam, Government Siddha Medical College, Chennai-106 attached to Arignar Anna hospital during 2015-2017 were analyzed. The observation were made and tabulated with following criteria.

- Age Distribution
- Gender Distribution
- Occupational status
- Socio economic status
- Dietary habits
- Seasonal occurrence
- Thinai
- Mukkutram- Vatham, Pitham, Kabam
- EzhuUdalKattugal
- EnvagaiThervugal
- Naadi
- Neikuri
- Grading of Results

AGE DISTRIBUTION

S.No	AGE IN YEARS	NUMBER OF CASES	PERCENTAGE (%)
1	20 - 30 yrs	7	17.5%
2	31 - 40 yrs	17	42.5%
3	41 - 50 yrs	12	30%
4	51 - 60 yrs	4	10%

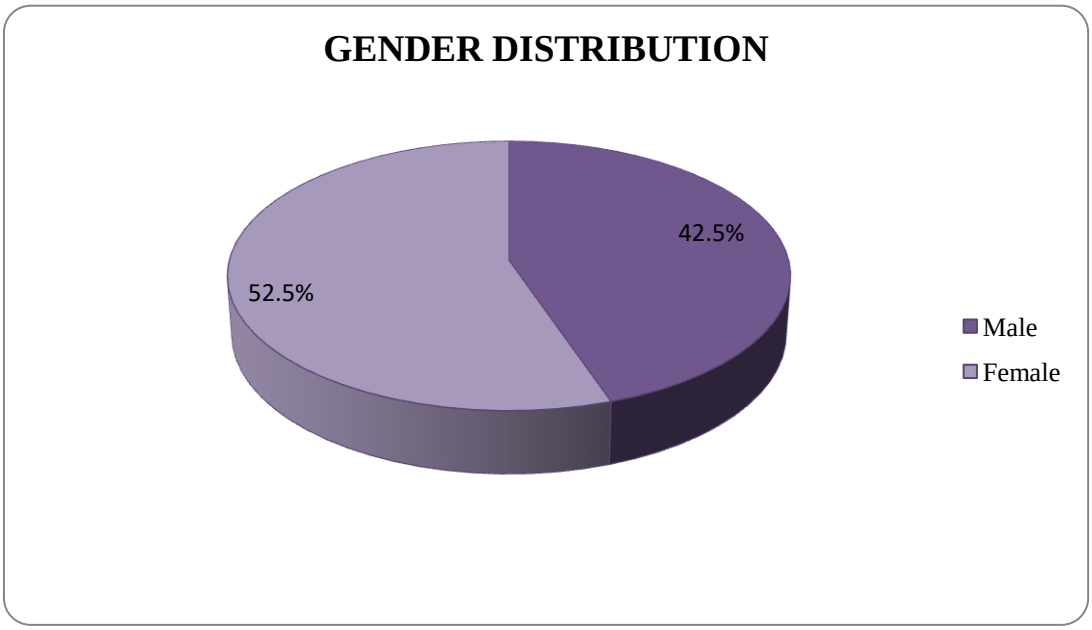


Inference:

According to the above mentioned data, 7 patients (17.5%) were in age group of 20-30 years, 17 patients (42.5%) were in age group of 31-40 years, 12 patients (30%) were in age group of 41-50 years, 4 patients (10%) were in age group of 51-60 years.

GENDER DISTRIBUTION

S. No	GENDER	NUMBER OF CASES	PERCENTAGE (%)
1	Male	19	47.5%
2	Female	21	52.5%

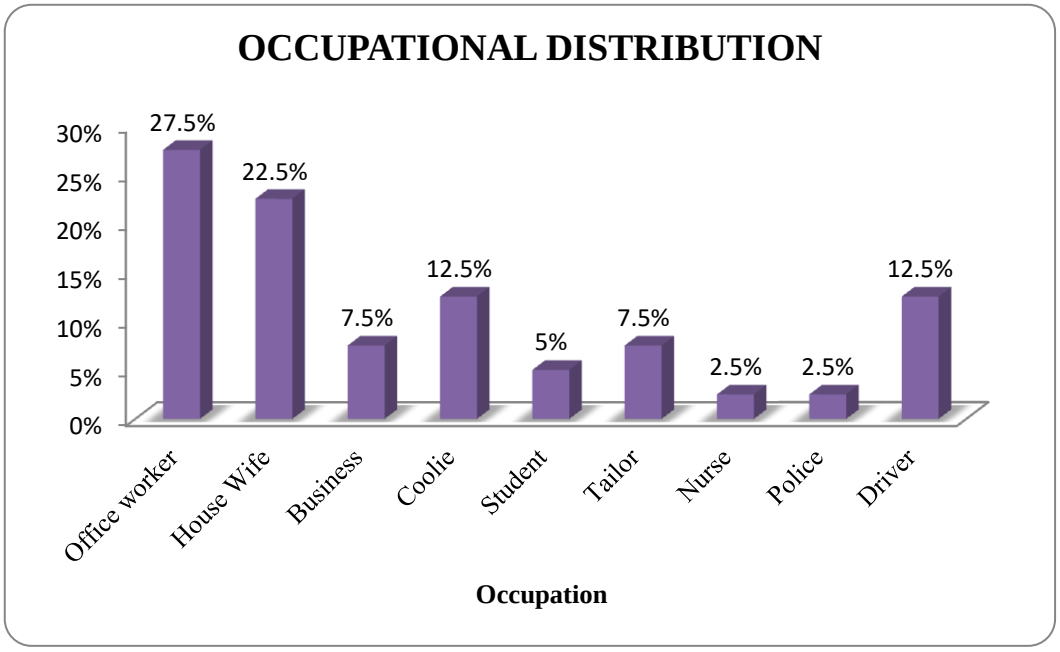


Inference

About 19 patients (47.5%) were males and 21 patients (52.5%) were females.

OCCUPATION

S.No	OCCUPATION	NUMBER OF CASES	PERCENTAGE (%)
1	Office worker	11	27.5%
2	House Wife	9	22.5%
3	Business	3	7.5%
4	Coolie	5	12.5%
5	Student	2	5%
6	Tailor	3	7.5%
7	Nurse	1	2.5%
8	Police	1	2.5%
9	Driver	5	12.5%

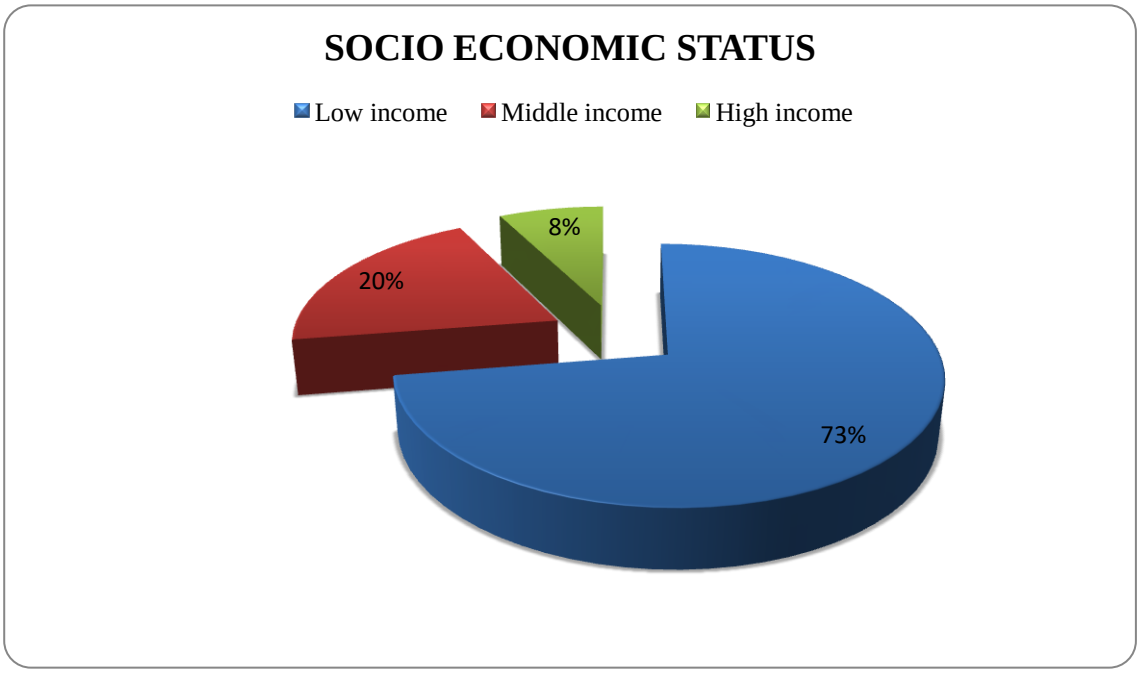


Inference:

Out of 40 patients, 11 patients (27.5%) were Office workers, 9 patients (22.5%) were House wives. 3 patients (7.5%) were Business persons. 5 patients (12.5%) were Coolie labourers, 2 patients (5%) were Students, 3 patients (7.5%) were Tailors, 1 patient (2.5%) was Nurse, 1 patient (2.5%) was Police and 5 patients (12.5%) were Drivers.

SOCIO ECONOMIC STATUS

S. No	SOCIO – ECONOMIC STATUS	NUMBER OF CASES	PERCENTAGE (%)
1	Low Income (below 2 Lakh per annum)	29	72.5%
2	Middle Income (2 - 5 Lakh per annum)	8	20%
3	High Income (Above 5 Lakh per annum)	3	7.5%

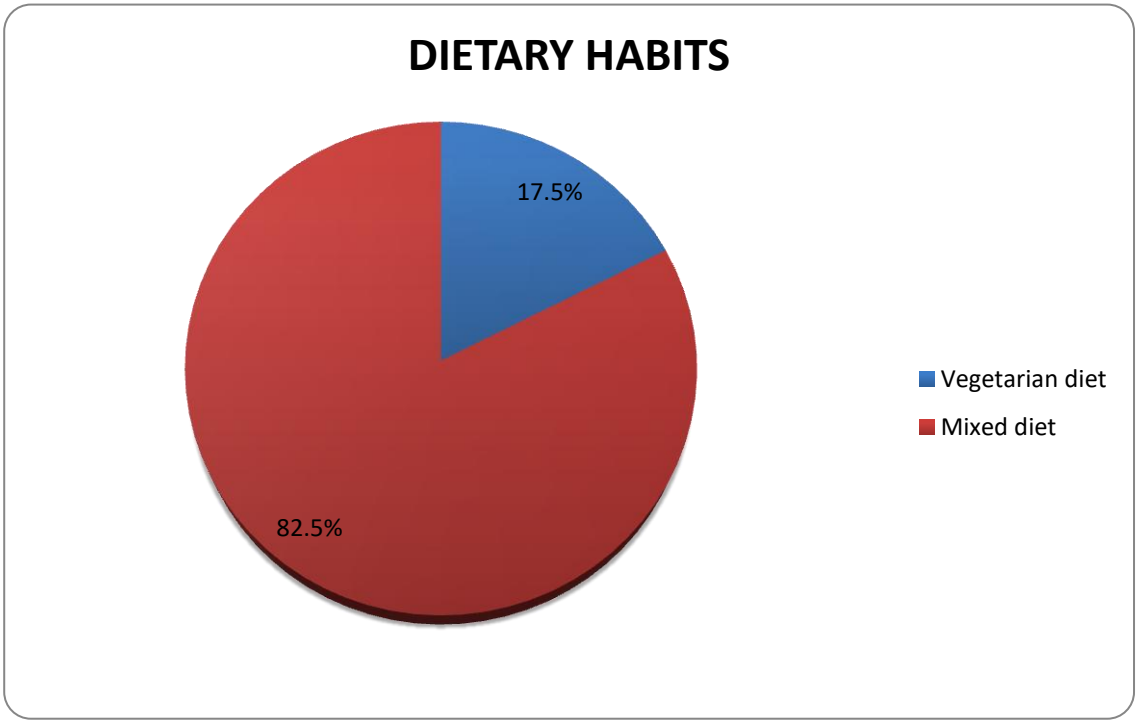


Inference:

Among 40 cases 29 cases (72.5%) comes under low economic status, 8 cases (20%) of them under moderate status and 3 cases (7.5%) of them under high income status.

DIETARY HABITS

S.No	DIET	NUMBER OF CASES	PERCENTAGE (%)
1	Vegetarian	7	17.5%
2	Mixed diet	33	82.5%

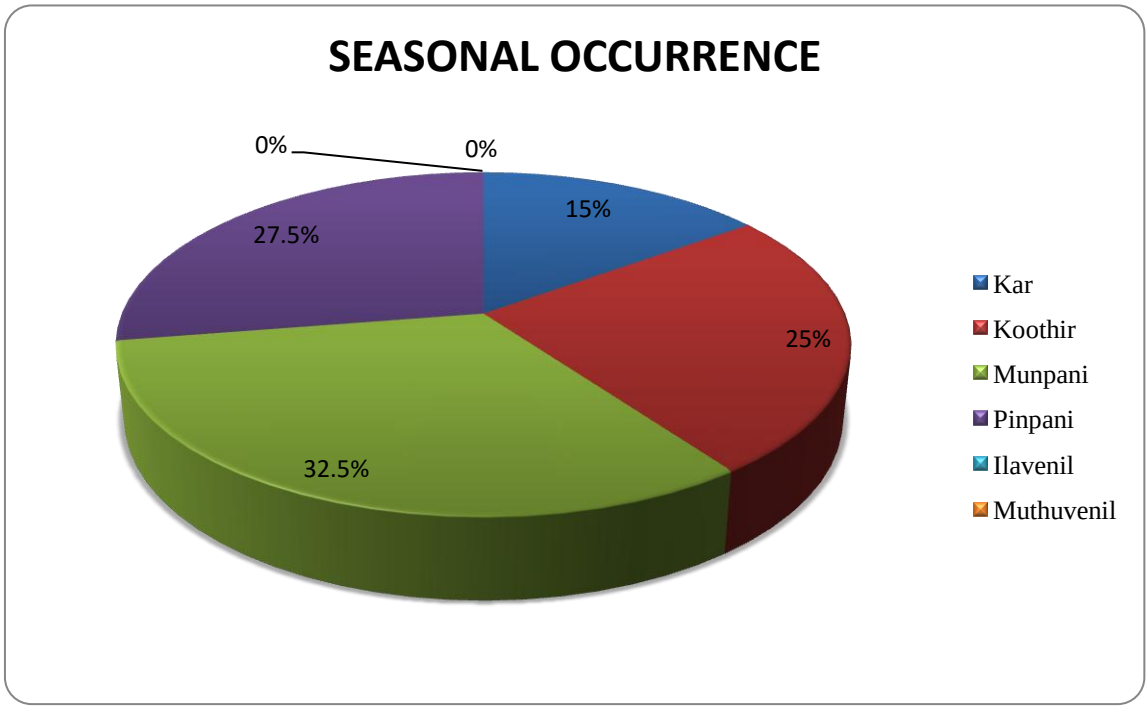


Inference

Among 40 patients, 7 patients (17.5%) were taking vegetarian food and 33 patients (82.5%) were taking mixed diet.

SEASONAL OCCURRENCE

S.No	KAALAM (Season)	NUMBER OF CASES	PERCENTAGE (%)
1	Kar kaalam (Aug 17 – Oct 16, 2016)	6	15 %
2	koothir Kaalam (Oct 17 – Dec 15, 2016)	10	25 %
3	Munpani kaalam (Dec 16,2016 – Feb 12, 2017)	13	32.5 %
4	Pinpani kaalam (Feb 13 – Apr 13)	11	27.5 %
5	Elavenir kaalam (Apr 14 – Jun 14, 2017)	0	0 %
6	Muthuvenir kaalam (Jun 15 – Aug 16, 2017)	0	0 %

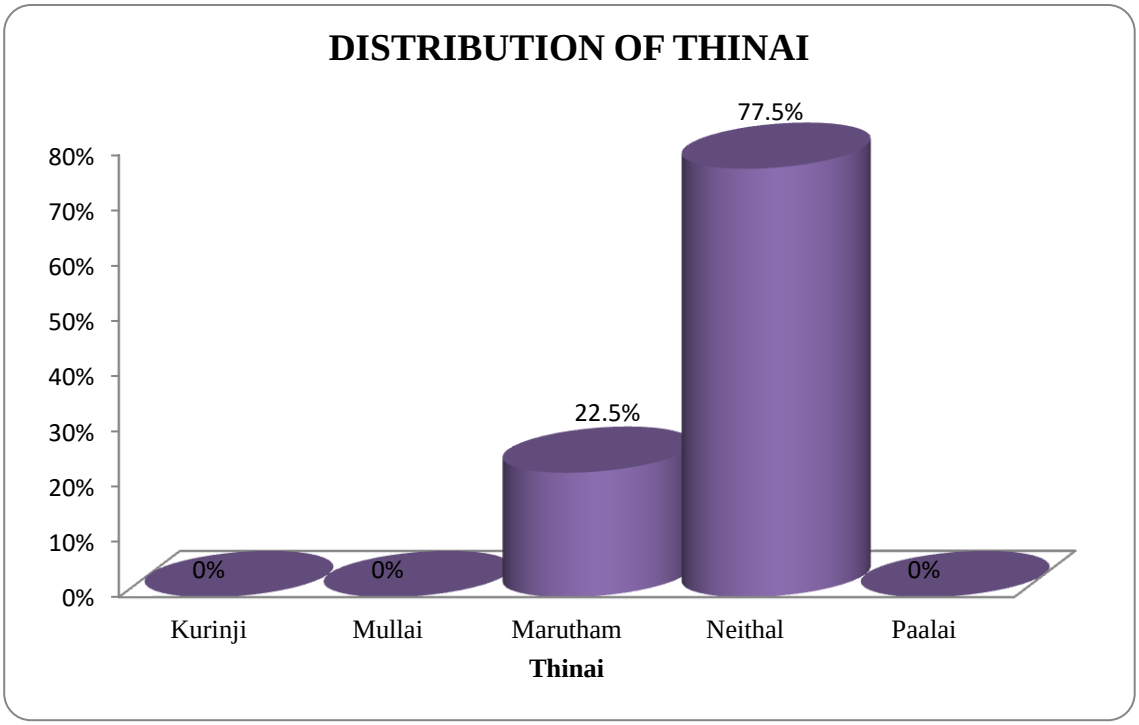


Inference

In paruvakaalam highest incident of cases, 13 cases (32.5%) were noted in Munpani kaalam , 11 cases (27.5%) were noted in Pinpani kaalam, 10 cases (25%) were noted in Koothir kaalam, 6 case (15%) were noted in karkaalam.

DISTRIBUTION OF THINAI

S.No	THINAI	NUMBER OF CASES	PERCENTAGE (%)
1	Kurinji	0	0 %
2	Mullai	0	0 %
3	Marutham	9	22.5 %
4	Neithal	31	77.5 %
5	Paalai	0	0 %



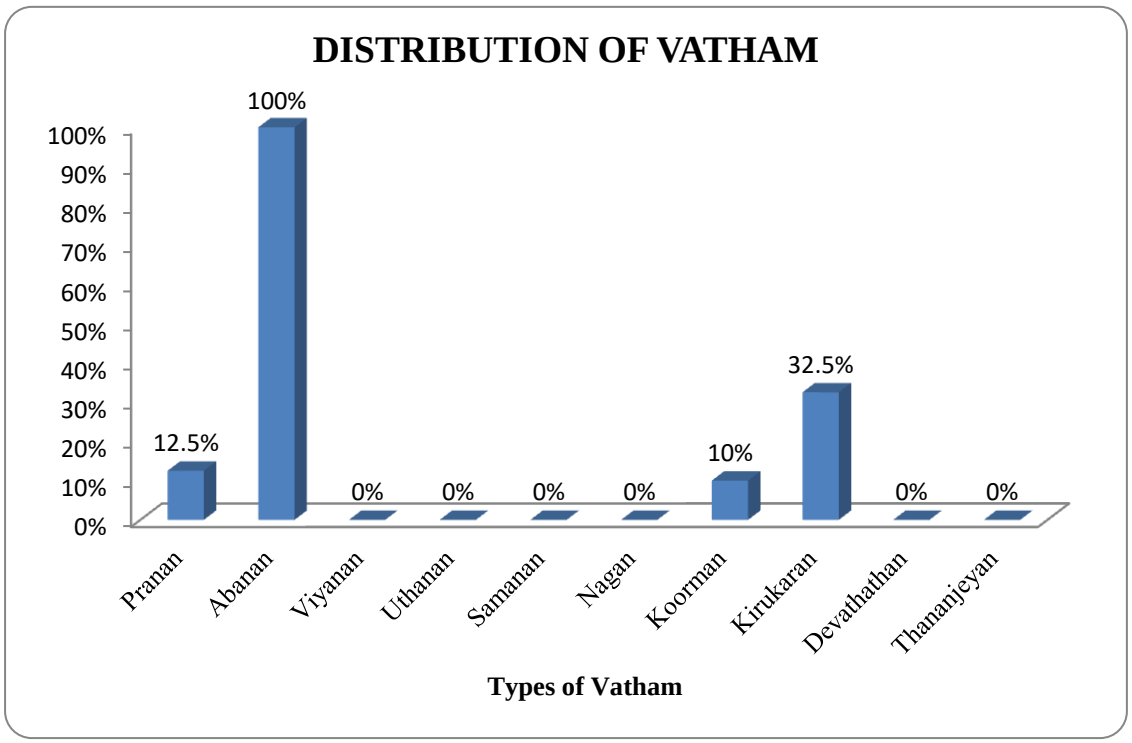
Inference:

Among 40 cases, 31 cases (77.5%) were from Neithal and 9 cases (22.5%) cases were from Marutha nilam

DISTRIBUTION OF MUKKUTRAM

VATHAM

S.No	VATHAM	NUMBER OF CASES	PERCENTAGE (%)
1	Pranan	5	12.5%
2	Abanan	40	100%
3	Viyanan	0	0%
4	Uthanan	0	0%
5	Samanan	0	0%
6	Nagan	0	0%
7	Koorman	4	10%
8	Kirukaran	13	32.5%
9	Devathathan	0	0%
10	Thananjeyan	-	-

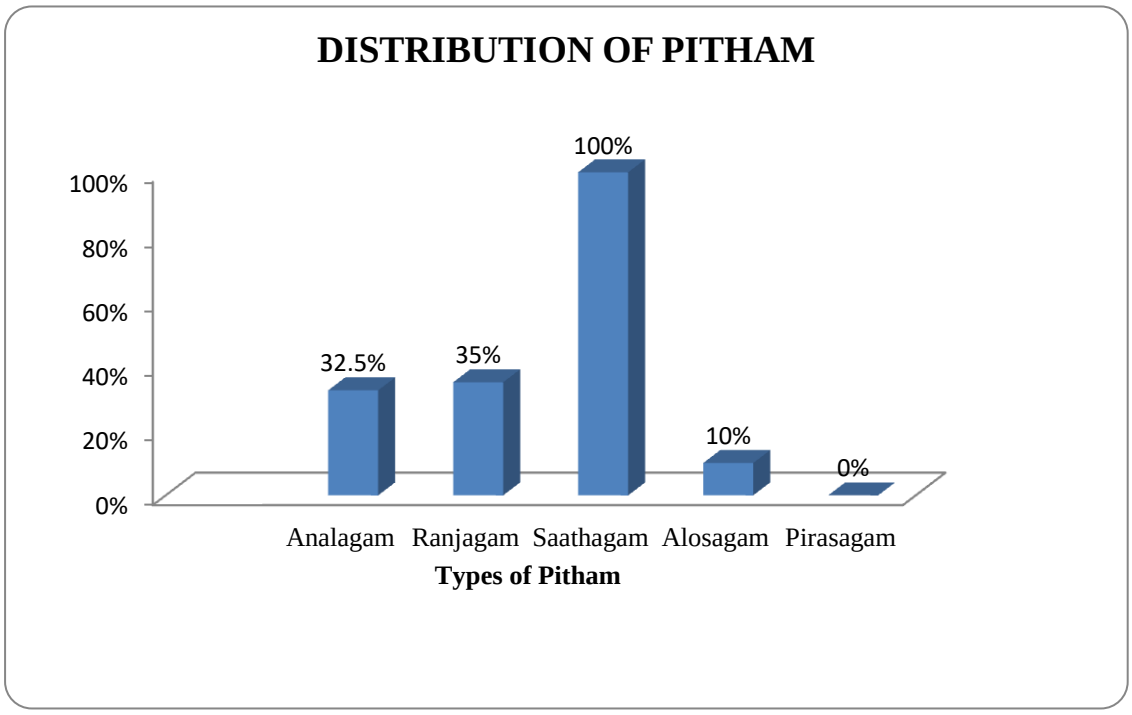


Inference

Out of 40 patients, Pranan was affected in 5 cases (12.5%), Abanan was affected in all the 40 patients (100%), Koorman was affected in 4 cases (10%) and Kirukaran was affected in 13 patients (32.5%).

PITTHAM

S.No	PITHAM	NUMBER OF CASES	PERCENTAGE (%)
1	Analagam	13	32.5%
2	Ranjagam	14	35%
3	Saathagam	40	100%
4	Alosagam	4	10%
5	Pirasagam	0	0%

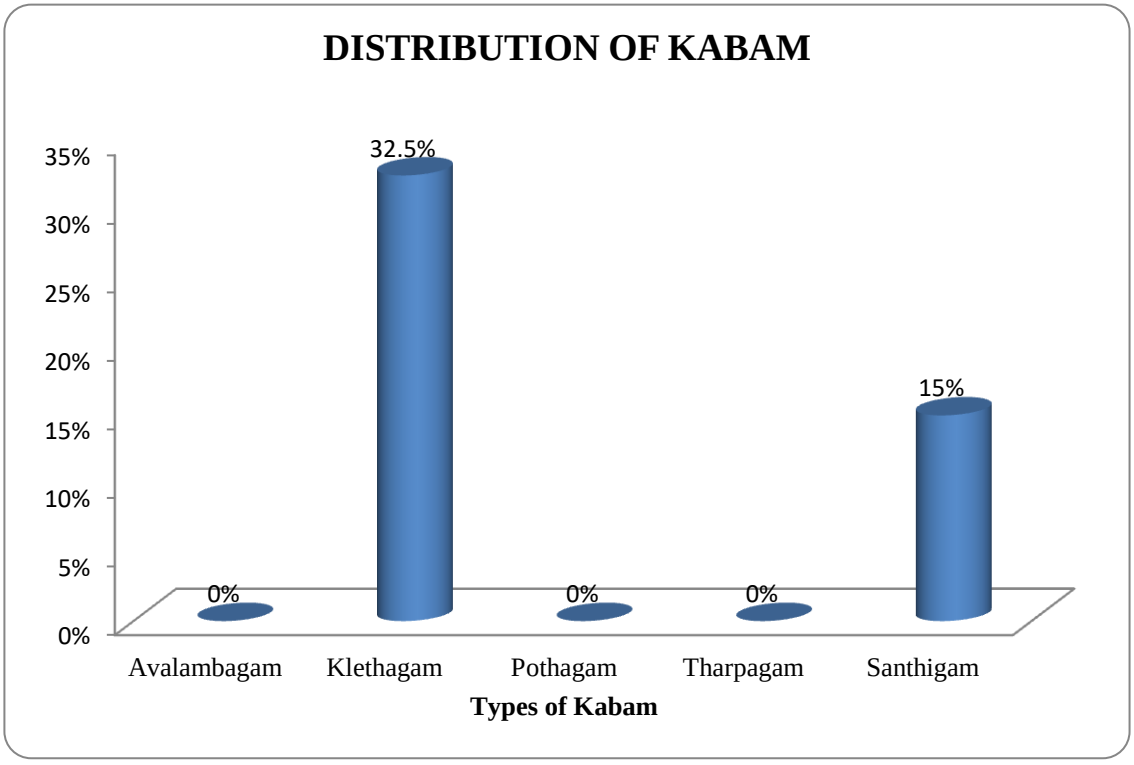


Inference

Among 40 patients, Analaga pitham was affected in 13 patients (32.5%), Ranjagam was affected in 14 patients (35%), Saathagam was affected in all the 40 patients (100%) and Alosagam was affected in 4 cases (10%).

DISTRIBUTION OF KABAM

S.No	KABHAM	NUMBER OF CASES	PERCENTAGE (%)
1	Avalambagam	0	0%
2	Klethagam	13	32.5%
3	Pothagam	0	0%
4	Tharpagam	0	0%
5	Santhigam	6	15%

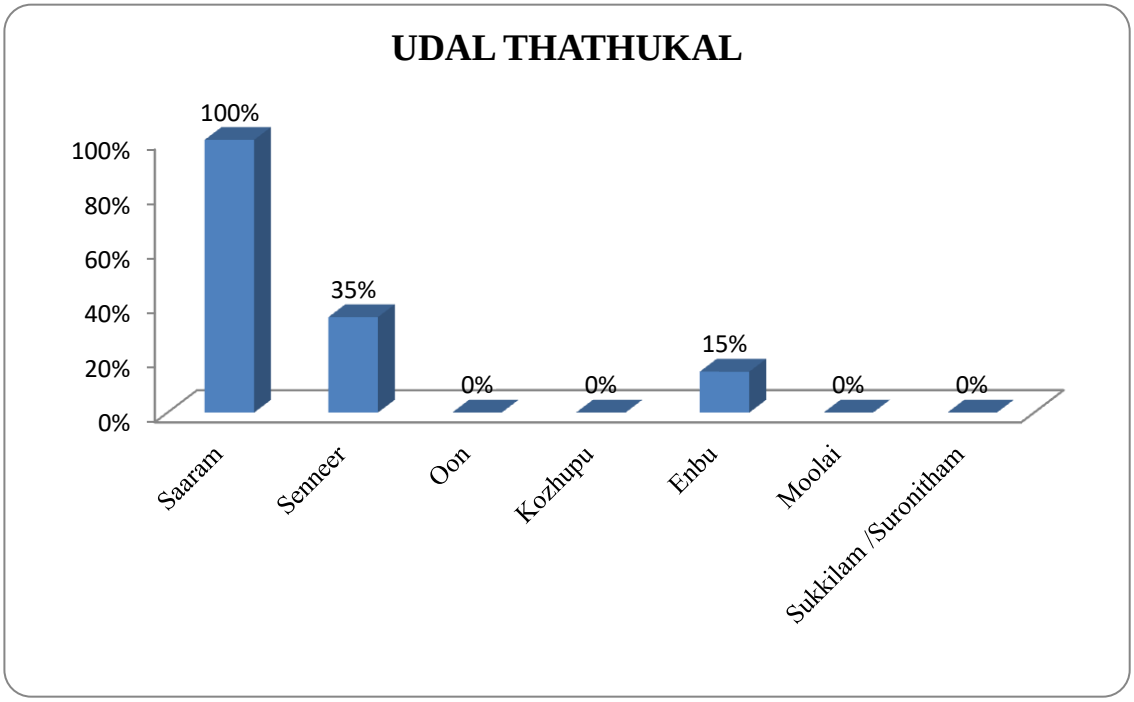


Inference

Among the 40 patients, Kilethagam was affected in 13 patients (32.5%) and Santhigam 6 patients (15%).

UDAL THATHUKKAL

S.No	EZHU UDAL THATHUKAL	NUMBER OF CASES	PERCENTAGE (%)
1	Saaram	40	100%
2	Senneer	14	35%
3	Oon	0	0%
4	Kozhupu	0	0%
5	Enbu	6	15%
6	Moolai	0	0%
7	Sukkilam /Suronitham	0	0%

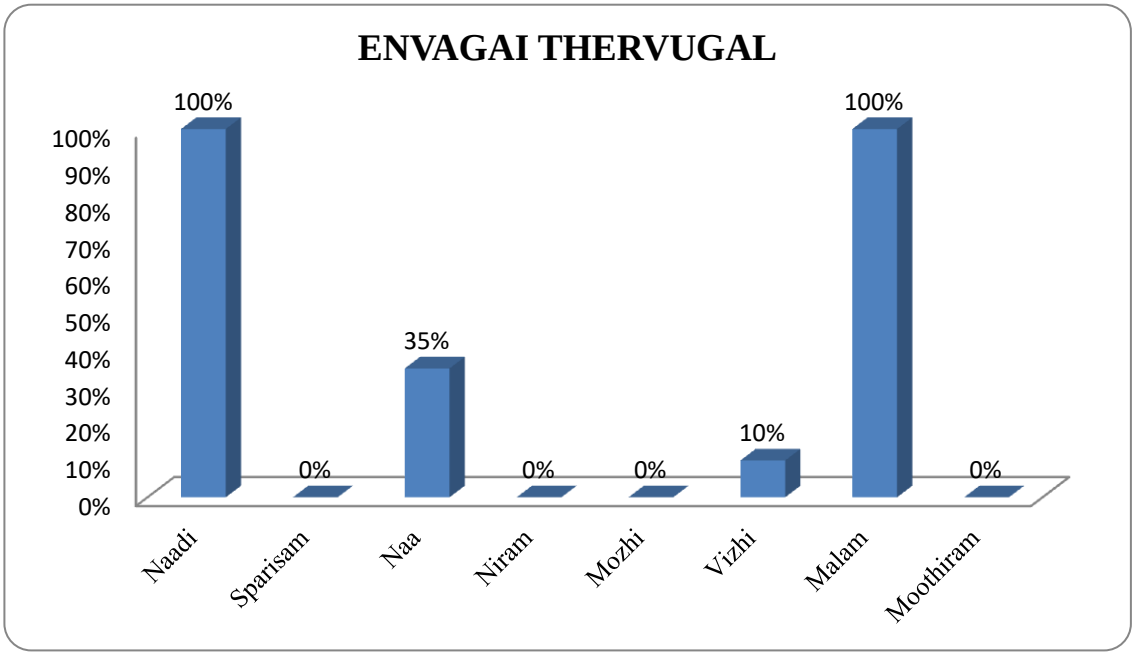


Inference

Among the 40 patients, Saaram was affected in all the 40 cases (100%), Senneer was affected in 14 cases (35%) and Enbu was affected in 6 cases (15%).

EN VAGAI THERVUGAL

S.No	EN VAGAI THERVUGAL	NUMBER OF CASES	PERCENTAGE (%)
	Nadi	40	100%
1	Sparism	0	0
2	Naa	14	35%
3	Niram	0	0%
4	Mozhi	0	0%
5	Vizhi	4	10%
6	Malam	40	100%
7	Moothiram	0	0%

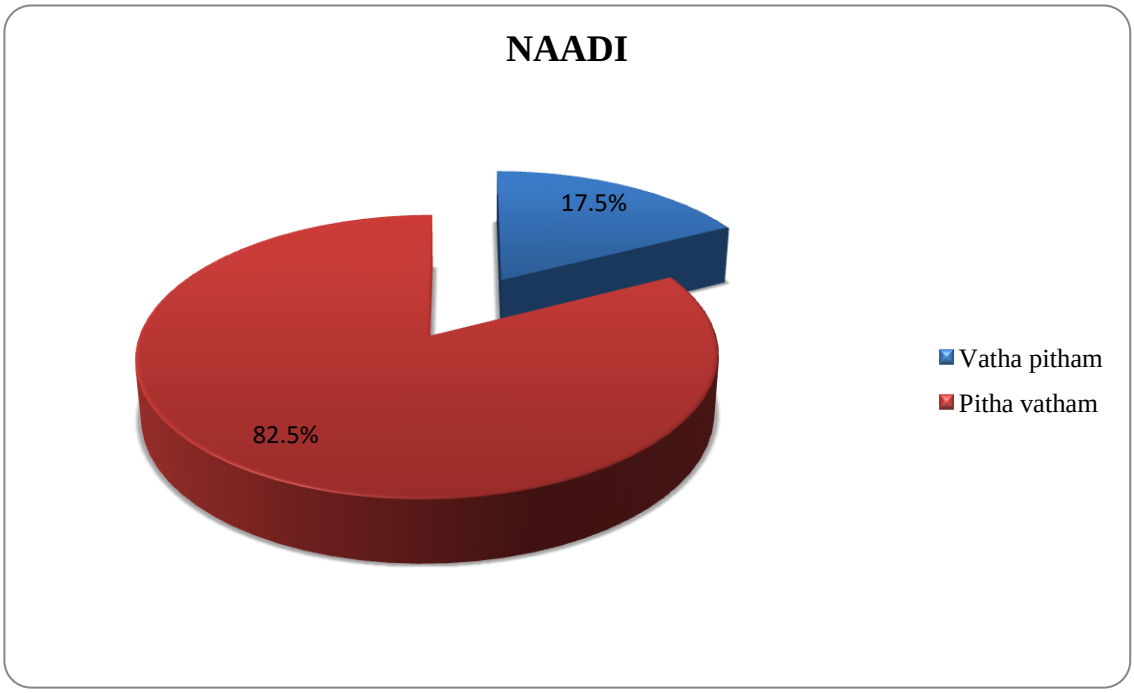


Inference

Among 40 patients, Nadi was affected in all the 40 patients (100%), Na was affected in 14 cases (35%), Vizhi was affected in 4 patients (10%) and Malam was affected in 40 cases (100%).

NAADI

S.No	NAADI	NUMBER OF CASES	PERCENTAGE (%)
1	Vatha pitham	7	17.5%
2	Pitha vatham	33	82.5%

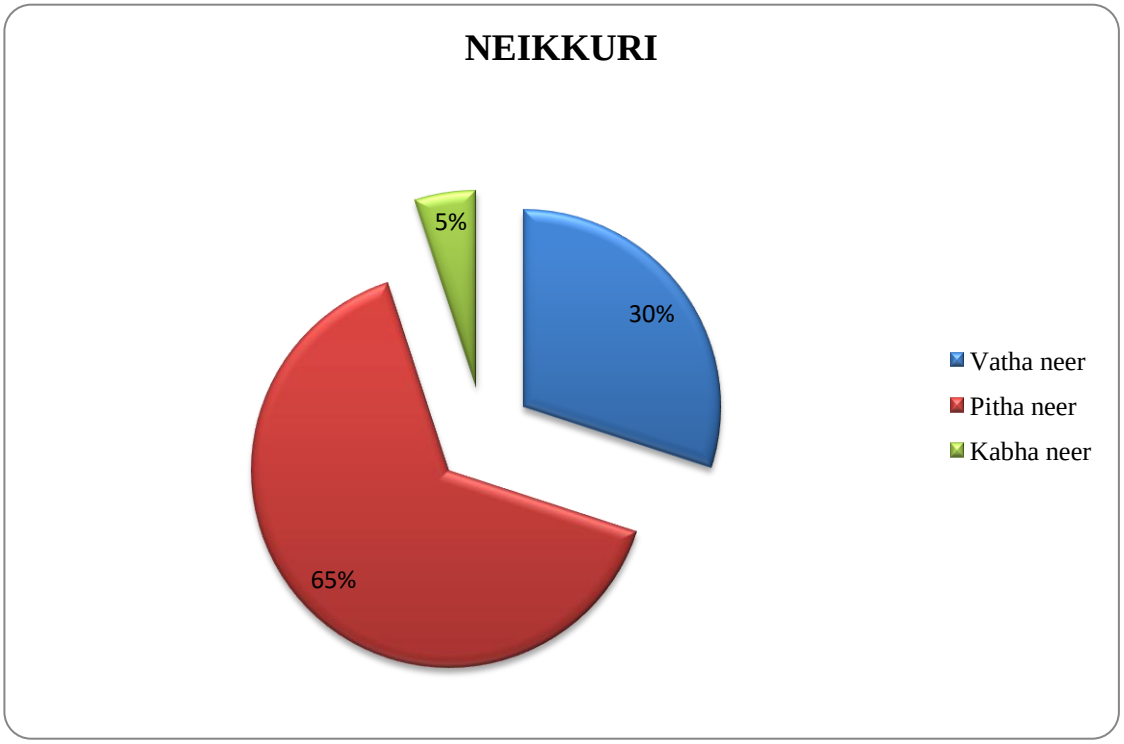


Inference

Among the 40 patients, 33 Patients (82.5%) had Pitha Vatha Naadi and 7 Patients (17.5%) had Vatha Pitha Naadi.

NEIKKURI

S.No	THATHU	NEIKURI	NUMBER OF CASES	PERCENTAGE (%)
1	Vatha neer	Spread like snake	12	30%
2	Pitha neer	Spread like ring	26	65%
3	Kabha neer	Spread like pearl	2	5%

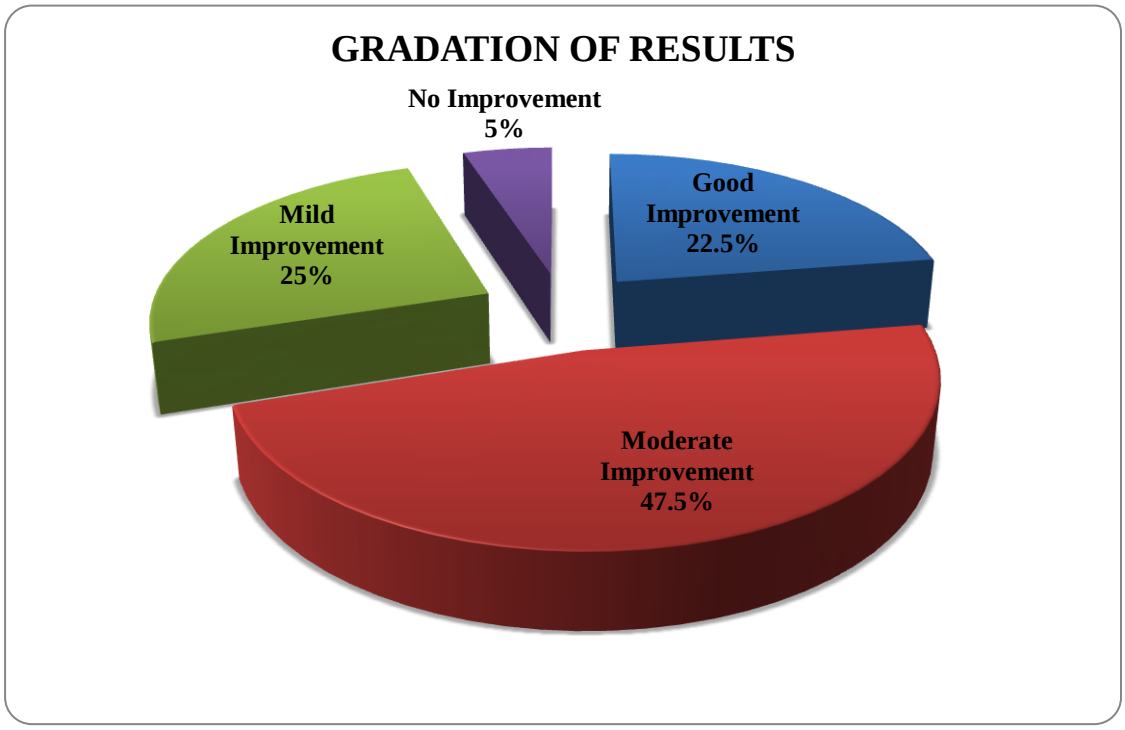


Inference

Among the urine sample of 40 patients, 26 samples (65%) show Pitha neer, 12 samples (30%) show Vatha neer and 4 samples (5%) show Kabha neer.

GRADATION OF RESULTS

S. No	Grading of Results	No of cases	Percentage
1	Good Improvement	9	22.5%
2	Moderate Improvement	19	47.5%
3	Mild Improvement	10	25%
4	No Improvement	2	5%



Inference

Among 40 cases, 9 cases (22.5%) show Good improvement, 19 cases (47.5%) show moderate improvement, 10 cases (25%) show Mild improvement and 2 cases (5%) show No improvement.

LIST OF PATIENTS

S.No	OP No	Age/Sex	Occupation	Date of Medcine started
1.	6950	40/M	Auto driver	31.08.2016
2.	6907	32/F	House wife	31.08.2016
3.	2468	49/M	Teacher	05.09.2016
4.	4564	22/M	Student	26.09.2016
5.	8271	41/F	Coolie	14.10.2016
6.	9550	50/M	Auto driver	16.10.2016
7.	9895	41/M	Police	28.11.2016
8.	675	35/M	Tailor	30.11.2016
9.	731	45/M	Coolie	30.11.2016
10.	1008	33/M	Coolie	02.12.2016
11.	1590	47/M	Coolie	05.12.2016
12.	1589	38/F	Teacher	05.12.2016
13.	2097	52/M	Coolie	07.12.2016
14.	2145	41/F	House wife	08.12.2016
15.	2136	38/M	Business man	08.12.2016
16.	2185	29/F	Teacher	08.12.2016
17.	4568	24/F	Engineer	20.12.2016
18.	5931	32/M	Engineer	26.12.2016
19.	6491	48/F	House wife	27.12.2016
20.	6633	47/F	House wife	27.12.2016
21.	7188	31/F	House wife	29.12.2016
22.	8034	36/F	Coolie	02.01.2017
23.	9276	37/F	Nurse	06.01.2017
24.	351	50/F	House wife	10.01.2017
25.	289	27/M	Engineer	10.01.2017
26.	478	48/M	Busines man	11.01.2017
27.	2241	59/M	Driver	20.01.2017
28.	2747	35/F	Coolie	23.01.2017
29.	3356	38/M	Business man	25.01.2017
30.	8473	27/M	Engineer	13.02.2017
31.	8686	35/F	Bank staff	14.02.2017
32.	9136	20/F	Student	15.02.2017
33.	1265	32/M	Tailor	25.02.2017
34.	1894	30/F	Bank staff	25.02.2017
35.	3631	53/F	House wife	03.03.2017
36.	3978	53/F	House wife	04.03.2017
37.	3942	33/M	Tailor	04.03.2017
38.	3949	32/F	House wife	04.03.2017
39.	5674	36/F	House wife	10.03.2017
40.	8365	41/F	House wife	20.03.2017

CLINICAL PROGNOSIS

HEALTH ASSESSMENT QUESTIONNIRE (HAQ) SCORE

S. No	Op no	BT	AT	Difference	Prognosis
1.	6950	16	1	15	Moderate
2.	6907	19	5	14	Moderate
3.	2468	15	8	7	Mild
4.	4564	16	14	2	Poor
5.	8271	12	0	12	Mild
6.	9550	15	2	13	Moderate
7.	9895	20	7	13	Moderate
8.	675	19	0	19	Good
9.	731	13	0	13	Moderate
10.	1008	17	2	15	Moderate
11.	1590	14	1	13	Moderate
12.	1589	12	1	11	Mild
13.	2097	20	1	19	Good
14.	2145	14	5	9	Mild
15.	2136	16	1	16	Moderate
16.	2185	18	12	6	Poor
17.	4568	19	0	19	Good
18.	5931	15	0	15	Moderate
19.	6491	10	0	10	Mild
20.	6633	17	0	17	Moderate
21.	7188	20	0	20	Good
22.	8034	11	2	9	Mild
23.	9276	19	0	19	Good
24.	351	15	2	13	Moderate
25.	289	14	1	13	Moderate
26.	478	20	1	19	Good
27.	2241	12	2	10	Mild
28.	2747	17	2	15	Moderate
29.	3356	18	2	16	Moderate
30.	8473	20	1	19	Good
31.	8686	14	0	14	Moderate
32.	9136	19	8	11	Mild
33.	1265	19	0	19	Good
34.	1894	14	1	13	Moderate
35.	3631	15	1	14	Moderate
36.	3978	14	0	14	Moderate
37.	3942	21	1	20	Good
38.	3949	15	0	15	Moderate
39.	5674	14	6	8	Mild
40.	8365	19	0	19	Good

Note: Improvement is assessed based on the difference in HAQ score

1-6 : Poor/No improvement, 7-12 : Mild improvement

13-18 : Moderate improvement, 19-24 : Good improvement

LABORATORY INVESTIGATIONS OF PATIENTS

S.No	Op No	Age	Before treatment				After Treatment				ESR (mm)				Hb (gms%)		Urine analysis					
			TC (cu/ mm	DC			TC (cu/ mm)	DC			BT		AT				BT			AT		
				P%	L%	E%		P%	L%	E%	½ hr	1 hr	½ hr	1 hr	BT	AT	Alb	Sug	Dep	Alb	Sug	Dep
1	6950	40/M	9700	56	38	6	9800	56	38	6	3	8	3	7	12.4	12.8	N	N	FE	N	N	N
2	6907	32/F	9600	54	42	4	9900	54	43	3	5	16	5	12	11.2	11.5	N	N	N	N	N	N
3	2468	49/M	9800	59	34	7	9900	62	32	6	4	8	4	6	12.6	12.9	N	N	N	N	N	N
4	4564	22/M	9600	55	39	6	9800	55	40	5	25	50	20	40	11.8	11.1	N	N	FE	N	N	FE
5	8271	41/F	9400	60	34	6	9500	58	38	4	8	16	10	20	9.2	10.8	N	N	FE	N	N	FE
6	9550	50/M	8100	61	35	4	8200	61	36	3	5	12	08	20	12.8	12.9	N	N	N	N	N	N
7	9895	41/M	8400	54	44	2	8800	58	39	3	2	6	3	6	10.5	11.3	N	N	FE	N	N	FE
8	675	35/M	9600	62	35	3	9700	60	37	3	10	25	8	18	12.8	13.5	N	N	FE	N	N	FE
9	731	45/M	8200	60	36	4	8600	58	40	2	13	22	10	18	13.4	14.4	N	N	N	N	N	N
10	1008	33/M	8600	51	45	4	8500	60	33	7	2	3	2	3	12.1	12.5	N	N	FE	N	N	FE
11	1590	47/M	9200	58	36	6	9300	56	36	4	4	9	3	8	11.4	12.6	N	N	N	N	N	N
12	1589	38/F	8300	55	41	4	9400	59	37	4	3	7	3	6	9.7	11.2	N	N	FE	N	N	N
13	2097	52/M	7500	56	40	4	7500	55	42	3	10	23	10	21	10.2	10.4	N	N	N	N	N	FE
14	2145	41/F	9100	51	46	3	9500	53	41	6	2	5	4	6	9.6	10.8	N	N	FE	N	N	N
15	2136	38/M	9700	52	43	5	9900	52	43	5	8	20	9	20	12.7	13.2	N	N	FE	N	N	N
16	2185	29/F	7850	55	39	6	7950	54	40	6	10	18	12	26	9.4	8.5	N	N	FE	N	N	N
17	4568	24/F	8500	59	36	5	8800	59	39	2	15	35	16	37	9.3	11.1	N	N	FE	N	N	N
18	5931	32/M	6900	55	42	3	6900	56	40	4	4	12	18	20	12.5	12.9	N	N	FE	N	N	N
19	6491	48/F	9600	55	39	6	9700	55	39	6	16	34	15	32	10.7	10.8	N	N	FE	N	N	N
20	6633	47/F	9100	60	38	2	9300	54	40	6	16	36	13	25	8.2	10.6	N	N	FE	N	N	FE

21	7188	31/F	8900	61	35	4	9100	60	39	1	5	12	8	20	9.8	11.2	N	N	N	N	N	N
22	8034	36/F	7300	56	40	4	8200	57	40	3	2	6	8	15	11.2	11.8	N	N	N	N	N	N
23	9276	37/F	9200	62	35	3	9500	60	37	3	10	25	8	26	9.1	11.2	N	N	FE	N	N	FE
24	351	50/F	9100	60	35	5	9300	54	40	6	16	36	13	25	8.4	10.5	N	N	FE	N	N	FE
25	289	27/M	8900	61	34	5	9000	60	33	7	8	18	12	23	12.6	13.1	N	N	FE	N	N	FE
26	478	48/M	7200	56	42	2	8100	56	41	3	3	9	8	15	13.2	13.5	N	N	N	N	N	N
27	2241	59/M	6700	59	35	6	7700	54	41	5	10	18	12	26	11.4	13.2	N	N	FE	N	N	N
28	2747	35/F	7800	51	45	4	7900	60	36	4	2	3	2	3	8.3	11.1	N	N	FE	N	N	FE
29	3356	38/M	7900	56	40	4	8000	55	42	3	3	7	12	16	12.5	12.7	N	N	FE	N	N	FE
30	8473	27/M	8100	60	36	4	8600	58	40	2	13	22	10	18	12.1	12.9	N	N	N	N	N	N
31	8686	35/F	9300	54	42	4	9600	54	43	3	5	16	5	12	11.5	12.7	N	N	N	N	N	N
32	9136	20/F	7600	56	40	4	7400	52	44	4	12	23	14	21	9.5	9.7	N	N	N	N	N	FE
33	1265	32/M	9600	62	35	3	9500	60	38	2	10	25	8	18	10.7	12.1	N	N	FE	N	N	FE
34	1894	30/F	8600	54	40	6	8600	53	41	6	2	6	3	6	10.6	10.9	N	N	FE	N	N	FE
35	3631	53/F	7600	56	40	4	7900	52	45	3	20	23	16	18	11.2	11.6	N	N	N	N	N	FE
36	3978	53/F	9200	60	38	2	9800	54	40	6	16	36	13	25	10.8	11.7	N	N	FE	N	N	FE
37	3942	33/M	8200	56	40	4	8200	54	42	4	5	12	8	20	13.4	14.2	N	N	FE	N	N	FE
38	3949	32/F	7100	62	34	4	7700	60	33	7	2	5	10	15	11.3	11.8	N	N	N	N	N	N
39	5674	36/F	7800	57	39	4	7900	55	40	5	6	12	9	18	9.7	11.4	N	N	FE	N	N	FE

BT – Before Treatment, AT – After Treatment, N – Nil, TC – Total Blood Count, DC – Differential Blood Count, P – Polymorphs, L – Leucocytes, E – Eosinophils
ESR – Erythrocytes Sedimentation Rate, mm – Milli meter, Hb – Hemoglobin, Alb – Albumin, Sug – Sugar, Dep– Deposits, FE – Few Epithelial cells, FP – Few Pus cells, N – Nil.

BLEEDING TIME AND CLOTTING TIME

S. No	O.P.NO	AGE	BLEEDING TIME		CLOTTING TIME	
			BT	AT	BT	AT
1.	6950	40/M	2’ 20”	2’ 20”	3’ 45”	3’ 45”
2.	6907	32/F	1’ 50”	1’ 50”	2’ 45”	2’ 45”
3.	2468	49/M	2’ 15”	2’ 15”	4’	4’
4.	4564	22/M	3’ 25”	3’ 25”	4’ 15”	4’ 15”
5.	8271	41/F	2’ 30”	2’ 30”	4’ 15”	4’ 15”
6.	9550	50/M	1’ 45”	1’ 45”	3’ 30”	3’ 30”
7.	9895	41/M	2’ 50”	2’ 50”	4’ 45”	4’ 45”
8.	675	35/M	3’ 45”	3’ 45”	3’ 50”	3’ 50”
9.	731	45/M	1’ 50”	1’ 50”	2’ 25”	2’ 25”
10.	1008	33/M	2’ 45”	2’ 45”	3’ 40”	3’ 40”
11.	1590	47/M	3’ 20”	3’ 20”	5’ 45”	5’ 45”
12.	1589	38/F	2’ 45”	2’ 45”	4’	4’
13.	2097	52/M	3’ 10”	3’ 10”	3’ 45”	3’ 45”
14.	2145	41/F	2’ 50”	2’ 50”	3’	3’
15.	2136	38/M	3’ 50”	3’ 50”	5’ 40”	5’ 40”
16.	2185	29/F	3’ 25”	3’ 25”	4’ 20”	4’ 20”
17.	4568	24/F	2’ 15”	2’ 15”	3’ 40 “	3’ 40 “
18.	5931	32/M	4’	4’	5’ 50”	5’ 50”
19.	6491	48/F	3’ 30”	3’ 30”	3’ 50”	3’ 50”
20.	6633	47/F	2’ 25”	2’ 25”	3’ 45”	3’ 45”
21	7188	31/F	2’ 45”	2’ 45”	3’ 25”	3’ 25”
22	8034	36/F	3’ 50”	3’ 50”	5’ 45”	5’ 45”
23	9276	37/F	3’ 35”	3’ 35”	4’ 30”	4’ 30”
24	351	50/F	3’ 45”	3’ 45”	4’ 50”	4’ 50”
25	289	27/M	2’ 20”	2’ 20”	4’	4’
26	478	48/M	3’	3’	4’ 20”	4’ 20”
27	2241	59/M	3’ 40”	3’ 40”	5’ 40”	5’ 40”
28	2747	35/F	3’ 45”	3’ 45”	4’ 50”	4’ 50”
29	3356	38/M	4’ 50”	4’ 50”	5’ 10”	5’ 10”

30	8473	27/M	2’ 30”	2’ 30”	3’ 25”	3’ 25”
31	8686	35/F	3’ 10”	3’ 10”	5’ 10”	5’ 10”
32	9136	20/F	4’	4’	5’ 15”	5’ 15”
33	1265	32/M	1’ 50”	1’ 50”	3’ 20”	3’ 20”
34	1894	30/F	3’ 25”	3’ 25”	4’ 10”	4’ 10”
35	3631	53/F	2’ 50”	2’ 50”	3’ 40”	3’ 40”
36	3978	53/F	4’ 10”	4’ 10”	4’ 50”	4’ 50”
37	3942	33/M	3’ 25”	3’ 25”	3’ 55”	3’ 55”
38	3949	32/F	2’ 15”	2’ 15”	3’ 50”	3’ 50”
39	5674	36/F	3’ 30”	3’ 30”	3’ 45”	3’ 45”
40	8365	41/F	2’ 15”	2’ 15”	3’ 10”	3’ 10”

Note: BT- Before Treatment AT- After Treatment

DISCUSSION

DISCUSSION

RATTHA MOOLAM, is a clinical entity described by Yugi munivar in his Yugi Vaidhya Chinthamani 800. The classical symptoms are Bleeding per rectum, Constipation, and loss of appetite. These features can be well compared with 1st degree haemorroids.

40 patients are selected in the Department of Pothumaruthuvam , Government Siddha medical college, attached to Arignar Anna Hospital, Arumbakkam, Chennai-106.

All necessary investigations were carried out to all patients and trial medicine was given. The results of before and after treatment of all patients were analysed and discussed as below.

IEC and CTRI APPROVAL

The study was approved by Institutional Ethical Committee (IEC) and the approval number is GSMC – CH-ME-4/2015/002. It was also approved by Clinical Trials Registry of India (CTRI) and the CTRI registration number is CTRI/2017/05/008568.

DRUG AUTHENTICATION

All the raw drugs were collected from their native places. Its organoleptic characters, microscopic and macroscopic examination were conducted and authenticated by Head of the Department, Dept of botany, Govt Siddha Medical College, Arumbakkam, Chennai 106.

IAEC APPROVAL

The trial drug got IAEC approval for Toxicological and Pharmacological Studies at Sathyabama University, Chennai. The Approval number is SU/CLATR/IAEC/IV/020/2016 and SU/CLATR/IAEC/VII/045/2016

TOXICOLOGICAL STUDY:

Acute oral toxicity study followed as per OECD 423 guidelines and Sub acute oral toxicity study done as per OECD 407 guidelines revealed no toxicity in the trial

medicine. There is no change between control and test group of animals in Serological and Hematological parameters. In Histopathological study no abnormalities were found in cells. This shows that the drug is safe.

PHARMACOLOGICAL STUDY:

Pharmacological activity of Moolaroga chooranam is screened against Aspirin induced bleeding time prolongation in Wistar Albino rats. The study show that there is significant change in Bleeding time and Clotting time.

PHYSICO CHEMICAL ANALYSIS

Loss on drying	-	5.13%
Total ash	-	16.46%
Water soluble ash	-	11.78%
Acid soluble ash	-	4.35%
Water soluble extractive	-	14.70%
Alcohol soluble extractive	-	7.80%
pH value	-	6.96

BIOCHEMICAL ANALYSIS

Moolaroga chooranam contains

Acid Radicals: Sulphide, Phosphate

Basic Radicals: Reducing sugar, Iron

CLINICAL STUDY

AGE DISTRIBUTION:

Out of 40 cases, high incidences of cases (42.5%) were noted in age group ranging from 31-40 years. Hemorrhoids generally occur in 30 to 50 years age group.

GENDER DISTRIBUTION

About 47.5% were males and 52.5% were females.

OCCUPATION:

Out of 40 patients, 11 patients (27.5%) were Office workers, 9 patients (22.5%) were House wives. 3 patients (7.5%) were Business persons. 5 patients (12.5%) were Coolie labourers, 2 patients (5%) were Students, 3 patients (7.5%) were Tailors, 1 patient (2.5%) was Nurse, 1 patient (2.5%) was Police and 5 patients (12.5%) were Drivers. Hemorrhoids usually occur among drivers, tailors who are constantly sitting during work. Here least number of those cases were recorded which may be due to low sample size.

SOCIO ECONOMIC STATUS

Among 40 cases 72.5% comes under low economic status, 8 cases (20%) of them under moderate status and 3 cases (7.5%) of them under high income status.

KAALAM: (SEASON)

In paruvakaalam highest incident of cases, 13 cases (32.5%) were noted in Munpani kaalam , 11 cases (27.5%) were noted in Pinpani kaalam, 10 cases (25%) were noted in Koothir kaalam, 6 case (15%) were noted in karkaalam. Though Rathamoolam generally aggravates in hot seasons it could also occurs in all seasons.

THINAI:

Among 40 cases most of the cases (31 cases) i.e 77.5% were from Neithal nilam. Though Rathamoolam occurs in all lands. Here 77.5 % cases belong to Neithal Nilam is due to locality of the study i.e. Chennai.

DIET:

Among 40 patients, 7 patients (17.5%) were taking vegetarian food and 33 patients (82.5%) were taking mixed diet. Rough western diet and consuming spicy foods are important cause for Rathamoolam.

PERSONAL HABITS:

Regarding personal habits, 6 patients (15%) were smokers, 3 patients (7.5%) were alcoholic, 2 patients (5%) were tobacco chewer, and 29 patients (72.5%) were none of the above. Majority of cases comes under none of the above.

OBSERVATION OF ALTERED MUKKUTRAM

VATHAM:

Out of 40 patients, Pranan was affected in 5 cases (12.5%), Abanan was affected in all the 40 patients (100%), Koorman was affected in 4 cases (10%) and Kirukaran was affected in 13 patients (32.5%). Abanan was affected due to constipation. Kirukaran was affected due to loss of appetite.

PITHAM:

Among 40 patients, Analaga pitham was affected in 13 patients (32.5%), Ranjagam was affected in 14 patients (35%), Saathagam was affected in all the 40 patients (100%) and Alosagam was affected in 4 cases (10%). Ranjagam was affected because of Pallor / anemia due to bleeding.

KABHAM:

Among the 40 patients, Kilethagam was affected in 13 patients (32.5%) and Santhigam 6 patients (15%). In Rattha moolam, Kilethagam was affected because of loss of appetite.

EZHU UDAL KATTUGAL:

Among the 40 patients, Saaram was affected in all the 40 cases (100%), Senneer was affected in 14 cases (35%) and Enbu was affected in 6 cases (15%). In Rattha moolam, Senneer was affected because of bleeding.

ENVAGAI THERVU:

Among 40 patients, Nadi was affected in all the 40 patients (100%), Na was affected in 14 cases (35%), Vizhi was affected in 4 patients (10%) and Malam was affected in 40 cases (100%). Na was affected due to anemia caused by bleeding.

NAADI:

Among the 40 patients, 33 Patients (82.5%) had Pitha Vatha Naadi and 7 Patients (17.5%) had Vatha Pitha Naadi.

NEIKURI:

Among the urine sample of 40 patients, 26 samples (65%) show Pitha neer, 12 samples (30%) show Vatha neer and 4 samples (5%) show Kabha neer.

INVESTIGATIONS:

Investigations like TC, DC, ESR, Hb, Bleeding time, Clotting time, Blood sugar, Serum cholesterol, Blood urea, Serum creatinine, were examined and urine analysis for albumin, sugar and deposits were also examined.

CLINICAL STUDY:

Treatment was given with the trial drug Moolaroga chooranam.

Dose : 1 gram, twice a day, with honey after food.

Duration : 48 days.

IMPROVEMENT

Clinical symptoms before and after treatment were noted. All were patients were given score based on Health Assessment Questionnaire (HAQ). The difference between the HAQ score before and after treatment is taken as improvement.

GRADING OF RESULTS:

Among 40 cases, 9 cases (22.5%) show Good improvement, 19 cases (47.5%) show moderate improvement, 10 cases (25%) show Mild improvement and 2 cases (5%) show No improvement.

BIO-STATISTICAL ANALYSIS

Since the P value is highly significant (<0.0001), the null hypothesis is not accepted. So the treatment was significantly improving the HAQ score among the patients for the treatment of Ratthamoolam.

SUMMARY

SUMMARY

The clinical study on **RATTHA MOOLAM** was carried out in Post graduate department of Maruthuvam, Government Siddha Medical College, Aringar Anna Hospital, Chennai – 106 during the period of 2015-2017.

A total of 40 patients were treated in the Outpatient department. The clinical and pathological assessment was carried out on the basis of Siddha and Modern aspects.

All the patients were treated with **MOOLAROGA CHOORANAM**, 1 Gm, daily with Honey for a duration of 48 days.

- The Toxicological studies of the trial medicine reveal no toxicity.
- The pharmacological studies reveal that, the trial drug has good styptic activity in rat models.
- Most of the patients were in the age group between 31-40 years (42.5%)
- Most of the patients were from Neithal nilam 77.5%.
- Most of the patients were Office workers (27.5%) and home makers (22.5%)
- Among 40 cases 72.5% comes under low economic status category
- Among 40 patients, 7 patients (17.5%) were taking vegetarian food and 33 patients (82.5%) were taking mixed diet.
- In paruvakaalam highest incident of cases, 13 cases (32.5%) were noted in Munpani kaalam
- In Vatham ,Abaanan (100%) was affected in all the cases.
- In Pitham, Saathagam, Ranjagam, and Analagam were affected in 100%, 35% and 32.5% cases respectively.
- In Iyyam, , Kilethagam was affected in 32.5% of cases.
- In Ezhu udal thathukkal, Saaram (100%), Seneer(35%) were affected.
- In Envagai thervu Nadi (100%), malam (100%) and Na (35%) were mostly affected.
- Regarding naadi, Pitha vatha naadi (82.5%) was the most common naadi observed.

- 22.5% of patients show good improvement, 25% of patients shows mild improvement and 47.5% patients show moderate improvement and 5% of patients the improvement was poor.
- Bio- statistical analysis of the clinical trial reveals significant p value < 0.0001 and concluded that the treatment is effective and significant.

CONCLUSION

CONCLUSION

- The drug, *Moolaroga chooranam* is a combination of nine herbs having astringent, laxative and Anti-inflammatory properties.
- Most of the ingredients of *Moolaroga chooranam* are indicated for hemorrhoids, which are mentioned in general characteristics in Siddha Materia medica. The taste of the trial drug is Astringent. As Rattha moolam is mainly due to the derangement of Pitha kutram, the astringent property of the drug neutralizes the Pitha kuttram. So, it is considered as Ethirurai maruthuvam.
- The drug, Moolaroga chooranam did not show any toxicity in the Toxicological studies and thus proved to be safe for human administration.
- From the Pharmacological studies it is evident that, the trial medicine has significant Styptic activity.
- Treatment improved the functions of abana vaayu, which regularizes the bowel habits.
- No adverse effects were reported during the course of the treatment.
- The trial medicine gave good relief from the symptoms of Rattha moolam.

The trial medicine Moolaroga chooranam can give a better solution for RATTHAMOOLAM (BLEEDING PILES). Along with the trial drug supportive therapies like diet and changing of their lifestyles may control the disease.

ANNEXURES

The Tamil Nadu Dr.M.G.R. Medical University

#69, Anna salai, Guindy, Chennai-600 032.

This certificate is awarded to

Dr./Mr./Ms. B. ANBARASAN

for participating as ~~Resource Person~~ / Delegate in the First Workshop on

"Pre-clinical Studies in Research"

for Faculties & PG students of ASU Systems

Organised by the Department of Siddha,

The Tamil Nadu Dr. M.G.R. Medical University on 16.12.2014

Dr. N. KABILAN M.D.(Siddha)
Reader; Dept. of Siddha

Dr. JHANSI CHARLES, M.D.
Registrar

Prof. Dr. D. SHANTHARAM, M.D., D.Diab.,
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Tamil Nadu 600106.

AUTHENTICATION CERTIFICATE

Based upon the organoleptic/macroscopic/microscopic examination of fresh/market sample, it is certified that the specimen given to Dr. B. Anbarasan B.S.M.S., doing M.D. (S) at Government Siddha Medical College, Arumbakkam, Chennai-106 is identified below as

Binomial name	Family
Solanum trilobatum	Solanaceae
Sansevieria roxburghiana	Liliaceae
Amorphophallus paeoniifolius	Araceae
Cissus quadrangularis	Vitaceae
Cassia senna	Ceasalpinoidea
Amorphophallus sylvaticus	Araceae
Cynodon dactylon	Poaceae
Hygrophila auriculata	Acanthaceae
Toddalia asiatica	Rutaceae

References: Flora of Presidency, Gamble, J. S

GSMC/MB-Voucher Specimen No. 19/2016

Date: 19.12.2016

19/12/2016

Dr. S. Sankaranarayanan M.Sc., M.Phil., Ph.D.,
Head
Dept. of Maruthuva Thavaraiyal
(Medicinal Botany and Pharmacognosy)
Govt. Siddha Medical College,
Arumbakkam, Chennai-106.

IAEC CERTIFICATE FOR TOXICOLOGICAL STUDY

CERTIFICATE

This is to certify that the project entitled "**TOXICITY EVALUATION OF *MOOLAROGA CHOORANAM* BY ACUTE TOXICITY -OECD 423 AND SUB-ACUTE REPEATED DOSE ORAL TOXICITY STUDY- OECD 407 IN RATS**" has been approved by the IAEC of Sathyabama University, Chennai.

IAEC Approval No.: **SU/CLATR/IAEC/IV/020/2016**
Animal Sanctioned: *Rattus norvegicus* / Wistar albino rats
Male: 9; Female: 15; Total: 24 (Twenty Four)
Date: 5.3.2016

DR.B.SHEELA RANI
Chair Person

DR.R.ILAVARASAN
CPCSEA Main Nominee

LABORATORY ANIMAL TECHNOLOGY AND RESEARCH (CLATR) ★ CENTRE FOR
SATHYABAMA UNIVERSITY
Chennai - 600 119

TOXICOLOGICAL STUDY

ACUTE TOXICITY STUDY

Acute toxicity study of the study drug *Moolaroga Chooranam* was carried out as per OECD guideline (Organization for Economic Co-operation and Development) Guideline-423.

Animal

Healthy adult Wistar albino rat weighing between 170-200 g were used for the study. The animals were housed in poly propylene cages and were kept in well ventilated with 100% fresh air by air handling unit (AHU). A 12 light / dark cycle were maintained .Room temperature was maintained between 22 $\pm$ 2^0 C and relative humidity 50–65%. They were provided with food (Sai feeds, Bangalore, India) and water *ad libitum*. All the animals were acclimatized to the laboratory for 7 days prior to the start of the study.

The experimental protocol was approved by The Institutional Animal Ethics Committee of Sathyabama University, Chennai, Tamil Nadu, India.

Acute toxicity Study

Acute toxicity study will be carried out in accordance with OECD guideline 423[50]. The animals were fasted overnight with free access to water. The study was conducted with single oral dose administration of *Moolaroga Chooranam.*

IAEC SU/CLATR/IAEC/IV/020/2016

Animal Grouping

One group consist of 6 female rats were used for this study. The dose utilized for evaluation of acute toxicity study is about 2000 mg/kg higher than that of the therapeutic dose.

Animal Grouping

GROUP I : Animals received Test drug 2000 mg/kg (p.o)

The animals were fasted overnight (12- 16 hrs) with free access to water. The study was conducted with single oral administration of study drug *Moolaroga Chooranam* 2000mg/kg (p.o). The animals were observed continuously for first 72 h

and then 14 days for emerging signs of behavioral changes, body weight changes and for mortality.

Occurrence of toxicity in animals were observed continuously for the first 4 to 24 h and observed periodically for the next 14 days. Observation includes the change in skin, fur, eyes and mucus membrane. Appearance of C.N.S,C.V.S and A.N.S related toxicity such as tremors, convulsions, sedation, steric behavior, respiratory distress, cardiovascular collapse, response to sensory stimuli, salivation, diarrhea, lethargy, sleep, coma and mortality were observed with special attention.

Body weight was recorded periodically. At the end of the experiment all animals were subjected for gross necropsy and observed for pathological changes.

SUB-ACUTE TOXICITY STUDY

Sub-acute toxicity study was carried out as per OECD guidelines Guideline-407[51].

Animals

Healthy adult Wistar albino rat weighing between 170-200 g were used for the study. The animals were housed in poly propylene cages and were kept in well ventilated with 100% fresh air by air handling unit (AHU). A 12 light / dark cycle were maintained .Room temperature was maintained between 22 $\pm$ 2^{o} C and relative humidity 50–65%. They were provided with food (Sai feeds, Bangalore, India) and water *ad libitum*. All the animals were acclimatized to the laboratory for 7 days prior to the start of the study.

The experimental protocol was approved by The Institutional Animal Ethics Committee of Sathyabama University, Chennai, Tamil Nadu, India.

IAEC SU/CLATR/IAEC/IV/020/2016

Animal Grouping

Animals were divided into three groups of 06 animals each consist of 3 male and 3 female rats.

GROUP I **:** Animals received saline 5 ml/kg b.w (p.o)

GROUP II **:** Animals received low dose of test drug 200 mg/kg (p.o)

GROUP III **:** Animals received high dose of test drug 400 mg/kg (p.o)

The animals were randomly divided into control group and drug treated groups for two different doses viz. low dose (200 mg/kg b.w) and high dose (400 mg/kg b.w).

The animals were administrated with the study drug once daily for 28 days. The animals in group I (control group) received normal saline 5 ml/kg b.w. The animals in group II received low dose of *Moolaroga Chooranam* 200 mg/kg b.w (p.o) and group III received high dose of *Moolaroga Chooranam* 400 mg/kg b.w (p.o).

The rats were weighed periodically and observed for signs of toxicity pertains to C.N.S, C.V.S, A.N.S including behavioral changes, food - water intake and morphological changes. At the end of 28^{th} day, the animals were fasted for overnight with free access to water. On 29^{th} day the animals were sacrificed with excess anesthesia. Blood samples were collected from aorta and stored in EDTA (ethylenediamine –tetra actate) for Hematological analysis and for serum generation for biochemical analysis.

The vital organs including heart, brain, lungs, spleen, kidneys, liver, stomach, testes, and ovary were harvested and carefully examined for gross lesions. The organs were preserved in 10% formalin for histopathological assessment and interpretation.

Hematological analysis

Blood samples were analyzed using established procedures and automated Bayer Hematology analyzer. Parameters evaluated include Packed Cell Volume (PCV), Red Blood Cells (RBC) count, White blood cell count (WBC), Platelet Count, Hemoglobin (Hb), Mean cell Haemoglobin Concentration (MCHC), Mean Red Cell Volume (MCV), Mean Cell Hemoglobin (MCH), Mean platelet volume (MPV), Neutrophils, Eosinophil's, Basophils, Lymphocytes and Monocytes.

Biochemical analysis [52]

Serum samples were analyzed for High Density Lipoprotein (HDL), Low density Lipoprotein (LDL) , Very low density Lipoprotein (VLDL) , Triglycerides (TGL), Total Cholesterol , Blood urea nitrogen (BUN), Creatinine, Albumin, Total Protein, Glucose, Uric acid, Aspartate Transaminase (AST), Alanine amino Transaminase (ALT) and Alkaline Phosphatase (ALP) using Mind ray auto analyzer model BS 120.

Histopathological evaluation [53]

Organs included of heart, brain, lungs, spleen, kidneys, liver, stomach, testes and ovary. Histological slides of organs were made and observed under the microscope. The pathological observations of cross section of these organs were performed on gross and microscopic bases. Histological examinations were performed on the preserved tissues with particular emphasis on those which showed gross pathological changes.

Statistical analysis

The statistical analysis was carried by one way ANOVA (GRAPH PAD PRISM 5 computer program). Results were expressed as mean ± standard error .A statistical comparison was carried out using the Dunnet's test for the control and treatment group.

Fecal Pellet Analysis

Methodology

Rats of control and treatment group were allowed to explore to open field on clean and sterile cage with blotting paper. The collected pellets were analyzed for consistency, color, Shape, Presence of blood cells etc.

Acute Toxicity Study

Analysis	**Group I**
Consistency	Soft
Shape	Point ended
Colour	Pale green
Mucous Shedding	Absence
Blood Cells	Absent
Signs of Infection	None Observed

Sub-Acute Toxicity Study			
Analysis	**Group I**	**Group II**	**Group III**
Consistency	Soft	Soft	Very Soft
Shape	Oblong	Oblong	Oblong
Colour	Brownish green	Pale green	Pale green
Mucous Shedding	Absence	Absence	Absence
Blood Cells	Absent	Absent	Absent
Signs of Infection	None Observed	None Observed	None Observed

Muscle Grip Strength Analysis

Methodology

The grip strength test is a simple non-invasive method designed to evaluate rat muscle force in vivo. Rats of control and drug treated group was allowed to hold the pull bar with both the hind limbs firmly then the animal was gently pulled back with the tail until the animal lost the grip toward the bar. The procedure was repeated to get the average value. Muscle grip ness of the drug treated group was compared to that of the control rat to ensure the change in coordination.

Metabolic Cage for Urine Collection

Rat of control and treatment group was placed individually in metabolic cage with free access to feed and water. Urine dropping from the animal was collected using specialized wire mesh system fixed at the base of the cage having provision to trap the fecal pellet mixed with urine sample. The collected urine sample was subjected to analysis with respect to colour, pH, glucose, ketone bodies, pus and blood cells.

RESULTS

Assessment of clinical signs in rats treated with *Moolaroga Chooranam* on Acute toxicity study

Parameter	**Group I**
Clinical Signs Parameters for the duration of 14 days	Test Drug 2000mg/ Kg
Number of animals observed	6 Female
Lacrimation	Absence
Salivation	Absence
Animal appearance	Normal
Tonic Movement	Absence
Clonic Movement	Absence
Laxative action	Absence
Touch Response	Normal
Response to Sound	Normal Response
Response to Light	Normal Response
Mobility	Normal Response
Respiratory Distress	Nil
Skin Color	Normal
Stereotype behavior	Absence
Piloerection	Absence
Limb Paralysis	Absence
Posture	Normal
Open field behavior	Normal
Gait Balancing	Normal
Freezing Behaviour	Absent
Sings of Stress and Anxiety	None Observed
Muscular coordination	Normal
Muscle grip	Normal
Sedation	Absence
Social Behavior	Normal
Urine Analysis	No Abnormality

Urine Colour	Yellowish
Urine pH	7
Urine - Glucose	Absence
Urine - Ketones	Absence
Urine- Bilirubin	Absence
Urine-Blood Cells	Negative
Urine - Pus cells	Negative
Mortality	Nil

Quantitative data on the body weight of rats treated with *Moolaroga Chooranam* in Acute toxicity study

Group I	Before Treatment Weight in Gms	After Treatment Weight in Gms
Mean	186.7	189.5
Std. Deviation	5.354	5.788
Std. Error	2.186	2.363

Values are mean ± S.D (n = 6 per group). Control and treatment group were compared statistically using one way ANOVA followed by Dunnett's test.

Assessment of clinical signs in rats treated with *Moolaroga Chooranam* on Sub-Acute toxicity study

Parameter	Group I	Group II	Group III
Clinical Signs Parameters for the duration of 28 days	Control	Test Drug 200mg/ Kg	Test Drug 400mg/ Kg
Number of animals observed	3 Male and 3 Female	3 Male and 3 Female	3 Male and 3 Female
Lacrimation	Absence	Absence	Absence
Salivation	Absence	Absence	Absence
Animal appearance	Normal	Normal	Normal
Tonic Movement	Absence	Absence	Absence
Clonic Movement	Absence	Absence	Absence
Laxative action	Absence	Absence	Absence
Touch Response	Normal	Normal	Normal

Response to Sound	Normal Response	Normal Response	Normal Response
Response to Light	Normal Response	Normal Response	Normal Response
Mobility	Normal	Normal	Normal
Respiratory Distress	Nil	Nil	Nil
Skin Color	Normal	Normal	Normal
Stereotype behavior	Absence	Absence	Absence
Piloerection	Absence	Absence	Absence
Limb Paralysis	Absence	Absence	Absence
Posture	Normal	Normal	Normal
Open field behavior	Normal	Normal	Normal
Gait Balancing	Normal	Normal	Normal
Freezing Behaviour	Absent	Absent	Absent
Sings of Stress and Anxiety	None Observed	None Observed	None Observed
Muscular coordination	Normal	Normal	Normal
Muscle grip	Normal	Normal	Normal
Sedation	Absence	Absence	Absence
Social Behavior	Normal	Normal	Normal
Urine Analysis	No Abnormality	No Abnormality	No Abnormality
Urine Colour	Yellowish	Yellowish	Yellowish
Urine pH	6	6	6
Urine - Glucose	Absence	Absence	Absence
Urine - Ketones	Absence	Absence	Absence
Urine- Bilirubin	Absence	Absence	Absence
Urine-Blood Cells	Negative	Negative	Negative
Urine - Pus cells	Negative	Negative	Negative
Mortality	Nil	Nil	Nil

Effect of *Moolaroga Chooranam* on Body weight of Rats in Sub-acute toxicity study

Group I	**Before Treatment Weight in Gms**	**After Treatment Weight in Gms**
Mean	189.5	193.8
Std. Deviation	5.788	5.492
Std. Error	2.363	2.242
Group II	**Before Treatment Weight in Gms**	**After Treatment Weight in Gms**
Mean	182.7	197.7
Std. Deviation	6.653	5.854
Std. Error	2.716	2.39
Group III	**Before Treatment**	**After Treatment Weight in Gms**
Mean	183.7	194.3
Std. Deviation	3.724	1.633
Std. Error	1.52	0.6667

Values are mean ± S.D (n = 6 per group of which 3 males and 3 females). Control and treatment groups were compared statistically using one way ANOVA followed by Dunnett's test.

Quantitative data on the food and water intake of rats treated with *Moolaroga Chooranam* for 28 days in Sub-acute toxicity study

GROUP I	**Food intake**	**Water intake**
Mean	17.33	33.92
Std. Deviation	3.82	2.727
Std. Error	1.91	1.363
GROUP II	**Food intake**	**Water intake**
Mean	20.17	40.75
Std. Deviation	3.707	1.287
Std. Error	1.853	0.6437

GROUP III	Food intake	Water intake
Mean	18.42	38.25
Std. Deviation	3.775	2.754
Std. Error	1.887	1.377

Values are mean ± S.D (n = 6 per group of which 3 males and 3 females). Control and treatment groups were compared statistically using one way ANOVA followed by Dunnett's test.

Effect of *Moolaroga Chooranam* on Haematology profile of rats in sub-acute toxicity study

GROUP I	WBC count ($\times 10^3$ µl)	RBC ($\times 10^6$ µl)	PLT ($\times 10^3$ µl)	MCV (fl)	MCH (pg)	MCHC (g/dl)	HGB (g/dl)
Mean	12.1	6.867	649.7	64.62	18.48	32.88	12.15
Std. Deviation	1.334	1.084	144.9	2.501	2.137	1.61	1.42
Std. Error	0.5447	0.4425	59.14	1.021	0.8723	0.6575	0.5795
GROUP II	**WBC count ($\times 10^3$ µl)**	**RBC ($\times 10^6$ µl)**	**PLT ($\times 10^3$ µl)**	**MCV (fl)**	**MCH (pg)**	**MCHC (g/dl)**	**HGB (g/dl)**
Mean	11	6.367	888.7	60.67	18.45	32.43	11.75
Std. Deviation	1.527	1.372	135.3	4.949	2.247	1.822	1.148
Std. Error	0.6234	0.5602	55.23	2.02	0.9175	0.7437	0.4689
GROUP III	**WBC count ($\times 10^3$ µl)**	**RBC ($\times 10^6$ µl)**	**PLT ($\times 10^3$ µl)**	**MCV (fl)**	**MCH (pg)**	**MCHC (g/dl)**	**HGB (g/dl)**
Mean	10.8	5.633	999.7	56.37	21.9	33.2	12.1
Std. Deviation	1.802	0.7607	146.6	2.594	2.313	1.652	1.293
Std. Error	0.7358	0.3106	59.83	1.059	0.9445	0.6743	0.5279

Values are mean ± S.D (n = 6 per group of which 3 males and 3 females). Control and treatment groups were compared statistically using one way ANOVA followed by Dunnett's test.

Effect of *Moolaroga Chooranam* on Haematology profile of rats in sub-acute toxicity study

GROUP I	**Lymph (%)**	**Mon (%)**	**Neutrophils (X 10^3/mm^3)**	**Eosinophils (%)**	**Basophils (%)**	**MPV (fl)**
Mean	77.38	3.15	2.517	1.583	0.3333	5.567
Std. Deviation	7.903	0.8264	0.9196	0.2787	0.5164	1.181
Std. Error	3.226	0.3374	0.3754	0.1138	0.2108	0.4821
GROUP II	**Lymph (%)**	**Mon (%)**	**Neutrophils (X 10^3/mm^3)**	**Eosinophils (%)**	**Basophils (%)**	**MPV (fl)**
Mean	77.82	3.967	2.017	1.533	0.1667	6.533
Std. Deviation	7.372	1.492	0.96	0.2733	0.4082	0.8892
Std. Error	3.01	0.6092	0.3919	0.1116	0.1667	0.363
GROUP III	**Lymph (%)**	**Mon (%)**	**Neutrophils (X 10^3/mm^3)**	**Eosinophils (%)**	**Basophils (%)**	**MPV (fl)**
Mean	79.22	3.633	2.1	1.267	0.1667	5.933
Std. Deviation	3.311	1.529	0.7616	0.2251	0.4082	1.795
Std. Error	1.352	0.6243	0.3109	0.09189	0.1667	0.7329

Values are mean ± S.D (n = 6 per group of which 3 males and 3 females). Control and treatment groups were compared statistically using one way ANOVA followed by Dunnett's test.

Effect of *Moolaroga Chooranam* on Serum Bio-chemistry profile of rats in sub-acute toxicity study

GROUP I	**Blood sugar ® (mg/dl)**	**BUN (mg/dl)**	**Serum creatinine (mg/dl)**	**Serum total cholesterol (mg/dl)**	**Serum triglycerides level (mg/dl)**	**Serum HDL cholesterol (mg/dl)**	**Serum LDL cholesterol (mg/dl)**	**Serum VLDL cholesterol (mg/dl)**
Mean	79.83	18.17	0.8333	125.8	88.17	61.67	45	17.57
Std. Deviation	12.17	2.927	0.1862	9.827	13.17	10.89	5.02	3.546
Std. Error	4.969	1.195	0.07601	4.012	5.375	4.447	2.049	1.447
GROUP II	**Blood sugar ® (mg/dl)**	**BUN (mg/dl)**	**Serum creatinine (mg/dl)**	**Serum total cholesterol (mg/dl)**	**Serum triglycerides level (mg/dl)**	**Serum HDL cholesterol (mg/dl)**	**Serum LDL cholesterol (mg/dl)**	**Serum VLDL cholesterol (mg/dl)**
Mean	82.33	18	0.65	120.2	75.83	60.67	35.17	18.92
Std. Deviation	12.97	2.898	0.2074	9.326	7.91	12.4	14.05	2.853
Std. Error	5.296	1.183	0.08466	3.807	3.229	5.064	5.735	1.165

GROUP III	Blood sugar ® (mg/dl)	BUN (mg/dl)	Serum creatinine (mg/dl)	Serum total cholesterol (mg/dl)	Serum triglycerides level (mg/dl)	Serum HDL cholesterol (mg/dl)	Serum LDL cholesterol (mg/dl)	Serum VLDL cholesterol (mg/dl)
Mean	83.5	17.67	0.6167	119.3	80	55.33	41.33	15.73
Std. Deviation	13.03	2.338	0.3061	15.36	12.57	11.17	16.33	4.305
Std. Error	5.321	0.9545	0.1249	6.27	5.132	4.558	6.667	1.757

Values are mean ± S.D (n = 6 per group of which 3 males and 3 females). Control and treatment groups were compared statistically using one way ANOVA followed by Dunnett's test.

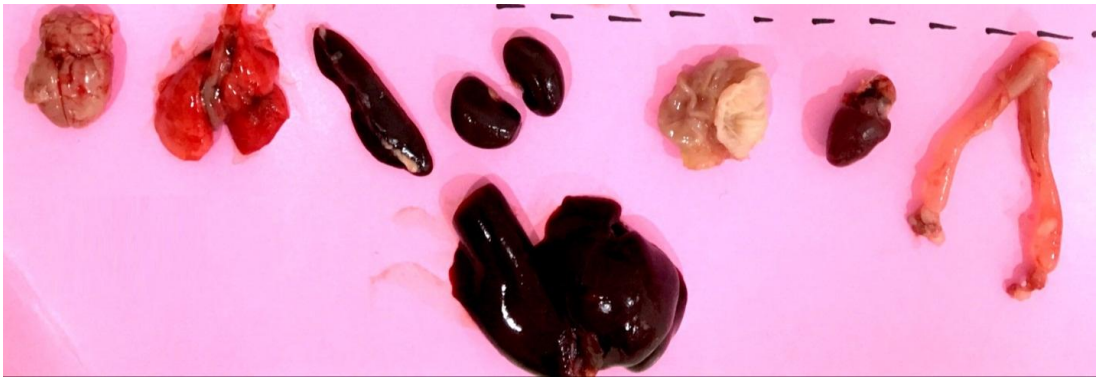
Effect of *Moolaroga Chooranam* on Serum Bio-chemistry profile of rats in sub-acute toxicity study

GROUP I	Serum total protein (g/dl)	Serum albumin (g/dl)	(AST) (IU/ml)	(ALT) (IU/L)	(ALP) (IU/L)
Mean	3.833	4.183	104	33.67	186
Std. Deviation	0.432	0.5879	21.16	10.48	41.02
Std. Error	0.1764	0.24	8.637	4.279	16.75
GROUP II	**Serum total protein (g/dl)**	**Serum albumin (g/dl)**	**(AST) (IU/ml)**	**(ALT) (IU/L)**	**(ALP) (IU/L)**
Mean	5.117	4.05	132.3	24.83	146.8
Std. Deviation	0.9704	0.4231	9.309	11.02	36.47
Std. Error	0.3962	0.1727	3.801	4.498	14.89
GROUP III	**Serum total protein (g/dl)**	**Serum albumin (g/dl)**	**(AST) (IU/ml)**	**(ALT) (IU/L)**	**(ALP) (IU/L)**
Mean	5.267	3.3	121	37.33	138.2
Std. Deviation	1.311	0.8414	26.63	7.202	47.82
Std. Error	0.5352	0.3435	10.87	2.94	19.52

Values are mean ± S.D (n = 6 per group of which 3 males and 3 females). Control and treatment groups were compared statistically using one way ANOVA followed by Dunnett's test.

Organ Gross Observation of rats treated with *Moolaroga Chooranam* for 28 days in Sub-acute toxicity study.

Treatment Female



Treatment Male

Quantitative data on absolute organ weight of rats treated with *Moolaroga Chooranam* for 28 days in Sub-acute toxicity study

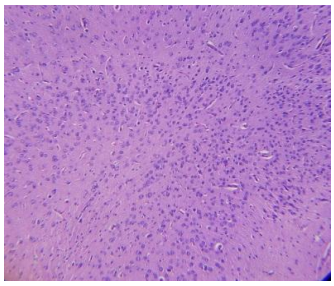
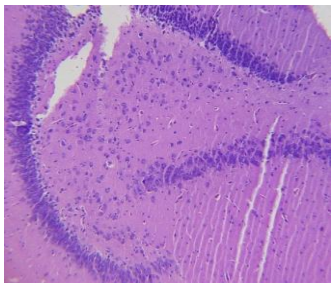
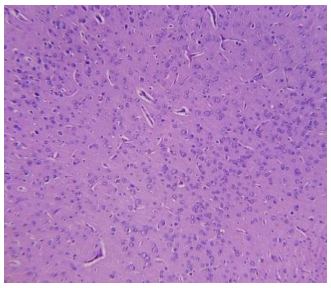
GROUP I	HEART (gms)	LIVER (gms)	KIDNEYS (gms)	SPLEEN (gms)	BRAIN (gms)	LUNG (gms)	STOMACH (gms)	TESTES (gms)	UTERUS & OVARY (gms)
Mean	0.6833	6.335	1.607	0.5167	1.567	1.683	1.25	3.067	1.167
Std. Dev	0.1065	1.142	0.2337	0.1941	0.216	0.1722	0.345	1.172	0.05774
Std. Error	0.04349	0.4663	0.09542	0.07923	0.08819	0.07032	0.1408	0.6766	0.03333

GROUP II	HEART (gms)	LIVER (gms)	KIDNEYS (gms)	SPLEEN (gms)	BRAIN (gms)	LUNG (gms)	STOMACH (gms)	TESTES (gms)	UTERUS & OVARY (gms)
Mean	0.7683	5.59	1.28	0.6	1.767	1.683	1.333	3.933	1.4
Std. Dev	0.1719	1.16	0.1002	0.1897	0.1506	0.2927	0.3882	0.7234	0.1
Std. Error	0.07016	0.4737	0.04091	0.07746	0.06146	0.1195	0.1585	0.4177	0.05774
GROUP III	**HEART (gms)**	**LIVER (gms)**	**KIDNEYS (gms)**	**SPLEEN (gms)**	**BRAIN (gms)**	**LUNG (gms)**	**STOMACH (gms)**	**TESTES (gms)**	**UTERUS & OVARY (gms)**
Mean	0.5833	6.222	1.307	0.5	1.667	1.65	1.45	2.167	1.433
Std. Dev	0.07005	1.446	0.1078	0.2098	0.2066	0.2881	0.2074	0.5508	0.05774
Std. Error	0.0286	0.5901	0.04402	0.08563	0.08433	0.1176	0.08466	0.318	0.03333

Values are mean ± S.D (n = 6 per group of which 3 males and 3 females) for Heart, Liver, Kidney, Brain, Spleen, Lung, Stomach. Values are mean ± S.D (n = 3 per group per sex) for testes , ovary and uterus for Control and treatment groups were compared statistically using one way ANOVA followed by Dunnett's test.

Histopathology of Brain (Male Rat) in Sub-acute toxicity Study

Low Power Magnification 10X

GROUP I **GROUP II** **GROUP III**

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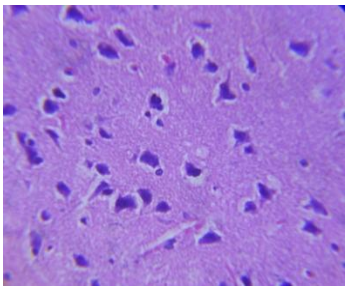
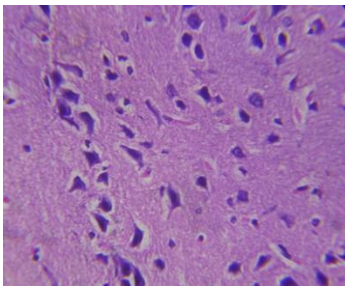
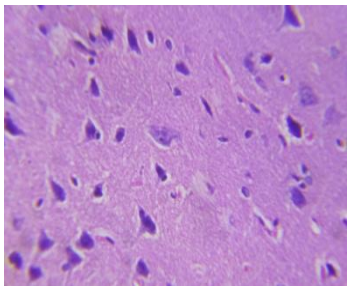
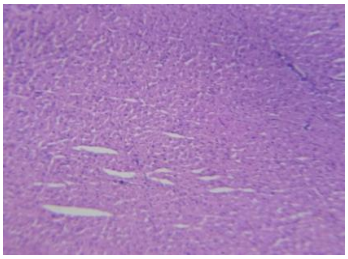
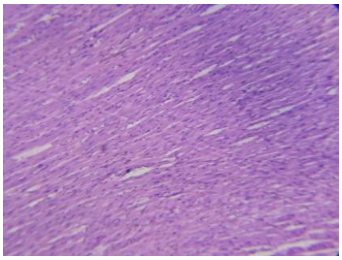
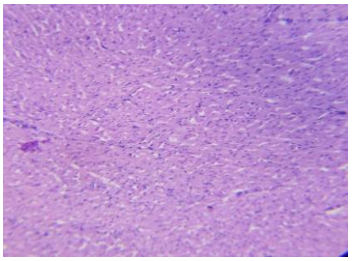




GROUP I **GROUP II** **GROUP III**

Histopathology of Heart (Male Rat) in Sub-acute toxicity Study

Low Power Magnification 10X

GROUP I **GROUP II** **GROUP III**

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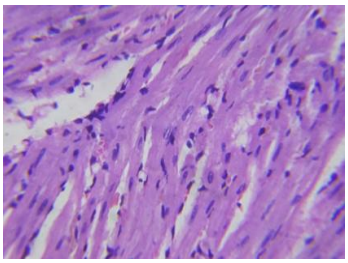
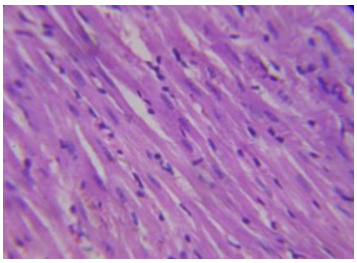
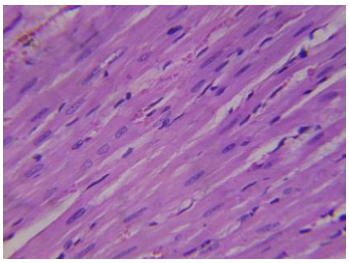
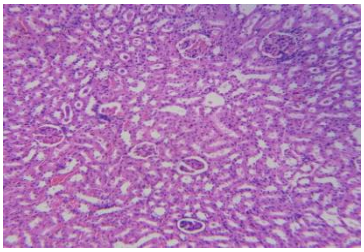
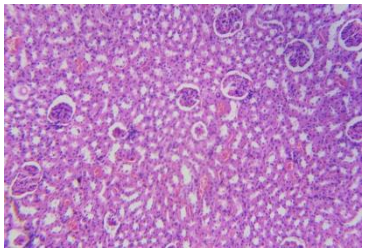
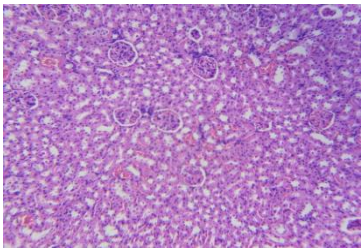




GROUP I **GROUP II** **GROUP III**

Histopathology of Kidney (Male Rat) in Sub-acute toxicity Study

Low Power Magnification 10X

GROUP I **GROUP II** **GROUP III**

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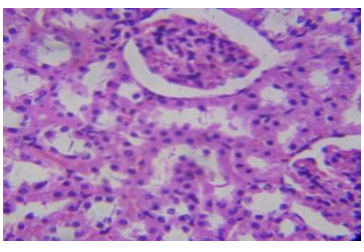
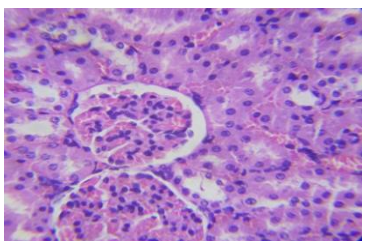
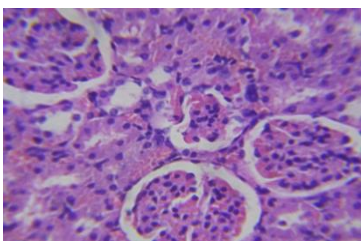

GROUP I **GROUP II** **GROUP III**

Histopathology of Liver (Male Rat) in Sub-acute toxicity Study

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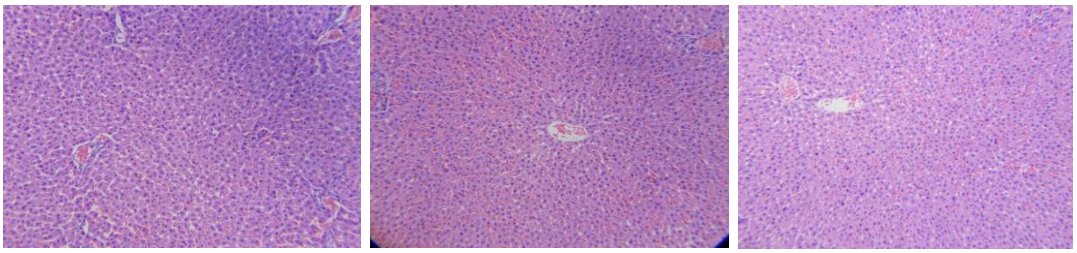

GROUP I **GROUP II** **GROUP III**

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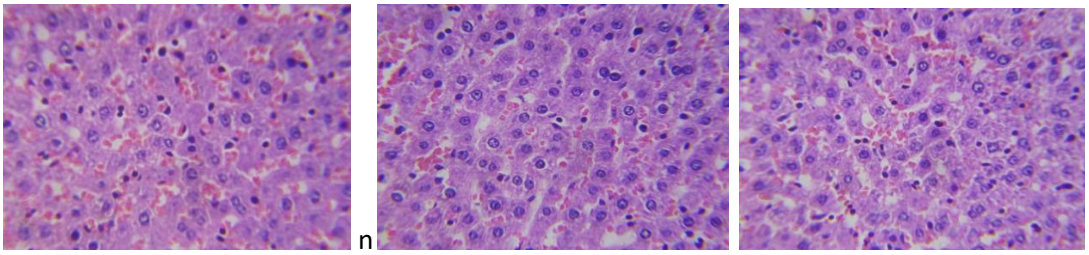
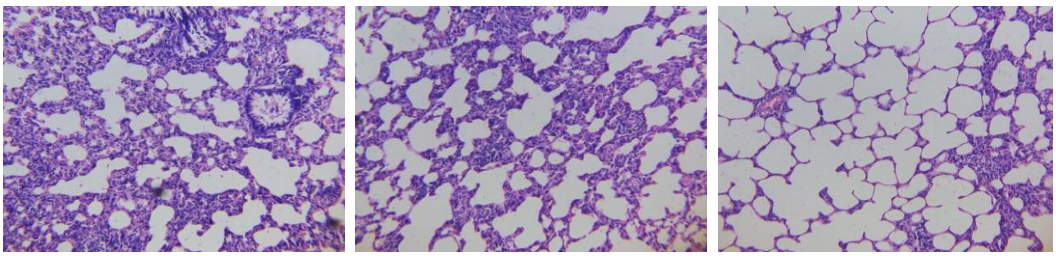


GROUP I **GROUP II** **GROUP III**

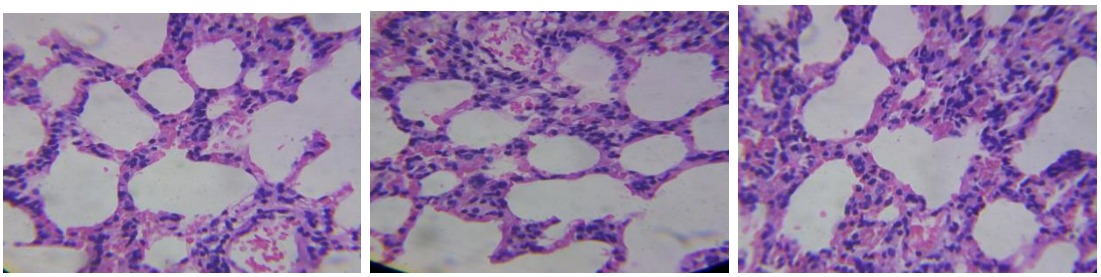
Histopathology of Lung (Male Rat) in Sub-acute toxicity Study

Low Power Magnification 10X



GROUP I **GROUP II** **GROUP III**

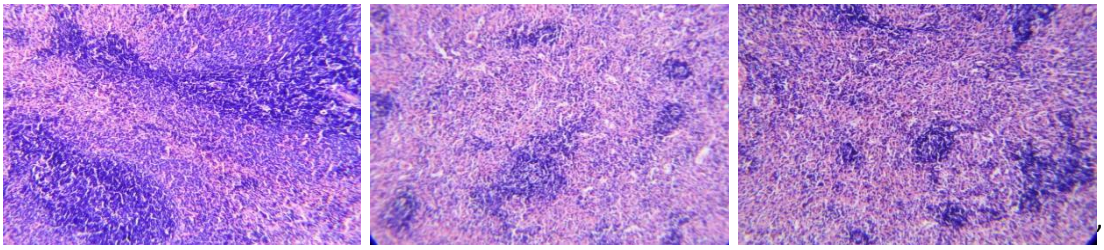
High Power Magnification 40X



GROUP I **GROUP II** **GROUP III**

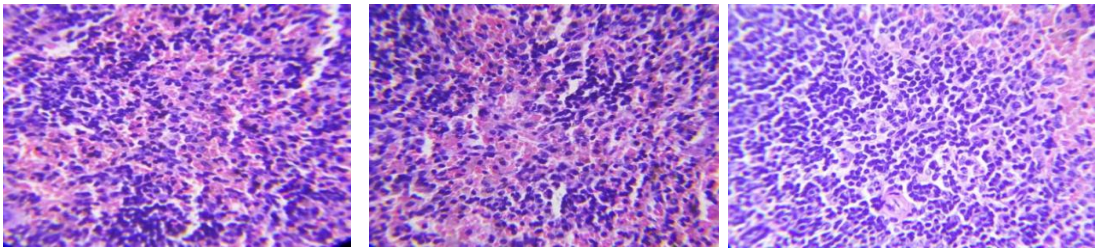
Histopathology of Spleen (Male Rat) in Sub-acute toxicity Study

Low Power Magnification 10X



GROUP I **GROUP II** **GROUP III**

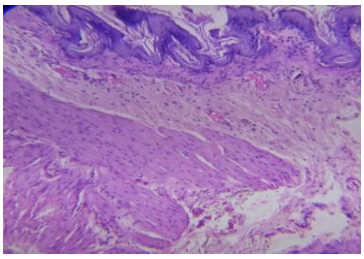
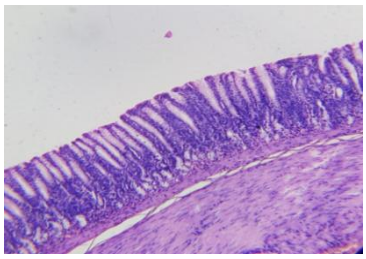
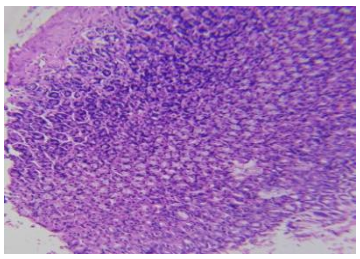
High Power Magnification 40X



GROUP I **GROUP II** **GROUP III**

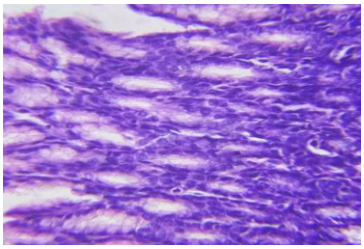
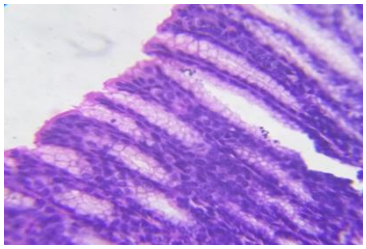
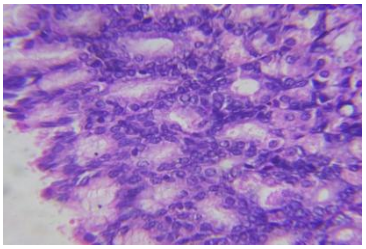
Histopathology of Stomach (Male Rat) in Sub-acute toxicity Study

Low Power Magnification 10X

GROUP I **GROUP II** **GROUP III**

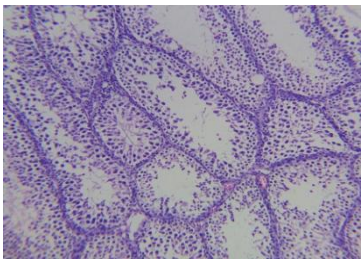
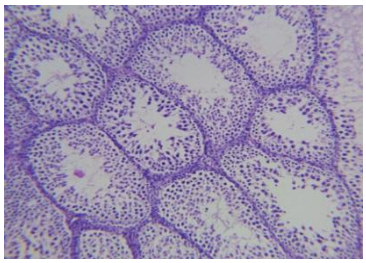
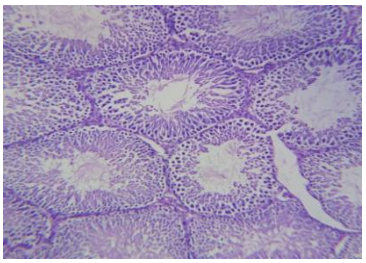
High Power Magnification 40X

GROUP I **GROUP II** **GROUP III**

Histopathology of Testes (Male Rat) in Sub-acute toxicity Study

Low Power Magnification 10X

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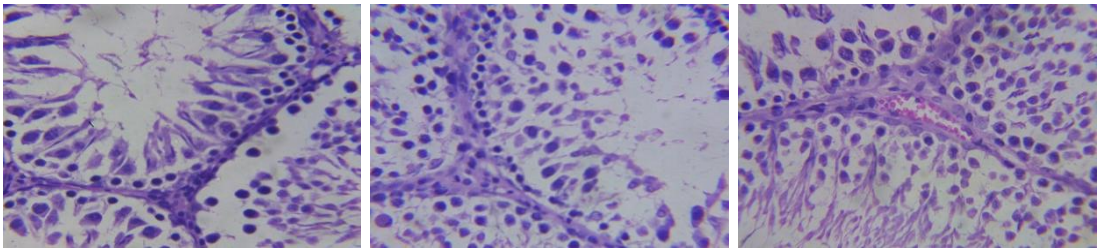
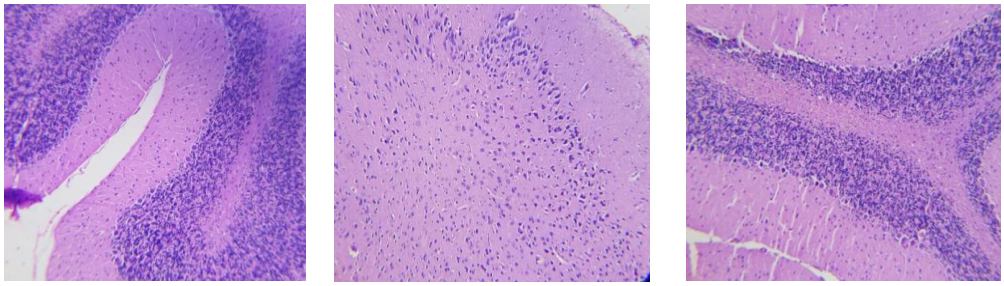


GROUP I **GROUP II** **GROUP III**

Histopathology of Brain (Female Rat) in Sub-acute toxicity Study

Low Power Magnification 10X



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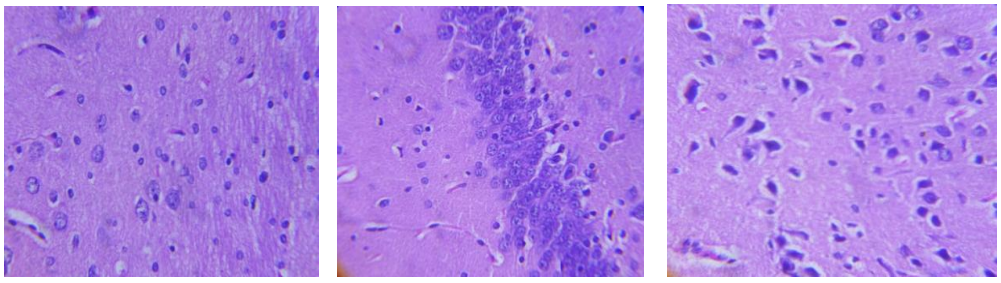

GROUP I **GROUP II** **GROUP III**

Histopathology of Heart (Female Rat) in Sub-acute toxicity Study

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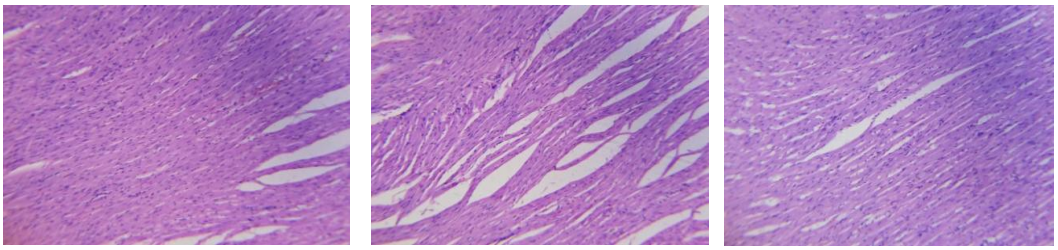

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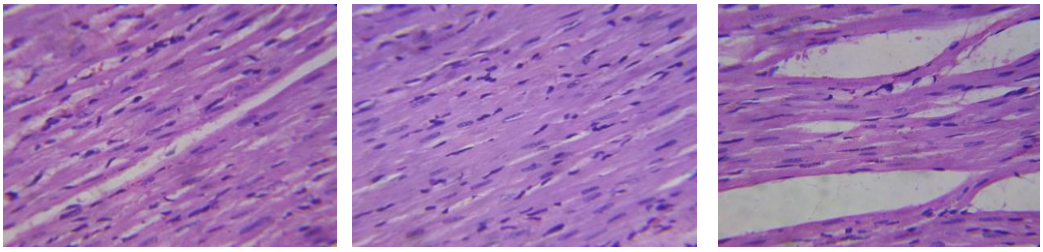

GROUP I **GROUP II** **GROUP III**

Histopathology of Kidney (Female Rat) in Sub-acute toxicity Study

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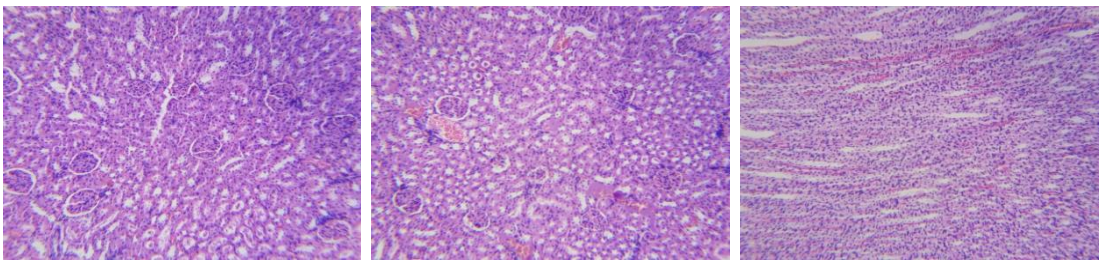

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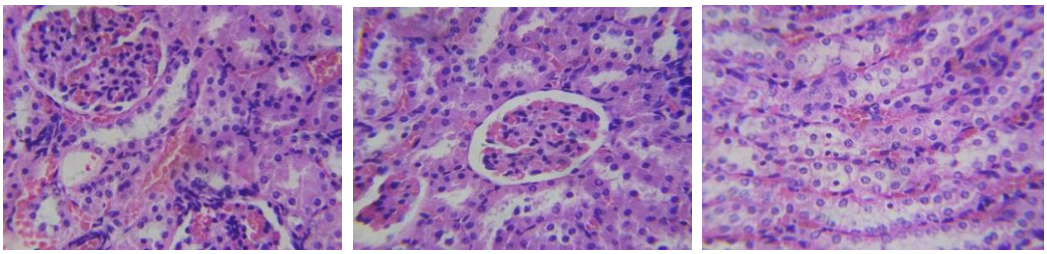

GROUP I **GROUP II** **GROUP III**

Histopathology of Liver (Female Rat) in Sub-acute toxicity Study

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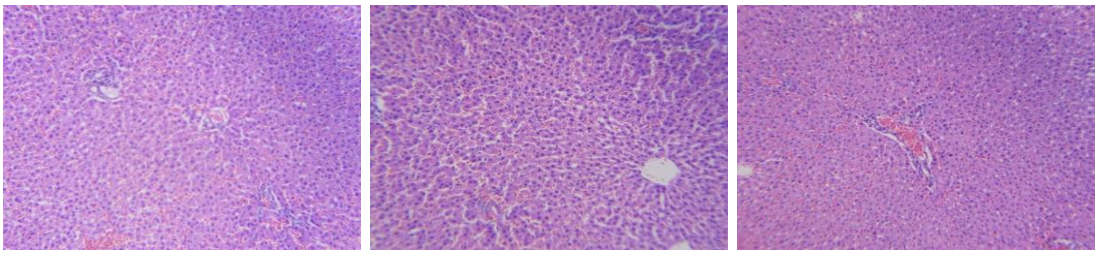

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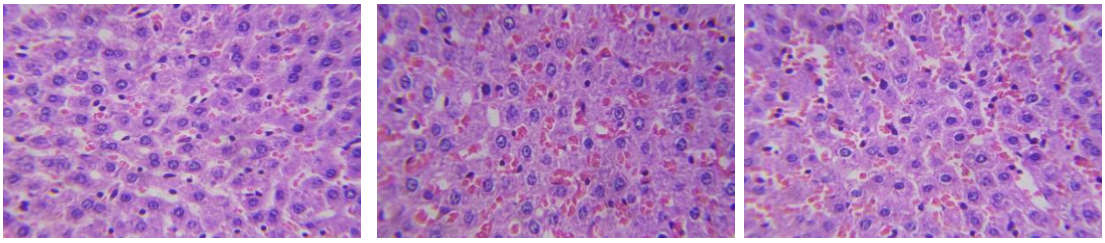
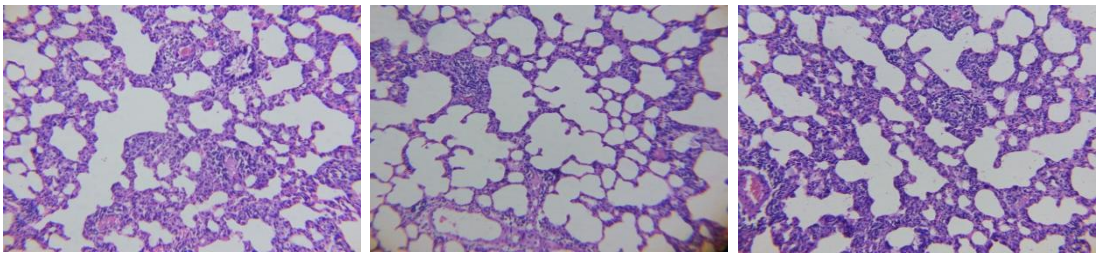


GROUP I **GROUP II** **GROUP III**

Histopathology of Lung (Female Rat) in Sub-acute toxicity Study

Low Power Magnification 10X



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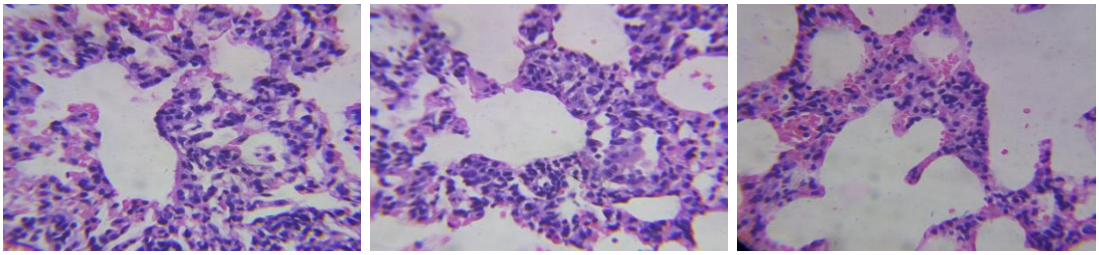
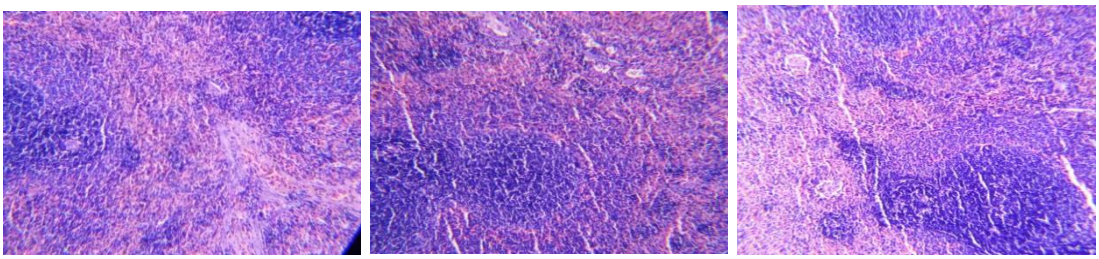


GROUP I **GROUP II** **GROUP III**

Histopathology of Spleen (Female Rat) in Sub-acute toxicity Study

Low Power Magnification 10X



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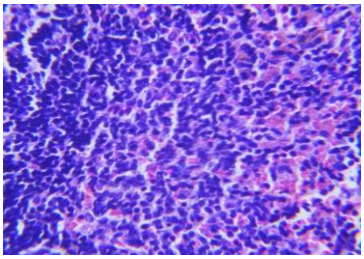
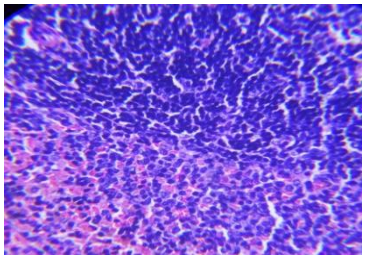
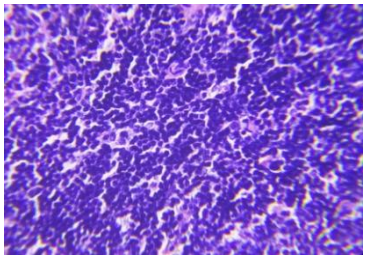

GROUP I **GROUP II** **GROUP III**

Histopathology of Stomach (Female Rat) in Sub-acute toxicity Study

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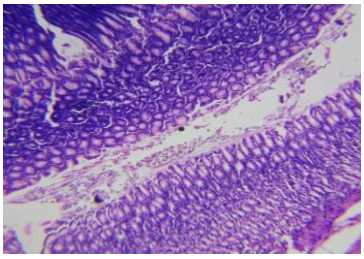
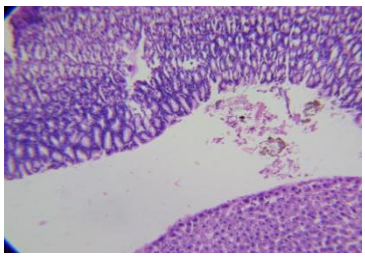
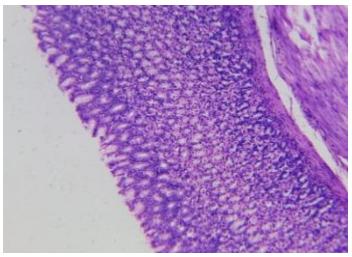

GROUP I **GROUP II** **GROUP III**

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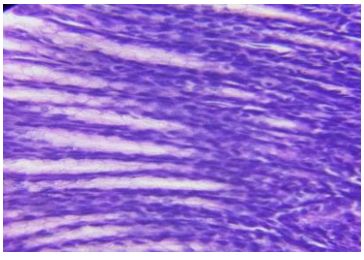
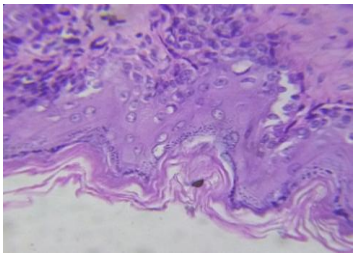
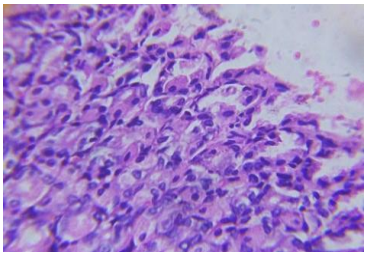

GROUP I **GROUP II** **GROUP III**

Histopathology of Uterus (Female Rat) in Sub-acute toxicity Study

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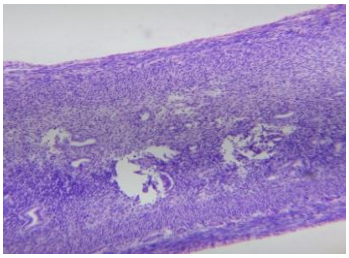
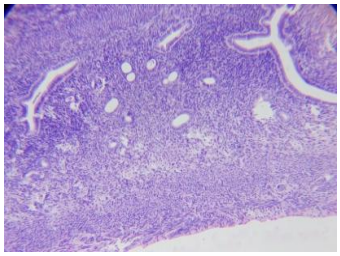
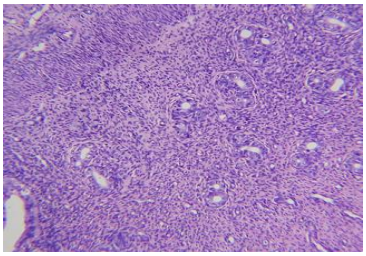

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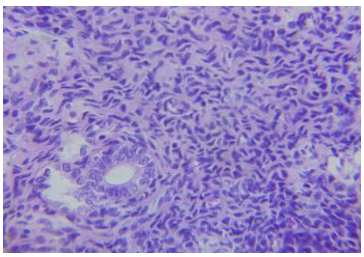
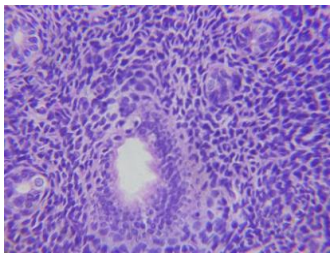
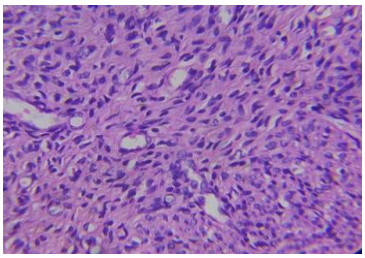

GROUP I **GROUP II** **GROUP III**

Histopathology of Ovary (Female Rat) in Sub-acute toxicity Study

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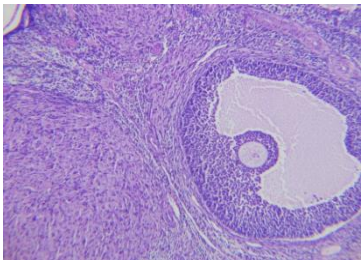
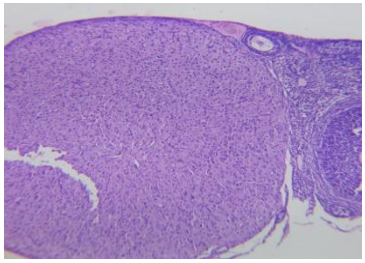
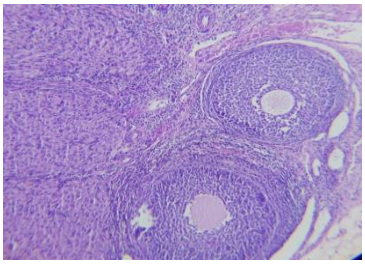

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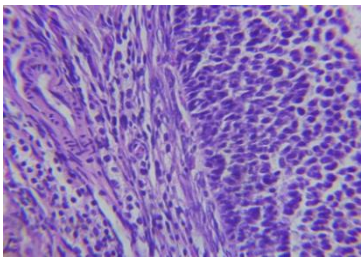

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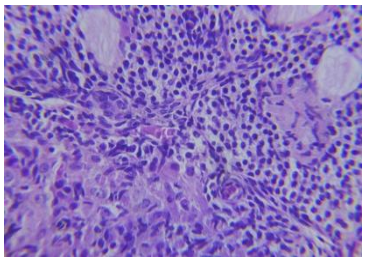

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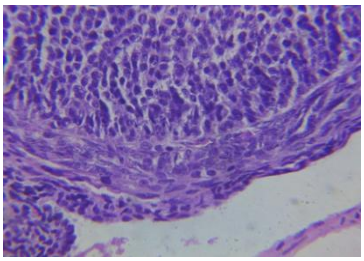


GROUP III

IAEC CERTIFICATE FOR PHARMACOLOGICAL STUDY

CERTIFICATE

This is to certify that the project entitled "**PHARMACOLOGICAL EVALUATION OF STYPTIC ACTIVITY OF MOOLARAGA CHOORNAM ON ASPIRIN INDUCED BLEEDING TIME PROLONGATION IN RATS**" has been approved by the Institutional Animal Ethics Committee of Sathyabama University, Chennai.

IAEC Approval No.: **SU/CLATR/IAEC/VII/045/2016**
Principal Investigator: Dr. B. Anbarasan
Animal Sanctioned: *Rattus norvegicus* / Wistar albino rats
Female: 9; Male: 9; Total: 18 (Eighteen)
Date: 05.10.2016

B. Sheela Rani

DR. B. SHEELA RANI
Chairperson

DR. R. ILAVARASAN
CPCSEA Nominee

LABORATORY ANIMAL TECHNOLOGY AND RESEARCH FACILITY * CENTRE FOR
SATHYABAMA UNIVERSITY
Chennai - 600 119

PHARMACOLOGICAL STUDY

Pharmacological Evaluation of styptic activity of *Moolaroga chooranam* on Aspirin induced bleeding time prolongation in rats.

Name: Dr. B. ANBARASAN

IAEC: SU/CLATR/IEAC/VII/045/2016

Animals

Healthy adult Wistar albino male rats weighing between 200-220 g were used for the study. The animals were housed in poly propylene cages and were kept in well ventilated with 100% fresh air by air handling unit. A 12 light / dark cycle were maintained .Room temperature was maintained between 22 $\pm$ 2^{o} C and relative humidity 50–65%. They were provided with food (Sai feeds, Bangalore, India) and water *ad libitum*. All the animals were acclimatized to the laboratory for 7 days prior to the start of the study. The experimental protocol was approved by The Institutional Animal Ethics Committee of Sathyabama University, Chennai, Tamil Nadu, India.

IAEC: SU/CLATR/IEAC/VII/045/2016

Experimental Methodology

The animals were grouped into four groups of 6 animals each. Group I (Control group) -received normal saline 5ml/kg, Group II – Aspirin control received 5mg/kg of aspirin, p.o. for 35 days. Group III - Received Aspirin (5mg/kg) for 21 days and then treated with 200mg/kg *Moolaroga chooranam* ,p.o one hour prior to Aspirin administration from day 22 to 35. Group III - Received Aspirin (5mg/kg) for 21 days and then treated with 400mg/kg *Moolaroga chooranam* ,p.o one hour prior to Aspirin administration from day 22 to 35.

Bleeding time prolongation in rats

Oral administration of Aspirin (5mg/kg),p.o for 21 days will cause significant change in the mean bleeding and clotting times.

Determination of Bleeding Time

At the end of 35^{th} day bleeding time was evaluated. The tail of the rat was warmed for 1min in water at 40°C and then dried. A small cut was made in tail tip with a scalpel. Bleeding time start and was noted when the first drop touched the circular filter paper and checked at 15 sec intervals until bleeding stops.

Determination of Clotting Time

Clotting time was determined by capillary tube method. Capillary tube was filled with rat blood collected through retro orbital sinus puncture. Tube was broken in to small piece for every 15 sec. As soon as threads of fibrin were noticed, the stopwatch was stopped and the time recorded as the clotting time for that particular rat.

Prothrombin time (PT)

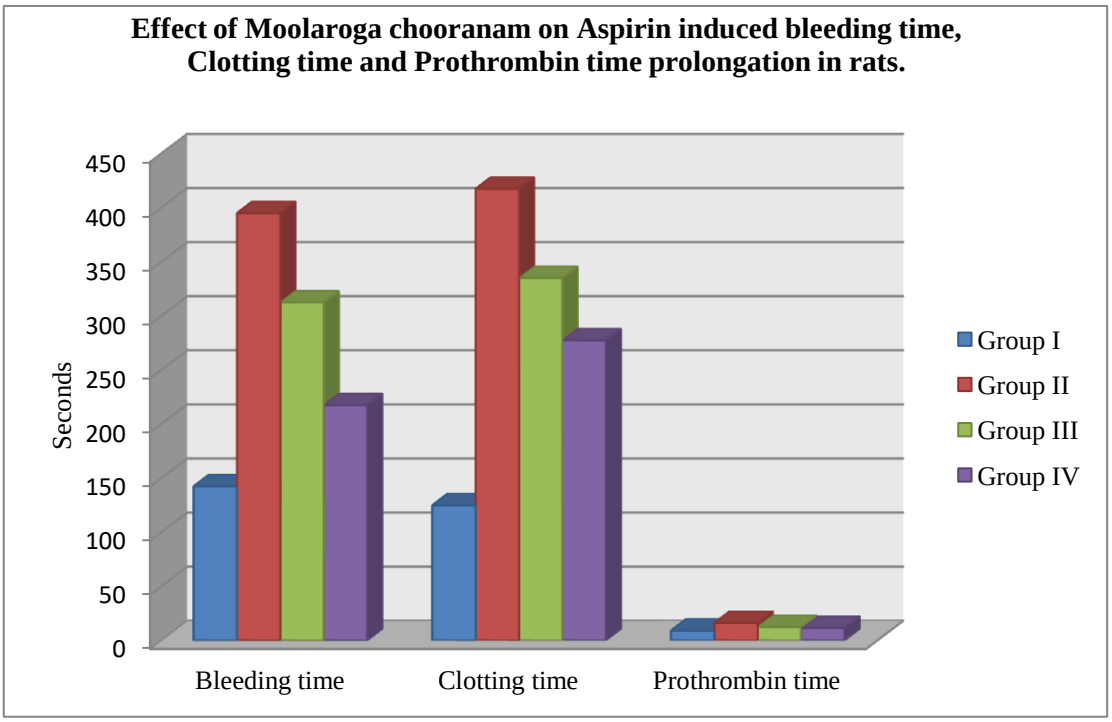
0.1 ml of plasma was mixed with 0.2 ml of PT reagent (Calcium thromboplastin) and then the reaction mixture was incubated at 37°C, and was absorbed until formation of the fibrin clot.

Effect of *Moolaroga chooranam* on Aspirin induced bleeding time, Clotting time and Prothrombin time prolongation in rats.

Group I	**Bleeding Time in Sec**	**Clotting Time in Sec**	**Prothrombin time in Sec**
Mean	142.5	125	9.167
Std. Deviation	31.1	15.49	1.169
Std. Error	12.7	6.325	0.4773
Group II	**Bleeding Time in Sec**	**Clotting Time in Sec**	**Prothrombin time in Sec**
Mean	395	417.5	16.17
Std. Deviation	24.49	22.08	1.602
Std. Error	10	9.014	0.654
Group III	**Bleeding Time in Sec**	**Clotting Time in Sec**	**Prothrombin time in Sec**
Mean	312.5	335	12.5
Std. Deviation	17.54	18.17	1.225
Std. Error	7.159	7.416	0.5
Group IV	**Bleeding Time in Sec**	**Clotting Time in Sec**	**Prothrombin time in Sec**
Mean	217.5	277.5	11.67
Std. Deviation	15.73	22.75	1.506
Std. Error	6.423	9.287	0.6146

Group of animals	Bleeding time	Clotting time	Prothrombin time
Group I	142.5±31.1	125±15.49	9.167±1.169
Group II	395±24.49**	417.5±22.08**	16.17±1.602**
Group III	312.5±17.54**	335±18.17**	12.5±1.225**
Group IV	217.5±15.73**	277.5±22.75**	11.67±1.506**

Values were expressed as means±S.D for N=6 rats in each group one way ANOVA followed by Dunnet's test. Significant indicates that *P<0.05, **P<0.01



PHYSICO-CHEMICAL ANALYSIS

சித்த மருத்துவ மைய ஆராய்ச்சி நிலையம், சென்னை - 600 106
सिद्ध केंद्रीय अनुसन्धान संस्थान,
अण्णा सरकारी अस्पताल परिसर, अरुम्बाक्कम, चेन्नई – 600 106
SIDDHA CENTRAL RESEARCH INSTITUTE
(Central Council for Research in Siddha, Ministry of AYUSH, Govt. of India)
Anna Govt. Hospital Campus, Arumbakkam, Chennai – 600106
Phone: 044-2621 4925, Fax: 044-2621 4809

21.6.2017

CERTIFICATE

Name of the student: Dr. C. Anbarasan, III year PG student, Department of Maruthuvam, Government Siddha Medical College, Arumbakkam, Chennai-600 106.

Name of the sample: Moolaroga Chooranam

Name of the Parameter	I	II	Mean
Loss on drying(at 105°C)	5.15%	5.11%	5.13%
Total ash	16.49%	16.42%	16.46%
Water soluble ash	12.04%	11.51%	11.78%
Acid insoluble ash	4.40%	4.30%	4.35%
Water soluble extractive	14.70%	14.70%	14.70%
Alcohol soluble extractive	7.90%	7.70%	7.80%
pH value (10%)	6.96		
TLC/HPTLC	Report Enclosed		

(R. Shakila)
Research Officer (Chemistry) & Head,
Department of Chemistry

21/6/17

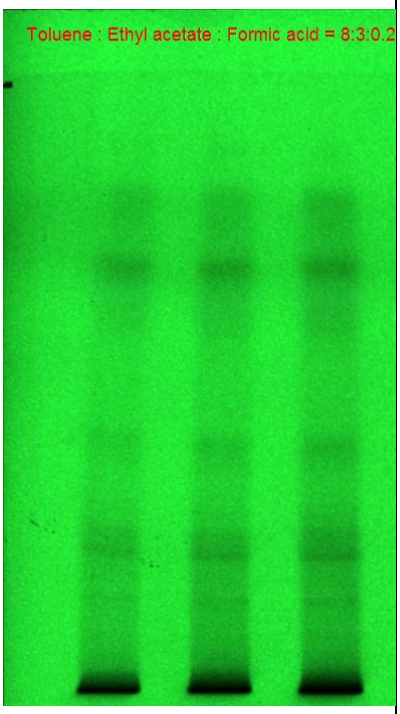
(Dr. P. Sathiyarajeswaran)
Assistant Director (Siddha) I/c

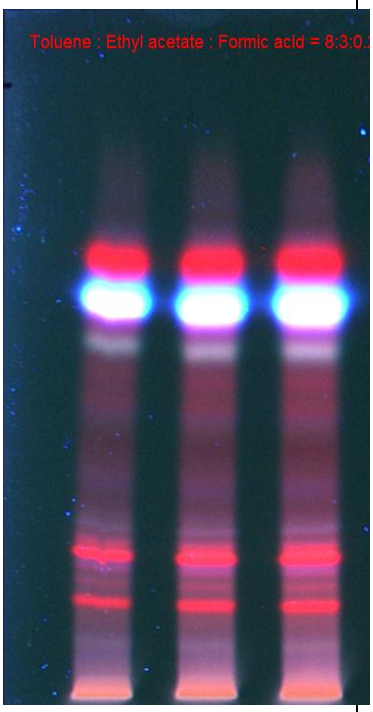
Sample Name: Moolaroga Chooranam

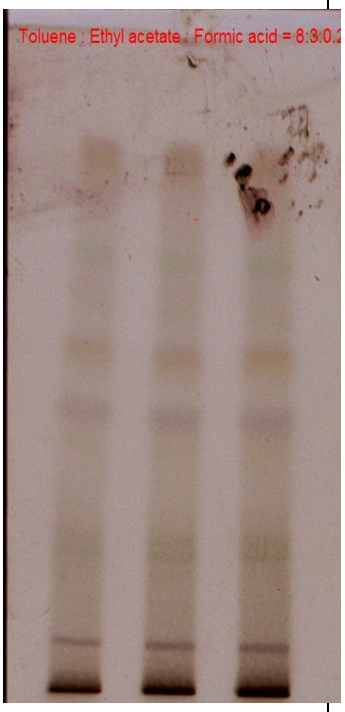
Chloroform Extract

Stationary Phase - Silica Gel 60 F_{254}

Mobile Phase – Toluene : Ethyl acetate : Formic acid = 8 : 3: 0.2

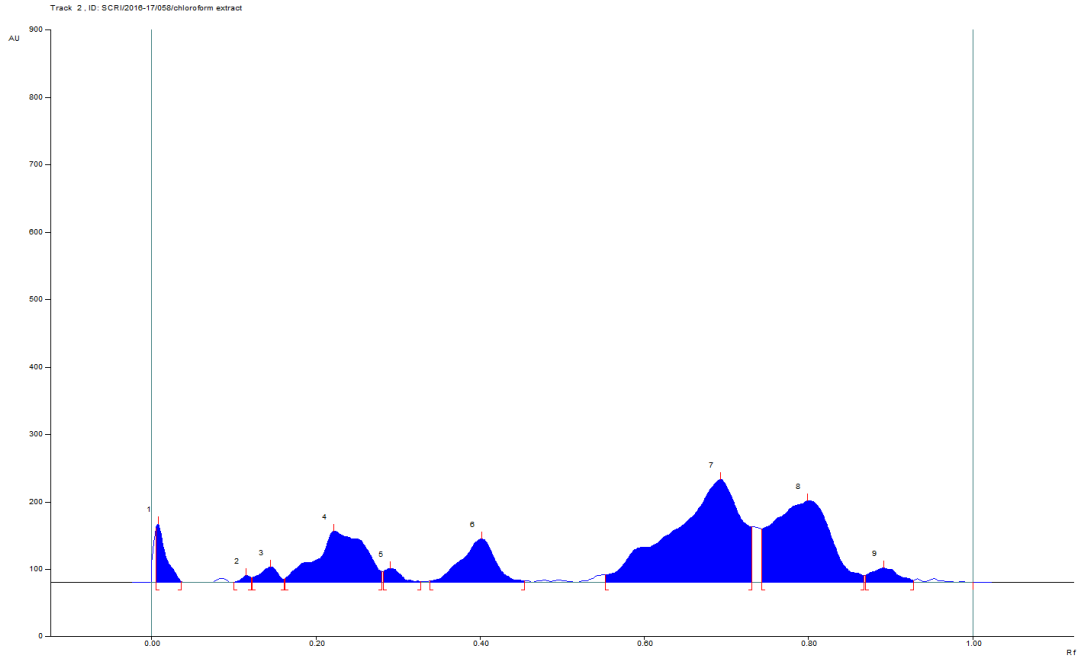






λ = 254 nm		**λ = 366 nm**		**λ = 520 nm (Derivatized)**	
Color	**R_f value(s)**	**Color**	**R_f value(s)**	**Color**	**R_f value(s)**
Green	0.14	Red	0.14	Violet	0.08
Green	0.22	Red	0.18	Green	0.22
Green	0.25	Red	0.20	Brown	0.25
Green	0.39	Red	0.22	Violet	0.45
Green	0.59	Red	0.47	Brown	0.54
Green	0.70	Red	0.70	Green	0.70

HPTLC Chromatogram @ 254 nm:

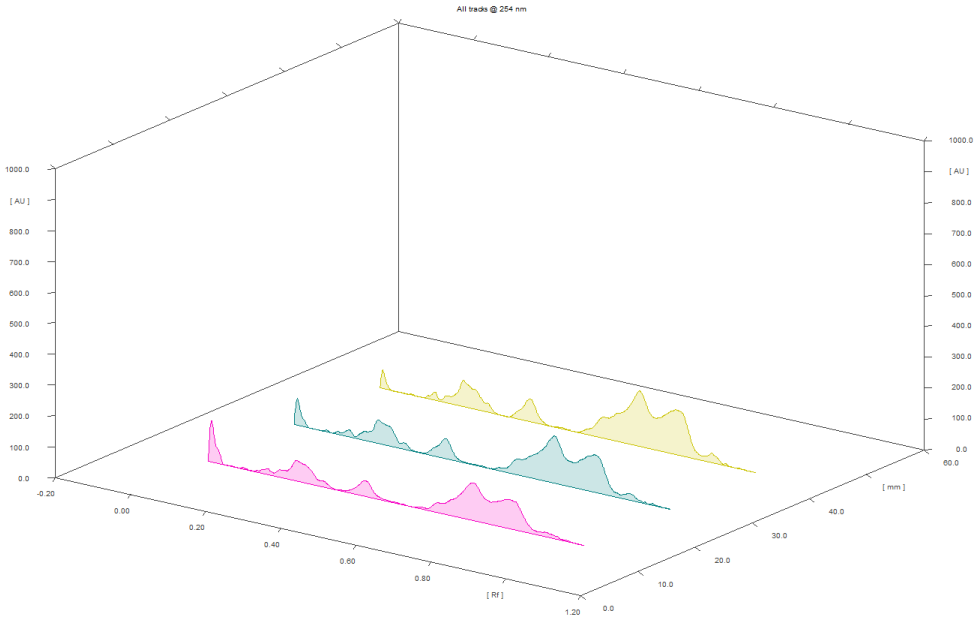


Peak Table @ 254 nm:

Track 2, ID: SCRI/2016-17/058/chloroform extract

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	0.00 Rf	79.9 AU	0.01 Rf	86.6 AU	15.01 %	0.04 Rf	0.9 AU	974.0 AU	3.42 %
2	0.10 Rf	0.0 AU	0.11 Rf	10.6 AU	1.83 %	0.12 Rf	7.2 AU	98.5 AU	0.35 %
3	0.12 Rf	7.3 AU	0.14 Rf	23.0 AU	3.98 %	0.16 Rf	5.0 AU	449.5 AU	1.58 %
4	0.16 Rf	5.5 AU	0.22 Rf	76.2 AU	13.22 %	0.28 Rf	16.3 AU	4168.6 AU	14.65 %
5	0.28 Rf	16.3 AU	0.29 Rf	20.6 AU	3.57 %	0.33 Rf	1.1 AU	382.4 AU	1.34 %
6	0.34 Rf	1.9 AU	0.40 Rf	64.3 AU	11.16 %	0.45 Rf	2.3 AU	2416.7 AU	8.49 %
7	0.55 Rf	10.8 AU	0.69 Rf	152.7 AU	26.48 %	0.73 Rf	82.2 AU	11489.6 AU	40.37 %
8	0.74 Rf	79.1 AU	0.80 Rf	121.1 AU	21.00 %	0.87 Rf	9.8 AU	7839.4 AU	27.54 %
9	0.87 Rf	10.2 AU	0.89 Rf	21.6 AU	3.74 %	0.93 Rf	2.5 AU	644.0 AU	2.26 %

3D Chromatogram @ 254 nm:



BIOCHEMICAL ANALYSIS

Preparation of sodium carbonate extract: 2 gm of the Moolaroga chooranam is mixed with 5 gm of sodium carbonate and taken in a 100 ml beaker and 20ml of distilled water is added. Then the solution is boiled for 10 minutes, cooled and then filtered. The filtrate is called sodium carbonate extract.

TEST FOR ACID RADICALS

S.NO	EXPERIMENT	OBSERVATION	INFERENCE
1.a	**Test for Sulphate**: 2 ml of the above prepared extract is taken in a test tube . to this add 2ml of 4% ammonium oxalate solution	Absence of white precipitate	Absence of sulphate
1.b	**Test for Sulphate**: 2 ml of the extract is added with 2 ml of dilute hydrochloric acid until the effervescence ceases off. Then 2ml of barium chloride solution is added.	Absence of white precipitate	Absence of sulphate
2.	**Test for chloride:** 2ml of extract is added with dilute nitric acid till the effervescence ceases . then 2ml of silver nitrate solution is added.	Absence of white precipitate	Absence of chloride
3.	**Test for phosphate:** 2ml of the extract is treated with 2ml of ammonium molybdate solution and 2ml of concentrated nitric acid.	Presence of yellow precipitate.	Presence of Phosphate

4.	**Test for carbonate:** 2ml of the extract is treated with 2ml of magnesium sulphate solution.	Absence of white precipitate.	Absent
5.	**Test for sulphide:** 1gm of the substance is treated with 2ml of concentrated hydrochloric acid.	Rotten egg smelling is obtained	Presence of Sulphide
6.	**Test for nitrate:** 1gm of the substance is heated with copper turnings and concentrated sulphuric acid and viewed the test tube vertically down.	Absence of reddish brown colour.	Absence of Nitrate
7.a	**Test for fluoride and oxalate:** 2ml of the extract is added with 2ml of dilute acetic acid and 2ml of calcium chloride solution and heated.	Absence of white precipitate.	Absence of Fluoride and oxalate
7.b	**Test for fluoride and oxalate:** 5 drops of clear solution is added with 2ml of dilute sulphuric acid and slightly warmed to this, 1ml of dilute potassium permanganate solution is added.	Absence of KMNO4 solution discoloration	Absence of Fluoride and oxalate
8.	**Test for nitrate :** 3 drops of the extract is placed on a filter paper . on that , 2 drops of acetic acid and 2 drops of benzidine solution is placed.	Absence of yellowish red colour .	Absent
9.	**Test for borate:** 2 pinches of the substance is made into paste by using sulphuric acid and alcohol (95%) and introduced into the blue flame.	Absence of green tinged flame	Absent

TEST FOR BASIC RADICALS:

10.	**Test for lead:** 2ml of the extract is added with 2ml of potassium iodide solution.	Absence of yellow precipitate.	Absent
11.a	**Test for copper:** one pinch of the substance is made into paste with concentrated hydrochloric acid in a watch glass and introduced into the luminous part of the flame.	Absence of bluish green coloured flame is obtained.	Absent
11.b	**Test for copper**: 2ml of the extract is added with excess of ammonia solution.	Absence of deep blue colour	Absent
12.	**Test for aluminium**: To the 2ml of the extract , sodium hydroxide solution is added in drops to excess.	Absence of white precipitate.	Absent
13.a	**Test for iron**: To the 2ml of the extract, 2ml of ammonium thiocyanate soilution is added.	Blood red colour is obtained	Presence of iron

13.b	**Test for iron :** To the 2ml of the extract , 2ml of the ammonium thiocyanate solution and 2ml mof concentrated nitric acid is added.	Blood red colour is obtained.	Presence of iron
14.	**Test for zinc:** To the 2ml of the extract , sodium hydroxide is added in drops to excess.	Absence of white precipitate.	Absent
15.	**Test for calcium**: 2ml of the extract is added with 2ml of 4% ammonium oxalate solution.	Absence of white precipitate.	Absence of calcium
16.	**Test for magnesium**: To the 2ml of the extract , sodium hydroxide is added in drops to excess.	Absence of white precipitate.	Absence of magnesium
17.	**Test for ammonium:** 2ml of the extract few ml of nessler's reagent and excess of sodium hydroxide solution are added.	Absence of Reddish brown precipitate	Absence of ammonium
18.	**Test for potassium:** A pinch of substance is treated with 2ml of sodium nitrite solution and then treated with 2ml of cobal nitrate in 30% glacial acetic acid.	Absence of yellow precipitate.	Absence potassium
19.	**Test for sodium :** 2 pinches of the substance is	Absence of yellow colour flame.	Absence of sodium

	made into paste by using hydrochloric acid and introduced into the blue flame.		
20.	**Test for mercury:** 2ml of the extract is treated with 2ml of sodium hydroxide solution.	Absence of yellow precipitate.	Absence of mercury
21.	**Test for arsenic :** 2ml of extract is treated with 2ml of silver nitrate solution**.**	Absence of yellow precipitate.	Absent
22.	**Test for starch :** 2ml of the extract is treated with weak iodine solution.	Absence of blue colour.	Absent
23.	**Test for reducing sugar :** 5ml of benedicts qualitative solution is taken in a test tube and allowed to boil for 2 minutes and added 10 drops of the extract and again boiled for 2 minutes. The colour changes are noted.	Green colour is obtained .	Presence of reducing sugar
24.	**Test for the alkaloids:** 2ml of the extract is treated with 2ml of the potassium iodide solution.	Absence of red colour.	Absent

25.	2ml of the extract is treated with 2ml of 5%NaOH, well and add 2 drops of copper sulpate solution.	Absence of Violet colour.	Absent

RESULTS:

The trial drug Moolaroga chooranam contains Sulphide, Phosphate in the Acid radicals, and Iron and reducing sugar in the basic radicals.

INSTITUTIONAL ETHICS COMMITTEE CERTIFICATE

GOVERNMENT SIDDHA MEDICAL COLLEGE
Arumbakkam, Chennai-106

Communication Of The Decision Of Institutional Ethics Committee (IEC)

IEC No: GSMC-CH-ME-4/2015/002

Protocol title: A CLINICALSTUDYON RATTHA MOOLAM WITH THE EVALUATION OF SIDDHA DRUG MOOLAROGA CHOORANAM	
Principal Investigator:	DR.B. ANBARASAN
Name & Address of Institution : Government siddha medical college, Arumbakkam, Chennai-106	
☑ New Review	☐ Revised Review ☐ Expedited Review
Date of review (DD/MM/YY):	26-03-2015
Date Of Previous Review, If Revised Application :	
Decision of the IEC	
☑ Recommended	☐ Recommended with suggestions
☐ Revision	☐ Rejected
Suggestions / Reasons / Remarks :	
Recommended for a period of 1 year from date of completion of preclinical studies:	

Please Note:

- Inform IEC immediately in case of any adverse events/serious drug reaction.
- Seek IECapproval in case of any change in the study procedure, site and investigator
- This approval is valid only for period mentioned above
- IEC member have the right to review the trial with prior intimation.

26/3/15

Dr.P.Jeyaprakashnarayanan
Chairman

Dr.V. Banumathi
Member Secretary

INSTITUTIONAL ETHICS COMMITTEE

Date:

Sub: IEC review of research proposals.

Ref:Your letter dated

MEMBERS	PARTICIPATION	SIGNATURE
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MR.P.SARAVANAN., Puplic Person	☑	

26/3/15.

Dr.P.Jeyaprakashnarayanan
Chairman

Dr.V.Banumathi
Member Secretary

BIOSTATISTICS REPORT

CLINICAL PROGNOSIS

Health Assessment Score:

Effect of Moolaroga Chooranam on Health Assessment Score in human subjects in the treatment of Rattha Moolam

S. No	BeforeTreatment	AfterTreatment
1.	16	1
2.	19	5
3.	15	8
4.	16	14
5.	12	0
6.	15	2
7.	20	7
8.	19	0
9.	13	0
10.	17	2
11.	14	1
12.	12	1
13.	20	1
14.	14	5
15.	16	1
16.	18	12
17.	19	0
18.	15	0
19.	10	0
20.	17	0
21.	20	0
22.	11	2
23.	19	0
24.	15	2
25.	14	1
26.	20	1
27.	12	2
28.	17	2
29.	18	2
30.	20	1
31.	14	0
32.	19	8
33.	19	0
34.	14	1
35.	15	1
36.	14	0
37.	21	1
38.	15	0
39.	14	6
40.	19	0

Software: spss17 version

Variables: HAQ Score– before treatment, after treatment

Number of cases: 40

Test: Paired t test

Confidence Interval: 95%

Correlation coefficient (r): 0.09784

Before and after treatment mean difference ± SEM: 13.925± 4.22

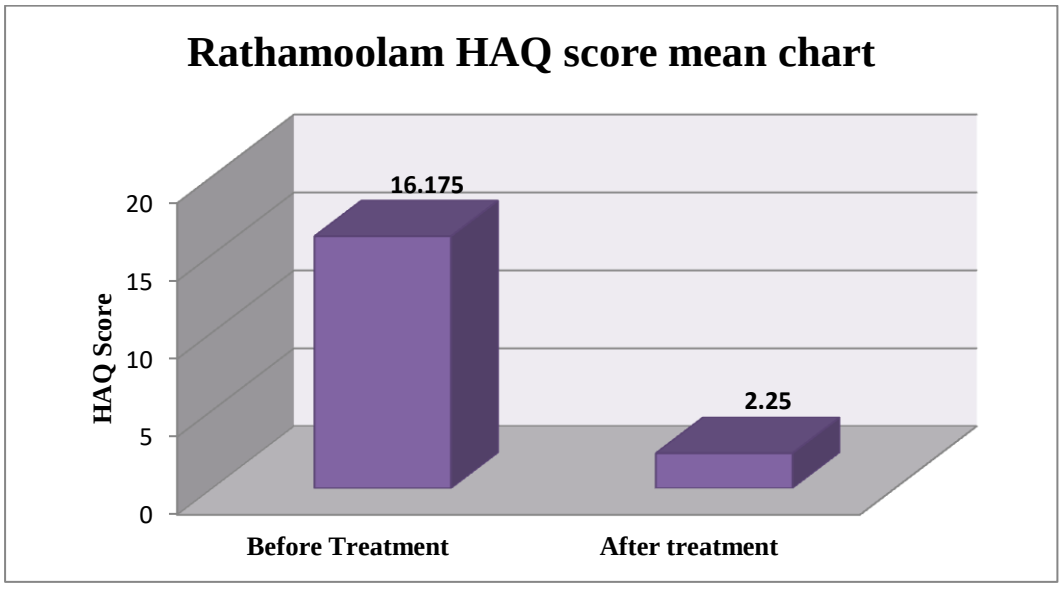
P Value (2 tailed): p<0.0001.

t Value: 20.866

Degrees of freedom: 39

Inference:

Since the P value is highly significant (<0.0001), the null hypothesis is not accepted. So, the treatment was significantly improving the HAQ Score among the patients for the treatment of Ratha Moolam.



GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

CLINICAL STUDY ON "*MOOLAROGA CHOORANAM*" IN THE TREATMENT OF

"RATTHA MOOLAM" (BLEEDING PILES)

INFORMED CONSENT FORM

"I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction.

I consent voluntarily to participate in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my further medical care".

"I have received a copy of the information sheet/consent form".

Date:

Signature of the participant:

In case of illiterate participant

"I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely."

Date:

Signature of the witness

(Selected by the participant bearing no connection with the survey team)

Date:

Station:

Signature of participant:

Signature of the Co-Investigator:

Signature of the Principal Investigator: **Signature of the HOD**

அரசு சித்த மருத்துவக் கல்லூரி, சென்னை
அறிஞர் அண்ணா மருத்துவமனை, சென்னை

இரத்த மூலம் நோய்க்கான சித்த மருந்தின் (மூலரோக சூரணம்)

பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம்
ஒப்புதல் படிவம்

ஆய்வாளரால் சான்றளிக்கப்பட்டது

நான் இந்த ஆய்வை குறித்த அனைத்து விபரங்களையும் நோயாளிக்கு புரியும் வகையில் எடுத்துரைத்தேன் என உறுதியளிக்கிறேன்.

தேதி : **கையொப்பம்:**

இடம்: **பெயர் :**

நோயாளியின் ஒப்புதல்

என்னிடம் இந்த மருத்துவ ஆய்வின் காரணத்தையும், மருந்தின் தன்மை மற்றும் மருத்துவ வழிமுறை பற்றியும், தொடர்ந்து எனது உடல் இயக்கத்தை கண்காணிக்கவும், அதனை பாதுகாக்கவும் பயன்படும் மருத்துவ ஆய்வுக்கூட பரிசோதனைகள் பற்றி திருப்தி அளிக்கும் வகையில் ஆய்வு மருத்துவரால் விளக்கிக் கூறப்பட்டது.

நான் இந்த மருத்துவ ஆய்வின் போது, காரணம் எதுவும் கூறாமல், எப்பொழுது வேண்டுமானாலும் இந்த ஆய்விலிருந்து என்னை விடுவித்து கொள்ளும் உரிமையை தெரிந்திருக்கின்றேன். நான் என்னுடைய சுதந்திரமாக தேர்வு செய்யும் உரிமையைக் கொண்டு **இரத்த மூலம்** நோய்க்கான **மூலரோக சூரணம்** (உள் மருந்து) மருந்தின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கு என்னை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி: **கையொப்பம் :**

இடம்: **பெயர் :**

தேதி: **சாட்சிக்காரர் கையொப்பம் :**

இடம்: **பெயர் :**
உறவுமுறை :

துறைத்தலைவர் கையொப்பம் : **ஆராய்ச்சியாளர் கையொப்பம்:**

CASE SHEET PROFORMA FOR RATTHA MOOLAM

GOVT.SIDDHA MEDICAL COLLEGE&HOSPITAL, CHENNAI-106

POST GRADUATE DEPARTMENT BRANCH –I MARUTHUVAM

Duration: 2015-2017

Op No / Ip No	:	Occupation	:
Ward No	:	Income	:
Bed No	:	Nationality	:
Name	:	Religion	:
Age	:	D.O.A	:
Sex	:	D.O.D	:
Address	:	Diagnosis	:

1. Complaints and duration :

2. History of present illness :

3. History of past illness :

4. Personal history :

5. Occupational history :

6. Menstrual history :

7. Personal Habits :Veg/nonveg/smoker/Alcocoholic/Tobacco chewer

8. Family History :

GENERAL EXAMINATION

Patient consciousness :

Body Built :

Nourishment :

Anaemia :

Jaundice :

Cyanosis :

Clubbing :

JVP :

Tracheal deviation :

Pedal oedema :

Lymph adenopathy :

VITAL SIGNS

Body Temp :

Pulse :

Respiratory rate :

Blood Pressure :

Weight :

SIDDHA ASPECT

NILAM

Kurinchi :

Mullai :

Marutham :

Neithal :

Palai :

PARUVA KALAM

Kaar (Aavani, Purattasi) :

Koothir (Aippasi, Karthigai) :

Munpani (Margazhi, Thai) :

Pinpani (Maasi, Panguni) :

Elavenil(Sithirai, vaigasi) :

Muduenil (aani, aadi) :

YAAKKAI(Udal)

Vaatham :

Pittham :

Kabam :

Kalappu :

GUNAM

Satthuvam :

Rajotham :

Thamasam :

PORI/PULANGAL (SENSORY ORGANS)

Mei (Sensation) :

Vaai (Taste) :

Kan (Vision) :

Mooku (Smell) :

Sevi (Hearing) :

KANMENTHRIYAM/KANNMA VIDAYAM [MOTOR ORGANS]

Kai (Dhaanam) :

Kaal (Kamanam) :

Vaai (Vasanam) :

Eruvaai (Visarkkam) :

Karuvaai (Aanantham :

UTHKAAYA ATHAKAAYAM

Puyam (forearm) :

Sayam (arm) :

Kaal (leg) :

Paaatham (feet) :

UYIR THATHUKKAL

A.VATHAM

Piranan :

Abanan :

Viyanan :

Udanan :

Samanan :

Nagan :

Koorman :

Kirukaran :

Devathathan :

Thananjeyan :

B.PITHAM

Anar pitham :

Ranjaga pitham :

Saathaga pitham :

Pirrasaga pitham :

Alosaga pitham :

C.KABAM

Avalambagam :

Kilethagam :

Pothagam :

Tharpagam :

Santhigam :

UDALTHAATHUKKAL

Saaram :

Senner :

Oon :

Kozhuppu :

Enbu :

Moolai :

Sukkilam/Suronitham :

ENVAGAI THERVUGAL

1.Naa :

2.Niram :

3.Mozhi :

4.Vizhi :

5.Sparisam :

6.Malam :

7.Moothiram

a)Neer Kuri :

b)Nei Kuri :

8.Naadi :

MALAM

Niram :

Edai :

Erugal :

Elagal :

MOOTHIRAM

1.Neerkuri

Niram :

Manam :

Edai :

Nurai :

Enjal :

2.Neikuri

MODERN ASPECT

Sytemic Examination

Inspection :

Palpation :

Percussion :

Auscultation :

Proctoscopy :

Others Systems

Cardio Vascular System :

Respiratory system :

Central nervous system :

Genito urinary system :

CLINICAL SIGNS AND SYMPTOMS OF RATTHA MOOLAM

Symptoms	**Before Treatment**	**After Treatment**						
		7 days	**14 days**	**21 days**	**28 days**	**35 days**	**42 days**	**48 days**
Rectal Bleeding								
Pruritus ani								
Constipation								
Loss of appetite								
Giddiness								

Health Assessment Questionnaire:

		BF	AF
I.	**How often do you have bleeding when passing a motion?**		
	1. Never	☐	☐
	2. Less than once per week		
	3. 1-6 per week		
	4. Every day		
II.	**What is the nature of bleeding?**	☐	☐
	1. No bleeding		
	2. Few drops of blood		
	3. Splashing of blood up to 5 ml		
	4. Splashing of blood more than 5 ml		
III.	**How often do you have itching/irritation in the anus?**		
	1. Never	☐	☐
	2. Less than once per week		
	3. 1 – 6 times per week		
	4. Every day		
IV.	**How severe is your itching/irritation in anus?**		
	1. No itching	☐	☐
	2. Mild itching		
	3. Moderate itching		
	4. Severe itching		
V.	**What is the consistency of the stool during defecation?**	☐	☐
	1. Like smooth soft snake		
	2. Sausage shape with cracks in the surface		
	3. Lumpy and sausage like		
	4. Separate hard lumps		

VI. How long do you spend during defecation?

1. **Less than 5 minutes**
2. **5 to 10 minutes**
3. **10 – 15 minutes**
4. **More than 15 minutes**

Total Score

Net Total Score
(Difference between Total score before
Treatment And Total score after treatment)

Note: Improvement is assessed based on the Difference between Total score before treatment And Total score after treatment.

1 - 6 = No improvement
7 – 12 = Mild improvement
13 – 18 = Moderate improvement
19 – 24 = Good improvement

INVESTIGATIONS

1. BLOOD

TC
DC
ESR
Bleeding time
Clotting time
Blood sugar
Blood urea
Serum cholesterol
VDRL

2. URINE

Albumin
Sugar
Deposits

3. MOTION

Ova

Cyst

Occult Blood

4. SPECIFIC INVESTIGATION

Proctoscopy

CASE SUMMARY

DIAGNOSIS

Rattha moolam

TRIAL DRUG

MOOLAROGA CHOORANAM

Dose : 1gm, twice a day

Anubanam : Honey

Duration of Treatment : 48days

Pathiam (Do's and Don'ts):

DO'S:

- Drink plenty of water
- Karunai kilangu
- Vilangu meen
- Thuthi keerai
- Thaali keerai
- Pasalai keerai
- Vendhaya keerai
- Karunaikizhangu

- Saenaikizhangu
- Vendaikkai
- Atthikkai
- Kovaikkai
- Pork
- Snail should be eaten

Don'ts:

Spicy food, chicken should be avoided.

Prognosis at the end of the Treatment

Prognosis is assessed by Reduction in clinical symptoms and by comparing the following parameters before and after treatment.

1. Bleeding per rectum.
2. Proctoscopy
3. Questionairre

Medical Officer **Head of the Department**

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