CLINICAL EVALUATION OF VILVA ENNAI *(*A Siddha Drug*)* IN THE TREATMENT OF VALI KANAM (Acute Pharyngitis) IN CHILDREN

The dissertation submitted by

Dr.K.ABINAYA

PG Scholar

Under the Guidance of

Dr.A.M.AMALA HAZEL, M.D(S)

Lecturer, Department of Kuzhandhai Maruthuvam

For the partial fulfillment of requirements to the Degree of

Doctor of Medicine (Siddha)

AFFILIATED TO THE TAMILNADU Dr. M.G.R MEDICAL UNIVERSITY

BRANCH IV – DEPARTMENT OF KUZHANDHAI MARUTHUVAM

NATIONAL INSTITUTE OF SIDDHA,TAMBARAM SANATORIUM,

CHENNAI– 600 047

OCTOBER-2017

DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled **"CLINICAL EVALUATION OF VILVA ENNAI (A Siddha Drug) IN THE TREATMENT OF VALI KANAM (Acute Pharyngitis) IN CHILDREN"** is a bonafide and genuine research work carried out by me under the guidance of **Dr.A.M.AMALA HAZEL M.D(S)., Lecturer** Department of Kuzhandhai Maruthuvam, National Institute of Siddha, Chennai -47, and the dissertation has not formed the basis for the award of any Degree, Diploma, Fellowship or other similar title previously.

Date: **Signature of the Candidate**

Place: Chennai-47 (Dr.K.Abinaya)

BONAFIDE CERTIFICATE

Certified that I have gone through the dissertation submitted by **Dr.K.ABINAYA**, (Reg.321414201) a Student of Final year MD(S), Branch IV, Department of Kuzhandhai Maruthuvam, National Institute of Siddha, Tambaram Sanatorium, Chennai-47 and the dissertation work has been carried out by the individual only. This dissertation does not represent or reproduced the dissertation submitted and approved earlier.

Date :

Place : Chennai - 47

Name and Signature of the HOD
Dr.M.MEENAKSHI SUNDARAM, M.D(S),
Asso.prof/ HOD(i/c)
Department of Kuzhandhai Maruthuvam,
National Institute of Siddha.

Name and Signature of the Guide
Dr.A.M.AMALA HAZEL, M.D(S)
Lecturer/ Guide
Department of Kuzhandhai Maruthuvam,
National Institute of Siddha.

Forwarded by the Head of the Institution
Prof. Dr.V.BANUMATHI, M.D(S), Director
National Institute of Siddha
Tambaram Sanatorium, Chennai - 600 047

ACKNOWLEDGEMENT

I surrender my prayers to the Spiritual soul, God and Siddhars who constantly guided with their invisible presence for the completion of my dissertation task. This dissertation is one of the milestones in the journey of my professional carrier as it is the key program in acquiring my MD(Siddha) degree.

Thus I came across this task which kept on completed with the support and encouragement of numerous people. So I take great pleasure in thanking all the people who made this dissertation study a valuable and successful one, which I owe to treasure it.

I express my sincere thanks to **Dr.A.M.Amala Hazel, M.D(S),Guide,** Department of Kuzhandhai Maruthuvam for her exemplary guidance, monitoring, unending patience, encouragement and hopeful support of my whole study and her expert advice, suggestions and supportive guidance for the frame work of the study.

I take this opportunity to express my gratitude and acknowledge to the **Vice-Chancellor**, **The Tamilnadu Dr.MGR medical University**. Chennai.

I express my sincere gratitude to **Prof.Dr.V.Banumathi M.D(S),Director**, National Institute of Siddha, Chennai for her hopeful support and providing all the basic facilities for this dissertation.

I express my sincere thanks to **Prof. Dr.S.Mohan, M.D(S),** Former Director (i/c), Hospital Superintendent, for giving me an opportunity to take this dissertation study. I express my sincere thanks to **Prof. Dr.M.Rajasekaran, M.D(S),** Former Director (i/c), for providing all the basic facilities for this dissertation.

I express my sincere thanks to **Dr.M.Meenakshi Sundaram M.D(S),** Asso.prof & Head of the Department (i/c), Department of Kuzhandhai Maruthuvam for his encouragement, precious advice and valuable guidance in this dissertation.

I express my sincere thanks to **Dr.K.Vetrivel M.D(S),** Associate Prof. Department of Kuzhandhai Maruthuvam for his hopeful support and encouragement

of my whole study. I express my sincere thanks to **Dr.K.Suresh M.D(S),** Lecturer, **Dr.P.Arul Mozhi M.D(S),** Lecturer, **Dr.K.Vennila M.D(S),** Lecturer, for their suggestions, hopeful support and encouragement of my whole study.

I express my sincere thanks to **Dr.D.Aravind M.D(S), M.Sc**., Assistant Professor of Medicinal Botany, for his guidance and botanical authenticity of the trial drug during study.

I wish to thank **Dr.A.Muthuvel, M.Sc., Ph.D.,** Asst. Professor, In-charge of Biochemistry laboratory, for his guidance and help in conducting the biochemical analysis of the trial drug during study.

I express my sincere thanks to **Mr.M.Subramanian M.Sc.,(statistics) Senior Research Officer**, for his input in the statistical analysis of clinical data and help in designing the protocol of this trial.

I express my sincere thanks to **Dr.Vaitheeswaran, M.B.B.S, M.D. (Paed),** Senior Assistant Professor, Govt Hospital Royapettah, Kilpauk Medical College for his valuable guidance in this work.

I express my gratefulness to all my Colleagues and my friends for lending their helping hands whenever needed during the course of the study.

Last but not least, I would like to pay high regards to my family members and my husband **Mr.S.Sugumaran B.Tech.,** for their sincere encouragement throughout my research work and lifting me uphill this phase of life.

CONTENTS

1. INTRODUCTION

The predominant aim and object of siddha science is to assure the full span of long healthy life to enable man acquired knowledge, Cultivate good character and conduct with which they could enjoy their legitimate worldly pleasures and ultimately attain salvation.

Siddha system is a psychosomatic system of medicine that deals with the relationship between the mind and body and aims at maintaining the physical, mental and moral health of individual.

As per the Siddha system, man is regarded as the microcosm and universe the macrocosm. The forces in the microcosm or man are identical with forces of the macrocosm. The living man is a conglomeration of three thodams (Three humors namely vadham, pitham and Kabham), Udalthathukkal (Saram, Senneer, Oon, Kozhuppu, Enbu, Moolai andSukkilam) and panchabhutham (Five basic elements – Prithivi (Mann), Theyu (Thee), Appu (Neer), Kaatru (Vaayu) and Veli (Aagasam). A Suitable proportion of these five elements, in combination with one another are responsible for the different structure and function of the body matrix.

Health is considered as the maintenance of equilibrium between the three humors and disease is the imbalance among them. The intrinsic and extrinsic factors can cause disturbance in this natural equilibrium giving rise to disease. As per ancient siddha text, Theraiyar karisal, any disease is caused due to Karma, Irregular dietary habits and lifestyle. Saint Thiruvalluvar has indicated the same view in the ancient Tamil literature, Thirukural as follows:

“Miginum kuraiyinum noi seyum noolor
Vali mudhala enniya moondru”.

The siddha system strongly advocates proper food habits and hygiene. It has talked of micro-organism that is capable of producing disease. This system not only aims at curing a disease but also claims the prevention of the disease, maintenance and promotion of health as well said “Prevention is better than cure”.

Siddhars have classified disease into 4448 types and its treatment. One of the literatures in siddha is Balavagadam which deals with pediatric disease and its management.

Kanam has been classified into 24 types according to Balavagadam. Vali Kanam is one of the subtype of Kanam. The signs and symptoms of Vali Kanam described in literature of siddha system correlates with Acute Pharyngitis. Vali Kanam has the symptoms of cough, low grade fever, lack of appetite, sore throat, rumbling noise in stomach, dysuria and excessive thirst. The etiology of the disease is due to maternal food habits during the antenatal and postnatal period.

Acute Pharyngitis is defined as an inflammation of pharynx. It is most often referred to simply as sore throat. It is usually associated with viruses or streptococcus pyogenes.Approximately 40-60% of cases of sore throat are caused by a virus such as adenovirus, rhinovirus, epstein-barr virus, influenza virus and about 15% are associated with streptococcal infection. It is most common for school going age group of children during the winter season. Transmission of this disease occurs mostly by hand contact with nasal discharge rather than by the oral contact.

Most of the medicine in Siddha system is mainly made with herbs and herbo-mineral drugs for pediatric population in order to eliminate this major issue.

In Balavagadam, a Siddha formulatory text, there is a preparation named Vilva Ennai which is indicated for Vali Kanam. This isa poly herbal formulation which mainly contains Aegle marmelos and Allium cepa as the main ingredients. Both of these drugs are having anti pyretic and anti-inflammatory activity. This drug is commonly used in clinical practice. But its efficacy is not evaluated scientifically till now. So the author has selected Vilva Ennaifor this dissertation work.

2. AIM AND OBJECTIVES

AIM

To evaluate the efficacy of VILVA ENNAI in the treatment of VALI KANAM (Acute Pharyngitis).

PRIMARY OBJECTIVE

To determine the therapeutic potential and effectiveness off the drug Vilva Ennai in treating Valikanam.

SECONDARY OBJECTIVES

- To collect and review the ideas mentioned in the ancient Siddha literature about the disease VALI KANAM.
- To explore Definition, Etiology, Clinical features, Diagnosis, Investigations and treatment of VALI KANAM as laid down from various siddha literature.
- To make the correlative study of the siddha and modern aspect of this diseases.
- To study the disease VALI KANAM on the basis of three thodam, envagaithervugal, neerkuri, neikuri, udalthadhukkal, paruvakaalangal, age, sex and economic status.

3. REVIEW OF LITERATURE

3.1 SIDDHA ASPECT

3.1.1 இயல்:(Definition)

கணம் என்பது கர்பச்சூடு எனக் கூறுவர். இது குழவிக்கு மாந்த நோய் ஏற்பட்டு முழுவதும் குணமாகாமல் உடலில் இருந்தே முற்றிவரும் நோயாகும்.

மாதா பிதாக்களின் நாத விந்துக்களடங்கிய வாதாதி தோஷங்களினின்று உற்பத்தியாகிக் கருப்பாசயத்து சிசுவைப் பற்றி அச்சிசுவானது ஏழுவகை தாதுக்களும் வன்மையடையுங்காலத்து அதை நோயால் வருந்த செய்யும் நோய்.

A congenital disease of the child arising from the maturity of bad humours inherited from the parents. It is an atrophy resulting from the enlargement of the bowels. This disease progresses in several forms as the child advanges in age. (T.V.Sambasivam Pillai part II)

குழந்தைகளுக்கு கணச்சூட்டினாலும் பாலின் குற்றத்தினாலும் வயிறு கோளாறடைந்து உடம்பில் கனப்புண்டாகிச் சுரம், வியர்வை, நரம்பு வலி முதலியன ஏற்பட்டு எலும்பு குறுகி உடம்பு இளைத்து வரும் நோய்.

A constitutional disease in children arising from congenital heat or bad nutrition resulting in diarrhoea of the stomach and glowing head in the body. It is marked by fever sweating of the head, nervous affection of the bones, general emaciation. (T.V.Sambasivam Pillai).

சித்த மருத்துவ நூலான பாலவாகடம் (குழந்தை மருத்துவம்), கணத்தினை மூன்று வகையில் வரைமுறைப்படுத்துகின்றது. அவை வரும் வழியினைப் பொறுத்து இரு பிரிவுகளும், தோன்றும் வயதினைப் பொறுத்து ஒரு பிரிவும் ஆகும்.

3.1.2 கணம் தோன்றும் வயது

“எண்ணவே கணமூன்று வருடந் தொட்டே
ஏழாண்டு மட்டுக்கு மிருக்குங் காலம்” - பாலவாகடம்.

வயதைப் பொறுத்து மூன்று கருத்துகள்:

- 3-7 வயதில் உண்டாதல்
- பாலும் சோறும் உண்ணும் பருவத்தில் உண்டாதல்
- 3-12 வயதில் உண்டாதல்

3.1.3 நோய் வரும் வழி (Etiology)

"பூங்குழல் மாதே கேளாய்
புதல்வருக்கு ஆண்டு சென்றால்
நீங்கரும் கணையின் தோஷம்
நிறைந்ததோர் நரம்பெல்லாம்
தாங்கியே நின்று தானும்
சாருமே ஊனைப் பற்றி
யாங்குள ரெத்த மெல்லாம்
அமுதன் உண்ணு மென்றே..."

பாலருக்கு ஆண்டு சென்றால் கணையின் தோசம் எழுகிறது. இத்தோசம் நரம்பெல்லாம் தங்கி நின்று ஊனை பற்றும். இதனால் ரத்தம் வற்றும்.

"நிறைந்த தொரு ஆண்டின் மேலாய்
பண்டுசேர் பாலர் மெய்யில்
பன்னிரெண்டாண்டு நிற்கும்
குன்றினில் உமையாள்க் கீசன்
குறித்திதை உரைத்தாரென்றெ..."

இப்படி வந்த கணைதோசம், எழுந்து பொங்கி பாலகனின் உடம்பில் 12 ஆண்டு நிற்கும். குன்றின் மீது வியாபித்துள்ள சிவப்பிரான் உமையாளுக்கு இதை உரைத்துள்ளார்.

- குழந்தை கணை நோய் மருத்துவம்

"சொல்லிய சென்ன கூற்றால் துடர் பழவினையால் வந்து
நல்லவனருறுப்பின் சார்ந்து மருவிய தோஷத்தாலே
அல்லகசிரசில் நீரால் அன்னையின் பாலினாலும்
கல்லக நரம்பில் தாவி கபமது வந்துசாரும்"

கருமவினையாலும் உறுப்பை சார்ந்த தோசத்தாலும் தலை நீராலும், அன்னையின் பாலின் கேட்டாலும் குழந்தையின் உடலின் நரம்பில் தோசம் தாவி கபம் ஏற்படுகிறது.

"தொகையான கணங்கள் எல்லாம் கர்ப்பச்சூடு"

- அயோத்திதாசர் பாலவாகடம் -193

"சூடு" என்பதை "உடலின் வெப்பநிலை" என்று கொள்வோமானால் கருவுற்ற காலத்தில் தாய்மார்களுக்கு கிருமி தொற்றினால் சுரம் ஏற்பட்டு, அது பிறக்கும் குழந்தையையும் பாதிப்பதாக கொள்ளலாம்.

மாறாக 'சூடு'' என்பதை பித்தம் (அ) அழல் என உயிர்த்தாதுவாக கொண்டால், கருவின் அழல்தாது மாறுபாடு கீழ்க்கண்ட வகையில் உண்டாகலாம்.

- கலவியில் ஏற்படும் விகற்பம்.
- சுக்கில, சுரோணிதங்களின் விகற்பம்.
- கருவுற்ற தாய்மார்களின் உணவுமுறை, செயல்பாடுகள் இவற்றின் விகற்பங்கள்.

கலவியில் ஏற்படும் விகற்பம்

எண்ணெய் தேய்த்து மூழ்கியபின், உடனே உணவு அருந்தி, உறக்கம் கொள்வதால் உடலின் பித்ததோடம் அதிகரிக்கும். அதே நேரத்தில் உறவு கொள்ளும்போது உண்டாகும் கருவுக்கு கணம் உண்டாகலாம் என்று கருதப்படுகிறது.

சுக்கில, சுரோணிதங்களின் விகற்பம்

கணமானது, மாதாபிதாக்களின் நாதவிந்துக்களுள் அடங்கிய வாதாதி தோடங்களிலிருந்து உற்பத்தியாகி, கருப்பையின் சிசுவைப்பற்றி, அச்சிசுவினது சப்ததாதுக்களும் வன்மையை அடையும் காலத்தில் பாதிக்கின்றது. (தோடங்கள் விருத்தி அடைகின்றன). - ஜீவரட்சாமிர்தம்

''சுக்கிலத்தில் சுரோணிதங் கலக்குமன்று
புகுந்திடும் வியாதி மூன்றும்''

- தன்வந்திரி நாடி நூல்.

கருவுக்கு அழல்தாதுவினை சேர்ப்பது சுக்கிலமாகும் அதனை பின்வரும் நூல்கள் தெளிவாக கூறுகின்றன.

''பான்மை என்ற விந்தங்கே யூறும்போது
பாயுமடா வன்னியோடு வாயுதானே''

- அகத்தியர் வல்லாதி நாடி நூல்.

''உன்னிய கர்ப்பக் குழியாம் வெளியிலே
பன்னிய நாதம் பகர்ந்த பிருதிவி
வன்னியும் வாயுவு மாயிருஞ் சுக்கிலம்
மன்னிய சமனாய் வளர்க்கு முதகமே'' - திருமந்திரம்.

கருவிற்கு, விந்துவிலிருந்து - வாதம், பித்தம் என இரண்டு தாதுக்களும் உதகநீர், நாதம் இவற்றிலிருந்து கபமும் கிடைக்கிறது என கருதப்படுகிறது
அதே பாடலில்,

''உதகமுதிர முறுங்கனல் வாயுவால்
சித குறு மங்கங்கள் செய்து முடித்திடும்''

உதகமாகிய நீர், தீ மற்றும் வாயுவின் தன்மையால் செந்நீராக மாறி மற்ற உடல்தாதுக்களான ஊண், கொழுப்பு, என்பு, மூளை, சுக்கிலம் இவற்றை உண்டாக்கும் என கருதப்படுகிறது.

எனவே சுக்கில, சுரோணிதங்களின் குறைபாடு, உதகநீரின் குறைபாடு போன்றவற்றால் கருவின் உயிர்த்தாதுகளில் ஒன்றான அழல் பாதிப்படைவதால் கணம் ஏற்படுகிறது. 'கர்ப்பச்சூடு' என அழைக்கப்படுவதற்கும் அதுவே காரணம் என கருதலாம்.

கருவுற்ற தாய்மார்களின் செயல்பாடுகள்

''பையர வல்கு லாளும் பசியுடனிருந்த தாலும்
துய்யதோர் குழவிகட்கு கணங்களுந் தோன்றுமன்றே'' - பாலவாகடம்.

கருவுற்ற தாய்மார்களின் உணவு பழக்கவழக்கங்கள், செயல்பாடுகள் போன்றவற்றால் தாயின் உடலில் அழல்தாது பாதிப்படைந்து அது கர்பாசயத்தையும் தாக்கும் என ஜீவரட்சாமிர்தம் என்ற நூலில் கூறப்பட்டுள்ளது. எனவே கருவின் அழல்தாதுவில் குறைபாடு தோன்றுவதால் அதன் உடல் தாதுக்கள் பாதிக்கப்படுகின்றன. இதுவே 'கர்ப்பச்சூடு' என அழைக்க காரணமாகவும் அமைந்திருக்கும்.

மாந்த நோயின் தொடர்ச்சியாக கணம் தோன்றும் விதம்

மாந்தம்: தாய் மற்றும் குழந்தைகளின் உணவாதி (அ) குணவாதி பழக்க வழக்கத்தில் குற்றம் நேரிடும்போது குழந்தைகளுக்கு தோன்றும் செரிமானக் கோளாறுகள், அதனைத் தொடர்ந்த உணவுப்பாதை தொடர்பான உபாதைகளும் மாந்த நோய் என்று அழைக்கப்படுகின்றது.

உணவுப்பழக்கத்தால் மாந்தம் தோன்றுதல்

உண்ணும் உணவின் செரிமானத்திற்கு,

சமானன் - வாதம்

அனற்பித்தம் - பித்தம,

கிலேதகம் - கபம், ஆகிய மூன்றின் இயல்பான அளவு முக்கியமானதாகும்.

அனற்பித்தம் - உணவுப்பொருள்களின் செரிமானத்தில் முதன்மை பங்கு வகிக்கிறது.

கிலேதகம் - உண்ணும் உணவினை மெத்தென செய்யும்.

சமானன் - மேற்கண்ட இரண்டையும் சமநிலைபடுத்தி,சரியான செரிமானத்திற்கு உதவுகிறது. இது செயலற்றால் செரிமானமே நடக்காது.

மந்தாக்கினி

மேற்கண்ட மூன்றில் அனற்பித்தத்தின் வன்மை குறைந்தாலோ, கிலேதகத்தின் வன்மை அதிகரித்தாலோ, சமானவாயு தன் இயற்கை நிலையிலிருந்து தவறினாலோ மந்தாக்கினி உண்டாகும். இதனால் உணவுப் பொருட்கள் உடனே செரிப்பிக்காமல், வாயுவால் வயற்றிரைச்சல், குடலிரைச்சல், வயிற்றுப்பிசம் என்னும் இவற்றை உண்டாக்கி நெடுநேரம் கழித்து செரிப்பிக்கும். எனவே உணவின் சாரம் உடலுக்கு கிடைக்காமல் போகின்றது.

"ஐயது கூடிற் றென்றால்
அரிவையர் துயரந்தன்னால்
செய்ய பற் புனலருந்திச்
செறிசல தோடந்தன்னால்
பையர வல்குலாளும்
பசியுடனி ருந்ததாலும்
துய்யதோர் குழவி கட்குக்
கணங்களுந் தோன்று மன்றே" – (பாலவாகடம்)

மாந்தம் தொடர்ந்து நிலைப்பதால்

↓

உணவின் சாரம் உடற்கட்டுகளுக்கு சேர்வதில் தொய்வு ஏற்படுகிறது. (வியானனின் தொழில் பாதித்தல்)

↓

சாரம் செந்நீராக மாறும் வேலை பாதித்தல்

↓

மற்ற உடற்கட்டுகளை போடணிப்பதில் சிரமம் உண்டாதல்

↓

உடற்கட்டுகளின் வன்மை குறைதல்

↓

கணத்தின் குறிகுணங்கள் தோன்றுதல்

ஐயது கூடிற்றென்றால்: (ஐயம் - உயிர் தாது)

ஐயத்தின் இயற்கை நிலைகள், அதன் மிகுகுணம் போன்றவற்றை ஒப்பு நோக்கும் பொருட்டு கீழ்கண்டவாறு தொகுக்கப்படுகின்றது.

தன்மை:

- தன்மை,நெய்ப்பு,மென்மை,திண்மை
- மந்தம், வழுவழுப்பு

வாழுமிடம்:

- சமானவாயு, சுழுமுனை
- ஆக்கினை, விந்து
- நாக்கு, உண்ணாக்கு
- கொழுப்பு, மச்சை
- குருதி, மார்பு
- நரம்பு, எலும்பு

இயற்கைப் பண்பு:

- நிலைத்தல்
- நெய்ப்பு
- கீல்களின் அமைப்பின் கட்டுகள்
- பொறையுடைமை (பசி, நீர்வேட்கை, கலக்கம், வெப்பம் போன்றவற்றை பொறுத்துக் கொள்ளுதல்)

ஐய மிகுகுணம்

- அக்கினி மந்தப்படல்
- உப்பிசம்
- மிகுதூக்கம் உண்டாதல்
- வாய்நீர் ஊறல்
- இரைப்பு
- இருமல்
- ஊக்கம் குறைதல்
- உடல் கனமாக தோன்றுவதுடன் வெண்ணிறத்தையும், குளிர்ச்சியையும் அடைதல்.
- உடல் முற்றும் உள்ள கட்டுகள் தளரல்

அரிவையர் துயரந் தன்னால்

அரிவை - பெண்களின் பருவங்களில் ஒன்று.

20-25 வயதானது மகளிர் மகப்பேறு அடையும் பொதுவான காலம் என்பதால், பாடலில் அரிவை என்ற வார்த்தையை மேற்கொண்டிருப்பதை உணரலாம். அப்பருவத்தில் மகளிரின் துன்பங்களான உடல்நலக்குறைவு, பொருளாதாரக்குறைவு போன்றவை குழந்தைகளுக்கு பல இடர்பாட்டினையும், குறிப்பாக கணத்தினையும் உண்டாக்கும்.

செய்ய பற்புனலருந்தி செரிசல தோடந்தன்னால்

பல்வேறுவகைப்பட்ட நீரினை அருந்துவதால் சலதோடங்கள் உண்டாகி நிலைத்து கணநோய் தோன்றும் என்பது பொருளாகும். அத்தகைய நீரின் தன்மை, குடித்தலுக்கு ஆகாத நீர் என சித்தமருத்துவத்தில் கூறப்பட்டுள்ள கருத்துகளை காண்போம்.

நீரின் தன்மை: (சித்தமருத்துவாங்க சுருக்கம்)

நீரானது மனதுக்கு களிப்பையும், நிறைவையும் உண்டாக்குவது மட்டுமன்றி உட்கொள்ளும் உணவினை நன்றாய் உடலிற் பரவச் செய்து உடற்கு வன்மையைத் தரும். மேலும் உண்ட கடின உணவுப்பொருட்களை செரிப்பிக்கும்.

நீருக்கு தனிகுணம் இல்லை. அது தங்கும் இடத்தின் வேறுபாடுகளாலேயே வெவ்வேறு குணங்களை அடைகின்றது. இதனை,

''தண்ணீர் குணமெல்லாந் தான் கேள் மடமயிலே
மண்ணின் குணமல்லால் மற்றுண்டோ?''

- தேரன் பொருட்பண்பு

குளியல், குடித்தலுக்கு ஆகாத நீர்

''சந்திரா தித்தர் வளி சாராத நீர் புழுதுர்க்
கந்தமதி சேறு கனப்பிலையு - திரிந்த நீர்
தங்குசுவை யில்லா நீர் சாற்றுமிவை ஸ்நானபா
னங்களுக்கா காவுறிநோ யாம்.

- பதார்த்த குண சிந்தாமணி

திங்கள், ஞாயிறு இவற்றின் கதிரொளி காற்று இவைகள் அணுகாததும் கிருமி, துர்நாற்றம், சேறு தடித்தல், சருகு உதிரல், சுவையின்மை என்னும் இவைகள் பொருந்தியதும் ஆகிய நீர், குளியல், குடித்தல் இவைகட்கு ஆகாது. இதை உண்ணின் நோயை உண்டாக்கும்.

மேலும்,

''துலையாக் கிணறே கயந்திரட்டும் ''

- இறைப்பில்லா கிணற்று நீர் கபப்பிணி உண்டாக்கும்.

''வளர்க்குஞ் சுரத்தை சருகூறல்''

- சருகு ஊறிய நீர் சுரம் வளர்க்கும்.

''மாறாக் குளமே வியாதியுண்டு''

- பயன்படுத்தாத குளத்துநீர் வியாதி உண்டாக்கும்.

அவ்வாறு பல்வேறுபட்ட நீரினை அருந்துவதினால் சலதோடம் ஏற்பட்டு கணநோய் தோன்றும் என்று கூறப்படுகின்றது.

பையர வல்குலாளும் பசியுடனிருந்ததாலும்

(பையர - சூல்கொண்ட: வல்குலாள் - சூலுற்ற பெண்கள்).

சூலுற்ற பெண்கள சரிவிகித உணவினை உண்ணாததால் அவர்களின் உடல்நலன் குன்றி அது குழந்தைகளின் வளர்ச்சியையும் கணநோய் தோன்றுவிக்கும்.

பிற நூல்கள் கருத்து

- **திருவள்ளுவநாயனார் இயற்றிய நவரத்தினசிந்தாமணி** 800 ல் கூறியவாறு தந்தையின் வேட்கையால் பிண்டம் கனலில் அடிபட்டு கணம் வருவதாக கூறப்பட்டுள்ளது.

''பாரான கெற்பவெட்டை மீரும் பக்குவத்தில்
வேரான விரிந்து வெளிப் பட்டு யோனி விழுந்த தென்றாற்
காரான பிண்டங் கனலிலடி பட்டுக் காந்தினினாற்
கூராய் கணசுர மெய்து மென்றேயான் கூறினேமே''

- **தன்வந்திரி வைத்தியம்** எனும் நூல் கணமானது பூர்வஜென்மங்களில் செய்த தீவினைகளை தந்தையாகவும், இப்பிறப்பில் செய்யும் தீவினைகளை தாயாகவும் அடைந்து ''சயக் குமாரன்'' பிறக்கிறான் என்று கூறுகிறது.

''சீரிய தொன்மை செய்த தீவினை தந்தையாகப்
பாரிலிப் பிறப்பிற் செய்த பாவமே தாயதாகப்
பேரியச் சயக் குமாரன் விறந்திலா கிற மத்தப்பே
காரிய செவிலித் தாயாய் 'கணம்' பெற வளரும் நாளில்''.....

3.1.4 கணத்தின் வகைகள் (Types)

பல்வேறு நூல்கள் வெவ்வேறு எண்ணிக்கைகளில் கணத்தினை தொகுக்கின்றன.

பிள்ளைப்பிணி மருத்துவத்தில் கூறப்பட்டுள்ள கணங்கள்-64 வகைகள்

1. வளிகணம்
2. ஐய கணம்
3. நீர்க்கணம்
4. சூலிகணம்
33. அழற்கணம்
34. மாந்த கணம்
35. பிரளிக்கணம்
36. சுழிகணம்

5. மகாகணம்
6. வரள்கணம்
7. வீக்க கணம்
8. அக்கர கணம்
9. எரி கணம்
10. இரத்த கணம
11. மூல கணம்
12. உலரி கணம்
13. ஆம கணம்
14. உணக்கு கணம்
15. உன்ரோககணம்
16. ஊதுமாந்த கணம்
17. கரப்பான் கணம்
18. களிகணம்
19. குடல்சோகை கணம்
20. குடலேற்ற கணம்
21. எரி கணம்
22. இரத்த கணம்
23. மூல கணம்
24. மகேந்திர கணம்
25. மந்தார கணம்
26. மேக கணம்
27. வாவேந்திர கணம்
28. விஷ கணம்
29. விஷபாக கணம்
30. விரதி கணம்
31. வெப்பு கணம்
32. பொருமு கணம்
37. ஊதுகணம்
38. கொதிப்பு கணம்
39. பிறக் கணம்
40. மந்தார கணம்
41. நீராம கணம்
42. முக்கு கணம்
43. பேராம கணம்
44. சிங்கி மாந்த கணம்
45. சுத்தி கணம்
46. சர்ப்ப கணம்
47. சித்ரகணம்
48. சுரகணம்
49. தனிசுரகணம்
50. அதிசுர கணம்
51. தூங்கு கணம்
52. தெற்கத்தி கணம்
53. தெற்கத்து மாந்த கணம்
54. நீராம்ப கணம்
55. பட்சி கணம்
56. பால கணம்
57. மூலாதார கணம்
58. வாயு கணம்
59. வாலசந்திர கணம்
60. விஷநீர் கணம்
61. விஷ மாந்த கணம்
62. வீங்கு கணம்
63. குன்றி அக்கர கணம்
64. முடிலோக கணம்

ஆத்மரட்சாமிர்தம் என்னும் வைத்திய சாரங்க சங்கிரகம்

- கந்தசாமி முதலியார்

1. வாத கணம்
2. சிலேத்தும கணம்
3. நீர்க் கணம்
4. சூலைக் கணம்
5. மகா கணம்
6. வறட்சி கணம்
7. வீக்க கணம்
8. ஆமக் கணம்
9. முக்கு கணம்
10. இரத்த கணம்
11. ஊது மாந்த கணம்
12. மந்தார கணம்
13. பித்த கணம்
14. மாந்த கணம்
15. பிரளி கணம்
16. சுழி கணம்
17. ஊது கணம்
18. கொதிப்பு கணம்
19. பிறக் கணம்
20. வறட்சி கணம்
21. போர்க் கணம்
22. நச்சு மாந்த கணம்
23. எரி கணம்

அயோத்திதாசர் பாலவாகடம் 24 வகைகள் - பக்கம் - 180 பதிப்பு 1992

1. வளிகணம்
2. அழற்கணம்
3. ஐய கணம்
4. மாந்த கணம்
5. நீர்க்கணம்
6. பிரளிக்கணம்
7. சூலிகணம்
8. சுழிகணம்
9. மகாகணம்
10. ஊதுகணம்
11. வரள்கணம்
12. கொதிப்பு கணம்
13. வீக்க கணம்
14. பிறக் கணம்
15. அந்தக கணம்
16. மந்தார கணம
17. எரி கணம
18. நீராம கணம்
19. ஆம கணம்
20. முக்கு கணம்
21. மூல கணம்
22. பேராம கணம்
23. ரத்த கணம்
24. சிங்கி மாந்த கணம

பரராச சேகரம் பாலரோக நிதானம் - 18 வகைகள்

1. வாத கணை
2. சுரக் கணை
3. வறட்கணை
4. மகேந்திர கணை
5. அனற் கணை
10. பித்த கணை
11. அத்திசுர கணை
12. வாலசந்திரகணை
13. தூக்கு கணை
14. வீங்கு கணை

6. வெளுப்புகணை
7. இரத்த கணை
8. கருங்கணை
9. நிலக் கணை
15. சத்தி கணை
16. மூலக்கணை
17. மஞ்சட் கணை
18. வெப்பு கணை

பிள்ளைப்பிணி வாகடம் - 8 வகைகள்

1. நீர் கணம்
2. மூலகணம்
3. இதய கணம்
4. மலக்கணம்
5. வரள் கணம்
6. சீதகணம்
7. மகாகணம்
8. குண்டலிய கணம்

ஜீவரட்சாமிர்தம் 8 வகைகள்

1. சூலிகணம்
2. ஆமகணம்
3. மகாகணம்
4. கழிகணம்
5. முக்கு கணம்
6. தேரைகணம்
7. சுழிகணம்
8. வறள்கணம்

3.1.5 கணத்தின் பொது குணங்கள்

பாலவாகடம் கூறும் நோயின் குணங்கள்

- குழந்தைகளுக்கு மாந்த நோய் பலமுறை வந்து முற்றிலும் குணமடையாமல் இருப்பதால் இந்நோய் உண்டாகும்.
- பித்தமானது அதிகமாகி வாயுக்கள் தன் வேலையை செய்ய முடியாமல் தடுத்துவிடும். அதனால் குழந்தைகளின் உடலில் ஏற்பட்ட சூடு எந்நேரமும் விடாது காணும்.
- சுரம் காய்தல்
- இருமல்
- மூச்சு வாங்குதல்
- உடல் சோர்வடைதல்
- வயிறு நோதல்
- வயிறு கழிதல்
    - மலம் எண்ணெய் கசிவானதாக இருக்கும்
    - சீதமாக, இரத்தமாக (அ) இரத்தமும், சீதமும் கலந்து பேதியாதல்
    - பால் போல வெண்ணிறமாக கழிதல்
    - ஊண் கழுவிய தண்ணீர் போல் பேதியாதல்

- மலவாய் எரிச்சல்
- மலம் வெட்டையாதல் (மலச்சிக்கல்)

- உச்சியில் குழி விழுதல்
- முகம் சோர்வடைந்து காணுதல்
- குரல் கம்மலாக பேசுதல்
- கை, கால், முகம் வறண்டு காணும்
- அனல் வீசுவது போன்று உட்சுரம் காணல்
- வாய்நாற்றம்
- மார்பு கூம்பு போல் எழும்பி காணல்
- நீர் சுருங்கல்

கணத்தில் ஒன்றுடன் ஒன்று தொடர்புகளற்ற பல குறிகுணங்கள் தொகுப்பாகக் காணப்படுகின்றன. அதனால் கணத்தில் பல நோய் நிலைகள் இருப்பதனை அறியலாம்.

மேலும் பொதுக்குறிகுணங்களை பிரதானமாகக் கொண்டு, கணத்தின் சிறப்பு குணங்களுடன் பொருத்தி (கணத்தின் வகைகள்) நோயினை கணித்தல் சிறப்பானதாகும். பிற நூல்களில் காணும் கணத்தின் பொதுகுணங்களை அறிந்து கொள்ளும்போது, நோயினை குறித்த தெளிவான ஒப்புநோக்கு செய்ய முடியும் என்பதால் அதனையும் காண்போம்.

அபிதான சிந்தாமணி கூறும் நோயின் குணங்கள்

- மார்பில் வீக்கம்
- உட்சுரம் சுரம்
- வறண்ட மலம்

ஜீவரட்சாமிர்தம் கூறும் நோயின் குணங்கள்:

- வாய்நாற்றம்
- தலைசுற்றல்
- உள்சுரம் (அல்லது)
- ஒரு வேளை வெளிசுரம் (அல்லது)
- வயிற்றின் மேல் சுடுதல்
- மயக்கம்
- வறண்ட மலம்

இக்குணங்கள் சகல கணத்திற்கும் பொதுவாக வரும் என அறிக.

உள்சுரம் குறித்த விளக்கம்:

அகஸ்தியர் சுரநூல் 300 - 'சித்தமருத்துவம் - பொது' பக்கம் 57 - 6ம் பதிப்பு என்ற நூலில் 'சுரமதே கணையதாகும்'' என கூறப்பட்டுள்ளது.

அதன் விளக்கத்தில் குழந்தைகளுக்கு தோன்றுகின்ற என்புசுரம், அழல் சுரம், மாந்தசுரம் போன்றவைகள் குழந்தைகளை வருத்தமடையச் செய்து, பின்னர் கணை நோயினை பிறப்பிக்கும்.

கணம் - சுரம் தொடர்பு :

'கணை நோயில் உட்சுரமாக காயும்''

சித்தமருத்துவம் - பொது

'கணையில் காந்தள் மலர் போன்ற சுரம் காணும்''

மேற்கண்ட மேற்கோள்கள், கணத்தில் சுரத்திற்கும் பிற நோய் நிலைகளில் காணும் சுரத்திற்கும் வேறுபாடு உண்டு என்பதை தெளிவாக கூறுகின்றன.

(காந்தள் மலர் என்பது தீ பூதத்துடன் தொடர்பு கொண்டது. அந்த மலரின் அல்லி இதழ்கள் சுருக்கமானதாக காணும். கணை நோயிலும், தொடர்ந்து உட்சுரம் உள்ள குழந்தைகள் உடல் சோர்வடைந்து காணுவதாக பொது குறிகுணத்தில் குறிப்பிடப்படுவது சிறப்பாகும்).

'உட்சுரம்'' என்பது பிற சுரங்களிலிருந்து வேறுபட்டது. இச்சுரம், உடல் வன்மை குறைந்த பேர்க்கு வெளிக்கு தெரியாமல் உடலின் உள்ளே தகித்து, சுரம் இருப்பது போன்று காணப்பட்டு, சோகம், மனத்தளர்ச்சி, கைகால் ஓய்ச்சல், உணவில் விருப்பமின்மை, வாய்க்குமட்டல், எப்போதும் சுரம் காய்வது போலிருத்தல், உடல் மெலிந்து கொண்டே செல்லுதல் என்னும் குறி குணங்களை பிறப்பிக்கும்.

- சித்தமருத்துவம் - பொது - பக்கம் - 36.

பாலவாகடம் நூலின்படி வளி கணத்தின் குறிகுணங்கள்

''வாத கணத்தின் குணத்தியல்பை
வகுப்போம் உடலும் பாரமதாய்
போத இரைக்கும் நாவரளும்
புகைந்தே இருமுற தாகமுடன்
வாத கணத்தின் குணத்தியல்பை
வகுப்போம் உடலும் பாரதமாய்ப்
பேத மாக நீர்ச்சுருக்காம்''

- வயிறு இரையும்
- நா வரளும்
- புகைச்சல்

- இருமல்
- அதிக தாகம்
- சுரம்
- பசியின்மை
- நீர்ச்சுருக்கு

ஜீவரட்சாமிர்தம் - நூலின் படி வளி கணத்தின் குறிகுணங்கள்

- வயிறு இரையும்
- நா வரளும்
- இருமல்
- அதிக தாகம்
- சுரம்
- பசியின்மை
- நீர்ச்சுருக்கு
- மலம் இறுகும்

ஆத்மரட்சாமிர்தம் நூலின் படி வளி கணத்தின் குறிகுணங்கள்:

- வயிறு இரையும்
- நா வரளும்
- புகைச்சல்
- இருமல்
- அதிக தாகம்
- சுரம்
- பசியின்மை
- நீர்ச்சுருக்கு
- மலம் இறுகும்

பரராசசேகரம் - பாலரோக நிதானம் நூலின் படி வளி கணத்தின் குறிகுணங்கள்

"வாத கணத்தின் குணத்தியல் வகுப்போம் உடலும் பாரமதாய்
போத இரைக்கும் நாவரளும் புகைந்தே இருமுற தாகமுடன்
வாத கணத்தின் குணத்தியல்பை வகுப்போம் உடலும் பாரதமாய்ப்
பேத மாக நீர்ச்சுருக்காம்"

- வயிறு இரையும்
- நா வரளும்
- புகைச்சல்

- இருமல்
- அதிக தாகம்
- சுரம்
- நீர்ச்சுருக்கு
- பசியின்மை
- மலம் இறுகும்

3.1.6 நோய் கணிப்பு: (Diagnosis)

Piniyari muraimai is a method of diagnosing a disease. Siddha system has a very unique method of diagnosis.

"Pini" means = Disease

"Ari" means = Identify

"Muraimai" means = Method.

This is based upon three main principles and Envagai Thervugal. The three main principles are,

1. Poriyal arithal (Inspection)
2. Pulanal arithal (Palpation)
3. Vinathal (Interrogation)

Physician's 'Pori' and 'Pulan' are used as tools for examining the 'Pori Pulan' of the patients. The above principles correspond to the methodology of Inspection, Palpation and Interrogation in modern medicine, in arriving a clinical diagnosis of the disease.

Poriyaal arithal: (Inspection)

Porigal are considered as the five senses of perception namely,

1. Nose
2. Tongue
3. Eye
4. Skin
5. Ear

Pulanal arithal: (Palpation)

Pulangal are functions of five senses. They are,

1. Smell
2. Taste

3. Vision
4. Sensation of Touch
5. Hearing

Vinathal: (Interrogation)

Vinathal is asking the information regarding the history of the disease, its clinical feature etc., from the patient or his/her close relatives who are taking care of him/her.

சித்த மருத்துவத்தின் நோய்கணிப்பில் பின்வரும் காரணிகள் முக்கிய பங்கு வகிக்கின்றன.

நோயாளியைச் சார்ந்தது

1. உயிர் தாதுக்கள் (முக்குற்றம்)
2. உடல் தாதுக்கள் (ஏழு உடற்கட்டுகள்)
3. எண்வகைத் தேர்வு

நோயாளியைச் சாராதது

4. பொழுது

   சிறுபொழுது - வைகறை, விடியல், எற்பாடு, நண்பகல், மாலை, யாமம்

   பெரும்பொழுது-கார், கூதிர், முன்பனி, பின்பனி, இளவேனில், முதுவேனில்

5. ஐவகை நிலங்கள் : குறிஞ்சி, முல்லை, மருதம், நெய்தல், பாலை.

மேற்கூறிய காரணிகளின் மாறுபாடுகளை ஒன்றுடன் ஒன்று ஒப்பிட்டு நோய் கணிக்கப்படுகிறது.

உயிர் தாதுக்கள் (முக்குற்றம்)

வளி கணத்தில் முக்குற்ற விகற்பம்

வாதம், பித்தம், கபம் ஆகிய மூன்று தாதுக்களில் சமச்சீர் நிலையில் உண்டாகும் வேறுபாடுகளை நோயாக உற்பத்தியாகிறது.

(அ) ‘நடுங்கியதோர் பித்தமது கோபங் கொண்டு

நல்லவாயுவை பற்றி யழுத்திக் கொள்ளும் - பால வாகடம்

முதலில் பித்ததோடம் பாதிப்படைந்து (தன்னிலை வளர்ச்சி அடைந்து) பின்பு வளிகுற்றத்தின் தொழிலையும் (வேற்றுநிலை வளர்ச்சி அடைந்து) பாதிப்பதாக கொள்ளலாம். இதே கருத்தை ‘மந்தமலாது வாயுவராது’’ - நோய்நாடல் முதல் பாகம் என்ற தேரன் சேகரப்பா பாடலால் மந்தத்தினால் வாயு உண்டாகும் என அறியலாம். மேலும் மாந்தம் (மந்தம்) என்பது பித்தத்தின் தன்னிலை வளர்ச்சி குணம் என அறியவேண்டும்.

(ஆ) ‘ஐயது கூடிற் றென்றால்’’ - பால வாகடம்

இதன் பொருள் ஐயக்குற்றம் தன்னிலையில் வளர்ச்சி அடைதல் என்பதாகும்

இதே கருத்தை **“கபத்தினையன்றி காசசுவாசம் காணாதே”** - (நோய்நாடல் முதல் பாகம்) என்ற தேரன்சேகரப்பா பாடலால் ஐயக்குற்றத்தின் தன்னிலை வளர்ச்சியன்றி கணத்தின் குறிகுணமான காசம், சுவாசம் வராது என அறியலாம்.

அழல் குற்றம் தன்னளவில் மிகுந்து வாயுவை பற்றி அழுத்திக் கொள்ளும். அதனால் உடலில் அதிகப்பட்ட அழல் தணிவதற்கு வழியில்லாமல் குழந்தைக்கு அதிகமாக சூடு உண்டாகி உடல் கனகனப்பு ஏற்படுகின்றது.

வளி கணத்தில் உடல்தாதுக்களின் நிலை

உண்ட உணவின் அன்னசாரமானது குடலில் உறிஞ்சப்பட்டு உடற் தாதுக்களான சாரம், செந்நீர், ஊண், கொழுப்பு, என்பு, மூளை, சுக்கிலம் (அ) சுரோணிதம் போன்றவற்றை போடணிக்கின்றது என உடல்தத்துவ நூல்கள் கூறுகின்றன.

‘‘தந்திடு நரம்ப தெல்லாந் தாங்கியே யூணைப் பற்றி
உந்திடு மிரத்தமெல்லா மமுதென வுண்ணு மன்றே’’

-பரராசசேகரம்-பாலரோக நிதானம் பாடல்: 269

என்ற பாடலால் கணை நோய் உடல் தாதுக்களை பாதிக்கும் என அறியலாம்.

கணையில் உடல் தாதுக்கள் போடணிக்கப்படுவதிலும், உருவாக்கத்திலும் சிரமம் ஏற்படுகிறது என்பதால் நோய் தீவிரத்திற்கு ஏற்ப அனைத்து தாதுக்களும் (சுக்கில, சுரோணிதம் உள்பட) வரிசையாக ஒன்றன்பின் ஒன்றாக பாதிப்படையும் என கருதப்படுகிறது. சுக்கிலம், சுரோணிதம் இவற்றை நேரடியாக விந்து, நாதம் என்று பொருள் கொள்ளாமல், உடல் செல்கள் மற்றும் உறுப்புகள் தன்னையொத்த உருவப் பெருக்கிற்கு முதலாய் நிற்கும் உடல் தாது என பொருள் கொள்வது சிறப்பாகும்.

வளி கணத்தில் எண்வகைத் தேர்வுகள்:

பொறி, புலன்களால் அறிதல், வினாதல் போன்றவைகளின் மூலம் மருத்துவர் அறிந்தவற்றை எண்வகைத் தேர்வுகள் மூலம் உறுதிபடுத்த வேண்டும்.

‘‘நாடி ஸ்பரிசம் நா நிறம் மொழி விழி
மலம் மூத்திரமிவை மருத்துவராயுதம் - நோய்நாடல் முதல் பாகம்
”தேடிய வியாதிக் கெல்லம் தேகத்தில் பரிட்சையுண்டு
கூடியே நிற்குமெட்டு பரிட்சையாங் கூறக்கேளீர்
நாடியே தொட்டாற் தேகம் மூத்திரம் வார்த்தை கண்கள் நாக்கு
பாடியே மலசலங்கள் பல வண்ணம் பார்த்துக் கொள்ளே”

- சித்த மருத்துவமணிகள்

மேற்கூறிய பாடலின் மூலம் நாடி, ஸ்பரிசம், நா, நிறம், மொழி, விழி, மலம், மூத்திரம் ஆகியன மருத்துவரின் ஆயுதம் போன்றவை என அறியலாம்.

நாடி

எண்வகைத் தேர்வுகளில் பிரதானமானது. பிணியினை நாடியாலறிந்து மருந்தூட்டுதலே சிறந்தது என்று சித்த மருத்துவம் கூறுகின்றது. ஆனால் குழந்தைகளில் நாடிநடை சரியாக தோன்றாது என்பதை கீழ்கண்ட பாடலால் அறியலாம்.

"கொண்டிடவே கயரோகி காசரோகி
குறிப்பாக சிற்றின்பம் செய்த பேர்கள்
அண்டிடவே தரித்திரர்கள் விருத்தர் பாலர்
கொண்டிடவே இவர்களின் உறுப்பின் தாது
கூறவே முடியாது எவர்க்குக் கிட்டும்."

-நோய்நாடல் நோய் முதல்நாடல் திரட்டு

எனினும் கணத்தில் பித்தகுற்றம் முதன்மையாக பாதித்து பின் வாத, கப குற்றங்களும் பாதிப்பதால், கீழ்கண்ட நாடிநடையானது தேர்வாளரால் பரிசோதித்து எழுதப்பட்டது.

- பித்தகபம், பித்தவாதம் மற்றும் வாதபித்தம்

ஸ்பரிசம்

நோயாளியினை தொட்டு பார்த்தலின் மூலம் உணரப்படும் குறிகுணங்கள் ஆகும். வளி கணநோயில் கீழ்க்காணும் குறிகுணங்கள் அவ்வாறு உணரப்பட்டது.

- வயிறுவலி
- சுரம்
- உட்சுரம்

நா

நோயாளரின் நாக்கினை பார்த்து உணரப்படும் கணநோயின் குறிகுணங்களாவன.

- செந்நீர்த்தாது குறைந்து காணுதலை, நா வெளிறிட்டு இருத்தலால் அறியலாம்.

நிறம்

வளி கணநோயில் உடற்கட்டுகள் வன்மை குறைந்துள்ளதை அறிய நிறப்பரிசோதனை பயன்படும்.

தோலின் நிறம்	-	வெளிறிக்காணுதல்
		கறுத்துக்காணுதல்
நா, கண்	-	வெளிறிக்காணுதல்

மொழி

வளி கணநோய் குழந்தைகளில் கபம் அதிகரிக்கும் காரணத்தால் குரல்கம்மல் தோன்றி தாழ்ந்து பேசுவர்.

விழி

விழிச்சோதனையில், கணநோயின் கீழ்க்காணும் குறிகுணம் உணரப்பட்டது.

- கீழிமை வெளிறிக்காணுதல்

மலம்

கணநோய் குழந்தைகளில், வினாதலின் மூலம கீழ்கண்ட குறிகுணங்கள்அறியலாம்.

- கழிச்சல்
- மலச்சிக்கல்

மூத்திரம்

குழந்தைகளில், பேதி இருந்தால் உடலின் நீர்த்துவம் குறைந்து நீர்வரத்து குறைந்து காணும்.

நீர்க்குறி

''வந்த நீர் கரியெடை மணம் நுரை எஞ்சலென்
றைந்தியலுளவை யறைகுது முறையே'' - நோய் நாடல் முதல் பாகம்

நீரில் நிறம், மணம், நுரை, எடை, எஞ்சல், ஆகியவற்றை நோக்க வேண்டும்.

நெய்க்குறி

குழந்தைகளின் நாடிநடை சரியாக கணிப்பதில் சிரமம் உள்ளதால், நெய்க்குறி பரிசோதனை மூலம் நோயாளர் எக்குற்றத்தால் பாதிக்கப்பட்டுள்ளார் என்பதனை கணிக்கலாம்.

கணநோயாளியின் சிறுநீரை சோதனை வட்டிலில் ஊற்றி ஒளி மிகுந்த இடத்தில் நீரின் அலையில்லாத போது நல்லெண்ணெயத்துளி விட்டு பார்க்கப்பட்டது.

சிலரில் ஆழி போல் (மோதிரம்) பரவியும், சிலரில் முத்துபோல் நின்றும் காணப்பட்டது.

''அரவென நீண்டின் அ∴தே வாதம்
ஆழிபோற் பரவின் அ∴தே பித்தம்
முத்தொத்து நிற்கின் மொழிவதென் கபமே''

- நோய் நாடல் முதல் பாகம்

3.1.7 மருத்துவம்

1. வேற்றுநிலை வளர்ச்சியடைந்த பித்தத்தினை தன்னிலைப்படுத்த வேண்டும்
2. தன்னிலை வளர்ச்சியடைந்த ஐயத்தினை சமப்படுத்த வேண்டும்
3. பித்தகுற்றத்தால் பாதிப்படைந்துள்ள வாதத்தினையும் சரிப்படுத்த வேண்டும்.

4. வன்மை இழந்த உடற்கட்டுகளை வன்மை அடையச்செய்யும் வகையில் மருந்தளிக்க வேண்டும்.

Keeping in mind the need for bringing out an effective therapy for ***Vali Kanam*** from Siddha system of Medicine, the author has undergone this dissertation work with ***Vilva Ennai.***

The dosage of medicine is 3 ml (od)

Line of Treatment

Siddha treatment is not only for complete healing but also for prevention and rejuvenation. Saint Thiruvalluvar says about physician's duty as study the disease, study the cause, treat subsiding way and do what is proper and effect.

"நோய் நாடி நோய் முதல் நாடி அது தணிக்கும்
வாய் நாடி வாய்ப்பச் செயல்".

"உற்றான ளவும் பிணியளவுங் காலமுங்
கற்றான் கருதிச் செயல்".

- திருக்குறள்

So it is essential to know the disease, the etiology, the nature of patients, severity of the illness, the seasons and the time of occurrence.

Line of treatment is as follows.

1. Kaappu (Prevention)
2. Neekkam (Treatment)
3. Niraivu (Restoration)

Kaappu (Prevention)

Prevention and cure of the diseases are the basic principle of any medical system, but prevention is the main aim of Siddha system. Siddhars have described general preventive measures and special measures. (Which are applicable to diseases of certain organs)

And especially in **Balavagadam**, the preventive measures are explained in detail. Prevention of the disease of the child starts from the conception and goes on as the child grows up in intra uterine life and after delivery. Siddhars have dealt elaborately with the diet of pregnant women, her habit, the medicine to be taken in every month, her psychological conditions, and surroundings etc.

Neekam: (Treatment)

The aim of treatment is based on,

To bring the three thodams into normal equilibrium state, emetics and purgatives are given. But considering physical condition of the children administration of purgatives and emetics is excluded from line of treatment.

Niraivu: (Restoration)

1. Reassurance of disease recovery was given to all patients.
2. All the patients are advised to follow the life style that provides a disease free life.

Pathiyam (Diet):

During the course of treatment, the drug is administered to the patients according to the nature of disease and the patients were advised to follow certain restrictions regarding diet and physical activities.

This type of medical advice in siddha system of medicine is termed as "Pathiyam".

Importance of pathiyam is quoted as follows.

'பத்தியத்தினாலே பலனுண்டாகும் மருந்து
பத்தியங்கள் போனால் பலன் போகும் - பத்தியத்தில்
பத்தியமே வெற்றிதரும் பண்டிதர்க்கு ஆதலினால்
பத்தியமே உத்தியென்று பார்''

- தேரையர் வெண்பா

The patients with *Vali Kanam* were advised to avoid cool drinks, cold water and exposure to chill weather and allergens (dust, pollens, and odours)

During the course of treatment, according to the drug administered to the patients and nature of the disease, the patients were advised to follow certain precautions regarding diet and physical activities. This type of medical advice in Siddha system of medicine is termed as Pathiyam.

Siddhars advice regarding the diet regimen for Kaba patients is explained below:

'' கத்தரி பேய்புடல் வரை யிருபாகல் பருங்களா கண்டகாரி
அத்திக் காய்களும் வருக்கைமாபயற்றை கரையால் பீர்க்கரும் - பிஞ்சுவேர்
மொய்த்த சூரணங் கதலித் தண்டுகளைப் பூமுளங்கி முருக்கரும்பும்

அத்திப் பூசணிக் காயருள்ளி வள்ளியுங் கபத்தோர்க் காணமாமே''

'' வேளை மணத்தக்காளி மென் சீதை சக்ரவர்த்தி
பீளை வசலை சுக்கு பெண்சுணங்கள் - வேளையிலை
செந்தளிர் களைக் கீரை செய்வர் கபதேகர் நிதம்
வந்தனியுணத்தான் மகிழ்ந்து. ''

-பதார்த்த குண சிந்தாமணி

- கத்தரி
- பேய்புடல்
- பாகல்
- களா
- அத்திக்காய்
- பீர்க்கங்காய்
- கதலித் தண்டு
- முள்ளங்கி
- பூசணிக்காய்
- கரும்பு
- மணத்தக்காளி
- வசலை

Prevention methods

The patients were advised,

- To find out which agent makes allergy and avoid them.
- To avoid contaminated food and water and avoid cold weather.
- To avoid cold food stuffs, beverages etc.
- To take highly nutritious diet like vegetable soups to get their immunity developed

3.2 MODERN ASPECT

3.2.1 RESPIRATORY SYSTEM

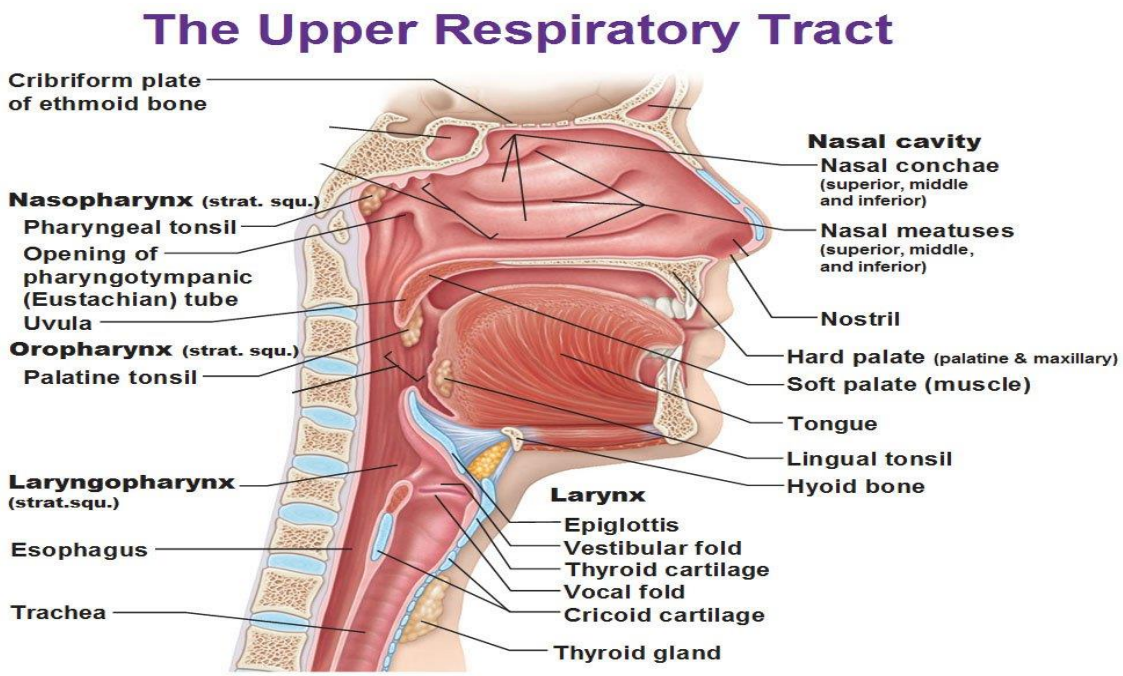
The cells of the human body require a constant stream of oxygen to stay alive. The respiratory system provides oxygen to the body's cells while removing carbon dioxide, a waste product that can be lethal if allowed to accumulate.

The 3 major parts of the respiratory system are the airway, the lungs, and the muscles of respiration. The airway, which includes the nose, mouth, pharynx, larynx, trachea, bronchi, and bronchioles, carries air between the lungs and the body's exterior. The lungs act as the functional units of the respiratory system by passing oxygen into the body and carbon dioxide out of the body. Finally, the muscles of respiration, including the diaphragm and intercostal muscles, work together to act as a pump, pushing air into and out of the lungs during breathing.

Generally, the Respiratory tract is divided into two parts

1. Upper respiratory tract and

2. Lower respiratory tract.



Upper Respiratory Tract

The upper respiratory tract, can refer to the parts of the respiratory system lying above the sternal angle above the vocal folds, or above the cricoid cartilage. It includes the nose and nasal passages, paranasal sinuses, the pharynx, and the portion of the larynx above the vocal cord. The larynx is sometimes included in both the upper and lower airways.

Lower Respiratory Tract

The lower airways or lower respiratory tract includes the portion of the larynx below the vocal folds, trachea, bronchi and bronchioles. The lungs can be included in the lower respiratory tract or as separate entity and include the respiratory bronchioles, alveolar ducts, alveolar sacs, and alveoli.

3.2.2 ANATOMY OF UPPER RESPIRATROY TRACT

3.2.2.1 Nose

The Nose is the only externally visible part of the respiratory system. Protruding prominently from the face, the nose serves as a vent for air exchange. The structures of the nose are divided into the External nose and the Internal nasal cavity. The external nose consists of a supporting framework of bone and hyaline cartilage covered with muscle and skin. The external openings of the nose, the external nostrils, are bounded laterally by the flared alae.

3.2.2.2 Nasal Cavity

The Nasal Cavity lies in and posterior to the external nose. During breathing, air enters the nasal cavity by passing through the external nares. The nasal cavity is divided equally into right and left halves by a midline nasal septum. The nasal cavity is continuous posteriorly with the nasal portion of the pharynx through the internal nares, also called the posterior nares or choanae. The portion of the nasal cavity just superior to the nostrils, called the vestibule, is lined with skin containing sebaceous and sweat glands and

numerous hair follicles. The hairs, or vibrissae filter coarse particles (lint, dust, pollen) from inspired air.

Therefore, the nose
1. Provides an airway for respiration
2. Moistens and warms entering air
3. Filters inspired air and cleanses it of foreign matter
4. Serves as a resonating chamber for speech, and
5. Houses the olfactory (smell) receptors

3.2.2.3 Paranasal Sinuses

The Paranasal Sinuses are air-filled cavities located within the bones of the face and around the nasal cavity and eyes. Each sinus is named for the bone in which it is located.

- **Maxillary sinus**- one sinus located within the bone of each cheek
- **Ethmoid sinus**- located under the bone of the inside corner of each eye, this is really a honeycomb-like structure of 6-12 small sinuses that is better appreciated on CT scan images through the face.
- **Frontal**- one sinus per side, located within the bone of the forehead above the level of the eyes and nasal bridge
- **Sphenoid**- one sinus per side, located behind the ethmoid sinuses; the sphenoid is not seen in a head-on view but is better appreciated looking at a side view

3.2.2.4 Mouth

The Mouth, also known as the oral cavity, is the secondary external opening for the respiratory tract. Most normal breathing takes place through the nasal cavity, but the oral cavity can be used to supplement or replace the nasal cavity's functions when needed. Because the pathway of air entering the body from the mouth is shorter than the pathway for air entering from the nose, the mouth does not warm and moisturize the air entering the lungs as well as the nose performs this function. The mouth also lacks the

hairs and sticky mucus that filter air passing through the nasal cavity. The one advantage of breathing through the mouth is that its shorter distance and larger diameter allows more air to quickly enter the body.

3.2.2.5 Pharynx

Pharynx is also known as the throat. The pharynx is a funnel-shaped fibromuscular tube that conducts air from the nasal cavity to the larynx. The pharynx resembles a short length of garden hose and extends about 5 inches from the base of the skull to the level of the sixth cervical vertebra.

Based on location, The pharynx is divided into 3 regions

1. Nasopharynx,
2. Oropharynx, and
3. Laryngopharynx.

Nasopharynx

Nasopharynx is the superior region of the pharynx lying posterior to the nasal cavity and connected to the cavity through posterior nares or choanae. It serves only as an air passageway. The lining epithelium of nasopharynx is the same pseudostratified columnar ciliated type. Goblet cells in the epithelium secrete mucus, which further cleans, warms, and moistens incoming air before it moves deeper into the respiratory tract.

Oropharynx

The oral part of the pharynx is called oropharynx lies posterior to the oral cavity. It extends inferiorly from the soft palate to the epiglottis. Given this location, both swallowed food and inhaled air pass through it. The oropharynx is lined with a more protective epithelium that is non-keratinized stratified squamous type.

Laryngopharynx

The laryngopharynx is the posterior most portion of the pharynx, reaching from the hyoid to the cricoid cartilage. The laryngopharynx also serves as a common pathway for food and air. It lies directly posterior to the upright epiglottis and extends to the larynx, where the respiratory and digestive pathways diverge.

3.2.2.6 Larynx

The larynx, also known as the voice box, is a short section of the airway that connects the laryngopharynx and the trachea. The larynx is located in the anterior portion of the neck, just inferior to the hyoid bone and superior to the trachea. Several cartilage structures make up the larynx and give it its structure. The epiglottis is one of the cartilage pieces of the larynx and serves as the cover of the larynx during swallowing. Inferior to the epiglottis is the thyroid cartilage, which is often referred to as the Adam's apple as it is most commonly enlarged and visible in adult males. Inferior to the thyroid cartilage is the ring-shaped cricoid cartilage which holds the larynx open and supports its posterior end. In addition to cartilage, the larynx contains special structures known as vocal folds, which allow the body to produce the sounds of speech and singing. The vocal folds are folds of mucous membrane that vibrate to produce vocal sounds. The tension and vibration speed of the vocal folds can be changed to change the pitch that they produce.

3.2.3 UPPER RESPIRATORY TRACT INFECTIONS

URTI range from common cold typically a mild self-limited catarrhal syndrome of nasopharnyx to life threatening illnesses such as epiglotitis.

URTI is specifically manifested as cough, fever, Rhinitis, Pharyngitis, Epiglottis, Laryngitis and Tracheitis.

3.2.4 PHARYNGITIS

Pharyngitis is typically a type of upper respiratory tract infection. Pharyngitis is inflammation of the back of the throat or the pharynx. . It is usually associated with viruses or streptococcus pyogenes. But the majority of the cases of acute pharyngitis are caused by viruses. It is most common in school going age group children during the

winter months. Approximately 40-60% of cases of sore throat are caused by a virus and about 15% are associated with streptococcal infection. Uncommon causes include other bacteria such as gonorrhea, fungus, irritants such as smoke, allergies, and gastroesophageal reflux disease.

Classification

It may be classified as acute or chronic.

- Acute pharyngitis may be catarrhal, purulent or ulcerative, depending on the causative agent and the immune capacity of the affected individual.
- Chronic pharyngitis may be catarrhal, hypertrophic or atrophic.

3.2.5 CAUSES

A wide variety of organism causes acute pharyngitis. The relative importance of the different pathogens can only be estimated. Since significant proportion of cases (30%) have no identified causes.

Respiratory viruses are the most common identifiable cause of acute pharyngitis, with rhinoviruses (20% of cases) and Corona viruses(at least 5%) accounting for a large proportion. Influenza virus, parainfluenza virus, and adenovirus also account for a measurable share of cases. Other important but less common viral cause include herpes simplex virus (HSV) type 1 and 2, Coxsacki virus A, Cytomegalovirus (CMV), and Epstein- Barr virus (EBV). Acute HIV infection can present as acute pharyngitis and should be considered in high risk population.

Acute bacterial pharyngitis is typically caused by streptococcus pyogens which accounts for 5-15% of all cases of acute pharyngitis in adults; rates vary depending on the season and on health care system utilization. Streptococci of groups C and G account for minority cases, although these serogroups are nonrheumatogenic.

The remaining cause of acute pharyngitis are seen infrequently(<1% each) but should be considered in appropriate exposure groups because of the severity of illness if

left untreated; these etiogenic agents include *Neisseria gonorroeae, Cornybacterium diphtheria, Cornybacterium ulcerans, Yersinia enterocoitica.* and *Treponema pallidum.*

3.2.5.1 Viral causes

Viral pharyngitis can be caused by numerous viruses and occur as part of common cold and influenza syndrome. These comprise about 40–80% of all infectious cases and can be a feature of many different types of viral infections.

Adenovirus

In children, Adenovirus causes uncomplicated pharyngitis (most commonly caused by adenovirus types 1-3 and 5) or pharyngoconjunctival fever. The latter is characterized by fever, sore throat, and conjunctivitis. Unlike rhinovirus infections, adenovirus directly invades the pharyngeal mucosa, as shown by the viral cytopathic effect.

Rhinovirus

More than 100 different serotypes of rhinovirus cause approximately 20% of cases of pharyngitis and 30-50% of common colds. These viruses enter the body through the ciliated epithelium that lines the nose, causing edema and hyperemia of the nasal mucous membranes. This condition leads to increased secretory activity of the mucous glands; swelling of the mucous membranes of the nasal cavity, eustachian tubes, and pharynx, and narrowing of nasal passages, causing obstructive symptoms. Bradykinin and lysyl-bradykinin are generated in the nasal passages of patients with rhinovirus colds, and these mediators stimulate pain nerve endings. The virus does not invade the pharyngeal mucosa. Transmission occurs by large particle aerosols or fomites.

Epstein-Barr Virus

Epstein-Barr Virus (EBV) is the causal agent of infectious mononucleosis. EBV usually spreads from adults to infants. Among young adults, EBV spreads through saliva and, rarely, through blood transfusion. In addition to edema and hyperemia of the tonsils and pharyngeal mucosa, an inflammatory exudate and nasopharyngeal lymphoid

hyperplasia also develop. Pharyngitis or tonsillitis is present in about 82% of patients with infectious mononucleosis.

Herpes Simplex Virus

Herpes Simplex Virus (HSV) types 1 and 2 cause gingivitis, stomatitis, and pharyngitis. Acute herpetic pharyngitis is the most common manifestation of the first episode of HSV-1 infection. After HSV enters the mucosal surface, it initiates replication and infects either sensory or autonomic nerve endings. The neurocapsid of the virus is intra-axonally transported to the nerve cell bodies in the ganglia and contiguous nerve tissue. The virus then spreads to other mucosal surfaces through centrifugal migration of infectious virions via peripheral autonomic or sensory nerves. This mode of spread explains the high frequency of new lesions distant from the initial crop of vesicles characteristic of oral-labial HSV infection. It can cause multiple mouth ulcers.

Influenza Virus

Pharyngitis and sore throat develop in about 50% of the patients with Influenza A and in a lesser proportion of patients with influenza B. Severe pharyngitis is particularly common in patients with type A. The influenza virus invades the respiratory epithelium, causing necrosis, which predisposes the patient to secondary bacterial infection. Transmission of influenza occurs by aerosolized droplets

Para Influenza Virus

Pharyngitis caused by Para Influenza Virus types 1-4 usually manifests as the common cold syndrome. Parainfluenza virus type 1 infection occurs in epidemics, mainly in late fall or winter, while parainfluenza virus type 2 infection occurs sporadically. Parainfluenza virus type 3 infection occurs either epidemically or sporadically.

Coronavirus

Pharyngitis caused by Coronavirus usually manifests as the common cold. As in rhinovirus colds, viral mucosal invasion of the respiratory tract does not occur.

Enterovirus

The major groups of Enteroviruses that can cause pharyngitis are coxsackievirus and echovirus. Although enteroviruses are primarily transmitted by the fecal-oral route, airborne transmission is important for certain serotypes. Enteroviral lesions in the oropharyngeal mucosa are usually a result of secondary infection of endothelial cells of small mucosal vessels, which occurs during viremia following enteroviral infection in the GI tract.

Respiratory Syncytial Virus

Transmission of Respiratory Syncytial Virus (RSV) occurs by fomites or large-particle aerosols produced by coughing or sneezing. Immunologic mechanisms may contribute to the pathogenesis of the severe disease in infants and elderly patients.

Cytomegalovirus

Acute acquired Cytomegalovirus (CMV) infection is transmitted by sexual contact, in breast milk, via respiratory droplets among nursery or day care attendants, and by blood transfusion. Infection in the immune-competent host rarely results in clinically apparent disease. Infrequently, immuno-competent hosts exhibit a mononucleosis like syndrome with mild pharyngitis.

Human Immuno deficiency Virus

Pharyngitis develops in patients infected with Human Immuno deficiency Virus (HIV) as part of the acute retroviral syndrome, a mononucleosis like syndrome that is the initial manifestation of HIV infection in one half to two thirds of recently infected individuals.

Epidemiology

In United States each year, Viral pharyngitis is responsible for more than 40 million visits to health care providers. Most children and adults experience 3-5 viral upper respiratory tract infections (including pharyngitis) per year.

Mortality

Worldwide, viral pharyngitis is one of the most common causes of absence from school or work. The National Ambulatory Medical Care Survey showed that upper respiratory tract infections, including acute pharyngitis, accounted for 200 annual visits to a physician per 1000 population between 1980-1996.

Sex

Viral pharyngitis affects both sexes equally.

Age

Viral pharyngitis affects both children and adults, but it is more common in children.

3.2.5.2 Bacterial Cause

A number of different bacteria can infect the human throat. The most common and important bacterial cause of pharyngitis is Streptococcus pyogenes(group A Streptococcus [GAS]) but others include Streptococcus pneumoniae, Haemophilus influenzae, Bordetella pertussis, Bacillus anthracis, Corynebacterium diphtheriae, Neisseria gonorrhoeae, Chlamydophila pneumoniae, and Mycoplasma pneumoniae. When suspected, bacterial pharyngitis should be confirmed with routine diagnostic tests and treated

Streptococcal Pharyngitis

Streptococcal pharyngitis or strep throat is caused by group A beta-hemolytic streptococcus (GAS). It is the most common bacterial cause of cases of pharyngitis (15–30%). Common symptoms include fever, sore throat, and large lymph nodes. It is a contagious infection, spread by close contact with an infected individual. A definitive diagnosis is made based on the results of a throat culture.

Fusobacterium Necrophorum

Fusobacterium Necrophorum is a normal inhabitant of the oropharyngeal flora and can occasionally create a peritonsillar abscess. In 1 out of 400 untreated cases, Lemierre's syndrome occurs.

Diphtheria

Diphtheria is a potentially life-threatening upper respiratory infection caused by *Corynebacterium diphtheriae* which has been largely eradicated in developed nations since the introduction of childhood vaccination programs, but is still reported in the Third World and increasingly in some areas in Eastern Europe. Antibiotics are effective in the early stages, but recovery is generally slow.

Epidemiology

Acute pharyngitis caused by bacteria accounts for approximately 12 million annual ambulatory care visits in the United States. It ranks within the top 20 most-common primary diagnosis groups.

In temperate climates, GAS pharyngitis occurs most commonly in the winter and early spring.

International an estimated 616 million cases of GABHS pharyngitis occur annually worldwide. Rheumatic heart disease, which may be a consequence of GABHS pharyngitis, is estimated to cause about 6 million years of life lost annually. The burden of rheumatic heart disease disproportionately affects populations from developing countries. In terms of estimated global mortality, GABHS is one of the top 10 pathogens, behind HIV infection and malaria and ahead of tetanus and pertussis.

Mortality

Although GABHS pharyngitis is usually a self-limited entity, on average, a single episode in a child results in 1.9 days absence from school and a parent missing 1.8 days from work to care for the child. Children with GABHS pharyngitis experience symptoms for an average of 4.5 days.

Sex

GABHS pharyngitis has no sexual predilection.

Age

GABHS pharyngitis is most common in individuals aged 5-15 years, although adults may also acquire the disease. Streptococcal pharyngitis is very uncommon in children younger than 3 years with the exception of children with risk factors such as an older close or household contact with GAS infection. Acute rheumatic fever is also rare in children younger than 3 years and in adults.

3.2.5.3 Fungal

Some cases of pharyngitis are caused by fungal infection such as Candida albicans causing oral thrush.

3.2.5.4 Non-Infectious

Pharyngitis may also be caused by mechanical, chemical or thermal irritation, for example cold air or acid reflux. Some medications may produce pharyngitis such as pramipexole and antipsychotics.

3.2.5.5 Others

A few other causes are rare, but possibly fatal, and include parapharyngeal space infections: peritonsillar abscess, submandibular space infection (Ludwig's angina), and epiglottitis.

3.2.6 MODE OF TRANSMISSION

GABHS is spread from person to person through large droplet nuclei. Consequently, close quarters (eg- barracks, daycares, and dormitories) facilitate transmission.

In temperate regions, the prevalence of GABHS infection increases in the colder months, presumably because of the tendency of people to congregate indoors.

Spread within families is common. The risk of acquiring GABHS from an infected family member is 40%, and nearly one in four of infected individuals eventually exhibit symptoms. Twenty-four hours after appropriate antibiotics are initiated, the patient is no longer considered contagious.

3.2.7 PATHOPHYSIOLOGY

In **viral pharyngitis,** viruses gain access to the mucosal cells lining the nasopharynx and replicate in these cells. Damage to the host is often caused by damage to the cells where the viruses are replicating.

In **bacterial pharyngitis,** .*S pyogenes,* which contains group A antigens and displays beta-hemolysis, is the most common species referred to as a group A beta-hemolytic streptococci (GABHS). Beta-hemolytic streptococci have the ability to cause large zones of hemolysis on blood agar.

S pyogenes attaches to the mucosal epithelial cells using M protein, lipoteichoic acid, and fibronectin-binding protein (protein F). It has a capsule composed of hyaluronic acid that prevents phagocytosis by host macrophages; because the hyaluronic acid in the bacterial capsule is identical to host hyaluronic acid. The capsule facilitates bacterial survival by covering the bacterial antigens. Extracellular factors produced by *S pyogenes* during the infection include protease and hyaluronidase. These extracellular factors assist the bacteria in invading the mucosa. An autoimmune reaction occurs in some patients following production of an immune response to these cross-reactive bacterial antigens and damages the patient's heart or kidneys.

The most important virulence factor of GABHS is the M protein. This protein, located peripherally on the cell wall, is required for invasive infection. T cells exposed to this M protein are postulated to cross-react with similar epitopes on human cardiac myosin and laminin, contributing to the pathogenesis of rheumatic heart disease

GABHS contains a hyaluronic acid capsule, which also plays an important role in infection. Bacteria that produce large quantities of this capsule exhibit a characteristic mucoid appearance on blood agar and may be more virulent.

Certain GABHS exotoxins act as superantigens by up-regulating T cells. These super antigens can prompt a release of proinflammatory cytokines and may synergize with lipopolysaccharide. It has been speculated that these superantigens evade the pharyngeal immune response, resulting in proliferation of GABHS while permitting immune-mediated elimination of commensal organisms.

Adhesins enable GABHS attachment at sites such as the pharynx. This attachment allows for colonization and competition with normal host flora.

Some strains produce erythrogenic exotoxins (A, B and C) which cause the rash of scarlet fever in susceptible hosts.

3.2.8 SYMPTOMS

Symptoms of pharyngitis may include the following:

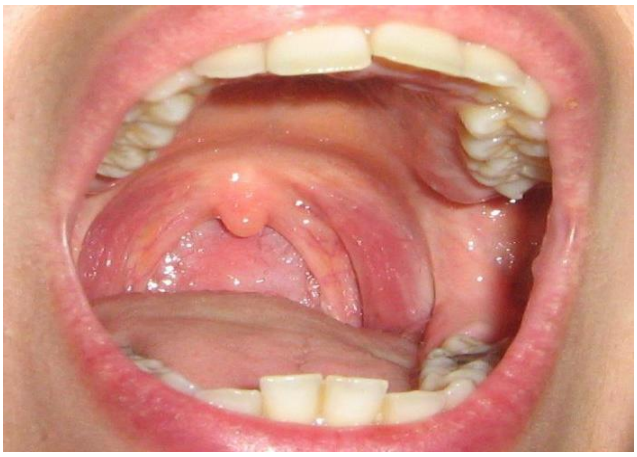
- Sore throat
- Fever
- Headache
- Joint pain and muscle aches
- Skin rashes
- Swollen lymph glands in the neck

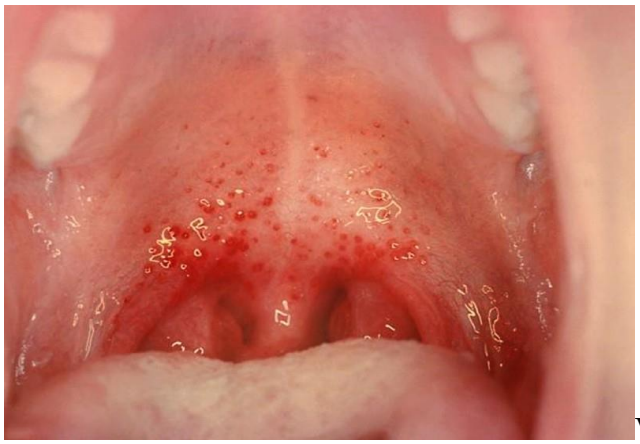
Sore throat with cold:

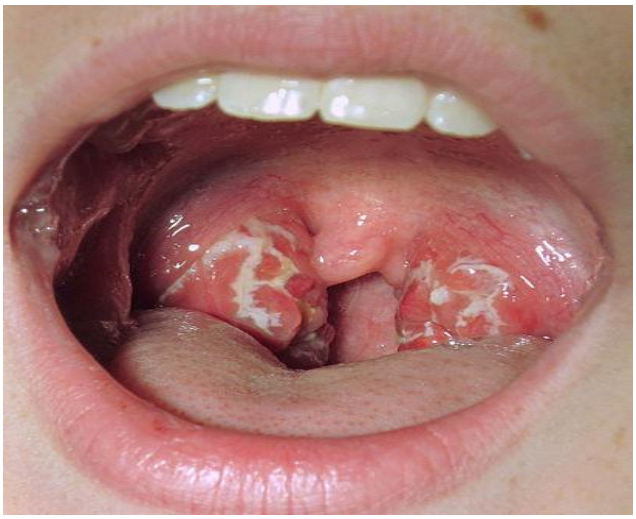
- Sneezing
- Cough
- A low fever (less than 102 degrees F)
- Mild headache

Sore throat with flu:

- It present with rapid onset high temperature >102 degrees F
- headache
- Fatigue
- Chills


Normal mouth


Viral phar


Strep throat

Sore throat with mononucleosis:

- Enlarged lymph nodes in neck and armpits
- Prominent tonsillar enlargement with exudate
- Headache
- Loss of appetite
- Hepatosplenomegaly
- Rash
- Generalized fatigue

Strep throat, another type of pharyngitis, can also cause:

- Rapid with prominent sore throats
- Headache and gastrointestinal symptom (Abdominal pain, vomiting) are frequent.
- difficulty in swallowing
- red throat and tonsils are enlarged and covered with white or gray patches
- Anterior cervical lymph nodes are enlarged and tender
- No fever and cough
- loss of appetite
- nausea
- unusual taste in the mouth
- general malaise

Adenopharyngitis:

- It may produce concurrent cojuctivitis and fever (Pharyngocojuctival fever)
- Typically the degree of neck lymph node enlargement is modest.
- The throat often does not appear red, although it is painful.

Coxsackivirus pharyngitis:

It may produce small (1-2mm) grayish vesicles and punched out ulcers in the posterior pharynx or small (3-6mm) yellowish- white nodules in the posterior pharynx(Acute lymphonodular pharyngitis.

3.2.9 PHYSICAL EXAMINATION

Temperature

- Fever is usually absent or low-grade in viral pharyngitis.

Head, ears, eyes, nose, and throat

- Conjunctivitis may be seen in association with adenovirus.
- Scleral icterus may be seen with infectious mononucleosis.
- Tonsillopharyngeal/palatal petechiae are seen in GAS infections.
- Oropharyngeal vesicular lesions are seen in coxsackievirus and Herpes virus.

3.2.10 COMPLICATION

Complications of the GABHS infection may result in

1. Suppurative or
2. non-suppurative

More common **suppurative infections** include

- ❖ retropharyngeal abscess
- ❖ peritonsillar abscess
- ❖ sinusitis
- ❖ cervical lymphadenitis
- ❖ otitis media
- ❖ mastoiditis
- ❖ Epiglottitis
- ❖ Thyroiditis

Non suppurative infections

Acute rheumatic fever

This disorder usually occurs 2-4 weeks after an episode of pharyngitis. Administration of proper antibiotics up to 9 days after the onset of pharyngeal symptoms has been shown to prevent this manifestation. Acute rheumatic fever is reported to result from one of every 400 untreated GABHS infections

Rheumatic heart disease

This is the chronic valvular manifestation of acute rheumatic fever. The mitral valve is the site most often affected, and either regurgitation or stenosis may result. In individuals with rheumatic heart disease, long-term secondary prophylaxis, often with benzathine penicillin, decreases the risk of subsequent episodes of acute rheumatic fever and further heart damage.

Poststreptococcal glomerulonephritis

This usually occurs 1-3 weeks following GABHS pharyngitis. Poststreptococcal glomerulonephritis, which may also follow a GABHS skin infection, has not been shown to be preventable with proper administration of antibiotics. Patients often present with hematuria, edema, and hypertension.

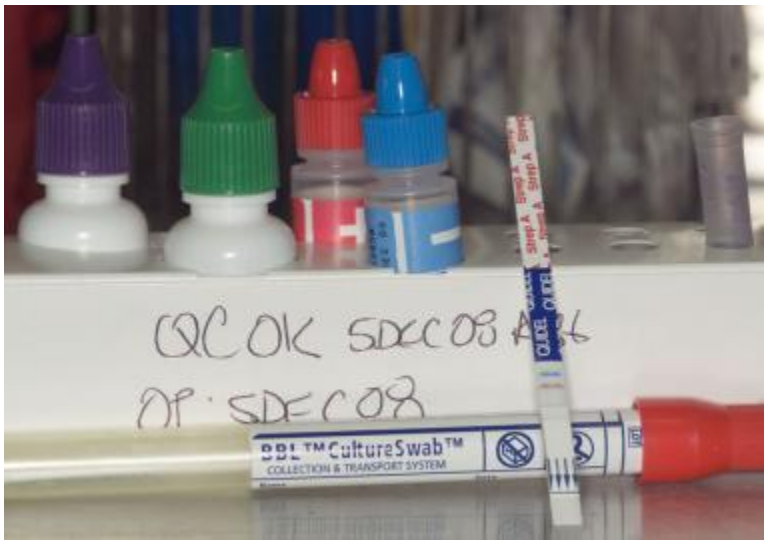
3.2.11 DIAGNOSTIC TEST

GABHS rapid antigen detection test

This is the preferred method for diagnosing GAS infection in the emergency department because of difficulties with culture follow-up.

Only patients with a high clinical likelihood of GAS pharyngitis should be tested. Antigens are specific, but sensitivities vary. The sensitivity of the GABHS rapid antigen detection test is 70-90%, and the specificity is 90-100%, depending on the manufacturer.

Children with a negative antigen test should have a follow-up culture unless the antigen being used in the office has been shown to be as sensitive as a culture.



The use of a GABHS rapid antigen detection test can decrease the use of unnecessary antibiotics in pediatric patients when used properly.

Adults do not need follow-up culture after a negative antigen test because of the low incidence of GAS in this population.

Throat culture

This is the criterion standard for diagnosis of GAS infection (90-99% sensitive). Although less expensive than the rapid antigen detection test, it is not be the best test to use in the emergency department because of difficulty with follow-up. The guidelines that recommend cultures for GAS screening are aimed at office-based practices and not the emergency department.

Patients can be treated up to 9 days after onset of symptoms to prevent acute rheumatic fever, so immediate antibiotic therapy is not crucial if patients can be easily contacted for follow-up should a culture become positive.

Other

Additional tests include the following:

- Mono spot is up to 95% sensitive in children (less than 60% sensitivity in infants)
- Peripheral smear may show atypical lymphocytes in infectious mononucleosis
- Perform gonococcal culture as indicated by history
- A complete blood count (CBC)
- erythrocyte sedimentation rate (ESR)
- C-reactive protein have a low predictive value and usually are not indicated

3.2.12 RISK FACTORS FOR PHARYNGITIS

- Cold and flu seasons
- Having close contact with someone who has a sore throat or cold
- Exposure to secondhand smoke
- Frequent sinus infections
- Allergies
- Attending daycare or crowded schools
- Air conditioning

- Chronic cough
- Hoarse voice
- Living in a hot, dry climate
- Reflux esophagitis
- Any condition that weakens the immune system, such as: Organ transplant
- Chemotherapy: the administration of medicines that kill cancer cells.

3.2.13 DIET FOR PHARYNGITIS

- The following remedies may help soothe a sore throat:
- Getting rest
- Drinking warm liquids, such as lemon tea or tea with honey
- Gargling with warm salt water (1/2 tsp of salt in 1 cup of water) throughout the day
- Running a cool-mist vaporizer or humidifier
- Drinking plenty of fluids to prevent dehydration
- Eating warm broth

3.2.14 PREVENTION OF PHARYNGITIS

Maintaining proper hygiene can prevent many cases of pharyngitis.

- avoid sharing food, drinks, and eating utensils
- avoid individuals who are sick
- Wash your hands often, especially before eating and after coughing or sneezing nose or after caring for a child with a sore throat.
- Use alcohol-based hand sanitizers when soap and water aren't available
- Avoid inhaling secondhand smoke
- If a toddler with pharyngitis has been chewing or sucking on toys, wash these objects thoroughly in water and disinfectant soap, then rinse well.
- Promptly dispose of any dirty tissues from runny noses and sneezes, and then wash your hands.
- Avoid caffeinated products.

3.3. DRUG REVIEW

3.3.1. வில்வம் (Aegle marmelos.Linn, corr)

Eng. Name : Bael (tree) Holy fruit free

Sans : Bilva

Family Name : Rutaceae

Part used : Leaf, flower, ripe and unripe fruit, root bark, root, gum

Suvai : Astringent

Thanmamai : Thatpam

Pirivu : Veppam

ACTIONS:

Leaves : Diaphoretic
Aphrodisiac
Febrifuge

Flower, Unripe fruit : Astringent
Stomachic
Digestive

Fruit : Laxative
Astringent
Stomachic

Root, Resin : Aphrodisiac

Pulp : Stimulant
Antipyretic
Antiscorbutic

Leaf juice : Bitter and pungent

GENERAL CHARECTERS

வில்லுவத்தின் வேருக்கு வீறுகுன்ம வாயுகபம்
சொல்லொணா பித்தந் தொடர்சோபை – வலகப
தாகசுரம் நீரேற்றஞ் சந்நியொடு மெய்வலியும்
வேகமொடு நீங்குமே.

அக்கனி மந்தம் அரோசிந்தி சாரம்விக்கல்
நிற்கரிய பித்தசுரம் நீள்வாந்தி - சுட்கநோய்
ஆதிய நோய் ஏகும் அழகோடு புஷ்டியுண்டாம்
கோதில்வில்வ வேரதனைக் கொள்.

வில்வ தளிர்- எல்லா மேகத்தையும், பூ- மந்தத்தையும், பிஞ்சு- குன்மத்தையும், பழம்- கண்ணிருளையும், பிசின்- வெந்நீர் குறைவையும், இலை- சுரத்தையும், மூக்குநீர் பாய்தலையும் நீக்கும்.

CHEMICAL CONSTITUENTS

Leaves : Aegeline
Aegelenine
Flavan -3-ols,
Sitosterol
Essential oil,
Marmilosin,
Reducing sugar

Root : Marmin,
Auraptene,
Lupeol

Fruit : Xanthotoxol,
Coumarins Scoparine,
Scopoletin,
Marmilosin
Tannic Acid,
Mucilage and Pectin

RESENT RESEARCH STUDIES ON AEGLE MARMELOS

1. ***Studies on the anti-inflammatory, antipyretic and analgesic properties of the leaves of Aegle marmelos Corr.***

   Journal of Ethnopharmacology

   Veerappan Arul, Shigeru Miyazaki, Renganathan Dhananjayan

   Reference:

   http://www.sciencedirect.com/science/article/pii/S0378874104004441

2. ***Evaluation of the anti-inflammatory activity of Aegle marmelos(Bilwa) root Indian Journal of pharmacology***

   Jyoti M.Benni, M.K.Jayanthi and R.N.Suresha

   Reference: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3153700/

3. ***Evaluation of the anti-inflammatory activity of hydroalcoholic extract of aegle marmelos leaves***

   Jaganmohan Chandran, Parthiban.S Shanmugam, T Tamizhmani

   Reference:https://www.researchgate.net/publication/263966707_evaluation_of_the_antinflammatory_activity_of_hydroalcoholic_extract_of_aegle_marmelos_leaves

4. ***Evaluation of Aegle marmelos (Bael) for Anti-inflammatory Activity in Rats***

   Ghangale G. R., Surve V. S., Anbarasan K., Gatne M. M.

   Reference:http://www.indianjournals.com/ijor.aspx?target=ijor:jbvc&volume=16&issue=1&article=006

5. ***Evaluation of antidiarrhoeal and antiinflammatory activity of Aegle marmelos on albino wistar rats***

   Pelagia Research Library European Journal of Experimental Biology, 2016, 6(2):26-29 ISSN: 2248 –9215 CODEN (USA): EJEBAU

   (D. Vijay Anand Raju, V. Sandhya, M. Vineel Chandra, M. Muralidhar Reddy and Bolay Bhattacharya)

   Reference:http://www.imedpub.com/articles/evaluation-of-antidiarrhoeal-and-antiinflammatory-activity-of-iaegle-marmelosi-on-albino-wistar-rats.pdf

6. ***Immunomodulatory Potential of Methanol Extract of Aegle marmelos in Animals***

Indian Journal of Pharmaceutical Sciences

Indian J Pharm Sci. 2011 Mar-Apr; 73(2): 235–240.

(H V Govinda and S. M. B. Asdaq)

Reference:https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3267313/

3.3.2 அவுரி (Indigofera tinctoria, Linn)

Eng. Name	: Indian Indigo plan
Sans	: Nilini
Family Name	: Fabaceae
Part used	: Leaf, root
Suvai	: Bitter
Thanmai	: Veppam
Pirivu	: Acrid
ACTIONS	: Germicide
	Antiperiodic
	Stimulant

GENERAL CHARACTERS

உரியலவு ரித்தழைத்தான் ஓது பதினெண்
அரியநஞ்சைத் தின்றவர்க்கும் ஆகும் - தெரிவரிய
வாதவெப்பு காமாலை மைந்தர் குறுமாந்தஞ்
சீதம் அகற்றுந் தெரி.

சன்னி பதிமூன்றுஞ் சந்தொடித்த வாதமுதல்
உன்னு விடக்கடியும் ஓடுங்காண் - மின்னுங்
கவுரிநிறம் உண்டாகுங் காசினியுள் நல்ல
அவிரியிலை தன்னால் அறி.

CHEMICAL CONSTITUENTS

- Indican (a glucoside)
- Indigotin or Indigo- blue
- Luc- Indigo or Indigo White
- Tannins
- Terpinoids
- Flavinoids
- Apigenin
- Kaempferol
- Luteolin
- Quercetin
- Indicaine
- 6,6'-dibromoindigotine
- Deguelin

RESENT RESEARCH STUDIES ON INDIGOFERA TINCTORIA

1. *Anti-Bacterial, Anti-Oxidant and Cytotoxicity effect*

Renkadevi K.P et al.,(2011) study has been under taken with an objective to determine the antibacterial, anti-oxidant and cytotoxic activity of the leaf extract of indigofera tinctoria. Anti-bacterial activity was carried out on in vitro lung cancer cell line. The extract screened for phyto chemical analysis was found to contain bioactive compounds like falvonoid, saponins, tannins, steroidal terpens, phenols and anthroquinone were identified by GC -MS analysis.

The leaf extract I.tinctoria having the ability to inhibit the growth of gram positive bacteria namely Staphylococcus aureus, Bacillus pumilus and Streptococcus pyrogens and zone of inhibition was observed 16 and 17 mm, respectively but not shown growth of inhibition on gram negative bacteria Escherichia and pseudomonas aeruginosa. Strong antioxidant activity was observed both qualitatily and quantitatively. The strong antioxidant was observed at 250ugml-1 with an IC 50 value of 51.66 which is higher than that of standarad ascorbic acid. The cytotoxic effect of I.tinctoria leaf extract on lung cancer cell line NCI-H69 was studied. The percentage cell viability of cells was found to

decrease at increasing concentration. GC-MS analysis of the leaf extract shows 6 compounds. This study suggests that ethanol extract of Indigofera tinctoria have profound antibacterial, antioxidant and cytotoxic effect.

2. Anti –Inflammatory effect

Pramodm K.Tyagi et al., (2010) elucidate the anti-inflammatory activity of ethanolic extract of I.tinctoria leaves (500 & 100 mg/kg).When compare to control as well as positive control Ibuprofen (Standard drug) group values are expressed as mean and SD. Statistical significance was determinded using the student's t-test. Values with $p<0.01$ were considered significance. the present study indicated that oral administration of ethanol extract of I.tinctoria linn dose dependently improve the potent anti-inflammatory activity. The extact lowers the carrageen an induced rat paw oedema. Further pharmacological and biochemical investigations are essential to elucidate the mechanism of action.

Review Paper Indigofera tinctoria Linn - A Phytopharmacological Review

International Journal of Research in Pharmaceutical and Biomedical Sciences ISSN: 2229-3701

(Saraswathi Motamarri N, Karthikeyan M, Rajasekar S and Gopal)

Reference:https://www.doc-developpement-durable.org/file/Culture-plantes-colorantes/FICHE_PLANTES/indigo/Indigotier/Indigofera%20tinctoria%20Linn%20-%20A%20Phytopharmacological%20Review.pdf

3. Preliminary phytochemical screening and Evaluation of Anti-inflammatory activity of Ethanolic extract of leaves of Indigofera tinctoria Linn

(B. R.Sarkar, V. K. Rai, B. Kapoor, S. Sharma, J.P. Mohanty, D. Sarkar,

M.K.Sharma, A. Kar)

Reference:https://www.researchgate.net/publication/262732289_Preliminary_phytochemical_screening_and_Evaluation_of_Anti_inflammatory_activity_of_Ethanolic_extract_of_leaves_of_Indigofera_tinctoria_Linn

4. Immunomodulatory Activity of Indigofera Tinctoria Leaf Extract on in Vitro Macrophage Responses and Lymphocyte Proliferation

International Journal of Pharmcy and Pharmaceutical Sciences

(Madakkannu Boothapandi, Ravichandran Ramanibai)

Ref: https://innovareacademics.in/journals/index.php/ijpps/article/view/9932

5. Physicochemical and Antioxidant Assays of Methanol and Hydromethanol Extract of Ariel Parts of Indigofera tinctoria Linn

Indian journal of Pharmaceutical sciences.

Indian J Pharm Sci. 2015 Nov-Dec; 77(6): 729–734

(Veena Sharma and Aastha Agarwal)

Ref:https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4778233/

6.Determination of Anti- Bacterial Anti-Oxidant and Cytotoxicity effect of Indigofera tinctoria on Lung cancer cell line NCI – h69.

Internationa journal of pharmacology 7(3):356-362, 2011

(K.P.Renukadevi and S.Suhani Sultana)

Ref;http://docsdrive.com/pdfs/ansinet/ijp/2011/356-362.pdf

3.3.3 வெங்காயம் (Allium cepa.Linn)

Eng. Name	: Onion
Sans	: Pallandu
Family Name	: Alliaceae
Part used	: Seeds, flower, Bulb
Suvai	: Bitter
Thanmai	: Veppam
Pirivu	: Acrid

ACTIONS : Stimulant

Diuretic

Expectorant

Emmenagogue

Rubefacient

Demulsent

Aphrodisiac

GENERAL CHARACTERS

வெப்பமூ லங்கிரந்தி வீறுரத்த பித்தமுடன்
செப்புநா அக்கரந்தீ ராத்தாகம் - வெப்புக்
கடுப்பறுமந் தஞ்சந்தி காசம்வயிற் றுப்பல்
தடிப்பேறும் வெங்காயத்தால்.

கிழங்கு வெங்காயத்தால், உடலின் வெப்பம், மூலம், சிரங்கு, குருதியழல் நோய், அக்கரம், நீர்வேட்கை, கழிச்சல் இவை நீங்கும்.

CHEMICAL CONSTITUENTS

- Quercetin
- Fructose
- Quercetin-3-glucoside
- Flavinoids
- Flavenols
- Cycloalliine
- Thiosulphates
- Isorhamnetin-4-glucoside
- Organosulphur compounds
- Allylsulfides
- Sulphur and selenium
- S-alkenyl cysteine sulfoxides.

RESENT RESEARCH STUDIES ON ALLIUM CEPA

1. ***Evaluation of analgesic and anti-inflammatory effects of fresh onion juice in experimental animals***

   African Journal of Pharmacy and Pharmacology Vol. 6(23), pp. 1679-1684, 22 June, 2012

   (Sima Nasri , Mahdieh Anoush, Narges Khatami)

   Reference:http://www.academicjournals.org/article/article1380798317_Nasri%2520et%2520al.pdf

2. ***Antibacterial activity of fresh juices of allium cepa and zingiber officinale against multidrug resistant bacteria***

   International Journal of Pharma and Bio Sciences

   (G.O.Adeshina, S.Jibo, V.E.Agu, J.O.Ehinmidu)

   Reference:http://www.ijpbs.net/download.php?download_file=volume2/issue2/bio/28.pdf

3.3.4 கடுக்காய் (Terminalia chebula. Retz)

Eng. Name	: Chebuic Myrobalan, Ink nut
Sans	: Pathya, Sudha, Bhishak
Family Name	: Combretaceae
Part used	: Fruits
Suvai	: Acrid
Thanmai	: Veppam
Pirivu	: Sweet

ACTIONS:

- Gentle laxative
- Astringent
- Alterative

GENERAL CHARACTERS

தாடை கழுத்தக்கி தாலு குறியிடப்
பீடை சிலிபதமுற் பேதிமுடம்-ஆடையெட்டாத்
தூலமிடி புண்வாத சோணிகா மாலையிரன்
டூலமிடி போம்வரிக்கா யால்.

- அகத்தியர் குணவாகடம்.

சொல்லு மரிதகிமேற் நோலை மதுவுடனே
யல்லும் பகலு மயிலவே-கல்லுங்
கரைய வுரமெழுப்புங் கயசித்தி யுண்டாம்
நரையுந் திரையுமிலை நை.

- தேரன்வெண்பா.

இருமல், தொண்டைக் கம்மல், கோழை வெளிப்படுதல், இரைப்பு, இளைப்பு, கண் நோய்கள், உதட்டு நோய்கள், தலை நோய்கள், நீர் வேட்கை, பாண்டு, சோபை,பெருவயிறு, புராணசுரம், விடசுரம், கபவாத ரோகம், அசீரணம், அழலை, உள்ளங்கால் எரிவு, காமாலை, உட்சுரம், தோஷம், வெள்ளை, ஈரல் நோய், குருதியழல், தமரக நோய், குருமம், குட்டம், மூர்ச்சாரோகம், மூலரோகம், அஸ்மரி, பவுத்திரம், வாய்ப்புண் முதலிய நோய்கள் நோங்கும்.

CHEMICAL CONSTITUENTS

- Tannic acid
- Gallic acid
- Chebulinic acid
- Mucilage

RESENT RESEARCH STUDIES ON TERMINALIA CHEBULA

1. ***Evaluation of in-vitro anti-inflammatory activity of chebulinic acid from Terminalia chebula Linn. against the denaturation of protein***

   Reference:https://sciforum.net/conference/ecsoc18/paper/2584/download/pdf (Sima Singh, Uma Ranjan Lal)

2. ***Anti-inflammatory acxtivity of constituents isolated from Terminalia chebula***

   Reference: https://www.ncbi.nlm.nih.gov/pubmed/25230505
   (Yang MH, Ali Z, Khan IA, Khan SI)

3.3.5 சிற்றாமணக்கு நெய் (எண்ணெய்) (Ricinus communis)

Eng. Name : Castor-oil

Sans : Lahu-Yeranda-tailam

Family Name : Euphorbiaceae

Part used : Leaf, Root, Seed

Suvai : Bitter

Thanmai : Veppam

Pirivu : Acrid

ACTIONS:

Root bark and Oil : Nonirritant purgative

Seeds : Counter irritant

Leaves : Galactogogue

Oil :

- Anti-inflammatory
- Emollient
- Anti-infectious
- Anti-rheumatic
- Fungicidal
- Laxative
- Immune stimulant
- Insecticidal
- Anti-viral
- Anti-allergic
- Anthelmintic
- Germicidal
- Disinfectant
- Analgesic

GENERAL CHARACTERS

ஆமணக்கு நெய்யால் நலமுண்டாம் யாவர்க்கும்
பூமணக்கு மேனி புரிகுழலே – வாய்மணக்கக்
கொள்ளில் வயிறுவிடுங் கோரமுள்ள வாயுவறும்
உள்ளில்வரு குன்மம்போ மோது.

அம்பொனிற மும்விந்து மாங்குடலி னேற்றமறும்
ஐம்பொறிச் சூடெரிவு மாறுங்காண் - அம்புவியிற்
பாமணக்கு மின்பமொழிப் பாவாய்! நலங்செறிந்த
ஆமணக்கு நெய்யை அருந்து.

ஆமணக் கெண்ணெய் தன்னை யணிநில மறியக் கேண்மின்
பூமணச் சந்துதோறும் பொருந்திய வாதம் போக்கும்
தீமந்தந் தானும் போக்குந் திகழ்வுடன் விரைவு முண்டாம்
தீமனக் குடலில் வாதஞ் சோர்குட லேற்றம் போமே.

- சிற்றாமணக்கெண்ணெய் - மருந்தின் வேகம் வலியினால் எருவாயிலுண்டாகும் அழலை (நீர்ச்சுருக்கு, வெள்ளை) ஆகியவைகளை நீக்கும்.
- குழந்தைகளைத் தாய்ப்போல் வளர்க்கும்.
- குழந்தைகளுக்கும், பிள்ளை பெற்ற பெண்மணிகளுக்கும் வயிறு கழியக் கொடுத்தற்கு, இ.ஃ.து ஒரு சிறந்த மருந்தாகும்.
- இதை கைக்குழந்தை, கிழ வயதுடையவர், சூல் கொண்டவர், பிள்ளை பெற்றவர், சீதகுருதி பேதியால் வருந்துபவர் முதலியவர்களுக்கும் அச்சமின்றிக் கொடுக்கலாம்.
- பசியின்மை வயிற்றுவலி இவற்றால் துன்புறுவோருக்கும் இதைத் தரலாம்.
- ஐயத்தின் பெருக்கால், கோழைக்கட்டு, இரைப்பு, இருமல் இவைகளால் ஈடுபட்டவர்களுக்கும் இவற்றைக் கொடுக்க வயிறு கழிந்து நன்மை உண்டாகும்.

CHEMICAL CONSTITUENTS

- Ricin
- Starch
- Mucilage
- Ricinoleste of glycerol or tri-ricinolein
- Palmitic acid

- Stearin
- Ricinolic acid- 94%
- Glycerides of dihydroxystearic acid
- Linoleic acid-0.2%
- Oleic acid,
- Stearic acid- 1.0%
- Linolenic acid- 4.3%
- Saturated fatty acid- 1.0%
- Unsaturated fatty acid -98.3 %

RESENT RESEARCH STUDIES ON CASTOR OIL

1. ***Evaluation of Analgesic Activity of Castor Oil in Experimental Animals***

   International Journal of Universal Pharmacy and Life Sciences

   (K.J. Kore, R.V. Shete., M.P.Kabra, R.M.Rachhadiya)

2. ***Effect of ricinoleic acid in acute and subchronic experimental models of inflammation.***

   Mediators of Infammation Mediators Inflamm. 2000; 9(5): 223–228

   (C Vieira, S Evangelista, R Cirillo, A Lippi, C A Maggi, and S Manzini)

   Reference:https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1781768/

3. ***Antimicrobial Activity of Castor oil Plants (Ricinus Communis) Seeds Extract against Gram Positive Bacteria, Gram Negative Bacteria And Yeast***

   (Hashem Rahmati, Saeid Salehi,Abdorrasoul Malekpour and Farzaneh Farhangi)

   Internationa Journal of Molecular Medicine and Advance Sciences 11 (1): 9-12, 2015. ISSN: 1813-176X

   Reference:http://docsdrive.com/pdfs/medwelljournals/ijmmas/2015/9-12.pdf

4. MATERIALS AND METHODS

4.1 PREPARATION OF THE TRIAL DRUG VILVA ENNAI

The required plants were collected from patcha malai and raw drugs were purchased from raw drug shop and are authenticated by the medicinal botanist Dr.D.Aravind MD(S), M.Sc., National Institute of Siddha, Chennai 47. The medicine was prepared in Gunapadam lab of National Institute of Siddha after proper purification. The prepared medicine was also authenticated by the concerned Head of the Department for its completeness.

Ingredients

Chitramanakku ennai	(*Ricinus communis*)	- 325 ml
Vilva elaicharu	(*Aegle marmelos*)	- 325 ml
Avuricharu	(*Indigofera tinctoria*)	- 325 ml
Vellai vengayacharu	(*Allium cepa*)	- 325 ml
Kadukkaithol	(*Terminalia chebula*)	- 40 g

Method of purification

All the ingredients mentioned in the formulation are purified as per the direction described in the Siddha literature.

Preparation Method

Castor oil (Ricinus communis), juice extracted from the leaves of vilvam (Aegle marmelos), avuri (Indigofera tinctoria), and vellai vengayam (Allium cepa) each 325ml are taken in a bowl. Add 40gm of powdered kadukkai to the mixture and it is allowed to boil until it reaches waxy consistency. Then it is filtered and collected and stored in a clean dry glass container.

Vehicle: Hot water **Dose:** 3 ml (OD – morning)

Indication: All types of Kanam. **Duration**: 5 days.

Drug Storage: Prepared medicine will be stored in clean and dry glass container.

Dispensing: Given 15 ml Vilva Ennai in air tight container.

INGREDIENTS OF VILVA ENNAI

Aegle marmilos

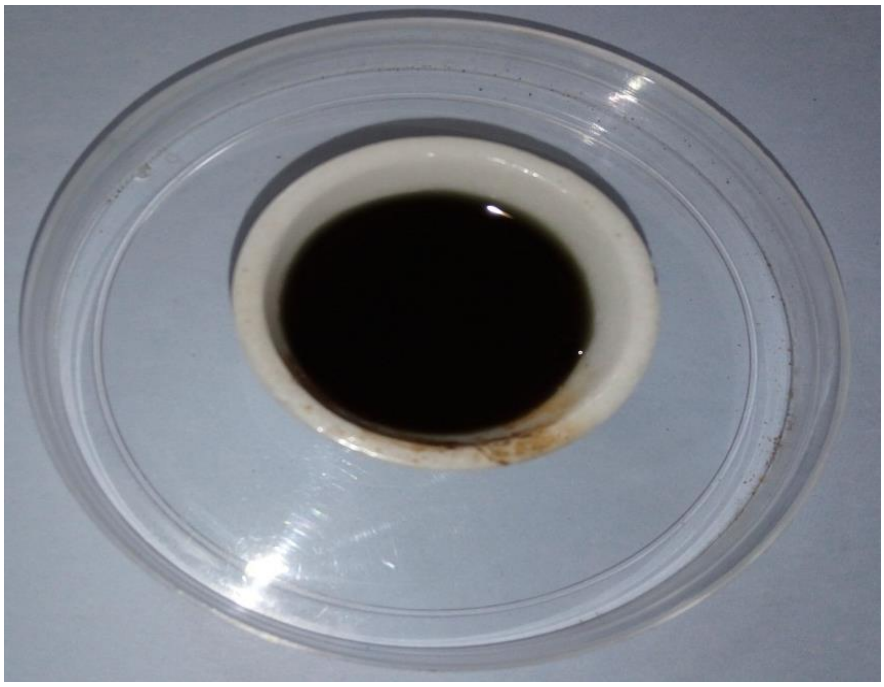
Terminalia chebula

Allium cepa

Indigofera tinctoria

Castor oil

PREPARED TRIAL DRUG – VILVA ENNAI



4.2 PRECLINICAL STUDIES

4.2.1 In-vitro Anti-Inflammatory Activity

The anti-inflammatory activity of the trial drug VILVA ENNAI was done at Noble Research Solutions, Sathyabama University, Chennai.

Albumin Denaturation Assay Procedure

In-vitro anti-inflammatory activity Vilva Oil (VO) was studied using albumin denaturation technique. The reaction mixture consisted of bovine serum albumin (5% aqueous solution) and test sample VO at varying concentration ranges from 100 to 500 mcg/ml and standard diclofenac sodium at the concentration of100 mcg/ml of final volume. pH was adjusted by using a small amount of 1N Hydrochloric acid. The samples were incubated at 37°C for 20 min and then heated at 57°C for 3 min. After cooling the sample, 2.5 ml of phosphate buffer solution was added into each test tube. Turbidity developed was measured spectrophoto-metrically at 660 nm, for control distilled water

was used instead of test sample while product control tests lacked bovine serum albumin. The experiment was performed in triplicate.

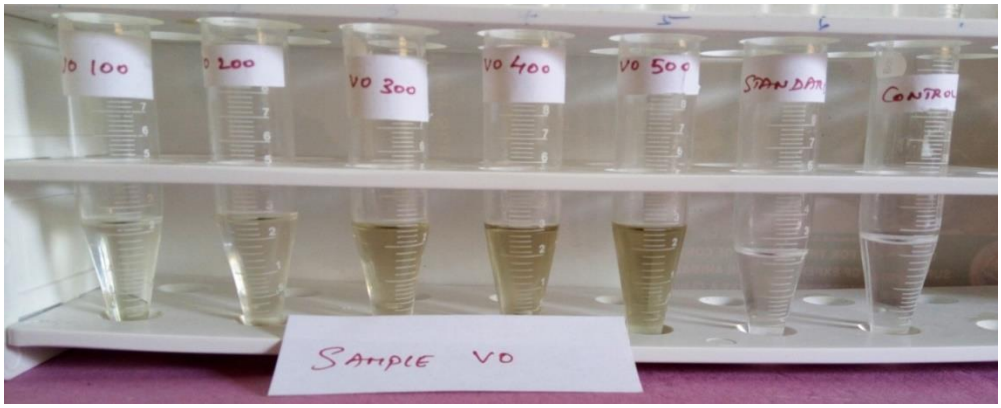
The Percentage protection from denaturation is calculated by using the formulae

$$\left[\frac{(A)_{\text{control}} - (A)_{\text{sample}}}{(A)_{\text{control}}}\right] \times 100.$$

Statistical analysis:

Results are expressed as Mean ± SD. The difference between experimental groups was compared by One-Way Analysis Of Variance (ANOVA) followed by Dunnet Multiple comparison test

Preparation of Test and control



Absorbance of reaction mixture – Test Sample

Absorbance of reaction mixture – Control and Standard

4.2.2 Physicochemical Evaluation

The Physicochemical analysis of the drug *VILVA ENNAI* was done at Noble Research Solutions, Sathyabama University, Chennai. Since the form of the drug is in oil the parameters such as Total ash, pH, Saponification value, Iodine value was done using Quality control methods for medicinal plants materials.

Percentage Loss on Drying

10gm of test drug (weight equivalent to oil) was accurately weighed in evaporating dish .The sample was dried at 105^{o}C for 5 hours and then weighed.

Percentage loss in drying = Loss of weight of sample/ Wt of the sample X 100

Determination of Total Ash

3 g of test drug (weight equivalent to oil) was accurately weighed in silica dish and incinerated at the furnace a temperature 400 ºC until it turns white in color which indicates absence of carbon. Percentage of total ash will be calculated with reference to the weight of air-dried drug.

Total Ash = Weight of Ash/Wt of the Crude drug taken X 100

Determination of pH

Sample being oily in nature the direct litmus evaluation method was adopted to check the pH of the sample.

Determination of Iodine value

About 20gm of oil was transferred into Iodine flask. To which 10 ml of chloroform was added and warmed slightly and cooled for 10 minutes. Followed by this

about 25 ml of Wiji's solution was added in the same flask and shaken well. The flask was allowed to stand for 30 min and refrigerated for an hour. About 10 ml of KI solution was added to this and titrated against 0.1 N Sodium thiosulphate solutions until the appearance of yellow colour. 1 ml of starch indicator was added and again titrated against the sodium thiosulphate solution from the burette. Disappearance of blue colour indicates end point. Repeat the above procedure without taking sample and note the corresponding reading for blank titration.

Determination of saponification value

About 2gm (weight equivalent to oil) of test sample was transferred into the round bottomed flask. To this about 20 ml of 0.5 N alcoholic KOH solutions was added to the round bottomed flask. Repeatthe same procedure without taking the sample for blank titration. Reflux both sample and blank round bottomed flasks for 1 hour. After reflux, allow both the round bottomed flasks to cool. Titrate the samples using 0.5 N HCl with phenolphthalein indicator. The disappearance of pink indicates the end point.

GCMS- Analysis

GCMS (Clarus 500 Perkin – elmer (Auto system XL)), NIST Ver.2.1 MS data library

Specification :

Start Time(min)	End Time(min)	Start m/z	End m/z Scan	Speed
2.50	18.00	50.00	650.00	2000

Sample Inlet Unit : GC

GC-MS Plays a key role in the analysis of unknown components of plant origin. GC-MS ionizes compound and measures their mass numbers. Ionization method includes EI (Electron Ionization). The EI method produces ions by colliding thermal electrons emitted from a filament with sample gas molecules. This method provides high stability in ionization and obtained mass spectra show good reproducibility. The EI method provides good result for quantitative analysis as well. Quantitative analysis with GC-MS, in which only ions specific to the compounds are measured, is highly selective method without interfering components. Gas chromatography Technique involves the separation of volatile components in a test sample using suitable capillary column coated with polar or non-polar or intermediate polar chemicals. Elite-1 column (100% Dimethyl

polysiloxane) is a non-polar column used for analysis of phyto-components. Elite -5 column (5% phenyl and 95% methyl polysiloxane) is an intermediate column and also used for the estimation of Phytochemical. An inert gas such as hydrogen or nitrogen or helium is used as a carrier gas .The compounds of test sample is evaporated in the injection port of the GC equipment and segregated in the column by absorption and adsorption technique with suitable GC programme.

TLC Analysis

Test sample VO was subjected to thin layer chromatography (TLC) as per conventional one dimensional ascending method using silica gel 60F254, 7X6 cm (Merck) were cut with ordinary household scissors. Plate markings were made with soft pencil. Micro pipette were used to spot the sample for TLC applied sample volume 10-micro liter by using pipette at distance of 1 cm at 5 tracks. In the twin trough chamber with different solvent system Ethyl acetate: Methanol: Water (100:13.5:10) After the run plates are dried and was observed using visible light Short-wave UV light 254nm and light long-wave UV light 365 nm.

High Performance Thin Layer Chromatography Analysis (HPTLC)

HPTLC method is a modern sophisticated and automated separation technique derived from TLC. Pre-coated HPTLC graded plates and auto sampler was used to achieve precision, sensitive, significant separation both qualitatively and quantitatively. High performance thin layer chromatography (HPTLC) is a valuable quality assessment tool for the evaluation of botanical materials efficiently and cost effectively. HPTLC method offers high degree of selectivity, sensitivity and rapidity combined with single-step sample preparation. In addition it is a reliable method for the quantitation of nano grams level of samples. Thus this method can be conveniently adopted for routine quality control analysis. It provides chromatographic fingerprint of phytochemicals which is suitable for confirming the identity and purity of medicinal plant raw materials.

Chromatogram Development

It was carried out in CAMAG Twin Trough chambers. Sample elution was carried out according to the adsorption capability of the component to be analysed. After elution, plates were taken out of the chamber and dried.

Scanning

Plates were scanned under UV at 366nm. The data obtained from scanning were brought into integration through CAMAG software. Chromatographic finger print was developed for the detection of phytoconstituents present in each extract and Rf values were tabulated.

Phytoconstituents of Vilva Ennai

Sample Preparation

Vilva oil (VO) was extracted with ethanol and the extract was subjected to the following analysis

Test for Alkaloid- Mayer's reagent

To the test drug about 2ml of Mayer's reagent was added and was observed for the presence of alkaloids. Appearance of dull white precipitate indicates the presence of alkaloids.

Test for flavonoid

To 0.1ml of the test sample about 5 ml of dilute ammonia solution were been added followed by addition of few drops of conc. Sulfuric acid. Appearance of yellow color indicates the presence of Flavonoids.

Test for Glycosides - Borntrager's Test

Test drug is hydrolysed with concentrated hydrochloric acid for 2 hours on a water bath, filtered and the hydrolysate is subjected to the following tests. To 2 ml of filtered hydrolysate, 3 ml of choloroform is added and shaken, choloroform layer is separated and 10% ammomia solution is added to it. Pink colour indicates presence of glycosides.

Test for Triterpenoids

To the test solution 2ml chloroform was added with few drops of conc. Sulphuric acid (3ml) at the side of the test tube. An interface with a reddish brown coloration is formed if terpenoids constituent is present.

Test for Steroids - Salkowski test

To the test solution 2ml of chloroform was added with few drops of conc. Sulphuric acid (3ml), and shaken well. The upper layer in the test tube was turns into red and sulphuric acid layer showed yellow with green fluorescence. It showed the presence of steroids.

Test for Carbohydrates - Benedict's test

To 0.5 ml of test drug about 0.5 ml of Benedic's reagent is added. The mixture is heated on a boiling water bath for 2 minutes. A characteristic coloured precipitate indicates the presence of sugar.

Test – Phenol- Lead acetate test

The test sample is dissolved in of distilled water and to this 3 ml of 10% lead acetate solution is added. A bulky white precipitate indicates the presence of phenolic compounds.

Test for tannins

About 0.5ml of test sample is boiled in 20 mL of distilled water in a test tube and then filtered. The filtration method used here is the normal method, which includes a conical flask and filter paper. The 0.1% FeCl3 is added to the filtered samples and observed for brownish green or a blue black coloration, which shows the presence of tannins

Test for Saponins

The test drugs were shaken with water vigorously for 10 mins , copious lather formation indicates the presence of saponins.

Test for Proteins (Biuret Test)

Biuret test: Equal volume of 5% solution of sodium hydroxide and 1% copper sulphate were added. Appearance of pink or purple colour indicates the presence of proteins and free amino acids.

Test of Coumarins

1 ml of extract, 1 ml of 10% sodium hydroxide was added. The presence of coumarins is indicated by the formation of yellow color.

Test for Anthocyanin

About 0.2 ml of the extract was weighed in separate test tube, 1ml of 2N Sodium hydroxide was added, and heated for 5 minutes at 100 ± 2°C. Observed for the formation of bluish green color which indicates the presence of anthocyanin.

Quantitative estimation of phytoconstituents of Villva Ennai

Determination of total Phenol content

The total phenol content was determined using Folin–Ciocalteu reagents with analytical grade Gallic acid as the standard. 1 ml of sample was added to deionized water (10 ml) and Folin–Ciocalteu phenol reagents (1ml). After 5 minutes, 20% sodium carbonate (2 ml) was added to the mixture. After being kept in total darkness for 1hr, the absorbance was measured at 750 nm using a spectrophotometer. Amounts of total Phenol was calculated using Gallic acid calibration curve. The results were expressed as Gallic acid equivalents (GAE) mg/g of dry plant matter.

Estimation of Alkaloid

VO weight equivalent to 5gm was weighed into a 250 ml beaker and 200 ml of 10% acetic acid in ethanol was added and covered and allowed to stand for 4 hr. This was filtered and the extract was concentrated on a water bath to one-quarter of the original volume. Concentrated ammonium hydroxide was added drop wise to the extract until the precipitation was complete. The whole solution was allowed to settle and the precipitated was collected and washed with dilute ammonium hydroxide and then filtered. The residue is the alkaloid, which was dried and weighed.

4.2.3 Biocemical Analysis

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

Preparation of Extract

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

Test for Silicate

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

Action of Heat

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

Flame Test

2ml of the sample is made into a paste with con. Hcl in a watch glass and introduced into non- luminous part of the bunsan flame.

Ash Test

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

4.2.3.1 Test for Acid Radicals

Test for sulphate

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

Test for Chloride

2ml of the above prepared extract is added with diluted Hno_3 till the effervescence ceases. Then 2ml of silver nitrate solution is added.

Test for Phosphate:

2ml of the extract is treated with 2ml of ammonium molybdate solution and 2ml of con.Hno_3.

Test for Carbonate

2ml of the extract is treated with 2ml magnesium sulphate solution

Test for Nitrate

1gm of substance is heated with copper turnings and concentrated H_2So_4 and viewed the test tube vertically down.

Test for Sulphide

1gm of the substance is treated with 2ml of con. HCL

Test for Fluoride & Oxalate

2ml of extract is added with 2ml of dil. Acetic acid and 2ml calcium chloride solution and heated.

Test for Nitrite

3drops of the extract is placed on a filter paper, on that – 2 drops of acetic acid and 2drops of Benzidine solution is placed.

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.

4.2.3.2 Test for Basic Radicals

Test for Lead

2ml of the extract is added with 2ml of potassium iodide solution.

Test for copper

1 Pinch of substance is made into paste with con. HCL in a watch glass and introduced into the non-luminuous part of the flame

Test for Aluminium

To the 2ml of the extract sodium hydroxide is added in drops to excess.

Test for Iron

To the 2ml of extract add 2ml of ammonium thiocyanate solution.

Test for Zinc

To 2ml of the extract sodium hydroxide solution is added in drops to exess.

Test for Calcium

2ml of the extract is added with 2ml of 4% Ammonium oxalate solution.

Test for Magnesium

To 2ml of extract sodium hydroxide solution is added in drops to exess.

Test for Ammonium

To 2ml of extract few ml of Nessler's reagent and exess of sodium hydroxide solution are added.

Test for Pottasium

A pinches of the substance is treated with 2ml of sodium nitrite solution and then treated with 2ml of cobalt nitrate in 30% glacial acetic acid.

Test for Sodium

3 pinches of the substance is made into paste by using HCL and introduced into the blue flame of Bunsen burner.

Test for Mercury

2ml of extract is treated with 2ml of sodium hydroxide solution

Test for Arcenic

2ml of the extract is treated with 2ml of sodium hydroxide solution.

4.2.3.3 Miscellaneous

Test for Starch

2ml of extract is treated with weak iodine solution.

Test for Reducing Sugar

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

Test for the Alkaloids

2ml of the extract is treated with 2ml of potassium iodide solution.

Test of Tannic acid

2ml of extract is treated with 2ml of ferric chloride solution.

Test for Unsaturated Compound

To the 2ml of extract 2ml of potassium permanganate solution is added.

Test for Amino Acid

2 drops of the extract is placed on a filter paper and dried well.

Test for Type of Compound

2ml of the extract is treated with 2ml of ferric chloride solution.

4.3 CLINICAL STUDIES

A Protocol was prepared and submitted before IEC of National Institute of siddha. The IEC approval number is NIS/IEC/9/2014-15/17, and my registered CTRI number is CTRI/2017/02/007753. After getting the approval from committee, the clinical study on Vali Kanam (Acute Pharyngitis) in children and the drug of choice was Vilva Ennai carried out as per the protocol.

The trial drug *"VIVA ENNAI"* is given for 5 days. For OP patients before and after treatment the clinical assessment will be done and prognosis is noted. For IP patients the drug is provided daily and prognosis is noted and clinical assessment will be done. After the end of the treatment, the patient were advised to visit the OPD for follow up regularly.

Study Enrollment

1. In this study, patients reporting at the NIS OPD with the three or more clinical symptoms of rumbling noise in stomach, irritant sensation in throat, cough, excessive thirst, low-grade fever, lack of appetite, dysuria will be examined clinically for enrolling in this study based on the inclusion and exclusion criteria.

2. The patients who are to be enrolled would be informed about the study, experimental medicine, possible outcomes and the objectives of the study in the language and terms understandable to them and to their informants.

3. After ascertaining the patient and informants willingness, informed consent would be obtained in writing from them in the consent form.

4. Complete clinical history, complaints and duration, examination findings-- all would be recorded in the prescribed Performa in the history and clinical assessment forms separately. Screening Form- I will be filled up. Form –IV will be used for recording the patients' history, clinical examination of symptoms and signs and laboratory investigations respectively.

5. Patients would be advised to take the trial drug and appropriate dietary advice would be given according to the patients' perfect understanding.

Population and Sample

- The population consists of paediatric patients attending the OPD of Ayothidoss Pandithar Hospital, National Institute Of Siddha, Chennai-47.
- The sample consists of 8-12 years age group fulfilling all the inclusion criteria and none of the exclusion criteria.

Study type: An Open Clinical Trial

Sample size: 40 patients (Both male & female)

Study place:

Department of Kuzhanthai Maruthuvam

OPD & IPD of Ayothidoss pandithar hospital,

National Institute of Siddha,

Chennai – 47

Inclusion Criteria

- Age 8-12 years
- Both sex (male &female children)
- Patients with symptoms of
  - cough,
  - Low grade fever,
  - Sore throat.
  - loss of appetite,

- Willing to attend the OPD.
- Willing to give biological sample if necessary

Exclusion Criteria

- ❖ H/O Active primary complex
- ❖ Tonsillitis
- ❖ Congenital heart disease
- ❖ Severe asthma
- ❖ Long term fever
- ❖ Any other serious illness

Withdrawl Criteria

- ❖ Occurrence of any drug adverse effect such as diarrhea, nausea, vomiting, abdominal pain, indigestion.
- ❖ Poor patient compliance &defaulters.
- ❖ Patient turned unwilling to continue in the course of clinical trial drug.
- ❖ Exacerbation of symptoms.

Study duration: 24 Months

Dose: 3 ml (OD – morning)

Dose calculation for paediatric group is based on Age, Formula mentioned in the Gunapadam Thathu Jeeva Vaguppu text.

ASSESSMENT

- ❖ Clinical assessment
- ❖ Routine Investigation
- ❖ Siddha method of assessment

Clinical Assessment

- Sore throat scale
  - G0 -normal
  - G1 -Mild discomfort
  - G2 -Hoarsness of voice only.
  - G3 -Hoarsness of voice associated with Throat pain while speaking.
  - G4 -Hoarsness of voice associated with throat pain and difficult to swallowing
  - G5 -Severe throat pain with all above symptoms.
- Cough Assessment

  (Each item carries two points and the total score will be assessed from the following
  - Had chest pain or stomach pain during cough
  - Sputum production while coughing
  - Sleep disturbances due to cough
  - Cough interrupting conversation
  - Cough present at rest
- Appetite scale
  - G0 -Normal
  - G1 -Mild appetite but eating time being
  - G2 -Interest only to take junk foods
  - G3 -No interest to take any type of food but on compulsion he/she takes foods.
  - G4 -doesn't take food even on compulsion.
- Temperature scale
  - G0 -Normal
  - G1 –Low grade fever

Investigation

TC, DC, ESR

Siddha Method of Assessment

- Nilam
- Kaalam
- Uyir Thathukkal
- Udal Thathukkal
- Envagai Thervugal

OUTCOME

Primary outcome

- Reduction in the cough is assessed by modified LCQ (Leicester Cough Questionnaire).
- Reduction in the temperature is assessed by clinical thermometer.
- Reduction in sore throat and associated symptoms.

Secondary outcome:

- Clinical efficacy of the trial drug and side effects if any…
- The experimental drug may have good efficacy and safety in clinical study.

Data Management

- After enrolling the patient in the study, a separate file for each patient will be opened and all forms will be filed in the file. Whenever study patient visits OPD during the study period, the respective patient file will be taken and necessary recordings will be made at the assessment form or other suitable form.
- The screening forms will be filed separately.
- The Data recordings will be monitored for completion and adverse event by HOD and data logical recording and completeness will be monitored by statistician (Sr.Research Officer (Statistics)). All forms will be further scrutinized in presence of Investigators by Sr.Research Officer (Statistics) for logical errors and incompleteness of data before entering onto computer to avoid any bias. No modification in the results is permitted for unbiased report.

- ❖ Any missed data found in during the study, it will be collected from the patient, but the time related data will not be recorded retrospectively
- ❖ All collected data will be entered using MS access software onto computer.
- ❖ Investigators will be trained to enter the patient data and cross checked by SRO

Adverse Effect/Serious Effect Management

If the trial patient develops any adverse reaction such as diahrroea, vomiting, nausea, abdominal pain, indigestion he/she would be immediately withdrawn from the trial and proper management will be given in OPD of National institute of siddha and the same will be reported to regional pharmacovigilance center.

Ethical Issues

1. To prevent any infection, with proper sterilization of lab equipments will be used.
2. No other external or internal medicines will be used.
3. The data collected from the patient's informant will be recorded. The patient's informant will be informed about the diagnosis, treatment and follow-up.
4. After the consent of the patient's informant (through consent form), patient will be enrolled in the study.
5. Informed consent will be obtained from the patient's informant explaining in the understandable language to the patient's informant.
6. Treatment would be provided free of cost.
7. In conditions of treatment failure, adverse reactions, patients will be given alternative treatment at the National Institute of Siddha with full care.

DATA COLLECTION FORMS

Form I Screening & Selection Performa

Form II Consent Form

Form II A Assent Form

Form III Case Report Form

Form IV Patient Information sheet

Form V Diet form

Form VI Drug compliance

Form VII Adverse Effect Form

Form VIII Withdrawl Form

Form IX Pharmacovigilance

5. RESULTS AND OBSERVATIONS

5.1 PRECLINICAL STUDIES

5.1.1 In-vitro Anti-Inflammatory Activity

Protein (Albumin) denaturation Assay

Table: 1. Influence of trial drug against Protein Denaturation.

Concentration in µg/ml	Percentage Inhibition of Protein Denaturation
VO 100	29.32 ± 9.92
VO 200	37.31 ± 10.24
VO 300	46.76 ± 10.99
VO 400	61.43 ± 5.64
VO 500	72.12 ± 5.08
Diclofenac sodium (100 µg)	86.16 ± 5.07

Table: 2. Absorbance of Reaction micture

Concentration in µg/ml	Absorbance
Control	0.87 ± 0.05
VO 100	0.51 ± 0.026
VO 200	0.44 ± 0.036
VO 300	0.35 ± 0.032
VO 400	0.23 ± 0.017
VO 500	0.13 ± 0.025
Diclofenac sodium (100 µg)	0.013 ± 0.005

Each value represents the mean ± SD. N=3

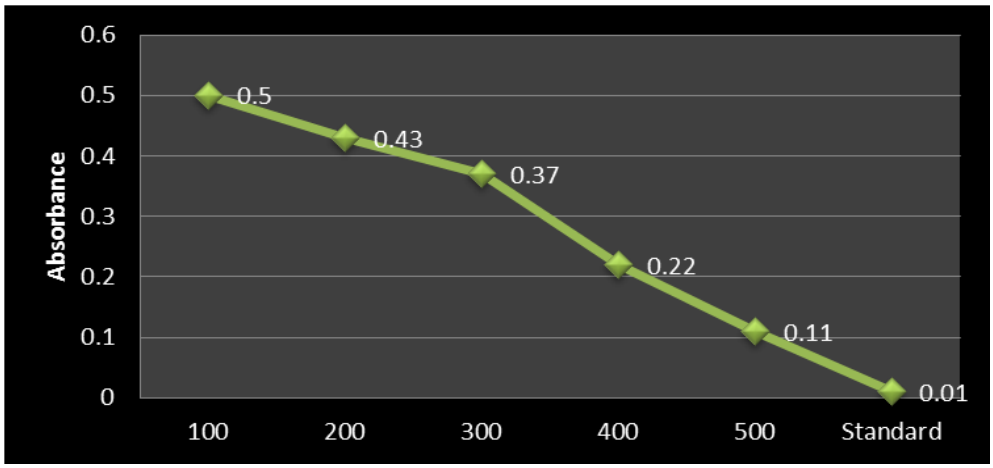
Result Analysis

The result obtained from the present clearly indicates that the test drug VO was effective in inhibiting heat induced albumin denaturation. Maximum percentage inhibition of about 72.12 % was observed at 500 µg/ml when compare to that of the Diclofenac sodium, a standard anti-inflammatory agent with the maximum inhibition 86.16 % at the concentration of 100 µg/ml.

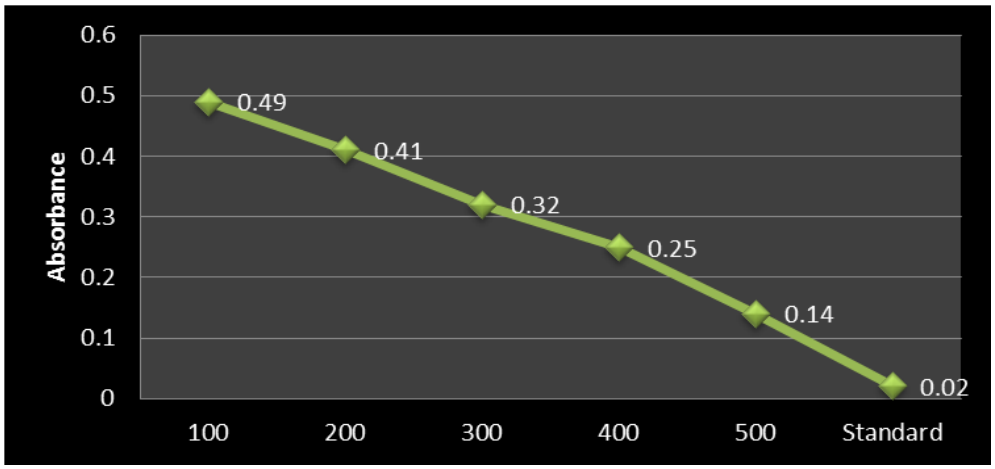
Conclusion

From the result of the study it was concluded that the test drug VO possess promising anti-inflammatory property in protein denaturation assay.

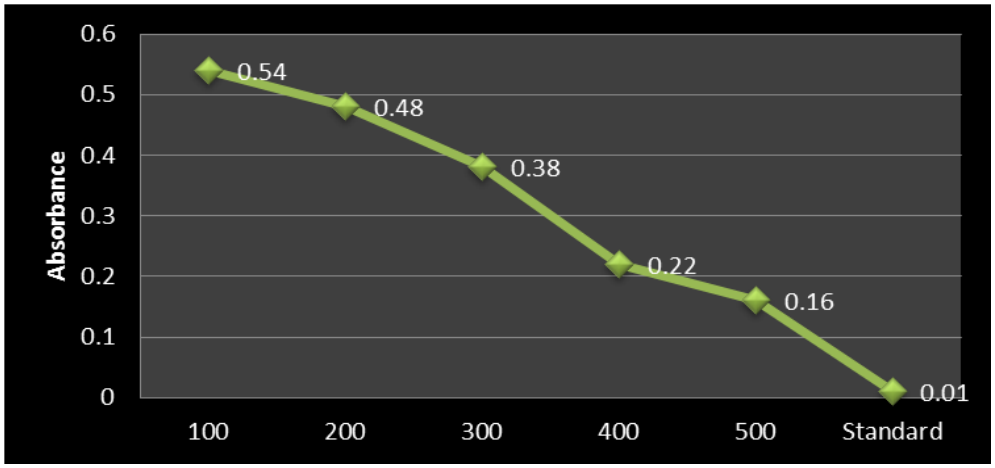
Absorbance Range of test and standard at Trial 1



Absorbance Range of test and standard at Trial 2



Absorbance Range of test and standard at Trial 3



5.1.2 Physicochemical evaluation of Vilva Ennai (Table: 3 & 4)

Parameter	**Observation**
Color	Dark Greenish black
Smell	Characteristic odour
Touch	Oily
Appearance	Dense

S.No	**Parameter**	**Mean (n=3) SD**
1	Loss on Drying at 105 °C (%)	0.9 ± 0.43
2	Total Ash (%)	0.588 ± 0.11

Inference

In Vilva Ennai, the loss on drying at 105^{o}C was found to be 0.9%. Low moisture content shows the good stability of the drug.

The total ash in Vilva Ennai found to be 0.58%. The minimal level of *total ash* shows the purity of the drug.

Table: 5 Physicochemical evaluation of Vilva Ennai.

S.No	Specific Test	VO
1	pH	6
2	Refractive index	1.46
3	Iodoine value (mg I2/g)	102
4	Saponification Value (mg of KOH to saponify 1gm of fat)	211

GC-MS Chromatogram of Vilva Ennai

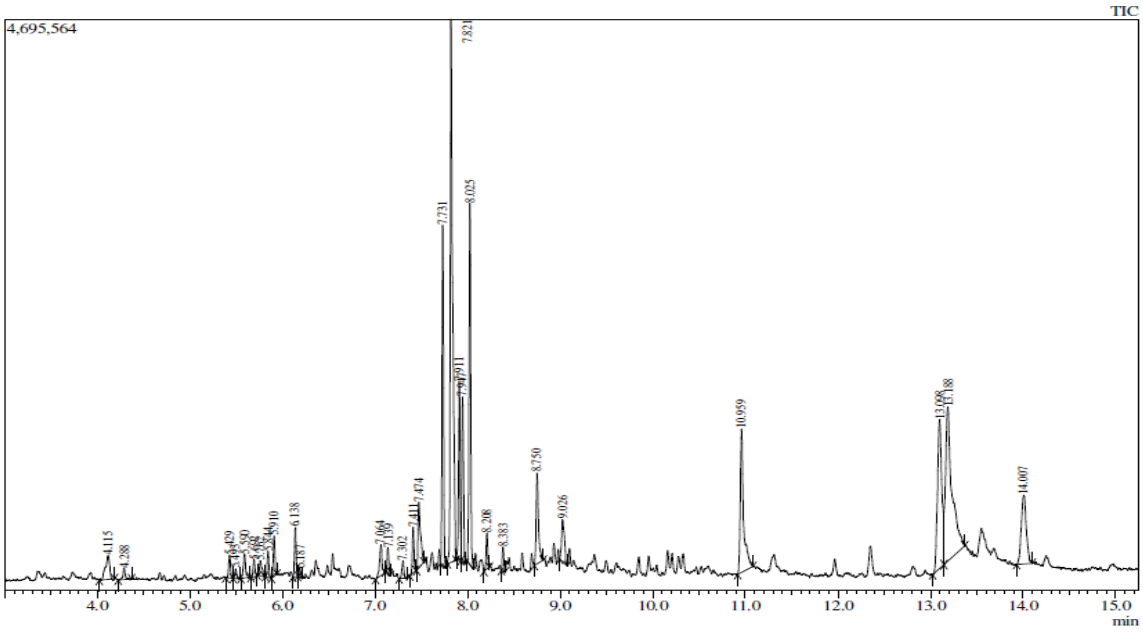
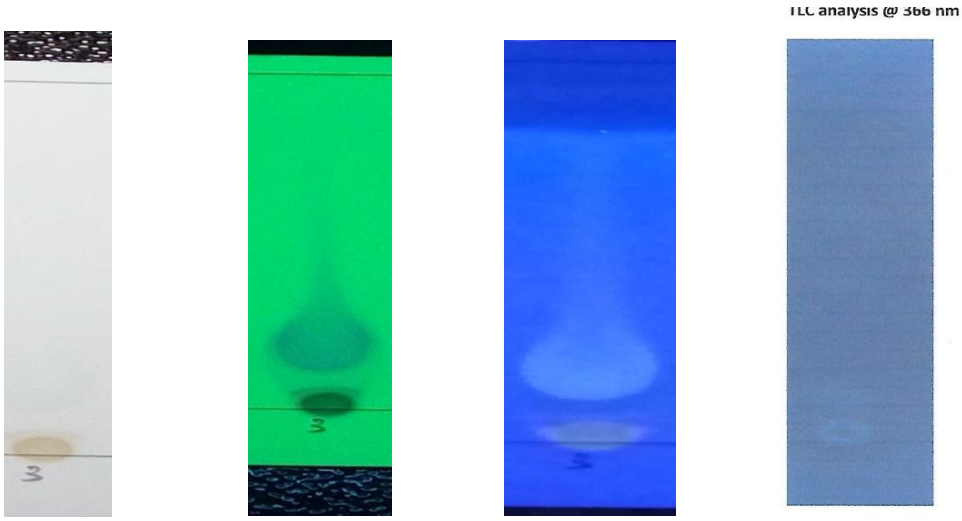


Table: 6. Peak Report of Vilva Ennai

Peak#	R.Time	Area	Area%	Height	Height%
1	4.115	590645	1.43	196400	0.87
2	4.288	167128	0.40	95797	0.43
3	5.429	249089	0.60	188313	0.84
4	5.493	102147	0.25	78344	0.35
5	5.590	324384	0.78	199007	0.89
6	5.692	195138	0.47	142302	0.63
7	5.762	216306	0.52	123297	0.55
8	5.844	257244	0.62	213747	0.95
9	5.910	404391	0.98	330633	1.47
10	6.138	497363	1.20	405334	1.81
11	6.187	83831	0.23	74439	0.33
12	7.064	468697	1.13	253101	1.13
13	7.139	260117	0.63	214755	0.96
14	7.302	224848	0.54	143098	0.64
15	7.411	447202	1.08	375811	1.67
16	7.474	994172	2.40	539934	2.39
17	7.731	3176822	7.68	2799722	12.47
18	7.821	7888389	19.07	4466597	19.89
19	7.911	1726460	4.17	1463642	6.52
20	7.947	1612300	3.90	1353469	6.03
21	8.025	3566936	8.62	2972562	13.24
22	8.208	335051	0.81	294266	1.31
23	8.383	231928	0.56	198576	0.88
24	8.750	1318912	3.19	744576	3.32
25	9.026	715722	1.73	348025	1.55
26	10.959	2957143	7.15	1179320	5.25
27	13.098	4051123	9.79	1227482	5.47
28	13.188	6218773	15.03	1267411	5.64
29	14.007	2085784	5.04	565872	2.52
		41368045	100.00	22455832	100.00

TLC Analysis:

Visible Short UV Long UV **TLC Chromatogram**



High Performance Thin Layer Chromatogram of Vilva Ennai

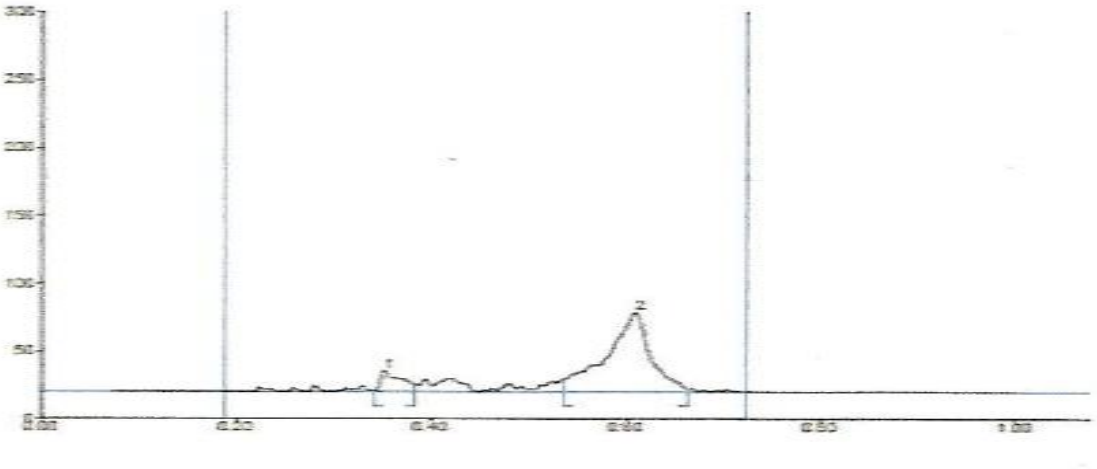


Table:7. Peak Table of HPTLC finger printing of Vilva Ennai

Peak	Start Rf	Start Height	Max Rf	Max Height	Max %	End Rf	End Height	Area	Area %
1	0.34	1.1	0.35	16.5	21.67	0.39	5.8	260.9	11.26
2	0.54	9.4	0.61	59.6	78.33	0.67	2.6	2056.3	88.74

Table: 8. Qualitative estimation of Phytoconstituents of Vilva Ennai

PHYTOCOMPONENTS	VILVA ENNAI
ALKALOIDS	+
FLAVONOIDS	-
GLYCOSIDES	-
STEROIDS	+
SUGAR	+
TRITERPNOIDS	-
COUMARINS	-
PHENOLS	+
TANNINS	-
SAPONINS	+
PROTEINS	+
ANTHOCYANIN	-

+ Indicates positive

- Indicates Negative

Table: 9. Quantitative estimation of phytoconstituents of Vilva Ennai

Phyto- constituents	Vilva Ennai
Total phenols (GAE mg/gm)	0.67 ± 0.18
Total alkaloids(mg/gm)	1.56 0.31

Mean with 3 replicates ± SD.

Inference:

In Vilva Ennai, the presence of Phytoconstituents such as Alkaloid, Steroid, Sugar, Phenols, Saponin and protein are present.

Test for Alkaloid- Mayer's reagent

Test for Glycosides - Borntrager's Test

Test for flavonoid

Test for Triterpnoids

Test for Steroids Salkowski test

Test for Carbohydrates Benedict's test

Test for Anthocyanin

Test of Coumarins

.

Test – Phenol- Lead acetate test

Test for tannins

Test for Saponins

Test for Proteins (Biuret Test)

5.1.3 Test for Heavy Metals

Method of Testing

BVCPSCH/INS/SOP/053 by ICP OES

Table: 10 Result of heavy metals in trial drug.

S.No	Test Parameters	Units of Measurement	Result
1	Cadmium	mg/kg	ND (DL - 0.01)
2	Lead	mg/kg	ND (DL - 0.01)
3	Mercury	mg/kg	ND (DL - 0.01)
4	Arsenic	mg/kg	ND (DL - 0.01)

Inference

The heavy metals such as Cadmium, Lead, Mercury, Arsenic are not detected in my trail drug Vilva Ennai.

5.1.4 Test for Aflatoxin

Method of Testing

AOAC2008.02

Table: 11. Result of Aflatoxin in trial drug

S.No	Test Parameters	Units of Measurement	Result
1	Aflatoxin B1	µg/kg	BLQ (LOQ: 0.5)
2	Aflatoxin B2	µg/kg	BLQ (LOQ: 0.5)
3	Aflatoxin G1	µg/kg	BLQ (LOQ: 0.5)
4	Aflatoxin G2	µg/kg	BLQ (LOQ: 0.5)

Inference

The level of Aflatoxin is below the limit of quantification. So the drug Vilva ennai shows the absence of aflatoxin.

5.1.5 Test for Pesticide

Test for Organochlorine

Method of Testing

EURL Method by GC MSMS/ LC MSMS

Table: 12. Result of Organochlorine in trial drug

S.No	Test Parameters	Units of Measurement	Result
1	Aldrin(Aldrin and dieldrin combined expressed as dieldrin)	mg/kg	BLQ (LOQ: 0.01)
2	Chlordane(cis & trans)	mg/kg	BLQ (LOQ: 0.01)
3	Chlorothalonil	mg/kg	BLQ (LOQ: 0.01)
4	DDT (all Isomers)	mg/kg	BLQ (LOQ: 0.01)
5	Dicofol (sum of p,p' and o,p' Isomers)	mg/kg	BLQ (LOQ: 0.01)
6	Dieldrin (see Aldrin)	mg/kg	BLQ (LOQ: 0.01)
7	Endosulphan(all Isomers)	mg/kg	BLQ (LOQ: 0.01)
8	Endrin	mg/kg	BLQ (LOQ: 0.01)
9	HCH (sum of isomers, except the gamma isomers)	mg/kg	BLQ (LOQ: 0.01)
10	Heptachlor (sum of heptachlor and heptachlorepoxide expressed as heptachlor)	mg/kg	BLQ (LOQ: 0.01)
11	Lindane(gamma-HCH)	mg/kg	BLQ (LOQ: 0.01)

Test for Organophosphosphorus

Method of Testing

EURL Method by GC MSMS/ LC MSMS

Table: 13. Result of Organophosphorus in trial drug

S.No	Test Parameters	Units of	Result
12	4-bromo-2-chlorophenol (metabolite	mg/kg	BLQ (LOQ - 0.01)
13	Acephate	mg/kg	BLQ (LOQ - 0.01)
14	Chlorfenvinphos	mg/kg	BLQ (LOQ - 0.01)

15	Chlorpyrifos	mg/kg	BLQ (LOQ - 0.01)
16	Chlorpyrifosmethyl	mg/kg	BLQ (LOQ - 0.01)
17	Diazinon	mg/kg	BLQ (LOQ - 0.01)
18	Dichlorvos	mg/kg	BLQ (LOQ - 0.01)
19	Dimethoate(including Omethoate)	mg/kg	BLQ (LOQ - 0.01)
20	Edifenphos	mg/kg	BLQ (LOQ - 0.01)
21	Ethion	mg/kg	BLQ (LOQ - 0.01)
22	Etrimphos	mg/kg	BLQ (LOQ - 0.01)
23	Fenitrothion	mg/kg	BLQ (LOQ - 0.01)
24	Fenthion	mg/kg	BLQ (LOQ - 0.01)
25	Iprobenphos	mg/kg	BLQ (LOQ - 0.01)
26	Malathion (sum of malathion and	mg/kg	BLQ (LOQ - 0.01)
27	Methamidophos	mg/kg	BLQ (LOQ - 0.01)
28	Monocrotophos	mg/kg	BLQ (LOQ - 0.01)
29	Omethoate (refer to Dimethode)	mg/kg	BLQ (LOQ - 0.01)
30	Oxydemeton-methyl (sum of	mg/kg	BLQ (LOQ - 0.01)
31	Parathion ethyl	mg/kg	BLQ (LOQ - 0.01)
32	Parathion Methyl (sum of parathion	mg/kg	BLQ (LOQ - 0.01)
33	Phenthoate	mg/kg	BLQ (LOQ - 0.01)
34	Phorate (sum of phorate, its oxygen	mg/kg	BLQ (LOQ - 0.01)
35	Phosalone	mg/kg	BLQ (LOQ - 0.01)
36	Phosphamidon	mg/kg	BLQ (LOQ - 0.01)
37	Pirimiphos methyl	mg/kg	BLQ (LOQ - 0.01)
38	Profenophos	mg/kg	BLQ (LOQ - 0.01)
39	Propetamphos	mg/kg	BLQ (LOQ - 0.01)
40	Ouinalphos	mg/kg	BLQ (LOQ - 0.01)
41	Temephos	mg/kg	BLQ (LOQ - 0.01)
42	Thiometon	mg/kg	BLQ (LOQ - 0.01)
43	Triazophos	mg/kg	BLQ (LOQ - 0.01)

Test for Synthetic Pyrethroids

Method of Testing

EURL Method by GC MSMS/ LC MSMS

Table: 14. Result of Synthetic pyrethroids in trial drug

S.No	Test Parameters	Units of Measurement	Result
44	Allethrin and Bioallerthin	mg/kg	BLQ (LOQ: 0.01)
45	Bifenthrin	mg/kg	BLQ (LOQ: 0.01)
46	Cypermethrin(including other mixture of constituent isomers sum of isomers)	mg/kg	BLQ (LOQ: 0.01)
47	Deltamethrin	mg/kg	BLQ (LOQ: 0.01)
48	Ethofenprox(Etofenprox)	mg/kg	BLQ (LOQ: 0.01)
49	Fenpropathrin	mg/kg	BLQ (LOQ: 0.01)
50	Fenvalerate(sum of RR & SS isomers)	mg/kg	BLQ (LOQ: 0.01)
51	Lambda-cyhalothrin	mg/kg	BLQ (LOQ: 0.01)
52	Permethrin (sum of isomers)	mg/kg	BLQ (LOQ: 0.01)
53	tau-Fluvalinate	mg/kg	BLQ (LOQ: 0.01)
54	Transfluthrin	mg/kg	BLQ (LOQ: 0.01)

Inference

This study reveals the absence of pesticides, Organophosphorus, Organochlorine and synthetic pyrethroids in the trail drug Vilva Ennai.

5.1.6 Test for Microbiological

Method of Testing

API Volume-II

Table: 15. Result of Micro-organism in trial drug

S.No	Test Parameters	Units of Measurement	Result
1	E.coli	Per g	Absent
2	Pseudomonas aeruginosa	Per g	Absent
3	Salmonella	Per g	Absent
4	Staphylococcus aureus	Per g	Absent

Inference

The Microbiological test reveals the absence of micro-organism such as E.coli, Pseudomonas aeruginosa, Salmonella and Staphylococcus aureus in the trial drug Vilva Ennai.

5.1.7 Biochemical analysis

Results of Acid radicals studies (Table:16)

S.No	Parameter	Observation	Result
1	Test for Sulphate	-	Negative
2	Test for Chloride	Cloudy appearance present	Positive
3	Test For Phosphate	-	Negative
4	Test For Carbonate	-	Negative
5	Test For Nitrate	-	Negative
6	Test for Sulphide	-	Negative
7	Test For Fluoride & oxalate	Cloudy appearance present	Positive
8	Test For Nitrite	-	Negative
9	Test For Borax	-	Negative

Interpretation

The acidic radicals test shows the presence of Chloride, Fluoride & Oxalate.

Table: 17. Results of basic radicals studies

S.NO	Parameter	Observation	Result
1	Test for Lead	-	Negative
2	Test for Copper	-	Negative
3	Test For Aluminium.	-	Negative
4	Test For Iron.	-	Negative
5	Test For Zinc	-	Negative
6	Test for Calcium	-	Negative
7	Test For Magnesium	-	Negative
8	Test For Ammonium	Mild brown color appears	Positive
9	Test For Potassium	-	Negative
10	Test For Sodium	-	Negative
11	Test For Mercury	-	Negative
12	Test For Arsenic	-	Negative

Interpretation

The basic radical test shows the presence of Ammonium, and absence of heavy metals such as lead, Iron, arsenic and mercury.

Table: 18. Results of Miscellaneous

S. No	Parameter	Observation	Result
1	Test for Starch	-	Negative
2	Test for Reducing sugars	-	Negative
3	Test For Alkaloids.	-	Negative
4	Test For Tannic acid	-	Negative
5	Test for unsaturated compounds	-	Negative
6	Test for Type of compounds	-	Negative

Interpretation

The Miscellaneous test shows the absence of Alkaloids, Tannic acid, Type of compounds**.**

5.2 CLINICAL STUDIES

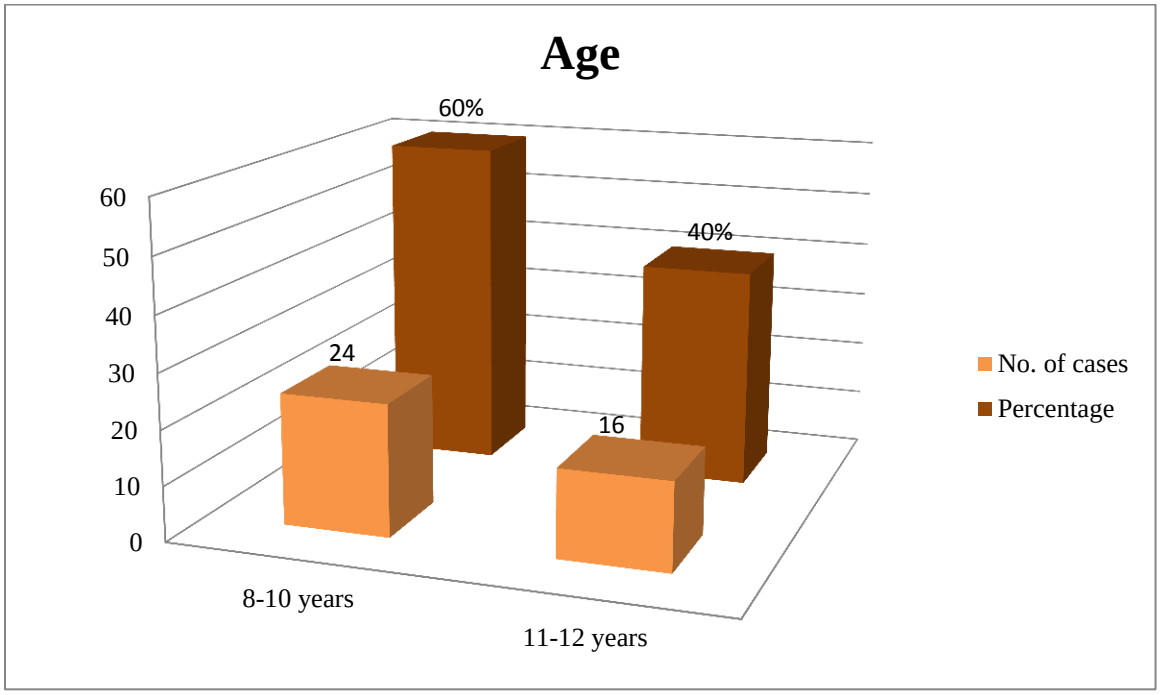
40 patients with confirmed diagnosis of VALI KANAM with satisfying inclusion criteria were enrolled after obtaining written informed consent and were received VILVA ENNAI with dosage of 3ml OD for 5 days.

Results were observed with respect to the following criteria:

1. Age
2. Sex
3. Patient's Socio Economic Status
4. Religion
5. Diet
6. Nilam
7. Paruvakaalam
8. Uyir thathukkal
9. Udal thathukkal
10. Envagaithervugal
11. Neikuri
12. Clinical features
13. Biochemical Analysis

Table: 19. Distributions of Children with *Vali Kanam* according to Age

S.No	Age	No. of cases	Percentage
1	8-10 years	24	60%
2	11-12 years	16	40%

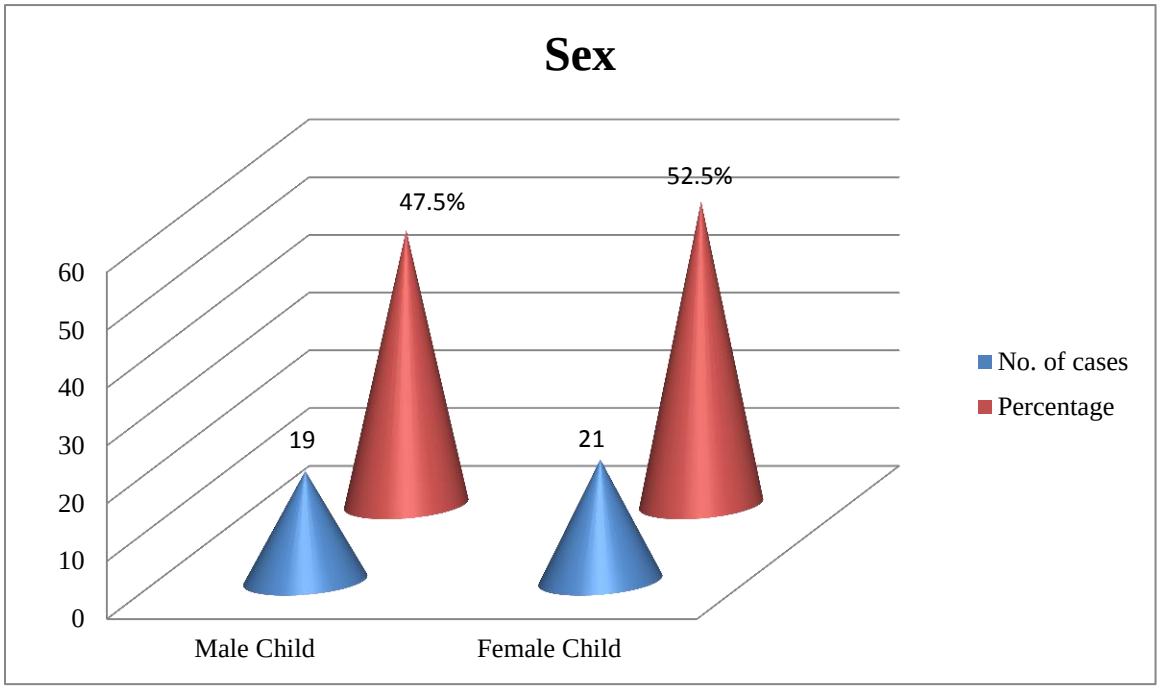


Inference:

Out of 40 patients, 60% of cases were 8-10 years, 40% of cases were 11-12 years. The highest incidence was seen in the age group of 8-10 years. School going age group is most affected.

Table:20. Distributions of Children with *Vali Kanam* according to Gender

S. No	Sex	No. of cases	Percentage
1	Male Child	19	47.5%
2	Female Child	21	52.5%

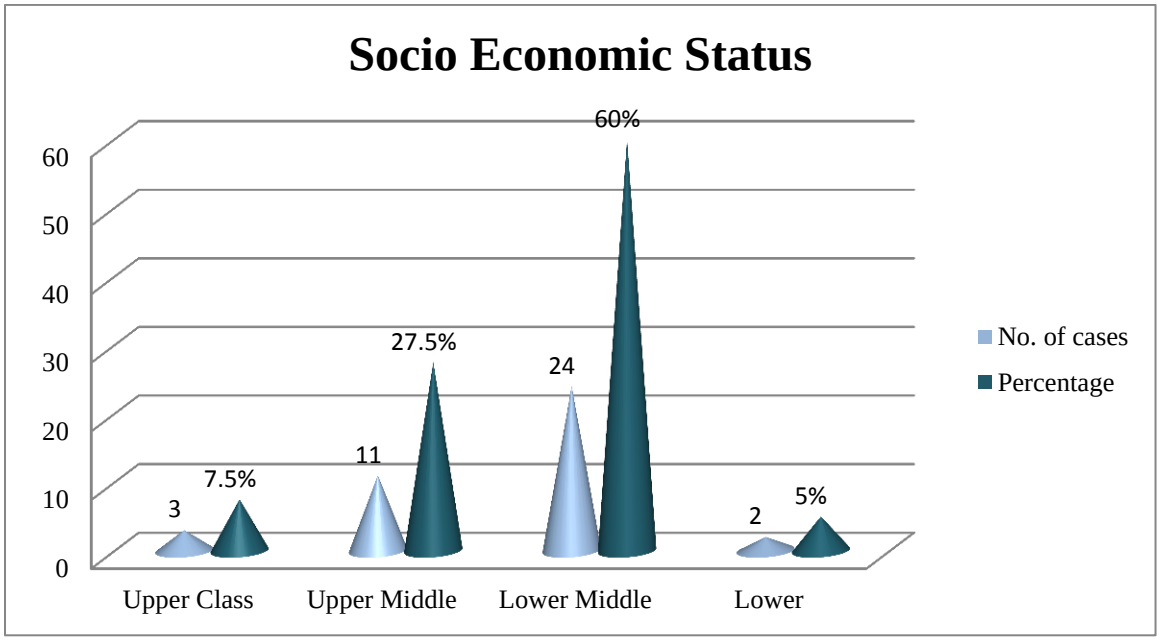


Inference:

Out of 40 patients 47.5% were male children and 52.5% were female children. According to this study both sexes were more or less equally affected which shows Vali Kanam is not predominant on sex.

Table: 21. Distribution of Children with *Vali Kanam* according to socio-economic status

S.No	Socio Economic Status	No. of cases	Percentage
1	Upper Class	3	7.5%
2	Upper Middle	11	27.5%
3	Lower Middle	24	60%
4	Lower	2	5%

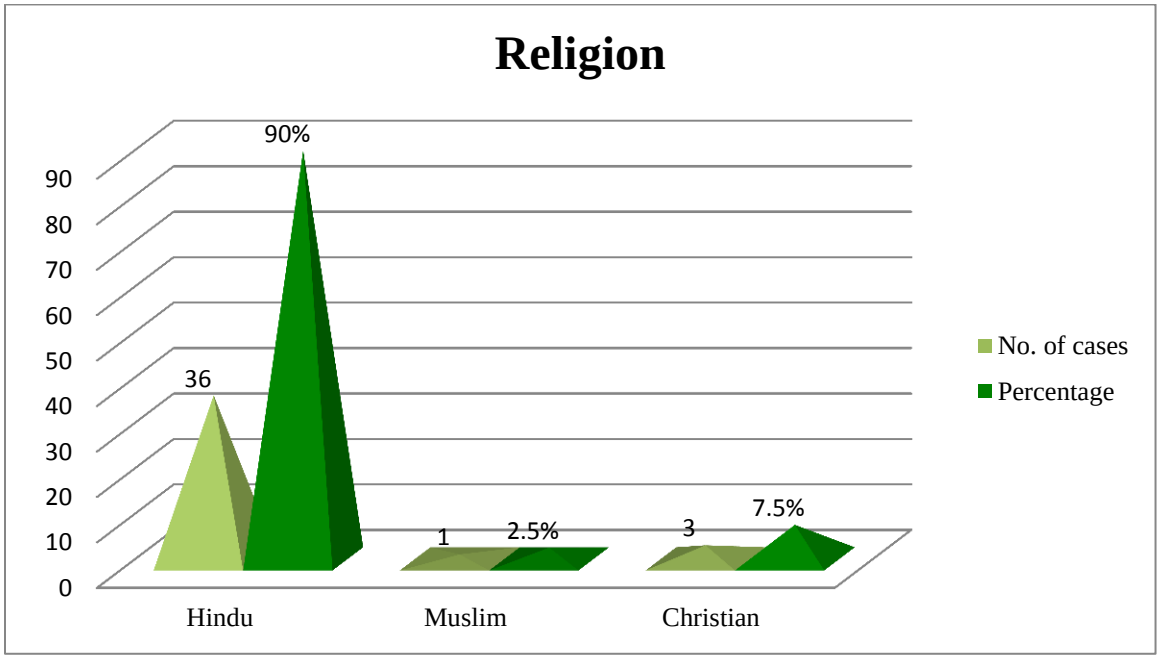


Inference:

About 7.5% patients were under upper class, 27.5% patients were under upper middle class, 60% patients were under Lower middle class and 5% patients were lower class. The highest incidence occurred in lower middle income group due to overcrowding and poor sanitation.

Table:22. Distribution of Children with *Vali Kanam* according to religion

S.No	Religion	No. of cases	Percentage
1	Hindu	36	90%
2	Muslim	1	2.5%
3	Christian	3	7.5%

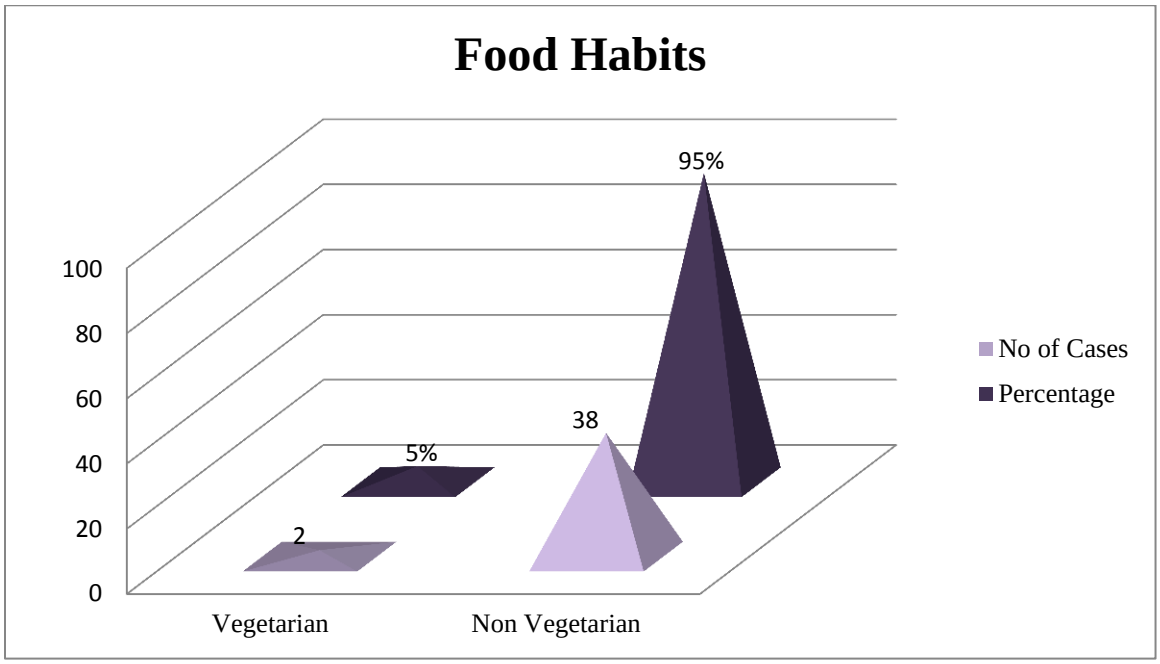


Inference:

About 90% patients were Hindu, 7.5% patients were Christian, 2.5% patients were Muslim.

Table:23. Distribution of Children with *Vali Kanam* according to Diet reference

S.No	Food Habits	No. of cases	Percentage
1	Vegetarian	2	5%
2	Non Vegetarian	38	95%

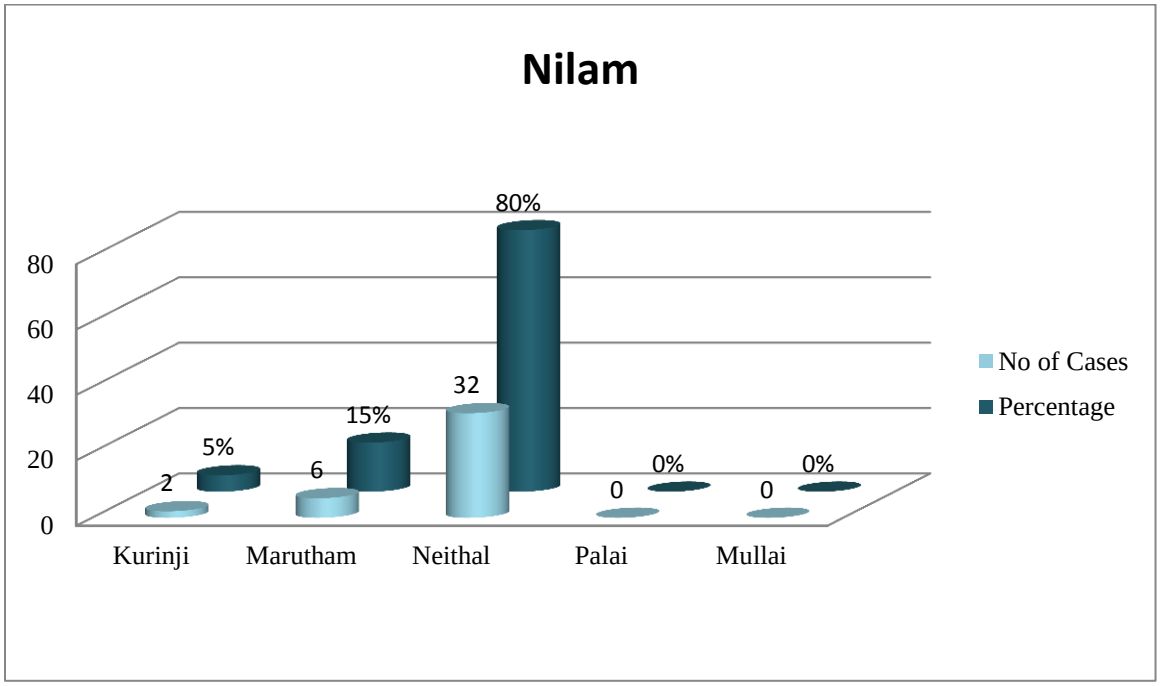


Inference:

According to diet, Vegetarian 5%, Non vegetarian 95% were noted. The highest incidence was seen in Non-Vegetarian. But Vali Kanam has no influence on diet.

Table:24. Distribution of Children with *Vali kanam* according to Nilam

S.No	Nilam	No. of cases	Percentage
1	Kurinji	2	5%
2	Marutham	6	15%
3	Neithal	32	80%
4	Palai	0	0%
5	Mullai	0	0%

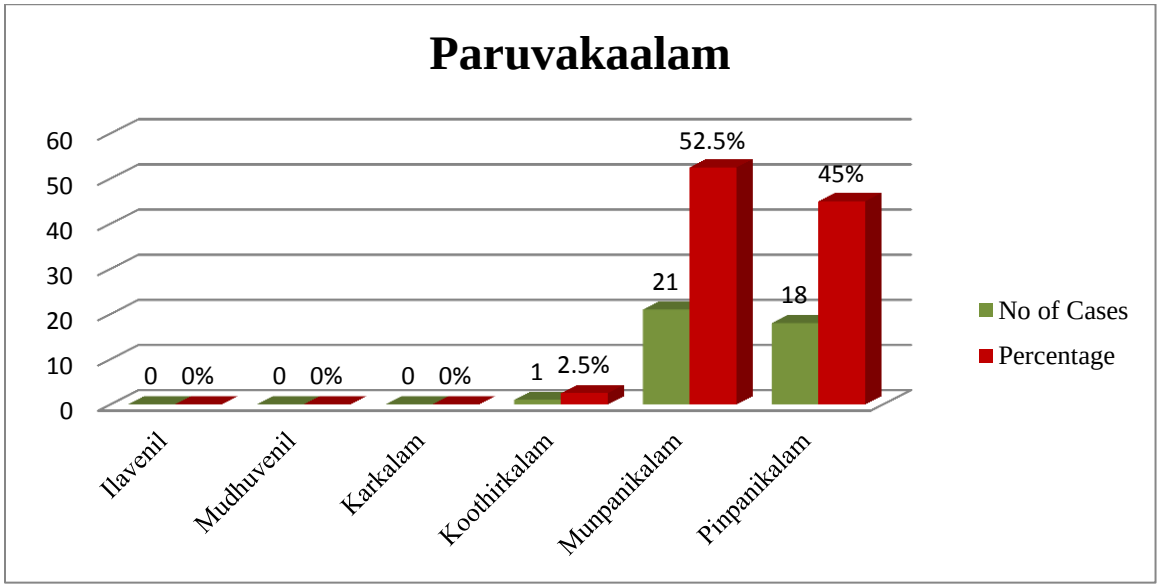


Inference:

Among 40 patients, 80% were from Neithal land, 15 % from Marutham land, 0 % from Mullai land, and 5% from Kurinji land. Since this study was carried out in Chennai. The highest incidence of people seaking treatment were from the sourrounding of Chennai, highest incidence was noted in Neithal nilam.

Table:25 Distribution of Children with *Vali Kanam* according to Paruvakaalam

S.No	Paruvakaalam	No. of cases	Percentage
1	Ilavenil (Chitirai, Vaigasi)	0	0%
2	Mudhuvenil (Aani, Aadi)	0	0%
3	Kar kaalam(Avani – puratasi)	0	0%
4	Koothir kaalam (Iyppasi –karthikai)	1	2.5%
5	Munpani kaalam(Markazhi uvak–Thai)	21	52.5%
6	Pinpani kaalam (Masi – Panguni)	18	45%

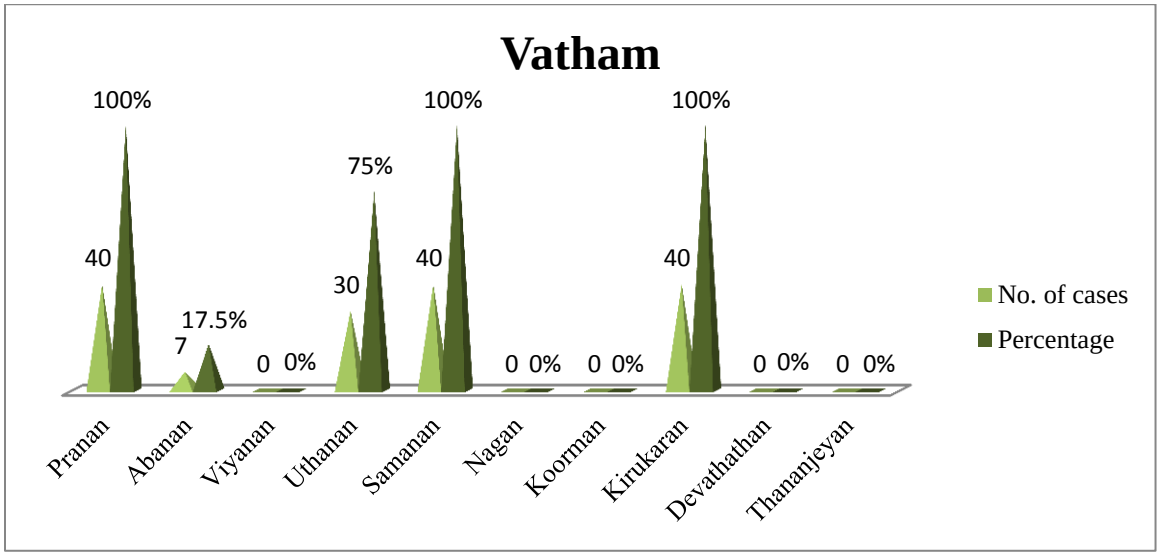


Inference:

Among 40 patients, 52.5 % were from Munpani kaalam, 45 % from Pinpani kaalam, 2.5% from Koothir kaalam. The highest incidence was noted in munpanikaalam.

Table:26. Distribution of Children with *Vali Kanam* according to derangement of Vatham

S.No	Vatham	No. of cases	Percentage
1	Pranan	40	100%
2	Abanan	7	17.5%
3	Viyanan	0	0%
4	Uthanan	30	75%
5	Samanan	40	100%
6	Nagan	0	0%
7	Koorman	0	0%
8	Kirukaran	40	100%
9	Devathathan	0	0%
10	Thananjeyan	0	0%

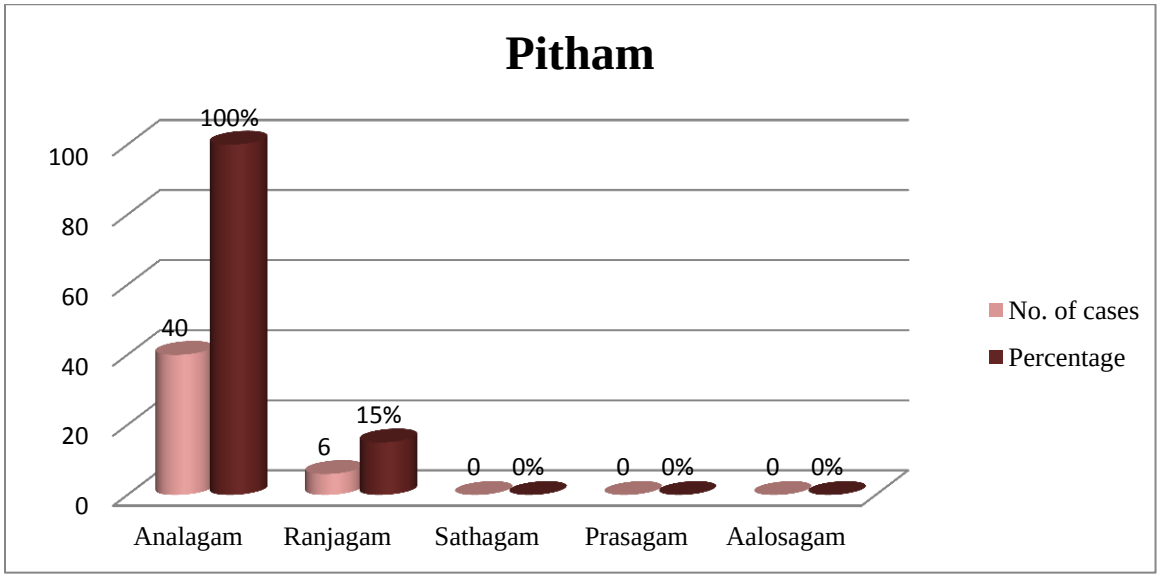


Inference:

According to vatham, derangement of Pranan was 100% due to poor appetite, Abanan was 17.5% due to constipation, Uthanan was 75% due to sore throat and difficulty in swallowing, samaanan was affected 100% due to vatham and Kirukaran was deranged in 100%.

Table:27. Distribution of Children with *Vali Kanam* according to derangement of Pitham

S.No	Pitham	No. of cases	Percentage
1	Analagam	40	100%
2	Ranjagam	6	15%
3	Sathagam	0	0%
4	Prasagam	0	0%
5	Aalosagam	0	0%

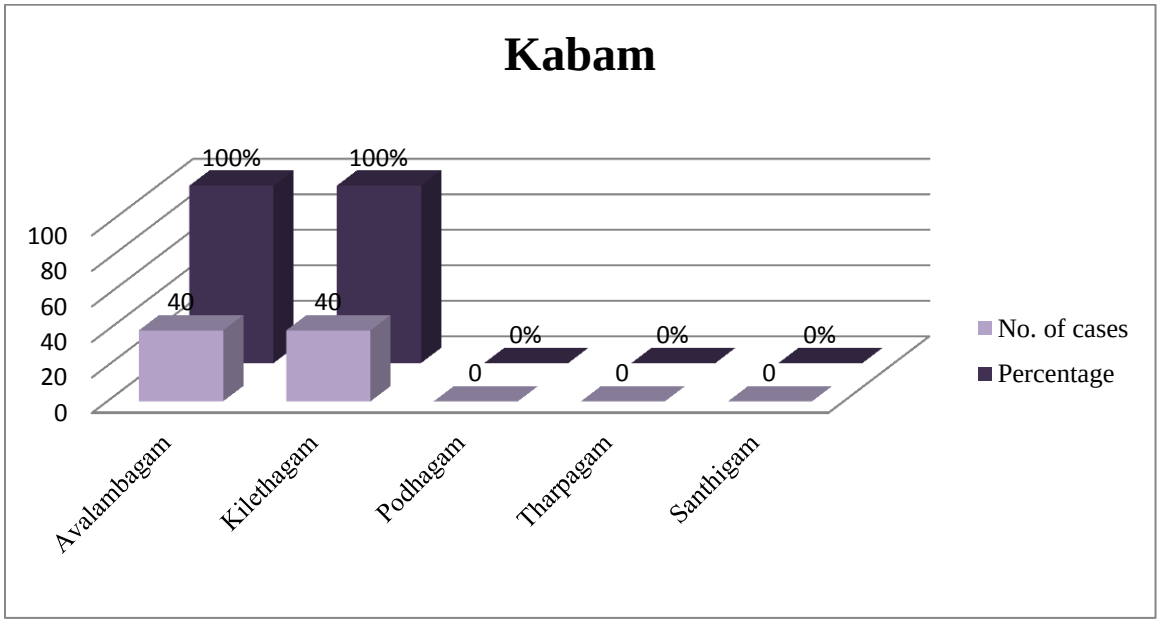


Inference:

According to Pitham, derangement of Analapitham was 100% due to poor appetite and Ranjagapitham was deranged in 15% due to pallor of tongue and conjuctiva.

Table:28. Distribution of Children with *Vali Kanam* according to dearrangement of Kabam

S.No	Kabam	No. of cases	Percentage
1	Avalambagam	40	100%
2	Kilethagam	40	100%
3	Podhagam	0	0%
4	Tharpagam	0	0%
5	Santhigam	0	0%

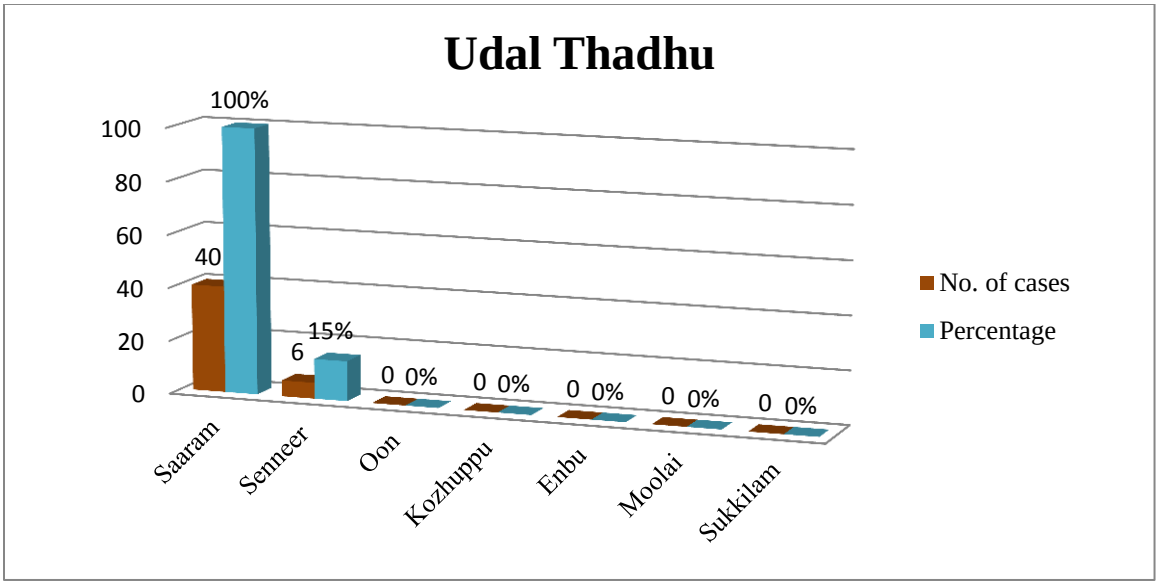


Inference:

According to Kabam, derangement of Kelathagam was 100 % due to poor appetite and Avalambagam was deranged in 100%.

Table:29. Distribution of Children with *Vali Kanam* according to derangement of Ezhu Udalthadhukkal

S.No	Udalthadhu	No. of cases	Percentage
1	Saaram	40	100%
2	Senneer	6	15%
3	Oon	0	0%
4	Kozhuppu	0	0%
5	Enbu	0	0%
6	Moolai	0	0%
7	Sukkilam	0	0%

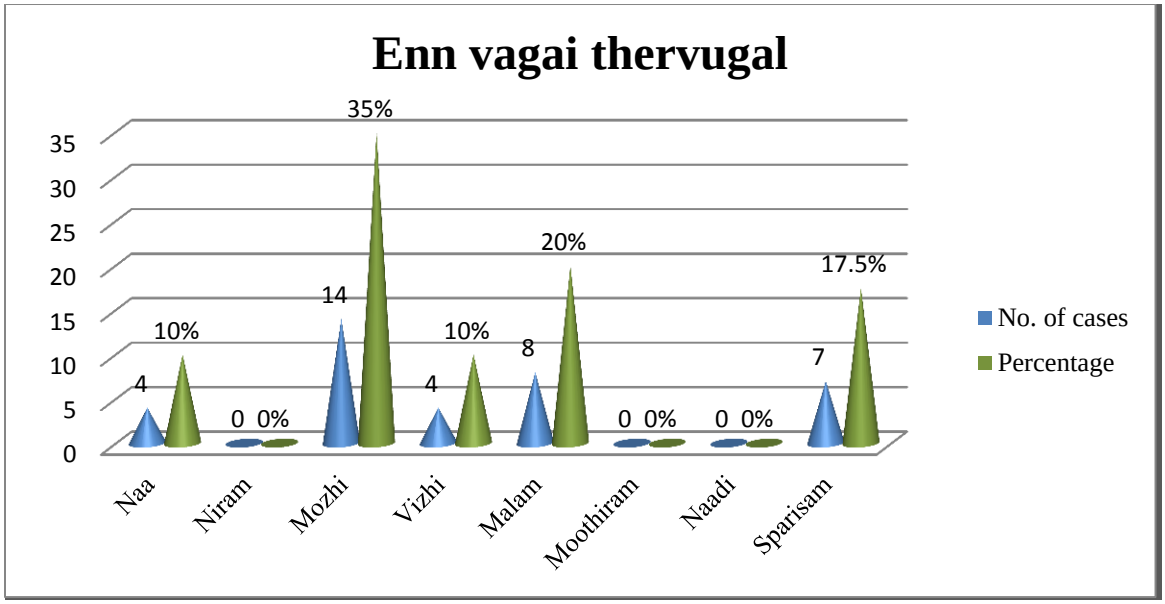


Inference:

According to the study, Saram was affected in 100% of cases due to presence of fatigue, Senneer was affected in 15% due to pallor of tongue and conjunctiva.

Table:30. Distribution of Children with *vali kanam* according to derangement of Enn vagai Thervugal

S.No	Envagai Thervugal	No. of cases	Percentage
1	Naa	4	10%
2	Niram	0	0%
3	Mozhi	14	35%
4	Vizhi	4	10%
5	Malam	8	20%
6	Moothiram	0	0%
7	Naadi	0	0%
8	Sparisam	7	17.5%

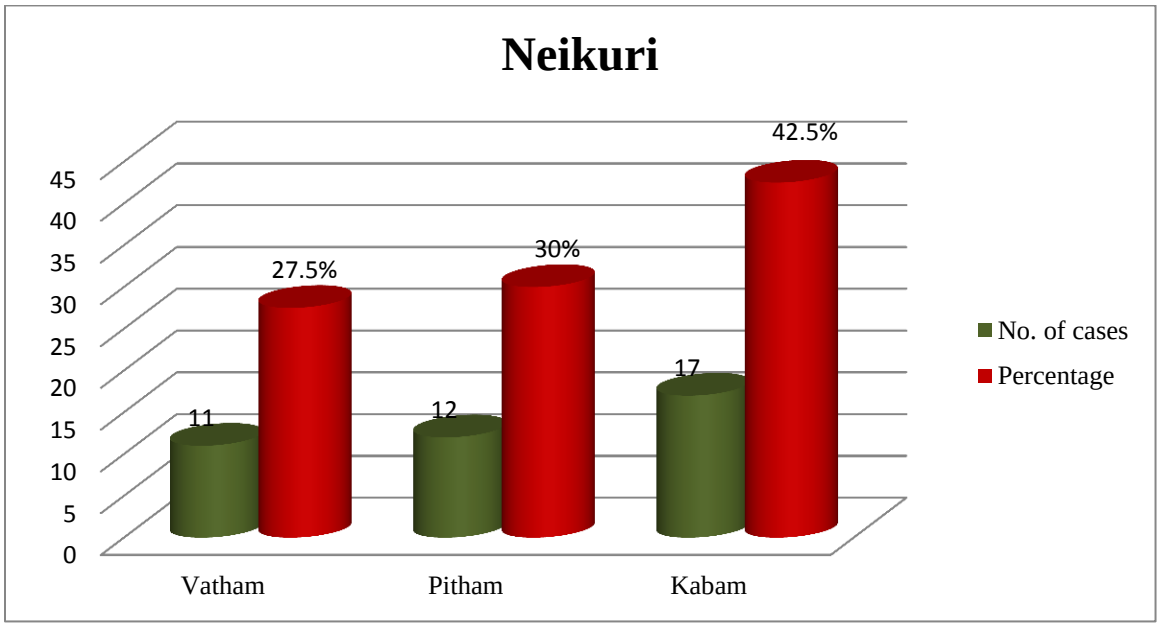


Inference:

Out of 40 cases, 35% of the cases were affected by Mozhi. Malam was affected in 20% of patients due to constipation, 17.5% of cases affected by sparisam due to fever, 10% 0f cases affected by naa and 10% of the cases affected by vizhi due to pallor of the tongue and conjunctiva. In Naadi, Vathapitham was observed in 50 % of cases, Pithavatham was observed in 40 % of cases, Pithakabam was observed in 10 % of cases.

Table:31. Distribution of Children with *Vali Kanam* according to observation of Neikuri analysis

S.No	Neikuri	No. of cases	Percentage
1	Vatham	11	27.5%
2	Pitham	12	30%
3	Kabam	17	42.5%



Inference

According to Neikuri, Vatha neer was observed in 27.5 % of cases, pitha neer was observed in 30% of cases, Kaba neer was observed in 42.5 % of cases.

5.2.1 Clinical assessment

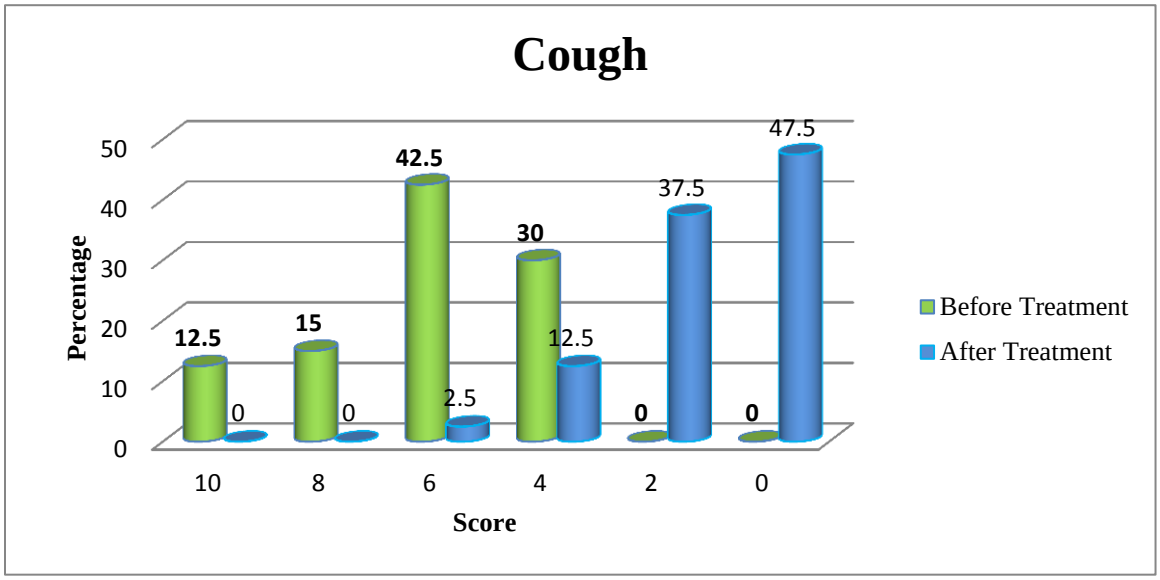
- **Cough Scale**

  (Each item carries two points and the total score will be assessed from the following)

  1. Had chest pain or stomach pain during cough
  2. Sputum production while coughing
  3. Sleep disturbances due to cough
  4. Cough interrupting conversation
  5. Cough present at rest

Table:32. Distribution of children with Cough scale

S.NO	Score	Before Treatment	Percentage	After Treatment	Percentage
1	10	5	12.5	0	0
2	8	6	15	0	0
3	6	17	42.5	1	2.5
4	4	12	30	5	12.5
5	2	0	0	15	37.5
6	0	0	0	19	47.5



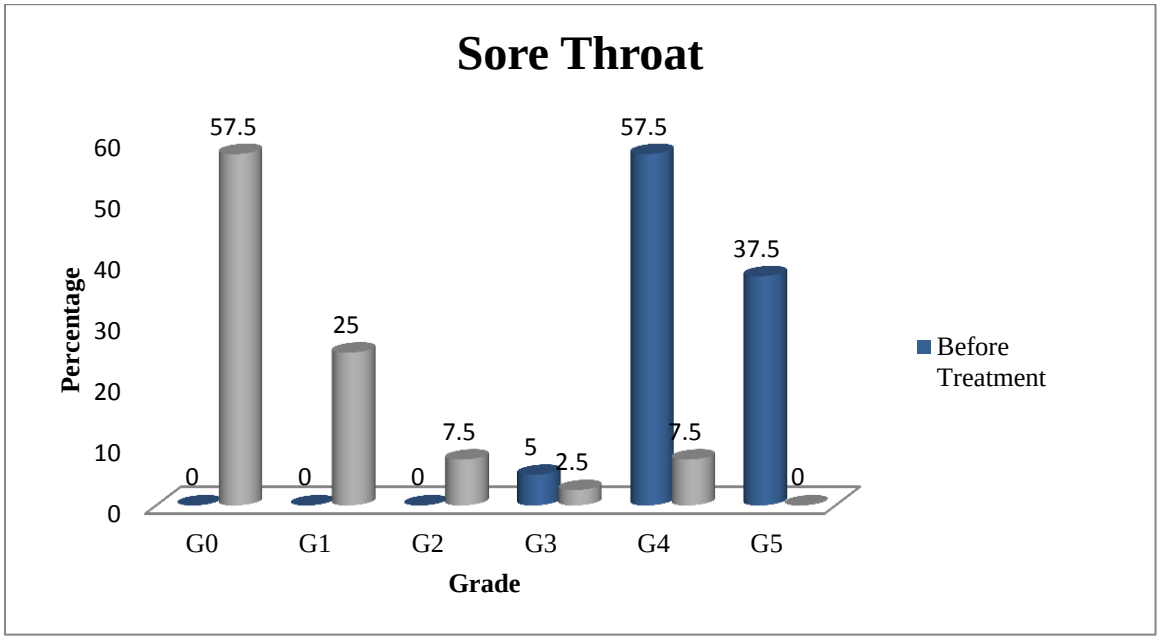
Infernce:

Among the 40 cases, 12.5% of the patients were noted to have score of 10, 15% of the patients were noted to have score of 8, 42.5% of the patients were noted to have the score of 6, 30% were noted to have score of 4, at the base of treatment. At the end of the treatment 0% of the patients were noted to have score of 10 & 8, 2.5% of the patients were noted to have score of 6, 12.5% of the patients were noted to have score of 4, 37.5% of the patients were noted to have the score of 2, 47.5% of the patients were noted to have score of 0.

- **Sore Throat Scale**
  - G0 -Normal
  - G1 -Mild discomfort
  - G2 - Hoarseness of voice only.
  - G3 - Hoarseness of voice associated with Throat pain while speaking.
  - G4 -Hoarseness of voice associated with throat pain and difficult to swallowing
  - G5 -Severe throat pain with all above symptoms

Table:33. Distribution of children with Sore Throat Scale

S.NO	Grade	Before Treatment	Percentage	After Treatment	Percentage
1	G0	0	0	23	57.5
2	G1	0	0	10	25
3	G2	0	0	3	7.5
4	G3	2	5	1	2.5
5	G4	23	57.5	3	7.5
6	G5	15	37.5	0	0



Inference:

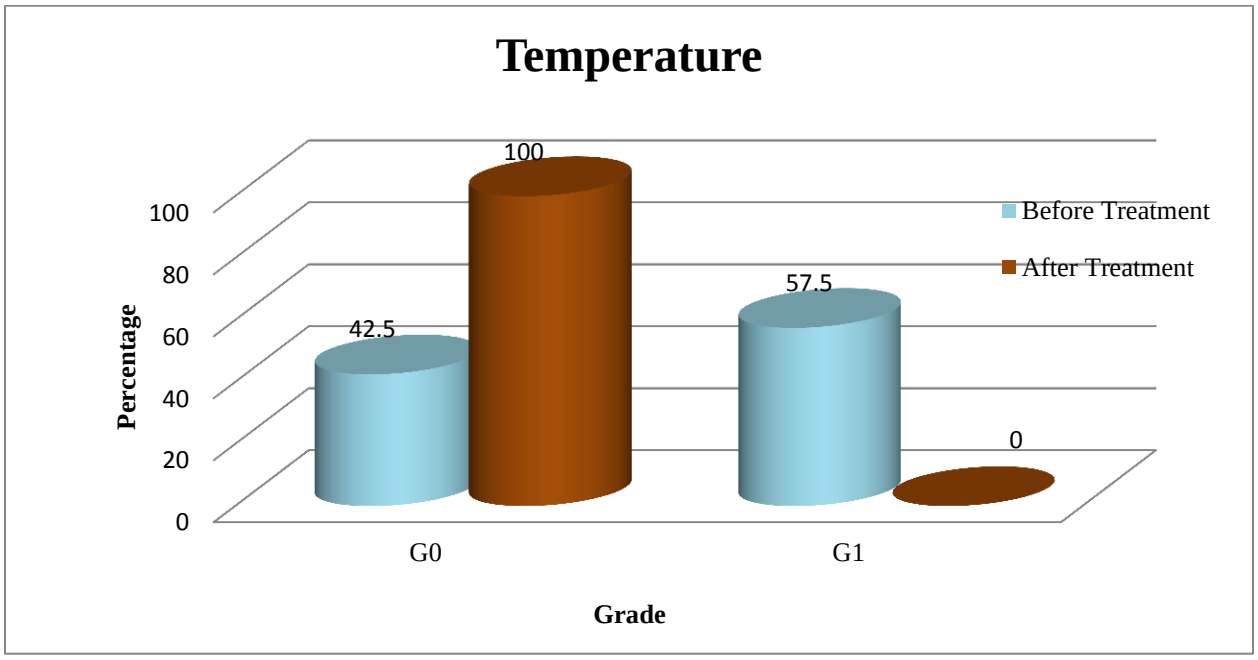
Among the 40 cases, 15 % of the patients were noted in G5, 23% of patients were noted in G4, 2% were noted in G3 at the base of treatment. At the end of the treatment 57.5% of the cases were noted in G0, 25% of the patients were noted in G1, 7.5% of the patients were noted in G2&G4, 2.5% of the patients were noted in G3.

❖ **Temperature scale**

- G0 -Normal
- G1 –Low grade fever

Table:34. Distribution of patients with Temperature scale

S.NO	Grade	Before Treatment	Percentage	After Treatment	Percentage
1	G0	17	42.5	40	100
2	G1	23	57.5	0	0



Inference:

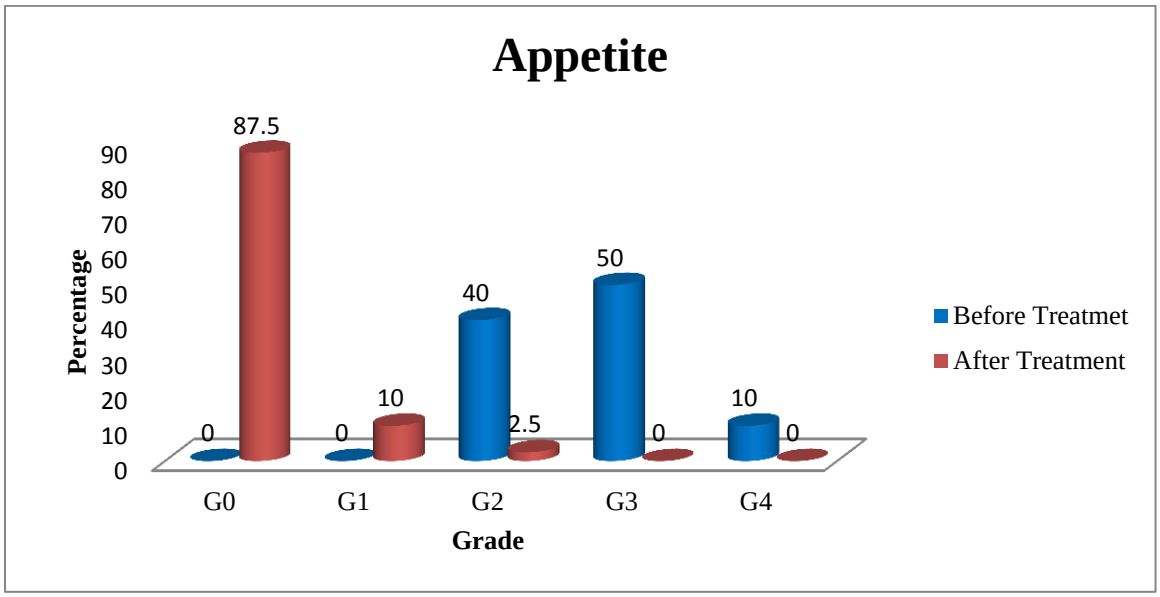
Among the 40 cases, after completion of treatment, 0 % of the patients were noted in G1, 100% of patients were noted in G0.

❖ **Appetite scale**

- G0 -Normal
- G1 -Mild appetite but eating time being
- G2 -Interest only to take junk foods
- G3 -No interest to take any type of food but on compulsion he/she takes foods.
- G4 -doesn't take food even on compulsion.

Table:35. Distribution of children with Appetite scale

S.NO	Grade	Before Treatment	Percentage	After Treatment	Percentage
1	G0	0	0	35	87.5
2	G1	0	0	4	10
3	G2	16	40	0	0
4	G3	20	50	1	2.5
5	G4	4	10	0	0
6	G5	0	0	0	0



Inference:

Among the 40 cases, 42.5 % of the patients were noted in G4, 32.5 % were noted in G3,5 % were noted in G2, at the base of treatment. At the end of the treatment 10% of the cases were noted in G3, 22.5% of the cases were noted in G1, 7.5 % of the cases were noted in G0.

Distribution of Children with *Vali Kanam* according to treatment results obtained

Table:36. Cough

S.No	Before Treatment	After Treatment				Total Number of Cases
	Score	0	2	4	6	
1	Mild (4)	6	6	0	0	**12**
2	Moderate (6)	4	9	3	1	**17**
3	Moderate Severe (8)	4	0	2	0	**6**
4	Severe (10)	5	0	0	0	**5**
5	**Total**	**19**	**15**	**5**	**1**	**40**

According to this study, 40 children came with the complaints of mild, moderate and severe cough. After the treatment, out of 40 children 19 (47.5%) has completely cured.

Table:37. Sore throat

S.No	Before Treatment	After Treatment					Total Number of Cases
	Grade	G0	G1	G2	G3	G4	
1	G3	2	0	0	0	0	**2**
2	G4	14	6	0	1	2	**23**
3	G5	7	4	3	0	1	**15**
4	**Total**	**23**	**10**	**3**	**1**	**3**	**40**

According to this study, 40 children came with the complaints of G3, G4, G5. After the treatment, out of 40 children 23 (57.5%) has completely cured.

Table:38. Appetite

S.No	Before Treatment	After Treatment			Total Number of Cases
	Grade	G0	G1	G3	
1	G2	15	1	0	**16**
2	G3	17	2	1	**20**
3	G4	3	1	0	**4**
4	**Total**	**35**	**4**	**1**	**40**

According to this study, 40 children came with the complaints of G2, G3, G4. After the treatment, out of 40 children 35 (87.5%) has completely cured.

Table:39. Temperature

S.No	Before Treatment	After Treatment		Total Number of Cases
	Grade	G0	G1	
1	G0	17	0	**17**
2	G1	23	0	**23**
3	**Total**	**40**	**0**	**40**

According to this study, Out of 23 children who have reported with Low grade fever, 23 children (100%) have become normal after the treatment.

Stastical Analysis

All collected data were entered into MS Excel software using different columns as variables and rows as patients. STATA software was used to perform statistical analysis. Basic descriptive statistics include frequency distributions and cross- tabulations were

performed. Bar diagram were used to describe the value of different variables for pictorial representation. The quantity variables were expressed as Mean and standard deviation and qualitative data as percentage. A probability value of less than 0.05 was considered to indicate as statistical significance. Paired‘t’ test was performed for determining the significance between before and after treatment.

Table:40. Statistical significance of treatment on clinical symptoms.

Treatment	Mean ± std	E Value	P Value
Before	13.8 ± 2.22	19.75	<0.0001
After	2.35 ± 2.5		

The mean and standard deviation of *Vali Kanam* Before and after treatment were 13.5 ± 2.22 and 2.35 ± 2.5 respectively. Which is statistically significant P <0.0001 t-value =19.75.There is a highly significant difference between before and after treatment. i.e 83% reduction in the clinical symptoms after the treatment.

6. DISCUSSION

"VALI KANAM" is the most common Respiratory tract infections of children encountered in primary health care in worldwide. Vali Kanam more or less resembles Acute Pharyngitis in modern literature. The disease is characterized by Cough, Sore throat, Poor appetite, Low grade fever.

In the present study, forty cases were treated in the outpatient department, according to clinical features mentioned in textbook of Balavagadam. The choosen drug Vilva Ennai is indicated for Kanam and here a clinical trial is initiated with treating children. The diagnosis is confirmed based on clinical feautures and treated with the drug "VILVA ENNAI" and the prognosis is clearly observed. Modified Leicester cough questionnaire (LCQ), Sore throat and Appetite scoring system and temperature be measured in the under axilla are taken as the prognostic tool to evaluate the efficacy of the trial drug.

The study is conducted after the proposal was screened by the Screening committee of National Institute of Siddha. The Clinical study has been approved by IEC of NIS, approval No: NIS/IEC/9/2014-15/17. The trial is registered in Clinical trial Registry of India with Reg.No.CTRI/2017/02/007753. The Authentication of ingredients of the trial drug was obtained from Medicinal Botanist Dr.D.Aravind,MD(S),MSc., National Institute of Siddha, Chennai.

The trial drugs were prepared by the author in the Gunapadam practical laboratory of National Institute of Siddha, under the guidance and supervision of the guide. The trial drug was prepared by the standard operating procedure as mentioned in the protocol.

Physicochemical analysis was done as a preliminary evaluation and the trial drug Vilva Ennai. Loss on drying (LOD) is a method of measuring the amount of water and volatile matters in a sample when the sample is dried. Low moisture content is always desirable for higher stability of drugs. In Vilva Ennai, the loss on drying at $105^{o}C$ was found to be 0.9±0.43. So the determination of moisture content shows the good stability of the drug Vilva Ennai.

The total Ash values are helpful in determining the quality and purity of drugs, especially in powder form. The total Ash value in Vilva Ennai found to be 0.588±0.11.

The minimal level of total ash shows the less inorganic residue and purity of the drug Vilva Ennai.

Strongly Acidic nature of the drug can cause the harmful effects to the body, so the screening for the pH is important for drugs. It represents the chemical nature of the drug and the site of absorption of non-polar drug. The pH of Vilva Ennai is found to be 6, that is weekly acidic and safe in pH. The weekly acidic drugs are rapidly absorbed from stomach. So the drug Vilva Ennai can act rapidly on oral administration.

The refractive index is a measure of purity of a sample. It is a ratio of velocity of light in vacuum. If any adulteration is present in the sample the refractive index will increase or decrease, which is very helpful in determination of unsaturation. Refractive index increases with increase in unsaturation. Since the refractive index is 1.46 it interprets that there is no adulteration in the sample and degree of unsaturation is low.

Iodine value, Saponification value is used to measure the relative degree of unsaturated fatty acid in the sample. Smaller the molar weight of the fat higher the saponification value. The saponification value indicates the mean molecular weight of fatty acid of triglycerides comprising of fat. Lower the saponification value larger the molecular weight of fatty acids and triglyceride vice versa. Since the Iodine value (mg I2/g) is 102 & saponification value (mg of KOH to saponify 1gm of fat) is 211. The observation shows medium chain fatty acid or triglycerides as the main component. Medium chain triglycerides passively diffuse from the GI Tract to the portal system. It facilitate easily absorbed and metabolization of the trial drug.

The trail drug Vilva Ennai shows the presence of Phytoconstituents such as Alkaloids, Steroids, Sugar, Phenols, Saponin an proteins. Alkaloids have anti-bacterial activity. So, it reduces the infection. Steroids helps as immune modulators and control the inflammation, So it may be reduce the symptoms of fever, cough, sore throat. Saponins have the activity of Alterative, Expectorant, Anti-spasmodic, anti- catarrhal, anti-oxidant, and anti-inflammatory. So it may reduce the symptoms of fever, cough, sore throat. Phenols have the activity of anti-microbial, anti-inflammation and anti-oxidant. So, it may reduce the infection..

The test reveals there the absence of heavy metals and micro- organism, Below limit of quantification of pesticides and aflatoxin.The trial drug is also free from microbial contamination, Aflatoxin and Pesticide residues. So it is safe to be administrated in children. There is no adverse effect produced by the trail drug Vilva Ennai during the entire course of treatment.

The anti-inflammatory activity of the trial drug VILVA ENNAI was done at Noble Research Solutions, Sathyabama University, Chennai. In-vitro Anti-inflammatory activity of VILVA ENNAI was performed by protein (Albumin) denaturation method. The result obtained from the present study clearly indicates that the test drug was effective in inhibiting heat induced albumin denaturation. Maximum percentage inhibition of about 72.12% was observed at 500 µg/ml when compare to that of the Diclofenac sodium, a standard anti-inflammatory agent with the maximum inhibition 86.16 % at the concentration of 100µg/ml.

The Bio-chemical analysis revealed the presence of Chloride, Ammonium, Fluoride and Oxalate.

In clinical studies the patients were recruited for the trial based on inclusion and exclusion criteria and after getting the consent from the patient. 40 patients were included in this study. The 40 patients were treated in OPD of Ayothidoss Pandithar Hospital of National Institute of Siddha. Separate proforma was maintained for every patient. Progress chart was also maintained to monitor the clinical signs and symptoms of the disease.

The treatment was aimed at normalizing the deranged thodams and providing relief from symptoms. Before treatment the patients were advised to adapt lifestyle modifications such as oil bath weekly once and to follow good dietary regimen.

The patients were treated with trial drugs VILVA ENNAI for 5 days. Patients were instructed to take the medicines regularly and advised to follow pathiyam and to avoid exposure to allergic substances if any. Patients were asked to visit the hospital on 6^{th} day for assessment. After completion of the study; the patients were advised to visit the Out-Patient ward of Department of Kuzhanthai Maruthuvam for 1 month for follow-up. The results observed during the study period were discussed by the author below.

This study elicies the efficasy of “VILVA ENNAI” in relieving the symptoms of Vali kanam.

CLINICAL REVIEW

- **Age**

  Out of 40 patients, 60% of cases were 8-10 years, 40% of cases were 11-12 years. The highest incidence was seen in the age group of 8-10 years. School going age group is most affected.

- **Sex**

  Out of 40 patients 47.5% were male children and 52.5% were female children. According to this study both sexes were more or less equally affected which shows Vali Kanam is not predominant on sex.

- **Socio-economic status**

  About 7.5% patients were under upper class, 27.5% patients were under upper middle class, 60% patients were under Lower middle class and 5% patients were lower class. The highest incidence occurred in lower middle income group due to overcrowding and poor sanitation.

- **Seasonal variation**

  Among 40 patients, 52.5 % were from Munpani kaalam, 45 % from Pinpani kaalam, 2.5% from Koothir kaalam. The hieghest incidence was noted in munpanikaalam.

- **Food habits**

  According to diet, Vegetarian 5%, Non vegetarian 95% were noted. The highest incidence was seen in Non-Vegetarian. But Vali Kanam has no influence on diet.

- **Nilam**

  Among 40 patients, 80% were from Neithal land, 15 % from Marutham land, 0 % from Mullai land, and 5% from Kurinji land. Since this study was carried out in Chennai, the highest incidence of people seeking treatment were from the sourrounding of Chennai and hence highest incidence was noted in Neithal nilam.

- **Vali (Vatham)**

  Due to the derangement of different vatha the following symptoms occur. According to vatham, derangement of Pranan was 100% due to poor appetite, Abanan was 17.5% due to constipation, Uthanan was 75% due to sore throat and difficulty in swallowing, samaanam was affected 100% due to derangement of other vatham and Kirukaran was deranged in 100% due to cough.

- **Azhal (Pitham)**

  According to Pitham, derangement of Analapitham was 100% due to poor appetite and Ranjagapitham was deranged in 15% due to pallor of tongue and conjuctiva.

- **Iyyam (Kabam)**

  According to Kabam, derangement of Kelathagam was 100 % due to poor appetite and Avalambagam was deranged in 100%.

- **Ezhu udarkattugal**

  According to the study, Saram was affected in 100% of cases due to presence of fatigue, Senneer was affected in 15% due to pallor of tongue and conjunctiva.

- **Envagai thervugal**

  According to this study, Out of 40 cases,

  - In 35% of the cases Mozhi was affected due to hoarseness of voice.
  - Malam was affected in 20% of patients due to constipation.
  - In 17.5% of cases Sparisam was affected due to fever.
  - In 10% 0f cases naa was affected due to pallor of the tongue.
  - In 10% of the cases vizhi was affected by due to pallor of the conjunctiva.

- **Naadi**

  According to this study, Out of 40 cases,

  Vathapitham was observed in 50 % of cases,

  Pithavatham was observed in 40 % of cases,

  Pithakabam was observed in 10 % of cases.

According to naadi, high distribution was observed in vali Azhal, Azhal vali and Azhal iyyam naadi. In siddha literature, the character of vali Azhal is mainly poor appetite, indigestion and nausea.

- **Neerkuri**

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

- **Neikuri**

  In the present study, 27.5% had vatha neikuri, 30% was observed as pitha neikuri and 42.5 % was kaba neikuri.

Statistical analysis

The clinical feature of Vali kanam, before and after treatment were 13.8±.22 and 2.35 ± 2.5 respectively. The reduction in the symptoms is 83% from the start of the treatment.

DRUG REVIEW

The trial medicine Vilva Ennai is chosen for treatment of Vali kanam. The ingredients of this drug have the property of controlling the symptoms Vali kanam.

The pharmacological studies already carried out on the individual drugs also favour its effect in disease of Respiratory tract illness as given below: Aegle marmelose have a potent anti-inflammatory activity, anti-pyretic activity and anti- oxidant activity, Allium cepa have anti-inflammatory activity, anti- microbial activity and anti- oxidant activity, Indigofera tinctoria have anti-microbial activity and anti-oxidant, Terminalia chebula has anti-oxidant property and anti-microbial activity and Ricinus communis have anti-inflammatory activity and anti-oxidant activity. The results of the study suggest that treatment with VILVA ENNAI has significant improvement in patients with Vali kanam.

7. SUMMARY

Acute inflammation of the throat is a frequent reason for medical consultations in all age groups. Although generally mild in nature, it may give rise to significant suffering and morbidity, including throat pain, pain on swallowing, high fever, difficulty in eating and drinking, and the need for time off work or school. The literature evidence of both the siddha and modern literatures were reviewed and the reviews and recent studies on the individual drugs of the trial drug were collected. Patients attending the OPD of NIS having the compliants of Vali kanam diagnosed clinically and the patients were observed for clinical diagnosis. Classical symptoms of Vali kanam emphasis with the symptoms of pharyngitis like cough, Sore throat, Poor appetite, Lowgrade fever. The Clinical study has been approved by IEC of NIS and the trial was registered in Clinical trial Registry of India. The Authentication of ingredients of the trial drug was done obtained from Medicinal Botanist Dr.D.Aravind MD(S), M.Sc., National Institute of Siddha, Chennai. Purification of drugs and preparation of trial drug was done at Gunapadam Laboratory, Department of Gunapadam, NIS, Chennai. Biochemical Qualitative analysis of trial drug was done in Biochemistry laboratory, Department of Biochemistry, National Institute of Siddha, Chennai. Clinical diagnosis of Vali kanam was done on the basis of the clinical features described in Balavagadam text.

The patients with Vali kanam were recruited based on Inclusion and Exclusion criteria and a detailed study was done. Separate proforma was maintained for each patient along with progress chart to monitor the prognosis. The medicine chosen for clinical study of Vali kanam is Vilva Ennai administered internally one time in a day for 5 days.

All the patients were adviced to follow healthy dietary regimen during the treatment. The observation on effect of the therapy was encouraging.

The trial drug Vilva Ennai have potent anti-inflammatory activity.

The physicochemical analysis reveals the high saponification value and Iodine Value, Good refractive index.

The trial drug Vilva Ennai, shows the presence of Phytoconstituents such as Alkaloids, Phenols, Steroids, Sugar, Saponin and Protein and the absence of heavy metals and micro- organism, pesticides and aflatoxin.

The biochemical analysis revealed the presence of Chloride, Ammonium, Fluoride & Oxalate.

The patients have not complained of any adverse effects or difficulties during the course of treatment. Thus the drug is found to be safe and effective in the management of Vali kanam. The clinical efficacy of the drug was analyzed statistically on all the symptoms mentioned in the assessment criteria. The observation made during the clinical study showed that the trail drug vilva ennai was clinically effective.

8. CONCLUSION

The Siddha system of medicines has certainty with safer medications to treat children. In the present study, the trial drug vilva ennai is treated in the children of age group, 8-12 years who are all diagnosed to have Vali kanam. The ingredients of vilva ennai are feasible and useful and these compounds may serve as potentially useful drug at a lower cost since most of them had anti-inflammatory, anti-pyretic activity. Clinical results were found as highly significant before and after treatment. i.e 83% reduction in clinical symptoms after the treatment. The present clinical study has established that vilva ennai is having good result in reducing the majority of the symptoms of vali kanam. This has inturn, provided a further research and opportunity for new drug established in the management of Vali kanam.

By encouraging results of above study the drug may be taken for larger study in treatment of Vali kanam.

9. BIBLIOGRAPHY

- Balavagadam – Dr.Pon.Kurusironmani & Murugesa Mudhaliyar Text Book Of Balavagadam Published By Indian System Of Medicine And Homeopathy.2007
- Kuzhandhai Kanai Noi Maruthuvam- Panditha Rathna Sithambaradhanu Pillai
- Pillaipini maruthuvam-2 – Indian medicine and Homeopathithurai.
- Dr.A.Sundarrasan - Pillaippini Maruthuvam
- Siddha Maruthuvanga Surkkam
- Aathmarakshamirtham Ennum Vaithiya Saara Sangiragam –Kandhasamy Mudhaliyar
- C. Kanusamy Pillai – Material Medica
- Sarakku suthi seimurigal
- Dr.k.Na.Kuppusamy - Siddha Maruthuvam Podhu
- Dr.M. Shanmugavelu - Nooi Nadal Noi Mudhal Nadal Thiratu –Part(1)
- Kannuswamy Pillai.C, Scihitcha Ratna Deepam, B.Rathna Nayakkar&Sons-Chennai,2007,P-209-210
- Clinical Practice Guideline For The Diagnosis And Management Of Group A Streptococcal Pharyngitis: 2012 Update By The Infectious Diseases Society Of America. *Clin Infect Dis*. 2012;55(10):E86-E102. Pmid: 22965026 Www.Ncbi.Nlm.Nih.Gov/Pubmed/22965026
- PARARASA SEKARAM Balaroga nidhanam
- Pharmacopoeial Laboratory for Indian Medicine (PLIM) Guideline for standardization and evaluation of indian medicine which include drugs of Ayurveda, Unani and Siddha systems. Department AYUSH .Ministry of Health & Family Welfare, Govt. of India
- Indian standard methods of sampling and test for oils and fats Indian standard institution New Delhi 47-50. 1964
- G.Leelaprakash, S.Mohan Dass. In-vitro anti-inflammatory activity of methanol extract of enicostemma axillare. Int. J. Drug Dev. & Res., 2011, 3 (3): 189-196.
- M. V. Anoop, A. R. Bindu . In-vitro Anti-inflammatory Activity Studies on Syzygium zeylanicum (L.) DC Leaves. International Journal of Pharma Research & Review, August 2015; 4(8):18-27.

- 3.Lukasz Komsta, Monika Waksmundzka-Hajnos, Joseph Sherma . Thin Layer Chromatography in Drug Analysis . CRC Press, Taylor and Francis.
- Wagner H. Plant Drug Analysis. A thin Layer chromatography Atlas.2nd ed. Heidelberg: Springer-Verlag Belgium; 2002:305, 227.
- 2, Ganesh N. Sharma K, Nitin S, Jyotsana S. Phytochemical screening and estimation of Total Phenolic Content in *Aegle marmelos* Seeds. *Int J Pharma Clinc Res*.2011; 3(2): 27-29.
- Ganga rao B, Umamaheswara rao, Sambasiva rao, Mallikarjuna rao T. Studies on phyto chemical constituents, quantification of total phenol, alkaloid content and *In-vitro* anti-oxidant activity of *Coccinia cordifolia*. *Int. J. pharm. life sci*.2011; 2(10):1177-1182.
- Dr. S Chidambaradhanu Pillai, Kuzhandhaikalin noigal,Siddha Medical Literature Research Centre, part 3, 1 st Edition .
- Dr. Nelson, Text book of Paediatrics Volume II second edition
- Dr. K. S. Murugesa Mudhaliar, Gunapadam, Porut Panbu Nool, Mooligai Vagupu, 2 nd Edition, 2006.
- T. V.Sambasivam Pillai, Tamil – English Dictionary of Medicine, 2 nd Edition, Directorate of Indian Medicine, Chennai.
- Dr. R. Thiyagarasan, Gunapadam (Thathu – Seeva vagupu), 4 th Edition, 2004.
- Dr. Shanmugavelu, Noikaluku Siddha Parikaram, 2nd Edition, 2001, Directorate of Indian Medicine, Chennai.
- Maruthuva thavaraviyal (dr .s.somasundharam –Msc,mphil,phd vol1
- Journal of Ethnopharmacology
- Veerappan Arul, Shigeru Miyazaki, Renganathan Dhananjayan
- Pelagia Research Library European Journal of Experimental Biology, 2016, 6(2):26-29 ISSN: 2248 –9215 CODEN (USA): EJEBAU
- (D. Vijay Anand Raju, V. Sandhya, M. Vineel Chandra, M. Muralidhar Reddy and Bolay Bhattacharya)
- Indian Journal of Pharmaceutical Sciences
- Indian J Pharm Sci. 2011 Mar-Apr; 73(2): 235–240.(H V Govinda and S. M. B. Asdaq)

- International Journal of Research in Pharmaceutical and Biomedical Sciences ISSN: 2229-3701 (Saraswathi Motamarri N, Karthikeyan M, Rajasekar S and Gopal)
- International Journal of Pharmcy and Pharmaceutical Sciences(Madakkannu Boothapandi, Ravichandran Ramanibai)
- Internationa journal of pharmacology 7(3):356-362, 2011
- (K.P.Renukadevi and S.Suhani Sultana.
- African Journal of Pharmacy and Pharmacology Vol. 6(23), pp. 1679-1684, 22 June, 2012
- International Journal of Universal Pharmacy and Life Sciences
  - (K.J. Kore, R.V. Shete., M.P.Kabra, R.M.Rachhadiya)
- Mediators of Infammation, Mediators Inflamm. 2000; 9(5): 223–228
- Internationa Journal of Molecular Medicine and Advance Sciences 11 (1): 9-12, 2015. ISSN: 1813-176X
- Pharmaceutico analytical study and standardization of panchtikta ghrita. International Research Journal of Pharmacy. Haldal pronab.

10. ANNEXURES

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

CLINICAL EVALUATION OF VILVA ENNAI (A SIDDHA DRUG) IN THE TREATMENT OF VALI KANAM (ACUTE PHARYNGITIS) IN CHILDREN.

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

SCREENING FORM

INCLUSION CRETERIA:	**Yes**	**No**
Age: Between 8-12 years		
Cough	☐	☐
Low grade fever	☐	☐
Sore throat	☐	☐
Loss of appetite	☐	☐
EXCLUSION CRITERIA:		
Congenital heart disease	☐	☐
Tonsillitis	☐	☐
Bronchial asthma	☐	☐
Primary complex	☐	☐
Long term fever	☐	☐
ADMITTED TO THE STUDY	☐	☐
If Yes, OPD	☐	IPD ☐

Signature of Guide Signature of Principal Investigator

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 47.

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

CLINICAL EVALUATION OF VILVA ENNAI (A SIDDHA DRUG) IN THE TREATMENT OF VALI KANAM (ACUTE PHARYNGITIS) IN CHILDREN.

INFORMATION SHEET FOR PATIENTS PARTICIPATING IN THE OPEN CLINICAL TRIAL.

I, _____Studying as PG Scholar in the department of Kuzhandhai Maruthuvam at National Institute of Siddha, Tambaram Sanatorium is doing a clinical study on VALI KANAM (ACUTE PHARYNGITIS). In this regard, I am in a need to ask you few questions. I will maintain confidentiality of your response and data obtained from you. There will be no risk is involved by taking part in this study.

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

If you agree your child to be a participant in this study, he/she will be included in the study primarily by signing the consent form and then you will be given the internal medicine "VILVA ENNAI"(3 ml- Once a day in morning after food for 5days).

The information I am collecting in this study will remain between you and the principal investigator (myself). If you wish to find out more about this study before taking part, you can ask me any related questions or contact me through my mobile number: +91 74488 30555

You can also contact the Member-secretary of Ethics committee, National Institute Siddha, Chennai 600047, Tel no: 91-44-22380789, for rights and participation in the study.

தேசிய சித்த மருத்துவ நிறுவனம்

அயோத்திதாச பண்டிதர் மருத்துவமனை, சென்னை-47

குழந்தை மருத்துவத் துறை

வளிகணம் நோய்க்கான வில்வ எண்ணெய்யின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ பட்டமேற்படிப்பு

தகவல் படிவம்

ஆராய்ச்சியாளர் பெயர் : மரு.கி.அபிநயா

மருத்துவ ஆய்விற்கான தகவல் படிவம்

தேசிய சித்த மருத்துவ நிறுவனத்தில் குழந்தை மருத்துவத் துறையில் பட்ட மேற்படிப்பு பயின்று வரும் மரு.கி.அபிநயா ஆகிய நான் வளிகணம் நோய்க்கான வில்வ எண்ணெய்யின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆராய்ச்சியில் ஈடுபட்டுள்ளேன். இது சம்பந்தமான குழந்தையின் அனைத்து விவரங்களும் இரகசியமாக வைக்கப்படும் என உறுதி அளிக்கிறேன்.

இது போன்ற

விவரங்களை தெரிவிப்பதால் தங்களுக்கோ தங்களது குழந்தைக்கோ தங்களின் வேலை தளத்திலோ எந்த ஒரு பாதிப்பும் ஏற்படாது. இதில் பயணப்படி முதலிய எந்த உதவித்தொகையும் வழங்கப்படமாட்டாது.இந்த ஆராய்ச்சிக்கு நோயினராக சேர்ந்த பிறகு உங்களுக்கு விருப்பம் இல்லையெனில் எப்போது வேண்டுமானாலும் தங்களது குழந்தையை விலக்கிக் கொள்ளலாம். இருந்தாலும் இந்த மருத்துவ ஆய்வில் சேர்வதன் மூலமாக தங்களது குழந்தையின் நோய் குறைவது மட்டுமல்லாமல் மருத்துவத் துறை சார்ந்த வல்லுநர்களுக்கு இந்த நோய்க்கான தீர்வுகளை கண்டறிவதற்கு மிகவும் உதவியாக இருக்கும்.இந்த ஆராய்ச்சிக்கு தங்களது விருப்பத்தின் பேரில் தங்களது குழந்தையை உட்படுத்தும் பட்சத்தில் முதன்மையாக ஒப்புதல் படிவத்தில் கையெழுத்திட்ட பின்பு தாங்கள் உள்மருந்தாக வில்வ எண்ணெய் (3மி.கி) ஒரு வேளை தரவேண்டும்.

இந்த மருத்துவ ஆய்வின் தொடர்பாக உங்களிடமிருந்து சேகரிக்கப்படும் அனைத்து விவரங்களும் உங்களுக்கும் ஆராய்ச்சியாளரான எனக்கும் மட்டுமே அறிந்திருக்கக் கூடியதாக இருக்கும்.இந்த ஆராய்ச்சி சம்மந்தமாக மற்ற விபரங்களையும் நோயின் தன்மை பற்றியும் அறிவதற்கு ஆராய்ச்சியாளரான மரு.இரா.சரஸ்வதி கைபேசி எண் 766773440 தொடர்பு கொள்ளலாம்.மேலும் இந்த ஆராய்ச்சி தொடர்பாக நிறுவன நீதிநெறி குழு,தேசிய சித்த மருத்துவ நிறுவனம், தொலைபேசிஎண் 91-44-22380789 தொடர்பு கொள்ளலாம்.

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600047.

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

CLINICAL EVALUATION OF VILVA ENNAI (A SIDDHA DRUG) IN THE TREATMENT OF VALI KANAM (ACUTE PHARYNGITIS) IN CHILDREN.

CONSENT FORM

CERTIFICATE BY INVESTIGATOR

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

Date: Signature : _____

Station: Name : _____

CONSENT BY PARENT

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

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

I, exercising my free power of choice, hereby give my consent to include my son/daughter as a subject in the clinical trial of **'VILVA ENNAI'** for the treatment of '**VALI KANAM'**

Date: Signature _____

Name _____

Signature of witness _____

Name _____

Relationship _____

தேசிய சித்த மருத்துவ நிறுவனம்

அயோத்திதாச பண்டிதர் மருத்துவமனை, சென்னை-47

குழந்தை மருத்துவத் துறை

வளிகணம் நோய்க்கான வில்வ எண்ணெய்யின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்வு

ஒப்புதல் படிவம்

ஆய்வாளரால் சான்றளிக்கப்பட்டது

நான் இந்த மருத்துவ ஆய்வு குறித்த அனைத்து விபரங்களையும் நோயாளியின் பெற்றோருக்குப் புரியும் வகையில் எடுத்துரைத்தேன் என உறுதி அளிக்கிறேன்.

தேதி: **கையொப்பம்:**

இடம்: **பெயர்:**

நோயாளியின் பெற்றோர் ஒப்புதல்

என்னிடம் இந்த மருத்துவ ஆய்வின் காரணத்தையும்,மருந்தின் தன்மை மற்றும் மருத்துவ வழிமுறை பற்றியும், இந்த மருத்துவத்தைத் தொடர்ந்து எனது குழந்தையின் உடல் இயக்கத்தைக் கண்காணிக்கவும்,அதனைப் பாதுகாக்க பயன்படும் மருத்துவ ஆய்வுகள் பற்றியும் திருப்தி அளிக்கும் வகையில் ஆய்வு மருத்துவரால் விளக்கிக் கூறப்பட்டது.

நான் இந்த மருத்துவ ஆய்வின் போது காரணம் எதுவும் கூறாமல் எப்பொழுது வேண்டுமானலும் என் குழந்தையை விடுவித்துக் கொள்ளும் உரிமையைத் தெரிந்திருக்கிறேன்.

நான் என்னுடைய சுதந்திரமாகத் தேர்வு செய்யும் உரிமையைக் கொண்டு வளிகணம் நோய்க்கான வில்வ எண்ணெய்யின் பரிகரிப்புத்திறனை கண்டறியும் மருத்துவ ஆய்வுக்கு எனது குழந்தையை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி: பெற்றொர் கையொப்பம்:

இடம்: பெயர்:

சாட்சிக்காரர் கையொப்பம்:

பெயர்:

சாட்சிக்காரர் உறவுமுறை:

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 47.

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

CLINICAL EVALUATION OF VILVA ENNAI (A SIDDHA DRUG) IN THE TREATMENT OF VALI KANAM (ACUTE PHARYNGITIS) IN CHILDREN.

ASSENT FORM (by patient)

I---------- understand that my parents (mom and dad)/guardian have /has given permission (said it's okay) for me to take part in a project about CLINICAL EVALUATION OF VILVA ENNAI FOR VALI KANAM done by Dr.K.Abinaya.

I am taking part because I want to take part. I have been told that I can stop at any time I want to do so and nothing will happen to me if I want to stop.

Date: Signature of the Patient

Station:

Signature of the Parent

தேசிய சித்த மருத்துவ நிறுவனம்

அயோத்திதாச பண்டிதர் மருத்துவமனை, சென்னை-47

குழந்தை மருத்துவத் துறை

வளிகணம் நோய்க்கான வில்வ எண்ணெய்யின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ பட்டமேற்படிப்பு

ஒப்புதல் படிவம் குழந்தைக்கானது

_____ ஆகிய நான் தேசிய சித்த மருத்துவ நிறுவனத்தில் பட்டமேற்படிப்பு குழந்தை மருத்துவத் துறையில் பயிலும் மரு.கி.அபிநயா அவர்களால் நடத்தப்படும் வளிகணம் நோய்க்கான வில்வ எண்ணெய்யின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்வில் பங்கேற்பதற்கு எனது பெற்றோர்/காப்பாளர் திரு/திருமதி._____சம்மதம் தெரிவித்திருப்பதை நன்கு அறிவேன்.

எனக்கு இந்த ஆராய்ச்சி பற்றி புரியும் வகையில் எடுத்துரைக்கப்பட்டுள்ளது. இவ்வாராய்ச்சியில் இருந்து எப்போது வேண்டுமானாலும் விலக எனக்கு உரிமை இருக்கின்றது என்பதைப் பற்றியும் நன்கு தெரிந்துகொண்டு இந்த ஆராய்ச்சியில் பங்கேற்க சம்மதிக்கிறேன்.

தேதி:

இடம்:

குழந்தையின் கையொப்பம்:

பெயர்:

பெற்றொர் கையொப்பம்:

பெயர்:

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 47.

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

CLINICAL EVALUATION OF VILVA ENNAI (A SIDDHA DRUG) IN THE TREATMENT OF VALI KANAM (ACUTE PHARYNGITIS) IN CHILDREN.

CASE REPORT FORM

Demographic data:

Patient Id :	OP/IP No:	Visit Date :
Name		
Age		
Date of Birth		
Gender	Male ☐ Female ☐	
Father/ Mother /Guardian Name		
Father Occupation		
Father Monthly Income		
Religion		
Socioeconomic Status		
Informant		
Postal Address		
Contact Number		

Complaints and Duration:

Present illness:

History of Past Illness:

History / Symptoms / Signs	Yes	No	If, Yes Details
Any Similar Complaints	☐	☐	_____
Bronchial Asthma	☐	☐	_____
Dust Allergy	☐	☐	_____
Hospitalization	☐	☐	_____
Any other	☐	☐	_____

Family History:

Any Hereditary/ Familial Disease Yes ☐ No ☐

If Yes, Details _____

Immunization History:

Proper Immunization given Yes ☐ No ☐

.....

Food habits:

1. Veg ☐ 2. Non-Veg ☐

General assessment:

1. Pica Yes ☐ No ☐
2. Nail biting Yes ☐ No ☐
3. Bowel habits Normal ☐ Abnormal ☐

General Examination:

1. Pallor Yes ☐ No ☐
2. Jaundice Yes ☐ No ☐
3. Cyanosis Yes ☐ No ☐
4. Clubbing Yes ☐ No ☐
5. Pedal oedema Yes ☐ No ☐
6. Lymph adenopathy Yes ☐ No ☐

Vital signs:

1. Pulse rate _____ / min
2. Heart rate _____ / min
3. Respiratory Rate _____ / min
4. Temperature _____^{o} F

Anthropometry:

Height : _____ cm

Weight : _____ kg

Systemic Examination:

Examination of Respiratory System

A) Inspection:

Shape : Normal ☐ Barrel Shaped ☐ Pigeon chest ☐

Shoulder Drooping : Absent ☐ Present ☐

Intercostal spaces : Normal ☐ Bulge ☐ Indra-wing ☐

Spine : Normal ☐ Kyphosis ☐ Scoliosis ☐

Supraclavicular fossae: Normal ☐ Flattening ☐ Hollowing ☐

Position of mediastinum:

Trail's sign: Present ☐ Absent ☐

Apical impulse _____

B) Palpation:

Tenderness Yes ☐ No ☐

If Yes _____

Tactile vocal Fremitus: Normal and Equal ☐

Increased ☐

Decreased ☐

C) Percussion:

Percussion on all areas: Normal ☐

Hyper resonance ☐

Dullness ☐

D) Auscultation:

Intensity of breath sounds:

Normal ☐ Decreased ☐ Increased ☐

Vocal resonance:

Normal ☐ Decreased ☐ Increased ☐

Adventitious sounds:

Wheeze ☐ Crepitation ☐ Rub ☐ None ☐

Other systems:

	Normal	**Affected**
Cardio vascular system:	☐	☐
Gastro intestinal system:	☐	☐
Musculoskeletal system:	☐	☐
Central nervous system:	☐	☐
Endocrine system:	☐	☐

Nilam:

Kurinji ☐ Mullai ☐ Marutham ☐ Neithal ☐ Paalai ☐

Kaala Iyalbu:

Kaarkalam ☐	Koothirkaalam ☐	Munpanikaalam ☐
Pinpanikaalam ☐	Illavenirkaalam ☐	Muthuvenirkaalam ☐

Yaakai:

Vatham ☐	Vatha Pitham ☐	Vatha Kabam ☐
Pitham ☐	Pitha vatham ☐	Pitha Kabam ☐
Kabam ☐	Kaba Vatham ☐	Kaba Pitham ☐

Gunam:

Sathuvam ☐ Rasatham ☐ Thamasam ☐

Pori / Pulangal:

	Normal	Affected	Normal	Affected	Remarks
Mei / Unarvu	☐	☐	☐	☐	
Vaai / Suvai	☐	☐	☐	☐	
Kan / Parvaai	☐	☐	☐	☐	
Mooku / Naatram	☐	☐	☐	☐	
Sevi / Oli	☐	☐	☐	☐	

Kanmendhirium / Kanmavidayam:

	Normal	Affected	Normal	Affected	Remarks
Kai / dhanam	☐	☐	☐	☐	
Kaal / ghamanam	☐	☐	☐	☐	
Vaai / vaku	☐	☐	☐	☐	
Eruvai / visarkam	☐	☐	☐	☐	
Karuvai / anantham	☐	☐	☐	☐	

Uyir Thathukkal

Vatham:

	Normal	Affected	Remarks
Pranan	☐	☐	
Abanan	☐	☐	
Viyanan	☐	☐	
Uthanan	☐	☐	
Samanan	☐	☐	
Nagan	☐	☐	
Koorman	☐	☐	
Kirukaran	☐	☐	

Devathathan	☐	☐
Dhanajeyan	☐	☐

Pitham

	Normal	Affected	Remarks
Analam	☐	☐	
Ranjagam	☐	☐	
Saathagam	☐	☐	
Alosagam	☐	☐	
Prasagam	☐	☐	

Kabam:

	Normal	Affected	Remarks
Avalambagam	☐	☐	
Kilethagam	☐	☐	
Pothagam	☐	☐	
Tharpagam	☐	☐	
Santhigam	☐	☐	

Udalthathukkal:

	Normal	Affected	Remarks
Saaram	☐	☐	
Senneer	☐	☐	
Oon	☐	☐	
Kozhuppu	☐	☐	
Enbu	☐	☐	
Moolai	☐	☐	
Sukilam / Suronitham	☐	☐	

Envagai Thervugal:

	Normal	Affected	Remarks
a) Naa			
Niram	☐	☐	
Thanmai	☐	☐	
Suvai	☐	☐	
b) Niram	☐	☐	
c) Mozhi	☐	☐	
d) Vizhi			
Niram	☐	☐	
Thanmai	☐	☐	
Parvai	☐	☐	
e) Sparisam	☐	☐	
f) Malam			
Niram	☐	☐	
Nurai	☐	☐	
Elagal	☐	☐	
Erugal	☐	☐	
g) Moothiram			
Neerkuri			
Niram	☐	☐	
Edai	☐	☐	
Nurai	☐	☐	
Manam	☐	☐	
Enjal	☐	☐	

Neikuri

Vatham ☐ Pitham ☐ Kabam ☐ Others ☐

h) Naadi

Vadham	☐	Pitham	☐	kabam	☐
Vatha Pitham	☐	Pitha Vatham	☐	Kaba Vatham	☐
Vatha Kabam	☐	Pitha Vabam	☐	Kaba vatham	☐

Clinical Assessment:

S.No	Clinical Symptoms	1st day	6th day
1.	Cough		
2.	Low grade fever		
3.	Sore throat		
4.	Loss of appetite		
5.	Excessive Thirst		
6.	Borborygmus		
7.	Dysuria		

Cough Assessment:

(Each item carries two points and the total score will be assessed from the following)

	Before Treatment	After Treatment
1. Had chest pain or stomach pain during cough	☐	☐
2. Sputum production while coughing	☐	☐
3. Sleep disturbances due to cough	☐	☐
4. Cough interrupting conversation	☐	☐
5. Cough present at rest	☐	☐

SORE THROAT SCALE:

G0 -Normal

G1 -Mild discomfort

G2 -Hoarsness of voice only.

G3 -Hoarsness of voice associated with Throat pain while speaking.

G4 -Hoarsness of voice associated with throat pain and difficulty to swallowing.

G5 -Severe throat pain with all above symptoms.

APPETITE SCALES:

G0 -Normal

G2 -Mild appetite but eating time being

G3 -Interest only to take junk foods

G4 -No interest to take any type of food but on compulsion he/she takes foods.

G5 -doesn't takes food even on compulsion.

TEMPERATURE:

G0 –Normal (98.6 F)

G1 –Low grade fever (99-100.4 F)

Laboratory Investigations :

Routine Blood Investigations		Normal values	Before TMT Date:	After TMT Date:
T.RBC (milli /cu.mm)		4-4.9		
ESR (mm)	½ hr.	0- 4		
	1 hr.	0-13		
T.WBC (milli /cu.mm)		5000-14500		
Differential Count (%)	Polymorphs	40-75		
	Lymphocytes	28-48		
	Monocytes	3-6		
	Eosinophils	0-3		
	Basophils	0-1		

Diagnosis _____

Drug Issued : _____

Date : _____

Station : _____

Signature of the Guide Signature of Principal Investigator

Signature of the HOD

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

CLINICAL EVALUATION OF VILVA ENNAI (A SIDDHA DRUG) IN THE TREATMENT OF VALI KANAM (ACUTE PHARYNGITIS) IN CHILDREN.

FORM IX-DIETARY ADVICE FORM

✓ THINGS TO TAKE	× THINGS TO AVOID
Milk with palm sugar	Refridged items
Tulsi leaf juice	Tin and can foods, broiler chicken.
Fresh vegetable soups/Country chicken or mutton soups	Cream containing biscuits and cakes
Boiled water/Baked foods like idly	Junk and fast foods
Pepper, turmeric and cumin seeds	White sugar

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 47.

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

CLINICAL EVALUATION OF VILVA ENNAI (A SIDDHA DRUG) IN THE TREATMENT OF VALI KANAM (ACUTE PHARYNGITIS) IN CHILDREN.

1. S.No: 2. OP/ IP No: 3. Name:

4. Age: 5. Gender: 6. Date of Enrollment:

7. Informant: 8. Reliability:

DRUG COMPLIANCE

Name of the drug : **vilva ennai**

Form of the drug : oil

Administration : per oral

Dose & duration : 3 ml – od for 5 days

Amount of drug given :

Amount of drug returned :

DAY	DATE OF DRUG INTAKE	MORNING
DAY 1		
DAY 2		
DAY 3		
DAY 4		
DAY 5		

Date: Signature of Principal Investigator

Signature of the Guide Signature of HOD

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 47.

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

CLINICAL EVALUATION OF VILVA ENNAI (A SIDDHA DRUG) IN THE TREATMENT OF VALI KANAM (ACUTE PHARYNGITIS) IN CHILDREN.

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

ADVERSE REACTION

Date of Occurrence :

Date of Withdrawal from trial :

Description of Adverse reaction :

Clinical Condition :

Date: Signature of Principal Investigator

Signature of Guide Signature of HOD

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 47.

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

CLINICAL EVALUATION OF VILVA ENNAI (A SIDDHA DRUG) IN THE TREATMENT OF VALI KANAM (ACUTE PHARYNGITIS) IN CHILDREN.

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

WITHDRAWAL FORM

Date of trial commencement :

Date of withdrawal from trial :

Reason(s) for withdrawal

Long absence at reporting : Yes / No

Irregular treatment : Yes / No

Shift of locality : Yes / No

Complication adverse reactions if any: Yes / No

Exacerbation of symptoms : Yes / No

Patient not willing to continue : Yes / No

Date: Signature of Principal Investigator

Signature of the Guide Signature of HOD

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

NATIONAL PHARMACOVIGILANCE PROGRAMME FOR SIDDHA DRUGS

Reporting Form for Suspected Adverse Reactions to Siddha Drugs

Please note: i. All consumers / patients and reporters information will remain confidential.
ii. It is requested to report all suspected reactions to the concerned, even if it does not have complete data, as soon as possible.

Peripheral Center code: State:

<table>
<tr><td>Name</td><td>Father name</td><td rowspan="2">Patient / Record No.</td></tr>
<tr><td>Ethnicity</td><td>Occupation</td></tr>
<tr><td colspan="2" rowspan="2">Address
Village / Town
Post / Via
District / State</td><td>Date of Birth / Age:</td></tr>
<tr><td>Sex: Male / Female
Weight :
Degam:</td></tr>
</table>

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

Date and time of initial observation		Season:
Description of reaction		Geographical area:

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

Medicine	Daily dose	Route of administration & Vehicle – Adjuvant	Date		Diagnosis for which medicine taken
			Starting	Stopped	
Siddha					
Any other system of medicines					

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

Details	Drug – 1	Drug – 2	Drug - 3
a) Name of the medicine			
b) Manufacturing unit and batch No. and date			
c) Expiry date			
d) Purchased and obtained from			
e) Composition of the formulation / Part of the drug used			

b) Dietary Restrictions if any

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

d) Any other relevant information.

5. Treatment provided for adverse reaction:

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

<table>
<tr><td>Recovered:</td><td>Not recovered:</td><td>Unknown:</td><td>Fatal:</td><td>If Fatal

Date of death:</td></tr>
<tr><td colspan="2" rowspan="2">Severe: Yes / No.</td><td colspan="3">Reaction abated after drug stopped or dose reduced:</td></tr>
<tr><td colspan="3">Reaction reappeared after re introduction:</td></tr>
</table>

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

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

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

Hepatic Renal Cardiac Diabetes Malnutrition

Any Others

9. H/O previous allergies / Drug reactions:

10. Other illness (please describe):

11. Identification of the reporter:

Type (please tick): Nurse / Doctor / Pharmacist / Health worker / Patient / Attendant / Manufacturer / Distributor / Supplier / Any others (please specify)
Name:
Address:
Telephone / E – mail if any :

Signature of the reporter: **Date:**

Please send the completed form to:

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

The Director

National Institute of Siddha,

(Pharmacovigilance Regional Centre For Siddha Medicine),

Tambaram Sanatorium, Chennai-600 047.

☏ (O) 044-22381314 Fax : 044 – 22381314

Website: www.nischennai.org

Email: nischennaisiddha@yahoo.co.in

* ** * * * *

This filled-in ADR report may be sent within one month of observation /occurrence of ADR

Who Can Report?

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

What to Report?

⇒ All reactions, Drug interactions,

Confidentiality

⇒ The patient's identity will be held in strict confidence and protected to the fullest extent.

⇒ Submission of report will be taken up for remedial measures only not for legal claim

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: Signature of the HOD

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

69,Anna Salai,Guindy,Chennai - 600 032.

This Certificate is awarded to Dr/Mr/Mrs.....K.....Abinaya.....

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

" RESEARCH METHODOLOGY & BIOSTATISTICS "

*For **AYUSH Post Graduates & Researchers***

Organized by the Department of Siddha

The Tamil Nadu Dr. M.G.R. Medical University from 07 th to 11 th September 2015.

Dr.N.KABILAN, M.D.(Siddha)
READER,DEPT.OF SIDDHA

Prof. **Dr.P.ARUMUGAM,** M.D.,
REGISTRAR I/C

Prof. **Dr.D.SHANTHARAM,** M.D., D.Diab.,
VICE CHANCELLOR

NATIONAL INSTITUTE OF SIDDHA
राष्ट्रीय सिद्ध संस्थान
Department of AYUSH- MINISTRY OF HEALTH & FAMILY WELFARE
आयुष विभाग - स्वास्थ एवं परिवार कल्याण मंत्रालय
GOVERNMENT OF INDIA-भारत सरकार
TAMBARAM SANATORIUM, CHENNAI -600 047 -ताम्बरम सानटोरियम चेन्नई -600 047
फ़ोन\Tele : 044-22411611 फैक्स\Fax : 22381314
ईमेल: nischennaisiddha@yahoo.co.in वेब :www.nischennai.org

F.No.NIS/6-20/IEC/15-16 Dt: 05.10.2015

CERTIFICATE

Address of Ethics Committee: National Institute of Siddha, Tambaram Sanatorium, Chennai-600047, Tamil Nadu, India	
Principal Investigator:Dr.K.Abinaya, Department of Kuzhandhai Maruthuvam	
Protocol title: A Clinical Evaluation of "VILVA ENNAI" a Siddha Drug in the treatment of "VALIKANAM" (Acute Pharyngitis) in Children.	
Documents filed	1) Protocol, 2) Data Collection forms 3) SAE(Pharmacovigilance)
Clinical trial Protocol (others – Specify)	Yes
Informed consent documents	Yes
Any other documents	-
Date of IEC approval & its number	**NIS/IEC/9/2014-15/17 – 26.08.2015**

We approve the trial to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study.

Chairman Member Secretary

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 600047

BOTANICAL CERTIFICATE

Certified that the following plant drugs used in the Siddha formulation **"Vilva Ennai"** (Internal) for taken up for Post Graduation Dissertation studies by **Dr.K.Abinaya**, M.D.(S), II year, Department of Kuzhanthai Maruthuvam, 2016, are identified through Visual inspection, Experience, Education & Training, Organoleptic characters, Morphology and Taxonomical methods as

Aegle marmelos (L.) Corr.Serr. (Rutaceae), Leaf
Indigofera tinctoria Linn. (Fabaceae), Whole plant
Allium cepa Linn. (Liliaceae), Bulb, White variety
Terminalia chebula Retz. (Combretaceae), Fruit
Ricinus communis Linn. (Euphorbiaceae), Seed oil

MEDICINAL BOTANY CHENNAI 600 047 National Institute of Siddha

Certificate No: NISMB2632016

Date: 16-12-2016

Authorized Signatory
Dr. D. ARAVIND, M.D (S).M.Sc.,
Assistant Professor
Department of Medicinal Botany
National Institute of Siddha
Chennai - 600 047, INDIA

Noble research solutions
We Trust in Quality and Ethics

Noble Research Solutions

We Trust in Quality and Ethics

E-mail: nobleresearchsolutions@ gmail.com
Contact: 9710437419, Admin: 044 - 42691289

Date: 23.03.2017

To,

Dr.Abinaya

National Institute of Siddha

Tambaram Sanatorium, Chennai - 600 047, Tamil Nadu, India.

Project Id : NRS/AS/0022/02/2017

This is to certify that Dr.Abinaya from National Institute of Siddha, Chennai has carried out the following activity at our facility for the trial drug *Villva oil (VO)*

Project Delivery Report

S.No	Study Description	Annexure no
1.	Standardization and Physicochemical Evaluation of study drug *Villva oil (VO)*	I
2.	In-vitro Anti-Inflammatory Activity *Villva oil (VO)* by Protein (Albumin) denaturation Assay	II

Note:

- *Annexures was attached as a separate enclosure along with this report.*

NOBLE RESEARCH SOLUTIONS TAMIL NADU INDIA CHENNAI

TEST REPORT

SAMPLE NOT DRAWN BY LABORATORY

Issued to:

Dr. K.Abinaya
Ladies Hostel,
National Institute of Siddha,
Tambaram Sanatorium,
Tambaram, Chennai - 47.

Report Number	: 7817-181-0025	Report date	: 07.07.2017
Sample Name	: **Vilva Ennai (Oil)**	Page	: 1 of 3
Quantity	: 150 ml	Received on	: 30.06.2017
Customer Reference	: Test Request Form Date.: 30.06.2017	Commenced on	: 30.06.2017
		Completed on	: 06.07.2017

Sl. No.	Test Parameters	Units of Measurement	Result	Method of Testing
Heavy Metals:				
1.	Cadmium	mg/kg	ND (DL - 0.01)	BVCPSCH/INS/SOP/053 by ICP OES
2.	Lead	mg/kg	ND (DL - 0.01)	
3.	Mercury	mg/kg	ND (DL - 0.01)	
4.	Arsenic	mg/kg	ND (DL - 0.01)	
Aflatoxin:				
1	Aflatoxin B1	µg/kg	BLQ (LOQ : 0.5)	AOAC 2008.02
2	Aflatoxin B2	µg/kg	BLQ (LOQ : 0.5)	
3	Aflatoxin G1	µg/kg	BLQ (LOQ : 0.5)	
4	Aflatoxin G2	µg/kg	BLQ (LOQ : 0.5)	
I. Organochlorine:				
1.	Aldrin (Aldrin and dieldrin combined expressed as dieldrin)	mg/kg	BLQ (LOQ - 0.01)	EURL Method by GC MSMS / LC MSMS
2.	Chlordane (cis & trans)	mg/kg	BLQ (LOQ - 0.01)	
3.	Chlorothalonil	mg/kg	BLQ (LOQ - 0.01)	
4	DDT (all Isomers)	mg/kg	BLQ (LOQ - 0.01)	
5	Dicofol (sum of p,p' and o,p' isomers)	mg/kg	BLQ (LOQ - 0.01)	
6	Dieldrin (see Aldrin)	mg/kg	BLQ (LOQ - 0.01)	
7	Endosulphan (all Isomers)	mg/kg	BLQ (LOQ - 0.01)	
8	Endrin	mg/kg	BLQ (LOQ - 0.01)	
9	HCH (sum of isomers, except the gamma isomers)	mg/kg	BLQ (LOQ - 0.01)	
10	Heptachlor (sum of heptachlor and heptachlorepoxide expressed as heptachlor)	mg/kg	BLQ (LOQ - 0.01)	
11	Lindane (gamma-HCH)	mg/kg	BLQ (LOQ - 0.01)	

..... Contd .....

M. Murugan
Assistant Manager

Bureau Veritas
Consumer Products Services (I) Pvt Ltd.
F2, Thiru. Vi. Ka. Industrial Estate,
Phase III, Ekkattuthangal, Guindy, Chennai-600 032.
Phone : +91 44 - 4967 4000, 4967 4002
Fax : +91 44 - 4967 4001
Email : bvcpschennai.enquiry@in.bureauveritas.com
Web : www.bureauveritas.co.in/cps

Sl No. : 2017 / **12977**

Terms and Conditions:

- The test results relate only to the items tested.
- The test report shall not be reproduced in full or part without the written approval of BVCPS.
- The test items will not be retained for more than 15 days from the date of issue of test report excepts in the case as required by the applicable regulations.
- The Laboratory's responsibility under this report is limited to proven wilful negligence and will in no case be more than the invoiced amount.
- A satisfactory test report in no way implies that the product so tested is approved by NABL.
- Laboratory is not responsible for the authenticity of photocopied test reports.

TEST REPORT

Report No. : 7817-181-0025

Report Date : 07.07.2017
Page : 2 of 3

Sl. No	Test Parameter	Units Of Measurement	Result	Method of Testing
II. Organophosphorus:				
12	4-bromo-2-chlorophenol (metabolite of Profenophos)	mg/kg	BLQ (LOQ - 0.01)	EURL Method by GC MSMS / LC MSMS
13	Acephate	mg/kg	BLQ (LOQ - 0.01)	
14	Chlorfenvinphos	mg/kg	BLQ (LOQ - 0.01)	
15	Chlorpyrifos	mg/kg	BLQ (LOQ - 0.01)	
16	Chlorpyrifos methyl	mg/kg	BLQ (LOQ - 0.01)	
17	Diazinon	mg/kg	BLQ (LOQ - 0.01)	
18	Dichlorvos	mg/kg	BLQ (LOQ - 0.01)	
19	Dimethoate (including Omethoate)	mg/kg	BLQ (LOQ - 0.01)	
20	Edifenphos	mg/kg	BLQ (LOQ - 0.01)	
21	Ethion	mg/kg	BLQ (LOQ - 0.01)	
22	Etrimphos	mg/kg	BLQ (LOQ - 0.01)	
23	Fenitrothion	mg/kg	BLQ (LOQ - 0.01)	
24	Fenthion	mg/kg	BLQ (LOQ - 0.01)	
25	Iprobenphos	mg/kg	BLQ (LOQ - 0.01)	
26	Malathion (sum of malathion and malaoxon expressed as malathion)	mg/kg	BLQ (LOQ - 0.01)	
27	Methamidophos	mg/kg	BLQ (LOQ - 0.01)	
28	Monocrotophos	mg/kg	BLQ (LOQ - 0.01)	
29	Omethoate (refer to Dimethoate)	mg/kg	BLQ (LOQ - 0.01)	
30	Oxydemeton-methyl (sum of oxydemeton methyl and demeton-S-methyl sulfone expressed as oxydemeton methyl)	mg/kg	BLQ (LOQ - 0.01)	
31	Parathion ethyl	mg/kg	BLQ (LOQ - 0.01)	
32	Parathion methyl (sum of parathion methyl and paraoxon methyl expressed as parathion methyl)	mg/kg	BLQ (LOQ - 0.01)	
33	Phenthoate	mg/kg	BLQ (LOQ - 0.01)	
34	Phorate (sum of phorate, its oxygen analogue and their sulfones expressed as phorate)	mg/kg	BLQ (LOQ - 0.01)	
35	Phosalone	mg/kg	BLQ (LOQ - 0.01)	
36	Phosphamidon	mg/kg	BLQ (LOQ - 0.01)	
37	Pirimiphos methyl	mg/kg	BLQ (LOQ - 0.01)	
38	Profenophos	mg/kg	BLQ (LOQ - 0.01)	
39	Propetamphos	mg/kg	BLQ (LOQ - 0.01)	
40	Quinalphos	mg/kg	BLQ (LOQ - 0.01)	
41	Temephos	mg/kg	BLQ (LOQ - 0.01)	
42	Thiometon	mg/kg	BLQ (LOQ - 0.01)	
43	Triazophos	mg/kg	BLQ (LOQ - 0.01)	

..... Contd .....

M. Murugan
Assistant Manager

Bureau Veritas
Consumer Products Services (I) Pvt Ltd.
F2, Thiru. Vi. Ka. Industrial Estate,
Phase III, Ekkattuthangal, Guindy, Chennai-600 032.
Phone : +91 44 - 4967 4000, 4967 4002
Fax : +91 44 - 4967 4001
Email : bvcpschennai.enquiry@in.bureauveritas.com
Web : www.bureauveritas.co.in/cps

Sl No. : 2017 / **12978**

Terms and Conditions:

- The test results relate only to the items tested.
- The test report shall not be reproduced in full or part without the written approval of BVCPS.
- The test items will not be retained for more than 15 days from the date of issue of test report excepts in the case as required by the applicable regulations.
- The Laboratory's responsibility under this report is limited to proven wilful negligence and will in no case be more than the invoiced amount.
- A satisfactory test report in no way implies that the product so tested is approved by NABL.
- Laboratory is not responsible for the authenticity of photocopied test reports.

TEST REPORT

Report No. : 7817-181-0025

Report Date : 07.07.2017
Page : 3 of 3

Sl. No	Test Parameter	Units Of Measurement	Result	Method of Testing
III. Synthetic Pyrethroids:				
44	Allethrin and Bioallerthin	mg/kg	BLQ (LOQ - 0.01)	EURL Method by GC MSMS / LC MSMS
45	Bifenthrin	mg/kg	BLQ (LOQ - 0.01)	
46	Cypermethrin (including other mixture of constituent isomers sum of isomers)	mg/kg	BLQ (LOQ - 0.01)	
47	Cypermethrin (including other mixture of constituent isomers sum of isomers)	mg/kg	BLQ (LOQ - 0.01)	
48	Deltamethrin	mg/kg	BLQ (LOQ - 0.01)	
49	Ethofenprox (Etofenprox)	mg/kg	BLQ (LOQ - 0.01)	
50	Fenpropathrin	mg/kg	BLQ (LOQ - 0.01)	
51	Fenvalerate (sum of RR & SS isomers)	mg/kg	BLQ (LOQ - 0.01)	
52	Lambda-cyhalothrin	mg/kg	BLQ (LOQ - 0.01)	
53	Permethrin (sum of isomers)	mg/kg	BLQ (LOQ - 0.01)	
54	tau-Fluvalinate	mg/kg	BLQ (LOQ - 0.01)	
55	Transfluthrin	mg/kg	BLQ (LOQ - 0.01)	
Microbiological:				
1.	*E.coli*	Per g	Absent	API Volume -II
2.	*Pseudomonas aeruginosa*	Per g	Absent	
3.	*Salmonella*	Per g	Absent	
4.	*Staphylococcus aureus*	Per g	Absent	

ND - Not Detected / DL - Detection Limit / BLQ: Below Limit of Quantification / LOQ - Limit of Quantification

.....End .....

Report Prepared by : C.Selvaraj

M. Shanthi
Asst. Manager

M. Murugan
Assistant Manager

Bureau Veritas
Consumer Products Services (I) Pvt Ltd.
F2, Thiru. Vi. Ka. Industrial Estate,
Phase III, Ekkattuthangal, Guindy, Chennai-600 032.
Phone : +91 44 - 4967 4000, 4967 4002
Fax : +91 44 - 4967 4001
Email : bvcpschennai.enquiry@in.bureauveritas.com
Web : www.bureauveritas.co.in/cps

Sl No. : 2017 / **12979**

Clinical Trial Details (PDF Generation Date :- Tue, 04 Jul 2017 16:28:36 GMT)

CTRI Number	CTRI/2017/02/007753 [Registered on: 01/02/2017] - **Trial Registered Prospectively**
Last Modified On	27/01/2017
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Drug Siddha Screening
Study Design	Single Arm Trial
Public Title of Study	Efficacy Of Vilva Ennai in sore throat.
Scientific Title of Study	clinical evaluation of vilva ennai(a siddha drug) in the treatment of valikanam (acute pharyngitis) in children.

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

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

Details of Principal Investigator	
Name	Dr K Abinaya
Designation	PG Scholar
Affiliation	National institute of siddha
Address	Department of Kuzhandhai Maruthuvam National institute of siddha Ayothidoss pandithar hospital Tambaram sanatorium Chennai 47 National institute of siddha Ayothidoss pandithar hospital Tambaram sanatorium Chennai 47 Chennai TAMIL NADU 600047 India
Phone	7667773440
Fax	
Email	dr.abikrishna@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr M Meenatchi suntharam
Designation	Associate professor
Affiliation	National Institute of Siddha
Address	Department of kuzhanthai maruthuvam National institute of siddha Ayothidoss pandithar hospital Tambaram sanatorium Chennai 47 National institute of siddha Ayothidoss pandithar hospital Tambaram sanatorium Chennai 47 Kancheepuram TAMIL NADU 600047 India
Phone	9940266442
Fax	
Email	mmssiddha@rediffmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr M Meenatchi suntharam
Designation	MD Siddha
Affiliation	National Institute of Siddha
Address	National institute of siddha Ayothidoss pandithar hospital Tambaram sanatorium Chennai 47 National institute of siddha Ayothidoss

		pandithar hospital Tambaram sanatorium Chennai 47 Kancheepuram TAMIL NADU 600047 India
	Phone	9940266442
	Fax	
	Email	mmssiddha@rediffmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> SELF

Primary Sponsor

Primary Sponsor Details	
Name	National Institute of Siddha
Address	Department of kuzhandhai maruthuvam National institute of siddha ayothidoss pandithar hospital Tambaram sanatorium chennai-47
Type of Sponsor	Research institution and hospital

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr K Abinaya	NATIONAL INSTITUTE OF SIDDHA	OP NO 9 Department of Kuzhandhai maruthuvam National Institute of Siddha Ayothidoss pandithar hospital Tambaram sanatorium Chennai 47 Kancheepuram TAMIL NADU	7667773440 dr.abikrishna@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethical Committee	Approved	26/08/2015	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Patients with the symptoms of cough fever sore throat loss appetite

Intervention / Comparator Agent

Type	Name	Details
Comparator Agent	NOT APPLICABLE	NOT APPLICABLE
Intervention	VILVA ENNAI	VILVA ENNAI is a polyherbal formulation sirukarandi(3ml) 8-12 years(od) oral route 5 days

Inclusion Criteria

Inclusion Criteria	
Age From	8.00 Year(s)
Age To	12.00 Year(s)
Gender	Both
Details	Patients with symptoms of cough Low grade fever

		Sore throat Loss of appetite

Exclusion Criteria

Exclusion Criteria	
Details	H/O congenital heart disease H/O Tonsillitis H/O Bronchial asthma H/O Primary complex H/O Long term fever

Method of Generating Random Sequence	Not Applicable
Method of Concealment	Not Applicable
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
Number and screening of clinical symptoms are slightly reduced such as cough sore throat fever lack of appetite etc	5 days

Secondary Outcome

Outcome	Timepoints
Clinical efficacy of the trail drug and its side effects if any.	15 days

Target Sample Size	**Total Sample Size=**40 **Sample Size from India=**40
Phase of Trial	Phase 2
Date of First Enrollment (India)	15/02/2017
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	NONE YET
Brief Summary	In siddha system of medicine, symptoms of valikanam are described as cough, low grade fever, lack of appetite, rumbling noice in stomach, dysuria, exessive thirst and it may be correlated with acute pharyngitis. In our NIS OPD many number of cases are approaching kuzhandhai maruthuvam department daily with the symptoms of vali kanam. so i select this drug vilva ennai which consist of vilva elai saru, avuri saru, vellai vengaya saru, kadukai, citramanakennai which is boild till it reaches the oil consistency. To evaluate the efficacy of vilva ennai (a siddha drug) in the treatment of vali kanam (acute pharyngitis) in children.