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PRECLINICAL AND CLINICAL STUDY ON

AZHAL KEEL VAAYU

(DISSERTATION SUBJECT)

For the partial fulfillment of the Requirements to the Degree of

DOCTOR OF MEDICINE (SIDDHA)

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INTRODUCTION

Siddha system of medicine is a potent and unique indigenous system of medicine, which deals with the diseases of men efficiently with the knowledge of both subtle and also the gross material body. The main aim of Siddhars is attaining eternal things through spirituality. They found diseases as one of the obstacles to reach spiritual. So they bestowed to the world the Siddha medicines to cure diseases.

They had investigated that the body, though transient was the one and only instrument for attaining success in the spiritual development and growth and so worked out to attain the eight supernatural powers, as Anima, Magima, Lagima, etc., essential for their goal, as mentioned in Silappathigaram. They further realized that if the body could only be made strong and perfect they could get rid of birth and death and live for ages together. They are the greatest men holding tremendous powers in themselves by way of yoga practice and rejuvenation. They are capable of enjoying spiritual success in their mortal bodies.

According to Siddha science, the human body is composed of five elements viz., Earth, Water, Fire, Air and Ether. This is in fact just takes place in the case of dead bodies. The following instances will show the transformed conditions of the five elements in the human body:

1. Earth - Bones, flesh, nerves, Skin and Hair.
2. Water - Bile, Blood, Semen, Secretion and Sweat
3. Fire - Hunger, Thirst, Sleep, Beauty and Indolence.
4. Air - Contraction, Expansion and Motion.
5. Ether - Interspaces of the stomach, Heart and the Head.

All earthly things live, move, grow and die to be resolved themselves again into five elements after death. They are the fundamental principles of creation, preservation and destruction in the universe. On examine their functions, it should be known first, that these elements first combine with one another to form cells, the requiste materials or organism for the animal body; and secondly, they discharge the functional forces called cellular activities, which are in themselves, the guiding principles of mind and the body.

1. The creative activity in the physical body is known as Vaatham.
2. The protective one as Pitham.
3. The destructive one is Kabam. (Phelgm)

In normal healthy condition these three vital humours exists with the ratio of 1:1/2:1/4 respectively, when the normal of these humours disturbed, disease will occur.

According to Siddha literature, Azhal Keel Vayu is one among the Vaatha diseases. Normally joints are considered to be the place for the vital humour called Iyam. When it is affected by deranged Vaatham and Pitham it will leads to Azhal Keel Vayu and it is characterized by pain, swelling and restricted movements. Sometimes it may leads to difficulty in walking.

This condition can be correlated to Osteoarthritis in Modern Orthopedics. Osteoarthritis is defined as a degenerative, non - inflammatory joint disease characterized by destruction of articular cartilage and formation of new bone at the joint surfaces and margins. Recent study suggests that Osteoarthritis beats all other most prevalent diseases.

Primary osteoarthritis is a common disorder of the elderly, and patients are often asymptomatic. Approximately 80-90% of individuals older than 65 years have evidence of primary osteoarthritis. Patients with symptoms usually do not notice them until after age 50 years. The prevalence of the disease increases dramatically among persons over age 50, likely because of age-related alterations in collagen and proteoglycans that decrease the tensile strength of the joint cartilage and because of a diminished nutrient supply to the cartilage.

There is considerable number of patients reporting daily for the treatment for Azhal Keel Vayu in National Institute of Siddha. Hence the author has chosen this disease for Dissertation study.

In Siddha literatures, many poly herbal and herbo mineral formulations were mentioned for this particular condition. Hence the author is interested to try cost effective remedy to the patients as said in Siddha literatures which the application of basic principles of Siddha and also supporting by Modern parameters.

The drugs **Avuri Karpam** (Internal drug, Reference: Pathartha Guna Vilakkam; Pg no: 43) and **Vatha Noikku Ennai** (External drug, Reference: Theraiyar Vagadam; Pg no: 64) are indicated for Vaatha diseases including Azhal Keel Vayu. These drugs have not so far been evaluated for Azhal Keel Vayu.

Hence the author has chosen “Avuri Karpam” as internal drug and and “Vatha Noikku Ennai” for external application to evaluate their efficacy in treating Azhal Keel Vayu (Osteoarthritis) along with varmam.

AIM AND OBJECTIVES

Primary objective

- To evaluate the Therapeutic efficacy of "**Avuri Karpam**"(Internal medicine) and "**Vatha Noikku Ennai**" (External medicine) in the Treatment of "**Azhal Keel Vayu**" (Osteoarthritis) for the reduction of pain, swelling and to improve the range of movements.

Secondary objectives:

- To study the effectiveness of Varmam along with the efficacy of "Avuri Karpam" (Internal medicine) and "Vatha Noikku Ennai" (External medicine) in the Treatment of "Azhal Keel Vayu (Osteoarthritis)".
- To study Azhal Keel Vayu, on the basis of Siddha principles like Envagai thervu, Mukkutram, Kaalam, Naadi, Neerkkuri, Neikkuri etc, in order to evaluate the pathology.
- To access the predominance of the disease related to age, sex, socio-economic status, habits, family history etc.
- To evaluate the safety of the trial drug by doing toxicological studies in animal models.
- To find out any side effect/adverse effect during the trial.

SIDDHA ASPECTS

The concepts of Siddha system are based on fundamental principles of 96 - Thathuvams. Vaatham, Pitham, Kabam are called as three humours of the human system. When the hormony of the above said humours gets deranged owing to a relative increase or decrease of one or more of the principal humours, disease is caused. The normal ratio of Vaatham, Pitham and Kabam is 1: 1/2:1/4 respectively. It is explained in the following verse,

"வழங்கிய வாதம் மாத்திரை யொன்றாகில்
தழங்கிய பித்தந் தன்னிலரை வாசி
அழங்குங் கபந்தானடங்கியே காலோடில்
பிறங்கிய சீவர்க்கும் பிச கொன்றுமில்லையே"

- குணவாகடம்.

The alteration in the normal produces disease. The signs and symptoms are produced according to the particular deranged kuttrams.

AZHAL KEEL VAAYU

In Siddha literature Azhal keel vaayu described under Vaatha diseases. Keel vaayu is the general term that includes all kinds of joint disorders.

Description of the nomenclature

Azhal keel vaayu	=	Azhal + Keel + Vaayu
Azhal	=	Pitham
Keel	=	Joint
Vaayu	=	Vaatham

Initially the joint is affected by the vitiated Vaatham. Pitham and Kabam accompany later. It is a disease which is common in Pitha kaalam (middle 1/3 of the lifespan).

TYPES OF KEEL VAAYU

Azal keel Vaayu is one among the ten types of Keel vaayu, which is mentioned in the text Siddha Maruthuvam, the ten types of Keel vaayu are:

1. Vali keel vaayu
2. Azhal keel vaayu
3. Iyya keel vaayu
4. Vali Azhal keel vaayu

5. Vali Iyya keel vaayu
6. Azhal Vali keel vaayu
7. Azhal Iyya keel vaayu
8. Iyya Vali keel vaayu
9. Iyya Azhal keel vaayu
10. Mukkutra keel vaayu

AETIOLOGY:

1. Environmental factors:

"வாத வர்த்தன காலமேதோ வென்னில்
மருவுகின்ற ஆனி கற்கட மாதம்
ஆதனைப் பசியோடு கார்த்திகை தன்னில்
ஆடருமே மற்ற மாதங்கள் தன்னில்
போகவே சமிக்கின்ற கால மாகும்".

- யூகி வைத்திய சிந்தாமணி

It is said that the Vaatha diseases are precipitated in the months from Aani to Karthigai (June to December), hence the seasonal factors are involved and facilitate the Vaatha diseases.

2. Diets that increase Vaatha diseases:

"வளி காய்கிழங்கு வரைவிலா தமிலல் கோழை
புளிதயிர் போன்மிருக்கு முறையிலா வுண்டி கோடல்
குளிர் தரு வளியிற் றேகங் குனிப்புற வுலவல் பெண்டிர்
குளிதரு முயக்கம் பெற்றோர் கடிசெயல் கருவியாமால்".

- சபாபதி கையேடு

“தொழில் பெறு கைப்புக் கார்த்தல் துவர்த்தல் விங்சுகினுங்சோறும்
பழையதாம் வரகு மற்றைப் பைந்தினை யருந்தினாலும்
எழில் பெறப் பகலுறங்கி இரவினிலுறங்காத தாலும்
மழைநிகா குழலினாலே வாதங்கோ பிக்குங் காணே".

- பரராச சேகரம்

Vaatha disease is caused by the following reasons:

- Excessive intake of tubers
- Excessive intake of chill foods

- Excessive intake of bitter, astringent, acrid taste foods
- Intake of varagu, thinai.
- Wandering in chill air
- Getting drenched in rain
- Living in hilly region
- Heredity and
- Altered sleep pattern also contribute to Vaatha disease.

3. Habits:

“தானென்ற கைப்போடு துவர்ப்புவர்ப்பு
சாதகமாய் மிஞ்சுகிலும் சமைத்த அன்னம்
ஆனென்ற ஆறினது புசித்தலாலும்
ஆகாசத் தேற்றநீர் குடித்தலாலும்
யானென்ற பகலுறக்கம் இராவிழிப்புப்
பட்டினியே மிகவுறுதல் பாரமெய்தல்
தேனென்ற மொழியார் மேல் சிந்தையாதல்
சீக்கிரமாய் வாதமது செனிக்குந்தானே”

-யூகிமுனி வைத்திய சிந்தாமணி

"வெய்யிலில் நடக்கையாலும் மிகக்தண்ணீர் குடிக்கையாலும்
செய்யிழை மகளினரைச் சேர்ந்தனுப விக்கையாலும்
பையனே உண்மையாலும் பாகற்காய் தின்கையாலும்
தையலே வாதரோகம் சனிக்கு மென்றறிந்து கொள்ளே".

- தேரையர் வாகடம்

The factors like, excessive walking in sun and excessive in take of bitter guard etc, also disturbs the normal functions of Vaatham.

4. Involvement of Mukkutram ie Vaatham, Pitham and Kabam:

- Abanan and Viyanan are affected in Vaatham.
- In Pitham, Sathaga pitham is affected.
- Santhigam is affected in Iyyam.

5. Characteristic features of Vaatham:

"வாதமே கதித்த போது வாயுவுமெழும்புங் காண்பீர்
வாதமே கதித்த போது வாயுவந்திடுஞ் சன்னி தோஷம்
வாதமே கதித்த போது வல்லடுன் மெலிந்து கொல்லும்"

- அகத்தியர் சிகிச்சா ரத்னா தீபம்

"வாத வீறு அன்னமிறங்காது கடுப்புண்டாம் வண்ணமுண்டாம்
மோதுகட்கு ரோகம் சுரமுண்டா மிருமலுமா முறங்காதென்றும்
ஓதரிய வாதமனலாகு நடுக்கமுண்டாம் பொருள் களயர்ந்த
தீதெனவே நரம்பித்து சந்துகள் தோறுங்கடக்குந் தினமுந்தானே"

- தேரையர் வாகடம்

When the Vaatha kuttram aggravates in will produce the following signs and symptoms:

- loss of appetite,
- excruciating pain,
- fever,
- cough,
- insomnia,
- shivering of the body,
- nervous weakness,
- Joint pain.

Clinical features of Keel Vayu:

"பித்த கீல்வாயு தன்னாற் கீல்மூட்டுவீங்கிச்
சித்தர் செய்மருத்துவச் சீர்படாத
தக்கறு காய்ச்சல் கண்டு சாலவே தனைதான தந்தே
மெத்தறு சிகிச்சை தன்னதல் மென்மேல் நீக்குமப்பா"

- சபாபதி கையேடு

It is characterized by swelling of joints associated with severe pain and fever.

Since it is not quickly responding to medicine the prolonged medical care is said to be essential.

Diagnosis in Siddha:

Piniyari muraigal (Method of Diagnosis) is based upon three main principles,

1. Poriyal Arithal
2. Pulanal Arithal
3. Vinaathal

1. Poriyal Arithal (Inspection):

"Poriyal arithal" means examining the "Pori" of the patient by the "Pori" of the physician for proper diagnosis. Pori is considered as the "Five sense organs" of perception namely,

1. Mei (Skin)
2. Vai (Tongue)
3. Kan (Eye)
4. Mookku (Nose)
5. Sevi (Ear)

2. Pulanal arithal (Palpation):

Pulanal arithal means examining the "Pulan" of the patient by the "Pulan" Physician to diagnose a disease. Pulan are five senses. They are,

1. Smell
2. Taste
3. Vision
4. Sensation of touch
5. Hearing

3. Vinaathal (Interrogation): Vinaathal is gathering information regarding the history of disease, its clinical features etc., from the patient or his/her close relatives useful when the patient is not in a position to speak or in the case of a child.

ENVAGAI THERVUGAL (Eight diagnostic Tools):

It is a unique method of diagnosis in Siddha system of medicine. They are clearly explained by Siddhar Theraiyar;

"நாடி ஸ்பரிசம் நா நிறம் மொழி விழி
மலம் மூத்திரமிவை மருத்துவராயுதம்"

- *தேரையர்*

1. Naadi (Pulse):

"திருத்தமாம் வாதத்தோடே தீங்கோடு பித்தம் சேரிற்
பொருத்துகள் தோறும் நொந்து போதவே பிடிக்கும்"

- நோயின் சாரம்

"வாட்டிடும் சேத்துமத்தில் வந்திடும் வாதமாகில்
நாட்டிய கால்கள் போல நரம்பெல்லாம் வலித்து நிற்கும்"

-அகத்தியர் நாடி

In Azhal Keel Vaayu the following Naadi can be seen commonly:

Vaathapitham, Vaathakabam, Pithavaatham, Pithakabam, Kabavaatham

2. Sparism (Sensation to touch):

In Azhal keel vaayu mild warmth noticed over the affected joint.

3. Naa (Tongue):

In Azhal keel vaayu no abnormality is seen in Naa.

4. Niram (Colour):

In Azhal keel vaayu no abnormality is seen in Niram.

5. Mozhi (Voice):

In Azhal keel vaayu no abnormality is seen.

6. Vizhi (Eyes):

In Azhal keel vaayu no abnormality is seen.

7. Malam (Faeces):

In Azhal keel vaayu constipation was reported in some cases.

8. Moothiram (Urine):

In urine (Moothiram) Neerkkuri and Neikkuri (Oil on urine sign) examination are also done.

a. Neikkuri:

"அருந்து மாறிரதமும் அவிரோமதாய்
அஃகல அலவர்தல் அகாலவூன் தவிர்ந்தழற்
குற்றள வருந்தி உறங்கி வைகறை
ஆடிக் கலசத் தாவியே காதுபெய்
தோரு முகூர்த்தக் கரைகுட் படுநீரின்
நிறக்குறி நெய்க்குறி நிருமித்தல் கடனே"

- சித்த மருத்துவாங்கச் சுருக்கம்

Prior to the day of urine examination the patient is instructed to take a balanced diet and quantities of food must be proportionate to his routine intake. The patient could have no disturbed sleep. After waking up in the morning, the first urine voided is collected in a clear wide mouthed glass dish or China clay container and is subjected to analysis of "Neerkkuri and Neikkuri" within one and a half an hour.

The collected specimen was examined by the following method. The collected urine specimen is kept in a glass dish or china clay container and observed under direct sunlight without shaking the vessel. Then drip one drop of gingely oil and observe the spreading pattern and concludes as follows,

"அரவென நீண்டீடின் அஃதே வாதம்
ஆழிபோல் பரவின் அஃதே பித்தம்
முத்தொத்து நிற்கின் மொழிவதென் கபமே
அரவில் ஆழியும் ஆழியில் அரவும்
அரவில் முத்தும் ஆழியில் முத்தும்"

- சித்த மருத்துவ நோய்நாடல் நோய் முதல் நாடல் திரட்டு

b. Neerkkuri:

"வந்த நீர்க்கரி யைடை மணம் நுரை எஞ்சலென்
றைந்திய லுளவை யறைகுது முறையே"

- சித்த மருத்துவாங்கச் சுருக்கம்

Urine is examined for the following neerkkuri:

- Niram - Colour
- Edai - Specific Gravity
- Manam - Smell
- Nurai - Frothy nature
- Enjal - Quantity of urine voided

Apart from these, frequency of urination, abnormal constituents, such as sugar, protein, presence of blood, pus, presence of crystals also to be found out.

In Azhal keel vaayu straw or hay coloured urine was noticed in Neerkkuri.

PARUVAKAALAM (Seasonal variations):

"வாதவர்த்தனை காலமெதோ வென்னில்
மருவுகின்ற ஆனிகற் கடமாகும்
ஆத அற்பசியோடு கார்த்திகை தன்னில்
அடருமே மற்றமாதங்கள் தன்னில்
போதவே சமிக்குகின்ற காலமகும்
பொருந்தியே யிவர்தொழில்தான் கண்திறத்தல்
காதவே கண்மூடல் கைகாலசைத்தல்
கடிந்தொட்ட முடக்கலோடு நீட்டலென்னே"

-யூகிமுனி வைத்திய சிந்தாமணி

Sl. No	STATE OF KUTTRAM	KAALAM
1.	Vaatham thannilai adaithal	Munpani kaalam, Pinpani kaalam,Koothir kaalam, Elavenil kaalam
2.	Vaatham thannilai valarchi	Muthuvenil kaalam
3.	Vaatham vetrunilai valarchi	Karkaalam

THINAI (Geographical Distribution):

It is divided into five types. They are,

- Kurinji - Mountainous regions and surroundings
- Mullai - Forest region and surroundings
- Marutham - Paddy fields and surroundings
- Neithal - Sea and coastal regions
- Palai - Desert land

Geographical distribution plays a vital role in altering Mukkutrams. According to Siddha, Vaatha diseases are predominant in Mullai and Neithal Thinai.

UDAL KATTUGAL:

Our body consists of seven Udal kattukal. It gives strength and structure to our body. Their functions are:

SL. No	UDAL KATTUGAL	FUNCTIONS
1.	Saaram	It gives strength to the body and mind.
2.	Senneer	Saram after absorption is converted into senneer. It is responsible for knowledge strength, boldness and healthy complexion.
3.	Oon	Gives structure and shape to the body and is responsible for the movements of the body.
4.	Kozhuppu	Lubricates the organs on its own works.
5.	Enbu	Protects the vital organs and used for movements and nominates the body structure.
6.	Moolai	Absent inside the bones and it gives strength and maintains the normal Condition of the bone.
7.	Sukkilam(or) suronitham	Responsible for the reproductive function of species.

SL. No	UDAL KATTUKAL	INCREASED CONDITIONS	DECRESED CONDITIONS
1.	Saaram	Loss of appetite, excessive salivation	Tiredness, Laziness, Diminished activity of the sense organs.
2.	Senneer	Boils and tumours in different Parts of the body, Splenomegaly, Colic pain, increased blood Pressure, reddish eye and skin,	Tiredness, Lassitude, Anaemia

3.	Oon	Tumours or extra growth around the neck, face, abdomen, thigh.	Muscle wasting
4.	Kozhuppu	Tumours or extra growth around the neck, face, abdomen, thigh, Genitalia etc., with dyspnoea and	Pain
5.	Enbu	Strong bones and teeth	Weak bones, teeth, nails and hair.
6.	Moolai	Heaviness, swollen eyes, Swollen phalanges, oliguria and	Osteoporosis and shrunken eyes
7.	Sukkilam or Suronitham	Increased sexual activity and signs identical to urinary calculi	Failure to reproduce, pain in genitalia

In Azhal keel vaayu,

Saaram, Kozhuppu, Moolai and Enbu thathukkal are commonly affected.

Saaram: Weakness, pain in knee joints

Kozhuppu: Morning stiffness occurs in affected knee joints

Enbu: Pain occurring in affected knee joints, crepitations Absent

Moolai: Inflammation, degeneration, swelling etc.

MUKKUTRAM:

Human body is influenced by Mukkutrams ie Vaatham, Pitham and Kabam. They are responsible for normal physiological conditions of the body. Vaatham is mainly responsible for proper loco-motor functions. Bones and joints are considered to be the main location of vaatha.

In Azhal keel vaayu the vaatha kutram is mainly affected followed by Pitham and Kabam. This produces the following signs and symptoms,

- Deranged Viyanan leads to pain and difficulty in movements.
- Deranged Abanan leads to constipation.
- Inflammatory changes of the joints, redness and warmth are developed due to deranged Pitham.
- Sathaga Pitham gets affected hindering the loco motor functions.

- Along with Vaatham, Kabam is also deranged, Santhikam is affected and this leads to abnormality in joint movements.
- Erosions of bone margin, increased secretion of synovial fluid are developed due to deranged fluid are developed due to deranged Kabam.

NAME	LOCATION	PHYSIOLOGIC FUNCTIONS
Abanan	Lower abdomen and Extremities	Responsible for urination, defecation and parturition, Menstruation, ejaculation of the sperm.
Viyanan	Heart	Responsible for movements of all parts of the body and sensation.
Samanan	Stomach	Responsible for proper digestion

VAATHAM:

In Azahal keel vaayu

- Abanan is affected and so constipation is produced.
- Viyanan is affected it renders difficulty in movements of the knee joints.
- Samanan is also affected because disturbed state of other Vaayus.

PITHAM:

In Azhal keel vaayu, Sathaga Pitham affected and produces difficulty in walking, climbing upstairs, squatting and sitting postures.

KABAM:

Kaba kutram stabilizes and maintains the movements of the joints and gives lubrications to all movements.

In Azhal keel vaayu Santhigam is affected and produce difficulty in movements of the knee joints.

IMPORIGAL:

Gnanenthiriyam are Mei, Vaai, Kan, Mooku and Sevi.

In Azhal keel vaayu no abnormalities are seen in Gnanenthiriyam.

KANMENTHIRIYAM:

Kanmenthiriyam are Kai, Kaal, Vaai, Eruvaai, Karuvai.

In Azhal keel vaayu "Kaal" is affected and because of pain and swelling, morning stiffness and deformities.

NOI KANIPPU VIVATHAM (DIFFERENTIAL DIAGNOSIS):

Azhal keel vaayu is differentiated from the followings diseases,

1. VALI KEEL VAAYU:

It is characterized by excruciating pain and swelling involving knee joints, hip joints, elbow joints, shoulder joints and associated with systemic disturbances like dryness of mouth, pyrexia, headache, palpitation, constipation and sweating. In advanced cases it may affect the heart and produce "Thamaraga vaayu".

2. IYA KEEL VAAYU:

It is characterized by severe pain in the joints associated with emaciation of the body, anorexia, insomnia, cough, hiccough, vomiting, anaemia and dropsy. The common sites are spinal cord, hip joints and knee joints.

3. VALI IYA KEEL VAAYU:

It is characterized by pain in the joints associated with effusions of joint fluid and swelling, restricted joint movements, pyrexia, fainting, insomnia, especially in knee joint asymmetrically, lymphadenopathy, generalized malaise, atrophy of the affected limb etc. The affected joint looks like "Fox's Head".

LINE OF TREATMENT

In Siddha system the main aim of the treatment is to cure Udarpini (due to Mukkuttram) and Manapini (due to changes in Mukkunam). Treatment is not only for perfect healing but also for the prevention and rejuvenation.

It is essential to know the disease, the aetiology, the nature of the patient, severity of the illness, the seasons and the time of occurrence must be observed clearly.

Line of treatment is as follows:

1. Neekkam (Treatment)
2. Niraivu (Rejuvenation)
3. Kaapu (Prevention)

Thiruvalluvar describes the duty of the physician, i.e. study the disease, aetiology, seek subsiding ways and do what is proper and effective.

"நோய் நாடி நோய் முதல் நாடி அது தணிக்கும்
வாய் நாடி வாய்ப்பச் செயல்"
"உற்றானளவும் பிணியளவுங் காலமும்
கற்றான் கருதிச் செயல்"

- திருக்குறள்.

1) **NEEKKAM (Treatment in Siddha):**

The aim of Neekkam is based on

- To bring the deranged Thodams to normal equilibrium state.
- To treat the patient with internal medicine and external medicine.

Siddha system of Medicine is based on Mukkutra Theory and hence the treatment is mainly aimed to bring the three thodams to equilibrium state and thereby restoring the physiological condition of the seven Thathus.

The three Thodams organise, regularise and integrate the body structure and their functions. They are always kept in a state of balance by thought, word, deed and food. Any imbalance will lead to disease. The imbalanced thodams are balanced by administrating purgatives or emetics or application of Anjanam (application on eyes) and followed by the appropriate systemic therapy by giving Siddha drugs. It mentioned as below:

"விரேசனத்தால் வாதந் தாழும்"
"வமனத்தால் பித்தம் தாழும்"
"நசிய அஞ்சனத்தால் கபம் தாழும்"

- சித்த மருத்துவாங்கச் சுருக்கம்

The purgatives should be given before starting the trial to normalize the deranged Thodams to normal.

In this study the purgation is induced by giving Agasthiyar kulambu - 130 mg with hot water in early morning in empty stomach on the first day.

Then the next day onwards the trial drugs Avuri karpam – 1gm twice a day given with honey after food. Vatha Noikku Ennai – External application.

2) NIRAIVU (Rejuvenation):

The word literally means the power of securing the body from the effect of age.According to Siddhars science rejuvenation does not necessarily mean restoring the old to youth for it may simply mean the maintenance of youth without reaching the old age.

So rejuvenation is a means for prolonging life & forms a part of immortality.

- *T.V. Sambasivam pillai dict.*

(Physical, psychological, social and economic rehabilitation and reassurance of individuals is known as Niraivu).

3) KAPPU (Prevention):

The prevention methods for Azal keel vaayu are as follows:

- Control the body weight by diet and exercise.
- Modify the nature of work which gives stress to a particular joint.
  e.g. - Avoid prolonged standing and long distance walking.
- Avoid to intake excess sour, astringent and bitter tasted foods.

4) DIETARY RESTRICTIONS:

In siddha system of medicine the importance of dietary habits also emphasiszed for the diseases management and prevention. This line is well understood in these verses,

“உணவே மருந்து மருந்தே உணவு”.

“மருந்தென வேண்டாவாம் யாக்கைக்கு அருந்தியது
அற்றது போற்றி உணின்”.

- *திருக்குறள்*

In diseased condition diet restrictions or paththiyam are strictly followed to increase the effectiveness of medicine, and to reducing the severity of diseases. This is given in the following verse,

“பத்தியத்தினாலே பலன் உண்டாகும் மருந்து
பத்தியங்கள் போனால் பலன்போகும் - பத்தியத்தில்
பத்தியமே வெற்றிதரும் பண்டிதர்க்கு ஆதலினால்
பத்தியமே உத்தியென்று பார்”

- *தேரையர் வெண்பா.*

இச்சா பத்தியத்தில் நீக்கும் பொருட்கள்:

"கடுகு நற்றிலத் தெண்ணைய் கூழ்பாண்டங்கள் கடலை
வருவதாகிய தெங்குமா வருக்கை நற்காயம்
மடிவிலாத வெள்ளுள்ளிகொள் புகையிலை மதுபெண்
இடறு பாகலோ டகத்தி நீக்கிடலிச்சா பத்தியம்"

- சித்த மருத்துவாங்கச் சுருக்கம்

கடுகு, எள்நெய், கல்யாணபூசணிக்காய், கள், கடலை, தேங்காய், மாங்காய், பலா, காயம், உள்ளிப்பூண்டு, கொள், புகையிலை, பெண்கள் சேர்க்கை, பாகல், அகத்தி இவைகளை இச்சா பத்தியத்தில் நீக்க வேண்டும்.

"புளிதுவர் விஞ்சும் கறியால் பூரிக்கும் வாதம்"

- நோய் நாடல் நோய் முதல் நாடல் திரட்டு

புளிப்பு, துவர்ப்பு சுவையுள்ள உணவு வகைகளை நீக்க வேண்டும்.

மருத்துவ அறிவுரை:

- ஈரமில்லாத் தரையிலும், படுக்கையிலும் படுத்தல் வேண்டும்,
- குளிர் காற்று படும்படியான இடத்தில் இருப்பதைத் தவிர்க்கவும்.
- உடல் அதிக எடை இருப்பின் எடையைக் குறைக்க வேண்டும்.
- அதிக தூரம் நடத்தல், அதிக நேரம் நிற்றல் தவிர்க்கவும்.

Special treatments:

Varmam:

Varmam is a science dealing with the impact to innumerable nerve junctions of the human body. The changes occurring in the body on being hit at some specific points on the body directly or indirectly with a particular force is known as varmam.

VARMAM POINTS TO BE MANIPULATED ONCE EVERYDAY IN AZHAL KEEL VAYU PATIENTS:

- Kaal Moottu Varmam
- Moottu Suzharchi Varmam
- Komberi
- Viruthi
- Ullangal vellai
- Kutri Varmam .

MODERN ASPECTS

ANATOMY OF JOINTS:

Joints can be classified as synovial, fibrous, or combination joints, based on the presence or absence of a synovial membrane and the amount of motion that occurs in the joint. Normal synovial joints allow a significant amount of motion along their extremely smooth articular surface. The joints are composed of the following:

- Articular cartilage
- Subchondral bone
- Synovial membrane
- Synovial fluid
- Joint capsule.

The normal articular surface of synovial joints consists of articular cartilage (composed of chondrocytes) surrounded by an extracellular matrix that includes various macromolecules, most importantly proteoglycans and collagen. The cartilage protects the underlying subchondral bone by distributing large loads, maintaining low contact stresses, and reducing friction at the joint.

Synovial fluid is formed through a serum ultra filtration process by cells that form the synovial membrane (synoviocytes). Synovial cells also manufacture the major protein component of synovial fluid, hyaluronic acid (also known as hyaluronate). Synovial fluid supplies nutrients to the avascular articular cartilage; it also provides the viscosity needed to absorb shock from slow movements, as well as the elasticity required to absorb shock from rapid movements.

ANATOMY OF THE KNEE JOINT

Introduction:

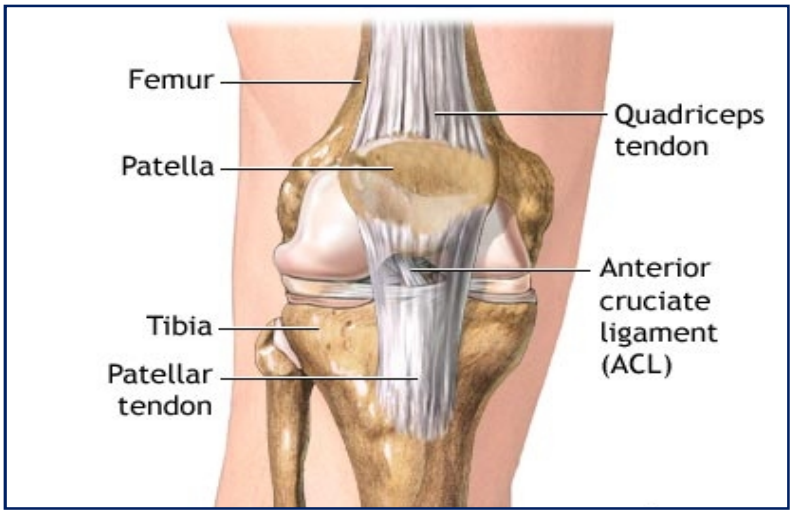
The knee joint is the largest joint in the body, consisting of four bones and an extensive network of ligaments and muscles. Injuries to the knee joint are amongst the most common in sporting activities and understanding the anatomy of the joint is fundamental in understanding any subsequent pathology.

Bones of the knee joint:

The knee is made up of four main bones. The femur (thigh bone), the tibia (shin bone), fibula (outer shin bone) and patella (kneecap). The main movements of the knee joint

occur between the femur, patella and tibia. Each are covered in articular cartilage which is an extremely hard, smooth substance designed to decrease the frictional forces as movements occurs between the bones. The patella lies in an indentation at the lower end of the femur known as the inter-condylar groove. At the outer surface of the tibia lies the fibula, a long thin bone that travels right down to the ankle joint.

Anatomy of the knee joint (right)



The capsule:

The knee joint capsule is a thick ligamentous structure that surrounds the entire knee. Inside this capsule is a specialized membrane known as the synovial membrane which provides nourishment to all the surrounding structures. Other structures include the infra-patellar fat pad and bursa which function as cushions to exterior forces on the knee. The capsule itself is strengthened by the surrounding ligaments.

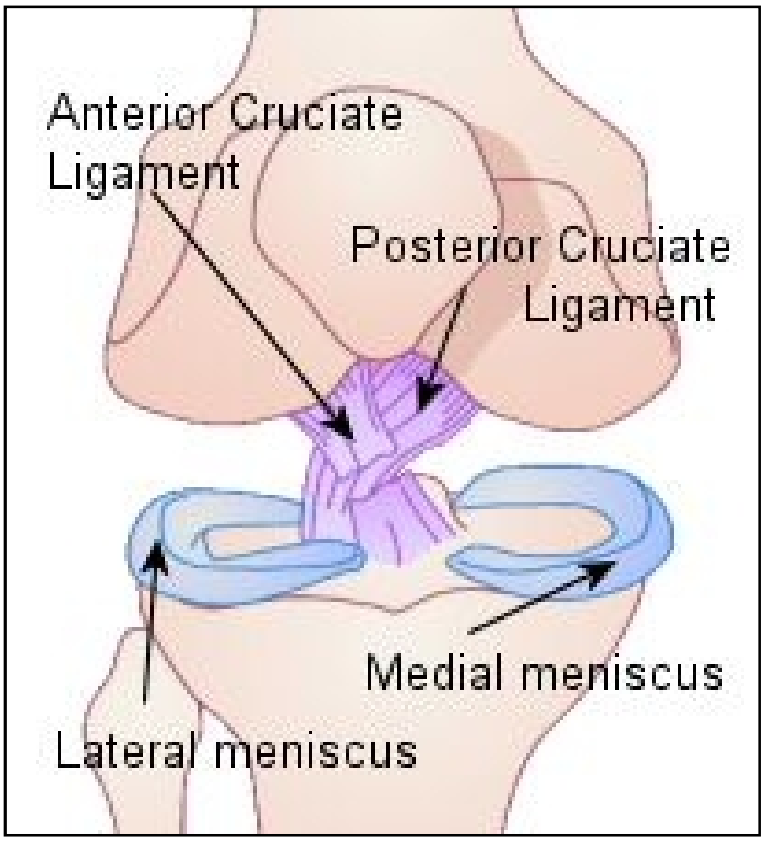
Ligaments of the knee joint:

The stability of the knee owes greatly to the presence of its ligaments. Each has a particular function in helping to maintain optimal knee stability in a variety of different positions.

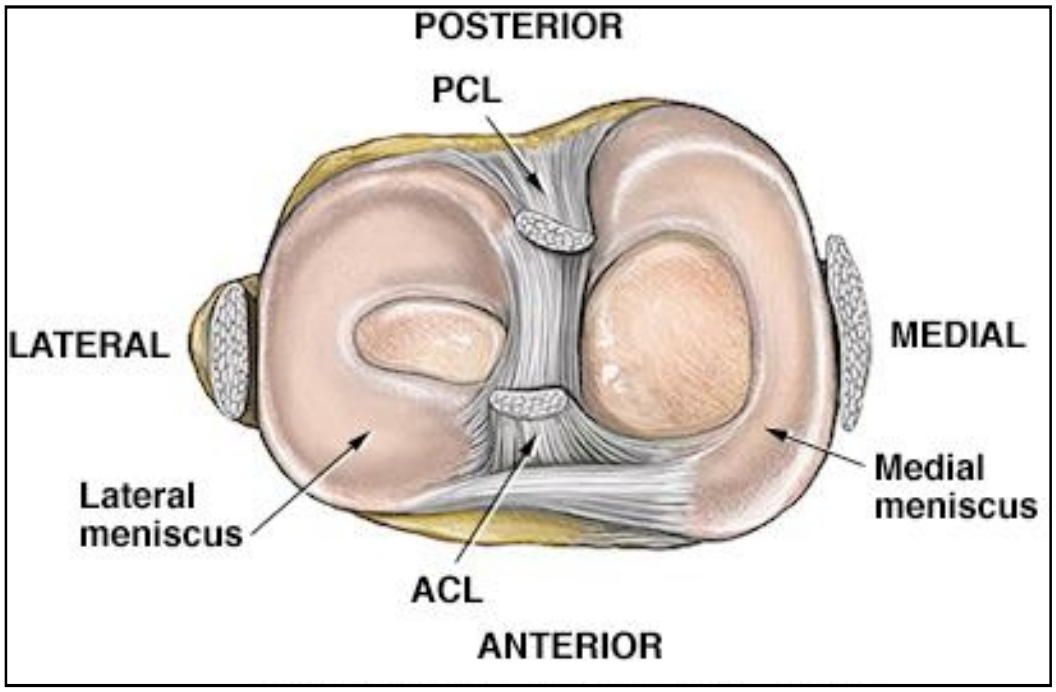
Menisci (knee cartilage):

Each knee joints has two crescent shaped cartilage menisci. These lie on the medial and lateral edges of the upper surface of the tibia bone. They are essential components, acting as shock absorbers for the knee as well as allowing for correct weight distribution between the tibia and the femur.

Ligaments knee joints



Menisci



Muscle groups surrounding the knee joint:

The two main muscle groups of the knee joint are the quadriceps and the hamstrings. both play a vital role in moving and stabilizing the knee joint.

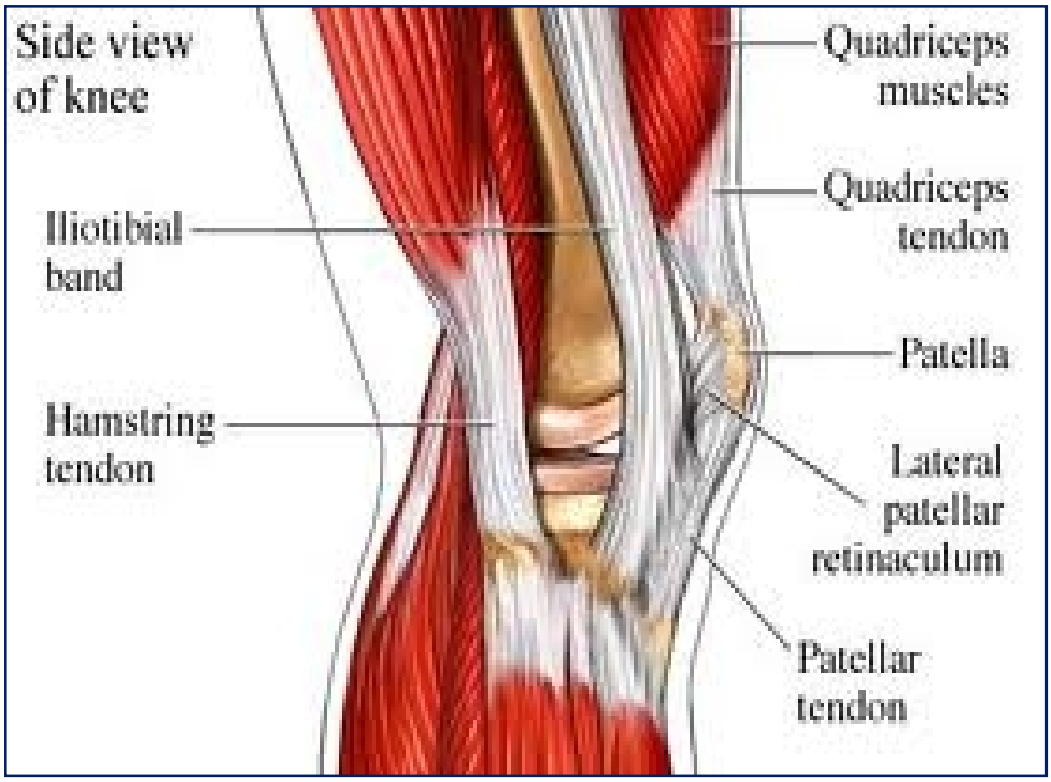
Quadriceps muscle:

The quadriceps muscle group is made up of four different individual muscles which join together forming the quadriceps tendon. This thick tendon connects the muscle to the patella which in turn connects to the tibia via the patellar tendon. Contraction of the quadriceps, pull the patella upwards and leads to knee extension.

Hamstrings muscle:

The Hamstrings muscle function in flexing the knee joint as well as providing stability on either side of the joint line.

Lateral view of knee joint



OSTEO ARTHRITIS (OA)

INTRODUCTION:

Osteoarthritis can be defined as a degenerative, non-inflammatory joint disease characterized by destruction of articular cartilage and formation of new bone at the joint surfaces and margins. It is a form of arthritis that results in the breakdown and eventual loss of the cartilage of one or more joints. Osteoarthritis is abbreviated as OA or referred to as degenerative arthritis or degenerative joint disease (DJD).

EPIDEMIOLOGY:

International statistics:

Internationally, osteoarthritis is the most common articular disease. Estimates vary among different populations. The prevalence of osteoarthritis differs among different ethnic groups. The disorder is more prevalent in Native Americans than in the general population. Osteoarthritis of the hip is seen less frequently in Chinese patients from Hong Kong than in age-matched white populations. In persons older than 65 years, osteoarthritis is more common in whites than in blacks. Knee osteoarthritis appears to be more common in black women than in other groups. In India knee arthritis is more common in females than males and it is the most frequent joint disease with prevalence of 22 - 39 %.

Age- and sex-related prevalence:

Primary osteoarthritis is a common disorder of the elderly, and patients are often asymptomatic. Approximately 80-90% of individuals older than 65 years have evidence of primary osteoarthritis. Patients with symptoms usually do not notice them until after age 50 years. The prevalence of the disease increases dramatically among persons over age 50, likely because of age-related alterations in collagen and proteoglycans that decrease the tensile strength of the joint cartilage and because of a diminished nutrient supply to the cartilage.

In individuals older than age 55 years, the prevalence of osteoarthritis is higher among women than men. Women are especially susceptible to osteoarthritis in the distal interphalangeal joints joints of the fingers. Women also have osteoarthritis of the knee joints more frequently than do men, with a female-to-male incidence ratio of 1.7:1. Women are also more prone to erosive osteoarthritis, with a female-to-male ratio of about 12:1.

At age 18-24 years, 7% of men and 2% of women show signs of osteoarthritis in the hands. At age 55-64 years, 28% of men and women show signs of osteoarthritis in the knee, and 23% show signs of osteoarthritis in the hip. At age 65-74 years, 39% of men and women

show signs of osteoarthritis in the knee and 23% show signs of osteoarthritis in the hip. At age 75-79 years, approximately 100% of men and women show some signs of osteoarthritis.

CLASSIFICATIONS:

It could be divided into 2 types

1. Primary or idiopathic osteoarthritis
2. Secondary osteoarthritis

1. Primary or idiopathic osteoarthritis:

It is due to wear and tear changes occurring in old age in which the weight bearing joints like the hips and knees are more commonly affected. It is uncommon in non-weight bearing joints like the shoulder and elbow. Obesity is a predisposing factor.

2. Secondary osteoarthritis:

It is due to an abnormal wear and tear in a joint, caused by mechanical incongruity of the articular surfaces. This incongruity is due to the

- Mal-union of fractures involving the articular surfaces of tibia, femur or patella
- Loose bodies in the joint
- Malalignment of the bones due to deformity like genu valgum or genu varum.

Sites of primary osteoarthritis:

Common sites:

- Apophyseal joint of the cervical spine
- Thoraco lumbar spine
- First carpometacarpal joint
- Distal interphalangeal joint
- Patello-femoral joint
- Tibio-femoral joint
- First metatarsalphalangeal joint

Less common sites:

- Acromio clavicular joint
- Hip joint

Uncommon sites:

- Shoulder joint
- Elbow joint

- Wrist joint
- Metaphalangeal joint
- Ankle joint

Difference between Primary OA and Secondary OA

PRIMARY OSTEOARTHRITIS	SECONDARY OSTEOARTHRITIS
Usually limited to one or a small number of joints.	May be limited to a small number of joints in injury related or may be in joints throughout body, if disease related
No specific inflammatory or metabolic condition known to be associated with arthritis is Absent .	Condition that cause damage to cartilage are Absent , such as - Inherited disease of iron, calcium or copper storage such as hemochromatosis, Hyperparathyroidism or Wilson's disease. Neurologic disorder that result in the loss of nerve function. Congenital disease that cause an imbalance in the joints.
No history of specific injury or trauma.	History of injury to joints, such as fractures and tears or history of trauma to joints, such as repetitive heavy lifting.

PATHOPHYSIOLOGY:

In early osteoarthritis, swelling of the cartilage usually occurs, due to the increased synthesis of proteoglycans, this reflects an effort by the chondrocytes to repair cartilage damage. This stage may last for years or decades and is characterized by hypertrophic repair of the articular cartilage.

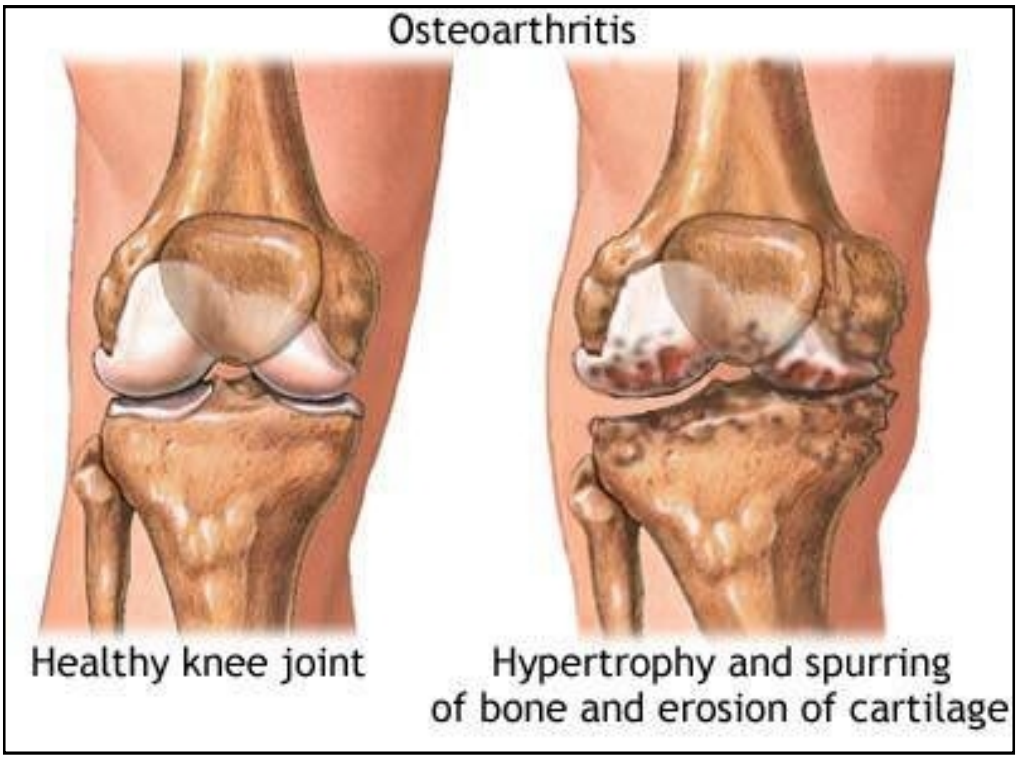
As osteoarthritis progresses, however, the level of proteoglycans eventually drops very low, causing the cartilage to soften and lose elasticity, thereby further compromising joint surface integrity.

Microscopically, as flaking and fibrillations (vertical clefts) develop along the normally smooth articular cartilage on the surface of an osteoarthritic joint, the loss of cartilage results in the loss of the joint space.

In major weight-bearing joints of persons with osteoarthritis, a greater loss of joint space occurs at those areas subjected to the greatest pressures; this effect contrasts with that of inflammatory arthritis, in which uniform joint-space narrowing is the rule. In the osteoarthritic knee, for example, one commonly observes the greatest loss of joint space in the medial femorotibial compartment, although the lateral femorotibial compartment and patellofemoral compartment may also be affected. Collapse of the medial or lateral compartments may result in varus or valgus deformities, respectively.

Erosion of the damaged cartilage in osteoarthritic joint progresses until the underlying bone is exposed. Bone denuded of its protective cartilage continues to articulate with the opposing surface. Eventually, the increasing stresses exceed the biomechanical yield strength of the bone. The subchondral bone responds with vascular invasion and increased cellularity, becoming thickened and dense (a process known as eburnation) at areas of pressure. The traumatized subchondral bone may also undergo cystic degeneration, due to either osseous necrosis secondary to chronic impaction or to the intrusion of synovial fluid.

Osteoarthritic cysts are also referred to as subchondral cysts, pseudocysts, or geodes, the preferred European term. These lesions are generally 2-20 mm in diameter.



AETIOLOGY OF OSTEOARTHRITIS:

The daily stresses applied to the joints, especially the weight-bearing joints (eg, ankle, knee, hip), play an important role in the development of osteoarthritis. Degenerative alterations in osteoarthritis primarily begin in the articular cartilage, as a result of either excessive loading of a healthy joint or relatively normal loading of a previously disturbed joint. External forces accelerate the catabolic effects of the chondrocytes and disrupt the cartilaginous matrix

Though exact cause is not known, the following factors are suspected to play an important role in the causation of primary osteoarthritis

1. Endocrine:

People with Diabetes may be prone to osteoarthritis. Other endocrine problems also may promote development, including acromegaly, hypothyroidism, hyper parathyroidism and obesity. Menopause often increases the progression of osteoarthritis.

2. Post Traumatic:

Traumatic causes can be further divided into macro trauma or micro trauma. An example of macro trauma is an injury to the joint such as bone break causing the bones to line up improperly (mal alignment), lose of stability or damage cartilage. Micro trauma may occur over time (chronically). An example of this would be repetitive movements or the overuse noted in several occupations.

3. Inflammatory Joint Disease:

This category would include infected joints, chronic gouty arthritis and rheumatoid disease.

4. Metabolic:

Disease causing errors of metabolism may cause osteoarthritis. Examples include Paget's disease and Wilson's disease.

5. Congenital or Developmental:

Abnormal anatomy such as unequal length of legs may be a cause of osteoarthritis.

6. Genetic:

A genetic defect may promote breakdown of the protective architecture of cartilage. Examples include collagen disturbances such as Ehlers- Danlos Syndrome.

7. Neuropathic:

Diseases such as Diabetes can cause nerve problems. The loss of sensation may affect how the body knows the position and condition of the joints or limbs. In other words, the body can't tell when it is injured.

8. Muscle dysfunction:

Muscle dysfunction compromises the body's neuromuscular protective mechanisms, leading to increased joint motion and ultimately resulting in osteoarthritis.

9. Others:

- Nutritional problems may cause osteoarthritis.
- Osteoporosis
- Valgus and varus deformities of the knee.
- Rheumatoid arthritis, infection, trauma, TB, etc.
- Haemophilia.
- Syringomyelia
- Overuse of intra- articular steroid therapy.

It is generally observed that secondary osteoarthritis occurs in the younger age groups and is more severe than the primary. Apart from all the features of osteoarthritis, secondary osteoarthritis has the features of the corresponding aetiological condition.

SIGNS AND SYMPTOMS:

The disease progression of osteoarthritis (OA) is characteristically slow, occurring over several years or decades. The patient can become progressively less active, leading to morbidities related to decreasing physical activity (including potential weight gain).

Early in the disease process of osteoarthritis, the joints may appear normal, and the patient's gait may be antalgic if weight-bearing joints are involved.

Pain:

Pain is the most common symptom of osteoarthritis. It is usually made worse by moving the joint or placing weight on it, and it is usually relieved by rest. As the condition progresses and inflammation develops, pain may become constant.

Pain mechanisms in osteoarthritis:

Pain, the main Absent ing symptom of osteoarthritis, is presumed to arise from a combination of mechanisms, including the following:

- Osteophytic periosteal elevation
- Vascular congestion of subchondral bone, leading to increased intraosseous pressure
- Synovitis with activation of synovial membrane nociceptors
- Fatigue in muscles that cross the joint
- Overall joint contracture
- Joint effusion and stretching of the joint capsule
- Torn menisci
- Inflammation of periarticular bursae
- Periarticular muscle spasm
- Psychological factors
- Crepitus (a rough or crunchy sensation)

Stiffness:

Stiffness of the affected joint is often noticed first thing in the morning, and after resting. Stiffness during rest (gelling) may develop, with morning joint stiffness usually lasting for less than 30 minutes.

Swelling:

Swelling, which is sometimes warm to touch, may be noticeable in an arthritic joint.

Deformity:

Deformity can occur with osteoarthritis due to bone growths and cartilage loss. Bone growths in the end joints of the fingers are called Heberden's nodes. Bouchard's nodes are bone growths in the middle joints of the fingers. Degeneration of knee cartilage can result in the outward curvature of knees (bow- leggedness).

PHYSICAL EXAMINATION:

Physical examination findings in patients with the disease are mostly limited to the affected joints. A deep, achy joint pain, presumably arising from a combination of mechanisms, is the main Absent ing symptom of osteoarthritis. Also, reduced range of motion and crepitus are frequently Absent .

Malalignment with a bony enlargement (depending on the disease's severity) may occur. Most cases of osteoarthritis do not involve erythema or warmth over the affected

joints. However, an effusion may be Absent . Limitation of joint motion or muscle atrophy around a more severely affected joint may occur.

Heberden nodes, which reAbsent palpable osteophytes in the distal interphalangeal joints, are characteristic in women but not in men. Inflammatory changes are typically absent or at least not pronounced.

DIAGNOSIS:

There is no single sign, symptom or test result that allows a definitive diagnosis of osteoarthritis. Instead the diagnosis is based on a consideration of several factors, including the presence of the characteristic signs and symptoms of osteoarthritis, physical examination and the results of laboratory tests and x-rays.

PROGRESSION OF OSTEOARTHRITIS:

The etiopathogenesis of osteoarthritis has been divided into 3 stages.

1. Proteolytic breakdown of the cartilage matrix occurs.
2. The fibrillation and erosion of the cartilage surface, with a subsequent release of proteoglycan and collagen fragments into the synovial fluid.
3. The breakdown products of cartilage induce a chronic inflammatory response in the synovium.

PROGNOSIS:

The prognosis of osteoarthritis depends on the joints involved and the severity of the condition. A several clinical features associated with more rapid knee osteoarthritis (OA) progression, these include age, body mass index, varus deformity, and multiple involved joints, and their presence may help identify those more likely to have knee OA progression.

The prognosis is good for patients with osteoarthritis who have undergone joint replacement, with success rates for hip and knee arthroplasty being generally more than 90%. However, a joint prosthesis may need revision 10-15 years after its installation, depending on the patient's activity level. Younger and more active patients will require revisions, whereas the majority of older patients will not.

DIAGNOSTIC CRITERIA:

Formal criteria helpful for diagnosis of osteoarthritis in synovial joints:

- Age greater than 60 years.
- Pain and swelling in knee joint
- Morning stiffness lasting less than 30 minutes.

- Crackling sensation (crepitus) Absent in knee joint.
- Joint- line or periarticular tenderness.
- Bony swelling (osteophyte) around joint margins.
- Restricted joint movements

INVESTIGATIONS:

1. **X- Ray**

Radiological features: The earliest change seen is the asymmetrical narrowing of the joint space and subchondral sclerosis in the medial compartment of the joint. Later, osteophytes are seen in the periphery of the articular surfaces of the femur, tibia and patella.

2. **Arthroscopic Examination**

It allows direct inspection and visualization of the damaged joint surface.

3. **Synovial fluid Analysis**

Shows non-inflammatory picture.

4. **Bone scan , CT, MRI.**

COMPLICATIONS OF OSTEOARTHRITIS:

The major complications of osteoarthritis of knee

- Joint deformities
- Subluxation
- Ankylosis
- Intra- articular loose bodies

PREPARATION AND PROPERTIES OF TRIAL DRUGS

STANDARD OPERATING PROCEDURE FOR THE PREPARATION OF AVURI KARPAM (Int.) AND VADHA NOIKKU ENNAI (Ext.)

Source of Trial Medicine:

The required raw drugs for the preparation of Avuri Karpam (Internal) and Vatha Noikku Ennai (External) were purchased from a well reputed country shop and the raw drugs were authenticated in the Medicinal Botany department of NIS. Then the raw drugs were purified as per siddha literatures.

AVURI KARPAM (INTERNAL MEDICINE)

Ingredients:

- Avuri ilai (Indicofera tinctoria) - 35gms
- Manjal karisalai (Wedelia chinensis) - 35gms
- Kuppaimeni ilai (Acalypha indica) - 35gms
- Kottai karanthai ilai (Sphaeranthus indicus) - 35gms
- Vellai karisalai (Eclipta alba) - 35gms
- Vallarai (Centella asiatica) - 35gms
- Seruppadai (Glinus lotoides) - 35 gms

Method of Purification:

Avuri:

Leaves are washed in pure water and dried in shadow.

Kaiyanthagarai:

Leaves are washed in pure water and dried in shadow.

Kuppaimeni:

Leaves are washed in pure water and dried in shadow.

Kottaikaranthai:

Leaves are washed in pure water and dried in shadow.

Vallarai:

Leaves are washed in pure water and dried in shadow.

Seruppadai

Leaves are washed in pure water and dried in shadow.

Method of Preparation:

The purified leaves are dried in shadow. The dried leaves are pulverized by an electric grinder into fine powder and then it is sieved by using a fine silk cloth (Vasthirakayam). The fine powder is mixed with milk and then backed in a backing pan (Pittavial method). Then it is dried and ultra filtered by a cotton cloth and made into fine powder again. The powder is stored in a clean, dry air tight glass bottle.

Drug storage:

The trial drug is stored in clean and dry glass bottles.

Dispensing:

The chooranam is given in packets.

VADHA NOIKKU ENNAI (EXTERNAL DRUG)

Ingredients:

Nathaisoori ver (Spermacoce hispida)	- 35 gms
Muthiyar koonthal samoolam (Cuscuta reflexa)	- 35 gms
Vidathari ver (Dichrostachys cinerea)	- 35 gms
Uthamani ver (Pergularia daemia)	- 35gms
Vembu ver (Azadirachta indica)	- 35gms
Poondu (Allium sativum)	- 35gms
Vasambu (Acorus calamus)	- 35gms
Nayuruvisamoolam (Acyranthes aspera)	- 35gms

Method of preparation:

The raw drugs were powdered into chooranam (fine powder) then the above choornam is prepared as karkam by adding sufficient water. Then the karkam is added with gingely oil and mixed well together then subjected to heat until it is brought to thailam consistency.

Drug storage:

The oil is stored in clean and dry narrow mouthed bottles.

Dispensing:

Oil is given in glass bottles.

PROPERTIES OF TRIAL DRUGS

INTERNAL DRUG:

1. AVURI-அவுரி (INDIAN INDIGO PLANT)

Botanical name: Indigofera tinctoria, Linn.

Family: Fabaceae

Actions:

Germicide
Antiperiodic
Stimulant
Antioxidant
Antinociceptive
Hypolipidemic
Antiproliferative
Antidiabetic
Hepatoprotective
Antimicrobial
Anti-inflammatory

General properties:

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

-அகத்தியர் குணவாகடம்.

Chemical constituents:

Indican
Indirubin
Glycosides
Carbohydrates
Saponins
Tannin
Flavanoides
Phenolic compounds
Protein ang aminoacids

2. **MANJAL KARISALAI: மஞ்சள் கரிசாலை**

Botanical name: Wedelia chinensis

Family: Astraceae

Actions:

Cholagogue

Tonic

Alterative

Emetic

Purgative

Deobstruent

Hepatotonic

General properties:

"பொற்றலைக்கை யாந்தகரை பொன்னிறமாக் கும்முடலை
சுத்த முறக்கட்குச் சுகங்கொடுக்குஞ் - சிற்றிடையாய்
சிந்தூரங் கட்காகுஞ் சிந்தை தனைத்துலக்கும்
உந்திவளர் குன்மமொழிக் கும்".

-அகத்தியர் குணவாகடம்.

Chemical constituents:

Wedecolacton

B-amyrin

3. VELLAI KARISALAI: வெள்ளைக் கரிசாலை

Botanical name: Eclipta alba

Family: Astraceae

Actions:

Alterative

Purgative

Deobstruent

Hepatotonic

Antioxidant

Antihyperglycemic

Analgesic

Antihyperlipidemic

Immunomodulatory

General properties:

"குரற்கம்மற் காமாலை குட்டமொடு சோபை
யுறற்பாண்டு பன்னோ யொழிய-நிரற்சொன்ன
மெய்யாந் தகரையொத்த மீளி ண்ணு நற்புலத்துக்
கையாந் தகரையொத்தக் கால்".

-அகத்தியர் குணவாகடம்.

Chemical constituents:

Flavonoides

Stigmasterol

a-terthienylmethanol

wedelolactone

demethyl wedelolactone

4. **KUPPAI MENI: குப்பைமேனி**

Botanical name: Acalypha indica. Linn

Family: Euphorbiaceae

Actions:

Anodyne

Anthelmintic

Cathartic

Diuretic

Emetic

Expectorant

Emmenagogue

General properties:

"தந்தமு லப்பிணிதீந் தந்திடுபுண் சர்வவிடம்
உந்துகுன்மம் வாதம் உதிரமு-லந்தினவு
சூலஞ்சு வாசம் தொடர்பீ சங்கபம்போம்
ஞாலங்கொள் மேனியத னால்".

-அகத்தியர் குணவாகடம்.

Chemical constituents:

Acalypus

Acalypine

Triacetonamine

Hydrocyanic acid

Stygmasterol

Acalyphamide

Kaemferol glycoside

Tannin

Beta sitosterol

Succinamide

Mauritianin

5. **KOTTAI KARANTHAI: கொட்டைக் கரந்தை**

Botanical name: Sphaeranthus indicus

Family: Astraceae

Actions:

Alterative

Demulcent

Depurative

Refrigerant

Tonic

General properties:

"கொட்டைக் கரந்தைதனைக் கூசாமலுண்டவர்க்கு
வெட்டை தணியுமதி மேகம்போந் - துட்டச்
சொறி சிரங்கு வன்கரப்பான் றோற்றாது நாளும்
மறிமலமுந் தானிறங்கு மால்".

-அகத்தியர் குணவாகடம்.

Chemical constituents:

Methyl charicol

a-Terpinine

literal

a-ionone

p methoxy cinnamaldehyde

tannin

6. **VALLARAI: வல்லாரை**

Botanical name: Centella asiatica

Family: Apiaceae

Actions:

Alterative

Tonic

Diuretic

Stimulant

Emmenagogue

General properties:

"அக்கர நோய் மாறும் அகலும் வயிற்றிழிவு
தக்கவிரத் தக்கடுப்பு தானேகும் - பக்கத்தில்
எல்லாரை யுமருந்தென் றேயுரைத்து நன்மனையுள்
வல்லாரை யைவளர்த்து வை".

-அகத்தியர் குணவாகடம்.

Chemical constituents:

Triterphenoid

Asiaticoside A &B

Sitosterol

Vallarine

Pectic acid

Tannin

Bramoside

7. SERUPPADAI : செருப்படை

Botanical name: Glinus lotoides

Family: Molluginaceae

Actions:

Stimulant

General properties:

"செருப்படைக்கு வாதமந்தஞ் சேர்வான மேகம்
இருப்படிகொள் பொல்லா இசிவும் - விறுப்படிக்குஞ்
சூலையொடு வாதகுன்மந் தோற்றா தொருநாளும்
வேலையொத்த கண்ணாய் விளம்பு".

-அகத்தியர் குணவாகடம்.

Chemical constituents:

Flavone-c-glycoside orientin

Vitexin

Reducing sugar

EXTERNAL DRUG:

1. **NATHAI CHURI : நத்தைசூரி**

Botanical name: Spermacoce hispida

Family: Rubiaceae

Actions:

Alterative

Tonic

General properties:

விதையினால் பெருங்கழிச்சல், சீதபேதி நீங்கும். வேர் உடலைத் தேற்றும்.

Chemical constituents:

Borreline

Ursolic acid

Beta sitosterol

Isorhamnetin

2. **MUTHIYAR KOONTHAL : முதியார் கூந்தல்**

Botanical name: Cuscuta reflexa

Family: Convolvulaceae

Actions:

Astringent

Alterative

Stomachic

General properties:

“கடுப்பு கழிச்சல் கணன்றசுர தாகம்
இடுப்புவலி வாத மிவற்றோ - டடுப்ப
விதிரைவா வென்றழைக்கு மேகமும் போகும்
குதிரை வாலிக்குக் குலைந்து”.

-அகத்தியர் குணவாகடம்.

Chemical constituents:

Cuscutin

Flavanoides

Resin

Quercetin

3. VIDATHAARI: விடதாரி

Botanical name: Dichrostachys cinerea

Family: miosaceae

Actions:

Astringent

Stimulant

Tonic

General properties:

"முளையைவரு விக்கின்ற மூலரோ கத்தை

யளையுமுதி ரத்தை யடங்கா - துளைதாக

வேகத்தைப் போக்கிவிடும் வெய்யவிடத் தேசக்கிர

வாகத்தைக் காய்முலையாய் வாழ்த்து".

-அகத்தியர் குணவாகடம்

Chemical constituents:

Fatty acid

Linoleic acid

Palmitic acid

Nitrogen

Leucin

4. UTHAAMANI: உத்தாமணி

Botanical name: Pergularia daemia

Family: Asclepiadaceae

Actions:

Expectorant

Anthelmintic

Emetic

General properties:

"ஆலித் தெழுந்தநோய் அத்தனை யுந்தீருமே
வேலிப் பருத்தியதின் மெல்இலையால் - வேலொத்துக்
கண்டிக்கும் வாதங் கடுஞ்சன்னி தோடமும்போம்
உண்டிக்கும் வாசனையாம் ஓது".

-அகத்தியர் குணவாகடம்.

Chemical constituents:

Alpha amyrin

Beta amyrin

Beta sitosterol

5. VEMBU : வேம்பு

Botanical name: Azadirachta indica

Family: meliaceae

Actions:

Stimulant

Anthelmintic

Discutient

General properties:

"புந்தியிதைத் தீட்டுவிக்கும் புன்பிணியை யோட்டுவிக்கு
மிந்தியத்தை நன்றா யிசைவிக்கும் - சந்ததமம்
வீறுண்டாங் கற்ப மிகவுண்டா மெஞ்ஞான்றும்
மாறன்றா ரையமில்லா மல்".

-அகத்தியர் குணவாகடம்.

Chemical constituents:

Azadiractin A,B,D,H

Nimbinin

Nimbidine

Nimbione

Nimbinone

Geducin

6. POONDU : பூண்டு

Botanical name: Allium sativam

Family: Liliaceae

Actions:

Carminative

Stomachic

Tonic

Alterative

Stimulant

Expectorant

Diuretic

Anthelmintic

General properties:

"சன்னியொடு வாதந் தலைநோவு தாள்வலி
மன்னிவரு நீர்க்கோவை வன்சீதம் - அன்னமே
உள்ளுள்ளி கண்பாய் உளைமூல ரோகமும் போம்
வெள்ளுள்ளி தன்னால் வெருண்டு".

-அகத்தியர் குணவாகடம்.

Chemical constituents:

Allicin

Essential oil

Fattyacids

Alkylcystines

Sulphur

Vitamins

Acrid volatileoil

Starch

7. **VASAMBU: வசம்பு**

Botanical name: **Acorus calamus**

Family: Araceae

Actions:

Stimulant

Stomachic

Anti periodic

Emetic

Disinfectant

Germicide

General properties:

"பாம்பாதி நஞ்சற் புதப்புண் வலிவிடபாகங் குன்மம்
சூம்பா ரிரத்தபித் தம்முக நாற்றம்வன் சூலைசன்னி
வீம்பாம்பை காசம் பிலீகஞ் சிலிபதம் வீறிருமல்
தாம்பாங் கிருமி யிவையெகு மாசிவ சம்பினையே".

-அகத்தியர் குணவாகடம்.

Chemical constituents:

Acorin

Palmitic acid

Eugenol

Acoretin

Calamine

Camphene

8. **NAAYURUVI SAMOOLAM : நாயுருவி**

Botanical name: Achyranthes aspera

Family: Amaranthaceae

Actions:

Astringent

Diuretic

Alterative

Anti periodic

General properties:

"மலிகாரங் கைப்புள்ள அபமார்க்கி யின்வேரால் வசிய முண்டாம்
இலை மூல உதிரமந்தம் பேதிகபம் வியர்வுதந்தி யிறங்கு மேகம்
மலையேறும் படிபுரியு முள்ளரிசி பசிமாற்றும் வனச மூலம்
பலமாதர்க் குள்ளழுக்கை நீக்குவங்கச் சிந்தூரம் பண்ணுமாதோ".

-அகத்தியர் குணவாகடம்.

Chemical constituents:

Achyranthine

Triterphenoid

Saponins

Aglycone

Oleanolic acid

Insect moulting hormone

9. நல்லெண்ணெய் – GINGELLY OIL

Botanical name: Sesamum indicum, Linn.

Family: Pedaliaceae

General properties:

"புத்திநயனக்குளிர்ச்சி பூரிப்பு மெய்ப்புளகஞ்
சத்துவங் கந்தி தனியிளமை - மெத்தவுண்டாங்
கண்ணோய் செவிநோய் கபாலவழல் காசநோய்
புண்ணோய்போ மெண்ணெய்யாற் போற்று".

- அகத்தியர் குணவாகடம்.

Actions:

Demulcent

Laxative

Nutritive

Emollient

INGREDIENTS OF INTERNAL MEDICINE(AVURI KARPAM)

AVURI

VELLAI KARISALAI

MANJAL KARISALAI

KUPPAIMENI

KOTTAI KARANTHAI

VALLARAI

SERUPPADAI

INGREDIENTS OF EXTERNAL MEDICINE(VATHA NOIKKU ENNAI)

NATHAISORI

MUTHIYARKONTHAL

VIDATHARI

UTHAMANI

VEMBU

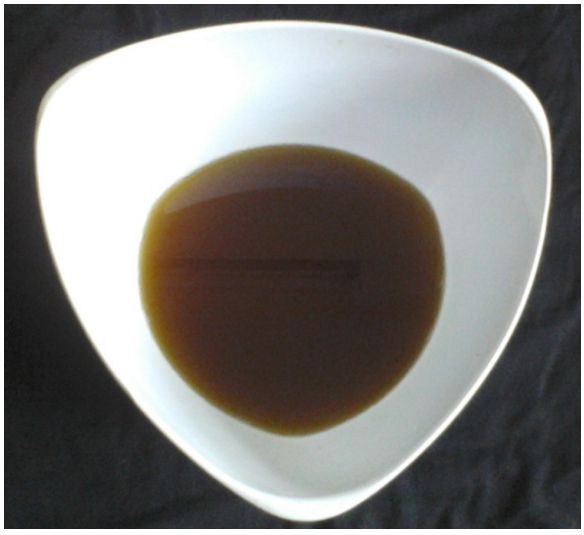
POONDU

VASAMBU

NAYURUVI

AVURI KARPAM

VATHA NOIKKU ENNAI



VARMAM

Varmam is a science dealing with the impact to innumerable nerve junctions of the human body. The changes occurring in the body on being hit at some specific points on the body directly or indirectly with a particular force is known as varmam.

Synonyms of Varmam:

Kalam, adakkam, marmam, sutcham, vanmam, emam, idu , karuvi, kalai, sarvaathma vazhum veedu, seevan swasam, maaigai, poruthu odivu etc..

Varmam – Art as well as science:

Varmam is an art as well as a science. As an art it can be employed to attack a person to disable him (which is normally not done) and as a science, it helps treat persons from the impact arising from traumatic injuries.

Varmam and other Martial arts:

Varmam has also many similarities to other martial arts such as silambam, sword fighting, kalari etc. In these arts, the life energy centers of men are made known to practitioners to enable them to achieve their ends.

Signs of life energy centers if affected:

Hundreds of life energy centers of human body lie dormant as bones, nerves, veins, muscles, joints and inner organs are found either deep or at the surface of the body. Vital life centers are dominant on bones and joints. Medium life centre on nerves. Inner life centers on muscles.

If the life energy centers are traumatized by hit or cut either directly or indirectly, and then whole body is left out of control. In other words the whole body is paralyzed. It is manifested by symptoms like fainting, sprain, swelling, bleeding, shivering, fractures, dislocations or even death.

Varmam points to be manipulated in Azhal Keel Vayu patients:

- Kaal Moottu Varmam
- Komberi
- Viruthi
- Ullangal vellai
- Kutri Varmam

KAAL MOOTTU VARMAM:

Synonyms:

முட்டு வர்மம் (வர்ம சுத்திரம்-101)

மூட்டு வர்மம் (கண்ணாடி- 500)

கால்மூட்டு வர்மம் (வர்ம விரலளவு நூல்)

Location:

தானதிலே முட்டிசைவில் மூட்டு வர்மம் (வர்ம கண்ணாடி-500)

Located in the popliteal fossa.

KOMBERI VARMAM:

Synonyms:

தும்பிக்கால வர்மம் (வர்ம நூலளவு நூல்)

கொம்பேறி வர்மம் (வர்ம சூத்திரம் 101)

Location:

ஏகும் முடவு இறைரண்டில் தும்பிக்காலம் (அடிவர்ம சூட்சம் - 500)

Located at the centre of the medial aspect of the leg.

VIRUTHI VARMAM:

Synonyms:

விற்தி வர்மம் (வர்ம கண்ணாடி-500)

விர்த்தி வர்மம் (அடிவர்ம சூட்சம்-500)

விருத்தி வர்மம் (வர்ம லாட சூத்திரம்-300)

Location:

போமென்ற பெருவிரல் மொழி மேல் விர்த்த காலம் (அடிவர்ம சூட்சம்–500)

Located in the space in between the great toe and second toe on the dorsum of the foot.

ULLANGAL VELLAI VARMAM:

Synonyms:

வெள்ளை வர்மம் (வர்ம ஒடிவுமுறிவு சரசூத்திரம்-1200)

அடங்கல் வர்மம் (வர்ம சூத்திரம் 101)

கால் வெள்ளை வர்மம் (அடிவர்ம சூட்சம்–500)

உள்ளங்கால் வர்மம் (வர்ம விரலளவு நூல்)

Location:

அகமான உள்ளம் கால் வெள்ளை வர்மம் (அடிவர்ம சூட்சம்–500)

Located on the depression in between the eminences of great toe and second toe in the plantar aspect of the foot

KUTRI VARMAM :

Synonyms:

குற்றிக் வர்மம் (வர்ம சாரி - 205)

குத்திக் காலம் (வர்ம கண்ணாடி – 500)

Location:

முன்னே சொன்ன செவிக்குத்திக் கிருவிரலில்

முக்கியமாம் குற்றிவர்மம் ரண்டதாகும் (வர்ம ஒடிவுமுறிவு சரசூத்திரம்-1200)

Located in the tragus of the ear.

MATERIALS AND METHODS

The study on Azhal keel vayu was carried out in the In-Patient and Out-Patient Department of Sirappu Maruthuvam in Ayothidoss Pandhithar Hospital, National institute of Siddha, Chennai - 47.

The disease "Azhal keel vayu" has been dealt in the Siddha Pothu Maruthuvam as one among the types of Keel vayu. Patients were selected according to the clinical features as mentioned in Azhal keel vayu.

Study design and conduct of study:

Study type:

A Pilot study

Sample:

Patients of Azhal keel vayu reporting at Out-Patient ward, Department of Sirappu Matuthuvam, Ayothidoss Pandithar Hospital of National Institute of Siddha, Tambaram Sanatorium, Chennai-47.

Sample size:

40 patients [20 OP + 20 IP]

Out of 20 IP patients - 10 with trial medicine and 10 with Varmam along with trial medicine.

Study place:

Out-Patient and In-Patient ward, Department of Sirappu Maruthuvam, Ayothidoss Pandithar Hospital, National Institute of Siddha, Tambaram sanatorium, Chennai-47.

Study period:

12 months

TREATMENT:

Internal medicine:

Avuri karpam:

Reference:	Pathartha Guna Vilakkam; Pg no: 43
Dosage:	Thirigadi (1gm) (twice a day)
Adjuvant:	Honey
Duration:	48 days

External medicine:

Vadha Noikku Ennai:

Reference: Theraiyar vagadam; Pg no: 64

Dosage: Q.S (for external application)

STANDARD OPERATING PROCEDURE:

Source of trial medicine:

The required raw drugs for the preparation of Avuri Karpam (Internal) and Vadha Noikku Ennai (External) were purchased from a well reputed country shop and the raw drugs were authenticated in the Medicinal Botany department of NIS. Then the raw drugs were purified as per siddha literatures.

Drug storage:

The trial drug Avuri Karpam is stored in clean and dry glass bottles and Vadha Niokku Ennai is stored in clean and dry narrow mouthed bottles.

Dispensing:

The chooranam is given in packets and oil is given in glass bottles.

VARMAM POINTS TO BE USED:

- Kaal Mootu Varmam (Varma Viralalavu Nool)
- Komberi (Varma soothiram 101)
- Viruthi (Varma laada soothiram 300)
- Ullangal Vellai(Adivarma sootcham 500)

SUBJECT SELECTION:

Patients reporting with symptoms of Azhal Keel Vayu will be subjected to screening using screening Proforma. Then they will be allowed for the study fulfilling the following criteria:

INCLUSION CRITERIA:

- Age : 30-65 Yrs
- Sex : Both male and female
- Patients having symptoms of arthritis of both knee joints, Pain, swelling, stiffness, crepitations, restricted movements of both knee joints.

- Patients who are willing to undergo radiological investigation, Laboratory investigations.
- Patients willing to sign the informed consent stating that he/she will conscientiously stick to the treatment during 48days but can opt out of the trial of his/her own conscious discretion.
- Willing to co operate to take photographs whenever required with his/her consent.

EXCLUSION CRITERIA:

- Cardiac diseases
- Hypertension
- Rheumatoid arthritis
- Use of Narcotics
- Pregnancy and lactation
- History of trauma
- Patient with any other serious systemic illness

WITHDRAWAL CRITERIA:

- Intolerance to the drug and development of adverse reactions during drug trial.
- Poor patient compliance and defaulters.
- Patient turning unwilling to continue in the course of clinical trial.
- Occurrence of any serious illness

TESTS AND ASSESSMENTS:

- Clinical assessment
- Laboratory investigations
- Radiological investigations
- Siddha system assessment

A.**CLINICAL ASSESSMENT:**

- Pain
- Swelling
- Stiffness
- Crepitations
- Tenderness

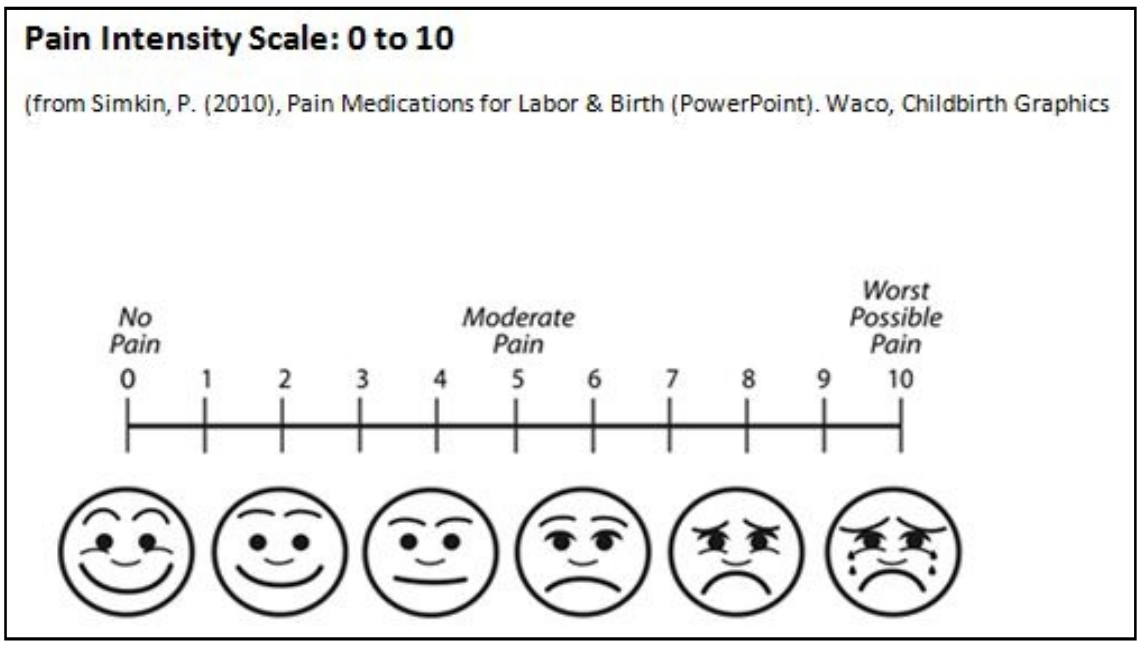
- Warmth
- Restricted movements

OUTCOME:

Outcome of the study will be assessed by the following:

1. Universal Pain assessment scale
2. Restricted movement assessment scale

1. UNIVERSAL PAIN ASSESMENT SCALE:[1]



Grade 0 : No Pain

Grade 1 -3 : Mild pain

Grade 4-6 : Moderate pain

Grade 7-10 : Severe pain

2. RESTRICTED MOVEMENT ASSESSMENT SCALE:

Gradation of movements:

Grade 1 - Fit for all activities, do their work without support.

Grade II - Mild pain Absent in knee joint, mild restricted movements.

Grade III - Pain Absent in knee joint, moderate restriction of movements.

Grade IV - Severe pain, bed ridden.

(Reference: Clinical manual for nursing practice (National Institute of Health Warren Grant Magnuson Clinical Centre)

B. Routine investigation

Blood:

- Hb
- Total WBC Count
- DC :
    - Polymorphs
    - Lymphocytes
    - Eosinophils
    - Basophils Monocytes

- Total RBC count
- ESR

    ½ Hr: 1 Hr:
- Blood sugar

    Fasting: PP:

Urine:

- Albumin
- Sugar
- Deposits

Renal function tests:

- Urea
- Creatinine

Liver function tests:

- Serum total bilirubin
- Direct bilirubin
- Indirect bilirubin
- Serum Alkaline phosphotases
- SGOT
- SGPT

C. RADIOLOGICAL INVESTIGATIONS

X- Ray Knee joints (AP and Lat view)

SPECIFIC INVESTIGATIONS:

- CRP
- ASO TITRE
- RA FACTOR

D. SIDDHA PARAMETERS:

Envagai thervugal:

- Naadi
- Sparisam
- Naa
- Niram
- Mozhi
- Vizhi
- Malam
- Moothiram
- NeerkKuri
- Neikkuri

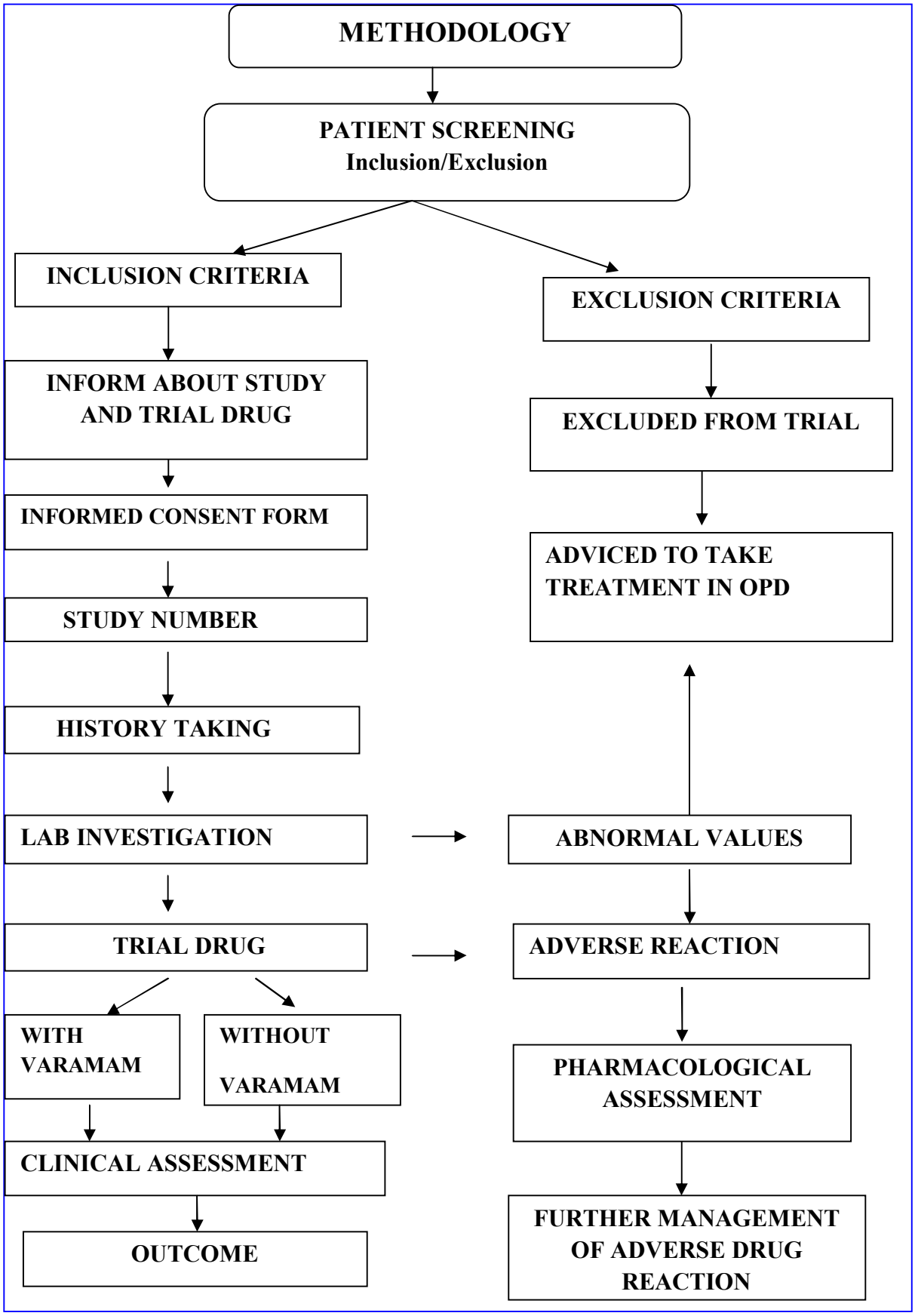
DATA COLLECTION FORMS:

Required information will be collected from each patient by using the following forms:

FORMS:

FORM I : Screening and Selection Proforma
FORM II : History taking Proforma
FORM III : Clinical assessment Proforma
FORM IV : Laboratory Investigation Proforma
FORM V : Informed Consent Form
FORM VI : Withdrawal Form
FORM VII : Patient information sheet
FORM VIII : Dietary Advice form
FORM IX : Adverse Reaction form

METHODOLOGY:



STUDY ENROLLMENT:

Patients reporting at the OPD with the clinical symptoms of Azhal Keel Vayu will be examined clinically for enrolling in the study based on the inclusion and exclusion criteria.

The patients who were enrolled would be informed (Form VI) about the study, trial drug, possible outcomes and the objectives of the study in the language and terms understandable to them and informed consent would be obtained in writing from them in the consent form (Form VI).

All these patients will be given unique registration card in which patients' Registration number of the study, Address, Phone number and Doctors phone number etc. will be given, so as to report easily should any complications arises.

Complete clinical history, complaints and duration, examination findings and laboratory investigations -- would be recorded in the prescribed Proforma.

Patients will be advised to take the trial drug and to follow the appropriate dietary advice.

CONDUCT OF THE STUDY:

Purgation with Agasthiyar kuzhambu 130mg with ginger juice at early morning in empty stomach will be given for balancing the deranged mukkutram a day before the treatment.

The trial drug Avuri Karpam, Internally and Vadha Noikku Ennai Externally are given continuously for 48 days. OP patients are requested to visit the hospital once in seven days. In each and every visit clinical assessment is done and prognosis is noted in the Prescribed Proformas. For In patients clinical assessment is done daily. 10 IP patients will be given Varmam treatment along with trial medicines. Laboratory investigations and Radiological investigation are done on the First day and the last day of the trial. Defaulters of will not be allowed to continue and be withdrawn from the study.

DATA ANALYSIS:

After enrolling the patient for the study, a separate file for each patient will be opened and all forms will be kept in the file. Study No. and Patient No. will be written on the top of file for easy identification. Whenever the patient visits OPD during the study period, the respective patient's file will be taken and necessary entries 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 pharmacovigilance committee. All forms will be further scrutinized in presence of Investigators by Sr. Research Officer (Statistics) for logical errors and incompleteness of data to avoid any bias. No modification in the results is permitted for unbiased report.

ADVERSE EFFECT/SERIOUS EFFECT MANAGEMENT

If the trial patient develops any adverse reaction, he/she would be immediately withdrawn from the trial and proper management will be given in OPD of National Institute of Siddha and the same will be informed to the Pharmaco-vigilance committee of NIS.

ETHICAL ISSUES:

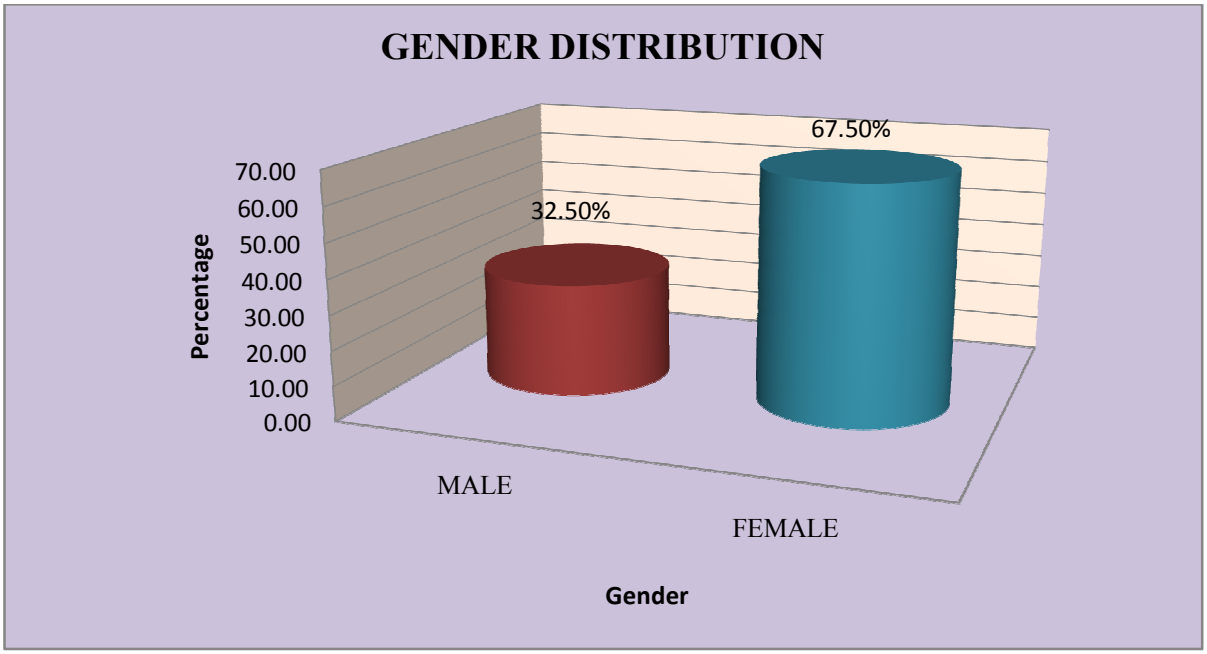
- To prevent any infection, while collecting blood sample from the patient, only disposable syringes, disposable gloves, with proper sterilization of laboratory equipments will be used.
- No other external or internal medicines will be used, other than the trial drug for osteoarthritis. There will be no infringement on the rights of the patient.
- The data collected from the patient will be kept confidential.
- After getting the consent of the patient only (through consent form in their own vernacular language) they will be enrolled in the study.
- Treatment would be provided free of cost.
- In any adverse reaction observed during the trial the patients will be given alternative treatment at National Institute of Siddha for further management.

OBSERVATION AND RESULTS

1. Gender distribution
2. Age Distribution
3. Kaalam distribution
4. Occupational Status
5. Seasonal variations
6. Thinai
7. Socio-economic Status
8. Dietary Habits
9. Precipitating Factors
10. Distribution of Mukkutram
11. Udal Kattugal
12. Ennvagai Thervugal
13. Neerkkuri Neikkuri
14. Naadi
15. Disturbances in Kanmenthiriyam
16. Duration of illness
17. Involvement of knee joints
18. Clinical features
19. Results after treatment

1. GENDER DISTRIBUTION:

GENDER	NUMBER OF CASES	PERRCENTAGE (%)
MALE	13	32.50
FEMALE	27	67.50
TOTAL	40	100

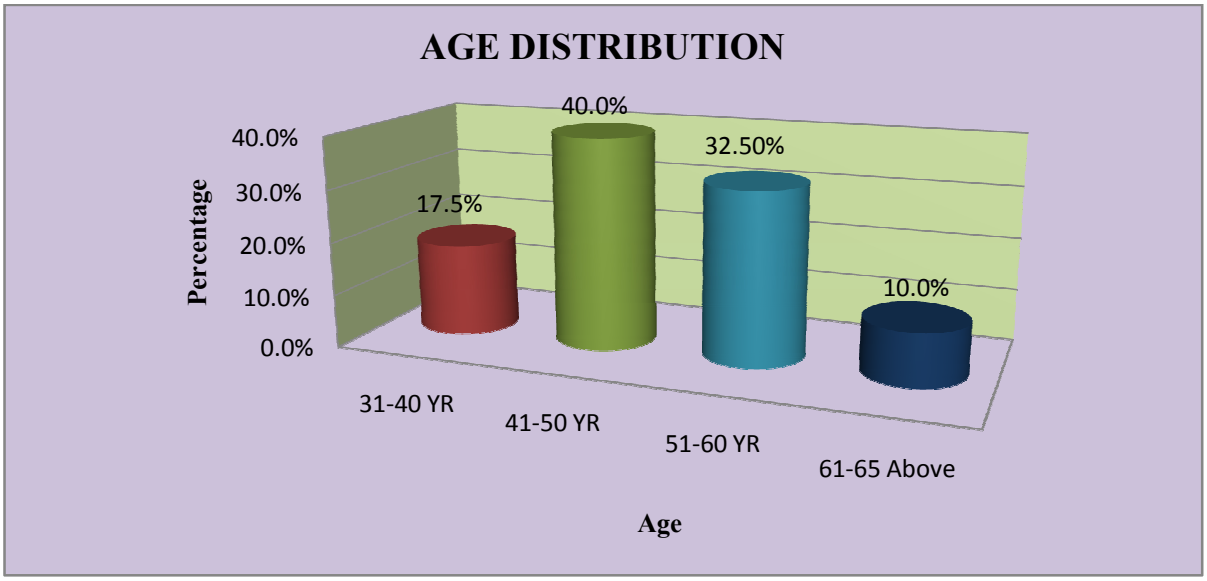


Inference:

Among 40 cases, the disease was found to be higher in Female i.e. (67.50 %).

2. AGE DISTRIBUTION:

AGE (YEAR)	NUMBER OF CASES	PERCENTAGE%
31-40	07	17.50
41-50	16	40.00
51-60	13	32.50
61-65	04	10.00
TOTAL	40	100



Inference:

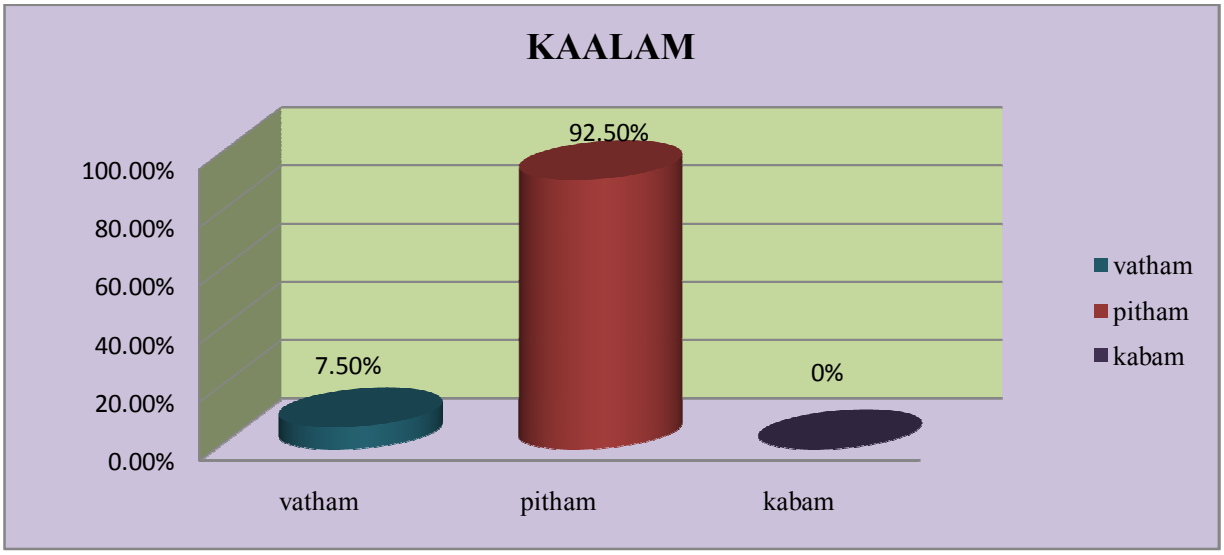
Among 40 cases, the disease was found to be higher in the age group 41-50 years.

3. KAALAM DISTRIBUTION:

Vaatha Kaalam - 3 cases (7.50%)

Pitha Kaalam - 37 cases (92.5%)

Kaba Kaalam - no cases (0%)

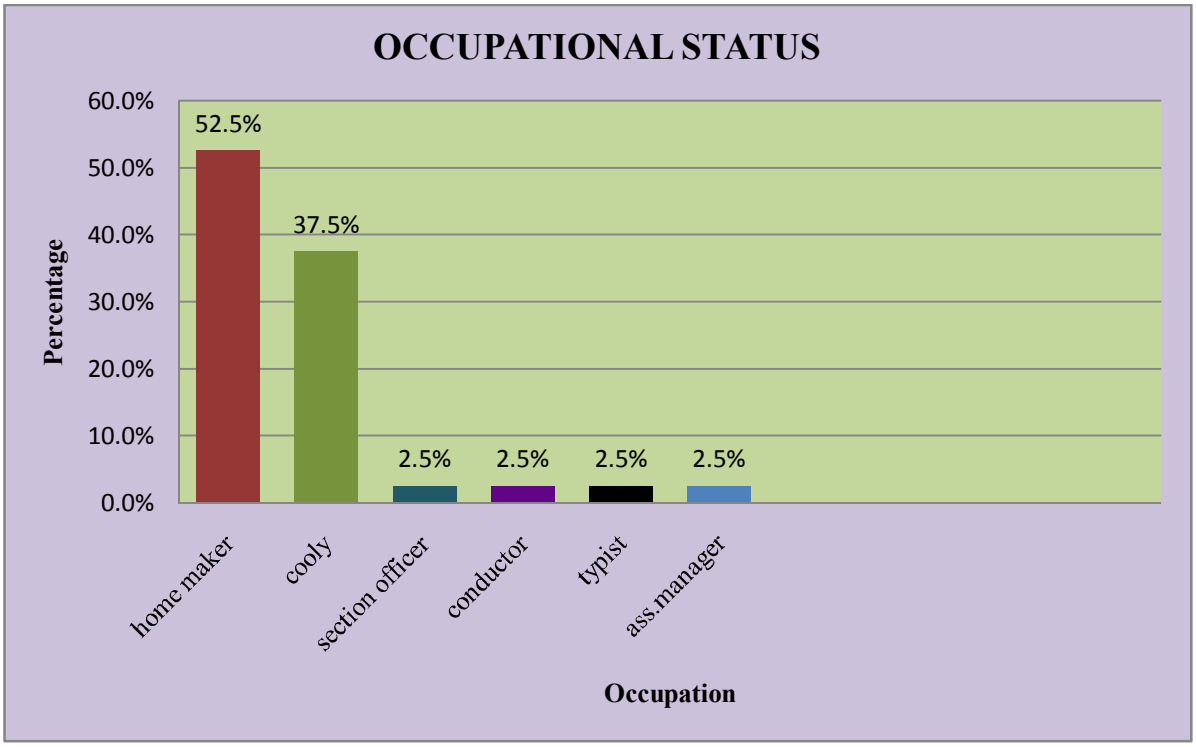


Inference:

Out of 40 cases, 37 cases were found to be in Pitha kaalam, i.e. between 33 – 66 years and 3 cases were found to be in Vaatha kaalam (31-32 years).

4. OCCUPATIONAL STATUS:

OCCUPATION	NUMBER OF CASES	PERCENTAGE (%)
COOLIE	15	25
SECTION OFFICER	1	2.5
BUS CONDUCTOR	1	2.5
HOME MAKER	21	52.5
TYPIST	1	2.5
ASST. MANAGER	1	2.5
TOTAL	40	100

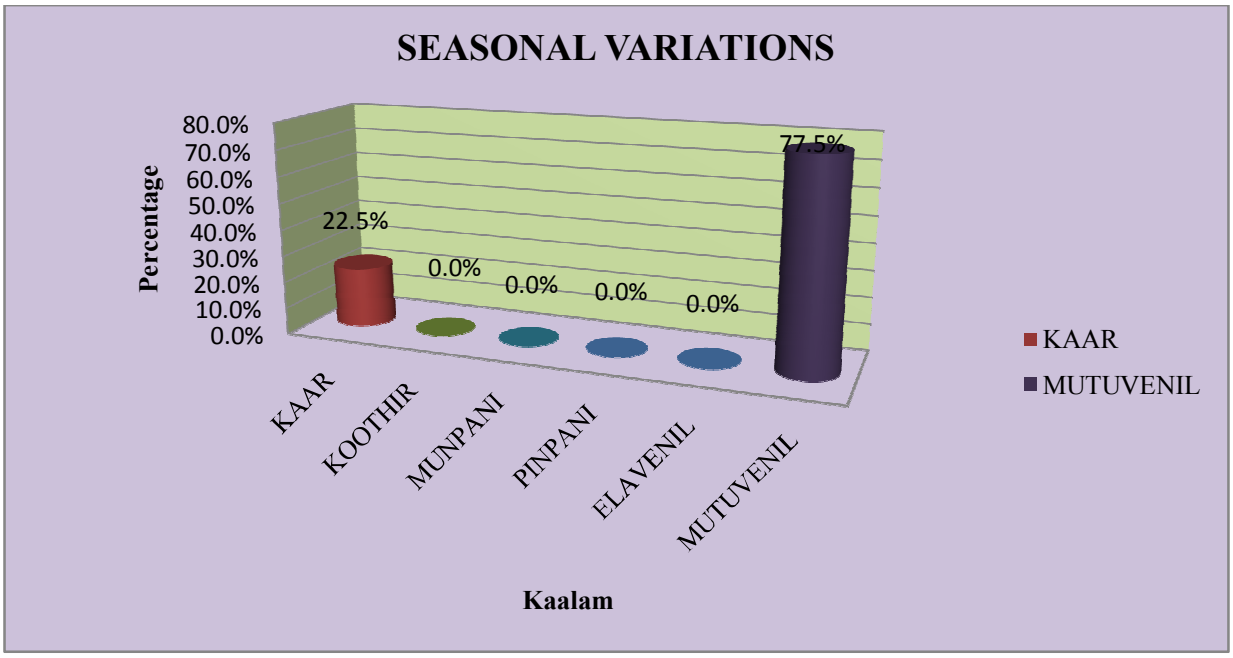


Inference:

Out of 40 cases, 21 patients (52.5 %) were Home makers.

4. SEASONAL VARIATIONS:

SEASON	NUMBER OF CASES	PERCENTAGE (%)
KAAR KAALAM	9	22.5
KOOTHIR KAALAM	-	-
MUNPANI KAALAM	-	-
PINPANI KAALAM	-	-
ELAVENIL KAALAM	-	-
MUTHUVENIL KAALAM	31	77.5
TOTAL	40	100

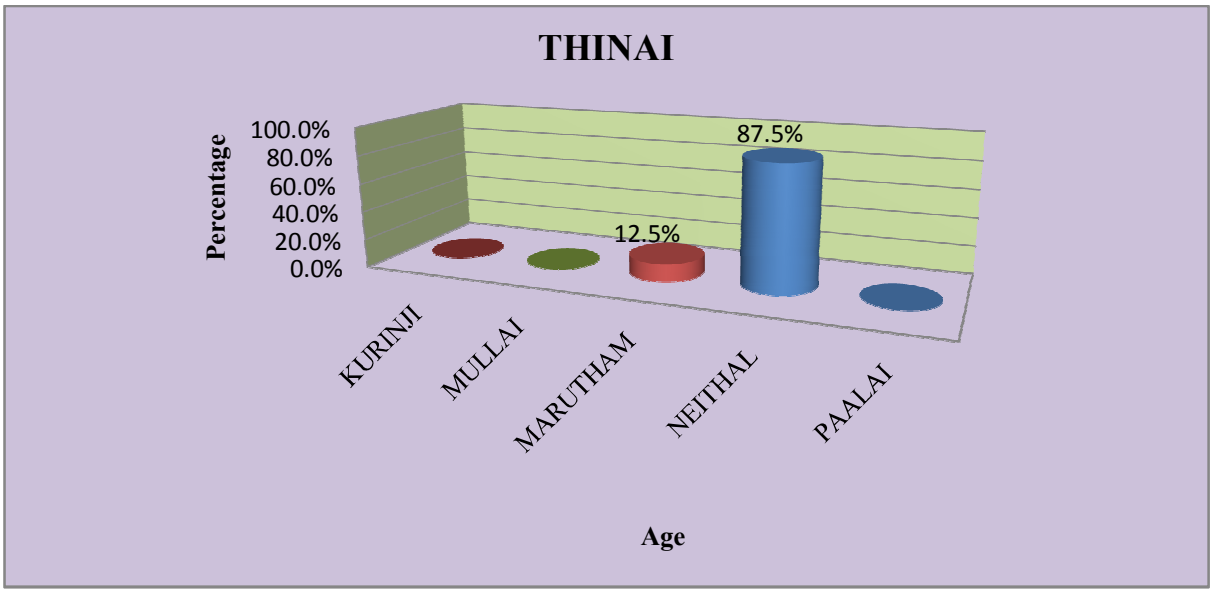


Inference:

Out of 40 cases, 9 patients (22.5%) were admitted in Kaar Kaalam and 31 patients (77.5%) were admitted in Muthuvenil Kaalam.

5. THINAI:

THINAI	NUMBER OF CASES	PERCENTAGE (%)
KURINJI	-	-
MULLAI	-	-
MARUTHAM	5	12.5
NEITHAL	35	87.5
PAALAI	-	-
TOTAL	40	100

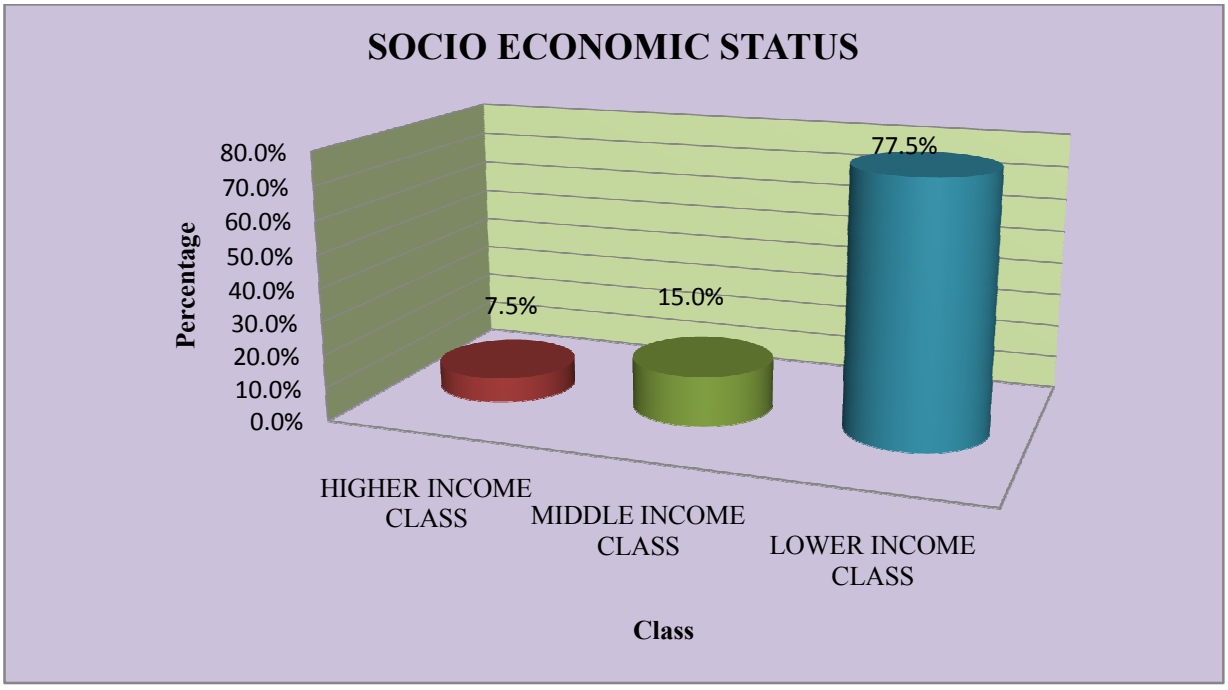


Inference:

Among the 40 patients, 5 patients (12.5 %) were from Marutham and 35 patients (87.5 %) were from Neithal thinai.

6. SOCIO- ECONOMIC STATUS:

SOCIO- ECONOMIC STATUS	NUMBER OF CASES	PERCENTAGE (%)
HIGHER INCOME	3	7.5
MIDDLE INCOME	6	15
LOWER INCOME	31	77.5
TOTAL	40	100

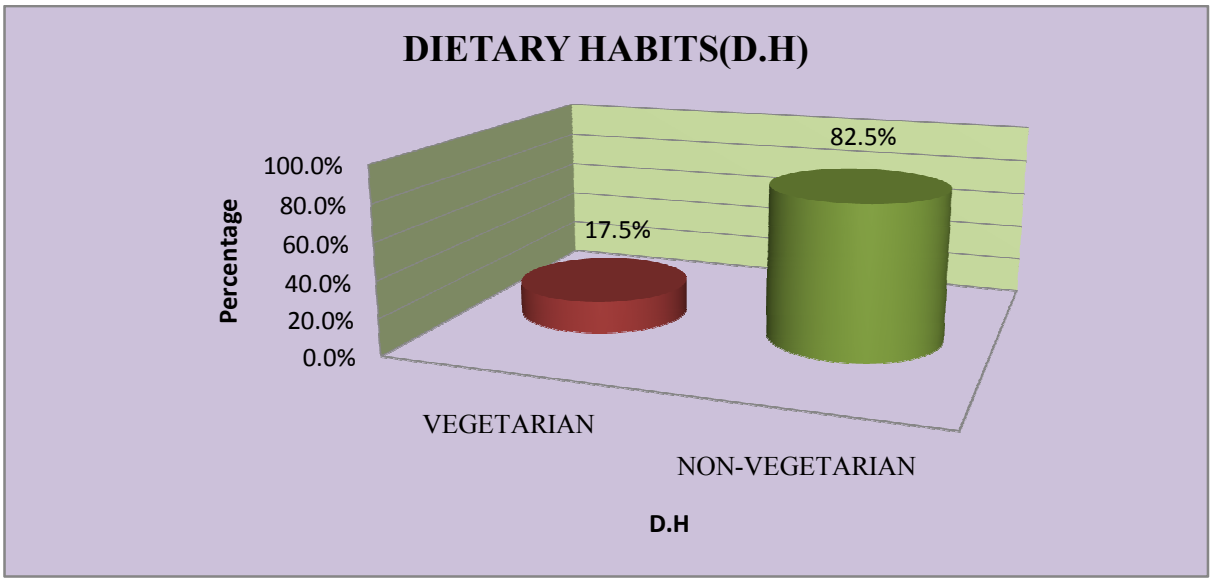


Inference:

Out of 40 cases 7.5% cases from upper and 15% cases were from middle class and 77.5% from lower class.

7. DIETARY HABITS (D.H.):

D.H.	NUMBER OF CASES	PERCENTAGE%
VEGETARIAN	7	17.5
NON-VEGETARIAN	33	82.5
TOTAL	40	100

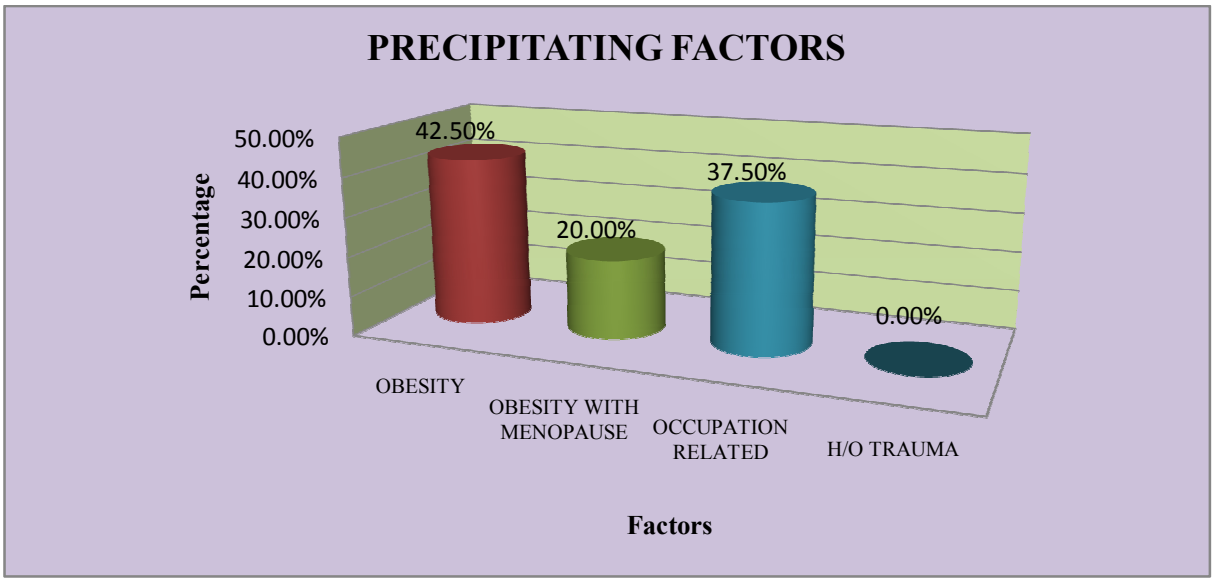


Inference:

Out of 40 cases 82.5% of cases were Non-vegetarians and 17.5% of cases were Vegetarians.

8. PRECIPITATING FACTORS:

PRECIPITATING FACTORS	NUMBER OF CASES	PERCENTAGE%
OBESITY	14	42.5
OBESITY WITH MENOPAUSE	12	20
OCCUPATION RELATED	14	37.5
H/O TRAUMA	-	-
TOTAL	40	100



Inference:

Out of 40 cases 42.5% of cases were Obesity.

10. DISTRIBUTION OF MUKKUTRAM:

a. VAATHAM:

Out of 40 cases Viyanan and Samanan were affected in all the 40 patients (100%).

b. PITHAM:

Out of 40 cases saathagam was affected in almost all the 40 cases (100%).

c. KABAM:

Out of 40 cases Santhigam was affected in almost all the 40 cases (100%).

11. UDAL THATHUKKAL:

The Seven thathukkal which constitute our body structure and help to maintain the normal physiological functions get changed in Pathological conditions.

Among the 7 Udal Kattugal, Saaram , kozhuppu and Enbu were affected in all the 40 cases (100%).

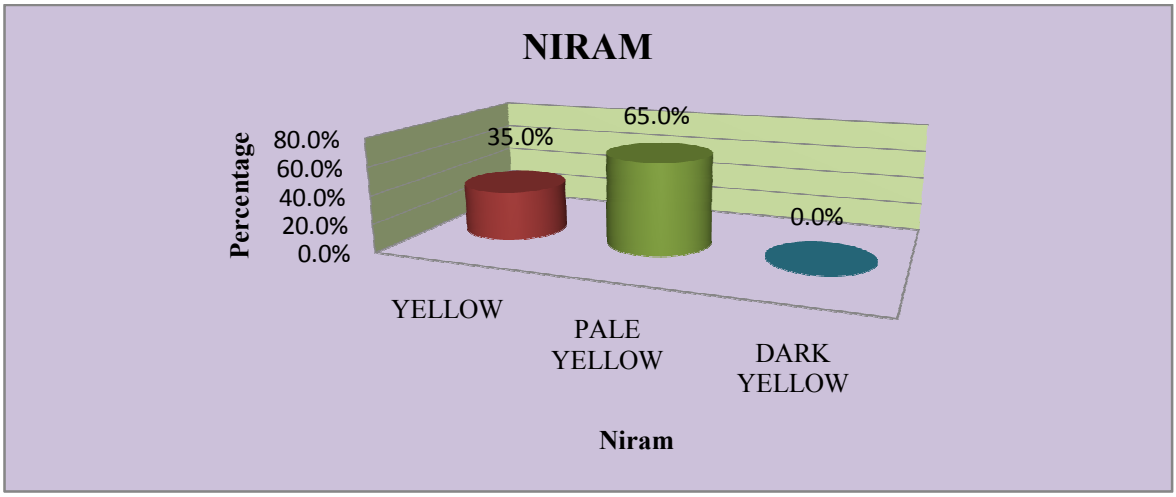
12. ENVAGAI THERVUGAL:

In Siddha system of Medicine, the eight types of investigative procedure were adopted for clinical approach and diagnosis. The investigations were done properly and observations were tabulated.

Among the 40 cases Sparism was affected in 40 cases.

13. NEERKKURI

NIRAM	NUMBER OF CASES	PERCENTAGE%
YELLOW	14	35
PALE YELLOW	26	65
DARK YELLOW	-	-

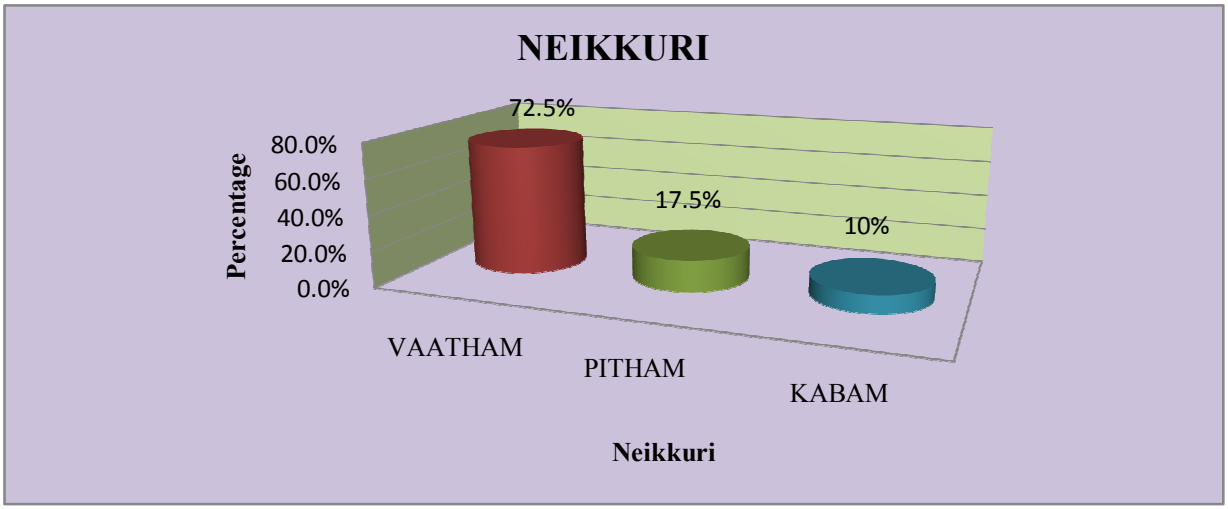


Inference:

Out of 40 cases, in 65% of cases urine was pale yellow in colour.

NEIKKURI:

NEIKKURI	NUMBER OF CASES	PERCENTAGE%
VAATHAM	29	72.5
PITHAM	7	17.5
KABAM	4	10
TOTAL	40	100

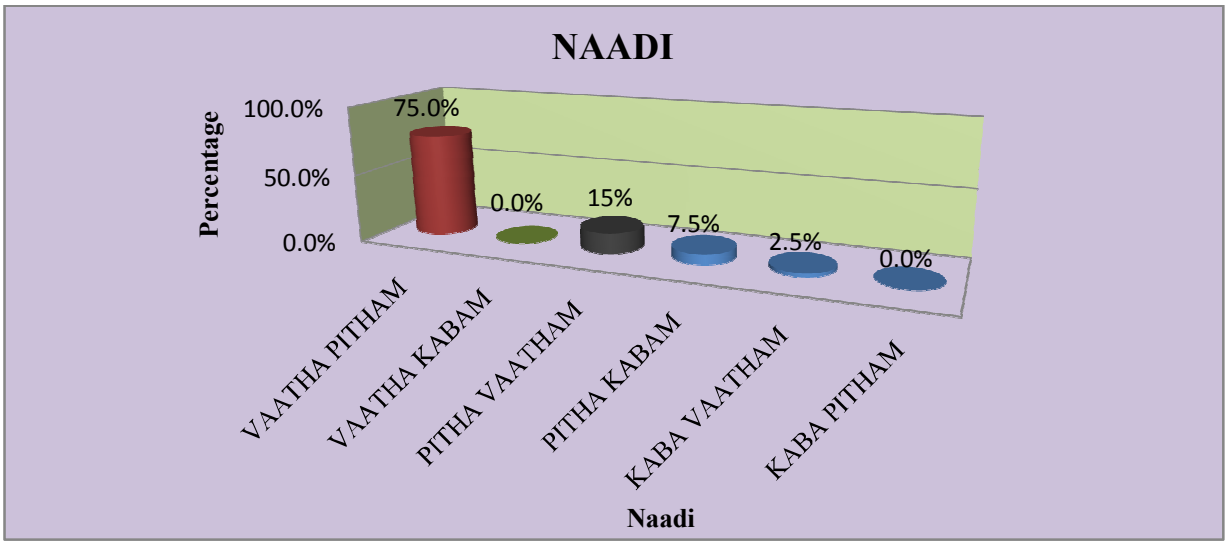


Inference:

Out of 40 cases, in 72.5% of cases Neikkuri was found as Vaatham.

4. NAADI:

NAADI	NUMBER OF CASES	PERCENTAGE%
VAATHA PITHAM	30	75
VAATHA KABAM	-	-
PITHA VAATHAM	6	15
PITHA KABAM	3	7.5
KABA VAATHAM	1	2.5
KABA PITHAM	-	-
TOTAL	40	100



Inference:

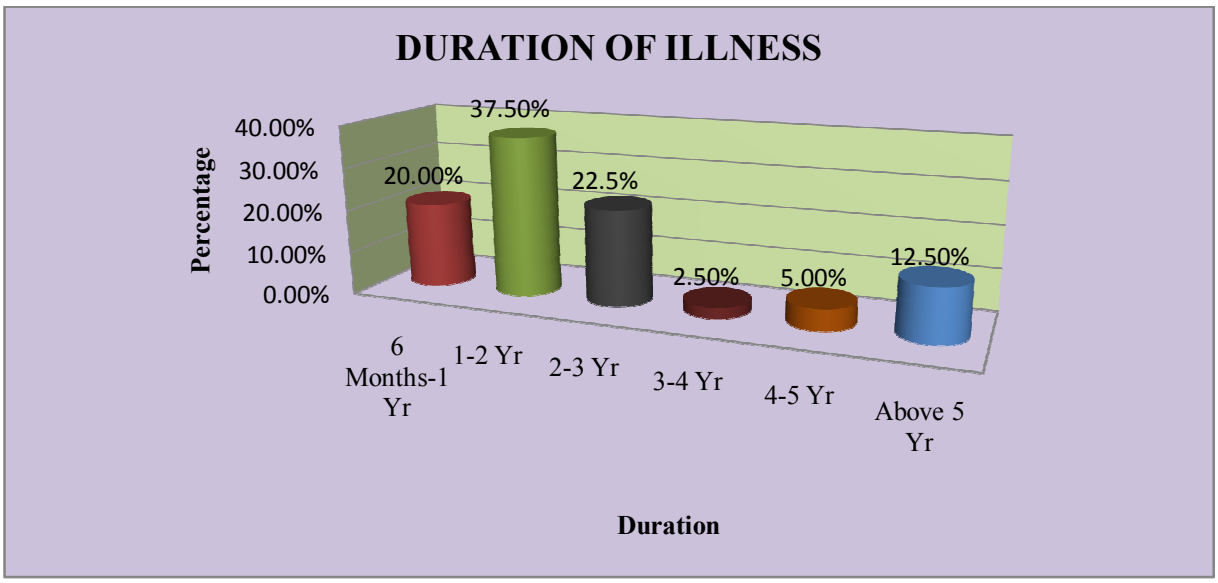
Among 40 cases, vaathapitham naadi was found in 30 patients, 6 were found in Pithavaatham.

15. DISTURBANCES IN KANMENTHIRIYAM:

Kaal was affected in all the 40 cases (100 %)

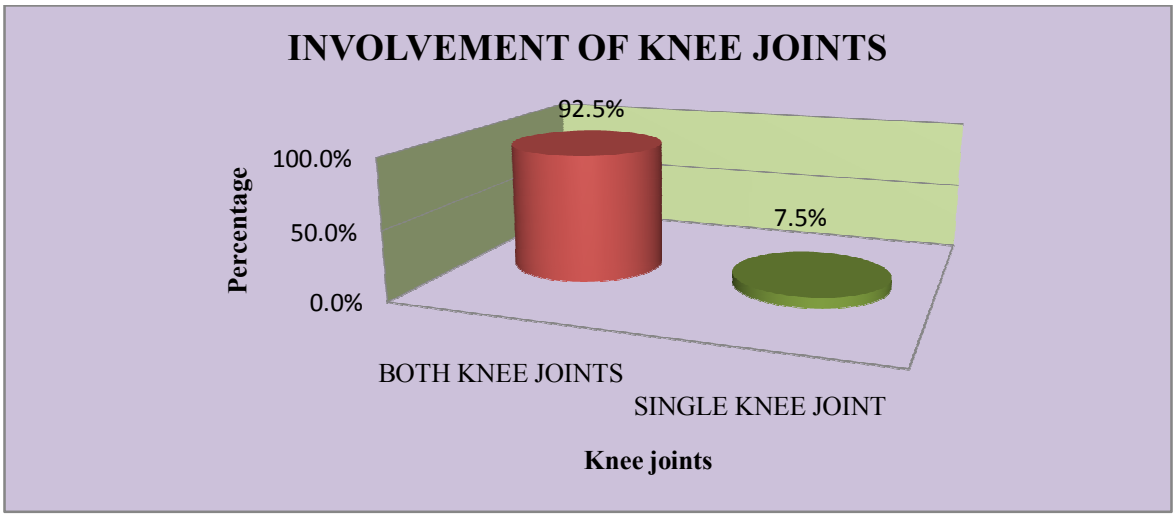
16. DURATION OF ILLNESS:

DURATION OF ILLNESS	NUMBER OF CASES	PERCENTAGE%
6 MONTHS – 1 YEAR	8	20
1 – 2 YEARS	15	37.5
2 – 3 YEARS	9	22.5
3 – 4 YEARS	1	2.5
4 – 5 YEARS	2	5
ABOVE 5 YEARS	5	12.5
TOTAL	40	100



17. INVOLVEMENT OF KNEE JOINTS:

KNEE JOINTS	NUMBER OF CASES	PERCENTAGE%
BOTH KNEE JOINTS	37	92.5
SINGLE KNEE JOINT ONLY	3	7.5
TOTAL	40	100

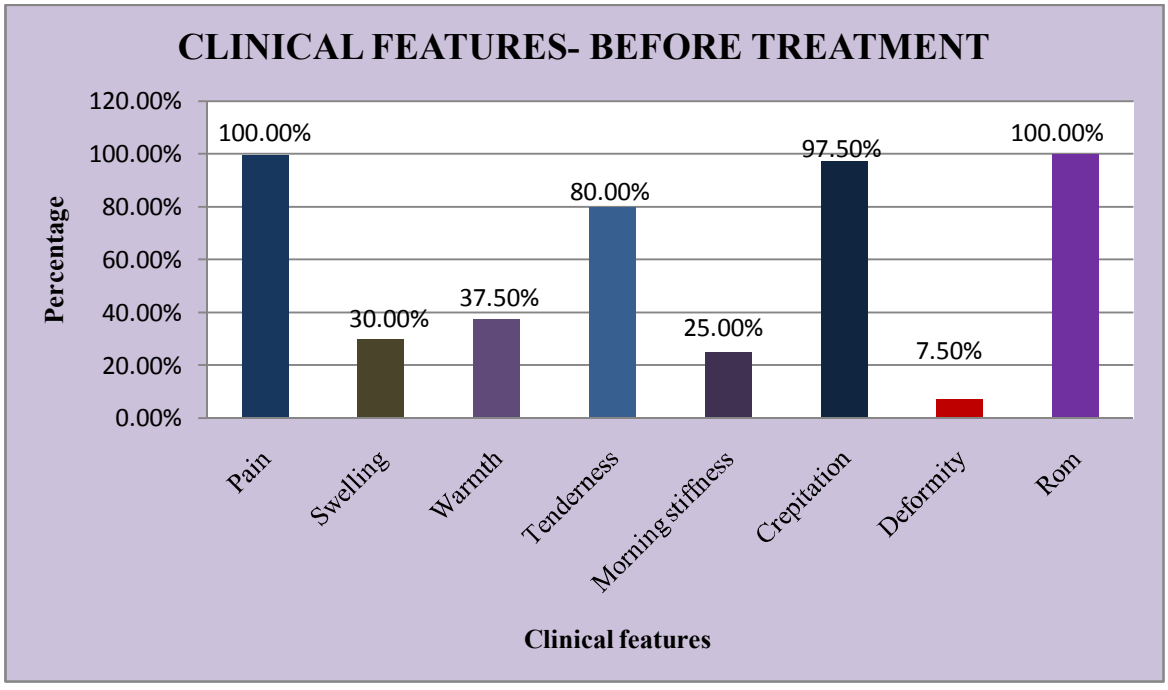


Inference:

Out of 40 cases both knee joints were affected in 37 patients (92.5%).

18. CLINICAL FEATURES – BEFORE TREATMENT:

CLINICAL FEATURES	NO. OF CASES	PERCENTAGE%
PAIN	40	100
SWELLING	12	30
WARMTH	15	37.5
TENDERNESS	32	80
MORNING STIFFNESS	10	25
CREPITATION	39	97.5
DEFORMITY	3	7.5
RESTRICTED MOVEMENTS	40	100

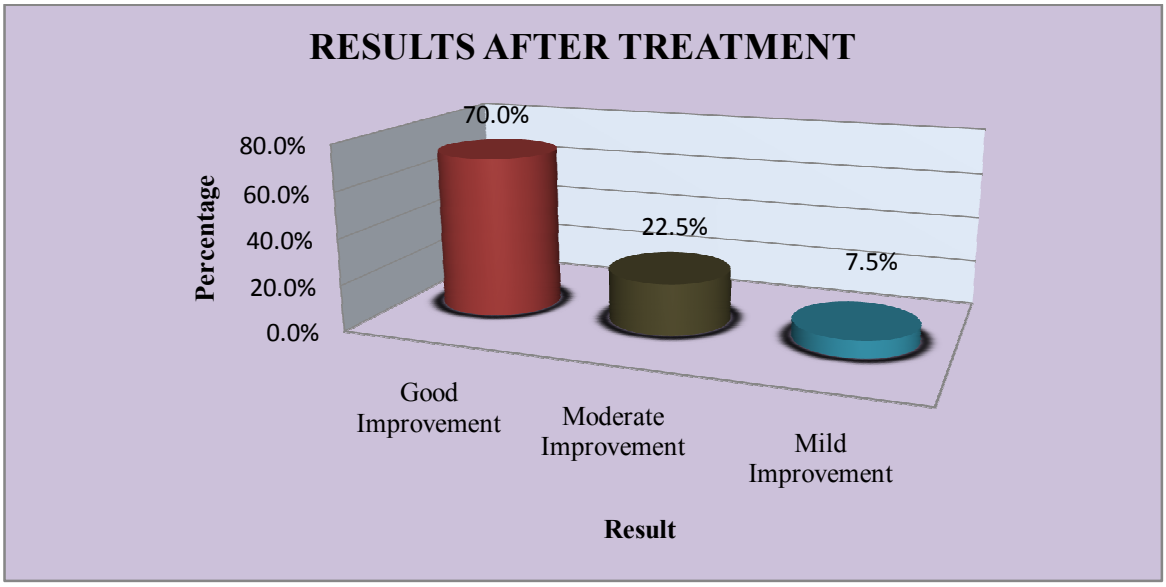


Inference:

Out of 40 cases, Pain and Restriction of movement Absent in all 40 cases.

19. RESULTS - AFTER TREATMENT:

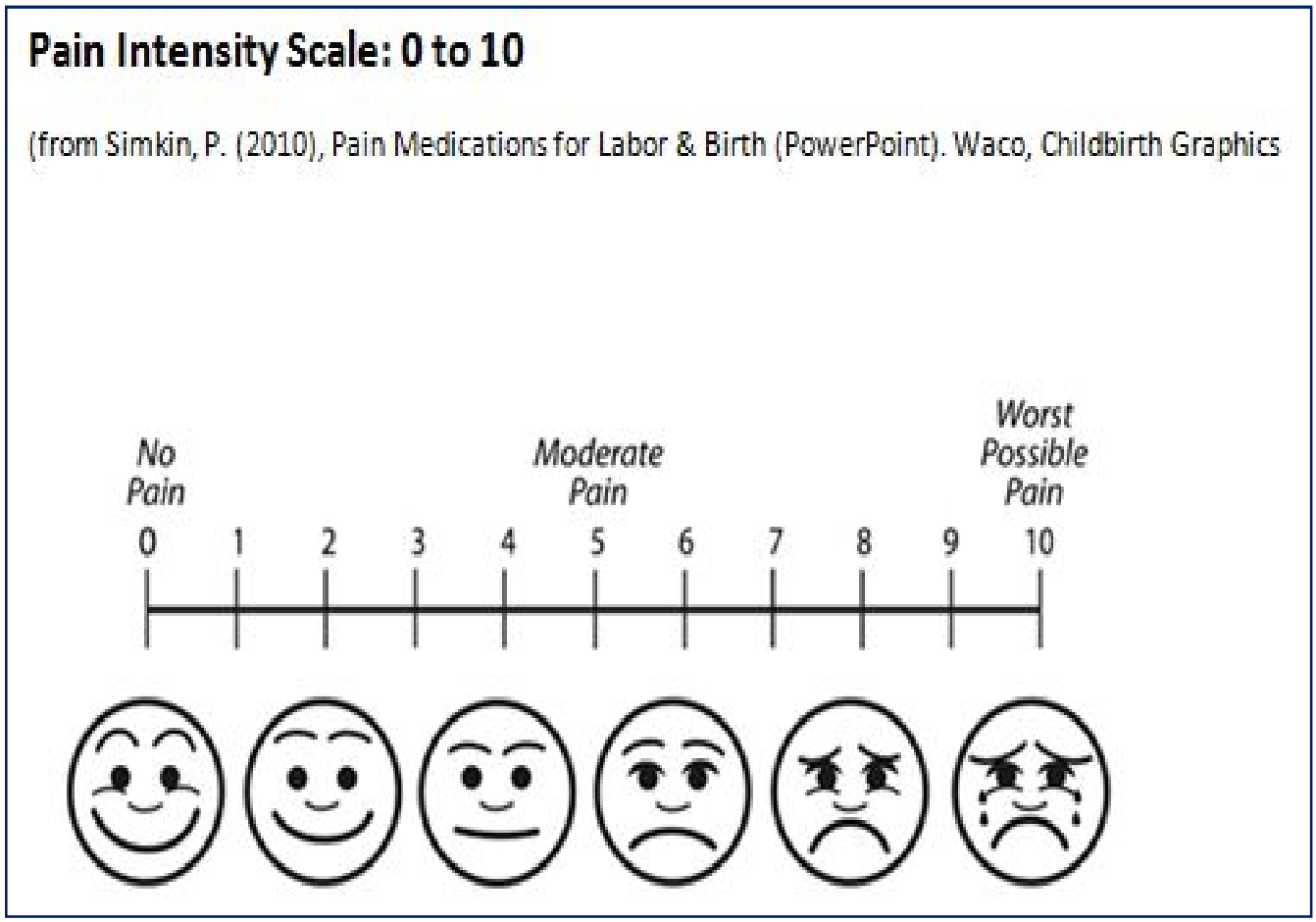
RESULT	NUMBER OF CASES	PERCENTAGE%
GOOD IMPROVEMENT	28	70
MODERATE IMPROVEMENT	9	22.5
MILD IMPROVEMENT	3	7.5
TOTAL	40	100



Inference:

Out of 40 cases, good improvement was observed in 28 patients, moderate improvement in 9 patients, and mild improvement in 3 patients.

1. **UNIVERSAL PAIN ASSESMENT SCALE:**



UNIVERSAL PAIN ASSESMENT SCALE:

A. 0 : No Pain

B. 1 -3 : Mild pain

C. 4-6 : Moderate pain

D.7-10 : Severe pain

Results of varmam manipulation according to pain scale

S. No	IP No	Name	Age/ Sex	Pain score	
				Before treatment	After treatment
1.	4941	Gnanam	31/M	6	0
2.	3993	Rajeshwari	54/F	5	0
3.	4999	Jagadeesan	47/M	2	2
4.	4994	Meghanadhan	51/M	9	2
5.	5002	Yettiyappan	57/M	6	3
6.	4048	Leelavathi	48/F	9	2
7.	5010	Ramesh	55/M	9	2
8.	4052	Kavitha	34/F	8	5
9.	4092	Elizabeth Mary	47/F	6	0
10.	4107	Sasikala	44/F	6	1

OP AND IP CASES CLINICAL IMPROVEMENT

Sl.	OP & IP NO	NAME	AGE	SEX	DOA	DOI	DOD	DAYS	RESULT
1	C81369	Gnanam	31	M	21.07.12	08 Months	09.09.12	48	GOOD
2	C78848	Rajeshwari	54	F	23.07.12	03 Year	15.09.12	48	GOOD
3	C85246	Jagadeesan	47	M	01.08.12	09 Months	20.09.12	48	MILD
4	C87229	Meghanadhan	51	M	01.08.12	01 Year	22.09.12	48	GOOD
5	B78877	Yettiyappan	57	M	03.08.12	05 Years	21.09.12	48	GOOD
6	C 80523	Leelavathi	48	F	06.08.12	01 Year	25.09.12	48	GOOD
7	C82066	Ramesh	55	M	06.08.12	03 Years	25.09.12	48	GOOD
8	C87632	Kavitha	34	F	07.08.12	05 Years	25.09.12	48	MODERATE
9	B90712	Elizabeth Mary	47	F	21.08.12	02 Years	10.10.12	48	GOOD
10	C92352	Sasikala	44	F	24.08.12	01 Year	12.10.12	48	MODERATE
11	C95716	Josephin Mary	41	F	05.09.12	10 Years	25.10.12	48	GOOD
12	C31382	Nazeer	60	M	30.08.12	10 Years	19.10.12	48	GOOD
13	C93231	Kanniga	62	F	10.09.12	08 Years	29.10.12	48	GOOD
14	C48875	Jambhulingam	60	M	01.09.12	02 Years	22.10.12	48	GOOD
15	C95248	Suseela	50	F	06.09.12	10 Years	24.10.12	48	MODERATE
16	C91495	Ranganathan	61	M	06.09.12	10 Months	25.10.12	48	MODERATE
17	AR9161	Saradha	55	F	09.08.12	08 Years	29.09.12	48	GOOD
18	C95197	Sumathi	50	F	08.09.12	11/2 Years	29.09.12	48	GOOD
19	C97708	Parvathi	38	F	18.09.12	01 Year	05.11.12	48	GOOD
20	C96778	Subramaniyam	52	M	20.09.12	01 Year	09.11.12	48	GOOD
21	C80887	Muniyammal	43	F	22.07.12	08 Months	10.09.12	48	GOOD
22	C85318	Thamizhselvi	38	F	22.07.12	01Year	14.09.12	48	MODERATE
23	C82447	Selvi	32	F	24.07.12	01 Year	17.09.12	48	MODERATE
24	C79569	Pugalendhi	38	M	24.07.12	03 Years	11.09.12	48	GOOD
25	C82592	Kalarani	53	F	24.07.12	01 Year	10.09.12	48	GOOD
26	C78485	Rosebabu	55	M	26.07.12	08 Months	20.09.12	48	GOOD
27	C84995	Kasthoori	56	F	26.07.12	09 Months	13.09.12	48	MODERATE
28	C38181	Revathy Sridhar	52	F	02.08.12	06 Years	22.09.12	48	GOOD
29	C83812	Sumathi	47	F	26.07.12	08 Months	24.09.12	48	GOOD
30	C83543	Karunanidhi	56	M	27.07.12	01 Year	20.09.12	48	GOOD
31	C86074	Poongothai	55	F	30.07.12	10 Years	17.09.12	48	MILD
32	C47715	Senthamaraiselvi	44	F	30.07.12	01 Year	24.09.12	48	MILD
33	C85904	Lakshmiprabha	50	F	31.07.12	01 Year	17.09.12	48	GOOD
34	C85223	Vijayalakshmi	32	F	31.07.12	08 Months	17.09.12	48	GOOD
35	C83530	Sulochana	45	F	02.08.12	03 Years	24.09.12	48	MODERATE
36	C84087	Arumugam	54	M	03.08.12	04 Years	24.09.12	48	GOOD
37	C22005	Bama	50	F	04.08.12	02 Years	27.09.12	48	GOOD
38	C85214	Malliga	48	F	02.09.12	03 Years	20.10.12	48	MODERATE
39	C91616	Jeeva	47	F	01.09.12	01 Year	19.10.12	48	GOOD
40	C95043	Chandra	48	F	08.09.12	02 Years	13.10.12	48	GOOD

Hb and RBC – INVESTIGATIONS BEFORE AND AFTER TREATMENT – IN IP & OP PATIENTS

SL. NO	OP/IP NO	NAME	Hb gm%		TRBC Million/cumm	
			Before treatment	After treatment	Before treatment	After Treatment
1.	4941	Gnanam	19.3	16.8	6.3	5.4
2.	3993	Rajeshwari	13.8	14.0	4.2	4.4
3.	4999	Jagadeesan	16.1	15.9	5.3	5.2
4.	4994	Meghanadhan	13.1	14.0	3.7	4.0
5.	5002	Yettiyappan	13.7	14.1	4.2	4.4
6.	4048	Leelavathi	14.6	13.8	4.8	4.6
7.	5010	Ramesh	14.7	14.9	4.6	4.6
8.	4052	Kavitha	11.7	11.4	4.6	4.6
9.	4092	Elizabeth Mary	14.0	12.0	4.6	4.6
10.	4107	Sasikala	12.7	10.5	4.2	4.2
11.	4158	Josephin Mary	12.9	13.6	4.6	4.8
12.	5084	Nazeer	14.6	12.8	5.2	5.3
13.	4170	Kanniga	12.9	11.0	4.4	4.5
14.	5088	Jambhulingam	13.3	12.0	4.4	4.9
15.	4161	Suseela	12.1	11.8	4.8	4.5
16.	4071	Kasthuri	13.6	13.7	4.7	4.8
17.	4058	Saradha	11.3	11.6	4.3	4.4
18.	4165	Sumathi	14.3	14.5	4.6	4.5
19.	4193	Parvathi	11.0	12.0	4.2	4.3
20.	5152	Subramaniyam	13.0	11.3	4.2	4.1
21.	C80887	Muniyammal	13.6	14.0	4.6	4.8
22.	C85318	Thamizhselvi	14.8	15.5	5.0	5.1
23.	C82447	Selvi	12.2	12.5	4.3	4.3
24.	C79569	Pugalendhi	13.8	13.6	5.1	3.0
25.	C82592	Kalarani	13.9	14.2	4.7	4.5
26.	C78485	Rosebabu	15.8	15.8	5.3	5.3
27.	C91495	Ranganathan	14.1	14	5.3	5.1
28.	C38181	Revathy Sridhar	12.7	12.9	4.1	4.0
29.	C83812	Sumathi	12.2	12.8	4.2	4.4
30.	C83543	Karunanidhi	12.8	13.1	4.9	4.9
31.	C86074	Poongothai	13.0	12.8	4.3	4.2
32.	C47715	Senthamaraiselvi	10.0	12.3	4.8	4.2
33.	C85904	Lakshmiprabha	12.8	13.0	4.5	4.6
34.	C85223	Vijayalakshmi	11.5	12.0	4.2	4.6
35.	C83530	Sulochana	13.0	13.6	4.4	4.6
36.	C84087	Arumugam	13.2	13.7	4.6	4.6
37.	C22005	Bama	12.9	12.7	4.4	4.4
38.	C85214	Malliga	11.9	11.7	4.2	4.7
39.	C91616	Jeeva	14.5	12.2	5.2	5.0
40.	C95043	Chandra	13.0	14.0	4.3	4.2

BT – BEFORE TREATMENT AT – AFTER TREATMENT

CHOLESTEROL PROFILE OF THE OPD AND IPD PATIENTS (BEFORE AND AFTER TREATMENT)

S.NO	OP/IP NO	T.CHOLESTEROL (mg/dl)		HDL (mg/dl)		LDL (mg/dl)		VLDL (mg/dl)		TGL (mg/dl)	
		BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1.	4941	193	168	33	34	103	79	29	28	145	141
2.	3993	183	128	32	36	106	73	27	31	136	158
3.	4999	219	164	36	40	140	84	38	30	192	154
4.	4994	150	155	29	28	75	84	49	20	241	101
5.	5002	152	96	27	27	84	52	17	20	86	103
6.	4048	203	154	38	38	136	79	27	37	136	185
7.	5010	168	209	30	40	109	99	18	26	90	131
8.	4052	191	199	35	40	122	100	12	18	64	94
9.	4092	227	246	39	43	140	121	27	28	138	143
10.	4107	127	133	30	32	98	73	17	21	86	106
11.	4158	154	146	32	36	108	90	25	21	127	120
12.	5084	164	184	28	35	84	87	30	33	154	167
13.	4170	188	205	34	34	126	94	29	19	148	96
14.	5088	158	172	37	34	67	76	14	25	72	126
15.	4161	188	200	35	36	129	100	32	21	160	108
16.	4071	219	253	31	45	110	126	34	28	173	144
17.	4058	197	198	34	38	161	95	21	15	106	75
18.	4165	156	140	34	36	89	80	43	38	217	196
19.	4193	186	200	36	43	88	112	32	35	161	158
20.	5152	190	238	30	43	96	111	38	37	192	186
21.	C80887	179	144	28	31	108	84	18	19	94	98
22.	C85318	177	212	30	43	126	106	23	22	118	114
23.	C82447	139	130	31	35	78	74	13	14	67	72
24.	C79569	180	169	35	34	100	117	33	27	166	137
25.	C82592	172	150	36	37	110	98	20	20	102	96
26.	C78485	179	157	28	32	97	79	17	18	85	93
27.	C91495	190	200	42	46	120	118	41	40	208	200
28.	C38181	110	149	21	30	42	72	09	14	47	73
29.	C83812	209	163	26	34	78	89	38	19	194	96
30.	C83543	156	163	39	32	88	72	14	14	73	71
31.	C86074	239	221	36	39	160	108	29	32	149	163
32.	C47715	184	200	38	35	73	96	29	26	145	133
33.	C85904	156	160	31	36	110	112	16	15	80	78
34.	C85223	186	170	37	40	129	110	20	20	103	98
35.	C83530	189	160	32	40	80	72	29	25	148	149
36.	C84087	213	218	34	40	109	106	47	28	238	144
37.	C22005	121	109	20	39	70	55	24	16	122	81
38.	C85214	184	196	27	36	164	94	20	25	103	128
39.	C91616	155	179	37	35	106	83	65	51	328	256
40.	C95043	244	168	45	48	132	140	57	32	286	141

BT – BEFORE TREATMENT AT – AFTER TREATMENT

BLOOD INVESTIGATIONS BEFORE AND AFTER TREATMENT- IP PATIENTS

S. NO	IP. NO	TC (million/ cu.mm)		DC (%)								ESR (mm/hr)	
				N		L		E		M			
		BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1.	4941	11900	8900	74	71	20	24	6	5	-	-	4/8	2/6
2.	3993	10500	9900	72	77	25	20	3	3	-	-	8/16	8/18
3.	4999	5600	5700	62	63	33	33	5	4	-	-	2/4	4/6
4.	4994	4800	4900	57	56	36	37	5	6	2	1	8/20	4/16
5.	5002	9400	9800	50	40	28	38	2	2	-	-	4/10	4/16
6.	4048	8200	7500	70	66	26	31	4	3	-	-	6/12	10/26
7.	5010	8700	9000	65	66	30	30	5	4	-	-	2/4	8/20
8.	4052	8000	9000	64	66	27	28	9	6	-	-	26/42	6/26
9.	4092	6800	6700	70	40	26	54	4	6	-	-	2/6	2/4
10.	4107	9300	9000	76	67	20	30	4	3	-	-	14/28	2/4
11.	4158	8600	8400	64	61	32	34	4	5	-	-	8/28	4/8
12.	5084	10100	10200	63	60	33	35	4	5	-	-	6/22	4/8
13.	4170	10700	11400	52	54	46	43	2	3	-	-	6/24	4/8
14.	5088	8100	6100	70	65	25	31	5	4	-	-	4/8	2/10
15.	4161	8500	9600	63	68	34	29	3	3	-	-	10/32	2/10
16.	4071	7600	7200	66	59	30	36	4	5	-	-	30/62	12/44
17.	4058	4000	7200	64	65	31	33	5	2	-	-	6/14	26/62
18.	4165	7700	8000	64	62	30	34	5	4	1	0	4/12	2/6
19.	4193	7600	9800	64	65	33	30	3	5	-	-	4/36	2/6
20.	5152	6000	6300	54	50	42	45	4	5	-	-	6/18	4/8

BLOOD INVESTIGATIONS BEFORE AND AFTER TREATMENT - OP PATIENTS

S. NO	0P. NO	TC (million/ cu.mm		DC (%)								ESR (mm/hr)	
				N		L		E		M		BT	AT
		BT	AT	BT	AT	BT	AT	BT	AT	BT	AT		
1.	C80887	6700	7300	60	59	33	36	6	5	1	-	2/6	6/12
2.	C85318	6200	6300	57	63	37	35	6	2	-	-	2/4	2/4
3.	C82447	6000	7200	60	65	33	30	5	5	-	-	10/22	6/14
4.	C79569	7200	7800	50	56	42	39	7	5	1	-	12/14	4/16
5.	C82592	9500	9700	51	54	44	41	5	5	-	-	4/12	2/6
6.	C78485	6100	6000	60	59	35	37	4	4	1	-	2/4	2/4
7.	C91495	7600	9300	67	72	27	23	6	5	-	-	10/22	4/12
8.	C38181	6100	6200	47	52	35	33	17	01	01	14	10/22	6/16
9.	C83812	6800	7000	44	46	32	31	22	23	2	-	80/100	24/70
10.	C83543	7100	7100	65	61	30	34	5	5	-	-	14/30	2/10
11.	C86074	5400	6600	55	62	38	33	5	5	2	-	4/12	2/4
12.	C47715	8800	6100	65	60	33	35	2	5	-	-	2/6	2/6
13.	C85904	5200	6000	56	65	36	30	4	5	4	-	6/16	4/8
14.	C85223	7500	8000	65	63	30	32	5	5	-	-	2/8	4/16
15.	C83530	12500	8500	42	56	41	36	17	6	-	-	6/16	4/8
16.	C84087	4500	5300	50	55	44	40	6	5	-	-	6/14	2/4
17.	C22005	5900	5800	55	55	40	41	5	4	-	-	6/16	4/12
18.	C85214	8000	8800	60	45	34	52	6	3	-	-	10/20	2/4
19.	C91616	10500	9000	68	62	30	33	2	5	-	-	8/16	2/6
20.	C95043	7400	8000	56	74	42	20	2	6	-	-	14/44	6/12

SERUM BILIRUBIN BEFORE AND AFTER TREATMENT - IP PATIENTS

Sl. No	IP NO	Serum bilirubin (mg/dl)					
		Direct		Indirect		Total	
		BT	AT	BT	AT	BT	AT
1.	4941	0.2	0.3	0.4	0.4	0.6	0.7
2.	3993	0.2	0.2	0.3	0.1	0.5	0.3
3.	4999	0.5	0.2	0.5	0.3	1.0	0.5
4.	4994	0.6	0.3	0.6	0.4	1.2	0.7
5.	5002	0.1	0.3	0.2	0.4	0.3	0.7
6.	4048	0.2	0.2	0.4	0.3	0.6	0.5
7.	5010	0.2	0.3	0.3	0.4	0.5	0.7
8.	4052	0.2	0.2	0.1	0.3	0.3	0.5
9.	4092	0.3	0.2	0.4	0.2	0.7	0.4
10.	4107	0.2	0.3	0.4	0.5	0.6	0.8
11.	4158	0.2	0.2	0.2	0.2	0.4	0.4
12.	5084	0.3	0.2	0.4	0.3	0.7	0.5
13.	4170	0.3	0.3	0.4	0.4	0.7	0.7
14.	5088	0.4	0.3	0.5	0.5	0.9	0.8
15.	4161	0.2	0.3	0.3	0.4	0.5	0.7
16.	4071	0.4	0.3	0.5	0.4	0.9	0.7
17.	4058	0.2	0.2	0.2	0.4	0.4	0.6
18.	4165	0.2	0.1	0.2	0.2	0.4	0.3
19.	4193	0.2	0.2	0.3	0.4	0.5	0.6
20.	5152	0.2	0.2	0.3	0.3	0.5	0.5

SERUM BILIRUBIN BEFORE AND AFTER TREATMENT - OP PATIENTS

S. No	OP NO	Serum bilirubin					
		Direct		Indirect		Total	
		BT	AT	BT	AT	BT	AT
1.	C80887	0.2	0.2	0.4	0.2	0.6	0.4
2.	C85318	0.7	0.6	0.6	0.6	1.3	1.2
3.	C82447	0.2	0.2	0.4	0.3	0.6	0.5
4.	C79569	0.2	0.2	0.2	0.3	0.4	0.5
5.	C82592	0.2	0.2	0.4	0.3	0.6	0.5
6.	C78485	0.2	0.3	0.3	0.5	0.5	0.8
7.	C91495	0.2	0.2	0.2	0.2	0.4	0.4
8.	C38181	0.5	0.3	0.5	0.5	1.0	0.8
9.	C83812	0.2	0.2	0.3	0.3	0.5	0.5
10.	C83543	0.2	0.3	0.4	0.4	0.6	0.7
11.	C86074	0.2	0.2	0.3	0.4	0.5	0.6
12.	C47715	0.2	0.2	0.2	0.3	0.4	0.5
13.	C85904	0.2	0.2	0.3	0.3	0.5	0.5
14.	C85223	0.2	0.2	0.1	0.2	0.3	0.3
15.	C83530	0.2	0.2	0.3	0.2	0.5	0.4
16.	C84087	0.3	0.3	0.4	0.5	0.7	0.8
17.	C22005	0.2	0.2	0.2	0.4	0.4	0.6
18.	C85214	0.2	0.2	0.3	0.2	0.5	0.4
19.	C91616	0.2	0.2	0.3	0.3	0.5	0.5
20.	C95043	0.2	0.2	0.4	0.3	0.6	0.5

LIVER FUNCTION TESTS BEFORE AND AFTER TREATMENT - IP PATIENTS

Sl. No	IP NO	SGOT (IU/dl)		SGPT (IU/dl)		Al.pho (U/dl)		Albumin (g/dl)		Globulin (g/dl)		T. Protein (g/dl)	
		BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1.	4941	36	29	38	30	232	191	4.2	3.6	2.6	3.0	6.8	6.6
2.	3993	16	11	18	14	260	182	3.5	3.8	2.0	2.1	7.0	5.9
3.	4999	20	16	21	18	174	155	4.1	4.0	2.3	2.2	6.4	6.2
4.	4994	20	12	24	16	160	175	3.9	3.3	3.5	2.7	7.4	6.0
5.	5002	27	20	24	23	165	166	4.3	3.8	3.1	3.1	7.4	6.9
6.	4048	10	14	11	16	140	183	5.1	3.7	2.0	2.4	7.1	6.1
7.	5010	51	11	45	13	220	156	4.2	3.7	3.0	2.8	7.2	6.5
8.	4052	24	13	06	14	172	159	4.0	3.7	2.0	2.4	6.0	6.1
9.	4092	91	53	122	71	220	260	4.1	4.3	3.0	2.0	7.1	6.3
10.	4107	26	11	27	13	142	170	3.1	3.9	2.4	2.3	5.5	6.2
11.	4158	12	21	14	30	150	146	3.2	3.1	2.0	2.4	5.2	5.6
12.	5084	12	18	13	21	135	165	4.6	4.3	3.2	2.7	7.8	7.0
13.	4170	20	11	22	12	196	143	4.0	3.2	2.0	2.5	6.0	5.7
14.	5088	26	25	28	28	169	201	3.7	3.7	2.0	2.6	5.7	6.3
15.	4161	13	12	14	14	183	153	3.8	3.4	2.8	3.0	6.6	6.4
16.	4071	19	13	20	16	236	165	3.4	3.9	3.3	2.8	6.7	6.7
17.	4058	22	12	23	14	175	130	4.1	3.7	2.0	2.3	6.1	6.0
18.	4165	29	26	30	28	195	170	3.6	3.8	2.9	3.0	6.5	7.0
19.	4193	12	12	14	13	156	160	3.9	3.0	2.8	2.6	6.7	5.6
20.	5152	13	16	15	18	199	156	3.6	3.7	2.9	2.0	6.5	5.7

LIVER FUNCTION TESTS BEFORE AND AFTER TREATMENT - OP PATIENTS

S. No	OP NO	SGOT (IU/dl)		SGPT (IU/dl)		Al.pho (U/dl)		Albumin (g/dl)		Globulin (g/dl)		T. Protein (g/dl)	
		BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1.	C80887	20	17	21	18	169	140	-	3.7	-	2.8	-	6.5
2.	C85318	12	10	13	12	156	176	3.6	5.0	3.0	2.0	7.2	7.0
3.	C82447	27	44	31	38	256	201	3.6	4.6	4.0	2.5	7.6	7.1
4.	C79569	24	20	28	22	193	166	3.2	3.9	2.6	2.8	6.5	6.7
5.	C82592	60	24	69	26	214	216	5.0	5.0	2.0	3.1	7.0	7.2
6.	C78485	26	15	27	17	156	166	4.0	4.1	2.3	2.3	6.3	6.4
7.	C91495	16	15	17	18	150	155	4.1	4.1	2.6	2.0	6.7	6.7
8.	C38181	20	10	21	12	176	186	3.0	3.8	2.0	2.8	5.0	6.6
9.	C83812	20	28	26	17	199	200	4.2	4.6	3.0	2.4	7.2	7.0
10.	C83543	30	18	32	20	249	172	3.3	3.7	4.1	2.8	7.4	6.5
11.	C86074	16	16	17	18	138	170	4.5	3.1	2.0	2.0	6.5	5.1
12.	C47715	23	25	29	27	198	151	3.7	4.2	3.1	2.3	6.8	6.5
13.	C85904	30	25	31	29	198	186	4.6	4.6	3.0	3.1	7.6	7.3
14.	C85223	14	18	15	20	150	156	4.9	4.6	3.0	3.0	7.9	7.4
15.	C83530	27	19	28	20	199	187	4.7	4.4	2.1	2.2	6.8	6.9
16.	C84087	30	23	31	25	186	140	5.1	4.8	2.0	2.7	7.1	7.5
17.	C22005	14	16	15	18	140	204	3.0	3.2	2.0	2.4	5.0	5.6
18.	C85214	24	35	25	24	170	170	3.6	3.8	2.7	2.0	6.4	5.8
19.	C91616	12	13	13	15	167	163	4.1	3.8	2.5	2.5	6.6	6.3
20.	C95043	24	20	26	24	189	180	3.0	3.6	2.1	3.0	5.1	6.6

URINE AND MOTIONS EXAMINATION BEFORE AND AFTER TREATMENT – IP

S. NO	IP NO	URINE							
		Before Treatment				After Treatment			
		Albumin	Sugar	Deposits		Albumin	Sugar	Deposits	
				Pus Cells	Epi. cells			Pus cells	Epi. cells
1.	4941	NIL	NIL	2-6	1-2	NIL	NIL	2-6	1-2
2.	3993	NIL	NIL	2-4	2-4	NIL	NIL	3-4	3-4
3.	4999	NIL	NIL	1-2	2-4	NIL	NIL	1-2	2-4
4.	4994	NIL	NIL	1-2	2-3	NIL	NIL	2-4	1-2
5.	5002	NIL	NIL	1-2	1-2	NIL	NIL	2-3	1-2
6.	4048	NIL	NIL	3-4	2-3	NIL	NIL	3-4	3-4
7.	5010	NIL	NIL	1-2	1-2	NIL	NIL	1-2	2-3
8.	4052	NIL	NIL	2-3	2-3	NIL	NIL	2-3	2-3
9.	4092	NIL	NIL	2-3	3-6	NIL	NIL	3-4	4-8
10.	4107	NIL	NIL	1-2	2-4	NIL	NIL	1-2	2-4
11.	4158	NIL	NIL	3-4	2-4	NIL	NIL	3-4	2-4
12.	5084	NIL	NIL	2-4	2-4	NIL	NIL	1-2	2-4
13.	4170	NIL	NIL	3-4	2-4	NIL	NIL	1-2	2-4
14.	5088	NIL	NIL	1-2	2-4	NIL	NIL	2-3	2-4
15.	4161	NIL	NIL	4-5	3-4	NIL	NIL	3-4	3-4
16.	4071	NIL	NIL	1-2	2-4	NIL	NIL	2-4	2-4
17.	4058	NIL	NIL	2-3	6-8	NIL	NIL	2-3	10-10
18.	4165	NIL	NIL	1-2	2-4	NIL	NIL	1-2	2-4
19.	4193	NIL	NIL	1-2	2-4	NIL	NIL	1-2	1-2
20.	5152	NIL	NIL	1-2	3-5	NIL	NIL	2-3	3-5

URINE AND MOTIONS EXAMINATION BEFORE AND AFTER TREATMENT –OP

S. NO	OP NO	URINE							
		Before Treatment				After Treatment			
		Albumin	Sugar	Deposits		Albumin	Sugar	Deposits	
				Pus Cells	Epi. cells			Pus cells	Epi. cells
1.	C80887	NIL	NIL	3-6	4-5	NIL	NIL	4-8	6-8
2.	C85318	NIL	NIL	1-2	8-10	NIL	NIL	1-2	10-12
3.	C82447	NIL	NIL	8-10	4-5	NIL	NIL	4-8	2-3
4.	C79569	NIL	NIL	4-8	2-3	NIL	NIL	4-8	2-3
5.	C82592	NIL	NIL	1-2	1-2	NIL	NIL	2-4	1-2
6.	C78485	NIL	NIL	1-2	1-2	NIL	NIL	2-3	2-4
7.	C91495	NIL	NIL	1-2	2-4	NIL	NIL	2-4	2-4
8.	C38181	NIL	NIL	3-4	4-5	NIL	NIL	4-5	3-4
9.	C83812	NIL	NIL	3-6	3-4	NIL	NIL	3-6	3-4
10.	C83543	NIL	NIL	2-4	2-3	NIL	NIL	2-4	1-2
11.	C86074	NIL	NIL	2-4	3-5	NIL	NIL	3-5	3-5
12.	C47715	NIL	NIL	2-4	2-4	NIL	NIL	1-2	2-4
13.	C85904	NIL	NIL	1-2	2-4	NIL	NIL	1-2	4-5
14.	C85223	NIL	NIL	2-4	1-2	NIL	NIL	2-4	1-2
15.	C83530	NIL	NIL	2-4	1-2	NIL	NIL	2-4	1-2
16.	C84087	NIL	NIL	2-4	4-5	NIL	NIL	2-4	4-5
17.	C22005	NIL	NIL	4-5	10-12	NIL	NIL	4-5	6-8
18.	C85214	NIL	NIL	1-2	2-4	NIL	NIL	1-2	2-4
19.	C91616	NIL	NIL	8-10	4-5	NIL	NIL	4-5	4-5
20.	C95043	NIL	NIL	1-2	2-4	NIL	NIL	1-2	2-4

Statistical Analysis:

All collected data were entered into MS Excel software using different columns as variables and rows as patients. SPSS software was used to perform statistical analysis. Basic descriptive statistics include frequency distributions and cross-tabulations were performed. The quantity variables were expressed as Mean ± Standard Deviation and qualitative data as percentage. A probability value of <0.05 was considered to indicate as statistical significance. Paired 't' test was performed for determining the significance between before and after treatment.

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Bt	6.65	40	1.545	.244
	At	3.13	40	1.697	.268

Paired Samples Test

		t	df	Sig. (2-tailed)
Pair 1	Bt - At	11.369	39	.001

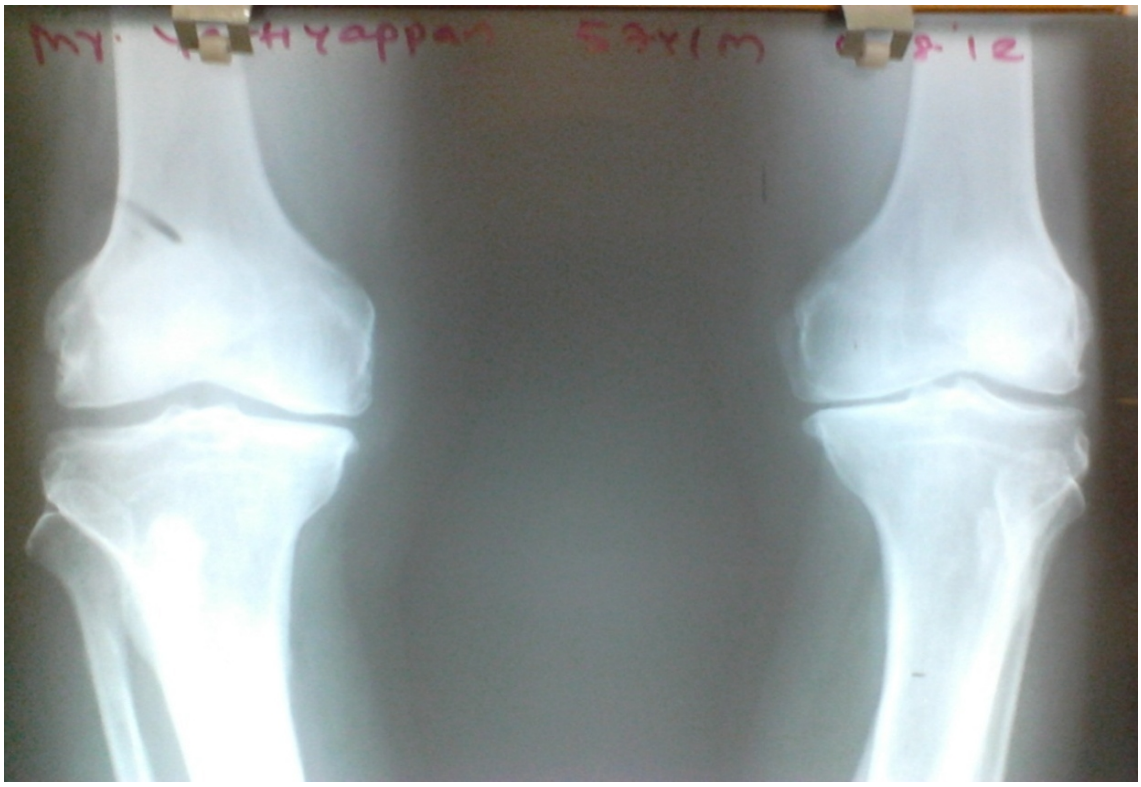
The mean± standard deviation of pain score at before and after treatment were 6.65 ± 1.55 and 3.13 ± 1.6 respectively which is statistically significant (t= 11.369 p<0.001).

VARMAM: **Report**

AT

var	Mean	N	Std. Deviation	P value
1	3.60	30	1.476	t=3.473 <0.001
2	1.70	10	1.567	
Total	3.13	40	1.697	

Yettiyappan 57M



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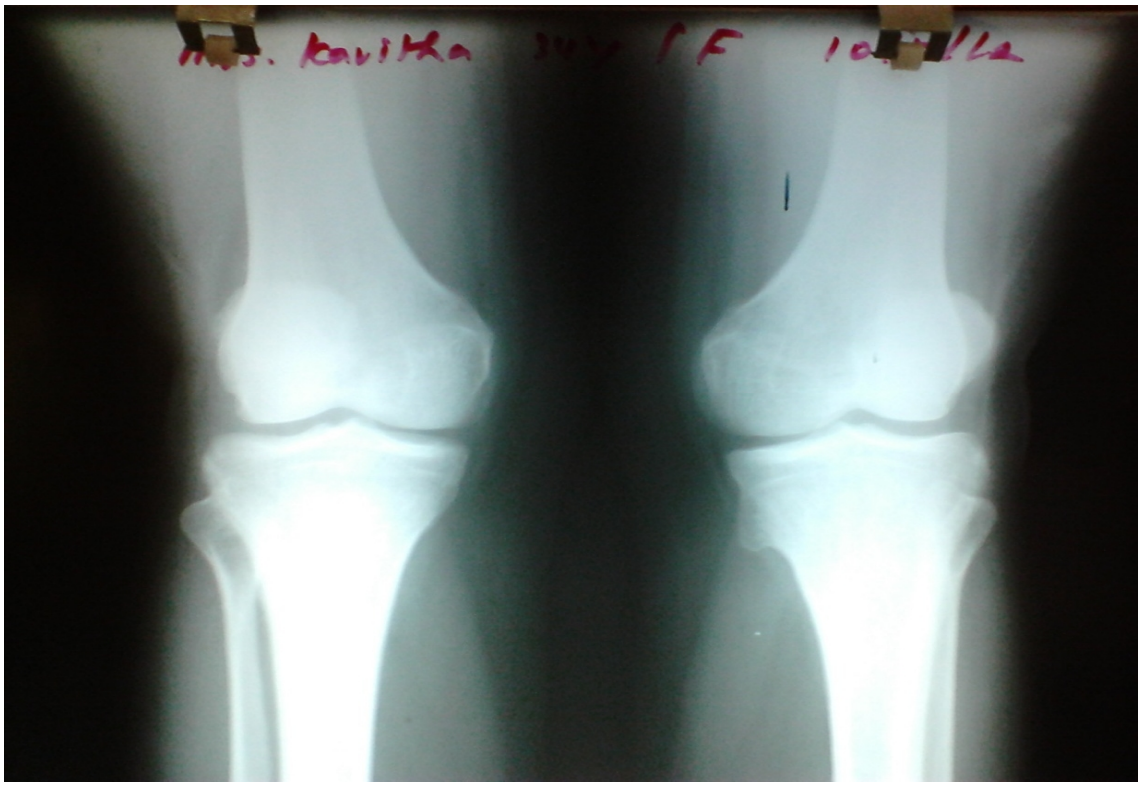

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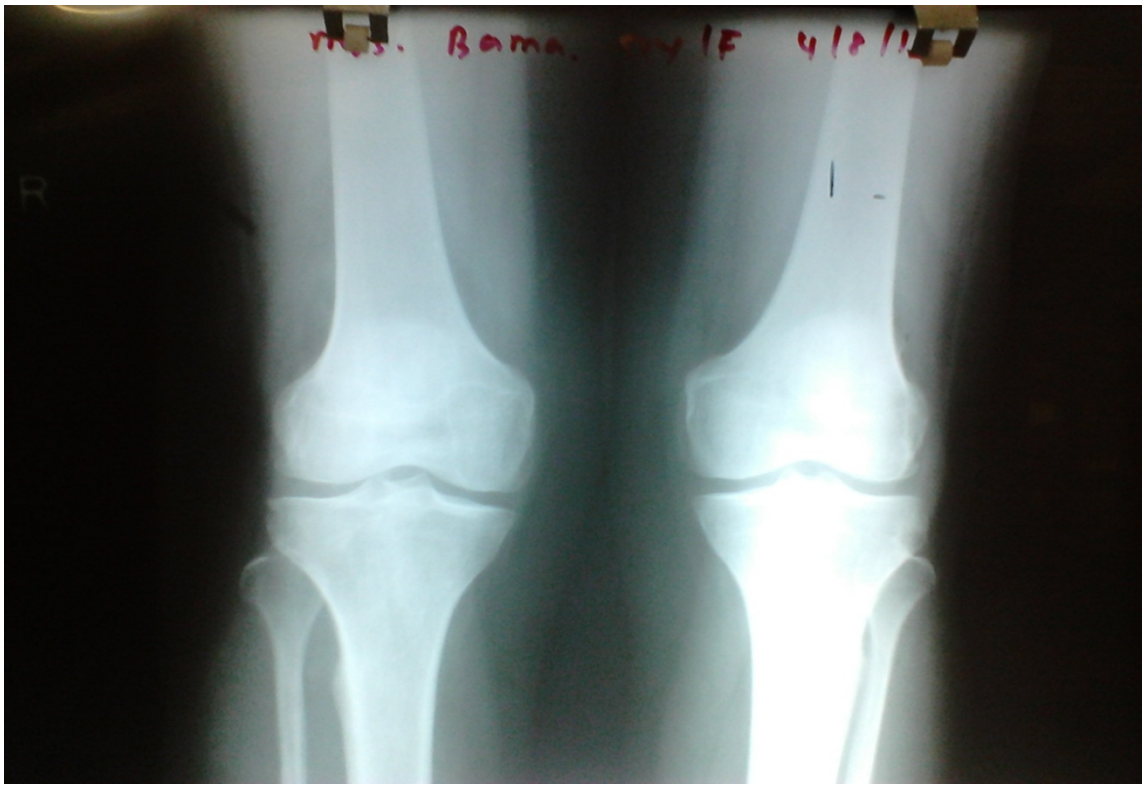
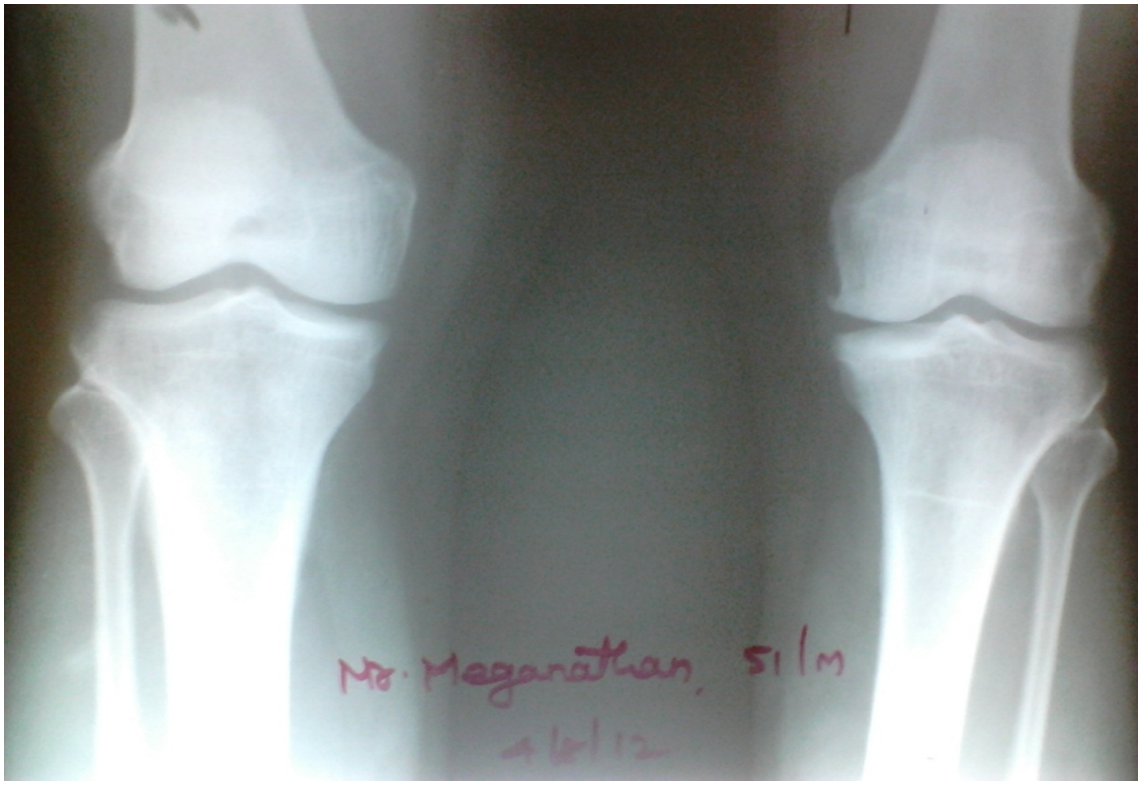


Mr. Meganathan 51M



DISCUSSION

According to Siddha literature, Azhal Keel Vayu is one among the Keelvayu .It is characterized by pain, swelling and restricted movements. Sometimes it may lead to difficulty in walking.

This condition can be correlated to Osteoarthritis in Modern Orthopaedics. Osteoarthritis is defined as a degenerative, non - inflammatory joint disease characterized by destruction of articular cartilage and formation of new bone at the joint surfaces and margins.

A detailed study of the disease Azhal keel vaayu was done and was correlated to the signs and symptoms of Osteoarthritis in modern science. The Absent clinical study was done as per the approved protocol and the data were collected by using the prescribed proforma from the 40 cases who were treated in the Inpatient ward and Outpatient department of Sirappu Maruthuvam.

Based on various criteria, the data were collected and tabulated. The criteria were the gender predominance, incidence of the disease with respect to age, kaalam, seasonal variation, clinical manifestation, relation to menstrual cycle, diet and the assessment of the outcome of the disease with the trial drug were observed.

The trial drugs for this study were prepared by the Author in the Gunapadam practical laboratory of National Institute of Siddha, under the supervision of the members of the teaching faculty and guided by the Head of the Department of Sirappu Maruthuvam of the National Institute of Siddha, Chennai - 47.

In Siddha system, before starting the treatment it is necessary to bring the Mukkutram to equilibrium. By giving purgation we can normalize the deranged Vaatham.

“விரேசனத்தால் வாதந் தாழும்”

The trial drugs Avuri Karpam (Internal) and Vatha Noikku Ennai (External**)** were given for 48 days. Out-Patients were asked to visit the hospital once in 7 days. For Out-Patients the drugs were given for 48 days and the clinical assessment was done on 0^{th} day, 12^{th} day, 24^{th} day, 36^{th} day and 49^{th} day.

For In-Patients the drugs were given for 48 days and the clinical assessment was done daily. 10 In-Patients were given Varmam treatment along with their trial drugs.

The results were compared at the end of the study. For In-Patients, who are not in a situation to stay in the hospital for a long time, were advised to attend the Out-Patient Department of Sirappu Maruthuvam for further follow- up.

Patients were instructed to take the medicines regularly and apply the external medicine. It was ensured that the diet restrictions imposed were followed properly by the patients.

After the treatment, the patients were advised to visit the Out-Patient ward of Department of Sirappu Maruthuvam for another 2 months for follow-up.

Observations:

- The majority affected sex is female (67.5%). The common cause for this may be depletion of calcium from their body, nutritional deficiency and increased house hold works. From history taking these were concluded as the reasons for female predominance.
- This study shows that the highest incidence of Azhal keel vaayu is between 41-50 years of age.
- In this study, 87.5% of cases were reported from Neithal land. In Siddha literatures, it was mentioned that Neithal, which is responsible for Vaatha diseases. This study also emphasized the same.
- Among 40 patients, 33 (82.5%) were non-vegetarians and 7 (17.5%) were vegetarians.
- Mudhuvenil kaalam showed the highest incidence of 77.5% and 22.5% were reported during kaar kaalam. According to Siddha literature, the Vaatham humour attains Vertrunilai valarchi during kaar kaalam. Whereas in Mudhuvenil kaalam Vaatham attains Thannilai valarchi.
- Viyanan, Samanan were affected in all 40 cases.
- In all the cases the Sathaga pitham was affected.
- Santhigam was affected in all the 40 cases. Santhiga kabam mainly lives in joints and so it was affected in all the cases.
- Pulse reading (Naadi) was observed in all patients. 30 cases had Vaathapitham, 6 cases had Pithavaatham.
- In 32 cases oil spread slowly, in 8 cases it appeared like pearl.

- Enbu was affected in all the 40 cases (100%), Saaram was also affected in all the 40 cases (100%), Oon and Kozhuppu was affected in all 40 cases (100 %), and there were no changes noted in other thathukkal like Moolai, Sukkilam and Suronitham.
- Kaal was affected in all the 40 cases (100%)**.**

Clinical manifestations:

Pain in the knee joint was Absent in 40 cases. Swelling was Absent in 12 cases. The other important features were morning stiffness in 10 cases, tenderness in 32 cases, restricted movements in 40 cases, crepitation were observed in all 39 cases and deformity developed in 3 cases.

Precipitating factors:

Already it was explained that aging is the most common cause for Azhal keel vaayu. Apart from that, increased household works, Obesity and menopause are the other precipitating factors.

Occupational references:

Household work accounts for the highest number of 21 cases. More weight bearing and improper positioning of knee are also the cause which leads to Osteoarthritis.

Laboratory investigations:

- By laboratory investigation ESR was found raised in early stages but after treatment it was found reduced. At the same time Total WBC counts, Total red blood cells were increased. In some cases haemoglobulin were increased and in some cases it was decreased. Total cholesterol and LDL were decreased in considerable cases. And HDL was increased.
- Blood Urea and Serum Creatinine levels showed no changes in this study.
- The radiographic studies showed narrowed joint space and presence of Osteophytes. The trial drug showed improvement in prognosis of the disease clinically rather than in radiographic changes.

Treatment:

The treatment was aimed at normalizing the deranged mukkutram and providing relief from symptoms. Before treatment the patients were advised to take Agasthiyar kulambu - 130

mg with hot water in the early morning for purgation. The patient was advised to take rest without internal medicine on that day.

The author treated the patients with trial drugs Avuri Karpam -1gm bid with honey (Internal) and Vatha Noikku ennai (External). During treatment, the patients were advised to follow Pathiyam (avoid tamarind, tubers etc.).

Effect of Treatment:

Good improvement was observed in 28 Patients, moderate improvement in 9 patients and mild improvement in 3 patients. The mean pain score before treatment was 6.65 and after treatment it was reduced to 3.13. The mean pain score before treatment patients who treated without varmam was 6.65 and after treatment it was reduced to 3.60.

No toxic and side effects were clinically observed in all cases.

Effect of varmam:

10 IP patients are treated with Varmam along with the trial drug. The remaining 10 IP patients received only trial medicines. The results are compared at the end of the study. In this clinical trial, patients who treated with Varmam showed very good result in the marked reduction of pain. The mean pain score before treatment was 6.65 and after treatment it was reduced to 1.70 Hence this study reveals the importance of Varmam treatment in the treatment of Osteoarthritis.

Evaluation of medicines:

The preliminary phytochemical study revealed the presence of several phyto-constituents. The test drug answered for the presence of calcium, ferrous iron, and phosphate, nitrate, reducing sugar, chloride and alkaloides. Repeated oral toxicity study conducted for15 days with the drug did not exhibit significant changes in blood counts. The biochemical markers of liver function test did not show any evidence of liver toxicity. The biochemical markers of renal function test did not show any evidence of renal toxicity.

There were no significant changes in biochemical parameters like blood cholesterol, body weight, food, water intake and behavioural parameters.

SUMMARY

The clinical study on Azhal keel vaayu with reference to its aetiology, pathogenesis, investigations, clinical features, diagnosis and treatment were conducted at the Sirappu maruthuvam Department, Ayothidoss Pandithar Hospital, National Institute of Siddha, Chennai – 47.

The drugs administered in the clinical study were used only after careful purification process.

40 cases of both the sexes (majority of females) with the signs and symptoms of Azhal keel vaayu were selected in the age group within 30 to 65 for the study. 10 cases in the In-Patient ward were given Varmam therapy along with the trial drugs and for the remaining 10 In-Patients were given only the trial drugs for 48 days. 20 cases were treated in the Out-Patient Department for 48 days only with the trial drugs.

All the details about the study and the drugs were informed to the patients in their vernacular language, dietary and information sheet were given to them and signed consent forms were obtained from them. Before starting the treatment, the blood samples of the selected patients were subjected to investigation.

On the first day of the treatment, purgation was given by administering Agasthiyar kulambu – 130mg with hot water in the early morning to normalize the deranged kuttram.

From the second day onwards, the patients were treated with the trial drugs Avuri karpam 1gm bid with honey was given internally and Vatha noikku ennai externally.

Every 8^{th} day, the patients were assessed for clinical improvement and adverse effects. During the treatment before (0^{th} day) and at the end of the treatment (48^{th} day) the laboratory investigations were repeated. The x-ray of the Joints were taken .The improvement was assessed.

During the course of treatment there were no adverse effects or unwanted drug reactions in Gastro intestinal tract, Respiratory system, Cardio vascular system and Excretory systems.

The toxicological studies were carried out in animals and the reports showed no hepato and renal toxicity.

10 IP patients are treated with varmam along with their trial medicine. The remaining 10 IP patients didn't received varmam treatment. The results are compared at the end of the study. The mean pain score of the 10 patients who received varmam treatment before

treatment is 6.65 and after treatment it is reduced to 1.70 Hence varmam treatment along with trial medicine is effective in the treatment of Osteoarthritis.

The study results showed that 70 % had Good improvement, 22.5 % had Moderate improvement and 7.5 % had mild improvement. The pain assessment was done in all the 40 patients participated in the trial using the universal pain assessment scale and at the end of the study the results showed, the mean pain score before treatment was 6.65 and after treatment it is reduced to 3.13. The restriction of movements after treatment was reduced in 31 cases and persists in 9 cases.

CONCLUSION

The study results showed that 70 % had Good improvement, 22.5 % had Moderate improvement and 7.5 % had mild improvement.

Varmam treatment along with the trial drugs showed good prognosis when compared to patients treated only with trial drugs. Hence the study reveals the importance of Varmam in treating Azhal keel vaayu.

Clinically, no adverse effects were reported during the trial and the laboratory investigations were also within normal limits. So, the drug is assumed to be safe for humans.

Acute toxicity study in animal models reveals that the trial drug “Avuri karpam” is safe. The safety of the trial drug was also proved from this study.

Hence the study concludes that, the trial drugs are clinically effective in reduction of pain, swelling, restriction of movements.

Because of the encouraging clinical results, it could be concluded that “Avuri karpam (Internally)” and “Vatha Noikku Ennai (Externally)” are effective in the treatment of “Azhal keel vaayu” (Osteoarthritis).

However further work with large number of patients should be carried out towards finding the ideal dose response.

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Ministry Of Health & Family Welfare, Government of India

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Name: Dr. G. SUGANYA Reg. NO : 32102207

Title: PRECLINICAL AND CLINICAL STUDY ON "AVURI KARPAM" (INTERNAL) AND "YATHA NOIKKU ENNAI" (EXTERNAL) FOR THE TREATMENT OF "AZHAL KEEL VAYU" (OSTEOARTHRITIS)

No. NIS/IEC/2011/3/23 - 24/12/2011

DECSION

Opinion of the Institutional Ethics Committee – Please Check one
✓ Approval _____ Modifications required prior to approval (Please specify one space below) _____ Disapproval Date of review: _____ K. Manickavasakam (Dr. K. MANICKAVASAKAM) Member Secretary Signed: _____ (Please print name) Dr.V.SUBRAMANIAN chair person (Please delee as appropriate, Chairperson, Secretary)
Modifications needed Modification given to candidate
The research proponent is hereby informed that the Institutional Ethics Committee will require the following: 1. All adverse drug reactions (ADRs) that are both serious and unexpected to be reported promptly to the IEC within 7 working days 2. The progress report to be submitted to the IEC atleast annually 3. Upon completion of the study, a final study status report needs to submitted to the IEC

IAEC PROTOCOL NO : 1248/ac/09/CPCSEA/4-23/2011

20/12/2011

CERTIFICATE

This is certify that the project title.. PRECLINICAL AND CLINICAL STUDY ON "AVURI KARPAM" (INTERNAL MEDICINE) AND "VATHA NOIKKU ENNAI" (EXTERNAL MEDICINE) FOR THE TREATMENT OF "AZHAL KEEL VAYU" [OSTEOARTHRITIS]

has been approved by the IAEC.

Prof. Dr. K. Manickavasakam
Name of Chairman/Member Secretary IAEC:

Dr. B. Jayachandran Dare
Name of CPCSEA nominee:

Signature with date

Chairman/Member Secretary of IAEC:

CPCSEA nominee:

(Kindly make sure that minutes of the meeting duly signed by all the participants are maintained by Office)

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 600047

CERTIFICATE OF BOTANICAL AUTHENTICITY

Certified that the following plant drugs used in the Siddha formulation **Avuri Karpam** (Internal) and **Vatha Noikku Ennai** (External) for the treatment of **Azhal Keel Vayu** (Osteoarthritis-Knee joint) taken up for Post Graduation Dissertation studies by **Dr.G.Suganya**, M.D.(S), II year, Department of Sirappu Maruthuvam, 2011-12, are identified and authenticated through Visual inspection / Experience, Education & Training/ Organoleptic characters/ Morphology / Micromorphology / Taxonomical/ Microscopical methods.

Indigofera tinctoria Linn. (Fabaceae), Leaf
Wedelia chinensis (Osbeck.) Merr. (Asteraceae), Whole plant
Acalypha indica Linn. (Euphorbiaceae), Leaf
Sphaeranthus indicus Linn. (Asteraceae), Leaf
Eclipta alba Hassk. (Asteraceae), Leaf
Centella asiatica (Linn.) Urban (Apiaceae), Whole plant
Glinus lotoides Linn. (Molluginaceae), Whole plant
Spermacose hispida Linn. (Rubiaceae), Root
Cuscuta reflexa Roxb. (Convolvulaceae), Whole plant
Dichrostachys cinerea W. & A. (Mimosaceae), Root
Pergularia daemia (Forssk.) Chiov. (Asclepiadaceae), Root
Azadirachta indica A. Juss. (Meliaceae), Root
Allium sativum Linn. (Liliaceae), Bulb
Acorus calamus Linn. (Araceae), Rhizome
Achyranthes aspera Linn. (Amaranthaceae), Whole plant

Certificate No: NIS/MB/49/2012

Date: 12-6-12

12/6/12

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

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

69, Anna Salai, Guindy, Chennai-600 032

This Certificate is awarded to Dr G. SUGANYA

for participating as a ~~Resource Person~~ / Delegate in the VI 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 12th September 2011 to 16th September 2011

Dr. MAYILVAHANAN NATARAJAN
M.S.Orth. M.Ch.Orth. (L'pool) Ph.D. D.Sc. F.R.C.S. D.Sc. (Hon)[3]
VICE CHANCELLOR

Dr. SUDHA SESHAYYAN, M.S.
REGISTRAR (FAC)

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

BIOCHEMICAL ANALYSIS OF AVURI KARPAM
ANALYSED AT NATIONAL INSTITUTE OF SIDDHA

Test Drugs

The following medicine was used in the study was processed by the methods prescribed in standard text books of siddha medicines.

Avuri karpam was prepared by the method prescribed in the text book of Pathartha Guna Vilakkam pg.no.43

Qualitative phytochemical analysis of Acidic/Basic radicals and constituents in test drugs

Preliminary Qualitative analysis of drug – Avuri karpam

Procedure	Observation	Inference
Test for Calcium : 2 ml of extract is taken in a clean test tube. To this add 2 ml of 4% ammonium oxide solution.	white precipitate is formed	Presence of calcium
Test for Sulphate : 2 ml of the extract is added to 5 % barium chloride solution.	No white precipitate is formed	Absence of Sulphate
Test for Chloride : The extract is treated with Silver nitrate solution	White precipitate is formed	Presence of Chloride
Test for carbonate : The substance is treated with Conc. HCl.	No effervescence is formed	Absence of carbonate
Test for Starch : The extract is added with weak iodine solution	No blue colour is formed	Absence of starch
Test for Iron (Ferric) : The extract is treated with glacial acetic acid and	No blue colour is formed	Absence of Ferric iron

potassium ferrocyanide		
Test for Iron (Ferrous) : The extract is treated with Conc. HNO_3 and ammonium thiocynate	Blood red colour is formed	Presence of Ferrous iron
Test for phosphate : The extract is treated with ammonium molybdate and conc. HNO_3	Yellow precipitate is formed	Presence of phosphate
Test for Tannic acid : The extract is treated with Ferric chloride	No Black precipitate is formed	Absence of Tannic acid
Test for Unsaturation : 1 ml of Potassium permanganate solution is added to the extract.	Does not get decolourised	Absence of unsaturated compound
Test for saponins: Dilute extract+ 1ml of distilled water shake well.	No Froth formation	Absence of saponins
Test for sugars : **Benedict method** ; 5ml of Benedict solution heated gently then add 8 drops of diluted extract then heated in a boiling water bath. **Molisch test**; Dilute extract+2 drops of Molisch+3ml conc.H_2SO_4.	No colour change occured No Reddish violet zones appeared	Indicates the Absence of sugar Absence of carbohydrate
Test for steroids : Liberman Burchard test ; Dilute extract +2 ml acetic anhydride+conc.H_2SO_4 .	No Formation of red colour	Absence of steroids

Test for amino acids: Dilute extract +2ml of Ninhydrin's soln .	Formation of violet colour	Presence of amino acids
Test for proteins: Biuret method ; 1ml of dilute extract+1mlof5%$CuSO_4$+ 1%NaOH.	Formation of deep blue colour	Presence of proteins
Test for Flavanoids : Dilute extract+ mg bits+2drops of conc.HCl and gently heated.	Formation of pink colour	Presence of Flavanoids

Preliminary Qualitative Phyto chemical tests procedure and interpretation of results

S.NO	CONSITUENTS	INFERENCE
1.	**Silicate**	Absent
2.	**Carbonate**	Absent
3.	**Chloride**	Present
4.	**Sulphide**	Absent
5.	**Iron**	Present
6.	**Alkaloids**	Absent
7.	**Copper**	Absent
8.	**Sodium**	Absent
9.	**Sulphate**	Absent
10.	**Phospate**	Present
11.	**Nitrate**	Absent
12.	**Oxalate**	Absent

13.	**Fluoride**	Absent
14.	**Borate**	Absent
15.	**Lead**	Absent
16.	**Aluminium**	Absent
17.	**Zinc**	Absent
18.	**Calcium**	Present
19.	**Magnesium**	Absent
20.	**Ammonium**	Absent
21.	**Potassium**	Absent
22.	**Mercury**	Absent
23.	**Arsenic**	Absent
24.	**Starch**	Absent
25.	**Reducing sugar**	Absent
26.	**Tannic Acid**	Absent
27.	**Unsaturated compound**	Absent
28.	**Amino Acid**	Present
29.	**Type of compounds**	Absent
30.	**Proteins**	Present
31.	**Flavanoides**	Present

NATIONAL INSTITUTE OF SIDDHA

ACUTE TOXICITY STUDY OF AVURI KARPAM

[WHO guidelines, 1993]

Principle:

Acute toxicity was carried out in Swiss albino mice with a single exposure of 10 times of the recommended therapeutic dose of test compound the study duration will be 14 days.

Animal species	**:**	Swiss albino mice
Age / Weight / Size	**:**	6 weeks. Mice-20-25 gms.
Gender	**:**	Both male and female
Number of Animals	**:**	Mice: 10
Acclimatization Period	**:**	7 Days
Clinical dose	**:**	2.0 gms\day

S.No	Group	No of mice
1	Vehicle control (saline)	10 (5 male, 5 female)
2	Toxic dose 10X therapeutic dose (0.036gm)	10 (5 male, 5 female)

Test Animals

Test animals were obtained from the animal laboratory of the King institute, Chennai and stocked at National institute of siddha, Chennai. All the animals were kept under standard environmental condition (27+ or – 2 degree c).The animals had free access to water and standard pellet diet (Sai Durga foods pvt.ltd, Bangalore).The principles of laboratory animal care were followed and the Institutional ethical committee approved the use of animals and the study design. **(1248/ac/09/CPCSEA/4-23 / 2011)**

Route of administration:

Oral route was selected, because it is the normal route of clinical administration.

Test substance and vehicle

Avuri Karpam is Brown in colour. The test substance is insoluble in water, in order to obtain and ensure the uniformity in drug distribution the drug is dissolved by aqueous Tween 80 solution (10%).

Administration of doses

Avuri karpam was suspended in aqueous Tween 80 solution (10%), with uniform mixing and it was administered to the groups in a single oral dose .The control groups were received equal volume of the vehicle. The animals were weighed before giving the drug. The dose level was calculated according to body weight, and surface area. Since the clinical dose was 2.0gms\day it was converted to animal dose (0.036gm) and then administered. The principle of laboratory animal care was followed.

Observations

Observations were made and recorded systematically and continuously observed as per the guideline after substance administration. The animals were monitored for behavioural parameters like,

1. Awareness
    - Alertness
    - Visual placing
    - Stereotype
    - Passivity
2. Mood
    - Grooming
    - Restlessness
    - Irritability
    - Fearfulness
3. Motor activity
    - Spontaneous activity
    - Reactivity
    - Touch response
    - Pain response.

Animals were observed for body weight and mortality for 14 days. If animals died during the period of study, the animals were sacrificed. At the end of the 14th day all animals were sacrificed and necropsy was done.

Body Weight

Individual weight of animals was determined before the test substance was administered and daily for 14 days. Weight changes were calculated and recorded. At the end of the test, surving animals were weighed and sacrificed.

Results:

Avuri karpam at the dose 0.036gm/animal did not exhibit any mortality in mice.

No behavior changes were noted for the first 4 hours and for the next 24 hours and throughout the study period of 14 days. No weight reduction was noted before and after the acute study duration. Reflexes were found to be normal before and after the study. All other observations were found to be normal before and after the study. In Necropsy, the organs of the animal such as, Liver, Heart, Lungs, Pancreas, Spleen, Stomach, Intestine, Kidney, Urinary bladder, Uterus all appeared normal.

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL

CHENNAI – 600 047.

POST- GRADUATE DEPARTMENT OF SIRAPPU MARUTHUVAM

PRECLINICAL AND CLINICAL STUDY ON **"AVURI KARPAM"** (INTERNAL) AND **"VATHA NOIKKU ENNAI"** (EXTERNAL) FOR THE TREATMENT OF **"AZHAL KEEL VAYU"** (OSTEOARTHRITIS-KNEE JOINT).

FORM I - SCREENING AND SELECTION PROFORMA

1.OP NO: .....

2. NAME: …….

3. AGE: …… 4.GENDER: …….....

5. OCCUPATION: …….. 6.INCOME: ……

7. ADDRESS: ……

……

……

8. CONTACT NO: ……

INCLUSION CRITERIA:

- Age : 30-65Yrs
- Sex : Both male and female
- Patients having symptoms of Pain, swelling, stiffness, crepitations, restricted movements of both knee joints.
- Patients willing to undergo radiological investigation, Laboratory investigations (blood and urine).
- Patients willing to sign the informed consent stating that he/she will conscientiously stick to the treatment during 48days but can opt out of the trial of his/her own conscious discretion.

EXCLUSION CRITERIA:

- Rheumatoid arthritis

- Tuberculosis knee
- Septic arthritis
- Gonococcal arthritis
- Gout
- Cardiac diseases
- Hypertension
- Diabetes mellitus
- Use of Narcotics
- Pregnancy and lactation
- History of trauma
- Patient with any other serious systemic illness

ADMITTED TO TRIAL:

YES ☐ **NO** ☐

IF YES,

OPD ☐ **IPD** ☐

If yes, serial NO: ☐☐

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

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FORM II -HISTORY TAKING PROFORMA

1. SERIAL NO: ……. 2.OP/IP NO: .....

3. NAME: …… 4. AGE: …….. 5. GENDER: ……..

5. OCCUPATION: …… 6. INCOME:……..

7. COMPLAINTS & DURATION:

8. PERSONAL HISTORY:

PERSONAL HABITS	YES	NO	IF YES, DURATION/ QUANTITY
Smoking			
Tobacco Chewing			
Alcoholism			

9. HISTORY OF PREVIOUS ILLNESS:

DRUG HISTORY:

10. FAMILY HISTORY:

Whether this problem runs in family?

1. Yes ☐ 2.No ☐

If yes, mention the relationship of affected person(s)

1._____

2._____

3._____

11.DIETARY HABIT:

1.Vegetarian ☐

2.Non-vegetarian ☐

12. MENSTURAL HISTORY:

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

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FORM III - CLINICAL ASSESSMENT PROFORMA

1. SERIAL NO. : ……

2.OP / IP NO.: .....

3. NAME: …… 4. AGE: …… 5.GENDER: .....

6. DATE OF ASSESSMENT :

0th day ☐ 8thday ☐ 15thday ☐ 22ndday ☐

29th day ☐ 36th day ☐ 43rdday ☐ 49thday ☐

7. SIDDHA SYSTEM OF EXAMINATIONS:

1. THEGI: [BODY CONSTITUTION]

1. Vathaudal ☐
2. Pithaudal ☐
3. Kabaudal ☐
4. Thonthaudal ☐

2. NILAM: [LAND WHERE PATIENT LIVED MOST]

1. Kurinji (Hilly terrain) ☐
2. Mullai (Forest range) ☐
3. Marutham (Plains) ☐
4. Neithal (Coastal belt) ☐
5. Paalai (Arid regions) ☐

3. KAALAM:

1. Kaarkaalam	☐	4. Pinpanikaalam	☐
2. Koothirkaalam	☐	5.Ilavenilkaalam	☐
3. Munpanikaalam	☐	6. Muthuvenilkaalam	☐

4. GUNAM:

1.Sathuvam ☐ 2.Raasatham ☐ 3.Thaamatham ☐

5. AIMPORIGAL (SENSORY ORGANS):

	0^{th}day	8^{th}day	15^{th}day	22^{nd}day	29^{th}day	36^{th}day	43^{rd}day	49^{th}day
Mei								
Vaai								
Kann								
Mookku								
Sevi								

6. KANMENDHIRIYAM (MOTOR ORGANS):

	0^{th}day	8^{th}day	15^{th}day	22^{nd}day	29^{th}day	36^{th}day	43^{rd}day	49^{th}day
Kai								
Kaal								
Vaai								
Eruvai								
Karuvai								

7. KOSANGAL (SHEATH):

	Before treatment	After treatment
Annamaya kosam		
Pranamaya kosam		

Manomaya kosam		
Vignanamaya kosam		
Ananthamaya kosam		

8. UYIR THAATHUKKAL: **[THREE HUMOURS – VATHAM, PITHAM, KABAM]**

A) VALI

	0th day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day
Praanan								
Abaanan								
Udhaanan								
Viyaanan								
Samaanan								
Naagan								
Koorman								
Kirukaran								
Devathathan								
Dhananjeyan								

B) AZHAL

	0th day	8th day	15th day	22nd day	29th day	36th day	43rdday	49th day
Analam								
Ranjakam								
Saathakam								
Prasakam								
Aalosakam								

C) IYAM

	0th day	8th day	15th day	22nd day	29th day	36th day	43rdday	49th day
Avalambagam								
Kilethagam								
Pothagam								
Tharpagam								
Santhigam								

9. SEVEN UDAL THATHUKKAL: (SEVEN SOMATIC COMPONENTS)

	Before treatment	After treatment
Saaram	NORMAL/AFFECTED	
Senneer	NORMAL/AFFECTED	
Oon	NORMAL/AFFECTED	
Kozhuppu	NORMAL/AFFECTED	
Enbu	NORMAL/AFFECTED	
Moolai	NORMAL/AFFECTED	
Sukkilam/ Suronitham	NORMAL/AFFECTED	

10. ENVAGAI THERVU:

I. NAADI: [PULSE PERCEPTION]

Days	Naadi
0th day	
8th day	
15th day	
22nd day	
29th day	

36th day	
43rd day	
49th day	

II. SPARISAM: [PALPATION]

Day	TENDERNESS	TEMPERATURE
0th day		
8th day		
15th day		
22nd day		
29th day		
36th day		
43rd day		
49th day		

III. NAA:[TONGUE]

Days	NAA
0th day	
8th day	
15th day	
22nd day	
29th day	
36th day	
43rd day	
49th day	

IV.NIRAM: [COMPLEXION]

1. Vatham ☐
2. Pitham ☐
3. Kabam ☐

V.MOZHI: [VOICE]

1. High Pitched ☐
2. Low Pitched ☐
3. Medium Pitched ☐

VI.VIZHI: [EYES]

Days	Vizhi
0th day	
8th day	
15th day	
22nd day	
29th day	
36th day	
43rd day	
49th day	

VII. MALAM: [BOWEL HABITS / STOOLS]

	0thday	8thday	15thday	22ndday	29thday	36thday	43rdday	49thday
Niram								
Edai								
Irugal								
Ilagal								

VIII. MOOTHIRAM [URINE EXAMINATION]

NEERKKURI:

Neerkkuri	Before treatment	After treatment
Niram		
Manam		
Edai		
Nurai		
Enjal		

NEIKKURI:

Neikkuri	Before treatment	After treatment
Snake like pattern		
Annular/Ringed pattern		
Pearl beaded pattern		
Other specific pattern		

	Before treatment	After treatment
Height (cms)		
Weight (kg)		
Temperature(°F)		
Pulse rate(/min)		
Heart rate(/min)		
Respiratory rate(/min)		
Blood pressure(mm/Hg)		
Pallor		
Jaundice		
Cyanosis		

Lymphadenopathy		
Pedal edema		
Clubbing		
Jugular vein pulsation		

11. GENERAL EXAMINATION

12. SYSTEMIC EXAMINATION

	Before treatment	After treatment
Cardiovascular System		
Respiratory system		
Gastrointestinal system		
Central Nervous System		
Urogenital system		
Endocrine System		

13. LOCOMOTOR SYSTEM:

CLINICAL SYMPTOMS:

Affected knee joints: Right ☐ Left ☐ Both ☐

Pain in knee joint: Mild ☐ Moderate ☐ Severe ☐

Onset: Sudden ☐ Gradual ☐

14. CLINICAL EXAMINATION OF KNEE JOINT

I.INSPECTION:

	0th day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day
Attitude:								
swelling								
Skin over the knee joints								
Muscle wasting								
Deformity								

II.PALPATION:

	0th day	8th day	15th day	22th day	29th day	36th day	43rd day	49th day
Tenderness								
Crepitation								
Local heat								

III. MOVEMENTS

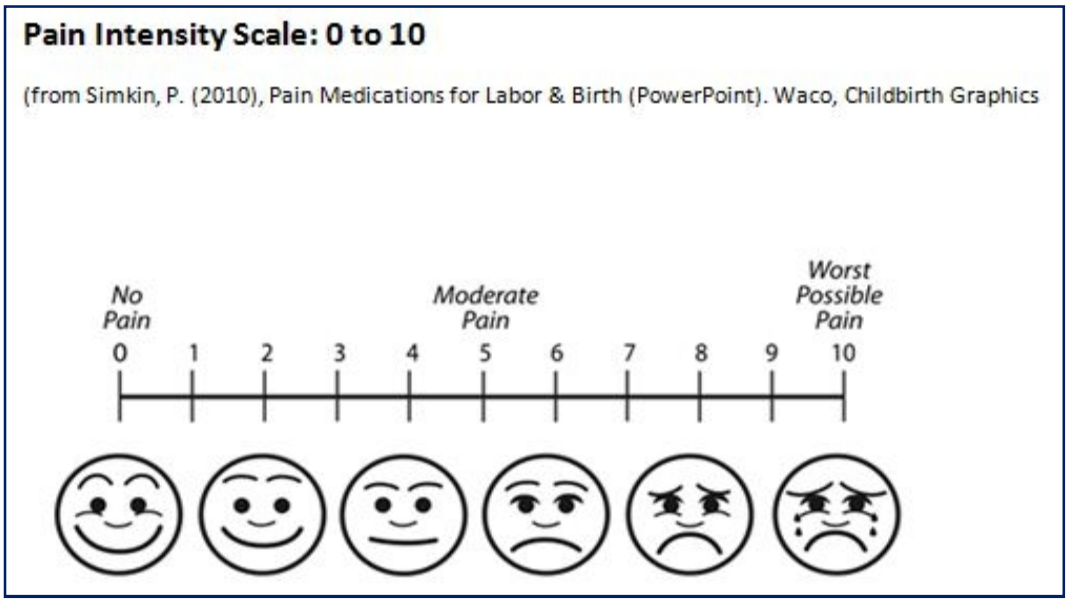
	0th day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day
Flexion								
Extension								

IV. JOINT MESUREMENT:

A. HEALTH ASSESSMENT QUESTIONNAIRE:

	0^{th} day	8^{th} day	15^{th} day	22^{nd}day	29^{th} day	36^{th} day	43^{rd}day	49^{th} day
PAIN A. Onset: Sudden/Gradual								
B. Early morning Stiffness (Absent /absent)								
C. Nature of pain (Mild/ Moderate/ Severe)								
D. Aggravating factor- Movement (Yes/No)								
E. Relieving factor –Rest (Yes/No)								
G. Tenderness (Absent /absent)								
RESTRICTION OF MOVEMENT (Fully/Partial/No) Knee joints								

B. UNIVERSAL PAIN ASSESMENT SCALE:



Grade 0	:	No Pain	
Grade 1 -3	:	Mild pain	
Grade 4-6	:	Moderate pain	
Grade 7-10	:	Severe pain	

C. RESTRICTED MOVEMENT ASSESSMENT SCALE:

Gradation:

Grade 1 - Fit for all activities, do their work without support. ☐

Grade II - Mild pain Absent in knee joint, mild restricted movements. ☐

Grade III - Pain Absent in knee joint, moderate restriction of movements. ☐

Grade IV - Severe pain, bed ridden. ☐

(Ref: Clinical manual for nursing practice (National Institute of Health Warren Grant Magnuson Clinical Centre)

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL

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VARMAM THERAPY – OBSERVATION CHART.

ASSESSMENT FORM

SL NO:

NAME:

AGE/SEX:

DATE:

ADDRESS:

COMPLAINTS AND DURATION:

VARMAM POINTS MANIPULATED:

- Kaal Moottu Varmam (Varma Viralalavu Nool)
- Komberi (Varmasoothiram 101)
- Viruthi (Varmalaadasoothiram 300)
- UllangalVellai(Adivarmasootcham 500)

SL. NO	DATE	PAIN	TENDERNESS	STIFFNESS	DURATION OF RELIEF	OTHER CLINICAL FEATURES
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						

23						
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25						
26						
27						
28						
29						
30						
31						
32						
33						
34						
35						
36						
37						
38						
39						
40						
41						
42						
43						
44						
45						

46						
47						
48						

OTHER REMARKS:

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: Signature of the H.O.D

NATIONAL INSTITUTE OF SIDDHA

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POST- GRADUATE DEPARTMENT OF SIRAPPU MARUTHUVAM

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FORM IV : LABORATORY INVESTIGATIONS PROFORMA

1. SL NO: ……

2.OP / IP NO: .....

3. NAME: …… 4.AGE: …… 5.GENDER: .....

A.BLOOD INVESTIGATIONS:

BLOOD INVESTIGATIONS		NORMAL VALUES	BEFORE TREATMENT	AFTER TREATMENT
Hb(gm/dl)		M:13-18 W:11-16		
T.RBC(millions cells /Cu.mm)		M:4.5-6.5 W:3.5-5.5		
ESR (mm)	½ hr.	-		
	1 hr.	M:0-10 W:0-20		
T.WBC (Cells /Cu.mm)		4000-11000		
Differential Count (%)	Polymorphs	40-75		
	Lymphocytes	20-35		
	Monocytes	2-10		
	Eosinophils	1-6		
	Basophils	0-1		

BLOOD INVESTIGATIONS		NORMAL VALUES	BEFORE TREATMENT	AFTER TREATMENT
Blood glucose (mg/dl)	Fasting	70-110		
	PP	80-140		
Lipid profile (mg/dl)	Serum cholesterol	150-200		
	HDL	30-60		
	LDL	Up to 130		
	VLDL	40		
	TGL	Up to 160		
RFT (mg/dl)	Blood urea	16-50		
	Serum creatinine	0.6-1.2		
LFT (mg/dl)	Total bilirubin	0.2-1.2		
	Direct bilirubin	0.1-0.2		
	Indirect bilirubin	0.2-0.7		
	Total protein	6-8		
	Serum Albumin	3.5-5.5		
	Serum globulin	2-3.5		
	SGOT (IU/L)	0-40		
	SGPT (IU/L)	0-35		
	Alkaline phosphatase (IU/L)	80-290		
	Serum calcium	9-11		
	Serum phosphorus	2-5		
	Serum Uric acid	M:3-9 W: 2.5-7.5		
CRP				
ASO titre				
RA factor				

B.URINE INVESTIGATIONS:

URINE INVESTIGATIONS	BEFORE TREATMENT	AFTER TREATMENT
Albumin		
Fasting sugar		
PP sugar		
Deposits		
Bile salts		
Bile pigments		

C.RADIOLOGICAL EXAMINATIONS

X- Ray: Knee joint:

1. **Antero posterior**
2. **Lateral view**

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL

CHENNAI – 600 047.

POST- GRADUATE DEPARTMENT OF SIRAPPU MARUTHUVAM

PRECLINICAL AND CLINICAL STUDY ON **"AVURI KARPAM"** (INTERNAL) AND **"VATHA NOIKKU ENNAI"** (EXTERNAL) FOR THE TREATMENT OF **"AZHAL KEEL VAYU"** (OSTEOARTHRITIS-KNEE JOINT).

FORM V: INFORMED CONSENT FORM

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

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

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

Date:

Signature of the participant:

In case of illiterate participant

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

Date:

Signature of a witness Left thumb Impression of the Participant

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

Date:

Station:

Signature of participant:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

தேசிய சித்த மருத்துவ நிறுவனம்,

அயோத்திதாஸ் பண்டிதர் மருத்துவமனை,

சென்னை-47

அழல் கீல்வாயு நோய்க்கான சித்த மருந்துகளின் (அவுரி கற்பம் மற்றும் வாத நோய்க்கு எண்ணைய்) பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம்.

ஒப்புதல் படிவம்

ஆய்வாளரால் சான்றளிக்கப்பட்டது

நான் இந்த ஆய்வைக் குறித்த அனைத்து விபரங்களையும் நோயாளிக்குப் புரியும் வகையில் எடுத்துரைத்தேன் என உறுதியளிக்கிறேன்.

தேதி : **கையொப்பம்:**

இடம்: **பெயர்** :

நோயாளியின் ஒப்புதல்

என்னிடம் இந்த மருத்துவ ஆய்வின் காரணத்தையும், மருந்தின் தன்மை மற்றும் மருத்துவ வழிமுறைப் பற்றியும், தொடர்ந்து எனது உடல் இயக்கத்தைக் கண்காணிக்கவும், அதனைப் பாதுகாக்கவும் பயன்படும் மருத்துவ ஆய்வுக்கூடப் பரிசோதனைகள் பற்றி திருப்தி அளிக்கும் வகையில் ஆய்வு மருத்துவரால் விளக்கிக் கூறப்பட்டது. எந்தவித வற்புறுத்தலுமின்றி என் சொந்த விருப்பத்தின் பேரில் என்னை இந்த ஆராய்ச்சிக்கு உட்படுத்த என் முழுமனதோடும் சுயநினைவோடும் சம்மதம் தெரிவிக்கிறேன்.

நான் இந்த மருத்துவ ஆய்வின் போது காரணம் எதுவும் கூறாமல், எப்பொழுது வேண்டுமானாலும் இந்த ஆய்விலிருந்து என்னை விடுவித்துக் கொள்ளும் உரிமையைத் தெரிந்திருக்கின்றேன்.

நான் என்னுடைய சுதந்திரமாகத் தேர்வு செய்யும் உரிமையைக் கொண்டு **அழல் கீல்வாயு** நோய்க்காக **அவுரிகற்பம்**(உள்மருந்து) மற்றும் **வாதநோய்க்கு எண்ணைய்**(வெளிமருந்து) மருந்துகளின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கு என்னை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி: **கையொப்பம்:**

இடம்: **பெயர் :**

தேதி: **சாட்சிக்காரர் கையொப்பம்:**

இடம்: **பெயர் :**

உறவுமுறை :

விரிவுரையாளர் கையொப்பம்:

துறைத்தலைவர்கையொப்பம்:

NATIONAL INSTITUTE OF SIDDHA

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CHENNAI – 600 047.

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FORM VI - WITHDRAWAL FORM

SI NO:

OP /IP NO:

NAME:

AGE/GENDER :

DATE OF TRIAL COMMENCEMENT:

DATE OF WITHDRAWAL FROM TRIAL:

REASONS FOR WITHDRAWAL:

- Long absence at reporting : Yes/ No
- Irregular treatment: Yes/ No
- Shift of locality : Yes/No
- Increase in severity of symptoms: Yes/No
- Development of severe adverse drug reactions: Yes/No

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

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FORM VII – PATIENT INFORMATION SHEET

Name of Principal Investigator: Dr.G.Suganya

Name of the institute: National Institute of Siddha,

Tambaram Sanatorium,

Chennai-47.

INFORMATION SHEET FOR PATIENTS PARTICIPATING IN THE OPEN CLINICAL TRIAL.

I, Dr.G.Suganya studying M.D Siddha at National Institute of Siddha, Tambaram Sanatorium is doing a clinical trial on ''Azhal Keel Vayu'' (Osteoarthritis). Osteoarthritis is a common degenerative disease, occurring throughout the world.

In this regard, I am in a need to ask you few questions. I will maintain confidentiality of your comments and data obtained. There will be no risk of disclosing your identity and no physical, psychological or professional risk is involved by taking part in this study. Taking part in this study is voluntary. No compensation will be paid to you for taking part in this study.

You can choose not to take part. You can choose not to answer a specific question. There is no specific benefit for you if you take part in the study. However, taking part in the study may be of benefit to the community, as it may help us to understand the problem of defaulters and potential solutions.

If you agree to be a participant in this study, you will be included in the study primarily by signing the consent form and then you will be given the internal medicine ‘‘Avuri Karpam’’(Internal medicine) 1gm BD with Honey for 48 days) and ‘‘Vatha Noikku Ennai’’(External medicine). If you wish to stay in the In- Patient ward Varmam Treatment will be given to you assuring that you will not be definitely hurt in any course of treatment.

The information I am collecting in this study will remain between you and the principal investigator (myself). I will ask you few questions through a questionnaire. I will not write your name on this form. I will use a code instead.

The questionnaire will take approximately 20 minutes.

If you want to know more about this study before taking part, you can ask me (Dr.G.Suganya, PG Scholar cum principal investigator of this study, attached to National Institute of Siddha, Chennai-47). You can also contact the Member-secretary of Ethics committee, National Institute Siddha, Chennai 600047, for rights and participation in the study.

தேசிய சித்த மருத்துவ நிறுவனம்,
அயோத்திதாஸ் பண்டிதர் மருத்துவமனை,
சென்னை-47.

அழல் கீல்வாயு நோய்க்கான சித்த மருந்துகளின் (அவுரி கற்பம் மற்றும் வாத நோய்க்கு எண்ணெய்) பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம்.

முதன்மை ஆராய்ச்சியாளர் பெயர் : மருத்துவர்.க.சுகன்யா

நிறுவனத்தின் பெயர் : தேசிய சித்த மருத்துவ நிறுவனம்
தாம்பரம் சானட்டோரியம்
சென்னை- 47

தேசிய சித்த மருத்துவ நிறுவனத்தில் பட்ட மேற்படிப்பு பயின்று வரும் நான் (மருத்துவர்.க.சுகன்யா) அழல்கீல்வாயு என்னும் மூட்டுகளை பாதிக்கும் நோய்க்கான மருத்துவ ஆராய்ச்சியில் ஈடுபட்டுள்ளேன்.

அழல்கீல்வாயு என்னும் நோயானது எலும்பு தேய்மானத்தாலும் எலும்புகளுக்கு இடையே இடைவெளி குறைவதாலும் முழங்கால் மூட்டுகளில் உள்ள நெய்ப்புத்தன்மை குறைவதாலும் உண்டாகிறது. இது முழங்கால் மூட்டுகளில் வலி,வீக்கம்,மூட்டுகளை நீட்ட மடக்க சிரமம்,நடப்பதில் சிரமம்,காலை நேரங்களில் விறைப்புத்தன்மை முதலிய குறிகுணங்களைக் கொண்ட நோய்

இது பரவக் கூடிய நோய் அல்ல.

இந்த ஆராய்ச்சி சம்பந்தமாக சில கேள்விகளைக் கேட்கவும், தேவையான ஆய்வக பரிசோதனைக்கு தங்களை உட்படுத்தவும் உள்ளேன்.

இந்த ஆராய்ச்சிக்கு தாங்கள் விருப்பத்தின் பேரில் உட்படும் பட்சத்தில் உள்மருந்தாக அவுரி கற்பம்1கி தேனில் குழைத்து 2 வேளை (காலை, மாலை) உணவுக்குப் பின் ஒரு மண்டலம் (48நாட்கள்) உட்கொள்ள வேண்டும். வெளி மருந்தாக வாத நோய்க்கு எண்ணைய் 48 நாட்களுக்கு நோயுள்ள டங்களில் வெளியே தடவ வேண்டும். தேசிய சித்த மருத்துவ நிறுவனத்தின் மருந்து செய்முறை கூடத்தில் இம்மருந்தானது சித்த மருத்துவர்களின் நேரடி மேற்பார்வையில் செய்யப்பட்டுள்ளது. வெளி நோயாளர்கள் 7 நாட்களுக்கு ஒருமுறை மருத்துவமனைக்கு வரவேண்டும். உள் நோயாளியாக தங்க விருப்பம் தெரிவிக்கும் பட்சத்தில் நோய்க்குத் தகுந்த வர்மச் சிகிச்சை அளிக்கப்படும்.

இந்த மருந்து சிறப்பாக அழல் கீல்வாயுநோய்க்காக அங்கீகரிக்கப்பட்ட சித்த மருத்துவ நூலில் கூறப்பட்டுள்ளது.

இந்த ஆராய்ச்சியில் தங்களை அனுமதித்தப் பிறகு உங்களுக்கு விருப்பம் ல்லையெனில் எப்போது வேண்டுமானாலும் ஆராய்ச்சியில் இருந்து விலகிக் கொள்ள உரிமை உள்ளது.

இந்த ஆராய்ச்சி சம்பந்தமாக நோயின் தன்மை பற்றியும் மற்ற விபரங்களுக்கும் முதன்மை ஆராய்ச்சியாளரான மருத்துவர்:**க.சுகன்யா**(பட்ட மேற்ப்படிப்பு மாணவர் சிறப்பு மருத்துவத் துறை) அவர்களை எந்த நேரத்திலும் தொடர்புக் கொள்ளலாம். கைப்பேசி எண் 9003541718.

மேலும் இந்த ஆராய்ச்சிக்குத் தக்க அனுமதிச் சான்று (IEC) பெறப்பட்டுள்ளது.

இந்த மருந்து முற்றிலும் பாதுகாப்பான மூலிகைகளைக் கொண்டு தயாரிக்கப்பட்டுள்ளது. பக்க விளைவுகளை ஏற்படுத்தாது.

மேலும் உணவு முறையில் மருத்துவரால் கூறப்படும் பத்தியம் காக்குமாறு அறிவுறுத்தப் படுகிறது.

இது சம்பந்தமான தங்களது அனைத்து விவரங்களும் ரகசியமாக வைக்கப்படும் என உறுதி அளிக்கிறேன்.

இதில் பயணப்படி முதலிய எந்த உதவித் தொகையும் வழங்கப் பட மாட்டாது.

இந்த ஆராய்ச்சியின் போது உடலுக்கு வேறு பாதிப்பு ஏற்படும் பட்சத்தில் தேசிய சித்த மருத்துவமனையில் தக்க சிகிச்சை அளிக்கப்படும்.

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL

CHENNAI – 600 047.

POST- GRADUATE DEPARTMENT OF SIRAPPU MARUTHUVAM

PRECLINICAL AND CLINICAL STUDY ON **"AVURI KARPAM"** (INTERNAL) AND **"VATHA NOIKKU ENNAI"** (EXTERNAL) FOR THE TREATMENT OF **"AZHAL KEEL VAYU"** (OSTEOARTHRITIS-KNEE JOINT).

FORM VIII- DRUG COMPLIANCE FORM

SERIAL NO: **OP/IP NO:**

NAME: **AGE/ GENDER:**

DRUG NAME: Avuri Karpam FOR Out Patients:

On 1st day-Date: Drugs issued: 14(Gms) Drugs returned: (Gms)

On 8th day-Date: Drugs issued: 14(Gms) Drugs returned: (Gms)

On 15th day-Date: Drugs issued: 14(Gms) Drugs returned: (Gms)

On 22th day-Date: Drugs issued: 14(Gms) Drugs returned: (Gms)

On 29th day-Date: Drugs issued: 14(Gms) Drugs returned: (Gms)

On 36th day-Date: Drugs issued: 14(Gms) Drugs returned: (Gms)

On 43th day-Date: Drugs issued: 14(Gms) Drugs returned: (Gms)

FOR In - Patients:

Day	Date	Morning	Evening	Day	Date	Morning	Evening
Day 1				Day 2			
Day 3				Day 4			
Day 5				Day 6			
Day 7				Day 8			
Day 9				Day 10			
Day 11				Day 12			

Day 13				Day 14			
Day 15				Day 16			
Day 17				Day 18			
Day 19				Day 20			
Day 21				Day 22			
Day 23				Day 24			
Day 25				Day 26			
Day 27				Day 28			
Day 29				Day 30			
Day 31				Day 32			
Day 33				Day 34			
Day 35				Day 36			
Day 37				Day 38			
Day 39				Day 40			
Day 41				Day 42			
Day 43				Day 44			
Day 45				Day 46			
Day 47				Day 48			
Day 49							

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

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AYOTHIDOSS PANDITHAR HOSPITAL

CHENNAI – 600 047.

POST- GRADUATE DEPARTMENT OF SIRAPPU MARUTHUVAM

PRECLINICAL AND CLINICAL STUDY ON **"AVURI KARPAM"** (INTERNAL) AND **"VATHA NOIKKU ENNAI"** (EXTERNAL) FOR THE TREATMENT OF **"AZHAL KEEL VAYU"** (OSTEOARTHRITIS-KNEE JOINT).

FORM IX - DIETARY ADVICE FORM

சேர்க்கக் கூடிய உணவுகள் (Diet to be included):

காய்கள் (Vegetables):

கத்தரிப்பிஞ்சு (Unripe brinjal)

முருங்கைப்பிஞ்சு (Unripe drumstick)

அவரைப்பிஞ்சு (Unripe Dolichos bean)

கீரைகள்(Greens):

பொன்னாங்கண்ணி (Sessile plant [*Alternanthera sessilis*])

மூக்கிரட்டை (Hog weed [*Boerhaavia diffusa*])

தூதுவேளை (Climbing brinjal [*Solanum trilobatum*])

முருங்கைக்கீரை (Leaves of Drumstick [*Moringa oleifera*])

கறிவேப்பிலை (Curry leaf [*Murraya koenigii*])

முடக்கறுத்தான் (Winter cherry [*Cardiospermum halicacabum*])

அறுகீரை (*Amaranthus tristis*)

கரிசாலை (trailing eclipta [Eclipta prostrate])

பழங்கள்(Fruits):

மாதுளை (Pomegranate)

ஆப்பிள் (Apple)

பப்பாளி (Papaya)

ஆரஞ்சு (Orange)

பேரீச்சை (Dates)

அத்தி (Fig)

நாவல் (Jambul [*Syzygium cumini*])

அசைவம் (Non-vegetarian diet):

வெள்ளாட்டுக்கறி (Meat)

காடை (Quail)

சிறு இறால்மீன் (Prawn)

தவிர்க்க வேண்டியவைகள் (Diet to be avoided):

சுரை (Bottle gourd)

பூசணி (Pumpkin)

வெள்ளரிக்காய் (Cucumber)

புடலை (Snake gourd)

பீர்க்கு (Ridged gourd)

உளுந்து (Black gram)

மொச்சை (Indian butter Bean)

காராமணி (Cow gram)

கொள்ளு (Horse gram)

கடுகு (Mustard)

எண்ணெய் (Gingelly oil)

புளிப்பு (Sour)

உப்பு (Salt)

வாயுப் பொருட்கள் (Vatha diet)

உருளைக் கிழங்கு (Potato)

வாழைக் காய் (Plantain)

புகையிலை (Tobacco)

மது அருந்துதல் (Alcohol)

பெண்போகம் (இச்சா பத்தியம்) [Sexual intercourse]

மருத்துவ அறிவுரை:

ஈரமில்லாத் தரையிலும், படுக்கையிலும் படுத்தல் வேண்டும்,

குளிர் காற்று படும்படியான இடத்தில் இருப்பதைத் தவிர்க்கவும்.

உடல் அதிக எடை இருப்பின் எடையைக் குறைக்க வேண்டும்.

அதிக தூரம் நடத்தல், அதிக நேரம் நிற்றல் தவிர்க்கவும்.

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL

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FORM X - ADVERSE REACTION FORM

SERIAL NO:

OP/IP NO:

NAME: **AGE:** **GENDER:**

DATE OF TRIAL COMMENCEMENT:

DATE OF OCCURRENCE OF THE ADVERSE REACTION: **TIME:**

DESCRIPTION OF ADVERSE REACTION:

MANAGEMENT:

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**