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A STUDY ON

VENPULLI

(DISSERTATION SUBJECT)



For the partial fulfillment of

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INTRODUCTION

Medicine is an art of fundamental importance to the healthy survival of humanity. Siddha, a Medical science is very ancient in origin, as old as the ancient civilization.

“கல்தேரன்றி மண் தேரன்றாக் கரலத்தே
வரளெரு முந்தேரன்றிய மூத்தக்குடி”

The word Siddha comes from ‘Siddhi’ which means perfection or healthy bliss. It generally refers to the ‘Attama Siddhi’ i.e the eight supernatural powers. Those who attained these powers are known as Siddhars.

The Universe is composed of five elements viz, Earth, Water, Fire, air Ether (Mann, Neer, Neruppu, Kaatru and Aakayam). The human anatomy, physiology, pathology of disease, materials for the treatment and the food for sustenance all fall with in the five elemental categories Siddha medicines revitalize and also rejuvenate the dysfunctional organs. According to Siddha system of Medicine diseases are classified into 4448 in number. Kuttam (dermatological diseases) is one among them. Kuttam is further classified into 18 types. The disease Venpadai is one among them. It is mentioned as “Suvetha Kuttam” in the text ‘Yugi Vaithya Chinthamani’.

Venpadai otherwise known as Venpulli is a serious cosmetic problem in adolescent life, as it affects the self esteem of patients. This is correlated to Vitiligo in modern science.

Vitiligo is a condition that causes depigmentation of the skin. It occurs when melanocytes, (the cells responsible for skin pigmentation,) die or are unable to function. The cause of Vitiligo is unknown, but research suggests that it may arise from autoimmune, genetic, oxidative stress, neural or viral causes. It is one of the non contagious dermatological problems which produce psychosomatic changes in the individual like mental stress, depression, social hinderance etc. Nowadays the prevalence of the disease is increasing and both male and female children are victims of the disease. Many more medicines described in Siddha system for venpulli “*SENKONRAI PATTAI KUDINEER*” (*INTERNAL*) and “*SENKONRAI PATTAI POOCHU*(*EXTERNAL*)” was selected for the present study which are purely herbal medicine, easily available and harmless to infants and children. The ingredients of “*SENKONRAI PATTAI KUDINEER*” and “*SENKONRAI PATTAI KUDINEER*” have the property of controlling venpulli without any adverse effects.

AIM AND OBJECTIVES

AIM:

The aim of study on venpulli noi is to ensure a name approach in diagnosis for the disease by using siddha and modern parameters and find out a safe and effective drug.

OBJECTIVES :

- To explore the most efficacious drug for venpulli.
- To collect the literal evidences regarding the disease venpulli as per Siddha System.
- To have a comparative study of the disease in Siddha and Modern aspect. (vitiligo)
- To evaluate the disease venpulli clinically by careful examination on aetiology, clinical features, investigations, diagnosis, treatment, diet, prognosis, etc.
- To have a clinical study on the venpulli affected children with **senkonrai pattai kudineer(internal) and senkonrai pattai poochu(external)**
- To find out whether any adverse effects caused by **senkonrai pattai kudineer(internal) and senkonrai pattai poochu(external)**

REVIEW OF LITERATURE

SIDDHA ASPECTS

VENPULLI

Synonyms:

Venkuttam, Suvetha Kuttam, Venhittu.

Definition:

Venpulli is defined as the discoloration of the skin characterized by the presence of the hypopigmented patches of irregular shape in the epidermis of skin and sometimes hair also is involved.

Siddhar Yugimuni, mentioned this condition as Suvetha Kuttam in his “Yugimuni Vaithiya Chinthamani – 800” which is one among the eighteen types of Kuttam.

“தடிப்பாக தவளநிறம் போல்வெ னுத்துச்
சர்வாங்கமும் வெளுத்தாற் றான்றி ரும்பும்
மடிப்பாக மயிர்வெளுத்தா லசாத்ய மாகும்
வரிவுதடு வள்ளங்கைக் குதங் குய்யந்தான்
நெடிப்பாக நெருப்புப்பட்டது போல புண்ணாய்
நிறமிருந்தா லசாத்தியமென்றே யுரைக்க லாகும்
வெடிப்பாக மேனியெல்லாம் வெளுத்து வீங்கில்
வெண்சுவேத குட்டமென்றே விளம்ப லாமே.”

-யூகி முனி வைத்திய சிந்தாமணி 800

Aetiology:

Siddha system attributes the aetiology of the disease to heredity, stress and strain, malnutrition and venereal exposure. No specific causes were mentioned for Venpulli but general descriptions have been given. Extrinsic and intrinsic causes have been attributed to the manifestation of Venpulli.

According to “Thirumoolar Karukkadai Vaithiya Nool”

“வியாதியுண் மூவாறு விளங்கிய குட்டங்கேள்
சுயாதிக் கிரந்தி சுழன் மேகத்தாலாறும்
பயாதி மண்ணுளப் பலவண்டினா லெட்டும்
நியாதி புழுநாலாய் நின்றதிக் குட்டமே”.

Among the eighteen types of Kuttam; six are caused by Kirandhi and Megam. Eight types are caused by insects in the soil and the remaining four types are caused by Worms.

2) According to “Yugimuni Vaithiya Chinthamani – 800” the causes for the 18 types of Kuttam are mentioned as:

“விளம்பவே மிகுந்தஉஷ் ணந்தன் னாலும்
மிகுந்த சீதளத்தாலு மழற்சி யாலும்
வளம்பவே மந்தத்தால் வாந்தி யாலும்
மகத்தான பெண்ணோடு மருவ லாலும்
கிளம்பவே கிலேசங்கள் மிகுத லாலும்
கெடியான வரக்கங்கள் டைத லாலும்
தளம்பவே மயிருகற்கள் தவிடு மண்கள்
சாதத்திற் பருகலால் மிகுக்குங் குஷ்டம்
குட்டந்தான் பதினெட்டு வரவே தென்னிற்
குருநிந்தை சிவநிந்தை மறையோர் நிந்தை
திட்டந்தான் தேவதையைத் தூஷணைக்கு ரோதம்
செப்பலாற் றிருடலாற் பரதா ரத்தை
அட்டந்தா னாசையால டைக்க லத்தை
அபகரித்த லகதிபர தேசி தன்னை
வட்டந்தான் வைதலாற் கற்ப ழித்தல்
வந்திடுமே பதினெட்டுக் குட்டந் தானே”

Excessive heat and cold exposure, laziness, excessive sleep in day time, unbridled sexual indulgence, robbery etc. These habits are supposed to be the factors, which lower the immune mechanism of the body (Udal vanmai) and makes the body liable for the disease.

Excessive intake of food which are hard to digest, imbalanced food and vomiting, frequent intake of food mixed with fragments of stone and hair, prolonged mental depression, intention to spoil others, raping, greedy, abusing god and noble people, neglecting refugees and beggars, cursing the elders are said to be the causes for this condition.

3) According to “Agathiyar Vaithyam”

“குயல்வாய் குஷ்டம் சயங்குன்ம நீரிழிவு சுரக்கிராணி
நீரடைப்பு பாண்டு மூல வாய்வு
கயல் வாயு வருங்கண்ணில் குத்தாய் கடிந்த தசவாய்வு
காணவாக முன் செய்த உயிர்களும் வினைதானே”.

Kuttam may be hereditary, apart from all other etiological factors Kuttam is also considered to be followed by Sins committed in the previous birth (Kanma vinai).

4) According to “Siddha Maruthuvam Sirappu”

The aetiology and the characters of Venpadai are clearly explained in the text “Siddha Maruthuvam Sirappu” as follows:

In the affected area, reduction or total loss of skin pigment melanin on the epidermis is observed. As the distinct aetiology is not known, there exist certain beliefs and hypothesis about the disease. They are: 1.Constant irritation to the skin owing to clothes, rubber, plastics or other chemical substances. 2. Some essential metal or mineral deficiency in the food.

Classification:

1) According to “Yugimuni Vaithiya Chinthamani – 800”

In “Yugimuni Vaithiya Chinthamani – 800”, Kuttam is classified into 18 types. Suvetha Kuttam (Venpadai) is one among them. It is mentioned as below:

“முத்தாகுங் குட்டந்தான் பதினெட்டுக்கும்
முனியான யுகிநான் சொல்லக் கேளாய்
புத்தாகும் புண்டரீக குட்டத் தோடு
பொருகின்ற விற்போடக குஷ்ட மாகும்
புத்தாகும் பரமகுஷ்டம் கேசர குஷ்டம்
பரிவான கர்ணகுட்டம் சிகும குட்டம்
கித்தாகுங் கிருஷ்ணகுட்ட அதுவும்பர் குட்டம்
கெடியான மண்டலகுட் டமுமா மென்னே
குட்டமாம் பரப்பரிச குட்ட மொடு
குடிமாம் விகர்ச்சீக குட்ட மாகும்
வட்டமாம் வையாதி குட்ட மோடு
மருவலாங் கிடபகுட்டஞ் சர்ம தேவம்
திட்டமா தேத்திருக் குட்ட மோடு
சித்துமா குட்டஞ்சா காறுகுட்டம்
துட்டமாஞ் சுவேதகுட்டந் தன்னோ டொக்கச்
சுயம்பான பதினெட்டு குட்ட மாச்சே”

- | | |
|----------------------|--|
| 1.Pundarega Kuttam | (Padarthamarai Peru Noi) |
| 2.Virpotaka Kuttam | (Koppula Peru Noi) |
| 3.Baama Kuttam | (Sirangu Peru Noi) |
| 4.Gaja Saruma Kuttam | (Yaanaithol Peru Noi, yaega Saruma Kuttam) |
| 5.Karna Kuttam | (Kaathu Peru Noi) |
| 6.Sigura Kuttam | (Thol Peru Noi) |
| 7.Krishna Kuttam | (Karu Peru Noi) |
| 8.Avudhumbara Kuttam | (Atthikkaai Peru Noi) |
| 9.Mandala Kuttam | (Valaiya Peru Noi) |
| 10.Abarisa Kuttam | (Vali Peru Noi) |
| 11.Visarchika Kuttam | (Sori Peru Noi) |
| 12.Vibaathika Kuttam | (Sempadai, Senkuttam) |
| 13.Kideeba Kuttam | (Pandrithol Peru Noi) |

14.Sarmathala Kuttam	(Tholvedi Peru Noi)
15.Thethru Kuttam	(Thadippu Peru Noi)
16.Sithuma Kuttam	(Naa Peru Noi)
17.Sathaaru Kuttam	(Purai Peru Noi)
18.Suvetha kuttam	(Venpadai, Venkuttam)

2) According to “Pararasa Sekaram”

Kuttam is classified into 5 types:

1. Venkuttam
2. Senkuttam
3. Karunkuttam
4. Vishakuttam
5. Azhukannikuttam

3) According to “Siddha Maruthuvam Sirappu”

According to “Siddha Maruthuvam Sirappu”, Venpadai has been classified into 4 types:

1. Vatha Venpadai
2. Pitha Venpadai
3. Kaba Venpadai
4. Mega Venpadai

4) According to “Siddhar Aruvai Maruthuvam” and “Anubava Vaithiya Deva Ragasiyam”

Venpadai has been classified into 3 types on the basis of Mukkutram. They are,

1. Vatha Venpadai
2. Pitha Venpadai
3. Kaba Venpadai.

Clinical features:

1) According to “Yugimuni Vaithiya Chinthamani – 800”

Yugimuni shortly attributed the Venpulli under the headline of Suvetha Kuttam which is one of the eighteen kuttams and he mentioned the clinical features of suvetha kuttam as below:

“தடிப்பாக தவளநிறம் போல்வெ ளுத்துச்
சர்வாங்கமும் வெளுத்தாற் றான்றி ரும்பும்
மடிப்பாக மயிர்வெளுத்தா லசாத்ய மாகும்
வரிவுதடு வள்ளங்கைக் குதங் குய்யந்தான்
நெடிப்பாக நெருப்புப்பட்டது போல புண்ணாய்
நிறமிருந்தா லசாத்தியமென்றே யுரைக்க லாகும்
வெடிப்பாக மேனியெல்லாம் வெளுத்து வீங்கில்
வெண்சுவேத குட்டமென்றே விளம்ப லாமே.”

Yugimuni gives a clear definition of Venpulli and he mentioned the conditions which will not responded to treatment (Asathiyam) as said below:

1. Whitish discoloration of the part of the body or entire body. Sometimes hair also turns white.
2. When white patches occur on the palms or muco-cutaneous junctions like lips, anus and genitals, it is said to be rarely curable.
3. If the hair becomes white, prognosis will be very bad.
4. Fissured body becomes oedematous.

2) According to “Siddha Maruthuvam Sirappu”

In the text ‘Siddha Maruthuvam Sirappu’, Venpadai has been classified into 4 types and the clinical features are also described:

- I. Vatha venpadai
- II. Pitha Venpadai
- III. Kaba venpadai
- IV. Mega Venpadai.

I. Vatha Venpadai:

It is characterized by the presence of depigmented patches, which are dry, rough and reddish or somewhat pale-black in color.

II. Pitha Venpadai:

It is characterized by the presence of depigmented patches red in color like lotus flower, spreading with burning sensation and loss of hairs on that area.

III. Kaba Venpadai:

It is characterized by the presence of depigmented patches white in color like the flower of Thumbai (*Leucas aspera*), spreading with itching sensation and mild elevation of the lesion.

IV. Mega Venpadai:

It is followed by venereal diseases. It may develop in 4 to 6 months after the venereal exposure. This Venpadai develops initially in the nape and the adjoining spaces. It then gradually spreads to involve the shoulder joints and back of the trunk.

Clinical features: Depigmented patches are small in number, pale in colour or light turmeric in colour or dark colour and margins marked by hyperpigmentation. These lesions are circumscribed with 2 mm to 3 mm diameter or above. This correct picture of hypopigmented and hyperpigmented skin seems to be more or less a multi eyed filter (sieve like).

Females are more prone to this Mega Venpadai and the treatment takes longer period. Therefore drugs to be given for the treatment of Mega noi (Venereal disease) before treating Venpadai.

Siddha Pathology:

The basic principle of Siddha system is 96 thathuvas of which panchapootha theory and mukkuutra theory are very important. The pathology in Siddha system depends upon the mukkuutra theory viz, Vatha, Pitha and Kaba. The normal order of Vatha, Pitha Kaba is in proportion of 1:1/2:1/4 respectively.

This is stated in the following verses.

“வழங்கிய வாதம் மாத்திரை யொன்றாகில்
தழங்கிய பித்தந் தன்னி லரைவாசி
அழங்குங் கபந்தாடைங்கியே காலைடில்
பிறங்கிய சீவர்க்குப் பிசக்கொன்று மில்லையே”
- குணவாகட நூடி

Imbalance in this results in disease this can be inferred from the following Thirukkural.

“மிகினும் குறையினும் நோய் செய்யும் நூலோர்
வளி முதலா எண்ணிய மூன்று”.

- திருவள்ளுவர்

Siddhars treated the body as well as mind and have also formulated the ways for the prevention of diseases. Siddhars defined medicine as follows,

“மறுப்பது உடல்நோய் மருந்தென லாகும்
மறுப்பது உளநோய் மருந்தென சாலும்
மறுப்பது இனிநோய் வாராதிருக்க
மறுப்பது சாவையு மருந்தெனலாமே”

The clinical methods through which the correct diagnosis made out by Envagai thervugal and ezhu udal kattukal Basic five principle (Pancha boothams) in our system are ingredient for the Thridhosam. That has been formed by the union of single or double boothas like as follows.

Vaatham	=	Vali + Vin
Piththam	=	Thee
Kabam	=	Mann + Neer

The most important clinical approach of our physicians is to assess the status and function of the above three thadhus . This has been described as Naadi sothanai and Naadi nadai Arithal.

The alteration of three thathu in their reaction to extrinsic or intrinsic factors results in disharmony. This altered harmony and balance variation of the three thathus results in disease. Their natural ratio to each other is discerned by the physician at the wrist and each nadi is individually assessed for its strength, speed and regularity.

Description of Three Humors

These three humour are divided in to various types and have their functions specifically.

VALI

According to the physiological function vali is of ten types. They are

(I) Uyir Kaal (pranan)

This is the first of ten vital airs. According to Yugi muni, pranan starts from moolatharam and comes through the nostrils and causes the act of inspiration and expiration. The inspiration and expiration are not equal and their ratio is 8:12. The process helps in the digestion of ingested food.

(ii) Kizhnokkumkaal(Abanan)

Apanan, the downward air, starts from swathittanam and descends towards the pelvis and is responsible for excretion of urine and faeces. This is green in color. It contracts the anus. It helps to take the essence of the digested food to the different parts of the body which requires food. The god attributed is varadarajan.

(iii) Paravukaal(Vyanan)

Vyanan arises from the shoulders and go through all the 72,000 nerves and thus activate voluntary and involuntary movements of the body and thus make them to extend the contract. This appreciates the sense of touch, helps to take the essence of the food to the strategic points of the body and guards the body.

(iv) Melnokkumkaal (Udhanan)

Udhanan starts from the umbilical region (udarakkini) and takes the essence of food and stations it at appropriate places. It helps in digestion and assimilation of food.

(v) Nadukkal (Samanan)

Samanan starts from the umbilical cord and spread out up to the lowerlimb. This is responsible for the balance of the other four vathas. It equalizes the six tastes, water, food etc and helps in assimilation.

(vi) Naagan

Naagan is responsible for higher intellectual functions, hearing, thinking etc. It causes closing and opening of the eye lids.

(vii) Koorman

Koorman starts from the mind and causes winking of the eyelids, yawning and closure of mouth. It gives strength and helps to visualize things and causes lacrimal secretion

(viii) Kirukaran

Kirukaran lies in the tongue and causes nasal and salivary secretions. It induces hunger. Sneezing and cough are attributed to kirukaran. It is black in color

(ix) Devadaththan

Laziness is attributed to devadaththan. Ocular movements and human passions are attributed to this vatham. It stays either at the anus or at urinary orifice.

(x) Dhananjeyan

Dhananjeyan functions from the nose and it is responsible for the bloating of the body after death and also for the foul smell.

AZHAL

It is not just heat in our body. Functionally this human bodies warmth/heat of life is divided in to five types. They are

(i) Akkuanal (Analagam)

It lies between the stomach and the intestine and causes digestion and dries up moist ingested substances

(ii) Vanna eri (Ranjagam)

This fire lies in the stomach and gives red color to the chyme and produces blood. It improves blood.

(iii) Attralangi (Sadhagam)

This fire lies mainly in limbs. It gives energy for activities

(iv) Nokku Azhal(Alosagam)

It lies in the eyes and causes the faculty of vision. It helps to visualize things.

(v) Ollolithe (Prasagam)

It gives color and complexion and brightness to the skin.

IYYAM:

It is of five types. They are

(i) Alli Iyyam (Avalambagam)

It lies in the lungs and helps in respiration. It causes firmness of the limbs. This is vital among all types of kapham for it controls the other four kapham and maintains equilibrium.

(ii) Neerpi Iyyam (Kilethagam)

It lies in the stomach. It mixes the consumed food and water and promotes the digestive process.

(iii). Suvaikanna Iyyam (Pothagam)

It lies in the tongue and helps to realize the taste of the consuming food.

(iv) Niraivu Iyyam (Tharpagam)

Sustaining in the head, this gives refrigerant effect to cool the eyes and other sense organs.

(v) Ondri Iyyam (Sadhigam)

Sustaining in the joints this makes them more freely and easily. Since venpadai patients are not having defined description of pathology, the pattern of disturbance in Vali, Azhal, Iyyam keeps on varying. The manifestation of these uyir thathu keep on changing according to the predominant symptom. But alteration in azhal thathu is seen mostly.

3.1.8 ஏழு உடற் கட்டுகள் (Seven Physical Constituents)

The human body is made of seven basic, physical constituents. These constituents should be in harmony and function normally. Any variation in them will lead to their functional deviations. The Natural characters of the seven physical constituents.

(i) **SAARAM** (Chyle) : This gives mental and physical perseverance.

- ✓ Increased Saaram : Leads to diseases of increased kapham like indigestion Etc..
- ✓ Decreased Saaram : Leads to loss of weight, tiredness, lassitude, dryness of the skin and diminished activity of the sense organs.

(ii) **SENNEER** : It Imparts color to the body, nourishes the body and is responsible for the ability and intellect of an individual.

- ✓ Increased Senneer : Causes boils in different parts of the body throbbing pain, anorexia, mental disorder, splenomegaly, Colicky pain., increased blood pressure, reddish eye and Skin, jaundice, haematuria etc.
- ✓ Decreased Senneer : Leads to anaemia, tiredness, neuritis and lassitude, Pallor of body.

(iii) **OON** : It gives shape to the body according to the physical activity and and covers the bones.

- ✓ Increased Oon : Oon in excess causes cervical lymph adenitis, venereal ulcer, tumour in face, abdomen, thigh genitalia etc are the signs of increased Oo n
- ✓ Decreased Oon : Leads to impairment of sense organs, joints jaw, thigh and genitalia gets shortened.

(iv) **KOZHUPPU** : (Adipose tissue): It lubricates the joints and other parts of the body to function smoothly

- ✓ Increased Kozhuppu: Identical to that of increased Oon associated with Dyspnoea and loss of acidity.
- ✓ Decreased Kozhuppu: Leads to pain in the hip region and diseases of the spleen.

(v) **ENBU** : (Bone) :Supports the frame and responsible for the postures and movements of the body.

- ✓ Excess Enbu : Growth in bones and teeth
- ✓ Decreased Enbu : Loosening of teeth and nails and Splitting and falling of hair.

(vi) **MOOLAI** : (Bone marrow): It occupies the medulla of the bones and gives strength and softness to them.

- ✓ Increased Moolai : Causes heaviness, swollen eyes, swollen phalanges, Oliguria and non healing ulcers
- ✓ Decreased Moolai : Causes osteoporosis and sunken eyes.

(vii) **SUKKILAM / SURONITHAM** : (Sperm and Ovum) : It is responsible for reproduction.

- ✓ Excess Sukkilam/Suronitham : Causes lust towards women and cause Urinary calculi.
- ✓ Decreased Sukkilam/Suronitham : Causes failure in reproduction, pain in the genitalia.

3.1.9 எண்வகை தேர்வு (Eight fold Siddha Examinations)

Nowadays advanced diagnostic tools have been developed by modern bio-medical scientists. But Siddhars have given eight diagnostic methodological tools. They are called as Envagai thervu.

(i) NAA

Signs and symptoms in the tongue are considered here. Size, appearance, thickness, color(pigmented, magenta) fissured (longitudinal, transverse) coated, geographical patches, oral hairy leucoplakia, candida, aphthous ulcers, sense of taste, saliva secretion

(ii) NIRAM

The color of skin is mainly considered here but also the change in other organs.

(iii) MOZHI

The change in the normal sound of voice mainly uratha olli (Valithel), thazhntha olli (Melithal), physiological and mental status can also be noted during conversation.

(iv). VIZHI

Color, warm, burning sensation, irritation, visual perception.

(v). PARISAM

Observations by touch, temperature, sensory impairment, masses, nodes, swelling, texture of the skin, pain, hardness, edematous, and dullness shall be noted.

(vi).MALAM

The stools are examined for quantity, hardening (malakattu) loose motion (baethi) color, smell.

(vii). MOOTHIRAM

Neer Kuri : Urine is to be observed for the following characters,

- Niram(color)
- Alavu(quantity)
- Edai (specific gravity)
- Manam (smell)
- Nurai (froth)
- Enjal (deposit)

3.1.10 NEI KURI

A unique traditional method for diagnosis with urine is Neikkuri. Urine is freshly collected in a clean glass vessel and a drop of Gingili oil is dropped in to it. The gingelley oil should be prepared by wooden press. Machine pressed oil is not an effective tool.

Mode of spreading is noted, usually

Vali noi - Aravu (Snake like spread)

Azhal noi - AAzhi (Ring like spread)

Iyyam -Muthu (Pearl like spread)

Venpulli starts with disturbed Azhal and eventually involves all the three uyir thathus – thus resulting in various patterns of oil spread in the urine surface. An unique pattern, is seen mostly like star fish with branches and sieve (plate with pores), irregular border, speed of spread is also to be noted. It has been observed that the initial star shaped spread reduces as the patients responds to treatment.

Prognosis of the disease:

The prognosis of the disease is also mentioned in Siddha literature:

1) According to the text “Yugimuni Vaithiya Chinthamani – 800”

curable types - 10:

“குட்டந்தான் பதினெட்டில் சாத்தி யந்தான்
கூறக்கேள் விற்போடக பரமற் குட்டம்
கிட்டந்தான் கேச்சர்ம குட்ட மோடு
கிருஷ்ண குட்டமவுதம்ப ரகுட்டந் தானும்
திட்டமாந் தேத்திருக் குட்ட மோடு
செயசித்து மாகுட்டங் கிடப குட்டம்
தட்டந்தான் மிகுந்தசா தாரு குட்டம்
சமகிருஷ்ண குட்டம் சாத் தியமா மென்னே”

Curable Kuttam

1. Virpodaga Kuttam
2. Baama Kuttam
3. Gaja Sarma Kuttam
4. Krishna Kuttam
5. Avuthumbara Kuttam
6. Thethru Kuttam
7. Sithuma Kuttam
8. Kideepa Kuttam
9. Satharu Kuttam
10. Sarmathala Kuttam

Incurable Types - 8:

“ஆமென்ற பத்துந்தான் சாத்ய மாகும்
அசாத்ய மதுதானெட்டு அறிந்து பாரு
போமென்ற பூர்வத்தின் கன்மத் தாலும்
புவிதனக் கும்மிகுகன்மஞ் செய்த பாவம்
பாமென்ற பெரியோர்கள் சாபத் தாலும்
பாதகங்கள் மனதறியப் பண்ணும் பேர்க்கும்
கோமென்ற குட்டமாம் ரோகம் வந்து
கூடுமென்று யூகிமுனி கூறினேனே”

1. Pundareega Kuttam
2. Karna Kuttam
3. Sigura Kuttam
4. Mandala Kuttam
5. Abarisa Kuttam
6. Visarchiga Kuttam
7. Vibaathiga Kuttam
8. Suvetha Kuttam

2) According to the text “Siddha Maruthuvam Sirappu”

Curable conditions in Venpadai are:

- Lesions without any change in hair colour.
- Lesions without coarse texture.
- Lesions that are not appearing like white burnt scar.

Incurable conditions in Venpadai are:

- Lesions with whitened hair.
- Lesions feeling rough.
- Lesion appearing like white burnt scar.
- If the lesion first appears on genitalia, anus palms and lips.
- Lesions of fast spreading nature.

Management in Siddha:

“மிகினும் குறையினும் நோய்செய்யும் நூலோர்
வளிமுதலா வெண்ணிய மூன்று”.

-திருக்குறள்.

According to Siddha System, the main aim of the treatment is to cure udarpini (physical illness) and manappini (mental illness). Treatment is not only for complete healing but also for the prevention and rejuvenation.

In Siddha system, the line of treatment consists of

1. Neekkam (Treatment)
2. Niraiivu (Rejuvenation of well being)
3. Kaappu (Prevention)

1. Neekkam (Treatment):

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 bodily 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".

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 Viresana Boopathy Tablet - 2 early morning with hot water.

Then the next day onwards the trial drugs Panchamuga Chenduram (Internally) Poovarasam Pattai Ennai (Externally) were given.

2. Niraivu (Rejuvenation):

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

3. Kaappu (Prevention):

As per Siddha science, even at the time of conception some defects may occur in the fertilized embryo forming the basic for the manifestation of certain constitutional diseases after birth. These are known as Kanma vinaigal.

Kanma Neekkam (Expiation):

To prevent and expiate the misdeeds of the kanmam, planting of trees, establishing gardens, laying roads and pathways, digging wells and ponds for public use, constructing temples, donating ornaments to poor children must be done.

Dietary Advice:

In siddha system of medicine the importance of dietary habits also emphasized 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”.

In diseased condition diet restrictions or paththiyam are strictly followed to increase the effectiveness of medicine for curing 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.

Dietary and other restrictions for Venpadai patients:

Diet restrictions or paththiyam should be strictly followed in Venpadai patients. These are prescribed to normalize the deranged thodam and to increase the potency of the drugs. Patients are a

Patients are strictly advised to follow the dietary and other restrictions:

- Avoid all non-vegetarian foods except goat's meat.
- Avoid food items which are enriched with alcohol.
- Avoid the Sesban, Brinjal, Kaar arisi, Green plantain, Bitter gourd, Pickles, Tamarind,

- Vitamin C rich fruits and vegetables like lemon, goose-berry, orange, etc. Vitamin C must be avoided in diet, since in the formation of melanin, tyrosine plays an important role. But in the metabolic pathway of tyrosine a metabolic error happens due to increased presence of vitamin C (Ascorbic acid). If this error occurs continuously the tyrosine cannot be absorbed by the body and is excreted through urine.
- To avoid substances allergic to the particular individual.
- To take Thiridhoda samapporulkaal (elam, manjal, seeragam, kaayam, chukku, venthayam, poondu, milagu).
- To take vegetables and green leafy vegetables
- To take more germinated grams, dates, figs and powder of fenugreek regularly.
- Using of soaps and detergents should be avoided. To take neutral value pH soaps for bath purpose.
- To use Nalunguma a Siddha herbal preparation which contains sandanam, vetti ver, vilamacham ver, kichili kizhangu, karbogi, paasipayiru instead of soap and other detergents for bath.

MODERN ASPECTS

SKIN

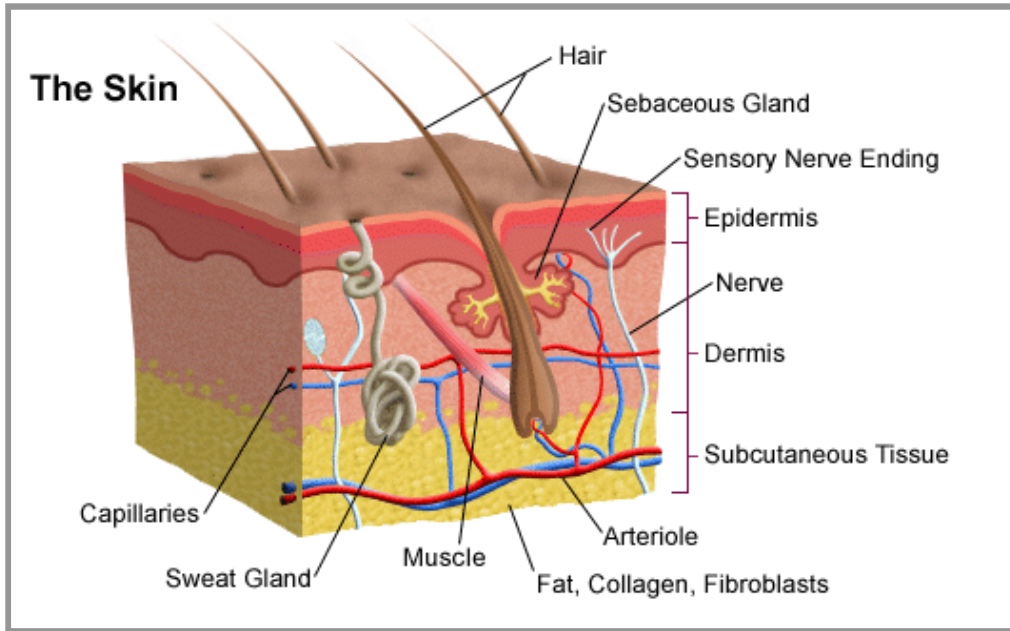
Introduction:

The skin is the body's largest organ, covering the entire body. The skin and external mucous membranes separate the human organism from the environment and accomplish a variety of functions.

In an adult, the skin surface measures 1.5 to 2 m² while the thickness of the skin varies from fractions of a millimeter to 4 mm. The thickness of the epidermis varies from 0.06 - 0.9 mm to 0.5 – 0.6 mm. The thickness of the subcutaneous fat varies considerably. Some area is devoid of fat while in others (on the abdomen and gluteal regions). It is several centimeters thick. The mass of skin an adult accounts for approximately 5% while together with the subcutaneous fat for about 10 to 17.7% of the total body mass.

The color of the skin may change because the amount of the pigment in it varies under the effects of external and internal factors.

The skin surface is covered with hairs over a great area. The areas devoid of hairs are the lips, the palms and soles, the palmar surface of the hand and the plantar surface of the toes, the glans penis, the inner surface of the prepuce and the inner surface of the labia majora and minora.



CROSS SECTION OF SKIN

Facts about the Skin:

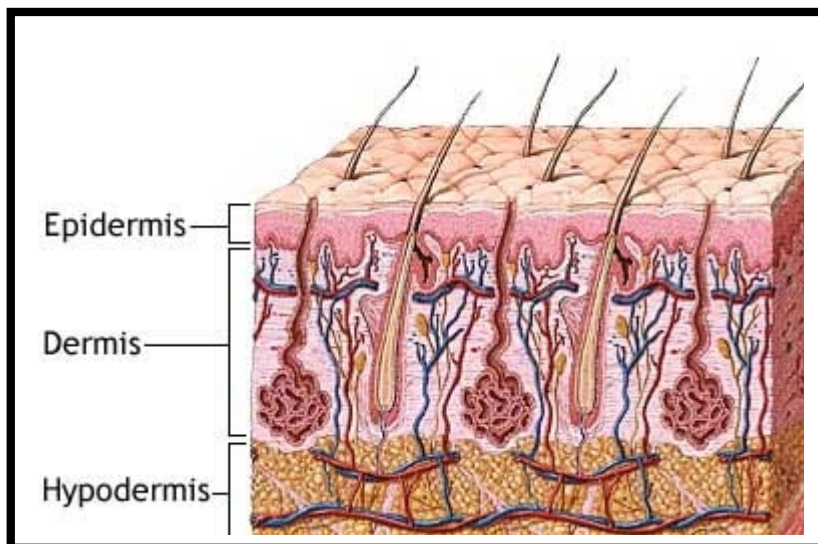
The skin and external nucleus membranes separate the human organism from the environment and accomplish a variety of functions. Normal functioning of the skin and its appendages of high significance for the organism activity as a whole and has a positive influence on its general condition.

The skin not only responds by its adaptive reactions to the different effects of the external (exogenic) environmental factors, but is also very sensitive to changes in the various body organs and systems and is often the first to signal the development of a pathological condition by different changes in its function. Consequently though the skin is an independent organ, it at the same time is in a constant dynamic connection with the external environment and with all the organs and systems of a human body. The skin communicates with the organism by means of the nervous system, circulation and endocrine glands. The skin takes an active part in protein, carbohydrate, fat, water, mineral and vitamin metabolism.

Histology:

The skin develops from two germinative zones. The ectoderm which is represented by the epidermis (the most superficial skin layer) and the mesoderm (the middle embryonal layer) represented by two layers namely the true skin, or dermis (the middle layer) and the subcutaneous fat or hypoderm the deepest skin layer. The boundary between the epidermis and dermis and dermis forms a wavy line because of the presence of skin papillar (special out growth on the surface of the true skin). The spaces between which are filled with epithelial processes.

The skin is divided into 3 divisions: Epidermis, Dermis and Hypodermis



Epidermis:

The epidermis is the most superficial layer of the skin and provides the first barrier of protection from the invasion of foreign substances into the body. The principal cell of the epidermis is called a keratinocyte.

The epidermis is subdivided into five layers or strata,

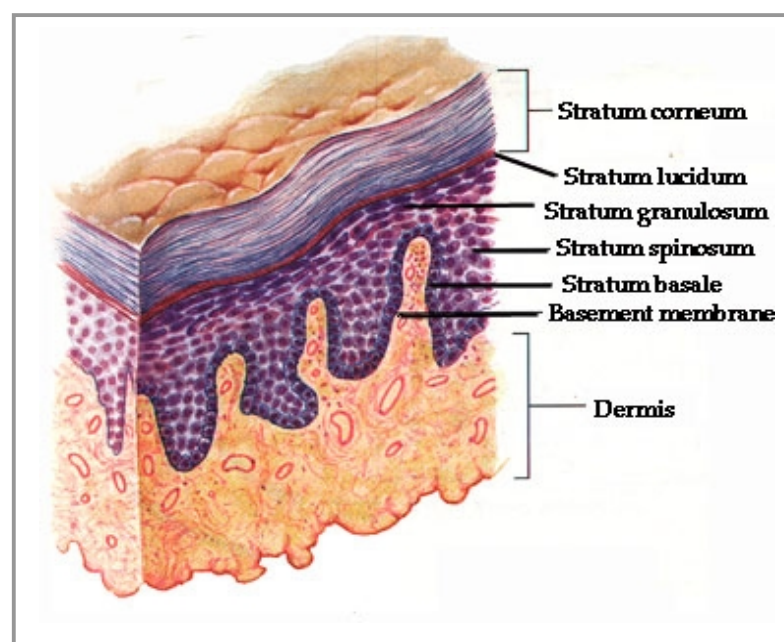
- The stratum germinativum (stratum basale),
- The stratum spinosum (malpighian layer),
- The stratum granulosum,
- The stratum lucidum and
- The stratum corneum

Specialized Epidermal Cells:

There are three types of specialized cells in the epidermis

- 1) The melanocyte produces pigment (melanin)
- 2) The Langerhan's cell is the frontline defense of the immune system in the skin
- 3) The Merkel's cell's function is not clearly known

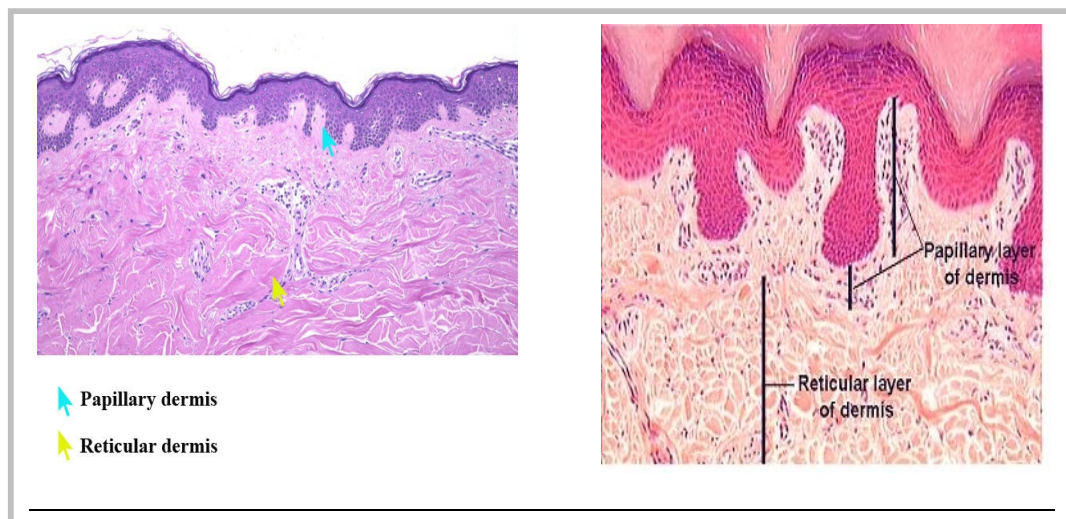
LAYERS OF THE EPIDERMIS



Dermis:

The dermis assumes the important functions of thermoregulation and supports the vascular network to supply the avascular epidermis with nutrients. The dermis contains mostly fibroblasts which are responsible for secreting collagen, elastin and ground substance that give the support and elasticity of the skin. Also present are immune cells that are involved in defense against foreign invaders passing through the epidermis. The dermis is typically subdivided into two zones;

1. Papillary dermis:
2. Reticular layer:



Vascular system of skin:

Vascular system of the skin is formed of several networks of blood vessels. A deep arterial plexus of skin forms, which gives rise to branches supplying the holes of the sweat glands, the hair follicles and the fat lobules. The epidermis is devoid of blood vessels.

Lymphatic system of the skin:

The lymphatic system of the skin forms a superficial and deep network. The superficial lymphatic network arises on the papillary layer as blind rounded dilated capillaries between which there are numerous anastomosis. The second network of lymph vessels is in the lower part of the dermis.

Functions of skin:

Skin performs the following functions:

- Protection
- Sensation
- Heat regulation
- Control of evaporation
- Aesthetics and communication
- Storage and synthesis
- Excretion
- Absorption
- Water resistance

Sl. No	FUNCTIONS	STRUCTURE
1	Barrier protection:	
	UV rays	Melanocytes
	Infection & Fluid homeostasis	Keratinocytes
	Protection from trauma	Epidermis & dermis
2	Thermoregulation	Blood vessels in superficial & deep dermal plexus
3	Immuno regulation	Langerhans cells & Inflammatory cells of all types
4	Sense perception	
	Pain, touch, temperature	Peripheral nerve trunks
	Pressure	Pacini vater corpuscles
	Discriminate touch	Meissners corpuscles

Pigmentation of the Skin:

The colour of the skin may be brown or even black according to the amount of pigment present. Even in white races most parts of the skin contain brown pigment granules in the deepest layers of the germinative zone of the epidermis.

In dark races they are more abundant and extend throughout the whole zone.

Melanocytes:

Melanocytes are derived from stem cells in the neural crest that normally migrate to the epidermis, where they are scattered along the basal layer. Melanocytes produce melanin within cytoplasmic packets called melanosomes. These contain greater amounts of melanin in dark - skinned individuals. The melanin is distributed to keratinocytes via dendrites when stimulated by exposure to ultraviolet radiation and other factors Melanin

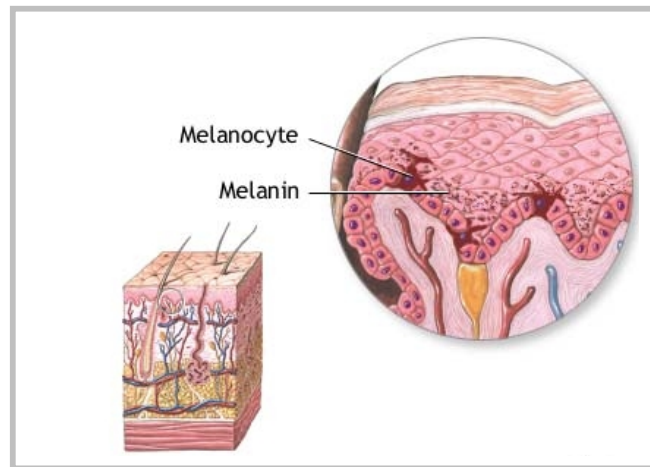
‘Melanin’ a word is derived from the Greek word Melas, meaning black. Melanin is a complex black-brown polymer synthesized from the amino acid L-DOPA. Melanin is endogenous non-haemoglobin derived or brown black pigment (formed). When the enzyme tyrosinase catalyses the oxidation of tyrosine to dihydroxy phenylalanine (DOPA) in melanocytes. It is widely distributed in the body but peculiarly enough it is limited only to those structures which have got an ectodermal origin, for skin, hair, choroid coat of retina and substantia nigra of the brain. It is formed from tyrosine by oxidation metabolism and polymerization.

The colour of the skin may be brown or even black according to the amount of pigment present. Even in white races most parts of the skin contain brown pigment granules in the deepest layers of the germinative zone of the epidermis. In dark races they are more abundant and extend throughout the whole zone.

Distribution:

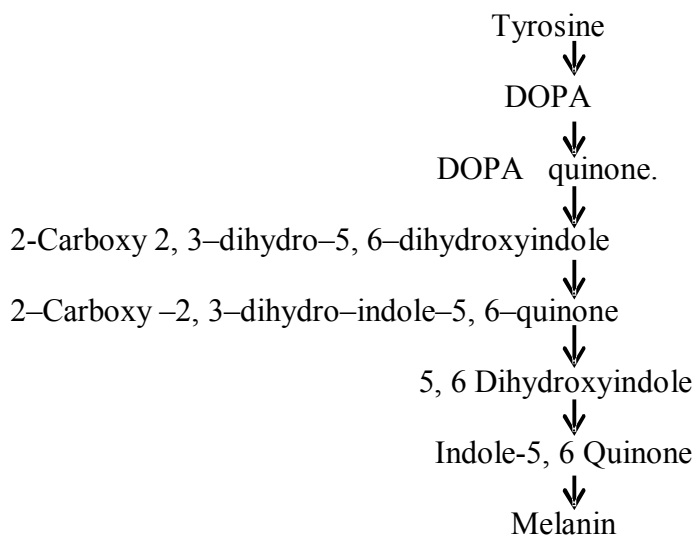
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It is formed from tyrosine by oxidation metabolism and polymerization.



Melanin Formation:

Melanin synthesis is initially catalysed by a copper containing enzyme known as tyrosinase. The pathway of melanin synthesis from the oxidation of phenylalanine or tyrosine are as follows.



Melanin formation in both human and amphibian skin is augmented by the hormone known as intermedin or melanocyte – stimulating hormone (MSH) secreted by the pars intermedia of the pituitary gland. Adrenocortico tropic hormone (ACTH) secreted by Anterior Pituitary has melanocyte – stimulating activity similar to MSH although to a much lower degree. Melatonin extract from bovine pineal gland, causes concentration of melanin near the nuclei of melanocytes in frog and as a result of this the skin becomes pallor. Its role in the human is not known. MSH causes the serum copper to rise and this

is accompanied by inner case in the melanin formation. Diminished formation of melanin is seen in albinism and leucoderma. In melanotic sarcoma, melanin may be found in the urine. Melanin absorbs all visible light, ultraviolet (UV), and infrared (IR) radiations. Leukoderma (Hypopigmentation) can be subdivided in to two types:

- Melanocytopenic disorders: Melanocytes are decreased in number or absent.e.g Vitiligo.
- Melanopenic disorders: Absence or reduction in the amount of melanin. Melanocytes are present although not functioning properly. e.g. Albinism

VITILIGO

The word ‘Vitiligo’ comes from Latin. ‘Viti’ means a mark or blemish, ‘ligo’ is a common ending meaning to cause. Thus, Vitiligo means ‘to cause a mark or blemish’, which is of course what the condition does. Celeus was the first Roman physician of the 2nd century to coin the word Vitiligo, because the disease resembles the white patches of a spotted calf (vitelus). The name ‘Vitiligo’ is derived from the latin word skin eruption, Victim meaning a blemish (spoil the beauty of) happens to be a synonym for it.

White skin is the literal meaning of leucoderma, being derived from the greek words, leucas and dermis. Leucas means white and dermis means skin.

Definition:

Vitiligo is a common skin disorder in which there is focal failure of pigmentation due to destruction of melanocytes that is thought to be mediated by immunological mechanism. It is an acquired idiopathic depigmentary condition and is characterized by sharply demarcated, milky white patches with hyperpigmented borders.

History:

Vitiligo is known to the medical word from time immemorial. It is mentioned in tarikh-e-tibb-e-Iran. (Persian History of Medicine) vol.I by Dr. Mohmood najmabadi, that the disease Vitiligo was known in the period of Aushorrians in 2200 B.C. The description of Vitiligo is also found in Athervanaveda which was written in 1400

B.C. The following authors and physicians have mentioned this disease in their works.

First in 1914, Danial Turner, dermatologist, described this skin disorder. In 1868 addision defined this as a non-infiltrated one.

Epidemiology:

It is most common in India, Egypt, and other tropical countries In India most common in Gujarat and Rajasthan. Vitiligo affects 0.5-2% of the world population, and the average age of onset is 20 years The incidence of Vitiligo is maximum in India. It is about 4% while the incidence is found to be 1.6.4% in Japan, 1% in U.S.A and 0.14% in U.S.S.R. Vitiligo may appear at any time from birth to senescence, although the onset is most commonly observed in persons aged 10-30 years. The age of onset is unlikely to vary between the sexes. Heightened concern about the appearance of the skin may contribute to an early awareness of Vitiligo among females .Vitiligo rarely is seen in infancy or old age. Nearly all cases of Vitiligo are acquired relatively early in life.

It is present in adult life in 25% of patients. About 0.5 to 1 percent of the world's population, or as many as 65 million people, have Vitiligo. Vitiligo affects 8.8% of population in India. Approximately 30% of Vitiligo cases occur with a familial clustering of cases.

The overall prevalence of Vitiligo is about 5 per 1,000 individuals. There are no significant sex or age differences in prevalence rates. About a 4.5-fold increase in prevalence is observed among close biological relatives of affected individuals. There is, however, no clearcut correspondence between relative risks and kinship coefficients. There are no significant differences in the frequencies of various types of vitiligo between probands with and without positive family history. The overall mean and modal ages of onset are about 22 years and 15 years, respectively. The mean ages among males (24.8 years) and females (19.3 years) are significantly different.

Patho-physiology:

Vitiligo appears to occur when immune cells destroy the cells that produce brown pigment (melanocytes). This destruction is thought to be due to an autoimmune problem, but the cause is unknown.

Vitiligo is a multifactorial polygenic disorder with a complex pathogenesis. It is related to both genetic and nongenetic factors. Although several theories have been proposed about the pathogenesis of vitiligo, the precise cause remains unknown. Generally agreed upon principles are an absence of functional melanocytes in Vitiligo skin and a loss of histochemically recognized melanocytes, owing to their destruction. However, the destruction is most likely a slow process resulting in a progressive decrease of melanocytes.

Theories regarding destruction of melanocytes include autoimmune mechanisms, cytotoxic mechanisms, intrinsic melanocyte defects, oxidant-antioxidant mechanisms, and neural mechanisms.

1. Autoimmune destruction of melanocytes;

The autoimmune theory proposes alteration in humoral and cellular immunity in the destruction of melanocytes of Vitiligo. Thyroid disorders, particularly Hashimoto thyroiditis and Graves disease; other endocrinopathies, such as Addison Disease and Diabetes Mellitus; and Alopecia Areata; Pernicious Anemia; Inflammatory Bowel Disease; Psoriasis; and Autoimmune Polyglandular Syndrome are all associated with Vitiligo.

2. Intrinsic defect of melanocytes:

Vitiligo melanocytes may have an intrinsic defect leading to melanocyte death. These melanocytes demonstrate various abnormalities, including abnormal, rough endoplasmic reticulum and incompetent synthesis and processing of melanocytes. In addition, homing-receptor dysregulation has also been detected. Early apoptosis of melanocytes has also been suggested as a cause of reduced melanocyte survival; however, subsequent investigation found that the relative apoptosis susceptibility of Vitiligo melanocytes was comparable with that of normal control pigment cells.

3. Disturbance in oxidant-antioxidant system in vitiligo:

Oxidant stress may also play an essential role in the pathogenesis of Vitiligo. Studies suggest that accumulation of free radicals toxic to melanocytes leads to their destruction. Because patients with Vitiligo exhibit a characteristic yellow/green or bluish fluorescence in clinically affected skin, this led to the discovery that the fluorescence is due to accumulation of 2 different oxidized pteridines. The overproduction of pteridines led to the discovery of a metabolic defect in tetrahydrobiopterin homeostasis in patients with Vitiligo, which results in the accumulation of melanocytotoxic hydrogen peroxide.

4. Neural theory:

Case reports describe patients afflicted with a nerve injury who also have Vitiligo have hypopigmentation or depigmentation in denervated areas. Additionally, segmental Vitiligo frequently occurs in a dermatomal pattern, which suggests that certain chemical mediators are released from nerve endings that affect melanin production. Further, sweating and vasoconstriction are increased in depigmented patches of Vitiligo, implying an increase in adrenergic activity. Finally, increased urinary excretion of homovanillic acid and vanilmandelic acid (neurometabolites) has been documented in patients with Vitiligo. This may be a secondary or primary phenomenon.

5. Genetics of Vitiligo:

Vitiligo is characterized by incomplete penetrance, multiple susceptibility loci, and genetic heterogeneity. The inheritance of Vitiligo may involve genes associated with the biosynthesis of melanin, a response to oxidative stress, and regulation of autoimmunity.

Human leukocyte antigens (HLAs) may be associated, but not in a consistent manner. For example, HLA-DR4 is increased in blacks, HLA-B13 is increased in Moroccan Jews, and HLA-B35 is increased in Yemenite Jews. An association with HLA-B13 is described in the presence of antithyroid antibodies.

The age of onset has a genetic component; in another genomewide association study, a quantitative locus for age of onset was found in the major histocompatibility complex class II region near a region associated with generalized vitiligo susceptibility.

6. Hereditary Factors

- Vitiligo has a genetic background.
- >30% of affected individuals have reported Vitiligo in a parent, sibling or child.
- Vitiligo in identical twins has been reported.
- Transmission is most likely polygenic with variable expression.
- The risk of Vitiligo for children of affected individual is unknown but may be <10%.

Familial incidence has been reported in 7.5 to 21% in India and 33 to 40% in western countries.

7. Allergy History:

- Occupation
- Irritant cosmetic things allergy. Ex. Rubber slipper, gloves etc.
- Monobenzyl ether of hydroquinone – present in the slipper, gloves or other articles of rubber irritate the skin and produce depigmentating disorder.
- Diet Vinegar, cooking soda and food enriched with alcohol must be avoided. These items may promote bleaching of skin pigment.

The role of copper in skin pigmentation can be well understood in terms of necessity copper for tyrosinase activity. Loss of pigments has been reported in acute zinc deficiency. Also reported in vitiligenous skin, zinc and copper contents are decreased.

- Using soaps and detergents also promote bleaching the skin.
- Vitiligo is also commonly seen on the flanks of ladies pressure is presumed leading to depigmentation.
- Loss of melanin pigment from the skin often occurs, following wound healing scar formation leading to depigmentation.

8. Emotional factors:

It is every day knowledge and observation that emotional factors affect the skin as shown by the blushing of embarrassment, the pallor of fear and depending on the subject and his emotional state. Experiments have demonstrated that emotional states can affect the following.

- Which is direct relevance in the aetiology of certain skin disorders.
- Control of vascularity of the skin.
- Control of sebaceous gland secretion.
- Control of sweat.
- Influencing the degree of oxidation. Influencing the tendency of pruritis.

This is due of the causative factor of this disease, venpadai from the following basic facts. It is generally considered to be a tropho neurosis. Psychic factors are known to be responsible for the precipitation and aggravation of the disease.

9. Psychology of Vitiligo Patients:

Although Vitiligo is usually not harmful medically and causes no physical pain, its emotional and psychological effects can be devastating. In fact, in India, those with the disease, especially women, are sometimes discriminated against in marriage. Developing Vitiligo after marriage can be grounds for divorce.

Regardless of a person's race and culture, white patches of Vitiligo can affect emotional and psychological well-being and self-esteem. People with Vitiligo can experience emotional stress, particularly if the condition develops on visible areas of the body (such as the face, hands, arms, and feet) or on the genitals. Adolescents, who are often particularly concerned about their appearance, can be devastated by widespread Vitiligo. Some people who have Vitiligo feel embarrassed, ashamed, depressed, or worried about how others will react.

This disease attaches a social stigma. Inferiority complex immediately following the start of disease, the patient thinks himself inferior to those with whom he was at par or excelled for so long. Naturally, at the beginning the individual tries to hide

the patches of lesion and when fails in this effort, the individual often feels shy of friends and relatives. When the patient feels his disease is incurable he becomes gradually depressed. As the patient tries to feel shy of the surrounding environment, he may gradually feel more and more lonely and withdrawn, ultimately plunging in to a state. As the disease spreads it may give rise to a state of acute anxiety and insomnia, mixed with depression. Idea of reference whenever they sees persons talking at a distance, they think it is definitely about them and their disease, which is not generally fact.

- **Depression:** when they feel disease is incurable and they becomes gradually depressed and it may even lead to suicide.
- **Psychosis:** As the patient tries to fight shy of the surrounding environment, they may gradually feel more and more lonely and withdrawn, ultimately plunging into a psychic state. Such a patient may have dilution of suspicion / doubt that his or her spouse is indulging in adultery, thus bringing in material disharmony.
- **Anxiety:** As the disease spreads it may give rise to a state of acute anxiety and insomnia, mixed with depression.
- **Aggression (or) Sublimation:** He / she may either develop a disbelief in God and mankind or become aggressive in his interpersonal behaviour or he / she may give way to sublimation and resort to leading a religious life as a possible escape from his / her own reality.

10. Important known causative factors for vitiligo:

- Nutritional - defects in copper, proteins and vitamins in diet, digestive upsets like amoebiasis, helminthiasis, chronic diarrhoea, dysentery etc.,
- Endocrines - Association with thyrotoxicosis and diabetes.
- Trophoneurosis and autonomic imbalance – emotional stress and strain.
- Infections and toxic products, Enteric fever, ill health, focal sepsis.
- Drugs and chemicals - like quinines, guano furacin, amyphenol, chlorthiazide, broad spectrum antibiotics and chloroquin.

Chemicals are known to inhibit melanogenesis, enzymatic actions and several chain biochemical reactions. They can also cause interference with nutrition of the tissues. Hence tie up of the chemicals and nutrition may provide the answer. Role of food

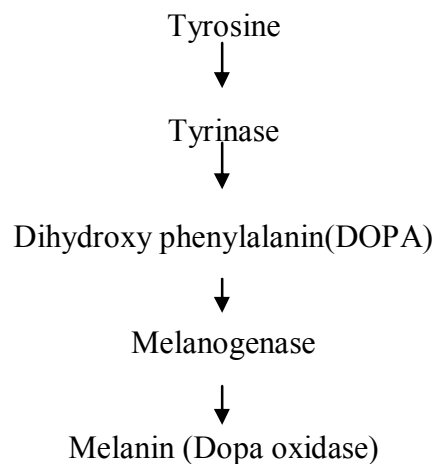
adulterants, industrial chemicals and dyes, contaminating water and foods may be guess work at this stage but may prove to be ultimate causes.

Pathology:

In the skin, the pigment is produced by the melanocytes from their precursor melanoblasts. The melanoblasts are supposed to be derived from the cells of neuro ectodermal origin during the embryonic life. After birth, these cells migrate to their definitive position. The melanocytes appear as clear cells within the basal cell layer of the epidermis and show dendritic processes after special staining. These processes come in contact to similar process of other melanocytes and epithelial cells through which the melanin pigments are donated to the basal cells of epidermis. The dermis of normal skin also shows macrophages containing melanin pigments known as melanophores, which are incapable to produce the melanin pigments.

Both the melanocytes and melanoblasts contain the enzyme melanogenase or Dopa oxidase, and they are able to convert dihydroxy phenylalanine into melanin and such cells are called DOPA positive. Chemically melanin pigment is a group of chromo proteins with coloured prosthetic groups, which is derived from the precursor tyrosine in the following way,

Melanin + Protein = Melano protein



Clinical features:

Vitiligo manifests as acquired white or hypopigmented macules or patches. The onset is slow and the course insidious but enigmatic. It may continue to increase slowly or come to a half and then increase again. It is reported that the malady usually starts and increasing in the summer months in northern India.

The lesions are usually well demarcated, and they are round, oval, or linear in shape. The borders may be convex. Lesions enlarge centrifugally over time at an unpredictable rate. Lesions range from millimeters to centimeters in size. Initial lesions occur most frequently on the hands, forearms, feet, and face, favoring a perioral and periocular distribution.

Vitiligo lesions may be localized or generalized, with the latter being more common than the former. Localized Vitiligo is restricted to one general area with a segmental or quasidermatomal distribution. Generalized Vitiligo implies more than one general area of involvement. In this situation, the macules are usually found on both sides of the trunk, either symmetrically or asymmetrically arrayed.

The most common sites of Vitiligo involvement are the face, neck, and scalp. Many of the most common sites of occurrence are areas subjected to repeated trauma, including the following:

- Bony prominences
- Extensor forearm
- Ventral wrists
- Dorsal hands
- Digital phalanges

Involvement of the mucous membranes is frequently observed in the setting of generalized Vitiligo. Vitiligo often occurs around body orifices such as the lips, genitals, gingiva, areolas, and nipples.

Body hair (leukotrichia) in vitiliginous macules may be depigmented. Vitiligo of the scalp usually appears as a localized patch of white or gray hair, but total depigmentation of all scalp hair may occur. Scalp involvement is the most frequent, followed by involvement of the eyebrows, pubic hair, and axillary hair, respectively. Leukotrichia may indicate a poor prognosis in regard to repigmentation. Spontaneous repigmentation of depigmented hair in vitiligo does not occur.

- Vitiligo is most noticeable in the summer when the normal skin is tanned by the sun. The white areas having not protected by pigment are easily made red and sore by exposure to sun or artificial ultraviolet light.
- Early lesions may be pale white and ill defined. At this stage, wood's lamp helps to confirm the diagnosis. Patches enlarge slowly and may affect the whole body. Patients skin is susceptible to even minor trauma, it heals with depigmentation.
- At time lesions develop along the distribution of a peripheral nerve, zosteriform vitiligo. It is interesting sometimes to see a bunch of hair burning in that area of skin. Occasionally, vitiligo develops around pigmented moles – 'Halo naevus'.
- Haemoglobin content of the blood is low and sometimes intestinal parasites and infections can be detected. Patients complaint of easy fatiguability.
- Vitiligo sometimes disappears spontaneously after months or years but more usually the conditions spreads slowly and may eventually involve nearly the whole of the skin.

Clinical variants:

1. Trichrome Vitiligo:

Trichrome Vitiligo has an intermediate zone of hypochromia located between the achromic center and the peripheral unaffected skin. The natural evolution of the hypopigmented areas is progression to full depigmentation. This results in 3 shades of color—brown, tan, and white in the same patient, as in the image (1) below.

2. Marginal inflammatory Vitiligo:

Marginal inflammatory vitiligo results in a red, raised border, which is present from the onset of vitiligo (in rare cases) or which may appear several months or years after the initial onset. A mild pruritus may be present, as in the image (2) below.



(1) Trichrome Vitiligo.



(2) Marginal inflammatory Vitiligo.

3. Quadrichrome Vitiligo:

Quadrichrome Vitiligo is another variant of Vitiligo, which reflects the presence of a fourth color (ie, dark brown) at sites of perifollicular repigmentation. A case of pentachrome Vitiligo with 5 shades of color has also been described.

4. Blue Vitiligo:

Blue vitiligo results in blue coloration of vitiligo macules. This type has been observed in a patient with postinflammatory hyperpigmentation who then developed Vitiligo.

5. Koebner phenomenon:

Koebner phenomenon is defined as the development of Vitiligo in sites of specific trauma, such as a cut, burn, or abrasion. Minimum injury is required for Koebner phenomenon to occur.

Classification:

The classification system is important because of the special significance assigned by some authorities to each type of Vitiligo. The most widely used classification of Vitiligo is localized, generalized, and universal types and is based on the distribution, as follows:

1. Localized Vitiligo:

1. Focal: This type is characterized by one or more macules in one area, most commonly in the distribution of the trigeminal nerve.

2. Segmental: This type manifests as one or more macules in a dermatomal or quasidermatomal pattern. It occurs most commonly in children. More than half the patients with segmental Vitiligo have patches of white hair or poliosis. This type of Vitiligo is not associated with thyroid or other autoimmune disorders.

3. Mucosal: Mucous membranes alone are affected.

2. Generalized Vitiligo:

1. Acrofacial: Depigmentation occurs on the distal fingers and periorificial areas.

2. Vulgaris: This is characterized by scattered patches that are widely distributed.

3. Mixed: Acrofacial and Vulgaris Vitiligo occur in combination, or Segmental and Acrofacial Vitiligo and/or Vulgaris involvement are noted in combination.

3. Universal vitiligo:

This is complete or nearly complete depigmentation. It is often associated with multiple endocrinopathy syndromes.

Classification of Vitiligo by Progression, Prognosis, and Treatment:

When progression, prognosis, and treatment are considered, Vitiligo can be classified into 2 major clinical types: Segmental and Non Segmental, as demonstrated in the images below.

1. Segmental:

This usually has an onset early in life and rapidly spreads in the affected area. The course of segmental Vitiligo can arrest, and depigmented patches can persist unchanged for the life of the patient.

2. Non-segmental:

This type includes all types of vitiligo, except segmental vitiligo.



Segmental Vitiligo

Non Segmental Vitiligo

A single-center study of 213 patients aged 17 years or younger with Segmental or Non Segmental Vitiligo found that Non Segmental Vitiligo was more strongly linked than Segmental Vitiligo to markers of autoimmunity or inflammation such as halo naevi and thyroid antibodies; patients with Non Segmental Vitiligo were also more likely to have a family history of Vitiligo or autoimmunity.

Clinical criteria for classification on Vitiligo:

Stage of Clinical Features:

Active (V1)

- i) New lesions developing
- ii) Lesions increasing in size
- iii) Border ill defined

Quiescent (V2)

- i) No new lesions developing
- ii) Lesion stationary in size
- iii) Border hyperpigmented and well-defined.

Improving (V3)

- i) Lesions decreasing in size
- ii) No new lesions developing
- iii) Border defined and signs of spontaneous repigmentation (follicular and peripheral).

Differential diagnosis:

- Usually in macular leprosy, seborrhoeides, pityriasis versicolour and nevoid condition, its assistance is called for.
- In Piebaldism the lesions are present at birth, are usually confined to the head and trunk and rarely show a hyper-pigmented border.
- Careful examination of the texture of the unpigmented skin should exclude lichen sclerosus and scleroderma.
- Hypomelanosis of the affected skin is commonly seen in pityriasis alba, producing slightly scaly areas with rather ill defined edges of children's faces.

- Hypopigmented, slightly scaly macules are seen in pityriasis versicolor. Examination of the skin in long wave UVR helps distinguish whether there is total depigmentation (as in Vitiligo) or not. It may also detect areas of depigmentation not easily seen in ordinary daylight, as well as detecting a lemon-yellow fluorescence seen in some cases of Pityriasis versicolor. Absence of scaling, crusting and itching help to eliminate seborrheoids and pityriasis versicolor. These areas often fluoresce a golden yellow when examined under a Wood's lamp.
- The hypomelanotic macules in leprosy are anaesthetic.
- Addison Disease
- Chemical leukoderma
- Idiopathic Guttate Hypomelanosis
- Malignant Melanoma
- Mycosis fungoides mimicking Vitiligo
- Post inflammatory depigmentation
- Prior treatment with corticosteroids
- Scleroderma
- Tinea Versicolor
- Treponematosi
- Tuberous Sclerosis

Differential Diagnosis of the important Depigmentary Disorders:

Distinguish Features	Albinism	Naevus Depigmentosus	Vitiligo	Leprosy	Pityriasis
Age	Congenital present at Birth	Congenital present at birth	Acquired and age	Any age	Any age
Distribution	Complete (or) partial	Unilateral	Any area	Any area	Trunk, Neck and face
Course	Stationary	Does not increasing in size or changing shape	Progressive	Progressive	Progressive worse in monsoon and summer
Hyper pigmentary Border	Nil	Nil	Present	Inflammation	Nil
Heredo familial	Hereditary	Not hereditary	May be	Nil	Nil
Other Features	Hair and eye may be affected	Nil	Nil	Anesthesia thickened nerves, nasal, bleeding slit smear and biopsy	Furfuraceous like dandruffy scaling in head macules and large patches fungus on micro scopic examination

Diagnosis:

- The distribution, the age of onset and the hyper pigmented border will suggest the diagnosis.
- Vitiligo areas are milky white while other lacks this milky white colouration.
- It is usually apparent. In doubtful and early case, Wood's lamp is of great help in diagnosis.
- Post-inflammatory leucoderma, which is frequent in the darker races, shows an irregular mottling of hyper pigmented and hypopigmented blotches.
- Stationary patches are well-defined and have hyperpigmented borders.
- Sensations are normal, so is texture unless the patches have been irritated with treatment.

Prognosis:

It has improved considerably in recent years because of better understanding of etiological factors and advances made in therapy. Analyses of cases which have failed to respond have usually shown the following features:

- 1) Poor nutritional state or digestion, use of broad – spectrum antibiotics over long periods. Emotional stress and nervous debility.
- 2) Presence of Vitiligo on resistant sites like the hands and the feet, front of wrists, the elbows, the waist, the eyelids and lips.
- 3) Depigmented hair in vitiliginous areas.

Management:

At the very outset, the patient and the relatives should be assured about its non-infectious and non-hereditary nature; further that it has no relationship to leprosy what so ever. This gives immense moral strength to the patient.

Patient should be instructed to avoid physical trauma, as far as possible, broad-spectrum antibiotics should not be prescribed for intercurrent illness to Vitiligo patients.

a. Control of etiological factor:

The patients nutritional state is improved as far as possible, this Vitamin-B of particular importance when the vitiligo is active progressively increasing. Multivitamins by mouth and injection of crude liver extract with vitamin B complex are beneficial.

b. Treatment:

The main goal of treating Vitiligo is to improve appearance. The choice of therapy depends on the number of white patches; their location, sizes, and how widespread they are; and what you prefer in terms of treatment. Each patient responds differently to therapy, and a particular treatment may not work for everyone. Current

treatment options for Vitiligo include medication, surgery, and adjunctive therapies (used along with surgical or medical treatments).

Medical therapies:

A number of medical therapies, most of which are applied topically, can reduce the appearance of Vitiligo. These are some of the most commonly used:

1. Topical steroid therapy:

Steroid creams may be helpful in repigmenting (returning the color to) white patches, particularly if they are applied in the initial stages of the disease.

2. Psoralen photochemotherapy:

Also known as psoralen and ultraviolet a therapy (PUVA) therapy, this is probably the most effective treatment for vitiligo available in the United States. The goal of PUVA therapy is to repigment the white patches. Psoralen is a drug that contains chemicals that react with ultraviolet light to cause darkening of the skin. The treatment involves taking psoralen by orally or applying as topically.

3. Depigmentation:

This treatment involves fading the rest of the skin on the body to match the areas that are already white. For people who have Vitiligo on more than 50 percent of their bodies, depigmentation may be the best treatment option.

Surgical therapies:

The surgical therapies must be considered only after proper medical therapy is provided. They are

1. Autologous skin grafts:
2. Skin grafts using blisters:
3. Micropigmentation (tattooing):
4. Autologous melanocyte transplants:

Diet and other advices:

- If anyone above is the reason for allergy it must be avoided.
- The patient's nutritional state has to be increased as high as possible. This is very particular when vitiligo is active and progressively increasing.
- Highly nutritious food like spinach, pomegranate, cheese, butter, milk, almond, germinating grams and foods rich in tyrosinase to be added.
- Vitamin-C (Ascorbic acid) must be avoided in diet.
- During bathing – the powder of Bengal gram and green gram or any other herbal products can be used.
- Vinegar, cooking soda, food enriched with alcohol must be avoided. These items may promote bleaching of skin pigment.
- Using soaps and detergents also promote bleaching of skin.
- Copper and zinc content vegetable such as cooked green gram or bengal gram at least one time a day.
- The role of copper in skin pigmentation can be well understood in terms of necessity of copper for tyrosinase activity. Loss of pigments has been reported in acute zinc deficiency. Also reported in vitiliginous skin, zinc and copper contents are decreased.
- Vitiligo is also commonly seen on the flanks of ladies. Pressure is presumed to lead to depigmentation.
 - Avoid irritant cosmetic

DRUG REVIEW

குடிநீர்

வேறுபெயர்:

மருந்துநீர், உண்ணீர்

இயல்:

உலர்ந்த சரக்குகளையாவது, ஈரமுள்ள சரக்குகளையாவது சுத்தம் செய்து வறுக்க வேண்டியவைகளை வறுத்தும், இடிக்க வேண்டியவைகளை இடித்தும் அதனுடன் 16பங்கு நீர் சேர்த்து ½பங்கு, ¼ பங்கு, 1/8 பங்கு, 1/16 பங்கு காய்ச்சி அருந்தி எடுப்பது குடிநீர் அல்லது கியாமும்.

(மருந்து செய் இயலும் கலையும்)

செங்கொன்றை

(CASSIA MARGIATA)

பயன்படும் உறுப்பு	-	பூ பட்டை
சுவை	-	கைப்பு
தன்மை	-	வெப்பம்
பிரிவு	-	கார்ப்பு

செங்கொன்றை குடிநீர்

செய்முறை:

17 - 35கி பட்டையை நன்றாக இடித்து 16 பங்கு நீர் விட்டு 1/8 பங்கை குறுக்கி எடுத்துக்கொள்ள வேண்டும்.

அளவு: 15 மி.லி - 30 மி.லி.

தீரும்நோய்: வெண்புள்ளி

நாள்: 40 நாட்கள்



குணபாடம் மூலிகை Pg 403

(CASSIA MARGIUATA)

பற்று:

இலை, பட்டை, வேர் இவற்றின் சாற்றையாவது, அரைத்து சில சரக்குகளை சுடவைத்தாவது அல்லது சுடவைக்காமலாவது நோயுள்ள இடத்தில் திண்மையாக அப்புதல்.

(மருந்து செய் இயலும் கலையும்)

செங்கொன்றை பூச்சு

17-35கி பட்டை தூளை ஒன்றாக நீர்விட்டு அரைத்து வெண்புள்ளி உள்ள இடத்தில் பூச வேண்டும்.

தீரும் நோய்: வெண்புள்ளி

குணபாடம் மூலிகை Pg 403

4. Materials and Methods

Patients suffering from venpulli selected for this study. Patients were well examined and diagnoses were confirmed with the consultation and direction to the Kuzhandhai Maruthuvam department. Then and their opinion of the modern pediatric professor was obtained. The protocol for the study was prepared and presented in the IEC and got approved.

The methodology was strictly followed as per the protocol the details of the protocol are attached in the annexure.

Clinical Study

4.1 Study Design

This was the open clinical observational study. There was no group for blinding. Eligible children with Venpulli i.e. who were fulfill the inclusion criteria for this study were enrolled and strictly follow the ASU clinical research guidelines. SENKONRAI PATTAI KUDINEER and SENKONRAI PATTAI POOCHU were distributed to the parents/ guardians of the children and label showed extensive details about the usage of the drug and also demonstrated practically.

4.2 Population and Sample Size

- Children affected with Venpulli were enrolled for the study.
- Dosages of the experimental drug have been calculated as per the Siddha text.
- Duration of the treatment period was 40 days and according to the patient requirement have prolonged.

4.3 PREPARATION OF TRIAL DRUGS:

Medicine Name:

Internal: Senkonrai kudineer

Dosage:** 15-30ml b.i.d

Refernce: Gunapaadam Mooligaivaguppu Part-I (Page No: 403).

5-7yr.....15ml b.i.d(marunthuseiiyalumkalium) (ScihitchaRatnaDeepam)

- 8-12yr.....30ml b.i.d (marunthuseiiyalumkalium) (ScihitchaRatnaDeepam)
- ** Dose calculation for pediatric group is based on Height and Weight chart, ICMR, 1990; and the formula mentioned in the Essential of medical pharmacology by K.D. Tripathi

External: Senkonrai poochu

Duration: 40 days

Standard Operating Procedurefor Senkonrai Kudineer (Int) & Senkonrai Poochu (Ext)

Source of Trial Medicine:

The required drugs for preparation of senkonraikudineer(Int) &senkonraipoochu(ext) will be purchased from a well reputed country shop and medicine is purified & prepared in Gunapadam lab of National institute of Siddha.

Method of Preparation:

Senkonrai Kudineer (Internal)

Ingredints : **Senkonraipattai**

Botanical Name : **Cassia margiuata**

Weight : **8gm-16gm**

A drug is purified and grind into a coarse of powder. Add to this 1:16pangu of water, boiiedupto 1/8of it original

Senkonrai Poochu: (External)

Ingredients : Senkonraipattai

Botanical Name : cassia margiuata

A drug is purified and grind then mixed with water and made as paste

Dosage:

Internal

5 to 7 years – 15 ml

8 to 12 years – 30 ml

External

As need

Indication: Venpulli

4.4 SUBJECT SELECTION CRITERIA:

4.4.1 Inclusion criteria:

- a. Age 5 to 12 years
- b. Patients, who are having classical symptoms like
 1. Hypo-pigmented patches of the skin without any structural changes.
 2. Patients willing to participate in trial and signing consent by fulfilling the conditions of Proforma.
 3. Willing to give blood sample for lab investigations when required.
 4. Willing for photograph before and after treatment.

4.4.2 Exclusion Criteria:

- a. A patients is not eligible for admission to the trail if any following is applicable
 1. Juvenile Diabetes mellitus
 2. Albinism
 3. Burns

- b. Patient not willing to give biological sample whenever required.
- c. Patient not willing to give consent for the study

4.4.3 Withdrawl Criteria:

- a. Exacerbation of symptoms
- b. Occurrence of any adverse effect such as diarrhea, abdominal discomfort.
- c. Patient turned to unwilling during the course of trial drug.

4.5 Methods Would Be Followed During The Course Of Study:

- The suspected patients were examined clinically and screened using screening form.
- If they met all inclusion criteria and not meeting any exclusion criteria, the patients were enrolled for this study.
- The patients who are to be enrolled were informed about the study, trial drug, possible outcomes and the objectives of the study in the language and terms understand able to the patients and informants.
- After ascertaining the informant's willingness, informed consent was obtained in writing from them in the consent form.
- These patients were given unique registration number.
- . Screening form was filled up. History Proforma
- Clinical assessment and Laboratory investigations were used for recording the patient's history, clinical examination of signs and symptoms and lab investigations respectively.
- Patients were advised to take the trial drug and appropriate dietary advice given according to the patient's and informants perfect understanding.

4.6 Assessment And Tests

4.6.1 Clinical Assessment

1. Site
2. Re-pigmentation
3. Number of lesions
4. New Colour change
5. Size of the lesions
6. Borders
7. Erythema
8. Re-pigmentation of Hair

4.6.2 Siddha Method Of Assessment

- a) Poriyal arithal
- b) Pulanal arithal
- c) Vinathal
- d) Uyirthathukkal
- e) Udal thathukkal
- f) Envagai thervugal

4.6.3 Laboratory Investigation

Blood Test :

- Total WBC Count
- DC- Polymorphs
- Lymphocytes
- Eosinophils
- Monocytes
- Basophils
- Total RBC count
- ESR

Urine Test:

- Albumin
- Deposit
- Puscells

4.7 Data Management:

- After enrolling the patient in the study, separate files for each patient were opened and all forms were filed in the file. Whenever study patient visits OPD during the study period, the respective patient file were taken and necessary recordings were made at the assessment form or other suitable form.
- The screening forms were filled separately.
- The Data recordings were monitored for completion and adverse event by HOD and data logical recording and completeness were monitored by statistician (Sr. Research Officer (Statistics)). All forms were further scrutinized in presence of Investigators by Sr.ResearchOfficer (Statistics) for logical errors and incompleteness of data before entering onto computer to avoid any bias. No modification in the results is permitted for unbiased report.
- Any missed data found in during the study, were collected from the patient
- All collected data were entered using MS access software onto computer.
- Investigators were trained to enter the patient data and cross checked by SRO.

4.8 Results Observational Grading:

- | | |
|-------------------------|---|
| a. Good Improvement | : Turning to normal skin |
| b. Moderate Improvement | : Reduction in size of all the lesions |
| c. Mild Improvement | :Reduction in size of selected lesions |
| d. No Improvement | : Static- remains the same - (no further lesions formed). |

4.9 Ae / Sae Management

If the patient is found to have any Adverse Effect / Serious Adverse Effect that were immediately informed to IEC and also treated for the untoward reactions.

4.10 Data Collection Forms:

- a. Screening and selection Proforma
- b. Consent form
- c. History Proforma on enrollment
- d. Clinical Assessment for during and after treatment assessment
- e. Laboratory investigation on enrollment
- f. Withdrawal form
- g. Diet Advice

4.11 Statistical Analysis:

Changes in subjective parameters will be analyzed using paired X^2 – test and changes in objective parameters will be analyzed using paired t – test.

4.12 Ethical Issues:

- a. To prevent any infection, while collecting blood sample from the patient, only disposable syringe, disposable gloves, with proper sterilization of lab equipments were used.
- b. The formulation mentioned in the, GUNAPADM MOOLIGAI VAGUPPU, will only be used for the study.
- c. No other external or internal medicines are used. There is no infringement on the right of patient.
- d. The data collected from the patient were kept confidentially. The patient was informed about the disease and treatment.
- e. After the consent of the patient (through patient consent form), he/she were enrolled in the study.
- f. Treatment were provided free of cost.
- g. In conditions of treatment failure, adverse reactions, patients were given alternative treatment at the National Institute of Siddha with full care through the end.
- h. The Director, H.O.D, SRO and Ethical members can monitor the patient profile at any time regarding the research.

5. RESULTS AND OBSERVATIONS

Clinical Study:

Under the clinical study the following parameters have been adopted to meet the efficacious and philosophical values.

1. Age reference
2. Sex reference
3. Religion reference
4. Socio Economic status of the reference
5. Etiology reference
6. Family history reference
7. Paruva kaalam
8. Diet reference
9. Site of lesion
10. Derangement in the types of Vatham
11. Derangement in the types of Pitham
12. Derangement in the types of Kabam
13. Ezhu Udar Kattugal reference
14. Ennvagai Thervugal reference
15. Distribution of nadi among the patient with Venpadai
16. Results after treatment reference

Age Reference

Table -5:

Age (in Years)	No. of Cases (Out of 40)	Percentage %
5-7 Years	13	33
8-12 Years	27	67

Chart No – 1

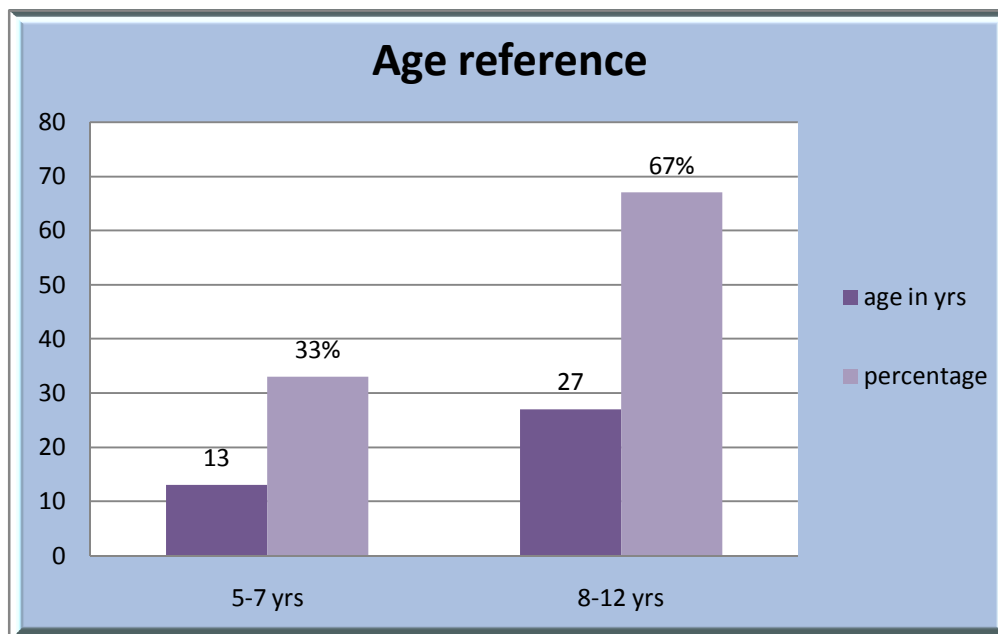


Table above bar diagram showed age reference of our clinical study

The above table and chart showed the Age references in our study population. In our study 67% of the patients from the age group of 8 – 12 years and 33% of the children from the 5-7 years.

2. Sex Reference

Table -6:

Sex	No. of Cases (Out of 40)	Percentage%
Male Children	21	42
Female Children	19	58

Chart No – 2

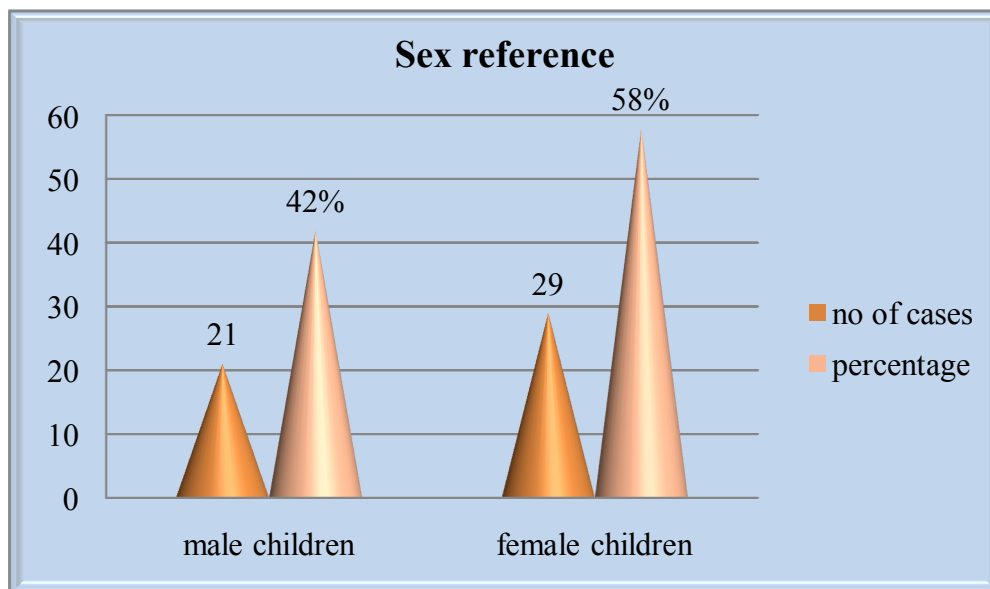


Table above bar diagram showed Sex reference of our clinical study.

The above table and chart showed the Sex references in our study population. In our study 29 (58%) were Female Children and 21 (42%) were Male children.

3. Religion Reference:

Table -7

Religion	No. of Cases (out of 40)	Percentage %
Hindu	33	82
Christian	4	10
Muslim	3	8

Chart No – 3

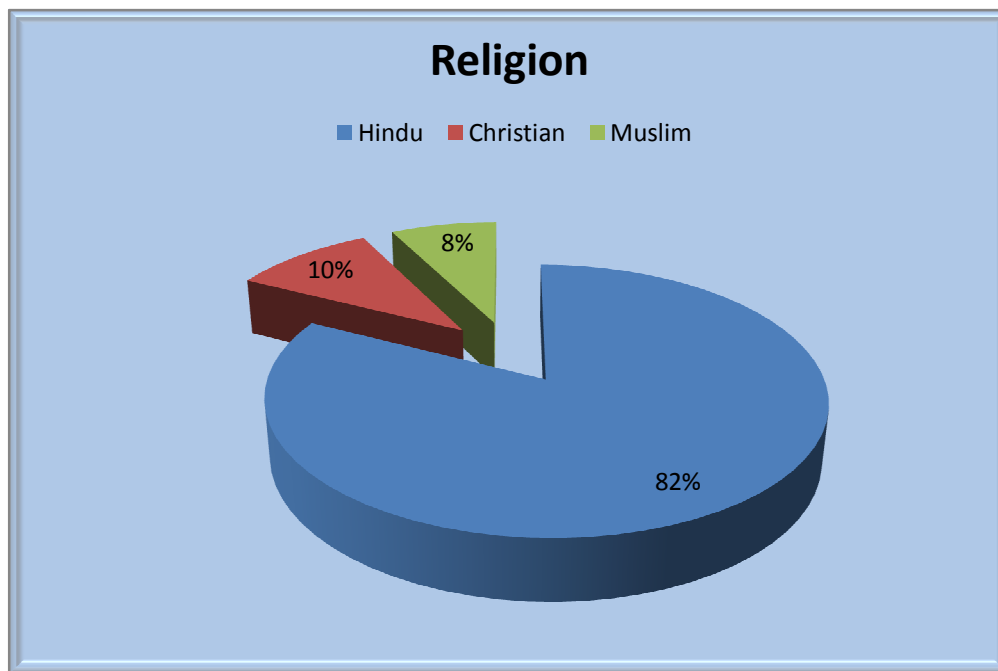


Table above bar diagram showed Religion reference of our clinical study.

The above table and chart showed the Religion references in our study population. In our study most of the children belong to Hindu (82%), then Christians (10 %) and Muslims (8%) children.

4.socio economic status:

Table -8

Socio – Economic Status	No. of Cases (out of 40)	Percentage %
Lower Income Group	10	25
Middle Income Group	20	50
High Income Group	10	25

Chart No – 4

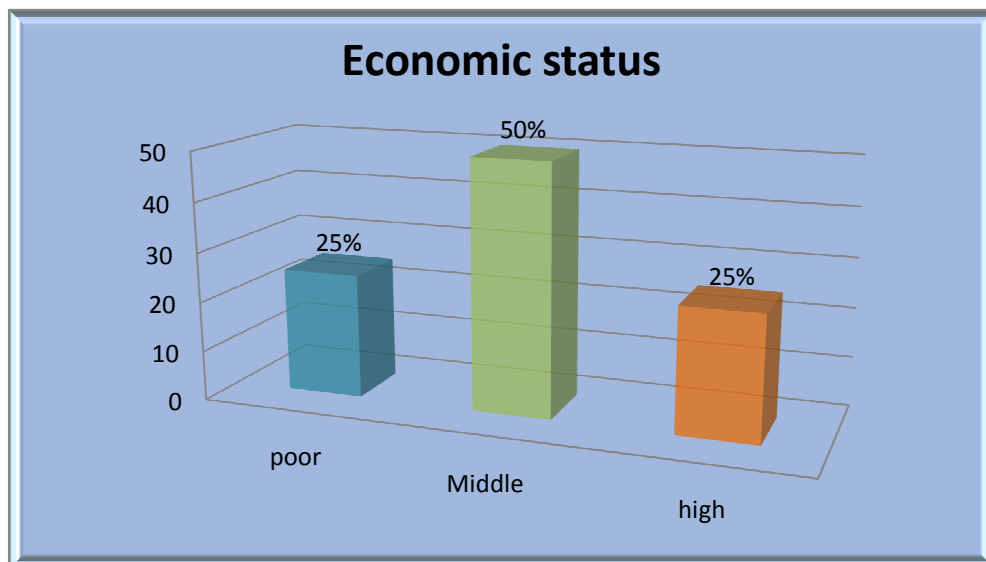


Table above bar diagram showed Economic status reference of our clinical study

The above table and chart showed the Economic status references in our study population. In our study about 50% of the parents were middle income group and 25% lower, and 25% high income children.

Etiology Reference:

Table -9

Etiology	No. of Cases(out of 40)	Percentage %
Hereditary	3	7
Anemia	6	15
Unknown	31	78

Chart No – 5 :

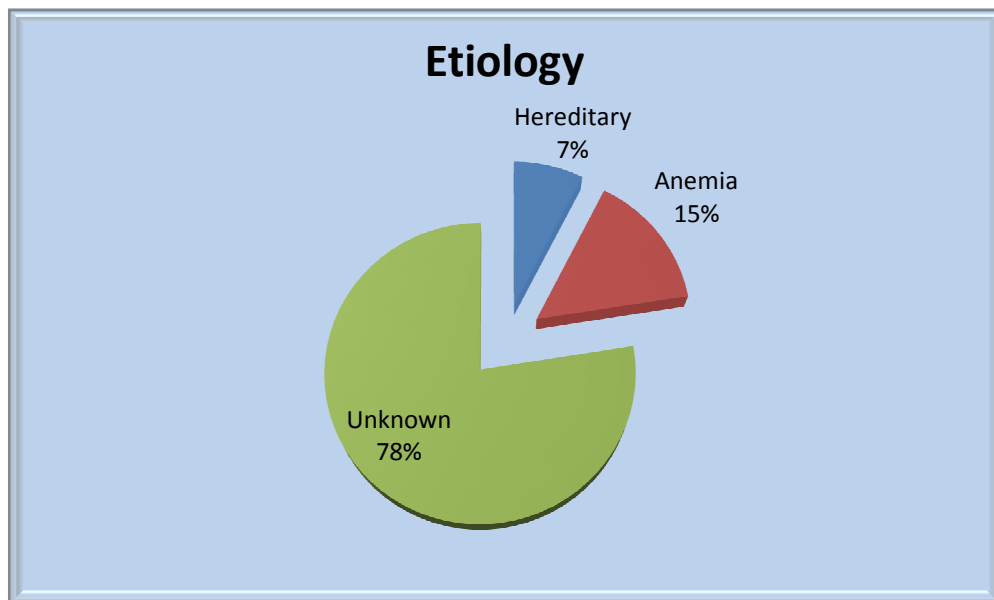


Table above bar diagram showed Etiology reference of our clinical study

The above table and chart showed the Etiology references in our study population. In our study about 78% of the cases were of unknown aetiology and 15% Anemia cases, 7% hereditary childrens.

6. Family History Reference:

Table -10:

Family History	No. of Cases out of 40	Percentage %
Present	2	5
Absent	38	95

Chart No – 6

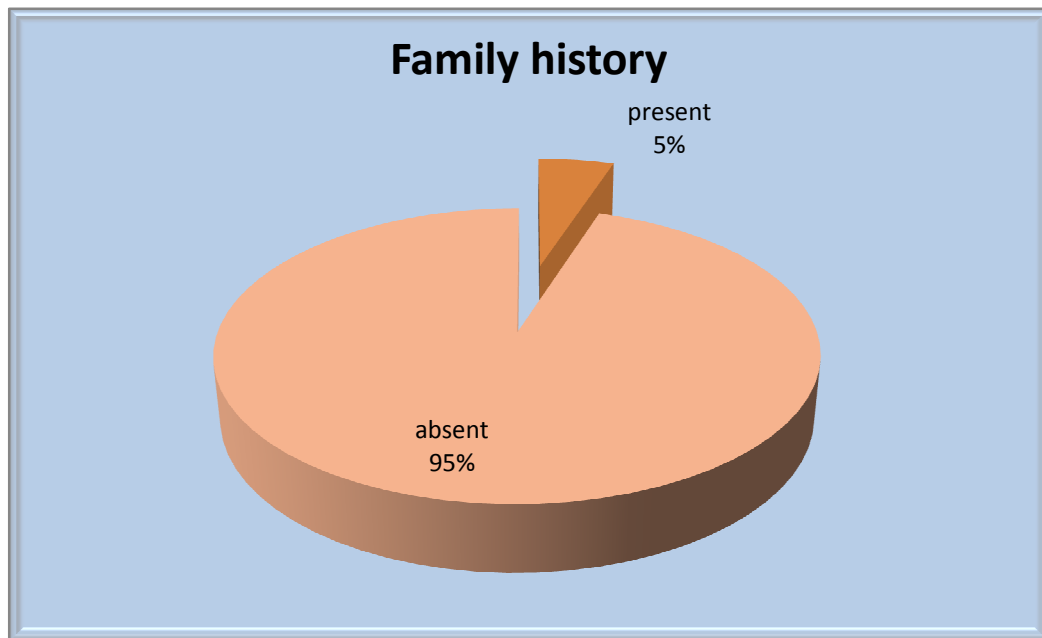


Table above bar diagram showed Family history reference of our clinical study

The above table and chart showed the Family history references in our study population. In our study About 95% cases were having no family history absent and in 5% of cases family history was present

7. Paruvakaalam:

Table -11:

Paruvakaalam	No. of Cases out of 40	Percentage %
Kaarkaalam	28	70
Koothirkaalam	12	30
Munpani	0	0
Pinpani	0	0
Elavenil	0	0
Mudhuvenil	0	0

Chart No – 7

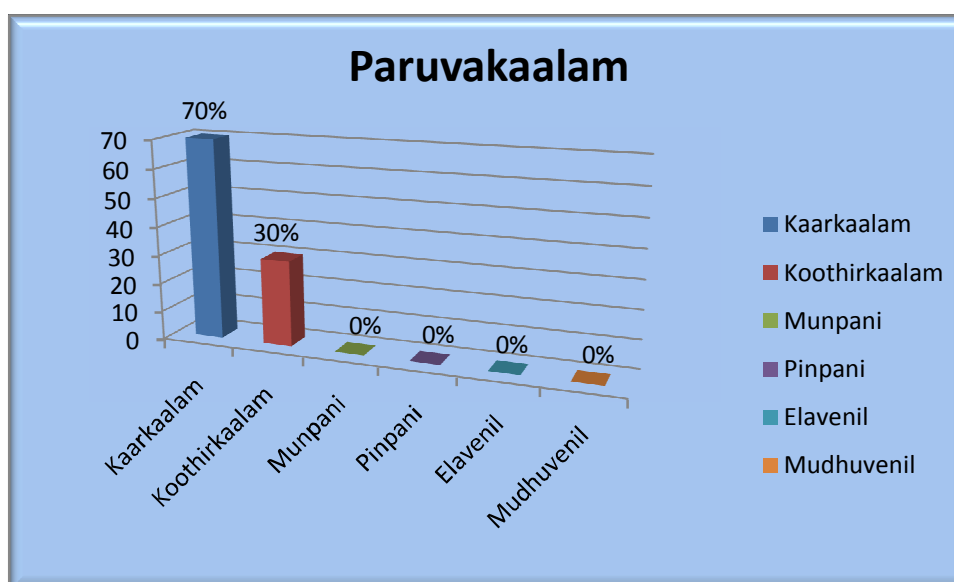


Table Above Bar Diagram Showed Paruvakaalam Reference Of Our Clinical Study.

The above table and chart showed the Sex references in our study population. In our study Paruvakkalam, highest incidence (70%) was noted in Karkaalam and Koothirkalam 30% children were noted.

8.Diet Reference:

Table -12:

Food Habit	No. of Cases(out of 40)	Percentage %
Vegetarian	8	20
Mixed	32	80

Chart No – 8

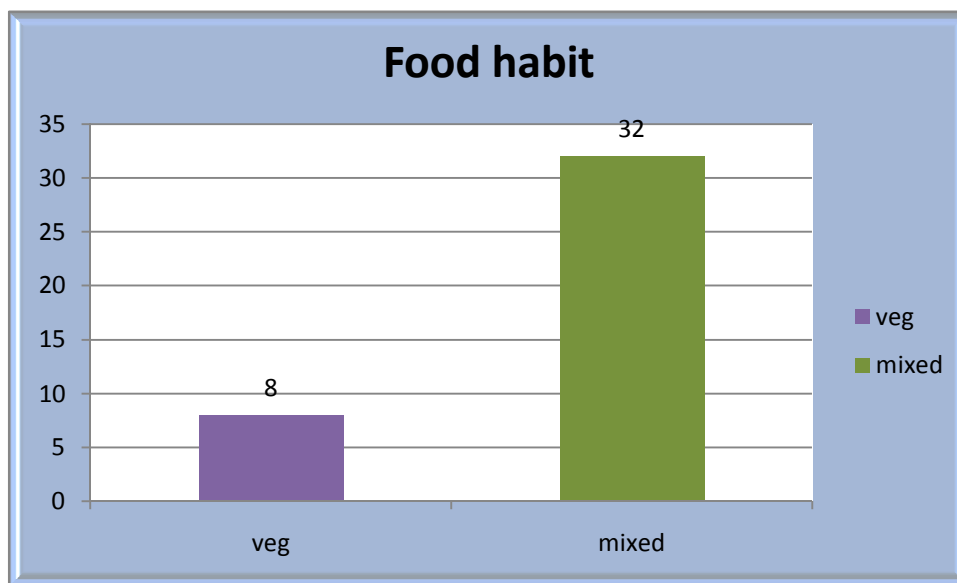


Table above bar diagram showed Foot habit reference of our clinical study

The above table and chart showed the Foot habit references in our study population. In our study 32 cases were taken mixed diet and 8 cases have Vegetarian

9. Site of Lesion:

Table -13:

Site of Lesion	No. of Cases (out of 40)	Percentage %
Scalp	3	8
Face	3	8
Lips	2	5
Chest	4	8
Upper Limb	4	10
Lower Limb	3	8
Genital	2	5
Multiple	19	48

Chart No – 9

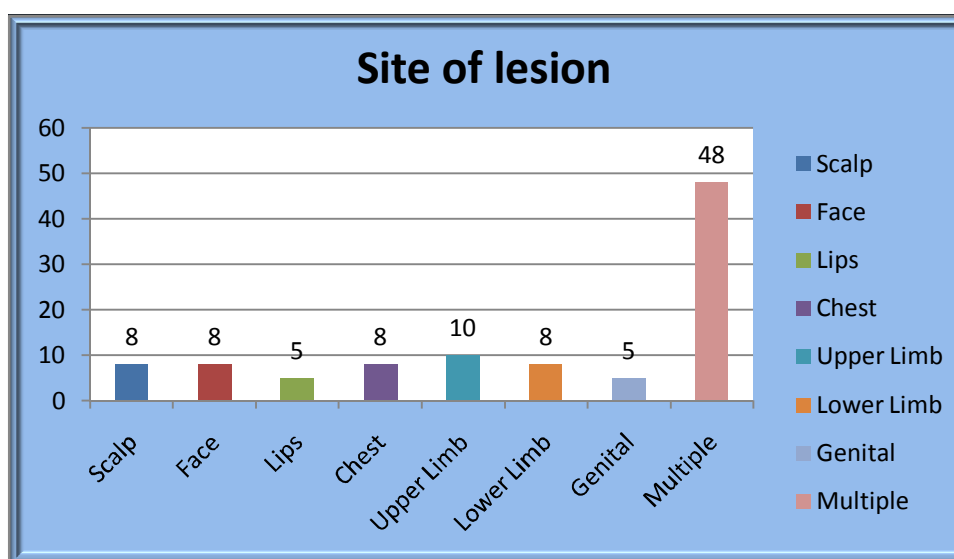


Table above bar diagram showed percentage of Site of lesion Reference of our clinical study.

Exposed areas of the body were multiply involved in 19 (40%) patients, Scalp 3 (8%), Lips 2(5%), Chest 4 (8%), Lower limb in 3 (8%) patients, upper limb 4 (10%), and face in 3 (8%) cases. Genitals were the least affected area, in 2 (5%) patients only. Symmetrical lesions were found in 22% patients. 20% had a single lesion 23% had less than 10 lesions and 8% patients had more than 10 lesions.

10. Derangement in the types of Vatham:

Table -14:

Classification	No. of Cases (out of 40)	Percentage %
Piranan	20	40
Abanan	12	30
Viyanan	40	100
Uthanan	12	30
Samanan	40	100
Nagan	4	10
Koorman	2	5
Kirukaram	0	0
Devathathan	0	0
Dananjeyan	0	0

Chart No – 10

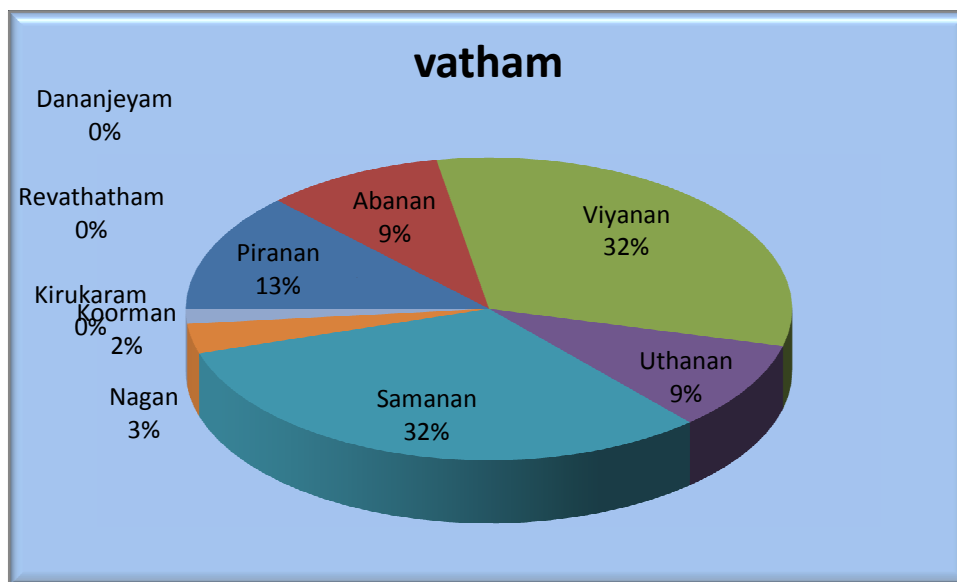


Table above bar diagram showed Vatham reference of our clinical study

The above table and chart showed the Vatham references in our study population. In our study of Viyanan and Samanan was deranged in 100% Piranan was 40%, Uthanan was deranged in 30% Nagan 10% Abanan 9% Koorman 5% in children.

11. Derangement in Types of Pitham

Table -15:

Types Of Pitham	No. of Cases (out of 40)	Percentage%
Analapitham	0	0
Ranjagam	10	25
Saathagam	0	0
Prasagam	40	100
Alosagam	3	8

Chart No – 11

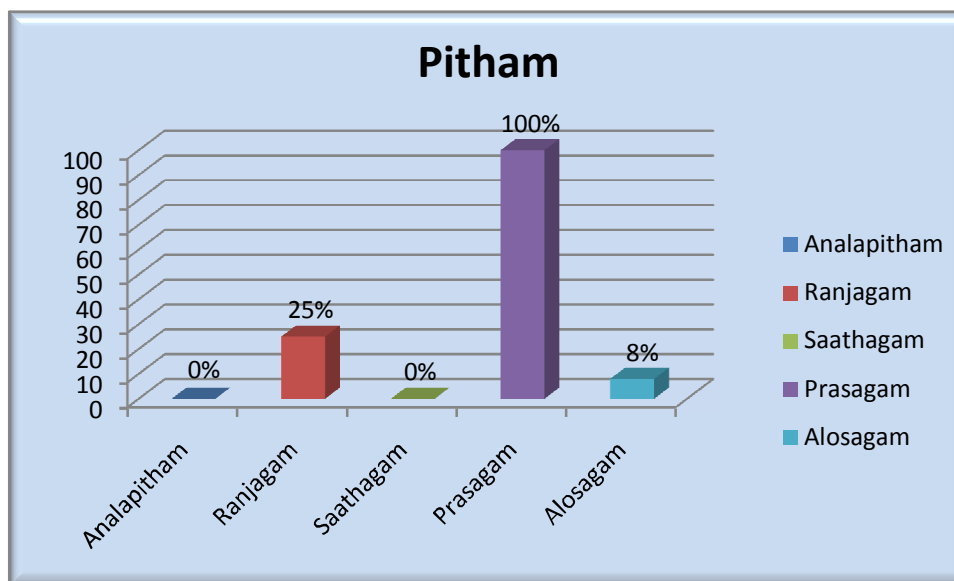


Table above bar diagram showed Pitham reference of our clinical study

The above table and chart showed the Pitham references in our study population. In our study Prasagam was affected in 100%, Ranjagam was affected in 25% Alosagam was affected in 8% children.

12. Derangement Types of Kabam:

Table -16:

Types of Kabam	No. of Cases (out of 40)	Percentage %
Avalambagam	20	50
Kilethagam	3	8
Pothagam	0	0
Tharpagam	0	0
Santhigam	0	0

Chart No – 12

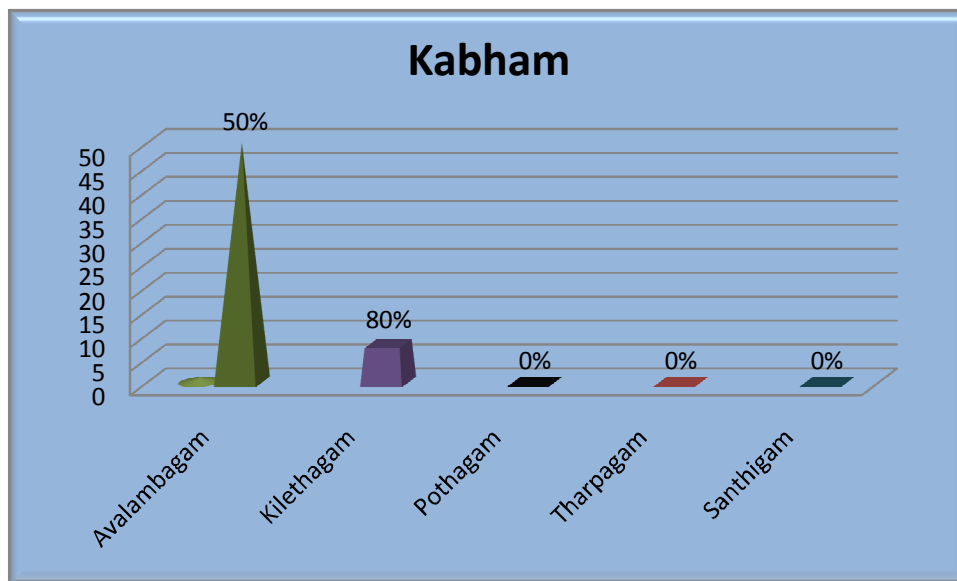


Table above bar diagram showed kabham reference of our clinical study

The above table and chart showed the Kabam references in our study population. In our study Avalambagam was deranged in 50%, Kilathagam was affected in 8%. of children.

13. Ezhu Udal Kattugal reference:

Table -17:

Udal Kattugal	No. of Cases(outof40)	Percentage %
Saaram	40	100
Senneer	40	100
Oon	40	100
Kozhuppu	0	0
Enbu	0	0
Moolai	0	0
Sukkilam/Suronitham	0	0

Chart No – 13

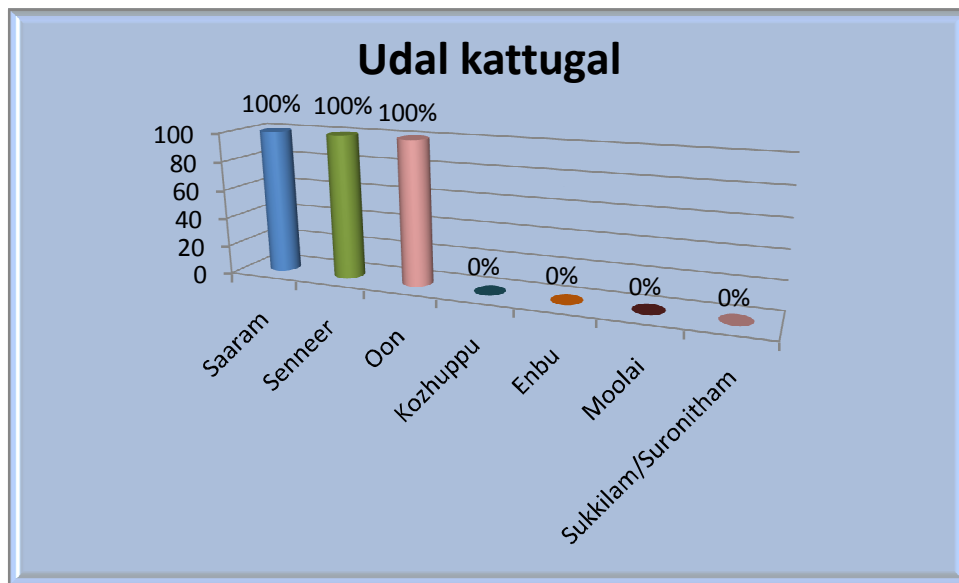


Table above bar diagram showed udal kattugal reference of our clinical study

The above table and chart showed the udal kattugal references in our study population. Saaram was affected in 100% of cases Senneer was affected in 100% of cases Oon was affected in 100% children.

14. Distribution of nadi among the patient with Venpulli:

Table -18;

Nadi	No. of Cases (out of 40)	Percentage %
Vali Azhal	8	20
Vali Iyyam	3	8
Azhal Vali	15	37
Azhal Iyyam	0	0
Iyya Vali	11	27
Iyya Azhal	3	8

Chart No – 14:

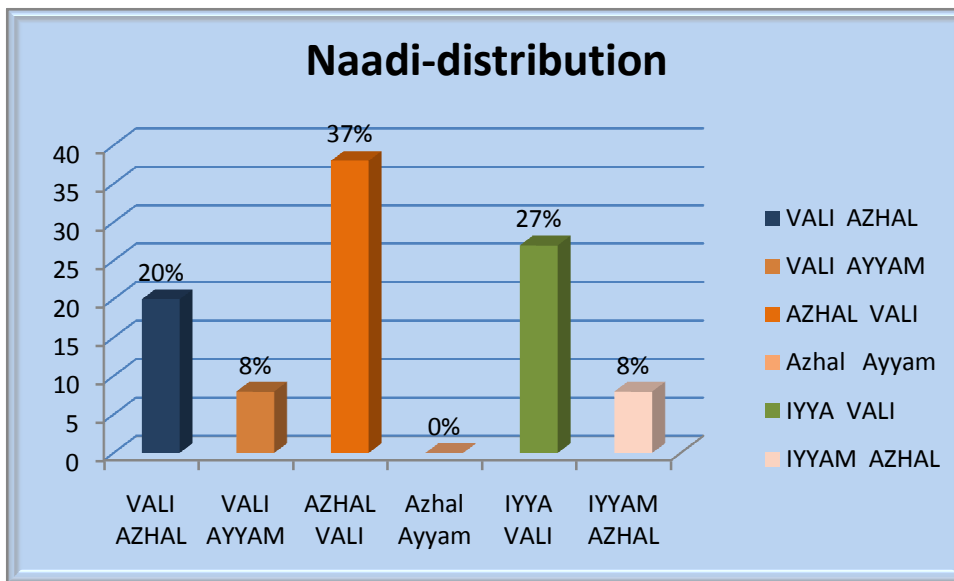


Table above bar diagram showed Naadi distribution reference of our clinical study

The above table and chart showed the naadi distribution references in our study population Azhal vali was observed in 37% Iyya vali was observed in 27 % Vali azhal was observed in 20. Vali Iyyam 8% Iyya azhal 8%.

15.RESULTS

Table -19:

Results	No. of Cases	percentage
Good improvement	0	0
Moderate improvement	6	15
Mild improvement	30	75
No improvement	4	10

Chart No – 15

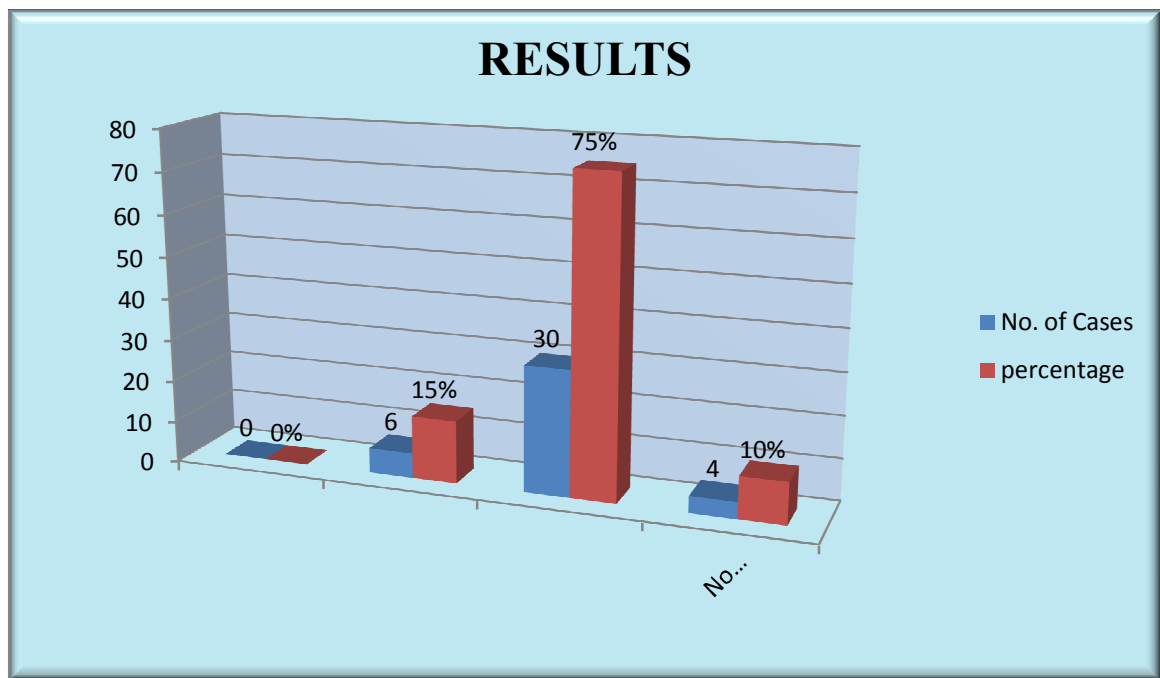


Table above bar diagram showed result reference of our clinical study

The above table and chart showed the result references in our study population. In our study mild improvement was observed in 75 % Moderate improvement was observed in 15 % No improvement was observed in 10 % children.

LABORATORY INVESTIGATION

			BEFORE								AFTER								Before		After	
S. NO	Op/ip NO	Age/ Sex	TC	DC			ESR		HB	RB C	TC	DC			Esr		Hb	Rb c	Urine test		Urine test	
				P	L	E	½	½				P	L	E	½	½			Alb	Dep	Alb	Dep
01	C19194	8/M	7700	51	44	5	3	6	10.8	3.0	7,900	55	43	2	2	4	11.2	3.6	Nil	2-4pus,2-4epi	Nil	1-2pus1-2 epi
02	B83764	12/M	7600	62	36	2	2	4	11.6	3.8	7,800	54	44	2	2	4	11.5	3.6	Nil	1-2pus, 1-2epi	Nil	1-2 pus1-2epi
03	C4583	12/M	6800	60	36	4	2	4	10	3.2	6,900	60	38	2	2	4	12.1	3.5	Nil	1-2pus0-1epi	Nil	1-2pus,1-2epi
04	C10158	10/F	5800	45	48	7	5	10	6.3	2.5	6,500	45	49	6	4	8	10.0	3.0	Nil	1-2pus1-2epi	Nil	1-2 pus1-2epi
05	C13752	5/M	8200	58	35	7	4	8	10.2	2.7	8500	55	35	5	2	4	10.5	3.2	Nil	2-4 pus 2-4epi	Nil	1-2pus1-2epi
06	C15778	10/F	7000	50	46	4	6	12	10.4	3.2	7,200	58	38	4	2	4	10.6	3.2	Nil	1-2 pus 2-4epi	Nil	1-2 pus0-1epi
07	B34028	5/M	8400	40	50	10	2	4	7.5	4.0	9,000	48	44	8	2	4	9.7	3.6	Nil	1-2pus1-3epi	Nil	1-2 pus1-2epi
08	C11546	8/F	6000	32	50	18	2	4	8.7	4.0	6,800	45	48	7	2	4	10	4.0	Nil	1-2pus1-2epi	Nil	1-2pus1-2epi
09	C16175	5/F	7000	63	33	4	2	4	10.8	3.4	7500	56	42	2	2	4	11.2	3.8	Nil	2-4pus2-4epi	Nil	1-2 pus1-2epi

10	C6610	9/F	8000	53	42	5	4	8	10.3	3.8	7,500	53	42	5	4	8	11.0	4.0	Nil	1-2pus2-6epi	Nil	1-2 pus1-2epi
11	B97717	12/F	9200	44	51	5	2	4	10.8	3.5	8,000	52	40	8	2	4	11.5	4.0	Nil	0-1pus1-2epi	Nil	1-2pus0-1epi
12	B16100	11/M	6900	60	34	6	2	4	9.7	4.0	7,200	53	43	4	2	4	11.0	4.0	Nil	0-1pus1-2epi	Nil	0-1 pus1-2epi
13	B69005	11/M	6800	39	41	20	2	4	9.2	3.4	7,200	52	42	5	1	2	10.0	3.5	Nil	0-1pus1-2epi	Nil	1-2 pus0-1epi
14	C15093	12/M	8000	63	33	4	4	8	9.5	3.0	8200	55	43	2	2	4	11.0	3.5	Nil	1-2pus1-2epi	Nil	0-1pus1-2epi
15	B90193	12/F	9600	36	49	15	8	16	10.8	4.0	9,800	55	44	1	4	8	11.2	4.0	Nil	1-2pus1-2epi	Nil	1-2pus 0-1epi
16	B82913	5/M	6000	32	50	18	6	12	10.8	3.5	6,200	53	43	4	2	4	11.0	3.8	Nil	2-4pus2-4epi	Nil	1-2 pus1-2epi
17	B82913	12/M	7000	52	46	2	4	8	10.2	3.2	7,200	54	44	2	10	4	11.5	3.5	Nil	4-6pus2-4epi	Nil	1-2 pus 1-2epi
18	B48261	8/F	5400	55	45	5	11	22	11.0	3.0	6,500	55	43	2	2	4	11.5	3.0	Nil	2-4pus1-2epi	Nil	1-2 pus 0-1epi
19	C11003	12/F	4600	53	39	8	2	4	9.9	3.5	6,200	53	43	4	2	4	11.0	3.5	Nil	1-2pus1-2epi	Nil	1-2 pus1-2epi
20	C14601	8/F	6500	31	60	9	2	4	10.9	4.0	7000	58	38	4	2	4	11	3.8	Nil	1-2pus2-4epi	Nil	1-2pus1-2epi

			BEFORE								AFTER								Before		After	
S. NO	Op/ip NO	Age/ Sex	TC	DC			ESR		HB	RB C	TC	DC			Esr		Hb	Rb c	Urine test		Urine test	
				P	L	E	½	½				P	L	E	½	½			Alb	Dep	Alb	Dep
21	B76935	10/F	8400	53	33	14	4	8	11.2	3.0	8,700	55	43	2	2	4	11.0	3.6	Nil	0-2pus,0-1epi	Nil	1-2pus0-1 epi
22	B77653	8/M	6000	58	40	2	4	8	7.5	3.8	6,700	52	42	6	2	4	11.2	3.6	Nil	2-4pus, 3-6epi	Nil	2-4 pus2-4epi
23	B81269	12/F	6300	57	42	1	2	4	11.7	3.2	6,900	60	38	2	2	4	12.1	3.5	Nil	4-8pus4-8epi	Nil	1-2pus,1-2epi
24	B43177	8/F	6600	54	43	3	3	8	8.2	2.5	6,900	56	42	2	2	4	10.9	3.0	Nil	2-3pus1-2epi	Nil	1-2 pus1-2epi
25	A8658	9/M	6800	53	41	6	6	14	9.5	2.7	7,000	55	43	2	2	8	10.5	3.2	Nil	1-2 pus 0-1epi	Nil	1-2pus0-1epi
26	B85951	8/F	8400	42	48	10	8	16	9.2	3.2	7,200	42	51	7	4	8	10.0	3.2	Nil	3-4 pus 1-3epi	Nil	1-2 pus0-1epi
27	C10061	6/F	8400	52	46	2	4	8	9.5	4.0	8,700	58	41	1	2	4	10.4	3.6	Nil	2-3pus1-2epi	Nil	2-4 pus0-1epi
28	B95663	11/F	6600	60	36	4	3	6	10.6	4.0	6,800	55	45	5	2	4	11.5	4.0	Nil	1-3pus2-4epi	Nil	1-2pus1-3epi
29	B48795	8/M	7000	60	36	4	4	8	9.1	3.4	7200	56	42	2	2	4	10.4	3.8	Nil	4-6pus2-4epi	Nil	1-2 pus1-2epi

30	C15202	5/M	6300	40	53	7	2	4	10.3	3.8	7,000	53	42	5	2	4	10.5	4.0	Nil	1-2pus2-4epi	Nil	1-2 pus1-2epi
31	B43277	10/F	9500	79	20	1	4	8	10.4	3.5	12,200	52	40	8	2	4	12.5	4.0	Nil	2-4pus4-5epi	Nil	1-2pus1-2epi
32	A8758	11/F	5900	53	43	4	4	8	10.8	4.0	7,200	53	43	4	2	4	12.0	4.0	Nil	0-1pus1-2epi	Nil	0-1 pus1-2epi
33	C4096	6/F	7300	39	55	6	4	8	10.4	3.4	7,200	52	46	2	2	4	11.0	3.5	Nil	1-2pus1-2epi	Nil	1-2 pus0-1epi
34	848	10/F	6800	45	52	3	15	30	9.7	3.0	7,000	55	43	2	4	10	10.5	3.5	Nil	1-2pus1-2epi	Nil	1-2pus1-2epi
35	851	5/F	6500	45	52	3	15	30	9.7	4.0	7,200	55	44	1	5	8	10.2	4.0	Nil	1-2pus1-2epi	Nil	1-2pus 0-1epi
36	857	6/F	8400	42	48	10	4	8	10.0	3.5	8,000	56	42	2	2	4	11.0	3.8	Nil	2-4pus2-4epi	Nil	1-2 pus1-2epi
37	849	12/F	8000	45	52	3	14	28	10.2	3.2	7,200	54	44	2	7	10	11.2	3.5	Nil	4-6pus2-4epi	Nil	1-3 pus 0-1epi
38	883	12/F	8000	44	52	4	2	4	10.6	3.0	8,500	55	43	2	2	4	11.5	3.0	Nil	2-4pus1-2epi	Nil	1-2 pus 0-1epi
39	846	6/M	7600	42	44	11	6	12	8.6	3.5	7,400	53	43	4	2	6	11.0	3.5	Nil	1-2pus2-4epi	Nil	0-1 pus1-2epi
40	861	7/F	6500	40	58	2	4	8	10.2	4.0	6,300	58	38	4	2	4	10.6	3.8	Nil	1-2pus2-4epi	Nil	1-2pus1-2epi

Op no : B 43277

Name : Bhuvaneswari

A/S : 10 / F

Before treatment



After treatment



6. DISCUSSION

The Siddha systems of medicine concentrate on the changes that occur in Vatham, Pitham and Kapam. These are responsible for the maintaining the normal equilibrium of the body. Venpulli is characterized by depigmentation in various parts of the body especially in orifices, eyes, nostrils, mouth, nipples, umbilicus, and genitalia etc. While the depigmented areas are painless they can be a source of embarrassment and emotional stress. Nowadays the Prevalence of the disease is increasing in children are victims of the disease. It may be resemblance with Vitiligo, according to the definition given in medical scientific literature. Management of Venpulli is often difficult and frustrating, both for the patient as well as the physician. The treatment commonly practicing dermatologist are topical corticosteroids; topical immunomodulators; phototherapy, including PUVA, topical PUVA, UVB and monochromatic excimer laser or light, as well as micro phototherapy; surgical options including autologous mini-punch grafting; blister roof grafting, and epidermal cell transplantation. It require prolonged use of these agent which results in significant therapy limiting side effects likely atrophy , hyper trichinosis, perilerional, hypo pigmentation etc. For this study the Internal and external Siddha poly herbal formulations from authenticated Sathric texts were chosen, Selected experimental drugs are namely *SENKONRAI PATTAI KUDINEER(INTERNAL)* *SENKONRAI PATTAI POOCHU(EXTERNAL)* for the management of Venpulli.

In this study children with Venpulli were enrolled in our Department of Kuzhandhai Maruthuvam and examined the children with Siddha diagnostic method. Before and after the course of treatment patients were subjected to laboratory investigations and photographs were taken.

The primary challenge for achieving feasibility was the recruitment of 40 participants aged 5 to 12 years old in the specified time period. It could be argued that the parents are some of the most psychologically fragile, where looks and social pressures have the most impact, thus the children targeted for this study as the need to treat their Venpulli was perceived to be the greatest. Although many people inquired about the study, we had difficulty recruiting the young participants specified in the inclusion criteria. Our findings are consistent with a previous report showing effectiveness in treating vitiligo with Siddha formulations.

Among the 40 children of both the gender 21 (42 %) were male children and 29(58%) were female children. Therefore we didn't come to the conclusion, the Venpulli have affected for particular gender. In Dietary Habits, 32 (80%) children were non -vegetarians and 8 (20 %) were vegetarian. This result showed simply we have enrolled non-vegetarian children in higher percentage. In Vatham, Samanan and Viyanan were affected for all those children. These both vayu are physiologically placing on the all over the body including skin.

The most likely confounding factor, however, is sun exposure, as it can stimulate the proliferation of melanocytes and affect the production of vitamin D, both of which can impact vitiligo. This study by starting in august, but some participants were recruited late in the summer, and completed the 40days study in November, thus experiencing substantial decreasing intensity of sun exposure over the last few months of their treatment. Most studies of Venpadai treatment set a 75% repigmentation rate as cosmetically acceptable, and are able to achieve it in 12.5 to 75% of patients after one year of treatment. But we have treated for only 40 days. Hence, we couldn't get cosmetically accepted repigmentation. There were no adverse events attributed to the study *SENKONRAI PATTAI KUDINEER* and *SENKONRAI PATTAI POOCHU* did not adversely affect serum WBC, LFT and RFT parameters. Given the inclusion of children participants in this study, much care was taken to monitor adverse events experienced due to the taking of *SENKONRAI PATTAI KUDINEER* and *SENKONRAI PATTAI POOCHU*. Our results suggest that the experimental formulations did not have a negative impact on these serum parameters. The impact of on serum parameters was not the primary outcome of our study, thus the study was not powered to evaluate the significance of these results.

As one of the common herbal medicine in the Siddha system of medicine, and accounting for more prescriptions in India, the use of senkonrai for Venpulli is appealing due to the ease of use of taking an oral compared with frequent and lengthy ultraviolet phototherapy sessions, and the relatively inexpensive cost of the herbal supplement when compared to phototherapy. Further, the relatively good safety profile of senkonrai pattai chooranm makes it appealing for self administration by Venpulli sufferers. However, it is recommended that any attempt to use senkonrai pattai kudineer and poochu and in the management of Venpulli should be carefully monitored by a Siddha practitioner given that there are still many questions about the correct dose, its true effectiveness, interactions with other conditions or therapies, and possible adverse reactions.

There are several limitations to our study senkonrai pattai kudineer and poochu at warrant discussion. The purpose of this study was to assess the feasibility of studying for the management of the Venpulli in a larger, blinded randomized controlled trial and as such this study was difficult designed to allow us to draw clear conclusions about its efficacy. The sample size was small, thus our findings are preliminary and definite conclusions about the efficacy and safety of the experimental formulations difficult be made. Because the study was open labeled, not controlled, and not randomized, it is quite likely that some of the demonstrated benefit. However, this is unlikely that all of the results we report can be accounted for by spontaneous repigmentation.

Our primary outcome measure has a degree of subjectivity associated with it. We attempted to strengthen the objectivity of the outcomes by us, and by verifying assessments using digital photographs. However, we assessed to approximate the area of Venpulli lesions and their intensity. Being the participants were children, the parents may also have impacted the results, as sufferers can respond more quickly to treatment. It is possible that the relatively smaller lesion sizes and durations in our Participants could have resulted in over-estimating the effectiveness of treatment. Despite these limitations, estimation of effectiveness that can be used to estimate a sample size for a larger study. And the results are compelling enough to proceed with a larger trial. This study focused on determining the feasibility of a future large randomized controlled trial of senkonrai pattai kudineer and poochu for the treatment of Venpulli. Given that our small study found statistically significant improvement on some secondary outcome measures, a larger methodologically rigorous double blind placebo- controlled randomized clinical trial is recommended.

7. SUMMARY & CONCLUSION

A number of drugs are available in the market, which have achieved improved efficacy and safety after incorporating the active agents in carrier systems. Therefore, putting new life into erstwhile discarded drug molecules by transforming them into novel formulations can serve as viable and cost effective alternative to the expensive and time consuming search of newer alternative drugs and therapies in Siddha systems of medicine. Efficacy of '***SENKONRAI PATTAI KUDINNER***' with topical application of **SENKONRAI PATTAI POOCHU** was showed to various categories. Clinical outcomes showed moderate improvement in 15%, mild improvement in 75% and No improvement in 10% of children. There was no adverse events noticed in throughout the study and the experimental formulations were cost effective. The results are better in children. Body and lower limb lesions respond much quickly as compared to lesions in other parts of the body while lesions on joints have relatively lower response. During our study, senkonrai pattai kudineer and poochu didn't show any adverse events as like Psoralen compounds, Placental extracts, Steroids (topical or systemic).

In recent time, Sasthric traditional Siddha formulations, and a better knowledge of the physicochemical and phytochemical properties of herbs and formulations have led to the development of evaluated Siddha drug delivery systems that have the potential to re-invent the internal and topical treatments of Venpulli (vitiligo). There is hope and enthusiasm from this study that further research enhanced collaboration with dermatology researchers will bring this hitherto untapped potential to fruition.

ANNEXURES

1. PROTOCOL

TITLE:

A study on “VENPULLI” (VITILIGO) and the drug of choice is
SENKONRAI KUDINEER (Internal) & SENKONRAI POOCHU(External).

STUDY NO: Reg no: 32102708

DATE OF SUBMISSION:14.12.11

NAME OF THE INSTITUTION:

National institute of siddha,
Tambaram sanatorium,
Chennai -47.

Name of the Investigators : Dr.s.vadivelan

II Year PG Scholar, Dept Kuzhanthai Maruthuvam.

Project Guide:

Prof .Dr.G.Ganapathy MD(S)

The Head of the department

Kuzhanthai Maruthuvam

BACKGROUND :

Vitiligo is an acquired idiopathic dermatological disorder characterized by well circumscribed milky-white macular devoid of identifiable melanocytes

It affects approximately 1% of world population in which 3-4% of Indian population had vitiligo. It affects both sexes equally in all races however it is more noticeable in people with dark skin

There is no cure for vitiligo but there are a number of treatments that improve the condition.

In modern medicine the conventional treatment is corticosteroid. Tropical steroid are often first line therapy especially in child. It require prolonged use of these agent which results in significant therapy limiting side effects likely atrophy, hyper trichinosis, perilerional, hypo pigmentation etc

Due to the significant side effects caused by the usage of the Modern medicine, there is a need to explore a remedy for this disease.

Dermatological problems pose a great threat and challenge in the developing scientific world. It affects the humans' personality physically and psychologically.

Siddha system of medicine is an ancient system of medicine. It is developed by Siddhars – the man who attained perfection in life. Siddha system not only deals with external body but also with the inner man or the soul.

In siddha system of medicine all the skin diseases have been brought under 18 types of Kuttam described in Yugi Vaidhya Chinthamani written by Siddhar Yugi.

The symptoms of the disease “VENPULLI” which is one of the skin disease coincides to the maximum with the symptoms of the disease “VITILIGO”

So, I proposed to carry out the study on Venpulli (Vitiligo) a chronic skin ailment with the trial drug SENKONRAI KUDINEER, and SENKONRAI POOCHU – indicated for Venpulli.

AIM & OBJECTIVES :**PRIMARY OBJECTIVE:**

To establish the clinical evaluation of the Venpulli by careful examination on aetiology, symptomatology, treatment, prognosis and correlate with Vitiligo

SECONDARY OBJECTIVE:

- To evaluate the clinical efficacy of senkonrai kudineer (Int) & senkonraipoochu(Ext) in the treatment of VENPULLI (VITILIGO).

Materials and Methods:**STUDY DESIGN & CONDUCT OF STUDY:****STUDY TYPE:**

An open clinical trial

STUDY PLACE:

OPD & IPD. Of Ayothidass pandithar hospital

National institute of siddha ,

Tambaram sanatorium, Chennai-47.

STUDY PERIOD:

12 months

POPULATION AND SAMPLE:

- Population consists of pediatric patients attending the OPD of Ayothidoss Pandithar Hospital, National Institute of Siddha, Chennai-47.
- The sample consists of patients 5-12 years age group fulfilling all the inclusion criteria and exclusion criteria.

SAMPLE SIZE: 40 patients

SUBJECT SELECTION:

As and when patients reporting with symptoms of venpulli and fulfilling inclusion criteria will be subjected to screening test & documented using screening proforma.

INCLUSION CRITERIA

2. Hypo-pigmented patches without any structural changes.
3. Age: between 5 - 12 years of both sex
4. Patients willing to participate in trial and sign in consent form
5. Willing to give blood sample for lab investigations when required.
6. Willing for photograph before and after treatment.

EXCLUSION CRITERIA:

1. Juvenile Diabetes mellitus
2. Albinism
3. Burns
4. HIV

WITHDRAWAL CRITERIA

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

TREATMENT:

MEDICINE NAME:

Internal: Senkonrai kudineer 15-30ml b.i.d .Gunapaadam Mooligai vaguppu Part-I (Page No: 403).

External: Senkonrai poochu Gunapaadam Mooligai vaguppu Part-I (Page No:403)

DOSAGE:**

- 5-7yr.....15ml b.i.d(marunthu sei iyalum kalium) (Scihitcha Ratna Deepam)
- 8-12yr.....30ml b.i.d (marunthu sei iyalum kalium) (Scihitcha Ratna Deepam)

** Dose calculation for pediatric group is based on Height and Weight chart, ICMR, 1990; and the formula mentioned in the Essential of medical pharmacology by K.D. Tripathi

DURATION: 40 days

STANDARD OPERATING PROCEDURE FOR SENKONRAI KUDINEER (Int) & SENKONRAI POOCHU(Ext)

SOURCE OF TRIAL MEDICINE:

The required drugs for preparation of senkonrai kudineer (Int) & senkonrai poochu (ext) will be purchased from a well reputed country shop and medicine is purified & prepared in Gunapadam lab of National institute of Siddha.

METHOD OF PREPARATION:

SENKONRAI KUDINEER (INTERNAL)

INGREDINTS	BOTANICAL NAME	WEIGHT
Senkonraipattai	Cassia margiuata	8gm-16gm

A drug is purified and grind into a coarse of powder. Add to this 1:16 pangu of water, boiied upto 1/8of it original

SENKONRAI POOCHU:(EXTERNAL)

INGREDINTS	BOTANICAL NAME
Senkonraipattai	cassia margiuata

A drug is purified and grind then mixed with water and made as paste

INDICATION: VENPULLI

ASSESMENTS & TEST

- A. Clinical assessment
- B. Routine investigations
- C. siddha method assessment

A.CLINICAL ASSESMENT:

Site
Repigmentation
Number of lesions
New Colour change
Size of the lesions
Borders
Erythema
Repigmentation of Hair
Itching

B.ROUTINE INVESTIGATION

BLOOD

- Hb
- Total WBC Count
- DC- Polymorphs
- Lymphocytes
- Eosinophils
- Monocytes
- Basophils
- Total RBC count
- ESR

URINE

Albumin

Deposits

C. SIDDHA METHOD OF ASSESSMENT

Nilam, Kalam, Uyirathukkal, Udal Thathukkal, Envagai Thervugal, Neerkuri, Neikuri. .

STUDY ENROLLMENT

Patients reporting at the OPD with the clinical symptoms of Hypo pigmentation, itching, burning sensation etc will be examined clinically for enrolling in the study based on the inclusion and exclusion criteria.

The patients who are to be enrolled would be informed about the study, trial drug, possible outcomes and the objectives of the study in the language and terms understandable to them.

After ascertaining the patient's willingness, informed consent would be obtained in writing from them in the consent form (Form IV). All these patients will be given unique serial number.

Complete clinical history, complaints and duration, laboratory findings-- all would be recorded in the prescribed Proforma. Screening Form- I will be filled up. Patients would be advised to take the trial drug and appropriate dietary advice would be given according to the patients perfect understanding. The patients are requested to bring back the unconsumed trial drug.

CONDUCT OF THE STUDY:

The trial drug SENKONRAI KUDINEER (Internal) is given for 40 days. The trial drug **SENKONRAI POOCHU** is given continuously for 40 days for external application. For OP patients, they should visit the hospital once in 15 days. At each clinical visit clinical assessment is done and prognosis is noted. For IP patients the drug is given for 40 days. For IP patients' clinical assessment is done daily. Laboratory investigations are done 0day&40 th day of the trial. For IP patients, who is not in a situation to stay in the hospital for a long time is advised to attend the OPD for further follow- up. After the end of the treatment, the patient is advised to visit the OPD for another 2 months for follow-up. If any patient who fails to collect the trial drug on the prescribed day but wants to continue in the trial from the next day or two, he/ she will be allowed, but defaulters of one week and more will not be allowed to continue and be withdrawn from the study with a fresh case being included.

DATA MANAGEMENT

- After enrolling the patient in the study, a separate file for each patient will be opened and all forms will be filed in the file. Study No. and Patient No. will be entered on the top of file for easy identification. Whenever study patient visits OPD during the study period, the respective patient file will be taken and necessary recordings will be made at the assessment form or other suitable form.
- The screening forms will be filed separately.
- The Data recordings in all forms will be monitored and scrutinized by HOD, Dept of kuzhanthai maruthuvam .

Data analysis will be done with the help of senior research officer (statistics) of NI

OUTCOME

✚ Primary – Results and observation during the study inclusive of clinical improvement etc.

Secondary – Efficacy of the trail drug and its side effects if any.

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

ETHICAL ISSUES

1. To prevent any infection, while collecting blood sample from the patient, only disposable syringes, disposable gloves, with proper sterilization of lab equipments will be used.
2. No other external or internal medicines will be used. There will be no infringement on the rights of patient.
3. The data collected from the patient will be kept confidentially. The patient will be informed about the diagnosis, treatment and follow-up.
4. After the consent of the patient (through consent form) they will be enrolled in the study.(Proper consent will be obtained from patient informer/guardian to document photos)
5. Informed consent will be obtained from the patient explaining in the understandable language to the patient.
6. Treatment would be provided free of cost.

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

1. FORM USED:

FORM I - SCREENING & SELECTION PROFORMA

FORM II - CONSENT FORM

FORM III - HISTORY PROFORMA

FORM IV - CLINICAL ASSESSMENT FORM

FORM V -LABORATORY INVESTIGATION FORM

FORM VI -PATIENT'S INFORMATION SHEET

FORM VII - WITHDRAWAL FORM

FORM VIII - ADVERSE REACTION FORM

**NATIONAL INSTITUTE OF SIDDHA
AYOTHIDOSS PANDITHAR HOSPITAL
CHENNAI –600047.**

POST GRADUATE DEPARTMENT OF KUZHANDHAI MARUTHUVAM

A study on “VENPULLI” (VITILIGO) and the drug of choice is
SENKONRAI KUDINEER (Internal) & SENKONRAI POochu(External).

I SCREENING FORM

1. OP / IP No.: _____ 2. Patient ID no: _____ 3. Name: _____
4. Age: _____ 5. Gender: Male/Female _____ 6. Patient informant: _____
7. Date: _____ 8. Reliability _____ 9. Contact No. _____

INCLUSION CRITERIA

- Age :5-12Yrs
- Sex : Both male and female child
- Patients having of symptoms of Hypo-pigmented patches without any structural changes
Yes / No
- Patients are willing to give blood and urine for laboratory investigations
Yes / No
- Patient parents or guardian willing to sign the informed consent stating that he/she will conscientiously stick to the treatment during 40days but can opt out of the trial of his/her Own conscious discretion
Yes / No
- Willing to take photograph before and after treatment.
Yes / No

EXCLUSION CRITERIA

1. Juvenile Diabetes mellitus
2. Albinism
3. Leprosy
4. Burns
5. HIV
6. Patients with any other serious illness.

Patients Admitted to trial: _____

(Signature of principle investigator)

(Signature of Lecturer)

**NATIONAL INSTITUTE OF SIDDHA
AYOTHIDOSS PANDITHAR HOSPITAL
DEPARTMENT OF KUZHANDHAI MARUTHUVAM**

A open clinical study to evaluate the safety and efficacy of senkonrai pattai kudineer (internal) senkonrai pattai poochu” (external) in treating ‘venpulli” (vitiligo)

II CONSENT FORM

Certificate by Investigator

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

Date:

Signature:

Name:

Consent of the informant:

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

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

I, exercising my free power of choice, hereby give my consent to include my son/daughter as a subject in the clinical trial of Nilapanai kilangu Chooranam Kandangkathiri Pazha Thailam” (External) in the treatment of **Venpullii” (Vitiligo)**

Name :

Signature:

Date:

Relationship:

**NATIONAL INSTITUTE OF SIDDHA
AYOTHIDOSS PANDITHAR HOSPITAL
CHENNAI –600047.**

POST GRADUATE DEPARTMENT OF KUZHANDHAI MARUTHUVAM

A study on “VENPULLI” (VITILIGO) and the drug of choice is
SENKONRAI KUDINEER (Internal) & SENKONRAI POOCHU(External).

III PROFORMA

Demographic data

Patient Id :	OP/IP No.	Visit Date : (_ / _ / _)
Name :		
Age :		
Gender	Male <input type="checkbox"/> Female <input type="checkbox"/>	Date Of Birth : (_ / _ / _)
Father/ Mother /Guardian Name :		
Fathers Occupation :		
Fathers Monthly Income :		
Religion :		
Socioeconomic Status :		
Patient Informant :		
Postal Address		
Contact No :		

Complaints and Duration:

Present illness:

History of Past Illness:

History /Symptoms/Signs	Yes	No	If, Yes Details
Any Similar Complains	<input type="checkbox"/>	<input type="checkbox"/>	_____
Bronchial Asthma	<input type="checkbox"/>	<input type="checkbox"/>	_____
Dust Allergy	<input type="checkbox"/>	<input type="checkbox"/>	_____
Hospitalization	<input type="checkbox"/>	<input type="checkbox"/>	_____
Any other	<input type="checkbox"/>	<input type="checkbox"/>	_____

Family History

Any Hereditary/ Familial Disease Yes No

If Yes, Details-----

Immunization History

Proper Immunization given Yes No

Food habits:

1. Veg 2. Non-Veg 3. Mixed

General assessment

- 1. Picca
- 2. Nail biting
- 3. Bowel movements

General Examination

- 1. Pallor YES NO
- 2. Jaundice YES NO
- 3. Cynosis YES NO
- 4. Clubbing YES NO
- 5. Pedal oedema YES NO
- 6. Lymph adenopathy YES NO

Vital signs:-

1. Pulse rate / mint
2. Heart rate / mint
3. Respiratory Rate / mint
4. Temperature

Anthropometry:-

Height

Weight

Clinical assessment

Affected Parts _____

1. Initial lesion/s :
2. Number of lesions :
3. Colour: Blackish white (Grey) Pink White
4. Size of lesion (Measurement in cms.):
Anatomical location Length Breadth Shape
5. Borders: Well-defined Diffuse
6. Erythema: Present Absent
7. Sensation: Normal Parasthesia Burning
8. Depigmentation of Hair: Present Absent
9. Depigmentaion at Muco-cutaneous junctions
Present Absent
10. Itching: Present Absent
11. Stage of Vitiligo: Spreading Relapsing Static

Examination of systems:-

	Normal	Affected
Cardio-vascular system:	<input type="checkbox"/>	<input type="checkbox"/>
Gastro intestinal system:	<input type="checkbox"/>	<input type="checkbox"/>
Central nervous system:	<input type="checkbox"/>	<input type="checkbox"/>
Genito- urinary system:	<input type="checkbox"/>	<input type="checkbox"/>
Endocrine system:	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
Respiratory system:		

Nilam:- Kuringi Mullai Marutham Neithal Paalai

Kaala Iyalbu:-

Kaarkalam	<input type="checkbox"/>	Koothirkaalam	<input type="checkbox"/>	Munpanikaalam	<input type="checkbox"/>
Pinpanikaalam	<input type="checkbox"/>	Illavenirkaalam	<input type="checkbox"/>	Muthuvenirkaalam	<input type="checkbox"/>

Yaakai

Vatham	<input type="checkbox"/>	Vatha Pitham	<input type="checkbox"/>	Vatha Kabam	<input type="checkbox"/>
Pitham	<input type="checkbox"/>	Pitha vatham	<input type="checkbox"/>	Pitha Kabam	<input type="checkbox"/>
Kabam	<input type="checkbox"/>	Kaba Vatham	<input type="checkbox"/>	Kaba Pitham	<input type="checkbox"/>

Gunam

Sathuvam	<input type="checkbox"/>	Rasatham	<input type="checkbox"/>	Thamasam	<input type="checkbox"/>
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Pori / Pulangal

	Normal	Affected	Normal	Affected	Remarks
<i>Mei / unarvu</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Vaai / suvai</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Kan / parvai</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Mooku / natram</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Sevi / olli</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Kanmendirium / Kanmavidayam

	Normal	Affected	Normal	Affected	Remarks
Kai / dhanam	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Kaal / ghamanam	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Vaai / vaku	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Eruvai / visarkam	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Karuvai / anantham	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Uyir Thathukkal:**Vatham:**

	Normal	Affected	Remarks
<i>Pranan</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Abanan</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Viyanan</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Uthanan</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Samanan</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Nagan</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Koorman</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Kirukaran</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Devathathan</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Dhanajeyan</i>	<input type="checkbox"/>	<input type="checkbox"/>	

Pitham

	Normal	Affected	Remarks
<i>Analam</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Ranjagam</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Saathagam</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Alosagam</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Prasagam</i>	<input type="checkbox"/>	<input type="checkbox"/>	

Kabam

	Normal	Affected	Remarks
<i>Avalambagam</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Kilethagam</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Pothagam</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Tharpagam</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Samthigam</i>	<input type="checkbox"/>	<input type="checkbox"/>	

Udalthathukkal:

	Normal	Affected	Remarks
<i>Saaram</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Senneer</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Oon</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Kozhuppu</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Enbu</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Moolai</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Sukilam / Suronitham</i>	<input type="checkbox"/>	<input type="checkbox"/>	

Envagai Thervugal

	Normal	Affected	Remarks
<i>Naa</i>			
Niram	<input type="checkbox"/>	<input type="checkbox"/>	
Thanmai	<input type="checkbox"/>	<input type="checkbox"/>	
Suvai	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Niram</i>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Mozhi</i>	<input type="checkbox"/>	<input type="checkbox"/>	
Vizhi	<input type="checkbox"/>	<input type="checkbox"/>	
Niram	<input type="checkbox"/>	<input type="checkbox"/>	
Thanmai	<input type="checkbox"/>	<input type="checkbox"/>	
Parvai	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Sparisam</i>	<input type="checkbox"/>	<input type="checkbox"/>	

Malam

Niram	Normal	<input type="checkbox"/>	Affected	<input type="checkbox"/>
Nurai	Normal	<input type="checkbox"/>	Affected	<input type="checkbox"/>
Elagal	Normal	<input type="checkbox"/>	Affected	<input type="checkbox"/>
Erugal	Normal	<input type="checkbox"/>	Affected	<input type="checkbox"/>

Moothiram***Neerkuri***

Niram	Normal	<input type="checkbox"/>	Affected	<input type="checkbox"/>
Edai	Normal	<input type="checkbox"/>	Affected	<input type="checkbox"/>
Nurai	Normal	<input type="checkbox"/>	Affected	<input type="checkbox"/>
Manam	Normal	<input type="checkbox"/>	Affected	<input type="checkbox"/>
Enjal	Normal	<input type="checkbox"/>	Affected	<input type="checkbox"/>

Neikuri

Vatham

Pitham

Kabam

Others

Naadi:**Thani Nadi**

Vadham pitham kabam

Thontha Nadi

Vatha pitham Pitha vatham Pitha kabam Kaba pitham

Thoda Nadi

Vatha kabam Kaba vatham

Mukutra Nadi**(Signature of principle investigator)****(Signature of Lecturer)**

**NATIONAL INSTITUTE OF SIDDHA
AYOTHIDOSS PANDITHAR HOSPITAL
CHENNAI-600047.**

POST GRADUATE DEPARTMENT OF KUZHANDHAI MARUTHUVAM

A study on “**VENPULLI**” (VITILIGO) and the drug of choice is
SENKONRAI KUDINEER (Internal) & SENKONRAI POOCHU (External).

IV CLINICAL ASSESSMENT FORM

1. OP / IP No.: _____ 2. Patient ID: _____ 3. Name: _____
4. Age: _____ 5. Gender: Male/Female _____ 6. Patient informant: _____
7. Date: _____ 8. Reliability _____ 9. Contact No. _____

Clinical symptoms	0	After 14 days	After 28 days	After 40days
Site				
Repigmentation				
Number of lesions				
New lesions appearance				
Colour change				
Size of the lesions				
Borders				
Erythema				
Repigmentation of Hair				
Itching				

(Signature of principle investigator)

(Signature of Lecture)

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V LAB INVESTIGATION FORM

Specimen: _____

Date of specimen collected ___/___/_____ (dd/mm/yyyy)

Lab test	Normal range	Before Treatment	After Treatment
Haemoglobin (gms %)	11.5-15.5gm/dl		
TC cells/cumm	5000-17000cells/ μ l		
DC- Neutrophil %	40-75%		
Eosinophils	1-6%		
Basophils	0-1%		
Lymphocyte	20-40%		
Monocytes	2-4%		
Total RBC count	4.0-5.2millions/ μ l		
ESR mm/hr 30min. 1 hour	1-13mm/hr 1-20mm/hr		

Urine

Date of specimen collected ___ / ___ / _____ (dd/mm/yyyy)

Lab test	Normal Range	Before Treatment	After Treatment
Deposits			
Albumin			

(Signature of principle investigator)

(Signature of Lecturer)

primarily by signing the consent form and then you will be given the internal medicine **senkonrai pattai kudineer (internal)** 5-7yrs...15ml.bid 8-12yrs...30 BD with milk for 40 days and **senkonrai pattai poochu” (external)** .

The information I am collecting in this study will remain confidential. 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 of your time.

If you wish to find out more about this study before taking part, you can ask me all the questions you want or contact Dr.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, and Tel No: 91-44-22380789, for rights and participation in the study.

**NATIONAL INSTITUTE OF SIDDHA
AYOTHIDOSS PANDITHAR HOSPITAL
CHENNAI -600 047.**

A study on “VENPULLI” (VITILIGO) and the drug of choice is
SENKONRAI KUDINEER (Internal) & SENKONRAI POOCHU (External).

VII WITHDRAWAL FORM

1. SERIAL NO OF THE CASE:

2.OP / IP NO:

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

6. DATE OF TRIAL COMMENCEMENT:

7. DATE OF WITHDRAWAL FROM TRIAL:

8. 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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NATIONAL INSTITUTE OF SIDDHA

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Website : www.nischennai.org

Name: Dr. S. VADIVELAN Reg No: 32162708
Title: preclinical and clinical study on Venpelli (vitiligo)
in children and the drug of choice is senkoraai kudineer
(Internal) and senkoraai poochi (external)
No. NIS/IEC/2011/3/32 - 24/12/2011

DECISION

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: S. Vadivelan (Please print name) Dr. V. SUBRAMANIAN
Chair person

(Please delee as appropriate, Chairperson, Secretary)

Modifications needed

Modification given to candidate

The research proponant 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/4-32/2011

20/12/2011

CERTIFICATE

This is certify that the project title Preclinical and clinical Study
on Venpuu [Yitiligo] in children and the drug of choice is
has been approved by the IAEC. Senkoxai Kudineer

Prof. Dr. K. Marickavasakam

Name of Chairman/Member Secretary IAEC:

Dr. B. Jayachandran Jare

Name of CPCSEA nominee:

Signature with date

K. Marickavasakam

Chairman/Member Secretary of IAEC:

B. Jayachandran Jare

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 formulation “**Senkonrai Kudineer**” (Internal) and “**Senkonrai poochu**” (External) for **Ven pulli** taken up for Post Graduation Dissertation by **Dr.S.Vadivelan**, M.D.(S), II year, Department of Kuzhandhai Maruthuvam, 2011-12, are identified and authenticated through Visual inspection / Experience, Education & Training / Organoleptic characters / Morphology / Taxonomical / Microscopical methods.


Cassia marginata Roxb. (Caesalpiaceae), Stem bark

Synonym: *Cassia roxburghii* DC.



Certificate No: NIS/MB/79/2012

Date: 16-6-12


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



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

69, Anna Salai, Guindy, Chennai-600 032

This Certificate is awarded to

-Mr / -Ms / Dr & **V.A.P.I.V.E.L.A.N.**.....

for participating as a Resource Person / Delegate in the IX Workshop

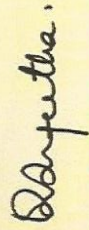
on **"Research Methodology & Biostatistics"**

for AYUSH Post-Graduates & Researchers
organized by the Department of Siddha

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

from 24th September 2012 to 28th September 2012.


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



Dr. K. SIVASANGEETHA MD
REGISTRAR (FAC)



DR. MAYILVAHANAN NATARAJAN D.Sc.
M.S.Orth. M.Ch.Orth. (L'pool) Ph.D. (Orth. Onco.) FR.C.S. (Eng)

7th VICE CHANCELLOR

NATIONAL INSTITUTE OF SIDDHA

ACUTE TOXICITY STUDY OF SENKONDRAI PATTAI KUDINEER

[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	:	14 Days
Clinical dose	:	5.0 gms/day

S.No	Group	No of mice
1	Vehicle control (saline)	10 (5 male, 5 female)
2	Toxic dose 10X therapeutic dose (144mg)	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 (SaiDurga 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/February/ 2012)

Route of administration:

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

Test substance and vehicle

Senkonrai Pattai Chooranam decoction is Brown in colour. In order to obtain and ensure the uniformity in drug distribution the drug is dissolved by normal saline.

Administration of doses

Senkonrai Pattai Chooranam decoction was suspended in normal saline, 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 5.0gms/day it was converted to animal dose (144mg) 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, surviving animals were weighed and sacrificed.

Results:

Senkonrai Pattai Chooranam decoction the dose 144mg/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.