A CLINICAL STUDY ON

PITHA PERUMBADU (MENORRHAGIA)

WITH EVALUATION OF SIDDHA DRUG

NAAVAL NEI

The dissertation submitted by

Dr.S. JAYAPRIYA (Reg. No. 321411104)

Under the Guidance of

Prof. Dr. K. KANAKAVALLI, M.D(S)

Submitted to

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

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

SIDDHA MARUTHUVA PERARIGNAR

DOCTOR OF MEDICINE (SIDDHA)

BRANCH I – MARUTHUVAM

POST GRADUATE DEPARTMENT OF MARUTHUVAM

THE GOVERNMENT SIDDHA MEDICAL COLLEGE

CHENNAI – 106

OCTOBER – 2017

CERTIFICATE

This is certify that the dissertation entitled "**A CLINICAL STUDY ON PITHA PERUMBADU"** is a bonafide work done by **Dr. S. JAYAPRIYA** Government Siddha Medical College, Chennai – 600106 in partial fulfilment of the University rules and regulations for award of **SIDDHA MARUTHUVA PERARIGNAR** under my guidance and supetvision during the academic year 2014 -2017.

Name & Signature of the Guide

Name & Signature of the HOD

Name & Signature of the Principal

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CONTENTS

INTRODUCTION

Siddha maruthuvam is one of the oldest Medicine System in the world which is still extant, particularly in Tamilnadu. It is at least 5000 years old. Siddha system is a traditional medicine system of southern India,mainly in Tamilnadu. It was founded and profounded by Siddhars who were yogis, philosophers, physicians, spiritual seers, scientists, poets. Traditionally it is taught that Siddhars laid the foundation for this system of medication. Siddhars were spiritual adepts who possessed the ashta Siddhis, or the eight supernatural powers. Agasthiyar is considered the first Siddha and guru of all Siddhars.

Siddha system of medicine cannot be called complementary or alternative medicine system, as many of the medical approaches and treatment are far beyond current scientific standards, so it is apt to be called as Traditional or conventional medical system of Tamilnadu. Traditionally through Guru – Sishya priniciple, the Siddha medicine was learnt and passed through generations.

Siddha system doesn't consider treatment and prevention separately. The main aim of this system is prevention of disease, as it is well said that "Prevention is better than cure". Siddha system emphasizes not only a healthy body but also a peaceful mind. Hence, it is unique when compared to other medical system.

In Tamil, Siddhi means "one who is accomplished''. It refers to perfected masters who have achieved a high degree of physical as well as spiritual perfection or enlightment. Siddha medicines are, not merely compounding mixtures of poly-herbals or herbo-minerals, pills, plasters, etc, But a multi disciplinary system which comprises knowledge from various subjects like chemistry, astrology, cosmology, physics, psychology, spirituality, philosophies, botany, etc. For a Medicine to be affective, the inorganic substances have to be brought to their atomic form. Siddhars developed the Knowledge of bringing inorganic substances into atomic and ionic form which is easily absorbed by the system.

According to the Siddha system, the individual is a microcosm of the universe. The human consists of five primordial elements-earth, water, fire, air and space, the three humours-vatha, pitha and kapha and seven physical constituents. Food is the basic building material of the human body and gets processed into humours, tissues and

wastes. The equilibrium of humours is considered as health and its disturbance or imbalance leads to diseased state.

The concept of Siddha for diagnosis is to investigate the cause of the disease, the signs and symptoms, complication if any, and pathological tissue changes. The Siddhars look at body and disease together to arrive at a conclusion regarding the condition or diagnosis of the patient. This condition is an essential pre-requisite for treatment.

Siddhars classified 4448 diseases in humans. Among them,the diseases of the women pertaining to the reproductive organs are also explained. PERUMBADU ROGAM which was explained by the great saint YUGIMUNI in his text VAITHYA CHINTHAMANI is one of the important gynaecological the problems that clinically correlate with MENORRHAGIA in modern system of medicine.An healthy women only can produce a healthy generation. Being a women, I prefer to take PITHA PERUMBADU (Menorrhagia) as my dissertation which is a main gynaecological problem nowadays and also to give a solution through our Siddha system of medicine.

The WHO reports that 18 million women aged 30-55 years perceive their menstrual bleeding to be exorbitant. Reports show that only 10% of these women experience blood loss severe enough to cause anaemia or be clinically defined as Menorrhagia[(1)].

Menorrhagia is the most common type of abnormal uterine bleeding characterized by heavy & prolonged menstrual bleeding without any change in cycle length[(2)]. The symptoms of menorrhagia are well correlated with YUGI'S PITHA PERUMBADU.

Menorrhagia affects 30% of women in reproductive age[(3)]. Annually approximately 5% of women seek medical care for excessive menstrual bleeding[(4)]. 50% of cases were diagnosed as DYSFUNCTIONAL UTERINE BLEEDING[(3)(4)].

Totally 30% of world wide population having heavy menstrual blood loss. In India, about 20% of DUB cases are seen among adolescent girls and 40% of cases among women above 40 years of age[(5)].

In modern system of medicine, as the treatment is not as much effective and most probably hysterectomy is the solution, I had selected NAAVAL NEI a Poly herbal formulation from AATHMARATCHAMIRTHA VAITHIYASAARA SANGIRAGAM[6], to give best solution for Perumbadu.

Siddha system of medicine has a enormous pharmacopoeia containing plants, animal and mineral products and treatment techniques consisting in use of 32 types of internal medicines and 32 types of external medicines. In that, NEI is one of the internal medicine.

NEI(MEDICATED GHEE) is prepared by adding Cow ghee to certain individual leaf juices, decoctions of herbs or tubers and boil till the raw drugs completely mix with the ghee. Then it can be filtered and preserved.

AIM AND OBJECTIVES

AIM:

The aim of the dissertation study is to analyse the selected disease **PITHA PERUMBADU**, both clinically and experimentally with the trial drug **NAAVAL NEI.**

OBJECTIVES:

To evaluate the therapeutic efficacy of **NAAVAL NEI** in **PITHA PERUMBADU (MENORRHAGIA)**.

- To collect the literature of both siddha and modern aspects of the disease **Pitha Perumbadu.**
- To study the clinical course of the disease with observation on the etiology, classification, pathology, differential diagnosis, prognosis, complications and treatment by siddha aspect.
- To have an idea about the incidence of the disease with age, occupation, economical status, habits, family history and climate conditions.
- To expose the clinical diagnostic methods mentioned by Siddhars to know

  how the disease manifest due to the deranged mukkutram, pori pulangal and ezhu udal thathukkal.
- To have detailed clinical investigations.
- To have the modern parameters to confirm the diagnosis and prognosis of the disease
- To have a clinical trial on the disease **Pitha Perumbadu** with the siddha drug **NAAVAL NEI**.
- To evaluate the drug **NAAVAL NEI**
  - Bio-Chemical Analysis (Qualitative and Quantitative)
  - Toxicological Analysis (Acute and Sub-acute) under OECD Guidelines
  - Pharmacological Study (Styptic activity in Wistar albino rat model)
  - Statistical Analysis.

REVIEW OF LITERATURE

SIDDHA ASPECT

பெரும்பாடு

IYAL (DEFINITION)

மாதவிடாய் ஒழுக்கு புணர்ச்சியினால் அக்கினி மீறி வெட்டையுண்டாகி அதிகரித்து உடம்பில் தாதுக்கள் பலங்குன்றி, கருப்பை தாதுக்களும் பலவீனப்பட்டு, கருக்குழியில் இரத்தம் அதிகமாகச் சேர்ந்து புண்ணாகி யோனியின் வழியாய் இரத்தம் செவ்விளநீர் போல் ஒழுகிக் கொண்டே இருக்கும். இதுவே பெரும்பாடு எனப்படும்[7].

According to T.V.Sambasivam Pillai in his dictionary,

Perumbadu is defined as the excessive loss of menstrual bleeding which may be increased in duration of menstrual bleeding or heavier blood flow without any change in the cycle length.

NOI VARUM VAZHI (AETIOLOGY)

“கருதியே கனமான கொடுமை செய்து
கணவனையே நிந்தனைதான் சொன்ன பேரும்
பருதியின்முன் மலசலத்தை விட்ட பேரும்
பரதேசியே ழைகளைப் பழிக்கின்றோர்க்கும்
குருதியே யிரைக்கின்ற காலந் தன்னில்
கூசாமல் புருஷசங்கை பண்ணினோர்க்கும்
கருதியே பரயோகம் விரும்பி னோர்க்கும்
சுருக்கிலே பெரும்பா டுற்பவிக்குந் தாமே
தானென்ற காரணிகள் மிகுக்கை யாலும்
சண்டாளக் கோபத்தின் சலிப்பினாலும்
ஊனென்ற மாமிசங்கள் பொசித்த லாலும்
உறக்கமின்றி விழித்தலா லூழித் தீயால்

பானென்ற பசியின்றிப் பொசிக்கை யாலும்

பாரமாஞ் சுமைவாங்கல் பகலுறக்கம்

கூனென்ற குறுக்கலாம் முடக்கித் தூங்கல்

குரூரமாம் பெரும்பாடு கொட்டுந்தானே''

-Yugi vaithiya chinthamani 800[8]

- ❖ Women those who abuse or show severe cruel activity to her husband.
- ❖ Women who void urine and faeces in front of sun.
- ❖ Women who criticize sages and poor people.
- ❖ Women who have sexual intercourse at the time of menstruation.
- ❖ Women who indulge in excessive sexual intercourse.
- ❖ Women with vigorous anger.
- ❖ Women often taking non-vegetarian foods.
- ❖ Sleeplessness without rest.
- ❖ Taking food without appetite.
- ❖ Lifting heavy loads.
- ❖ Daytime sleep.
- ❖ Sleeping in flexed position.

These conditions will cause the disease, Perumbadu Rogam.

In **Mega noi, Soothaga Nool and Arivaiyar Chinthamani,**

“கண்டாயோ பெரும்பாடு கலந்த மார்க்கம்

கருதிக் கேள் மின்னாளே நன்றாய் இன்னும்

கொண்ட படிகாரமுள்ள வகைகள் தின்றால்

விண்டாலும் வாய்வு அது மிஞ்சினாலும்

விளங்கும் மாமிசம் அதிகம் புசித்ததாலும்

உண்டாலும் மந்தமதில் புசித்ததாலும்

உறக்கமது ஒழிந்த விதத்தாலும்.

ஆகுமே கடும் சுமைடெடுப்பதாலும்

கதிப்பாக பகலுறக்கம் பகல் சம்போகம்

பாகு பெற குறுக்கதுதான் கூனிக் கொண்டு

பண்பாகவே உறங்கும் தன்மையாலும்

வாகு பெறவே அதிக புணர்ச்சியாலும்

வலுவாக மேகமது உற்பவித்து

தாகமுற சூடெழும்பி தளவாய் நீறி

தனி வயறும் கருக்குழியும் புண்ணுண்டாமே”

-Mega noi, Soothaga Nool and Arivaiyar Chinthamani[9]

- ❖ Excessive intake of spicy foods.
- ❖ Increase of vatha during menstrual period.
- ❖ Increased intake of non-vegetarian foods.
- ❖ Intake of food during indigestion.
- ❖ Loss of sleep.
- ❖ Taking heavy weights.
- ❖ Daytime sleep.
- ❖ During daytime sexual act
- ❖ Sleeping in flexed and improper posture.
- ❖ Increased sexual intellectual.

In **Agathiyar Gunavagadam,**

“பாரே நீ பெரும்பாடு வரும் வகையைக் கேளாய்

பக்குவமாய் வருகின்ற கண்டமாலை

ஊரே நீ மூத்திர குண்டிக்காயின் ரோகம்

உத்தமனே பீலிகா ரோகந் தானும்

தேரே நீ நாட்பட்ட பாண்டு ரோகம்

தெளிவாக இரத்தரோகம் தன்னா லையா

சீரே நீ சினைப்பைக்கும் கருப்பைக்கு மப்பா

சிறப்பாக அதிகரத்த மேறுங்கானே.

காணுவாய் சூதகம் வெளியாகுமப்பா

கருப்பைதான் அழலைகொண்டு போவ தாலே

பூணுவாய் சம்போக மதிகத்தா லும்
பொல்லாத புத்துகளாற் கட்டியா லும்
பேணுவாய் பெரும்பா டுண்டா மென்று
பெலமாக தீதான் சொல்லுவாய் உலகத்தோர்க்கு
காணுவாய் அப்போது கருப்பை நின்று
கருவான ரத்தத்தான் வருகுந்தானே”

-Agathiyar Gunavagadam(10)

Perumbadu occurs in association with the following diseases:

- Tubercular Adenitis.
- Renal diseases.
- Diseases of Spleen.
- Chronic Anaemia.
- Pelvic Inflammatory Diseases.
- Uterine Congestion.
- Excessive coitus.
- Benign and Malignant Tumours.

In **Aaviyalikum Amuthamurai Churukkam**,

“பார்த்திடவே மங்கையர்க் கிரத்த சூலை
பகருகிறே னடிவயிற்றில் பற்றி நிற்கும்
கோர்த்திடவே உதிரமது திரண்டு மேதான்
கொதிப்பெடுத்து மாதவிடாய்க் காலந் தன்னில்
சேர்த்திடவே சூதகமும் மிகுந்து காணும்
சிறுவழியாய்க் கருவழியும் புறண்டு ளைக்கும்
ஏர்த்துடனே தொடையிடுப்பு உளைச்ச லாகும்
இரத்தசூலைக் குணமிதுவே பாரு பாரே”

-Aaviyalikum Amuthamurai Churukkam(11)

- Heavy menstrual bleeding
- Mild abdominal pain

- Pain in thighs and hip region.

In **T.V.SAMBASIVAM PILLAI[12],**

- Perumbadu is an immoderate secretion of the menstrual discharge.

  Uterine blood vessels lose their strength, muscle fibres get congested leading to menorrhagia.

In **MAGALIR MARUTHUVAM[13],** had listed the aetiological factors of Perumbadu

- Tumours in uterus.
- Salphingitis and Oophoritis.
- Sepsis of Pelvic tumour.
- Early stages of Tuberculosis.
- Hormonal imbalance especially Hypothyroidism.
- Endometrial Tuberculosis.
- Peri-menopausal stage.
- Cardiac diseases.
- Psychological reasons.
- Family problems.

In **ANUBHOGA VAIDHYA DEVA RAGASIYAM-shthiriroga nithanamum, sigichchaiyum Part-II [14],** the aetiological factors of Perumbadu are:

- Intake of food which increases body heat.
- Excessive intake of food.
- Indigestion.
- Uterine congestion.
- Excessive coitus.
- Climbing hills.
- Excess walking and excess sleep.
- Fasting.
- Loss of body weight.
- Lifting heavy weights
- Injury by sticks and rods
- Daytime sleep.

சூதகம் உண்டாகும் விதம்

“திங்களுறு மங்கையர்கள் கெற்பாசயமதை
தாங்கியிரு சிவிகையுண்டு
சிவிகையிரு பக்கமும் வீசியே
நிற்குமதினின்றொரு குழல் நரம்பு
பங்கமறவேயெழும் அடிவயிறு யோனியும்
சுற்றிப் பிணைந்து கொண்டு
பகருமதிலொரு முனை இரத்தாசயமதைக்
கவ்விக் குவிந்திருக்கும்

இங்கிதமதாகவே மறுமுனையது
அரிவையர் கெற்பாசயம் புகுந்து
இனிதாயரவினுட வாயளவாகவே
மூவிரலசைந்து நிற்கும்
மங்களமதாயிந்த நாதக்குழல்
வழி ரத்தாசயத்தினின்று
மறுவகலவே காரிரத்தம் சுரந்தினி
கெற்பாசயததிலே தான்

நிதமுமிது தவறாது ஒரே துளிவிழும்
ஆறஞ்சதாம் நாளிலே
நேசமொரு குழல்வழி உருகியது வெளியிலே
பாயுமது யோனி வழியாய்
பதமாகவே சுகதேகியதுவாகிலொ
பூத்த முதல் மூன்று நாளும்
பகருதினி மோராற் கழஞ்சு நிறை பாயுமே
மேகமதினால் சூட்டினால்
இதமான வாயுவால் கிருமியின் ஏதுவால்

பூத்த பின் கணவனோடே
சேருவதினாலேயும் கடுநடைகளாலினி
சுமடு வெயில் தாக்குவதினால்
விதமான நாதமது கூடும் குறைந்திடும்
கெற்பமில்லாமலாகும்
விள்ளுமோராறு வகை வாயுவது
துதித்திடும் கேளு நீ ஒவ்வொன்றாய்

-Arivaiyar chinthamani[15]

PERUMBADU – CLINICAL FEATURES

In **Mega noi, Soothaga Nool and Arivaiyar Chinthamani**,

"கையுடன் காலுங் காந்துங் காத்திர முலர்ந்து வற்று
மையலாங் கலவி தன்னை மறுத்திடுங் கர்ப்பங் கேடாஞ்
செய்யநீர் போலுஞ் சற்றே சிவந்திடும் குருதிபோலும்
பெய்யுமே யாகில் மானே! பெரும்பாடென்றறிகுவீரே"

-Mega noi, Soothaga Nool and Arivaiyar Chinthamani[16]

- Burning sensation of upper and lower limbs
- Emaciation of body
- Loss of libido
- Failure to conceive
- Watery or reddish vaginal discharge

In **Agathiyar Gunavagadam 2000**-2**nd Part,**

"இரத்த மொருக்கால் தகையாமல் லெனவே யோடுபோல் வீழுந்
திருக்கும் சிரத்தில் கனப்புமுண்டாகும் திதமாய் சிதகிறே விழரத்தம்
சாத்த ரத்த ரோகமெனச் சொல்லும் நல்ல வல்லரே"

-Agathiyar Gunavagadam 2000[17]

- Excessive bleeding with clots
- Head ache
- Scattered blood

In **Mega noi, Soothaga Nool and Arivaiyar Chinthamani,**

"வெளிவாக இரத்த சூலை சொல்லக் கேளு
விரைவாக அடிவயிற்றில் இரத்தம் கெட்டி
தெளிவாக பூக்குமந்த காலம் தன்னில்
திட்டமாய் இரத்தமது அதிகம் பாயும்
களிவாக வயறதனில் நோவுண்டாகும்
கருவழிக்கும் வயறுபிரட்டும் கன நோவாகும்
அளிவாக இடுப்பு துடை அயர்ந்து போகும்
அறிகுவாய் இரத்த சூலையென்று செப்பே"

- Mega noi, Soothaga Nool and Arivaiyar Chinthamani [(18)]

- Excessive menstruation
- Lower abdominal pain
- Pain in thighs and hip region.

NOI ENN (CLASSIFICATION)

In **Yugi vaithiya chinthamani,**

"உரை செய்த பெரும்பாடு நால தாகும்
உகந்துமே வாதத்தின் சிராவ மொன்று
புரை செய்த பித்தத்தின் சிராவ மொன்று
பேரான சேட்டுமத்தின் சிராவ மொன்று
துரை செய்த தொந்தமாஞ் சிராவ மொன்று
துகையெல்லாம் நாவிதச் சிராவ மாச்சு"

-Yugi vaithiya chinthamani[(19)]

Perumbadu is of 4 types name types

- VATHA PERUMBADU
- PITHA PERUMBADU
- KABHA PERUMBADU
- THRITHOSA PERUMBADU.

CLASSIFICATION OF PERUMBADU

In **Yugi Vaithiya Chinthamani,**

PITHA PERUMBADU

"ஆமென்ற வன்னத்தை இறங்கொட் டாது
அழுகின்ற மஞ்சள் நிறம் போல ஊற்றும்
வேமென்ற யோனியிலே வேக்கா டுண்டாம்
மேனியுமோ வெளுத்துமே ரத்தம் போகும்
காமென்ற கால்கையு மழற்ற லாகும்
கருகலாய்க் கட்டிபோ லுதிரம் வீழும்
தேமென்ற சிறுகடுப்பா மங்க மெல்லாம்
சீரிய தோர் பித்தத்தின் சிராவ மாமே"

-**Yugi Vaithiya Chinthamani**[20]

- Loss of appetite
- Menstrual bleeding with slight yellowish color tinch.
- Soreness of vagina
- Pale color of the body.
- General weakness of Limbs
- Menstrual bleeding with Black coloured blood clots
- Pain in the body

In **Mega noi, Soothaga Nool and Arivaiyar Chinthamani,**

PITHA PERUMBADU

"சொல்லுவேன் பித்தத்தின் பெரும்பாடென்றால்
சுடும் மஞ்சள் நிறம் ரெத்தம் வெறுக்கும் அன்னம்
சல்லியமாய் யோனியது வெந்து நீறும்
சாவாக உடல் வெளுக்கும் ரத்தம் வற்றும்
மெல்லவே கால் கையும் காந்தலுண்டாம்
மெய்யுருகி கட்டியதாய் இரத்தம் போகும்
இல்லையினி தேகமது உளையும் சற்று
இது பித்த பெரும்பாடென்று உரைக்கலாமே"

-**Mega noi, Soothaga Nool and Arivaiyar Chinthamani**[21]

- ❖ Pale coloured menstrual bleeding with yellowish tinch.
- ❖ Aversion on food
- ❖ Burning sensation on vagina
- ❖ Pale color of the skin due to decreased haemoglobin
- ❖ Burning sensation on palms and soles
- ❖ Menstrual bleeding with clots
- ❖ Pain all over the body.

CLASSIFICATION OF OTHER PERUMBADU TYPES

In **Yugi Vaithiya Chinthamani,**

VATHA PERUMBADU

"கூடுமே தலைவலியு மேற்க டுப்பும்
கூறான முதுகிடுப்புக். குடைச்ச லுண்டாம்
வாடுமே தேகமெலாங் கருக்க லாகும்
மாதவிடாய் கரித்துமே மைந்தன் போலாம்
ஊடுமே வயிறூதி உளைச்ச லாகி
ஊற்றுமே செந் நிறமுங் கருக லாகத்
தேடுமே துற்கந்தஞ் சேர வொட்டா
செகமறிய வாதத்தின் சிராவ மாமே"

-Yugi Vaithiya Chinthamani(22)

- ❖ Head ache
- ❖ Pain in back and hip region
- ❖ Abdominal distension
- ❖ Body pain
- ❖ Dark coloured menstruation bleeding.
- ❖ Menstrual bleeding with foul smell.

KABHA PERUMBADU

"ஆகுமே வெள்ளை நிறமாக ஊற்றும்

அலியான நாற்றந்தான் மிகவுண் டாகும்
வேகுமே வுடம்பெங்கும் விபூதி பூக்கும்
வெந்தழலா யுடம்பெங்கும் எரிச்ச லாகும்
பாகுமே படபடப்பு மூச்சு முண்டாகும்
பாரமாங் கோழையொடு மயக்க மாகும்
தேகுமே யடிக்கடிக்கு மயக்க மாகும்
சேட்டுமத்தின் சிராவ மென்றே செப்பாமே"

-Yugi Vaithiya Chinthamani[23]

- Pale coloured menstrual bleeding
- Foul smell menstruation bleeding.
- Salty appearance on the body.
- Burning sensation on all over the body
- Palpitation
- Cough with fatigue.

THRITHOSHA PERUMBADU

"செப்பவே கருகல்லாய்ச் சிவப்பு மாகும்
சேர்ந்ததிலே கட்டியாய்க் கருப்பாய் வீழும்
உப்பவே வயிறது முல்லைச்ச லாகும்
ஊசலா நாற்றமுட னொழுக்க மாகும்
நம்பவே மஞ்சள் நிற நயப்பு மாகும்
நாணியே தலைதானு நடுக்க லாகும்
துப்பவே வாய் நீரு மிகவே வூற்றும்
தொந்தமாம் பெரும்பாடு சூட்டினோமே"

-Yugi Vaithiya Chinthamani[24]

- Dark brown coloured menstrual bleeding with clots.
- Abdominal distension with pain.
- Menstrual bleeding with foul smell.
- Tremors of the head.
- Increased salivation.

In **Mega noi, Soothaga Nool and Arivaiyar Chinthamani,**

VATHA PERUMBADU

"பாடாமல் வாதத்தின் பெரும்பாடுற்றால்
பண்பாக தலைவலிக்கும் தேகம் நோகும்
நாடாமல் முதுகொடு இடுப்பு தானும்
நொந்து மிக வருத்தமிகும் உளைவுண்டாகும்
கூடாகவுடல் மெலியும் கருகும் தேகம்
கொள்ளும் மாதவிடாய் காலம் வயறு நோகும்
ஊடாகவே உருளும் குழந்தை போலே
உறு பெருமல் செந்நிறமாய் இரத்தம் நாறும்"

-Mega noi, Soothaga Nool and Arivaiyar Chinthamani[25]

- Head ache
- Pain all over the body
- Pain in the back and hip region.
- Loss of weight
- Lower abdomen pain during menstruation
- Dark red coloured menstrual bleeding with foul smell.

KABHA PERUMBADU

"போமே சேர்ப்பனத்தின் பெரும்பாடென்றால்
பொருந்து வெள்ளை நிறமாக ரத்தம் விழும்
வாகுபெறவே நாறும் தேகம் தானும்
வளர் நீறும் போலெரியும் அழலும் தேகம்
தாகமுறும் படபடத்து மூச்சு வாங்கும்
தனித்த கபமிருமலொடு வேவுண்டாகும்
பாகுபெற அடிக்கடி மயக்கமுண்டாகும்
பகருவேன் சேர்ப்பனத்தின் பெரும் பாடென்றே"

-Mega noi, Soothaga Nool and Arivaiyar Chinthamani[26]

- Pale coloured menstrual bleeding
- Menstruation with foul smell

- ❖ Buring sensation on whole body
- ❖ Increased thirst
- ❖ Palpitation
- ❖ Dyspnoea
- ❖ Cough
- ❖ Fatigue.

THRITHOSHA PERUMBADU

"உண்டான திரிதோஷ பெரும்பாடென்றால்
உள்ளபடி கல்லுப் போல் கட்டியாகும்
விண்டு கறுப்ப்பாய் சிகப்பாய் மஞ்சள் போலும்
விதம் விதமாய் இரத்தமது நிறம் மாறிப் போம்
கண்டாலும் வயறுளையும் நாற்றம் மீறும்
கடிதான தலை நடுக்கம் வாய் நீரூறும்
மிண்டாத திரிதோஷ பெரும்பாடின்
மிகு பெருமையுள்ளபடி செப்பினேனே"

-Mega noi, Soothaga Nool and Arivaiyar Chinthamani[(27)]

- ❖ Black , red or yellow coloured menstrual bleeding.
- ❖ Abdominal distension.
- ❖ Foul smell bleeding
- ❖ Tremors of the head.
- ❖ Increased salivation.

சாத்தியம் மற்றும் அசாத்தியம்

In **Yugi Vaithiya Chinthamani,**

"சூடியதோ ரசாத்தியத்தைச் சொல்லக் கேளாய்
சொல்லும்சேட்ப பெரும்பாடு தொந்தசசி ராவம்
பூட்டினதோ ரிரண்டும் பிழைக் கொட் டாது
புகழான சாத்தியத்தை விளம்பக் கேளாய்
வாட்டினதோர் வாதத்தின் பெரும்பா டோடு

வகையான பித்தத்தின் சிராவந்த் தானும்
தீட்டினதோர் மருந்துக்குச் செயமு மாகும்
செப்பினதோர் நன்னூலைத் தெளிந்து பாரே”

-Yugi Vaithiya Chinthamani[28]

- ❖ Vatha perumbadu and pitha perumbadu were curable.
- ❖ Kabha perumbadu and thrithosha perumbadu were non-curable.

In **Mega noi, Soothaga Nool and Arivaiyar Chinthamani,**

“சாற்றுவேன் வாதத்தின் பெரும்பாடொன்று
சலியாமல் பித்த பெரும்பாடு தானும்
போற்றியதோர் சேர்ப்ப பெரும்பாடொன்று
பொருந்து திரிதோஷ பெரும்பாடு நாலாம்
ஆற்றியதோர் வாத பெரும் பாடினோடு
அதிகமாய் பித்த பெரும்பாடு தீரும்
மாற்றியதோர் சேர்ப்ப பெரும் பாடினோடு
மருவு திரிதோஷ பெரும்பாடு அசாத்தியம்”

-Mega noi, Soothaga Nool and Arivaiyar Chinthamani[29]

- ❖ Vatha perumbadu and pitha perumbadu were curable.
- ❖ Kabha perumbadu and thrithosha perumbadu were non-curable.

பெரும்பாட்டிலுண்டாம் தோடக்குறி குணங்கள்

“சையோக வெம்மை சார்ந்துமே வெட்டையாகும்
மெய்யாக விந்து வீழ்ந்திடம் வெந்து புண்ணாம்
மையூரும் கண்ணாட் காம்பெரும் பாடுதானும்
கொய்யூருங் குய்யங் கொப்பளிங் குங்குருதி.”

“தேகத்தூறு மனலும் தீதாமதி லெரிச்சல்
வேகப்பெரும்பாடு வெண்ணிறமாய்ப்—போகவதில்
நாற்றமேல் மூச்சு நவிலக்கப மயக்கம்

தோற்றவுடல் சாயுஞ் சொல்”

- Noi Naadal noi Mudal Nadal Part - I [30]

- ❖ Burning sensation on all over the body
- ❖ Pale coloured menstrual bleeding
- ❖ Foul smell menstruation
- ❖ Dyspnoea
- ❖ Cough
- ❖ Fatigue

MUKKUTTRA VERUPAADUGAL (PATHOLOGY)

According to Siddha system, Body is constituted by 96 thathuvaas. Normal structural and physiological state of the body is maintained by equilibrium with Mukkuttram and Seven Udarkattukal.

As the udarkattukal are affected by the extrinsic and intrinsic factors, there is deterioriation in the structural and functional status of the body. When the causative factor affects Udarkattukal and Mukkuttram, it results in incoordination of functions. Thereby the disease manifest and expose its clinical features.

In Perumbadu, the clinical condition is due to the imbalance of **PITHAM.** Pitham is deranged primarily and later it deranges vatha and the derangement of Pitha-vatha leads to the derangement of Abanaan which in turn cause the disease. The pathogenesis of the disease depends upon the affected Pitha and Vatha.

DIAGNOSIS OF PERUMBADU BASED ON SIDDHA SYSTEM :

According to Siddha System the diagnosis of a disease is reached by the method

ENVAGAI THERVU OR PINIARIMURAIMAI.

The disease Perumbadu Rogam was diagnosed by the following methods:

- ❖ Poriayaal arithal
- ❖ Pulanaal arithal
- ❖ Vinaathal
- ❖ Uyir thathukkal
- ❖ Udal thathukkal
- ❖ Envagai thaervu.

PORIYAAL ARITHAL – Porigal-5 organs of perception

- Nose
- Tongue
- Eye
- Skin
- Ear

PULANAAL ARITHAL – functional units of porigal

- Odour (smell)
- Taste
- Vision
- Touch (tactile)
- Sound (hearing)

VINAATHAL

Patient name, age, occupation, native place, socio-economic status, family history, diet habits prone for any allergens, period of suffering, history of previous episode, history of treatment, habits etc are noted through interrogation.

UYIRTHATHUKKAL

Panchaboothams are manifested in the body as three vital forces.

- Vaatham
- Pittham
- Kabham

VAATHAM

It is the combination of vayu and aakasha boothams. It is responsible for all the movements of the body. It helps in the uniform functioning of 7 Udalthathukkal.

The sites of vaatham:

Umbilicus, rectum, faecal matters, abdomen, anus, bones, hip joint, naval, plexus, joints, hair follicles and muscles.

Vaatham has ten types :

1. **Praanan** (Uyirkaal) :

   This controls knowledge, mind and five sense organs, which are useful for breathing and digestion.

2. **Abaanan** (Keezh nokku kaal) :

   This is responsible for all downward movements such as passing urine, stools, semen, menstrual flow etc.

3. **Samaanan** (Nadukkaal) :

   This aids in proper digestion.

4. **Viyaanan** (Paravukaal).

   This is responsible for all movements of all parts of the body.

5. **Uthaanan** (Mael Nokkukaal)

   Responsible of all upward visceral movements, such as vomiting, nausea and cough.

6. **Naagan** :

   Responsible for opening and closing the eyes.

7. **Koorman** :

   Responsible for vision and yawning.

8. **Kirukaran** :

   Responsible for salivation, nasal secretion and appetite.

9. **Devathatthan** :

   Resposible for Laziness, sleeping and anger.

10. **Thananjeyan** :

    Produces bloating of the body after death. It escapes on the third day after death bursting out of the cranium.

In Perumbadu Rogam

Pranan - Affected because of breathlessness and dyspnoea due to low Hb.

Abanan - Affected because of excessive and prolonged menstrual bleeding.

Samaanan - Affected because of loss of appetite.

Viyaanan - Affected because of lower abdominal pain, low back ache and body pain

Uthanan - Not affected

Naagan - Not affected

Koorman - Not affected.

Kirukaran - Not affected

Devathattan - Not affected

Thananjeyan - Not affected

PITTHAM

It is the life manifestations of 'THEE' bootham in the body. It is the metabolic thermal life force of the body. It carries out digestion, absorption, metabolism, colouring of blood etc.

The sites of Pittham:

Praana vaayu, urinary bladder, moolaakkini, heart, umbilical region, abdomen, stomach, sweat, saliva, blood, eyes and skin.

Pitham has 5 types

1. Analagam : It promotes appetite and helps in digestion.

2. Ranjagam : It gives colour to the blood.

3. Praasagam : It gives complexion to the skin.

4. Aalosagam : It brightens the eyes.

5. Saadhagam : It controls the whole body. It has the property to fulfill all the activities which the mind desires.

In Perumbadu Rogam

Analagam - Affected because of loss of appetite.

Ranjaga Pitham - Affected because of low Hb level

Saadhaga Pitham - Affected because the person is unable to do her regular work properly

Alosaga Pitham - Not affected

Prasaaga Pitham - Affected because of the pale and dry skin.

KABHAM

It has Neer and Mann boothams. It is responsible for co-ordination and defence mechanisms of the body.

The sites of Kabham :

Samaana vaayu, semen, suzhumunai, blood, phlegm, bone marrow, nose, chest, nerve, bone, brain, eyes and joints.

Kabham has 5 types

1. **Avalambagam** : Lies in the lungs, controls the heart and other kabhams.

2. Kilethagam : Lies in the stomach, makes the food moist, soft and helps in digestion.

3.**Pothagam** : Responsible for identifying taste.

4.Tharpagam : Present in the head and responsible for the coolness of both eyes.

5. **Santhigam** : Responsible for lubrication and free movements of joints. It is situated in the joints.

In Perumbadu Rogam

Avalambagam - Affected because of low Hb level.

Kilethagam - Affected because of loss of appetite.

Pothagam - Not affected

Tharpagam - Not affected

Santhigam - Affected because of pain in joints.

EZHU UDAL THATHUKKAL

Normal functions

Saaram

It gives the good spirit to body and mind.

Senneer

Blood imparts colour to the body and nourishes the muscle responsible for the ability, intellect of the individual.

Oon

It gives shape to the body according to the requirements for the physical activity,

nourishes bone.

Kozhuppu

It helps in lubrication of different organs.

Enbu

Supports and responsible for posture and movements of the body.

Moolai

It fills the bony cavity and gives nourishment.

Suronitham

It is responsible for the reproduction.

In Perumbadu Rogam

Saaram : Affected due to loss of appetite and Tiredness.

Senneer **:** Affected due to pallor of the skin and low Hb levels.

Oon : Not Affected

Kozhuppu : Not Affected

Enbu **:** Not Affected

Moolai : Not Affected

Suronitham : Affected due to excessive or prolonged menstruation.

ENVAGAI THERVU

"மெய்க்குறி நிறந்தொனி விழிநாவிருமலம் கைக்குறி"

-Noi Naadal Noi Mudal Nadal Part – I[31]

Envagai thervugal can be done by the following,

Naa

Niram

Mozhi

Vizhi

Malam

Moothiram

Naadi

Sparisam

NAA (Tongue)

Colour

Coated

Taste

Dryness

Ulceration

In Perumbadu Rogam ,tongue is not affected but non-specific and unrelated symptoms such as dryness ,coating and ulceration may be seen in some cases.

NIRAM (Colour)

Skin Colour

In Perumbadu Rogam,Paleness of skin was noted in most of the cases.

MOZHI (Voice)

Articulation or speech

In Perumbadu Rogam,low pitched voice was seen due to severe pain in lower abdomen.

VIZHI (Eyes)

Niram (Pallor, icterus)

In Perumbadu Rogam,pallor was seen in most of the cases but no other abnormality was seen.

MALAM (Motion)

Niram - Colour
Irugal, Ilagal - Consistency
Manam - Odour

In Perumbadu Rogam,constipation may be seen in some cases.

MOOTHIRAM (Urine)

The urine of the patient was collected are tested for Neerkuri and Neikuri.

Collection of urine for testing:

“அருந்துமாறிரதமும் அவிரோதமதாய்

அஃகல் அலர்தல் அகாலவூன் தவிர்ந்தழற்

குற்றளவருந்தி உறங்கி வைகறை

ஆடிக்கலசத் தாவியே காது பெய்

தொருமுகூர்த்தக் கலைக்குட்படு நீரின்

நிறக்குறி நெய்க்குறி நிருமித்தல் கடனே ”

-Noi Naadal Noi Mudal Nadal Part – I[32]

This stanza explains the rules for the collection of urine for Nirakuri and Neikuri.

NEERKURI

The collected urine should be noted for the following 5 characters,

Niram	-	Colour
Edai	-	Specific gravity
Nurai	-	Frothy
Manam	-	Odour
Enjal	-	Deposit

In Perumbadu the urine is clear without froth.

NEIKURI

“ நிறக்குறிக் குரைத்த நிருமாண நீரிற்
சிறக்க வெண்ணெய்யோர் சிறுதுளி நடுவிடுத்
தென்றுறத் திறந்தொலி ஏகாதமைத்ததி
நின்றதிவலை போம் நெறிவிழியறிவும்
சென்றது புகலுஞ் செய்தியை யுணரே ”

-Noi Naadal Noi Mudal Nadal Part – I[33]

This stanza describes the speciality of Neikuri.Of all diagnostic methods Neikuri reveals the true nature of the disease.

Snake like appearance - Vatham
Ring like appearance - Pitham
Pearl like appearance - Kabham

In Perumbadu when a drop of oil is put in the patient’s freshly collected urine the oil drop spreads like a snake which indicates Vatha neer.

NAADI(PULSE)

நாடி மூன்றையும் நாடிடுங் காலை
நடுவிரல் நாடியை நாடியே கணிப்பான்
நற்றவர்க்குருவென நவிலு மறையே

-Noi Naadal Noi Mudal Nadal Part – I[34]

ABNORMAL NAADI INDICATING PERUMBADU ROGAM

In perumbadu Rogam, Pitha naadi and vathathil ushna naadi was diagnosed

“உறுதியுள்ள பித்தமது தோன்றில் வெப்பு
உஷ்ணவாயு வத்திசுர மதிசா ரங்கள்
மறதியுடன் கிறுகிறுப்பு பயித்திய ரோகம்
வளர்சோகை யழலெரிவு காந்தல் கைப்பு
இருதயத்தில் கலக்கமது மறப்பு தாகம்
எழுங்கனவு மேயனைவு மயக்க மூர்ச்சை
சிறிதுபெரும் பாடுரத்தம் பிரமே கங்கள்
சேர்ந்துமிகு பிணிபலவுஞ் சிறக்குந் தானே ”

-Noi Naadal Noi Mudal Nadal Part – I[35]

“சிறப்பான வாதத்தி லுட்டிணந் தானே
சேர்ந்திடுகி லதிசார முளைச்சல் வாயு
உரைப்பான பொருமலொடு அக்கினி மந்தம்
உள்ளாகும் நீர்ச்சிறுப்பு பிரமே கங்கள்
பிறப்பாடு மதகரிநீர் கரப்பான் ரத்தம்
பிரமேகம் பெரும்பாடு புறநீர்க் கோவை
அறப்பான வாயுசூலை சேத்தும ரோகம்
ஆனபல பிணிகளுமே வந்தடருந் தானே ”[36]

-Noi Naadal Noi Mudal Nadal Part – I[36]

LINE OF TREATMENT

It is mentioned in the siddha system that treatment of disease should be in the basis of,

- KAAPU
- NEEKAM

- NIRAIVU

KAAPU

It is the method of preventing the disease.Prevention is better than cure. Sarabenthirar rules to be followed at the time of menstruation:

- Purgatives should be avoided
- Make-ups especially corryllium should be avoided
- Oil bath should be avoided
- Jumping,too much of crying, laughing and heavy works should be avoided.
- Sexual intercourse at the time of menstruation should be avoided.

NEEKAM

It is the method of eliminating the disease etiology.

For purgation:

Agasthiyar kuzhambu - 100mg with chukkukasayam should be administered as single dose at early morning before commencement of treatment.

Administration of trial drugs:

Naaval nei - 5 ml; thrice a day for one mandalam(48 days) after food during menstruation.

Pathiya pathartham:

Proper dietic regimen enhances the effect, bioavailability of the medicine and helps to maintain good health. This form of medical advice in Siddha is termed as Pathiyam. If Pathiyam is not followed properly, certain foods may become incompatible and antagonise the effect of medicine and produce harmful effects to the body.

Abathiya pathartham

“கொள்ளு காடி குமட்டிக்காய் பன்றி கொக்குடனே
முள்ளிற் பெரிய பாகற்காய் முதிரும் அவரை பயற்றங்கால்
பள்ளத் தெளுந்த மடற்சேம்பு படரும் வள்ளி பாலயிவை
எள்ளத் தனைதான் தின்பீரேல் எல்லா மருந்தும் இழந்தீரே”

-Pathartha Guna Chinthamani[37]

கொள்ளு, காடி, குமட்டிக்காய், பன்றி இறைச்சி, கொக்கு, பாகற்காய், அவரைகாய், உளுந்து, சேம்பு, எள்ளு முதலியவற்றை தவிர்க்க வேண்டும்.

Itchaa pathiyam

"கடுகு நற்றிலத் தெண்ணெய் கூழ்பாண்டங்கள் கடலை
வடுவ தாகிய தெங்குமா வருக்கை நற்காயம்
மடிவி லாதவெள் ளுள்ளி கொள்புகையிலை மதுபெண்
இடறு பாகலோ டகத்தி நீக்கிடலிச் சாபத்தியம்"

-Pathartha Guna Chinthamani[38]

கடுகு, நல்லெண்ணெய், கடலை, கூழ்பாண்டங்கள், தேங்காய், மா, பலா, பெருங்காயம், பூண்டு, கொள்ளு, புகையிலை, மது, பெண்போகம், பாகல், அகத்தி முதலியவற்றை தவிர்க்க வேண்டும்.

YOGASANA

Yoga helps us directly to hold physical forces in balance indirectly to develop mental and spiritual powers. Yoga practice tone up the pelvic organs and muscles and promote good circulation. Minor structural and functional defects of the body can be rectified by the systemic practice of Yogasanas and Pranayamas

Women should keep in mind that they should not do asanas during their monthly menstrual period.After the period ends, asanas can be practiced andit will give a lot of benefits.

The following aasanas are advised in menorrhagia:

- Trikonasana
- Vajrasana
- Halasana
- Patchimothasana
- Parvadhasana
- Garudasana
- Savasana
- Ardha chandrasana
- Uttanasana
- Baddhakonasana
- Sarvagasana[39]

Pranayamam - Abdominal breathing and Naadi shodhana

Precautions – Avoid strenuous and inverted postures while menstruating.

NIRAIVU (RESTORATION) :

LIFESTYLE MODIFICATION:

In "**THERAIYAR PINIANUGAAVITHI"** certain traditional principles of prevention are mentioned. In addition "**SARABENDHIRAR"** prescribes a few rules to be followed at the time of the menstruation.

DONT'S

- Avoid makeup
- Avoid anchanam for the eyes
- Avoid purgatives
- Avoid heavy works
- Avoid activities like jumping, too much of crying and laughing
- Avoid emotional stress
- Avoid tobacco chewing
- Avoid strong tea and coffee
- Avoid fast food and spicy items
- Avoid excess salt, spices, sweets and fat foodstuffs

DO'S

- Advice to take plenty of fibre rich foods like fruits, greens, nuts and leavy vegetables.
- Advice to take Iron enriched greens, vegetables and cereals. Iron containing vegetables and fruit supplementation (100mg/day) prevents anaemia.
- Vitamin C enriched diet which ensures Iron absorption and capillary constriction.
- Daily consumption of dates.
- Salt restricted diet.
- Reducing caffeine and sugar.
- **Hip bath –** Hot water hip bath as routine practice should be taken for 10mts.

- ❖ Gentle exercises such as deep breathing exercises, progressive muscle relaxation, range-of-motion exercises to keep the joints mobile and slow relaxed walking promotes good oxygenation and circulation and can even help to increase energy.
- ❖ Hygiene should be advised during menstruation.

Prevention of disease is also achieved by following proper diet and good habits. Proper diet not only means the intake of nutritious diet but also abstinence from edible substances which are injurious to health.

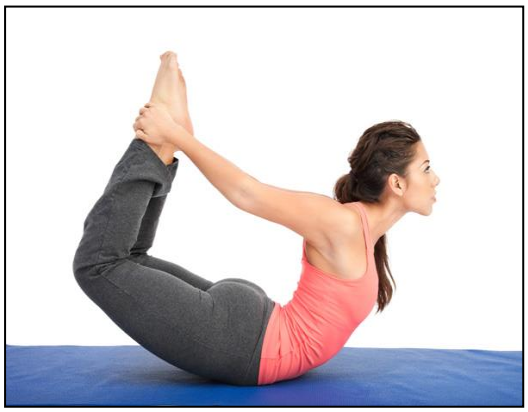
The line of treatment aims at bringing back the affected thaathus to normal by the administration of internal medicine **NAAVAL NEI**[40].

Finally, assurance of the patient gives her a moral boost thereby speeding up the recovery.

YOGASANA

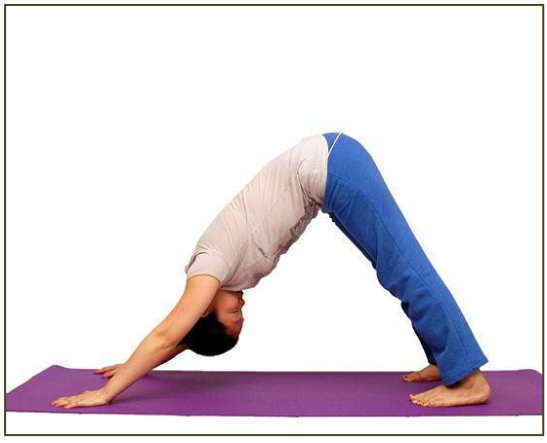
TRIKONASANA

VAJRASANA

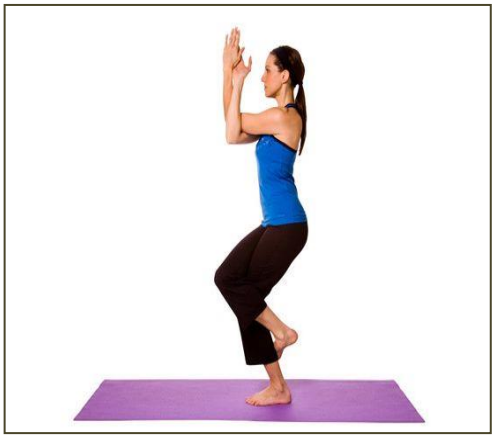


HALASANA

PATCHIMOTHASANA



PARVADHASANA



GARUDASANA

SAVASANA

ARDHA CHANDRASANA

UTTANASANA

BADDHAKONASANA

SARVAGASANA

PRANAYAMAM

MODERN ASPECT

FEMALE REPRODUCTIVE SYTEM

The female reproductive system consists of internal and external genitalia.The main functions of female reproductive system are

- Production of sex hormones
- Production of functioning gametes [ova]
- Support & protection of developing embryo

EXTERNAL GENITALIA

The external female genitalia are referred to as vulva. It consists of the following structures namely,

- Mons pubis
- Labia majora
- Labia minora
- Clitoris
- Opening of the urethra (Meatus)
- Hymen
- Perineum
- The vestibule is the space into which the vagina and urethra open. The urethra opens just anterior to the vagina.
- The vestibule is bordered by a pair of thin, longitudinal skin folds called

labia minora.

- Lateral to the labia minora two prominent rounded folds of skin called the

labia majora.

- The two labia majora unite anteriorly in an elevation of tissue over the pubic symphysis called the **mons pubis.** The lateral surface of the labia majora and the surface of the mons pubis are covered with coarse hair.
- The medial surface of the labia majora are covered with numerous sebaceous and sweat glands. The space between the labia majora is called the pudendal cleft.
- A small erectile structure is called the **clitoris** is located in the anterior margin of the vestibule. The two labia minora unite over the clitoris to form

a fold of skin called the prepuce[41].

- The **Perineum** is bounded above by the inferior surface of the pevic floor, below by the skin between the buttocks and thighs. Laterally by the ischiopubic rami, ischial tuberosities and sacrotuberous ligaments and posteriorly by the coccyx[42].

INTERNAL GENITALIA

The internal reproductive organs situated in the pelvis between the bladder and rectum. They are held in space within the pelvis by a group of ligaments. The internal genitalia includes

- VAGINA
- CERVIX
- UTERUS
- FALLOPIAN TUBES
- OVARIES

VAGINA

- The vagina is a muscular, hollow tube that extends from the vaginal opening to the cervix of the uterus. It also is known as the birth canal.
- It is a fibro muscular tube of about **10cm long.**
- It is female organ of copulation and allows menstrual flow and child birth.
- In young females it is covered by a thin mucous membrane called hymen[43].

CERVIX

- The cervix is the lower, narrow portion of the uterus where it joins with the top end of the vagina.
- During menstruation, the cervix stretches open slightly to allow the endometrium to be shed.
- During childbirth, contractions of the uterus will dilate the cervix up to 10 cm in diameter to allow the child to pass through[44].

UTERUS

- The uterus is a hollow, pear-shaped organ which is divided into parts namely Cervix, which is the lower part that opens into the vagina, and the main body of the uterus, called the corpus.

- The uterine wall is composed of **three layers,**
- Outer serous layer or **perimetrium,**
- Middle muscular layer or **myometrium,**
- Innermost **endometrium.**
- The endometrium consists of simple columnar epithelial cells with underlying connective tissue layer. The superficial part of endometrium is sloughed down during menstruation.

POSITION OF UTERUS

- Its normal position is anteversion and anteflexion. The uterus usually inclines to the right (dextrorotataion) so that the cervix is directed to the left (levorotation) and comes in close relation with the left ureter.

MEASUREMENT OF UTERUS

- The uterus measures about 8cm long, 5cm wide at the fundus and its walls are about 1.25cm thick. Its weight varies from 50-80 gm.

PARTS OF THE UTERUS

- Body or corpus
- Isthmus
- Cervix[45]

FALLOPIAN TUBES

- There are two uterine tubes also called **uterine tubes** or **oviducts.**
- One uterine tube is associated with each ovary.
- The uterine tubes extend from the ovaries to the uterus. They open pear the ovary to receive the oocyte and the opening is surrounded by long thin processes called fimbriae.
- As soon as oocyte is ovulated, it comes into contact with the surface of the fimbriae and the cilia on the fimbrial surface sweep the oocyte into the uterine tube.
- Fertilization usually occurs in the uterine tube near the ovary[46].

OVARIES

- The two ovaries are small oval shaped organs aattached to ligaments that suspend them in the pelvic cavity and from the ligament of the uterus.
- The suspensory ligament extends from each ovary to the lateral body wall and the ovarian ligament attaches the ovary to the uterus.

- ❖ A layer of visceral peritoneum called tunica albuginea covers the ovary.
- ❖ The outer cortex of the ovary is made up of dense connective tissue containing ovarian follicles.Each of the ovarian follicles contains an oocyte the female germ cell[47].

PHYSIOLOGY OF MENSTRUAL CYCLE

MENSTRUATION

DEFINITION

Menstruation is the visible manifestation of cyclic physiologic uterine bleeding due to shedding of the endometrium following invisible interplay of hormones mainly through hypothalamo-pituitary-ovarian axis.

For the menstruation to occur, the axis must be actively coordinated, endometrium must be responsive to the ovarian hormones (oestrogen and progesterone) and the outflow tract must be patent.

DURATION OF MENSTRUATION CYCLE

The period extending from the beginning of a period (mens) to the beginning of the next one is called menstrual cycle.

The first menstruation (menarche) occurs between 11-15 years with a mean of 13 years. It is more closely related to bone age than to chronological age. For the past couple of decades, the age of menarche is gradually declining with improvement of nutrition and environmental condition.

Once the menstruation starts, it continues cyclically at intervals of 21-35 days with a mean of 28 days. Physiologically, it is kept in abeyance due to pregnancy and lactation. Ultimately, it ceases between tne age 45-50 when menopause sets in.

The duration of menstruation is about 4-5 days and the amount of blood loss is estimated to be 20-80ml with an average of 35ml. Nearly 70% of total menstrual blood loss occurs in the first 2 days.

CONTENTS OF MENSTRUAL DISCHARGE

The menstrual discharge consists mainly of dark altered blood, mucus, vaginal epithelial cells, fragments of endometrium, prostaglandins, enzymes and bacteria[48].

MENSTRUAL SYMPTOMS

In majority, apart from bleeding from vaginam there is no symptom. Initially, it begins as pink discharge but on day 2 and 3 it becomes dark red.

In teenagers or nulliparous, there may be associated tolerable colicky pain at the beginning due to uterine contraction.

If the pain is of sufficient magnitude so as to incapacitate the day-to-day activities, it is called dysmenorrhoea.

There may be premonitory symptoms such as

- ❖ Pelvic discomfort
- ❖ Backache
- ❖ Fullness of the breasts or mastalgia
- ❖ Headache or depression
- ❖ Constipation or diarrhea
- ❖ Appetite changes or food carvings
- ❖ Irritability or mood swings

If these premonitory symptoms are predomimant, these are grouped into a syndrome called "Premenstrual syndrome"[(49)].

CHANGES DURING MENSTRUAL CYCLE

During each menstrual cycle, series of changes occur in ovary, uterus, vagina and in cervix.

OVARIAN CHANGES DURING MENSTRUAL CYCLE

It occurs in two phases, which includes

- ❖ Follicular phase
- ❖ Luteal phase

UTERINE CHANGES DURING MENSTRUAL CYCLE

Along with ovarian changes, uterine changes also occur simultaneously. This changes in uterus takes place in three phases which includes

- ❖ Menstrual phase
- ❖ Proliferative phase

- Secretory phase

CHANGES IN VAGINA AND CERVIX DURING MENSTRUAL CYCLE

- Proliferative phase
- Secretory phase[50]

PHASES OF MENSTRUAL CYCLE

The day count for menstrual cycle begins on the first day of menstruation when blood starts to come out of the vagina. In this section, the length of menstrual cycle has been assumed to be 28 days (which is the average among women). The entire duration of a Menstrual cycle can be divided into four main phases:

1. Menstrual phase (From day 1 to 5)
2. Follicular phase (From day 1 to 13)
3. Ovulation phase (Day 14)
4. Luteal phase (From day 15 to 28)

MENSTRUAL PHASE (day 1-5)

Menstrual phase begins on the first day of menstruation and lasts till the 5th day of the menstrual cycle.

The following events occur during this phase:

- The uterus sheds its inner lining of soft tissue and blood vessels which exits the body from the vagina in the form of menstrual fluid.
- Blood loss of 10 ml to 80 ml is considered normal.
- This phase is also known as **destructive phase or phase of bleeding.**
- During this phase,the uterus sheds its inner lining of soft tissue and blood vessels which exits the body from the vagina in the form of menstrual fluid.

FOLLICULAR PHASE (day 1-13)

This phase is also known as **preovulatory phase or proliferative phase or estrogen phase**

- This phase also begins on the first day of menstruation, but it lasts till the 13th day of the menstrual cycle. The following events occur during this phase:

- ❖ The pituitary gland secretes a hormone that stimulates the egg cells in the ovaries to grow.
- ❖ One of these egg cells begins to mature in a sac-like-structure called follicle. It takes 13 days for the egg cell to reach maturity.
- ❖ While the egg cell matures, its follicle secretes a hormone that stimulates the uterus to develop a lining of blood vessels and soft tissue called endometrium.

OVULATION PHASE (day 14)

On the 14th day of the cycle, the pituitary gland secretes a hormone that causes the ovary to release the matured egg cell. The released egg cell is swept into the fallopian tube by the cilia of the fimbriae. Fimbriae are finger like projections located at the end of the fallopian tube close to the ovaries and cilia are slender hair like projections on each Fimbria.

LUTEAL PHASE (day 15-28)

The phase is also known as **secretory phase or premenstrual phase or progestational phase.**

- ❖ This phase begins on the 15th day and lasts till the end of the cycle. The following events occur during this phase:
- ❖ The egg cell released during the ovulation phase stays in the fallopian tube for 24 hours.
- ❖ If a sperm cell does not impregnate the egg cell within that time, the egg cell disintegrates.
- ❖ The hormone that causes the uterus to retain its endometrium gets used up by the end of the menstrual cycle. This causes the menstrual phase of the next cycle to begin[(51)].

HORMONES REGULATING THE CYCLE:

A normal menstrual cycle depends on cyclical ovarian steroid secretions which in turn are controlled by the pituitary and the hypothalamus, and to some extent by the thyroid and adrenal glands. So the the hypothalamo-pituitary-ovarian axis is important. The following hormones play the major role,

Gonadotropin releasing hormone (GnRH)

Follicle stimulating hormone (FSH)

Luteinising hormone (LH)

Oestrogen

Progesterone.

GONADOTROPIN RELEASING HORMONE (GnRH):

Gonadotropin releasing hormone is secreted by the hypothalamus which modulates the neural control of FSH and LH by the anterior pituitary. GnRH is released in a pulsatile manner. In preovulatory phase it pulses every 60 minutes but slows down in luteal phase to one in 3 hours. GnRH is continuous in males but pulsatile in females. The hypothalamus is controlled by higher cortical centers (temporal lobe). Emotional upsets stimulate or depress the H-P-O axis and disturb the menstrual cycles.

ANTERIOR PITUITARY HORMONE

FOLLICLE STIMULATING HORMONE (FSH)

It is secreted by the beta cells of anterior pituitary gland. FSH controls the ripening of the primordial follicles and in combination with the luteinizing hormone activates the secretion of estrogen. Its action starts after cease of menstruation and reaches the peak by 7th day and then declines to disappear around 18th day. Another small peak occurs in the premenstrual phase. Low FSH causes defective folliculogenesis and short or defective corpus luteal phase.

LUTEINIZING HORMONE (LH)

It is secreted by the beta cells of anterior pituitary gland. In combination with FSH it activates the secretion of estrogen.

It brings about maturation of the ovum and causes ovulation.

LH stimulates the completion of the reduction division of the oocyte.Following ovulation it produces luteinization of the granulosa and the theca cells and initiates progesterone secretion. The LH surge precedes ovulation by 24 to 36 hours.

OVARIAN HORMONES

OESTROGEN

The main source of oestrogen are the theca end granulosa cells of the graafian follicles and corpus luteum,while the adrenal cortex is the secondary source.

Its level rises 6 to 7 days before ovulation and reaches the peak 2 days before ovulation and then declines.

It increases uterine vascularity and regenerates the endometrium after menstruation and is responsible for the proliferative hyperplasia of the endometrium.

PROGESTERONE

The corpus luteum is the main source of progesterone. The level rises after ovulation and reaches peak at mid luteal phase. With the degeneration of the corpus luteum its level falls and brings about menstruation.

If pregnancy occurs the corpus luteum continues to enlarge and secrete progesterone. The high level of the hormone prevents menstruation and leads to amenorrhoea of pregnancy[52].

MENORRHAGIA

SYNONYM

HYPERMENORRHOEA

MENOSTAXIS

DEFINITION:

Menorrhagia is defined as cyclic bleeding at normal intervals : the bleeding is either excessive in amount (> 80ml) or duration (> 7 days) or both. The term Menostaxis is often used to denote prolonged bleeding.

.**CAUSES**

Menorrhagia has some underlying pathology- organic or functional.

ORGANIC CAUSES

- Pelvic
- Systemic
- Endocrinal
- Blood dyscrasias
- Emotional upse

PELVIC PATHOLOGY

Due to congestion, increased surface area or hyperplasia of the endometrium.

- Fibroid uterus
- Fibroid polyp
- Adenomyosis
- Chocolate cyst
- PCOD
- Pelvic endometriosis
- IUCD inutero
- Chronic tubo-ovarian mass
- Tubercular endometritis (early cases)

- ❖ Pelvic inflammatory diseases
- ❖ Retroverted uterus – due to congestion
- ❖ Granulosa cell tumour of the ovary

SYSTEMIC CAUSES

- ❖ Congestive cardiac failure
- ❖ Severe hypertension

ENDOCRINAL CAUSES

- ❖ Hypothyroidism
- ❖ Initial stages of Hyperthyroidism

BLOOD DYSCRASIAS

- ❖ Idiopathic thrombocytopenic purpura
- ❖ Leukaemia
- ❖ Von Willebrand's disease
- ❖ Platelet deficiency (thrombocytopenia)

FUNCTIONAL CAUSES

Due to disturbed hypothalamo- pituitary- ovarian- endometrial axis

COMMON CAUSES OF MENORRHAGIA

- ❖ Dysfunctional uterine bleeding
- ❖ Fibroid uterus
- ❖ Adenomyosis
- ❖ Chronic tubo-ovarian mass

DYSFUNCTIONAL UTERINE BLEEDING

DUB is defined as a state of abnormal uterine bleeding without any clinically detectable organic, systemic and iatrogenic cause. In a large number of patients, menorrhagia is not associated with any structural abnormality, disease in the pelvis or evidence either of general or endocrine disease.

The aetiology is purely hormonal and that the hypertrophy and the hyperplasia of the endometrium are induced by a high titre of oestrogen in the circulating blood.

The prevalence varies widely but an incidence of 10% amongst new patients attending the out-patient seems logical.

PATHO –PHYSIOLOGY

The current concept concludes that the abnormal bleeding is most likely due to local causes in the endometrium. There is some disturbance of the endometrial blood vessels and capillaries and coagulation of blood in and around blood vessels. These are probably related to alteration in the ratio of endometrial prostaglandins which are delicately balanced in haemostasis of menstruation.

The endometrial abnormalities may be primary or secondary to inco-ordination in the hypothalamo-pituitary-ovarian axis. It is thus more prevalent in extremes of reproductive period – adolescence and premenopause or following childbirth and abortion.

Emotional influences, worries, anxieties or sexual problems sometimes are enough to disturb the normal hormonal balance[53].

SYMPTOMS OF MENORRHAGIA:

Saturating multiple sanitary pads or tampons per hour
Requiring two sanitary pads to contain uterine bleeding
Waking up at night to change sanitary pads or tampons
Prolonged bleeding that lasts beyond a week
Passing large blood clots
Inability to engage in routine daily activities
Fatigue and weakness (signs of anemia)
Tiredness
Shortness of breath.
Head ache
Lower abdominal pain

DIAGNOSIS:

Blood tests

A sample of blood may be evaluated for iron deficiency (anemia) and other conditions, such as thyroid disorders or blood-clotting abnormalities.

Pap test

In this test, cells from the cervix are collected and tested for infection, inflammation or changes that may be cancerous or may lead to cancer.

Endometrial biopsy

Take a sample of tissue from the inside of the uterus to be examined by a pathologist.

Ultrasound scan

This imaging method uses sound waves to produce images of the uterus, ovaries and pelvis.

Based on the results of the initial tests, doctor may recommend further tests :

Sonohysterogram

During this test, a fluid is injected through a tube into the uterus by way of vagina and cervix and then uses ultrasound to look for problems in the lining of the uterus.

Hysteroscopy

This exam involves inserting a tiny camera through the vagina and cervix into the uterus, which allow to see the inside of the uterus.

MANAGEMENT

- General measures to improve the health status of the patient. Advice regarding proper diet, adequate rest during menses, oral administration of haematinics, vitamins and protein supplements and to maintain a menstrual calendar noting duration and extent of blood loss.
- Treat the cause.

In women suffering from DUB, consider:

- Oral non-steroidal anti-inflammatory drugs like mefenamic acid 500 mg t.d.s along with antacids. Other drugs in the category include naproxen, ponstan and ibuprofen
- Cyclic oral contraceptive pills.

- ❖ Oral progesterone - When taken for 10 or more days of each menstrual cycle, the hormone progesterone can help correct hormone imbalance and reduce menorrhagia.
- ❖ The hormonal IUD (Mirena) - This intrauterine device releases a type of progestin called levonorgestrel, which makes the uterine lining thin and decreases menstrual blood flow and cramping.
- ❖ Hysterectomy in selected cases.

THERAPEUTIC MEASURES

This includes

- ❖ Removal of an offending intrauterine contraceptive device.
- ❖ Myomectomy or hysterectomy for uterine fibroids.
- ❖ Wedge resection or hysterectomy for adenomyosis of the uterus.
- ❖ Laparoscopic lysis of adhesions for chronic PID.
- ❖ Electrocautery or laser vaporization of endometriosis and drainage of chocolate cysts in pelvic endometriosis.
- ❖ Hysterectomy with or without removal of the adnexa as per the age and the individual needs of the patient.
- ❖ In patients suffering from bleeding disorders, a haematologist's opinion should be sought[(54)].

Dilation and curettage (D&C)

In this procedure, opens (dilates) cervix and then scrapes or suctions tissue from the lining of uterus to reduce menstrual bleeding. Although this procedure is common and often treats acute or active bleeding successfully, may need additional D&C procedures if menorrhagia recurs.

Uterine artery embolization

For women whose menorrhagia is caused by fibroids, the goal of this procedure is to shrink any fibroids in the uterus by blocking the uterine arteries and cutting off their blood supply.

During uterine artery embolization, the surgeon passes a catheter through the large artery in the thigh (femoral artery) and guides the uterine arteries, where the blood vessel is injected with microspheres made of plastic.

Focused ultrasound ablation

Similar to uterine artery embolization, focused ultrasound ablation treats bleeding caused by fibroids by shrinking the fibroids. This procedure uses ultrasound waves to destroy the fibroid tissue. There are no incisions required for this procedure.

Myomectomy

This procedure involves surgical removal of uterine fibroids. Depending on the size, number and location of the fibroids.

Endometrial ablation

Using a variety of techniques, permanently destroys the lining of the uterus (endometrium). After endometrial ablation, most women have much lighter periods.

Endometrial resection

This surgical procedure uses an electrosurgical wire loop to remove the lining of the uterus. Both endometrial ablation and endometrial resection benefit women who have very heavy menstrual bleeding.

Hysterectomy

Hysterectomy — surgery to remove the uterus and cervix — is a permanent procedure that causes sterility and ends menstrual periods.

COMPLICATIONS:

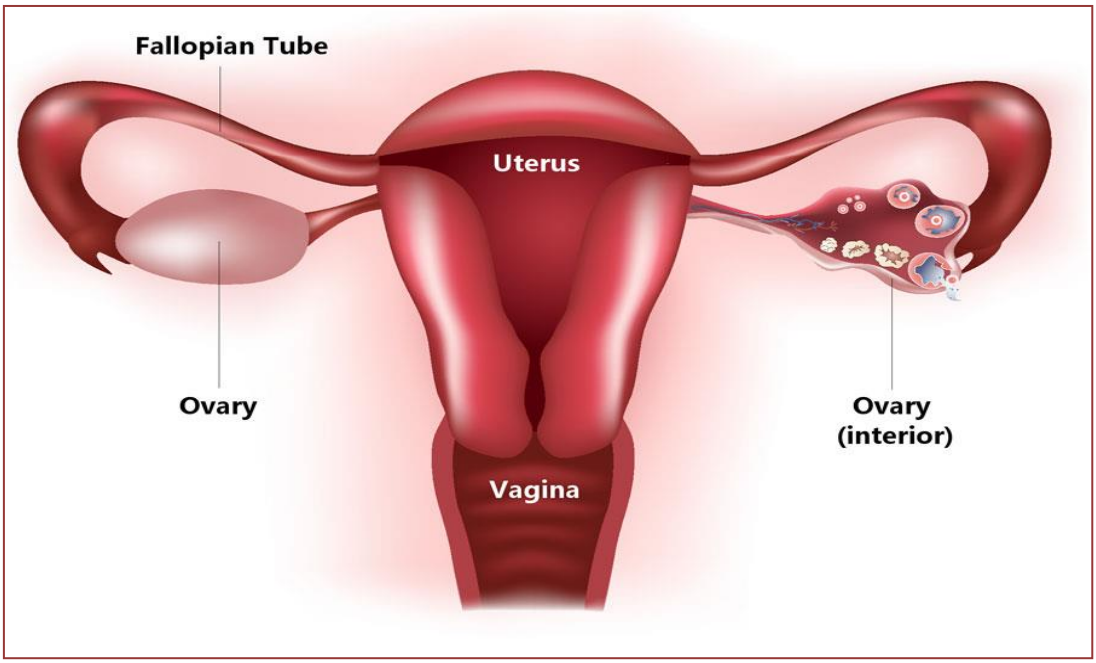
Iron deficiency anaemia

Tiredness

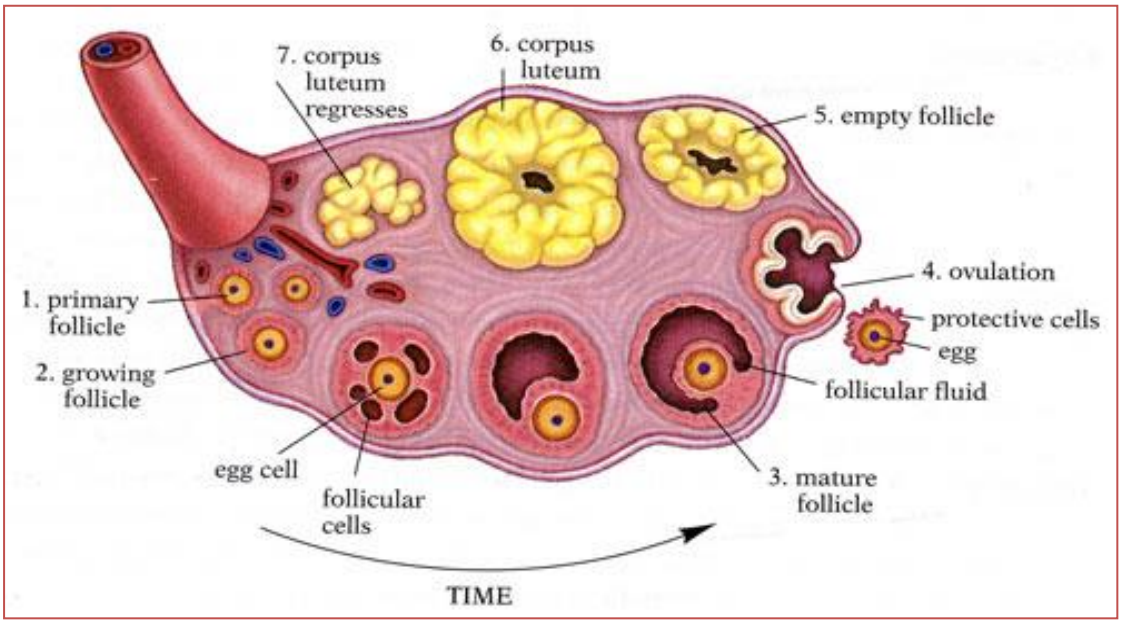
Psychological disturbances

Poor concentration[(55)].

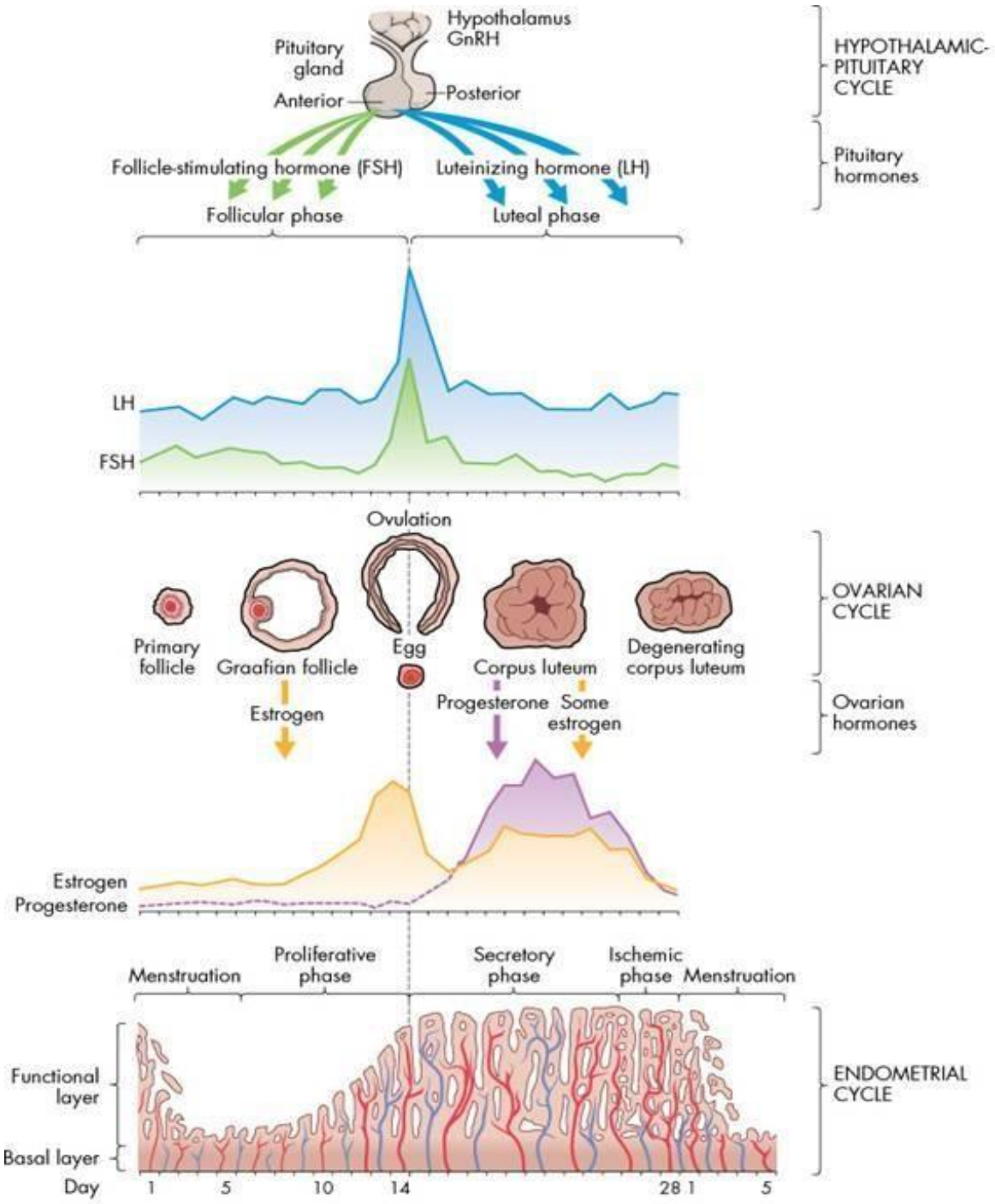
CROSS SECTION OF INTERNAL GENITAL ORGANS



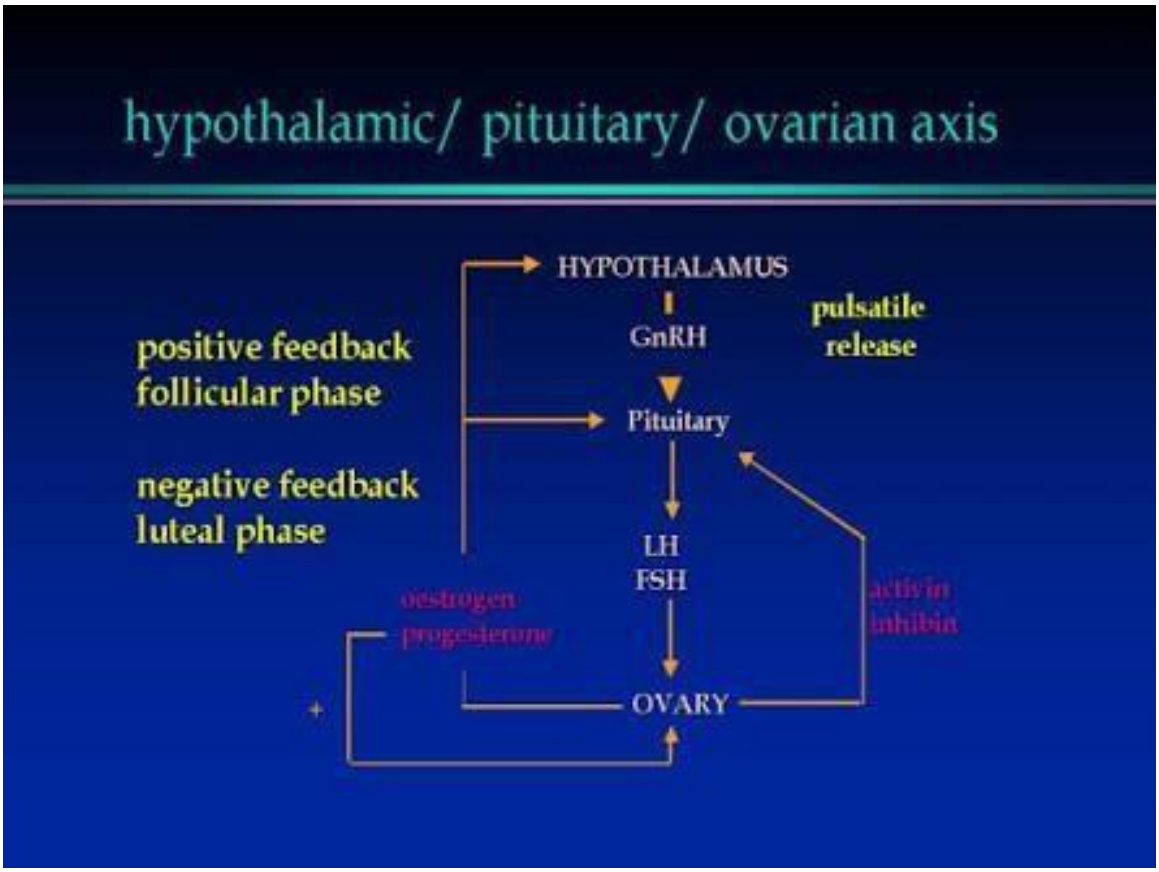
CROSS SECTION OF OVARY SHOWING ITS LIFE CYCLE



MENSTRUAL CYCLE



HYPOTHALAMO-PITUITARY-OVARIAN AXIS



TRIAL DRUG

NAAVAL NEI

INGREDIENTS

- **Naaval pattai *(Syzygium cumini)*** **: 1400 gm**
- **Perumarathupattai *(Sterculia foetida)*** **: 10.2 gm**
- **Aavarai arisi *(Cassia auriculata)*** **: 10.2 gm**
- **Aavarai vaerpattai *(Cassia auriculata)*** **: 10.2 gm**
- **Kottam*(Costus speciosus)*** **: 10.2 gm**
- **Lavanga pattai *(Cinnamomum verum)*** **: 10.2 gm**
- **Karkadaka singi *(Rhus succedanea)*** **: 10.2 gm**
- **Athimadhuram *(Glycyrrhiza glabra)*** **: 10.2 gm**
- **Athividaiyam *(Aconitum heterophyllum)*** **: 10.2 gm**
- **Sadamanjil *(Nardostachys grandiflora)*** **: 10.2 gm**
- **Kookai neer *(Maranta arundinacea)*** **: 10.2 gm**
- **Thevathaaram *(Cedrus deodara)*** **: 10.2 gm**
- **Sirunaagappoo *(Mesua nagassarium)*** **: 10.2 gm**
- **Nilappanai kilangu *(Curculigo orchioides)*** **: 10.2 gm**
- **Nannari vaer *(Hemidesmus indicus)*** **: 10.2 gm**
- **Ghee** **: 2 Litres**

STANDARD OPERATIVE PROCEDURE

SOURCE OF RAW DRUGS:

The required raw drugs are obtained from a well reputed indigenous raw drug shop. The raw drugs taken for study was authenticated by the Pharmacognosist of Gunapadam Dept, Govt. Siddha Medical College, Chennai 600106.

PURIFICATION OF RAW DRUGS:

Raw drugs are purified as mentioned in Sikitcha Ratna Deepam Sarakku Suthi Muraigal.

PREPARATION:

First purified Naaval pattai is made into kudineer, in that the above raw drugs are made in to fine powder and made into karkam with cow's milk.Then the karkam and sufficient amount of cow's ghee is added to kudineer and boiled,still it comes to nei consistency and stored in a air-tight container.

DRUG STORAGE:

The trial drug is stored in clean dry air tight container and it is dispensed to the patients in pockets.

DOSE **:** 5ml ; tds after food.

DURATION **:** For one Mandalam (48 days)

REFERENCE **:** AATHMARATCHAMIRTHA VAITHIYA SAARA SANGIRAGAM (PART II) Page No :252[56]

PROPERTIES OF TRIAL DRUGS

DRUG NAME	FAMILY	TASTE	POTENCY	PIRIVU	ACTION
Naaval pattai (Syzygium cumini)	Myrtaceae	Thuvarpu	Cold	Kaarppu	Astringent Stomachic[57]
Perumarathpattai (Sterculia foetida)	Malvaceae	Kaippu	Heat	Kaarppu	Laxative[58]
Aavarai arisi (Cassia auriculata)	Fabaceae	Thuvarpu	Cold	Inippu	Refrigerant[59]
Aavarai vaerpattai (Cassia auriculata)	Fabaceae	Thuvarpu	Cold	Inippu	Astringent Tonic[60]
Kostham (Costus speciosus)	Zingiberaceae	Kaippu	Heat	Kaarppu	Stomachic, Tonic[61].
Lavanga pattai	Lauraceae	Kaarppu	Cold	Inippu	Carminative[62]

(Cinnamomum verum)					
Karkadaka singi (Rhus succedanea)	Anacardiaceae	Thuvarpu	Heat	Kaarppu	Astringent Tonic[63]
Athimadhuram (Glycyrrhiza glabra)	Fabaceae	Inippu	Cold	Inippu	Tonic Emollient Demulcent[64]
Athividaiyam (Aconitum heterophyllum)	Ranunculaceae	Kaippu	Heat	Kaarppu	Stomachic Tonic Astringent[65]
Sadamanjil (Nardostachys grandiflora)	Caprifoliaceae	Kaarppu	Heat	Kaarppu	Anti spasmodic[66]
Kookai neer (Maranta arundinacea)	Marantaceae	Inippu	Cold	Inippu	Demulcent Nutrient[67]
Thevathaaram (Cedrus deodara)	Pinaceae	Thuvarpu	Heat	Kaarppu	Astringent[68]
Sirunaagappoo (Mesua nagassarium)	Calophyllaceae	Thuvarpu	Cold	Kaarppu	Astringent[69]
Nilappanai kilangu (Curculigo orchioides)	Hypoxidaceae	Inippu	Cold	Inippu	Astringent Tonic Carminative[70]
Nannari vaer (Hemidesmus indicus)	Apocynaceae	Inippu	Cold	Inippu	Tonic Demulcent Alterative[71]

நாவல் பட்டை :

ஆசியநோய் காசம் அசிர்க்கரஞ்சு வாசவினை

கேசமுறு பால கிரகநோய் – பேசரிய

மாவியங்க லாஞ்சனமிவ் வன்பிணியெ லாமேகும்

நாவலுறு பட்டையத னால்[72].

அசிர்க்கரம் – பெரும்பாடு[73].

TRIAL DRUG PHOTOS

DRUGS OF NAAVAL NEI

Syzygium cumini

Sterculia foetida

Seeds of *cassia auriculata*

Cinnamomum verum

Costus speciosus

Mesua ferrea

Glyccyrrhiza glabra

Aconitum heterophyllum

Nardastachys grandiflora

Cedrus deodara

Curculigo orchioides

Hemidesmus indicus

Maranta arundinacea

Rhus succedanea

TRIAL DRUG

NAAVAL NEI

MATERIALS AND METHODS

STUDY DESIGN:

The clinical trial on Pitha Perumbadu (Menorrhagia) was decided to conduct as an open label study.

The study was approved by Institutional Ethics Committe (IEC) and the approved number is GSMC-CH-ME-4/2015/005. The stydy was registered in Clinical Trials Registry – India (CTRI**)** and the reference Number is CTRI/2017/05/008615.

STUDY CENTER:

The entire study was conducted on patients at Out Patients Department of Govt Siddha Medical College, Chennai in the premises of Arignar Anna Government Hospital for Indian Medicine and Homeopathy, Arumbakkam, Chennai – 106, during the period of 2015 - 2017.

POPULATION:

The population consists of all patients were attending the OPD of Aringnar Anna Hospital, Arumbakkam, Chennai – 106. Sample consists of Pitha Perumbadu who satisifying the inclusion and exclusion criteria mentioned below:

SAMPLE SIZE:

20 patients in the age group 15-50 years.

STUDY DRUG:

NAAVAL NEI – 5 gm tds for 1 mandalam (48 days)

SELECTION CRITERIA:

The population of Pittha perumbadu rogam patients with the following signs and symtoms are taken into the clinical trial.

- Excessive menstruation
- Prolonged menstruation
- Presence of blood clots in menstrual bleeding
- Lower abdominal pain
- Low back ache
- Giddiness during menstruation
- Headache during menstruation
- Tiredness during menstruation
- USG report with fibroid uterus or PCOD.

EXCLUSION CRITERIA:

- Diabetis mellitus
- Hypertension
- Patient having IUCD
- Abortion
- Thromobocytopenic purpura
- Coagulopathy
- Severe anaemia (<6 gm)
- Hypothyroidism
- Vulnearable populations such as

  HIV positive

  TB affected individuals

WITHDRAWAL CRITERIA:

- Intolerance to the drug and development of any serious adverse effect during trial. (If ADR is reported the patient will be directed to RPC)
- Patient turning unwilling during course of trial.
- Poor compliance.
- Any other acute illness which needs a rescue medication.

EVALUATION OF CLINICAL PARAMETERS:

The case sheet proforma for Pitha Perumbadu was prepared based on Siddha diagnostic metholodgy with necessary modern techniques.

Patients are clinically evaluated by the following parameters

A. HISTORY TAKING:

Age, Occupation, Socio economic status, Complaints and its duration, Previous illness, Family history, Personal habits were recorded in the case sheet for every patient at the time of first visit to the OP.

B. INVESTIGATION:

At the patients were subjected to the laboratory investigations.

This was carried out regularly before and after treatment.

- BLOOD:

  TC, DC, ESR, Hb, Blood Sugar (Fasting and Post Prandial), Serum cholesterol, Blood Urea, Bleeding time & Clotting time, Thyroid Profile.

- URINE:

  Albumin, Sugar, Deposits.

- USG For Abdomen and Pelvis.

CLINICAL DIAGNOSIS BASED ON SIDDHA SYSTEM:

The paramaters used to diagnosis the DISEASE PITTHA PERUMBADU ROGAM based on Siddha System.

- Porial arithal
- Pulanaal arithal
- Vinaathal
- Envagai Thervugal
- Uyir thathukal
- Udal thathukal
- Neerkuri
- Neikuri.

CONDUCT OF THE STUDY:

Pittha Perumbadu Rogam patients satisfying the inclusion and exclusion criteria will be included in the trial. Informed consent form will be obtained from the patients. A day before starting the trial treatment, pacifying the mukkutram by purgation will be carried out by Agasthiya Kuzhambu-100 mg with chukku kasayam at empty stomach in the early morning.

The trial drugs will be issued for 7 days at a time and clinical assessment will be carried out 7days once.

CASE SHEET PROFORMA:

All the clinical signs and symptoms of Pittha Perumbadu Rogam, history of present and past illness, personal history, menstrual history, family history, personal habbits and occupation were recorded. Lab investigations and prognosis were recorded for analysis.

TRIAL MEDICINE:

NAAVAL NEI

DOSE	**:**	5 gm; thrice a day; After Food.
INDICATION	**:**	Menorrhagia
REFERENCE	**:**	AATHMARATCHAMIRTHA VAITHIYA SAARA SANGIRAGAM(PARTII) PAGE NO :252.

RESULTS AND OBSERVATION

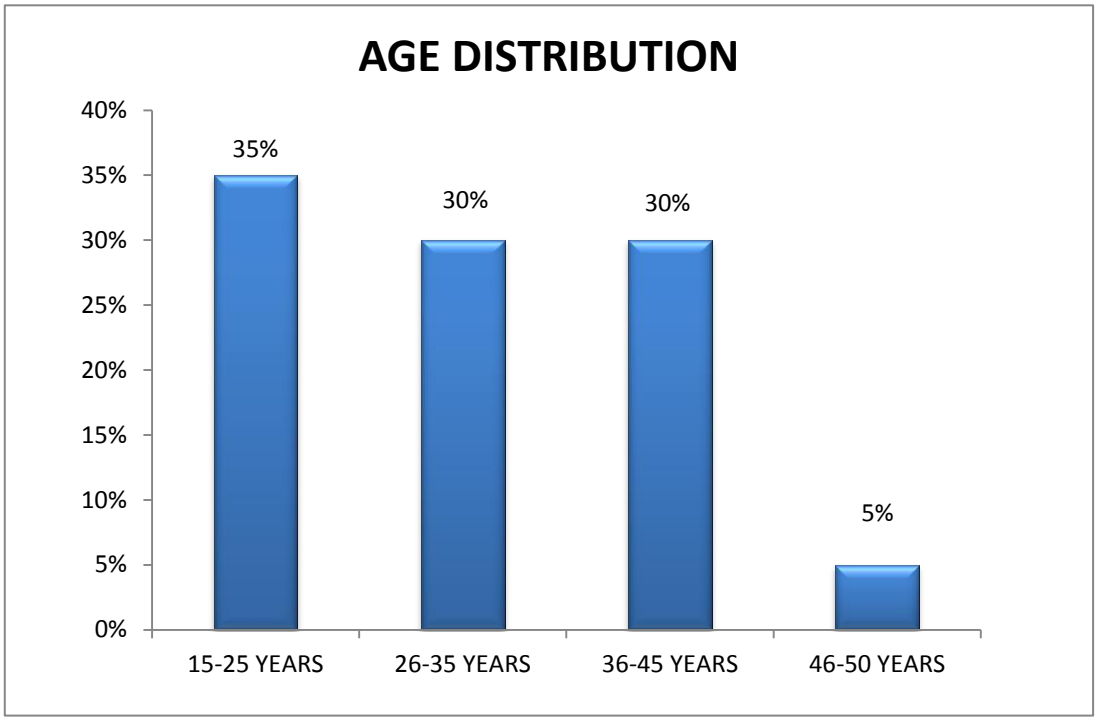
Pitha Perumbadu Rogam was carried out in 20 patients in the out patient Post Graduate department, Pothu Maruthuvam, Govt,Siddha medical College, Chennai-106 attached to Aringnar Anna Government Hospital during 2014 - 2017 analysed.

The observations were made and tabulated with following criteria:

- Distribution of Age
- Occupational Distribution
- Distribution of Marital status
- Distribution of Socio-economic status
- Distribution of Food habits
- Distribution of Paruvakkalam
- Distribution of Thinai
- Distribution of Mukkutram
  - Vathakutram
  - Pittha kutram
  - Kabha kutram
- Distribution of Udal Thaathukal
- Distribution of Envagai thervugal
  - Naadi
  - Miscellaneous
  - Neerkuri
- Signs and Symptoms before and after treatment
- Number of pads used before and after treatment
- Hemoglobin level before and after treatment
- Bleeding time and Clotting time before and after treatment
- Gradation of result.

AGE DISTRIBUTION

S.NO	AGE	NUMBER OF CASES/20	PERCENTAGE (%)
1.	15-25 YEARS	7	35
2.	26-35 YEARS	6	30
3.	36-45 YEARS	6	30
4.	46-50 YEARS	1	05

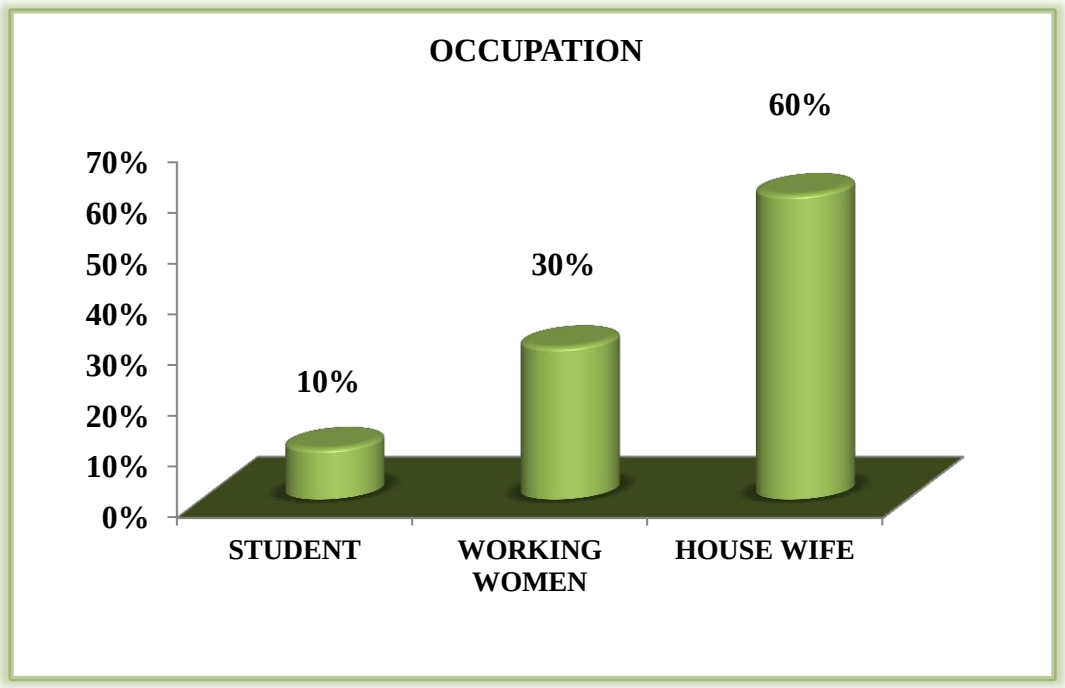


INFERENCE:

5% of patients were in the age group 46-50, 30% of patients were in the age group 36-45, 30% of patients were in the age group 26-35 and 35% of patients were in the age group of 15-25.

OCCUPATION

S.NO	NATURE OF WORK	NO.OF CASES/20	PERCENTAGE
1.	STUDENT	2	10%
2.	WORKING WOMEN	6	30%
3.	HOUSE WIFE	12	60%

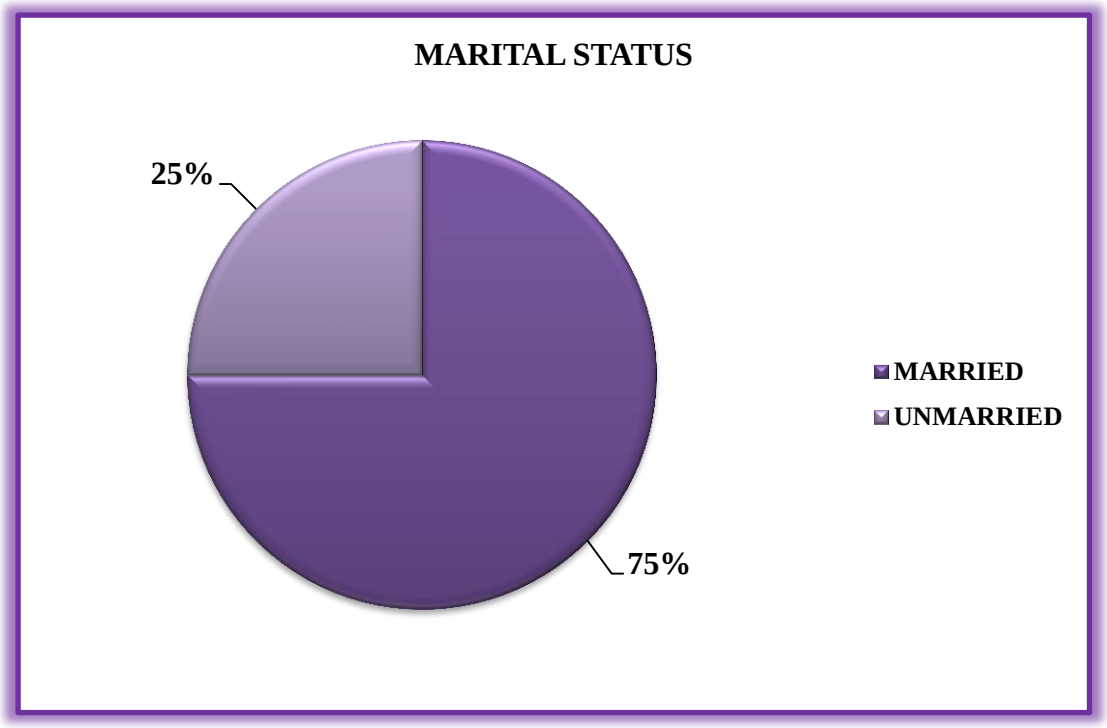


INFERENCE

60% of patients were house wife, 30% of patients were working women and 10% were student.

MARITAL STATUS

S.NO	STATUS	NO.OF CASES/20	PERCENTAGE
1.	MARRIED	15	75%
2.	UNMARRIED	5	25%

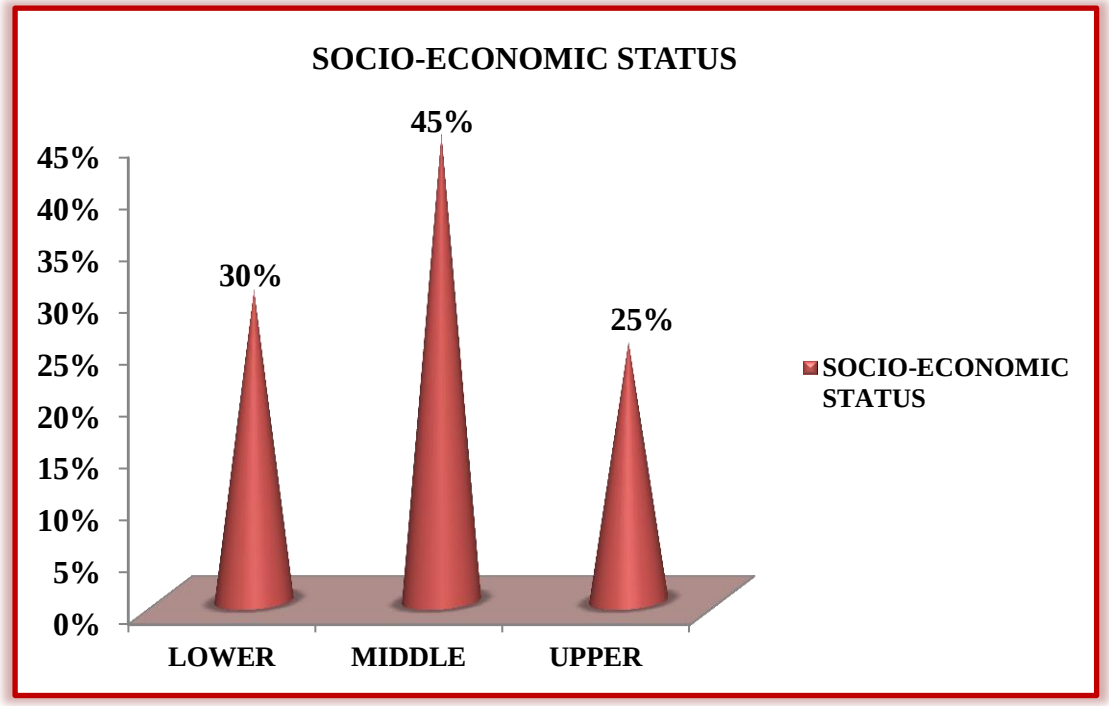


INFERENCE

75% of patients were married and 25% of patients were unmarried.

SOCIO-ECONOMIC STATUS

S.NO	STATUS INCOME PER ANNUM	NO.OF CASES/20	PERCENTAGE
1.	LOWER (UPTO 2 LAKHS/ANNUM)	6	30%
2.	MIDDLE (2-5 LAKHS/ANNUM)	9	45%
3.	UPPER (ABOVE 5 LAKHS/ANNUM)	5	25%

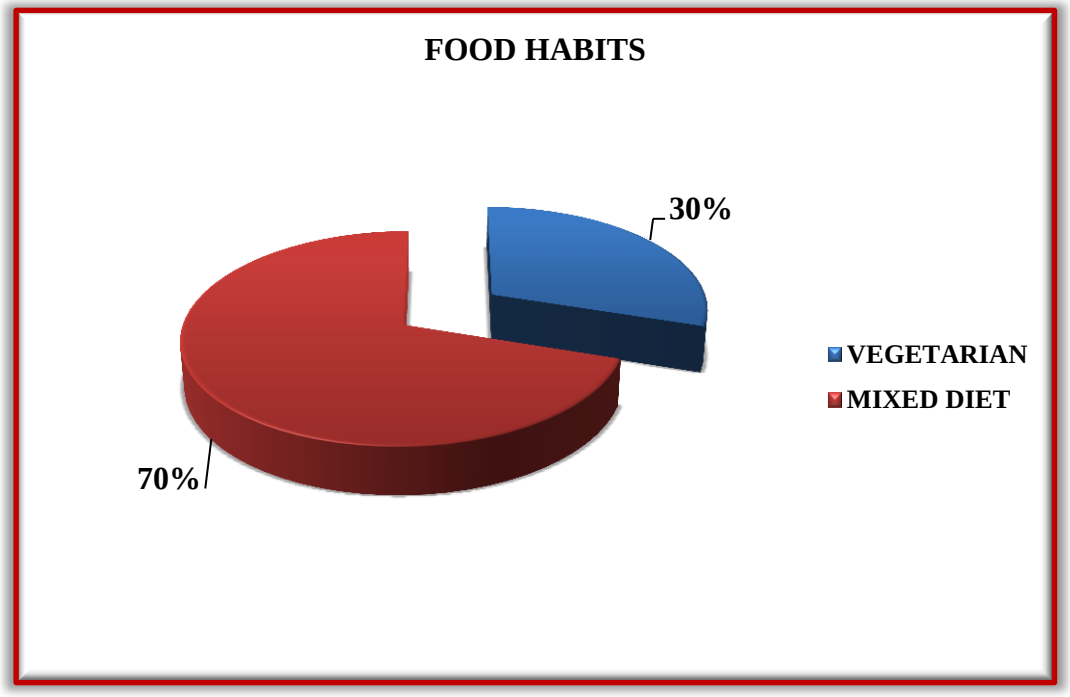


INFERENCE

30% of patients were from lower income group, 45% of patients were from middle income group and 25% were from upper income group

FOOD HABITS

S.NO	FOOD HABITS	NO.OF CASES/20	PERCENTAGE
1.	VEGETARIAN	6	30%
2.	MIXED DIET	14	70%

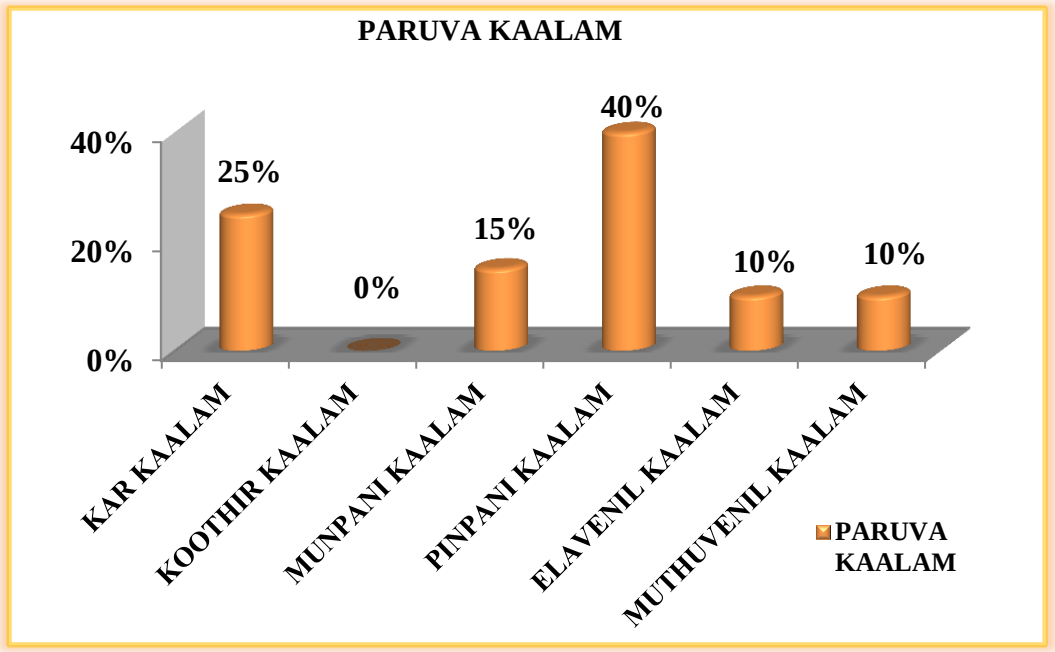


INFERENCE

70% of patients belong to mixed diet habit and 30% of patients belong to vegetarian diet habi

PARUVAKKALAM

S.NO	KAALAM	NO.OF CASES/ 20	PERCENTAGE %
1.	KAAR KAALAM(AAVANI,PURATTAASI) (AUG 16 - OCT 15)	5	25
2.	KOOTHIRKAALAM(AIPPASI,KAARTHIGAI) (OCT 16 – DEC 15)	0	0
3.	MUNPANIKAALAM(MAARKALI,THAI) (DEC 16 – FEB 15)	3	15
4.	PINPANIKAALAM(MAASI,PANGUNI) (FEB 16 – APR 15)	8	40
5.	ELAVENILKAALAM(SITHIRAI,VAIKAASI) (APR 16 – JUN 15)	2	10
6.	MUTHUVENILKAALAM(AANI,AADI) (JUN 16 – AUG 15)	2	10

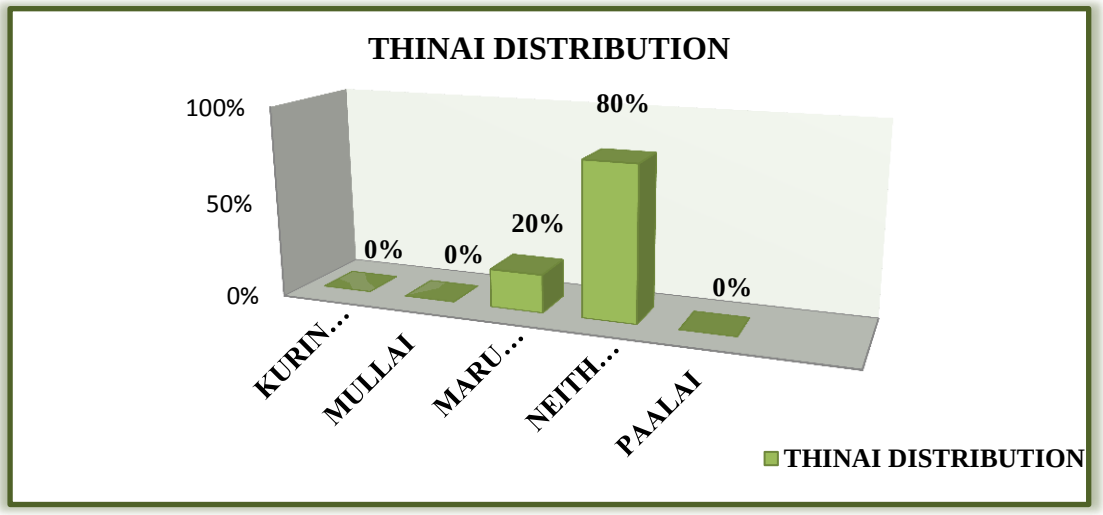


INFERENCE

10% of patients were reported in Elavenilkaalam and Muthuvenilkaalam, 25% of patients were reported in Kaarkaalam 15% of patients were Munpanilkaalam and 40% of patients were reported in pinmanikaalam.

THINAI

S.NO	THINAI	NO.OF CASES/20	PERCENTAGE
1.	KURINJI	0	0%
2.	MULLAI	0	0%
3.	MARUTHAM	4	20%
4.	NEITHAL	16	80%
5.	PAALAI	0	0%

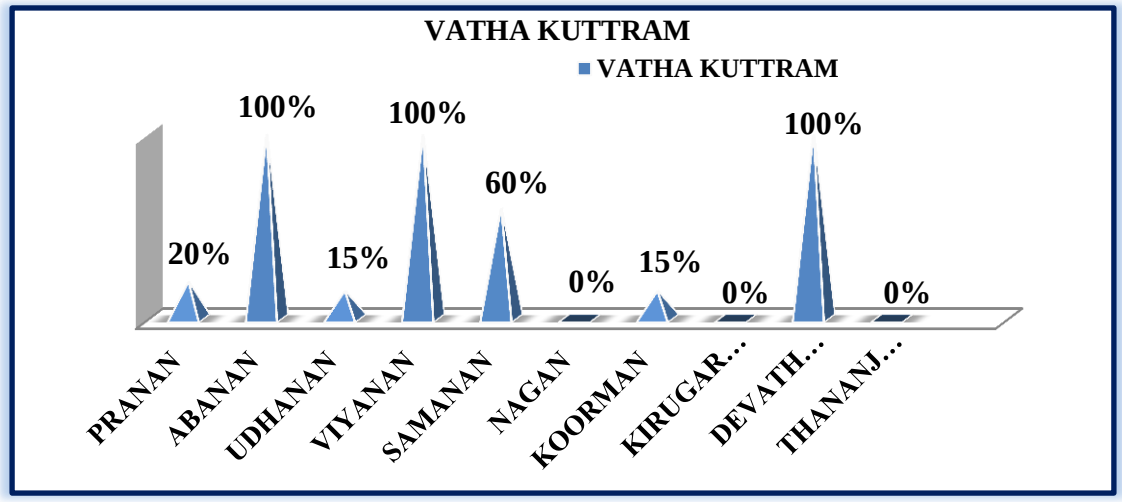


INFERENCE

The patients about 80% were from Neithal thinai and 20% of the patients were from Marutham thinai.

MUKKUTRAM : VATHA KUTTRAM

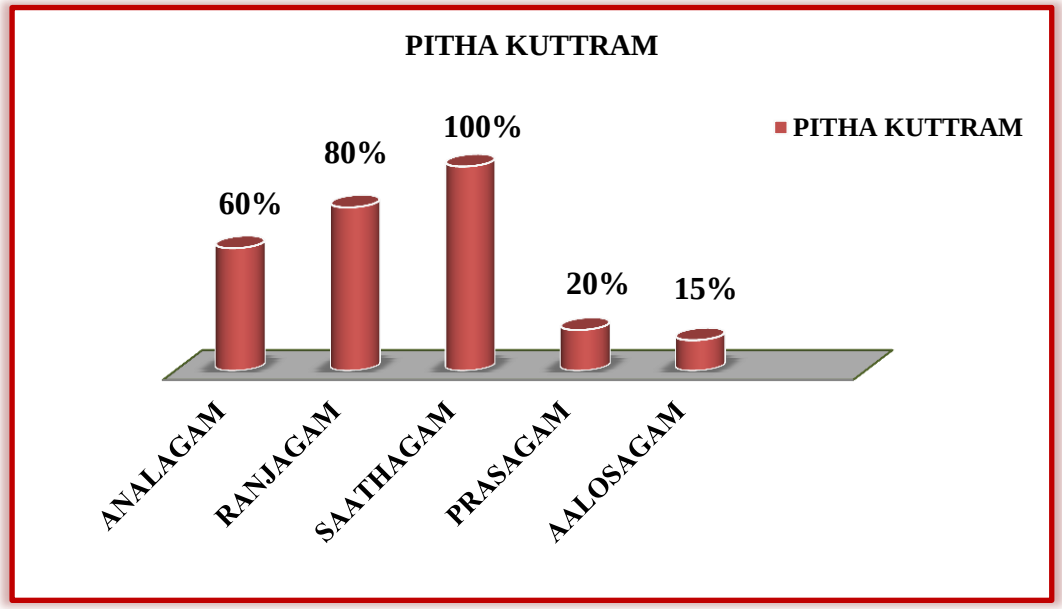
S.NO	TYPES OF VATHAM	NO.OF CASES/20	PERCENTAGE
1	**PRANAN**	4	20%
2	**ABANAN**	20	100%
3.	**UDHANAN**	3	15%
4.	**VIYANAN**	20	100%
5.	**SAMAANAN**	12	60%
6.	**NAAGAN**	0	0%
7.	**KOORMAN**	3	15%
8.	**KIRUGARAN**	0	0%
9.	**DEVATHATHAN**	20	100%
10.	**THANANJAYAN**	0	0%



INFERENCE: Abanan,Viyanan and Devathathan affected in all 100% of patients, Koorman affected in 15% of patients, Pranan affected in 20% of patients, Udhanan affected in15% of patients, Samanan affected in 60% patients.

PITHAKKUTRAM

S.NO	TYPES OF PITHAM	NO.OF CASES	PERCENTAGE
1.	ANALAGAM	12	60%
2.	RANJAGAM	16	80%
3.	SAATHAGAM	20	100%
4.	PRASAGAM	4	20%
5.	ALOSAGAM	3	15%

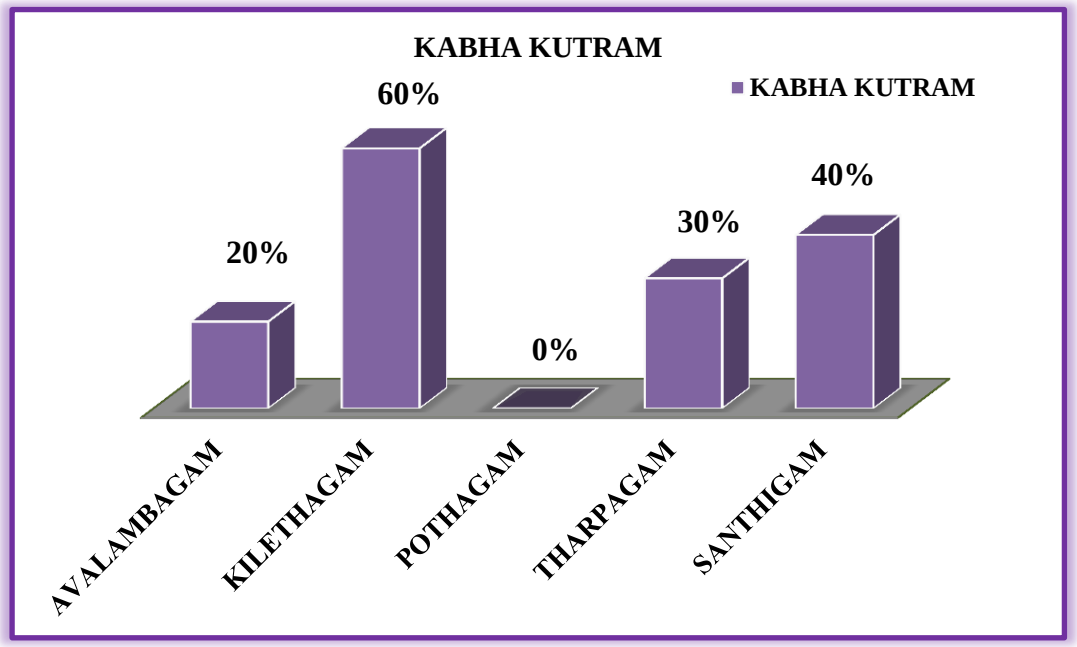


INFERENCE

Saathagam affected in all the patients 100%, Ranjagam affected in 80% of patients, Prasagam affected in 20% and alosagam affected in 15% of patients and Analagam affected in 60% of patients.

KABHAKUTTRAM

S.NO	TYPES OF KABHAM	NO.OF CASES	PERCENTAGE
1.	AVALAMBAGAM	4	20%
2.	KILETHAGAM	12	60%
3.	POTHAGAM	0	0%
4.	THARPAGAM	6	30%
5.	SANTHIGAM	8	40%

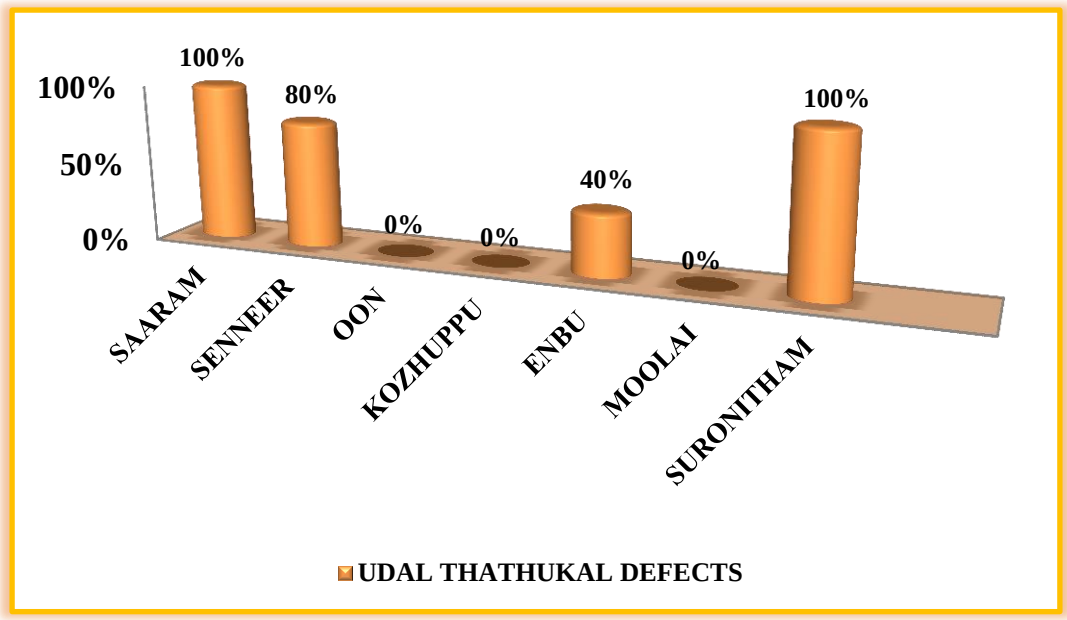


INFERENCE

Santhigam affected patients 40% of patients, Kilethagam affected in 60% of patients,Tharpgam affected in 30% of patients and Avalambagam affected in 20% of patients.

UDALTHATHUKKAL

S.NO	UDAL THATHUKKAL	NO.OF CASES	PERCENTAGE
1.	SAARAM	20	100%
2.	SENNEER	16	80%
3.	OON	0	0%
4.	KOZHUPPU	0	0%
5.	ENBU	8	40%
6.	MOOLAI	0	0%
7.	SURONITHAM	20	100%



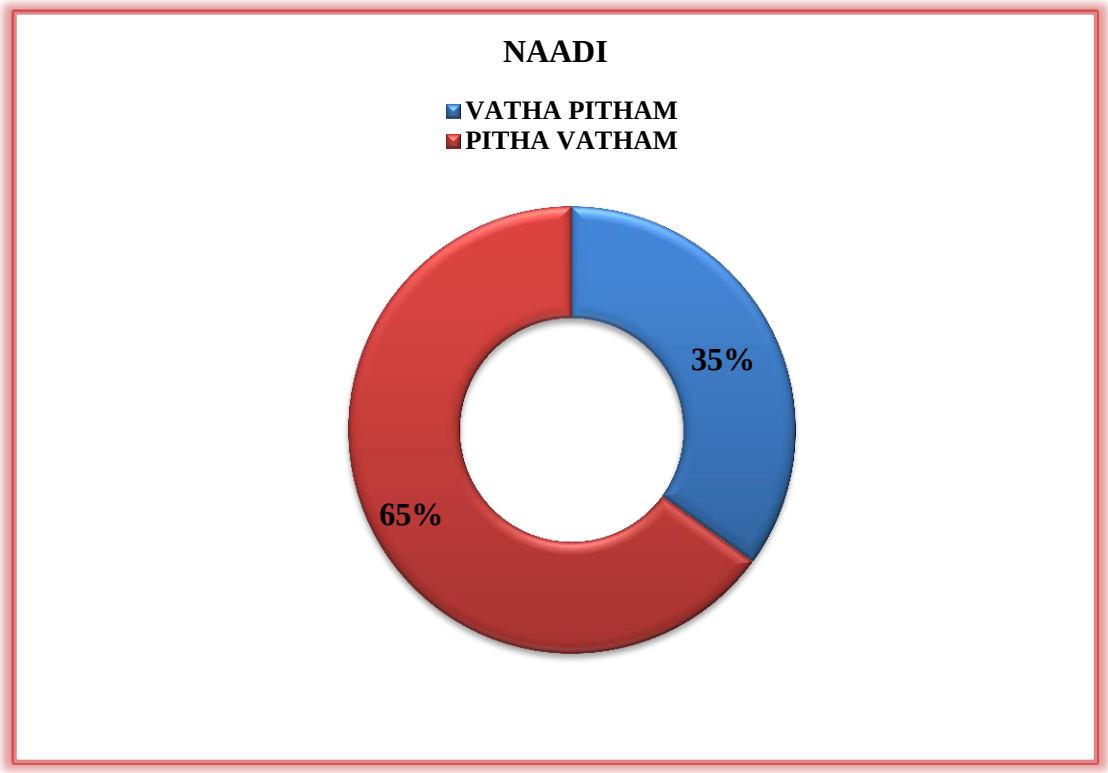
INFERENCE

Saaram and Suronitham affected in all the patients 100%, Senneer affected in 80% of patients and Enbu affected in 40% of patients.

EN VAGAI THERVUGAL

NAADI

S.NO	NAADI	NO.OF CASES	PERCENTAGE
1.	VATHA PITHAM	7	35%
2.	PITHA VATHAM	13	65%

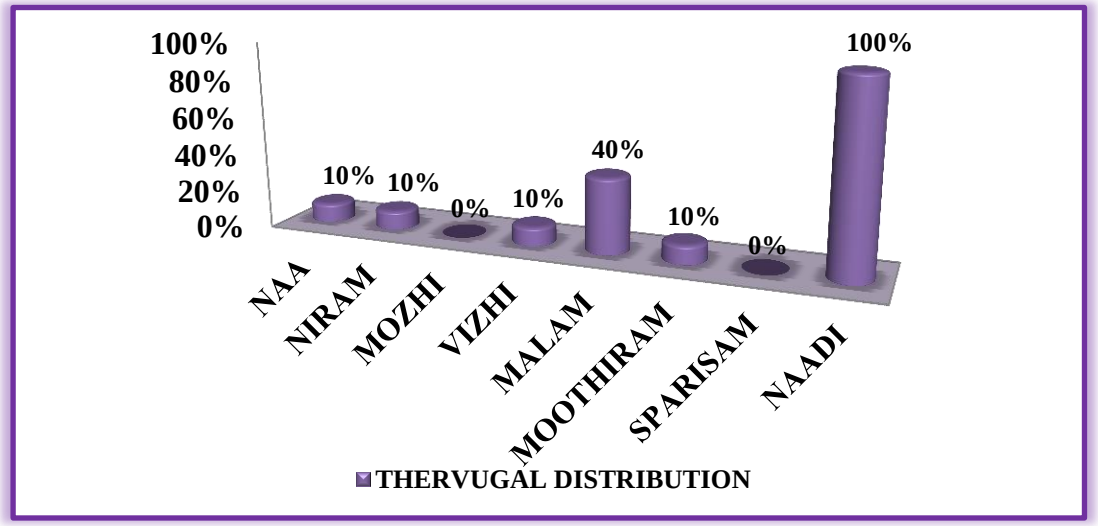


INFERENCE

65% of patients had Pitha Vatham naadi and 35% of patients had Vadha Pitha naadi.

MISCELLANEOUS

S.NO	ENVAGAI THERVUGAL	NO.OF CASES/20	PERCENTAGE
1.	NAA	2	10%
2.	NIRAM	2	10%
3.	MOZHI	0	0%
4.	VIZHI	2	10%
5.	MALAM	8	40%
6.	MOOTHIRAM	2	10%
7.	SPARISAM	0	0%
8.	NAADI	20	100%

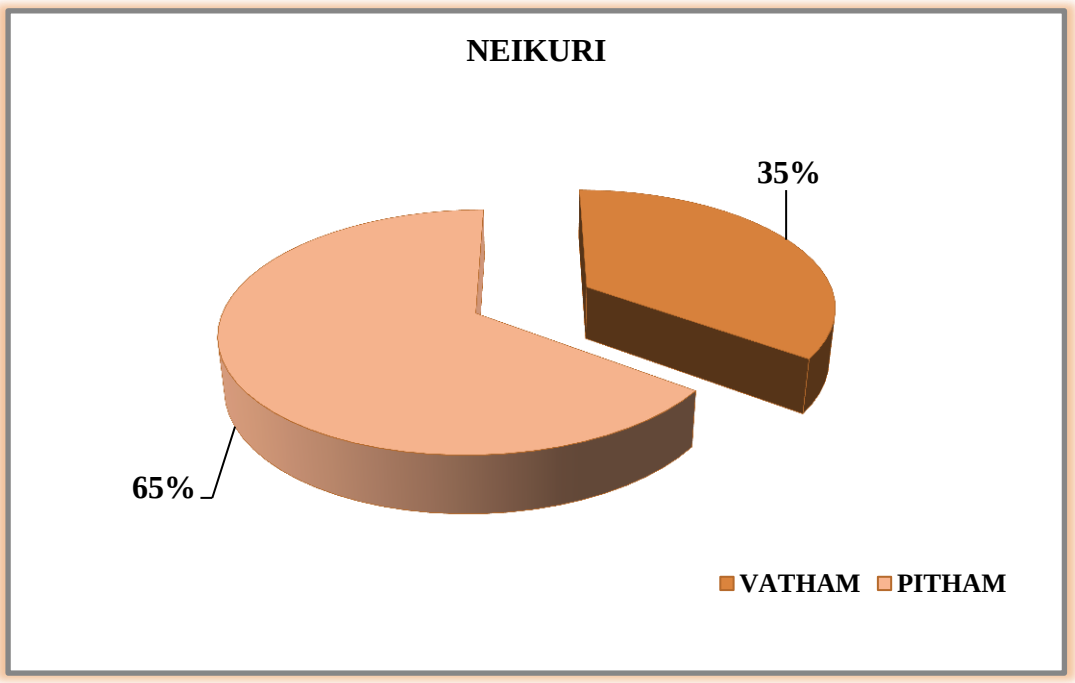


INFERENCE

Vizhi affected in 10% of patients, Naa affected in 10% of patients, Niram affected in 10% of patients, Malam affected in 40% of patients , Moothiram affected in 10% of patients and Naadi affected in 100% of patients.

NEIKURI

S.NO	NEER	NO.OF CASES/20	PERCENTAGE
1.	VATHAM	7	35%
2.	PITHAM	13	65%

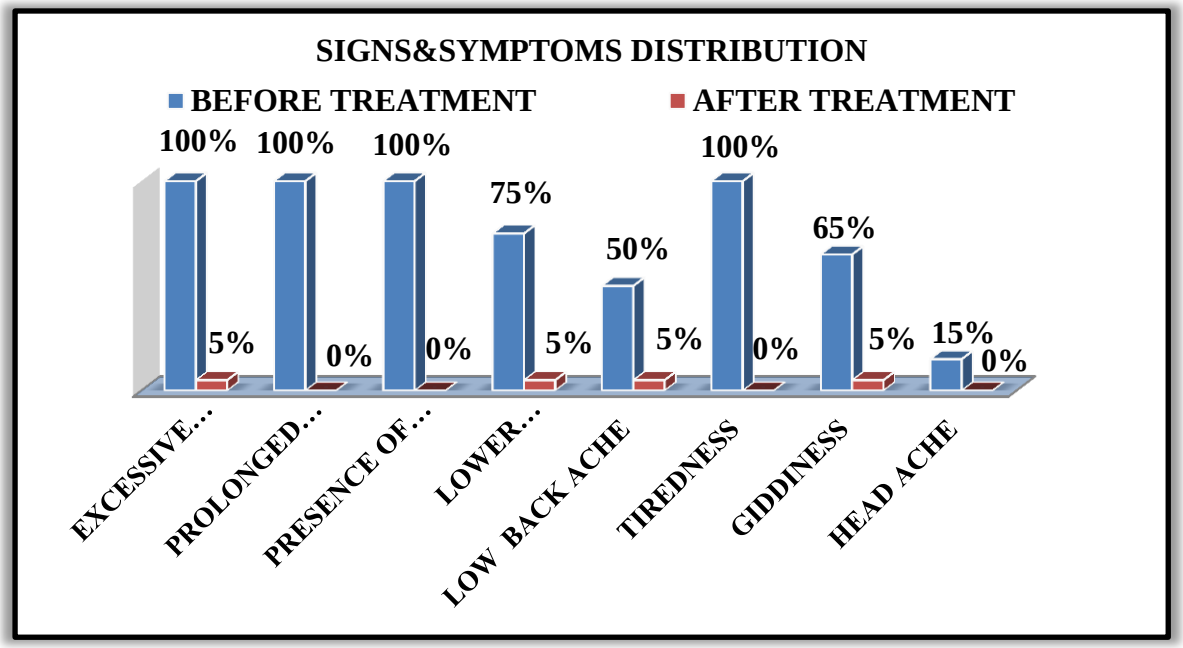


INFERENCE

65% of patients had Pitha neer and 35% of patients had Vatha neer.

SIGNS AND SYMPTOMS

S.NO	SIGNS AND SYMPTOMS	BEFORE TREATMENT		AFTER TREATMENT	
		NO.OF CASES	PERCE NTAGE	NO.OF CASES	PERCEN TAGE
1.	EXCESSIVE MENSTRUATION	20	100%	1	5%
2.	PROLONGED MENSTRUATION	20	100%	0	0%
3.	PRESENCE OF BLOOD CLOTS	20	100%	0	0%
4.	LOWER ABDOMINAL PAIN	15	75%	1	5%
5.	LOW BACK ACHE	10	50%	1	5%
6.	TIREDNESS	20	100%	0	0%
7.	GIDDINESS	13	65%	1	5%
8.	HEAD ACHE	3	15%	0	0%



INFERENCE

Excessive menstrual bleeding after treatment drawn from 100% to 5%, prolonged menstrual bleeding drawn from 100% and presence of blood clots drawn from 100% and tiredness drawn from 100% to 0% and head ache from 15% were drawn to 0%, lower abdominal pain from 75% and giddiness from 65% were drawn to 5%, low back ache from 50% drawn to 5%.

NUMBER OF PADS

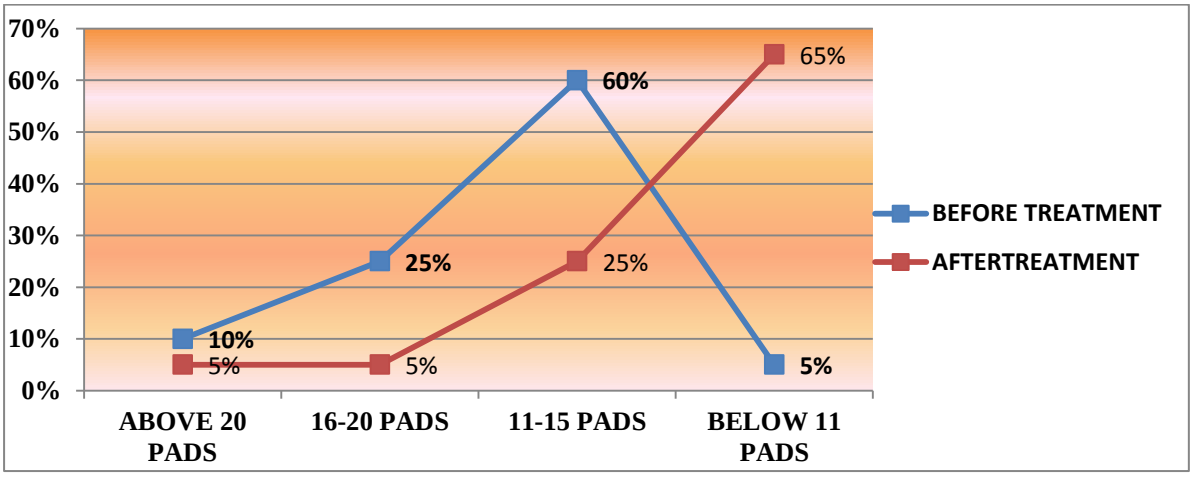
BEFORE TREATMENT

S.NO	NO.OF PADS/CYCLE	NO.OF CASES/20	PERCENTAGE (%)
1.	ABOVE 20 PADS	2	10
2.	16-20 PADS	5	25
3.	11-15 PADS	12	60
4.	BELOW 11 PADS	1	5

AFTER TREATMENT

S.NO	NO.OF PADS/CYCLE	NO.OF CASES/20	PERCENTAGE (%)
1.	ABOVE 20 PADS	1	5
2.	16-20 PADS	1	5
3.	11-15 PADS	5	25
4.	BELOW 11 PADS	13	65

NUMBER OF PADS BEFORE AND AFTER TREATMENT



INFERENCE

After treatment, patients using above 20 pads were drawn from 10% to 5%, the patients using 16-20 pads were drawn from 25% to 5%, patients using 11-15 pads were drawn from 60% to 25% and the patients using below 11 pads were increased from 5% to 65%.

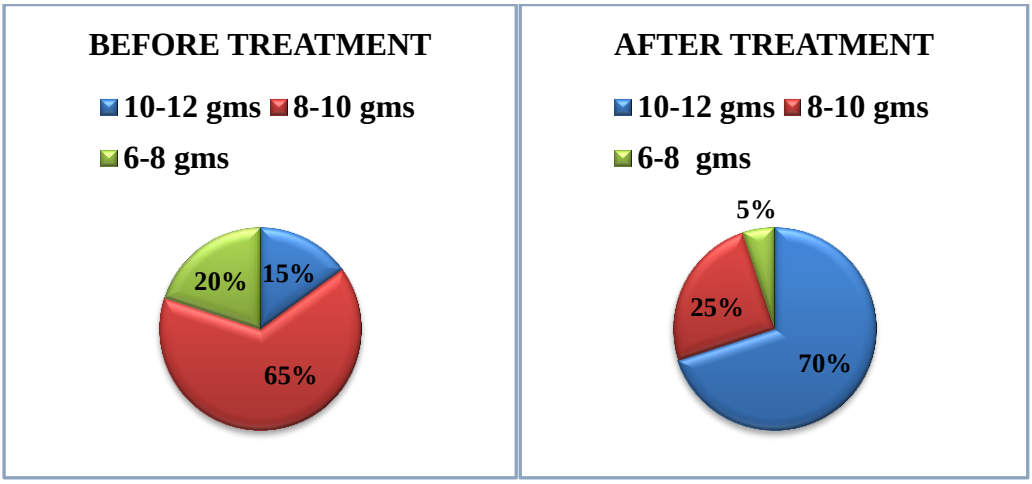
HAEMATOLOGICAL OBSERVATION

BEFORE TREATMENT

S.NO	HAEMOGLOBIN LEVEL	NO.OF CASES/20	PERCENTAGE
1.	10-12 gms	3	15%
2.	8-10 gms	13	65%
3.	6-8 gms	4	20%

AFTER TREATMENT

S.NO	HAEMOGLOBIN LEVEL	NO.OF CASES/20	PERCENTAGE
1.	10-12 gms	14	70%
2.	8-10 gms	5	25%
3.	6-8 gms	1	5%

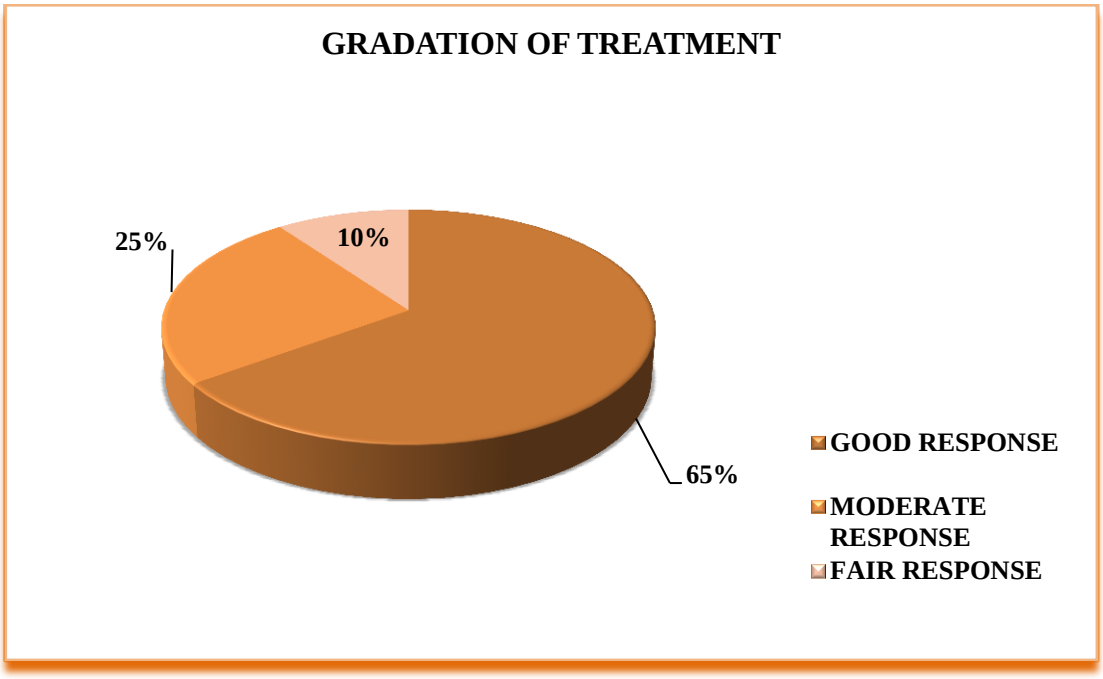


INFERENCE

After treatment 6-8 gms of Hb level were noticed in 5% of patients, 8-10gms of Hb were noticed in 25% of the patients and 10-12 gms of Hb level were noticed in 70% of the patients.

GRADATION OF RESULTS

S.NO	GRADE OF RESULTS	NO.OF CASES/20	PERCENTAGE
1.	GOOD RESPONSE	13	65%
2.	MODERATE RESPONSE	5	25%
3.	FAIR RESPONSE	2	10%



INFERENCE

Good response of treatment was about 65% and moderate response of treatment was about 25% and fair response was in 10% of the patients.

NUMBER OF PADS USED BY THE PATIENTS

BEFORE AND AFTER TREATMENT

S.NO	OP.NO	PATIENT'S AGE/SEX	NUMBER OF PADS FOR A CYCLE	
			BT	AT
1.	5006	36 Yrs/ female	16	10
2.	8350	30 yrs/ female	22	13
3.	3489	33 yrs/ female	14	10
4.	8150	35 yrs/ female	10	7
5.	7305	35 yrs/ female	15	10
6.	1191	43 yrs/ female	13	8
7.	1709	23 yrs/ female	18	11
8.	1687	40 yrs/ female	14	10
9.	1686	34 yrs/ female	26	21
10.	1737	45 yrs/ female	11	8
11.	1738	21 yrs/ female	22	13
12.	3457	20 yrs/ female	13	9
13.	3456	25 yrs/ female	15	10
14.	5348	20 yrs/ female	15	11
15.	5346	35 yrs/ female	16	11
16.	5347	25 yrs/ female	20	12
17.	5501	40 yrs/female	12	8
18.	9484	22 yrs/ female	14	10
19.	6585	50 yrs/ female	13	9
20.	1179	40 yrs/ female	15	10

HAEMOGLOBIN LEVEL

BEFORE AND AFTER TREATMENT

S.NO	OP.NO	PATIENT'S AGE/SEX	HAEMOGLOBIN LEVEL IN GMS/100ML OF BLOOD	
			BT	AT
1.	5006	36 Yrs/ female	8.0	9.1
2.	8350	30 yrs/ female	6.4	8.3
3.	3489	33 yrs/ female	8.1	9.5
4.	8150	35 yrs/ female	9.0	10.2
5.	7305	35 yrs/ female	9.6	10.5
6.	1191	43 yrs/ female	10.0	10.8
7.	1709	23 yrs/ female	9.2	10.5
8.	1687	40 yrs/ female	9.8	10.5
9.	1686	34 yrs/ female	7.0	7.9
10.	1737	45 yrs/ female	10.8	11.4
11.	1738	21 yrs/ female	9.4	10.6
12.	3457	20 yrs/ female	9.8	10.5
13.	3456	25 yrs/ female	9.4	10.2
14.	5348	20 yrs/ female	9.2	10.2
15.	5346	35 yrs/ female	10.6	11.2
16.	5347	25 yrs/ female	8.0	9.4
17.	5501	40 yrs/female	9.0	10.2
18.	9484	22 yrs/ female	9.7	10.6
19.	6585	50 yrs/ female	8.3	9.1
20.	1179	40 yrs/ female	8.5	10.3

BLEEDING TIME AND CLOTTING TIME

BEFORE AND AFTER TREATMENT

S.NO	OP.NO	PATIENT'S AGE/SEX	BLEEDING TIME Min' Sec"		CLOTTING TIME Min' Sec"	
			BT	AT	BT	AT
1.	5006	36 Yrs/ female	2'54"	2'20"	4'48"	5'12"
2.	8350	30 yrs/ female	2'10"	1'22"	4'49"	4'14"
3.	3489	33 yrs/ female	3'10"	2'54"	4'55"	4'17"
4.	8150	35 yrs/ female	2'12"	2'10"	6'42"	5'40"
5.	7305	35 yrs/ female	3'27"	2'44"	6'02"	6'41"
6.	1191	43 yrs/ female	2'36"	1'10"	4'52"	5'25"
7.	1709	23 yrs/ female	3'27"	2'10"	5'24"	4'18"
8.	1687	40 yrs/ female	2'10"	1'10"	5'44"	5'10"
9.	1686	34 yrs/ female	3'08"	2'58"	6'34"	6'02"
10.	1737	45 yrs/ female	2'42"	2'40"	5'38"	4'51"
11.	1738	21 yrs/ female	1'48"	1'18'	5'22"	5'32"
12.	3457	20 yrs/ female	2'40"	1'08"	4'36"	3'50"
13.	3456	25 yrs/ female	3'36"	2'10"	5'44"	5'10"
14.	5348	20 yrs/ female	2'10"	1'54"	3'55"	3'10"
15.	5346	35 yrs/ female	2'54"	2'06"	3'24"	3'20'
16.	5347	25 yrs/ female	2'10"	1'46"	5'10"	4'51"
17.	5501	40 yrs/female	3'09"	2'04"	5'48"	5'16"
18.	9484	22 yrs/ female	2'24"	2'02"	5'40"	4'39"
19.	6585	50 yrs/ female	2'54"	1'59"	6'24"	5'15"
20.	1179	40 yrs/ female	2'55"	2'02"	6'10'	5'39'

LAB INVESTIGATION REPORT OF PATIENTS

S NO	OP NO	BEFORE TREATMENT						AFTER TREATMENT						BEFORE TREATMENT			AFTER TREATMENT		
		TC	DC			ESR		TC	DC			ESR		SUGAR	UREA	CHOL	SUGAR	UREA	CHOL
			P	L	E	1/2	1		P	L	E	½	1	(mg/dl)	(mg/dl)	(mg/dl)	(mg/dl)	(mg/dl)	(mg/dl)
1	5006	8400	64	33	3	7	16	9100	67	32	1	3	9	98	32	160	102	31	169
2	8350	7800	64	32	4	18	26	8300	64	34	2	6	14	86	31	173	94	32	172
3	3489	8500	60	36	4	6	15	9450	63	35	2	1	6	80	31	165	92	30	170
4	8150	8200	50	45	5	26	54	8600	55	42	3	8	20	105	33	196	102	31	190
5	7305	7700	65	32	3	10	22	8100	64	35	1	4	9	96	27	166	100	29	168
6	1191	7400	50	45	5	15	40	7800	60	38	2	4	18	100	29	167	105	28	172
7	1709	9000	62	32	4	12	22	9200	62	36	2	3	9	110	31	160	108	30	156
8	1687	8300	61	34	5	26	50	8950	65	34	1	9	18	82	27	178	90	30	180
9	1686	8600	68	27	5	12	20	9300	66	33	1	2	8	93	32	189	99	31	182
10	1737	6300	75	21	4	2	7	7500	69	31	0	2	7	189	35	158	105	33	160
11	1738	8300	62	35	3	2	5	8650	63	36	1	0	2	110	31	143	96	32	150
12	3457	9600	68	29	3	16	30	9950	66	32	1	2	14	108	31	175	102	29	172
13	3456	7000	50	45	5	2	4	7000	54	44	2	1	2	120	34	158	124	33	166
14	5348	8900	64	31	5	18	34	9100	63	35	2	6	15	88	32	187	102	30	180
15	5346	8600	57	39	4	3	10	9200	59	38	3	1	4	98	28	173	96	32	188
16	5347	8700	62	35	3	12	20	8900	63	36	1	9	18	96	36	160	98	34	156
17	5501	8900	61	34	5	4	12	9400	64	35	1	2	6	99	24	156	105	23	160
18	9484	8600	64	32	4	8	26	9600	65	34	1	2	16	90	32	169	98	30	172
19	6585	7400	56	49	5	18	40	8100	59	37	4	8	15	82	34	144	90	31	152
20	1179	7900	68	28	4	2	6	8300	69	29	2	5	12	104	33	150	102	34	145

TC: TOTAL COUNT DC: DIFFERENTIAL COUNT ESR: ERYTHROCYTE SEDIMENTATION RATE

A:ALBUMIN S:SUGAR D:DEPOSITS

DISCUSSION

PITHA PERUMBADU ROGAM which has been compared with the modern clinical entity MENORRHAGIA. Menstrual disorders are the second most common gynaecological condition to be referred to hospitals. Among the menstrual disorders MENORRHAGIA is the most common gynaecological disorder in the reproductive system of women. Around 30% of women reports heavy menstrual bleeding.

Most common cause of Menorrhagia are Dysfunctional uterine bleeding, Fibroid uterus, endometrial polyp, poly cystic ovarian disease, Adenomyosis and chronic tubo-ovarian mass. Long duration of menstrual blood flow, passage of blood clots, use of increased number of sanitary pads, pallor and low level of haemoglobin give an idea about the correct diagnosis and magnitude of menorrhagia.

Menorrhagia interfere with a Women's physical, emotional, Social and mental quality of life. It can occur alone or in combination with other symptoms. It is related to increased limitations in physical activities and limitations in social and leisure activities.

The definitive treatment is appropriate to the cause for menorrhagia. Hence with the help of the trial medicine from the Siddha system of medicine, results and observations are noted for this study.

20 patients with PITHA PERUMBADU ROGAM were selected. The patients were examined based on Siddha and as well as modern aspects. All the necessary investigations were made for all patients during the study. All the patients were administered with the trial medicine.

The clinical improvement of the patients were completely observed and efficacy of the trial medicine have been studied . Results obtained were discussed below for better conclusion.

Trial drug administered was Naaval nei – 5gm thrice a day after food for one Mandalam (48 days).

DRUG AUTHENTICATION

The required raw drugs are obtained from a well reputed indigenous raw drug shop. The raw drugs taken for study was authenticated by the Botanist, Govt. Siddha Medical College, Chennai 600106.

PRE CLINICAL STUDIES

Physiochemical analysis

The Loss on drying (at 105° C) was 31.378%

The total ash value of Naaval Nei was 4.15%

The water soluble ash value was 2.205%

The acid insoluble ash value was 0.615 %

Water soluble extractive value was 15.06 %

Alcohol soluble extractive value was 2.165%

Acid value was 23.0

Saponification value was 244

Iodine value was 28.0

Peroxide value was 0.2006

pH value (10%) was 6.51

TOXICOLOGICAL STUDY

Acute toxicity study

Acute toxicity study of the study drug *Navaal Nei* was carried out as per OECD guideline (Organization for Economic Co-operation and Development) Guideline-423. The experimental protocol was approved by The Institutional Animal Ethics Committee of Sathyabama University, Chennai, Tamil Nadu, India. IAEC reference number : SU/CLATR/IAEC/IV/017/2016. The study was conducted with single oral dose administration of Navaal Nei. In acute toxicity test the NAAVAL NEI was found to be non toxic at the dose level of 2000mg/kg body weight.

Sub-acute toxicity study

Sub-acute toxicity study was carried out as per OECD guidelines – 407. At the end of the studies the animals were sacrificed and the haematological parameters,

biochemical parameters, urine parameters and the histopathology of the vital organs like liver, heart, spleen and kidney were carried out. The study results show that the trial drug was safe, and did not produced any toxic effects.

Pharmacological Evaluation

The experimental protocol was approved by The Institutional Animal Ethics Committee of Sathyabama University, Chennai, Tamil Nadu, India. IAEC: SU/CLATR/IEAC/VII/049/2016 . Pharmacological Evaluation of styptic activity of Naaval nei on Aspirin induced bleeding time prolongation in rats .The result shows that the trial drug NAAVAL NEI has styptic activity.

BIOCHEMICAL ANALYSIS

In Naaval nei, basic radicals like iron, calcium and reducing sugar were present .

CLINICAL STUDIES

Study design

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

The study was approved by Institutional Ethics Committe (IEC) and the approved number is GSMC-CH-ME-4/2015/005. The stydy was registered in Clinical Trials Registry – India (CTRI) and the reference no is CTRI/2017/05/008615.

Sample size

20 patients in the age group 15-50 years.

Age distribution

Women with the reproductive age 15-50 were affected with the disease. The incidence is more in the age of 15-25 years about 35%, in the age group of 26-35 years about 30%, in the age group of 36-45 years about 30% 46-50 years about 5%.

Occupational reference

60% of patients were house wife, 30% of patients were working women and 10% of patients were students.

Marital status

75% of patients were married and 25% of patients were unmarried.

Socio-economic status

45% of patients were from middle income group, 25% of patients were upper income group and 30% of patients were from low income group.

Food habits

70% of patients have mixed diet habit and 30% of patients were vegetarians.

Distribution of Landscapes (Thinai)

As the trial was conducted in Chennai which is Neithal nilam, most of patients about 80% were from Neithal Nilam and 20% of patients were from Marutha Nilam.

Seasonal Reference

25% of patients were reported in Kaarkaalam , 10% of patients were reported in Elavenil kaalam and Muthuvenil kaalam, 15% of patients were reported in munpanikaalam and 40% of patients were reported in pinpanikaalam.

Mukkutram

In Perumbadu, the clinical condition is due to the imbalance of **PITHAM.** Pitham is deranged primarily and later it deranges vatha and the derangement of Pitha-vatha leads to the derangement of Abanaan which in turn cause the disease. The pathogenesis of the disease depends upon the affected Pitha and Vatha.

Vatham

Abaanan (100%), Pranan (20%),Udhanan (15%), Viyanan (100%), Koorman (15%), Samanan (60%), and Devathathan (100)% were affected.

- Affected Abaanan results in causing excessive and prolonged menstruation bleeding.

- Affected Pranan results in causing dyspnoea and breathlessness due to low Hb level.
- Affected Viyanan results in causing lower abdominal pain and low back ache headache and body pain.
- Affected Udhanan results in producing nausea, vomiting and cough.
- Affected Koorman results in causing visual disturbances..
- Affected Samaanan and Devathathan results in producing loss of appetite or indigestion and tiredness respectively.

Pitham

Saathagam (100%), Ranjagam (80%), Alosagam (15%), Praasagam (20%) and Analagam (60%) were affected.

- Affected Saathaga Pitham results in causing general malaise, tiredness and giddiness.
- Affected Ranjaga pitham results in low Hb level.
- Affected Praasagam results in pallor of skin due to very low level of haemoglobin.
- Affected Aalosaga pitham results in producing dimness of vision.
- Affected Analaga Pitham results in causing loss of appetite respectively.

Kabham

Avalambagam (20%), Kilethagam (60%), Tharpagam (30%), Santhigam (40%) were affected.

- Affected Avalambagam results in producing low Hb levels.
- Affected Santhigam results in producing low back ache.
- Affected Kilethagam results in causing loss of appetite.
- Affected Tharpagam results in producing burning sensation.

Ezhu Udal Thathukkal

Saaram (100%), Senneer (80%), Enbu(40%), Suronitham (100%) were affected.

- Affected Saaram results in causing loss of appetite and tiredness.
- Affected Senneer results in causing decreased level of haemoglobin in blood.
- Affected Enbu results in causing Low back ache.
- Affected Suronitham results due to presence of excessive menstruation.

Envagai Thervugal

Among 20 patients,

Naa (10%), Niram (10%), Vizhi (10%), Malam (40%),Moothiram (10%) and Naadi (100%) were affected.

Pitha vatha naadi (65%) and Vatha pitha naadi (35%).

- Affcted Naa results in paleness of tongue.
- Affected Niram results in pallor of the skin due to low Hb level.
- Affected Vizhi results in paleness of lower eyelids due to low level of haemoglobin.
- Affected Malam was due to constipation.
- Affected Moothiram was due to burning micturation.

Naadi

Pitha vatha naadi (65%) and Vatha Pitha naadi (35%) were noticed. Pitha vatha naadi and Vatha Pitha naadi was due to derangement of Pitham and Vatham.

Neikuri

Pitha neer (65%) and vatha neer (35%) was observed.

Haematological findings

Blood routines were sampled.

It was observed that 100% of patients show elevation of haemoglobin level in blood.

Bleeding time and clotting time investigation was taken for affordable patients to exclude blood disorders.

Special investigation

USG Abdomen and pelvis was taken before the treatment.

The impression found on USG pelvis was Fibroid uterus, poly cystic ovarian disease and bulky uterus in most of the cases.

After confirming the results, the patients were given the trial medicines and instructed to follow the diet and other restriction based on siddha system.

Mode of action of the Trial drug

Based on taste (Suvai)

In the trial drug Naaval Nei - most of the incredients included in this trial drug were thuvarppu, kaippu and inippu suvai.

Basically astringent taste has the characteristic action of:

- Treats the derangement of pitham
- Causes vaso constriction
- Decreases the secretions
- Purifies the blood
- Cures the ulcer

Basically bitter taste has the following characteristics:

- Treats the derangement of Pitham.
- Cures loss of appetite.
- Removes toxins from body.

Basically sweetness taste has the following characteristics :

- Treats the derangement of Pitham.
- Nourishes the body

By this, the trial drug Naaval Nei treats the derangement of pitha which is the main cause of disease and also controls bleeding by vaso constriction. Hence it acts as an effective drug in Pitha Perumbadu Rogam and considered to be **Ethirurai maruthuvam.**

Based on Nature (Veeriyam)

The trial drug Naaval Nei is of Thatppam nature as the ingredients in this has thatppa nature.

Clinical Manifestation

Among the total 20 patients all were improved both subjectively and objectively.

Clinical symptoms before and after treatment were noted. To obtain the prognosis of each clinical symptoms the following formulae was used.

$$\frac{\text{Number of cases after Treatment}}{\text{Number of cases before Treatment}} \times 100$$

Thus the clinical trial study showed significant clinical improvement in certain clinical manifestations of Pitha Perumbadu Rogam such as excessive menstruation (95%), Prolonged menstruation (100%), Presence of blood clots (100%) Lower abdominal pain (70%), Low back ache (45%), Tiredness (100%) and Giddiness (60%), Head ache (15%) were relieved.

Haemoglobin level of blood is elevated in all the patients. Since, most of the ingredients present in the trial drug as haematinic activity.

Biostatistics

Since the p value is significant in all signs and symptoms. So there is significant reducing of signs & symptoms among the patients for the treatment of Pitha Perumbadu (Menorrhagia). Statistical analysis of clinical study was done from the subjective and objective parameters (Number of pads, Bleeding time and Clotting time) observed before and after treatment. They showed highly significant. Since the P value is highly significant (< 0.001), So the treatment was significantly improving the Hb level among the patients for the treatment of Pitha Perumbadu. Hence it is concluded that the treatment was effective and significant**.**

Grading of results

Out of 20 patients, 13 cases (65%) shows good result, 5 cases (25%) shows moderate result, 2cases (10%) shows fair result .

SUMMARY

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

A total of 20 patients were treated in the Outpatient department. The clinical and pathological assessment was carried out on the basis of Siddha and Modern aspects.

All the patients were treated with NAAVAL NEI (5 gm TDS). The duration of the treatment was fixed as ONE MANDALAM (48 DAYS).

- The comparatively larger incidence of Pitha perumbadu was found to be in 15-25 years of age.
- The prevalence of the disease was high among Middle class populations 45% followed by Lower class 30% and High class population 25%.
- Out of 20 patients, 2 patient (10%) were a student, 6 patients (30%) were working women,12 patients (60%) were house wife.
- In case of diet, 70% patients consume Mixed diet.
- From selected 20 patients, 5 patients (25%) comes under Kaarkaalam, 3 patients (15%) comes under Munpani, 2 patients (10%) comes under Elavenil, 2 patients (10%) comes under Mudhuvenil kaalam and 8 patients (40%) comes under Pinpanikaalam.
- Out of 20 patients, 80% comes under Neithal category.
- In mukkutram aspect - In Vatham

  Abanan (100%), Praanan (20%), Viyanan (100%), Udhanan (15%), Koorman (15%), Samanan (60%), and Devathathan (100)% were affected.

- In Pitham

Sathagam (100%), Ranjagam (80%), Alosagam (15%), Praasagam (20%) and Analagam (60%) were affected.

- In Kabham

Avalambagam (20%), Kilethagam (60%), Tharpgam (30%), Santhigam (40%) were affected.

- Among Ezhu Udal Thathukkal, Saaram (100%), Senneer (80%), Enbu (40%), Suronitham (100%) were affected.

- Among Envagai Thervugal Naa (10%), Niram (10%), Vizhi (10%), Malam (40%) Moothiram (10%) and Naadi (100%) were affected.
- Naadi showed Pitha vatha naadi (65%) and Vatha pitha naadi (35%).
- In neikuri examination Pitha neer (65%) and vatha neer (35%) were seen.

The ingredients of trial medicines were found to have the properties of reducing the symptoms of PITHA PERUMBADU ROGAM. In Naaval Nei, basic radicals like iron, calcium and reducing sugar were present.

The Toxicological studies of the trial medicine reveals no toxicity.

The Pharmacological studies of the trial medicine shows styptic activity.

The Bio statistical report of the clinical trial shows significant P value and thus concluded that, the treatment is effective and significant.

Among 20 patients, 65% of cases showed good result and 25% of cases showed moderate result and 10% of cases showed fair result in PITHA PERUMBADU ROGAM (MENORRHAGIA).

CONCLUSION

- Pitha Perumbadu is primarily due to the derangement of Pitha kutram. The ingredients of the medicine Naaval nei have the properties of neutralizing the deranged kutram.
- From the preclinical toxicity studies, the medicine Naaval nei revealed no toxicity and proved to be safe.
- From the preclinical pharmacological studies, it is evident that the medicine Naaval nei have Styptic activity.
- No adverse effects was reported during the course of the treatment.
- The medicine Naaval nei which gives a maximum relief from the considerable symptoms of Menorrhagia such as excessive menstruation, prolonged menstruation, presence of blood clots, lower abdominal pain and low back ache.
- The ingredients of the trial drug is easily available.
- The trial medicine is economical and palatable.

Therefore I conclude that, the medicine Naaval nei can give a better solution for Pitha Perumbadu.

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

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

This Certificate is awarded to Dr/~~Mr/Mrs~~.....S. Jaya Priya.....

for participating as ~~Resource Person~~ / Delegate in the Seventeenth (XVII) 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 15th to 19th June 2015.

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

Government Siddha Medical College
Department of Medicinal Botany

Dr.S.Sankaranarayanan M.Sc., M.Phil., Ph.D.,
Asst. Professor
Head of the Department

6, Anna Arch Rd,
NSK Nagar,
Arumbakkam, Chennai,
Tamil Nadu 600106.

AUTHENTICATION CERTIFICATE

Based upon the organoleptic/macroscopic/microscopic examination of fresh/market sample, it is certified that the specimen given by S. Jayapriya BSMS studying MD (S), Government Siddha Medical College, Arumbakkam, Chennai is identified below

Binomial name		Family	Regional names
Rhus succedanea Linn.	*Rhus* acuminata DC.	Anacardiaceae	Tamil: Karkatagachingi
Curcuma angustifolia Roxb.	Maranta arundinacea	Zingiberaceae	Tamil: India arrow root
Cassia auriculata Linn.	Senna auriculata (L.) Roxb.	Caesalpinioideae	Tamil: Avarai arisi
Syzygium cumini (L.) Skeels	*Eugenia jambolana* Lam	Myrtaceae	Tamil: Naval pattai
Curculigo orchioides Gaertn	*Curculigo brevifolia* Dryand.	*Hypoxidaceae*	Tamil: Nilapanai kizhangu
Cedrus deodara	*Cedrus atlantica*	Pinaceae	Tamil: Thevatharu
Glycyrrhiza glabra	*Liquirita officinalis* (L.)	Fabaceae	Tamil: Athimathuram
Cinnamomum tamala	Cinnamomum tejpata	Lauraceae	Tamil: Elavanga pattai
Mesua ferrea L.	*Mesua nagana* Gardn.	Clusiaceae	Tamil: *Siru Naga Poo*
Nardostachys jatamansi (D.Don) DC	*Nardostachys chinensis* Batalin	Valerianaceae	Tamil: Vetpalai
Cassia auriculata Linn.	Senna auriculata (L.) Roxb.	Caesalpinioideae	Tamil: Avarai Verpattai
Aconitum heterophyllum wall	*Aconitum atees* Royle	Ranunculaceae	Tamil: Athivitayam

Government Siddha Medical College
Department of Medicinal Botany

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Asst. Professor
Head of the Department

6, Anna Arch Rd,
NSK Nagar,
Arumbakkam, Chennai,
Tamil Nadu 600106.

Binomial name		Family	Regional names
Costus speciosus	*Costus pictus* D. Don	Costaceae.	Tamil: Kostum
Hemidesmus indicus (L.) R. Br.	*Periploca indica* L.	Asclepiadaceae	Tamil: Nanari ver
Sterculia foetida Linn.	*Clompanus foetida* (L.) Kuntze.	Sterculiaceae	Tamil: Perumarathu pattai

03/06/2016

Dr. S. Sankaranarayanan M.Sc., M.Phil., Ph.D.,

Dr. S. SANKARANARAYANAN, M.Sc., M.Phil., Ph.D.,
Assistant Professor
Dept. of Maruthuva Thavaraiyal
(Medicinal Botany and Pharmacognosy)
Govt. Siddha Medical College,
Arumbakkam, Chennai-600 106.

GSMC/MB-09/2016

Date:02.06.2016

CERTIFICATE

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

IAEC Approval No.: **SU/CLATR/IAEC/IV/017/2016**
Animal Sanctioned: *Rattus norvegicus* / Wistar albino rats
Male: 9; Female: 15; Total: 24 (Twenty Four)
Date: 5.3.2016

DR.B.SHEELA RANI
Chair Person

DR.R.ILAVARASAN
CPCSEA Main Nominee

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

CERTIFICATE

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

IAEC Approval No.: **SU/CLATR/IAEC/VII/049/2016**
Principal Investigator: Dr. S.Jayapriya
Animal Sanctioned: *Rattus norvegicus* / Wistar Albino rats
Male: 24; Total: 24 (Twenty Four)
Date: 05.10.2016

B. Sheela Rani.

DR. B. SHEELA RANI
Chairperson

DR. R. ILAVARASAN
CPCSEA Nominee

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

Project Report on Toxicity Profiling of Naval Nei

Name **:** Dr. S. Jayapriya

IAEC : SU/CLATR/IAEC/017/2016

Name of the Formulation : Naaval Nei

Abbreviation : NN

ACUTE TOXICITY STUDY

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

Animal

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

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

Acute toxicity Study

Acute toxicity study will be carried out in accordance with OECD guideline 423 [(74)]. The animals were fasted overnight with free access to water. The study was conducted with single oral dose administration of *Naval Nei*.

IAEC SU/CLATR/IAEC/IV/017/2016

Animal Grouping

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

Dose Equivalent = 1ml is equivalent to 1.0972 gm

Animal Grouping

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

The animals were fasted overnight (12- 16 hrs) with free access to water. The study was conducted with single oral administration of study drug *Naval Nei* 2000mg/kg equivalent to 0.5ml(p.o). The animals were observed continuously for first 72 h and then 14 days for emerging signs of behavioral changes, body weight changes and for mortality.

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

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

SUB-ACUTE TOXICITY STUDY

Sub-acute toxicity study was carried out as per OECD guidelines Guideline-407 [(75)].

Animals

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

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

IAEC SU/CLATR/IAEC/IV/017/2016

Animal Grouping

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

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

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

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

The animals were randomly divided into control group and drug treated groups for two different doses viz. low dose (200 mg/kg b.w) equivalent to 0.05 ml and high dose (400 mg/kg b.w) equivalent to 0.1 ml,p.o per rat.

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

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

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

Hematological analysis

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

Biochemical analysis **(76)**

Serum samples were analyzed for High Density Lipoprotein (HDL), Low density Lipoprotein (LDL), Very low density Lipoprotein (VLDL) , Triglycerides (TGL), Total Cholesterol , Blood urea nitrogen (BUN), Creatinine, Albumin, Total Protein, Glucose, Uric acid, Aspartate Transaminase (AST), Alanine amino Transaminase (ALT) and Alkaline

Acute Toxicity Study

Analysis	**Group I**
Consistency	Soft -Pasty
Shape	Oblong
Colour	Greenish
Mucous Shedding	Absence
Blood Cells	Absent
Signs of Infection	None Observed

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

RESULTS

Assessment of clinical signs in rats treated with *Naval Nei* on Acute toxicity study

Parameter	**Group I**
Clinical Signs Parameters for the duration of 14 days	Test Drug 2000mg/ Kg
Number of animals observed	6 Female
Lacrimation	Absence
Salivation	Absence
Animal appearance	Normal
Tonic Movement	Absence
Clonic Movement	Absence
Laxative action	Mild
Touch Response	Normal
Response to Sound	Normal Response
Response to Light	Normal Response

Mobility	Normal Response
Respiratory Distress	Nil
Skin Color	Normal
Stereotype behavior	Absence
Piloerection	Absence
Limb Paralysis	Absence
Posture	Normal
Open field behavior	Normal
Gait Balancing	Normal
Freezing Behaviour	Absent
Sings of Stress and Anxiety	None Observed
Muscular coordination	Normal
Muscle grip	Normal
Sedation	Absence
Social Behavior	Normal
Urine Analysis	No Abnormality
Urine Colour	Yellowish Orange
Urine pH	7
Urine - Glucose	Absence
Urine - Ketones	Absence
Urine- Bilirubin	Absence
Urine-Blood Cells	Negative
Urine - Pus cells	Negative
Mortality	Nil

Quantitative data on the body weight of rats treated with *Naval Nei* in Acute toxicity study

Group I	**Before Treatment Weight in Gms**	**After Treatment Weight in Gms**
Mean	181.8	187.2
Std. Deviation	6.94	7.36
Std. Error	2.833	3.005

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

Assessment of clinical signs in rats treated with *Naval Nei* on Sub-Acute toxicity study

Parameter	Group I	Group II	Group III
Clinical Signs Parameters for the duration of 28 days	Control	Test Drug 200mg/ Kg	Test Drug 400mg/ Kg
Number of animals observed	3 Male and 3 Female	3 Male and 3 Female	3 Male and 3 Female
Lacrimation	Absence	Absence	Absence
Salivation	Absence	Absence	Absence
Animal appearance	Normal	Normal	Normal
Tonic Movement	Absence	Absence	Absence
Clonic Movement	Absence	Absence	Absence
Laxative action	Absence	Absence	Moderate
Touch Response	Normal	Normal	Normal
Response to Sound	Normal Response	Normal Response	Normal Response
Response to Light	Normal Response	Normal Response	Normal Response
Mobility	Normal	Normal	Normal
Respiratory Distress	Nil	Nil	Nil
Skin Color	Normal	Normal	Normal
Stereotype behavior	Absence	Absence	Absence
Piloerection	Absence	Absence	Absence
Limb Paralysis	Absence	Absence	Absence
Posture	Normal	Normal	Normal
Open field behavior	Normal	Normal	Normal
Gait Balancing	Normal	Normal	Normal
Freezing Behaviour	Absent	Absent	Absent
Sings of Stress and Anxiety	None Observed	None Observed	None Observed

Muscular coordination	Normal	Normal	Normal
Muscle grip	Normal	Normal	Normal
Sedation	Absence	Absence	Absence
Social Behavior	Normal	Normal	Normal
Urine Analysis	No Abnormality	No Abnormality	No Abnormality
Urine Colour	Yellowish	Yellowish	Yellowish
Urine pH	7	7	7
Urine - Glucose	Absence	Absence	Absence
Urine - Ketones	Absence	Absence	Absence
Urine- Bilirubin	Absence	Absence	Absence
Urine-Blood Cells	Negative	Negative	Negative
Urine - Pus cells	Negative	Negative	Negative
Mortality	Nil	Nil	Nil

Effect of *Naval Nei* on Body weight of Rats in Sub-acute toxicity study

Group I	**Before Treatment Weight in Gms**	**After Treatment Weight in Gms**
Mean	187.3	198.7
Std. Deviation	5.645	6.408
Std. Error	2.305	2.616
Group II	**Before Treatment Weight in Gms**	**After Treatment Weight in Gms**
Mean	184.5	194.2
Std. Deviation	7.868	10.07
Std. Error	3.212	4.11
Group III	**Before Treatment Wt in Gms**	**After Treatment Weight in Gms**
Mean	188.2	200.8
Std. Deviation	4.07	4.215
Std. Error	1.662	1.721

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

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

Group I	**Food intake**	**Water intake**
Mean	19.25	41.25
Std. Deviation	3.072	1.371
Std. Error	1.536	0.6855
Group II	**Food intake**	**Water intake**
Mean	18.5	26.5
Std. Deviation	1.895	1.401
Std. Error	0.9477	0.7005
Group III	**Food intake**	**Water intake**
Mean	18.5	31
Std. Deviation	2.589	0.7201
Std. Error	1.295	0.36

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

Effect of *Naval Nei* on Haematology profile of rats in sub-acute toxicity study.

Group I	**WBC count ($\times 10^3$ µl)**	**RBC ($\times 10^6$ µl)**	**PLT ($\times 10^3$ µl)**	**MCV (fl)**	**MCH (pg)**	**MCHC (g/dl)**	**HGB (g/dl)**
Mean	13.5	7.217	684.3	63.22	19.37	31.47	11.88
Std. Deviation	1.536	1.559	90.86	4.269	3.838	2.083	2.109
Std. Error	0.6272	0.6364	37.09	1.743	1.567	0.8504	0.8612
Group II	**WBC count ($\times 10^3$ µl)**	**RBC ($\times 10^6$ µl)**	**PLT ($\times 10^3$ µl)**	**MCV (fl)**	**MCH (pg)**	**MCHC (g/dl)**	**HGB (g/dl)**
Mean	11.2	5.9	693.2	59.77	21.67	31.57	11.65
Std. Deviation	1.427	0.7403	361.4	3.869	1.878	2.055	1.3

Std. Error	0.5825	0.3022	147.5	1.579	0.7667	0.8389	0.5309
Group III	**WBC count ($\times 10^3$ µl)**	**RBC ($\times 10^6$ µl)**	**PLT ($\times 10^3$ µl)**	**MCV (fl)**	**MCH (pg)**	**MCHC (g/dl)**	**HGB (g/dl)**
Mean	10.45	7.15	874	60.97	18.1	32.92	11.63
Std. Deviation	2.344	0.9354	139.2	7.68	2.445	1.266	1.407
Std. Error	0.9568	0.3819	56.83	3.135	0.9983	0.5167	0.5743

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

Effect of *Naval Nei* on Haematology profile of rats in sub-acute toxicity study.

Group I	**Lymph (%)**	**Mon (%)**	**Neutrophils (X 10^3/mm^3)**	**Eosinophils (%)**	**Basophils (%)**	**MPV (fl)**
Mean	70.74	2.1	2.533	1.3	0.5	6.267
Std. Deviation	6.62	0.7874	1.001	0.2828	0.5477	1.283
Std. Error	2.702	0.3215	0.4088	0.1155	0.2236	0.5239
Group II	**Lymph (%)**	**Mon (%)**	**Neutrophils (X 10^3/mm^3)**	**Eosinophils (%)**	**Basophils (%)**	**MPV (fl)**
Mean	70.15	4.083	1.633	1.5	0.3333	5.617
Std. Deviation	7.654	1.379	0.4803	0.2449	0.5164	1.43
Std. Error	3.125	0.563	0.1961	0.1	0.2108	0.5839
Group III	**Lymph (%)**	**Mon (%)**	**Neutrophils (X 10^3/mm^3)**	**Eosinophils (%)**	**Basophils (%)**	**MPV (fl)**
Mean	66.12	2.7	2.833	1.55	0.3333	5.233
Std. Deviation	4.221	1.352	0.5785	0.2429	0.5164	0.9309
Std. Error	1.723	0.552	0.2362	0.09916	0.2108	0.3801

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

Effect of *Naval Nei* on Serum Bio-chemistry profile of rats in sub-acute toxicity study

Group I	**Blood sugar® (mg/dl)**	**BUN (mg/dl)**	**Serum creatinine (mg/dl)**	**Serum total cholesterol (mg/dl)**	**Serum triglycerides level (mg/dl)**	**Serum HDL cholesterol (mg/dl)**	**Serum LDL cholesterol (mg/dl)**	**Serum VLDL cholesterol (mg/dl)**
Mean	86.17	11.17	0.6167	117.2	80.67	68.67	29.67	16.82
Std. Deviation	8.931	3.251	0.2994	16.98	11.93	12.45	17.75	1.707
Std. Error	3.646	1.327	0.1222	6.93	4.869	5.084	7.246	0.6969
Group II	**Blood sugar®(mg/dl)**	**BUN(mg/dl)**	**Serum creatinine (mg/dl)**	**Serum total cholesterol (mg/dl)**	**Serum triglycerides level (mg/dl)**	**Serum HDL cholesterol (mg/dl)**	**Serum LDL cholesterol (mg/dl)**	**Serum VLDL cholesterol (mg/dl)**
Mean	85.67	16.67	0.7	100.3	73.67	51.33	33.83	14.55
Std. Deviation	8.869	3.983	0.1549	12.94	11.79	4.926	10.61	2.192
Std. Error	3.621	1.626	0.06325	5.283	4.814	2.011	4.331	0.8951
Group III	**Blood sugar® (mg/dl)**	**BUN (mg/dl)**	**Serum creatinine (mg/dl)**	**Serum total cholesterol (mg/dl)**	**Serum triglycerides level (mg/dl)**	**Serum HDL cholesterol (mg/dl)**	**Serum LDL cholesterol (mg/dl)**	**Serum VLDL cholesterol (mg/dl)**
Mean	86.5	13.67	0.8333	112.3	77	66.33	28.17	18.07
Std. Deviation	11.64	2.338	0.1862	17.29	12.93	8.454	9.806	2.936
Std. Error	4.752	0.9545	0.07601	7.06	5.279	3.451	4.003	1.199

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

Effect of *Naval Nei* on Serum Bio-chemistry profile of rats in sub-acute toxicity study

Group I	**Serum total protein (g/dl)**	**Serum albumin (g/dl)**	**(AST) (IU/ml)**	**(ALT) (IU/L)**	**(ALP) (IU/L)**
Mean	4.917	3.717	99.5	32.83	247
Std. Deviation	2.043	1.08	22.51	10.57	20.91
Std. Error	0.834	0.4408	9.19	4.316	8.536
Group II	**Serum total protein (g/dl)**	**Serum albumin (g/dl)**	**(AST) (IU/ml)**	**(ALT) (IU/L)**	**(ALP) (IU/L)**
Mean	4.517	3.433	93	34.67	216.7
Std. Deviation	1.021	0.575	24.1	8.618	66.68
Std. Error	0.4167	0.2348	9.839	3.518	27.22
Group III	**Serum total protein (g/dl)**	**Serum albumin (g/dl)**	**(AST) (IU/ml)**	**(ALT) (IU/L)**	**(ALP) (IU/L)**
Mean	4.583	3.4	97	24.33	172.2
Std. Deviation	1.304	0.7321	26.41	6.121	34.7
Std. Error	0.5326	0.2989	10.78	2.499	14.17

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

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

Group I	**HEART (gms)**	**LIVER (gms)**	**KIDNEYS (gms)**	**SPLEEN (gms)**	**BRAIN (gms)**	**LUNG (gms)**	**STOMACH (gms)**	**TESTES (gms)**	**UTERUS & OVARY (gms)**
Mean	0.5417	6.62	1.507	0.4	1.667	1.633	1.183	2.533	1.133
Std. Deviation	0.05269	0.7811	0.1987	0.1265	0.1751	0.1633	0.2639	0.9074	0.4041
Std. Error	0.02151	0.3189	0.0811	0.05164	0.07149	0.06667	0.1078	0.5239	0.2333
Group II	**HEART (gms)**	**LIVER (gms)**	**KIDNEYS (gms)**	**SPLEEN (gms)**	**BRAIN (gms)**	**LUNG (gms)**	**STOMACH (gms)**	**TESTES (gms)**	**UTERUS & OVARY (gms)**
Mean	0.7233	6.543	1.293	0.5333	1.6	1.75	1.417	3.033	1.2
Std. Deviation	0.1231	1.094	0.1593	0.1506	0.08944	0.2739	0.2483	0.9292	0.1
Std. Error	0.05024	0.4465	0.06505	0.06146	0.03651	0.1118	0.1014	0.5364	0.05774
Group III	**HEART (gms)**	**LIVER (gms)**	**KIDNEYS (gms)**	**SPLEEN (gms)**	**BRAIN (gms)**	**LUNG (gms)**	**STOMACH (gms)**	**TESTES (gms)**	**UTERUS & OVARY (gms)**
Mean	0.555	5.297	1.47	0.7667	1.583	1.617	1.333	4	1.467
Std. Deviation	0.1242	1.012	0.2161	0.216	0.1941	0.1835	0.4274	0.2646	0.05774
Std. Error	0.05071	0.4133	0.08824	0.08819	0.07923	0.07491	0.1745	0.1528	0.03333

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

HISTOPATHOLOGY REPORT

BRAIN

Arrangement of the neurons appears intact with no sings of degeneration or apoptotic changes were observed in sample belongs to group I,II and III.

HEART

Myocardial fiber mass appears denser with no signs of degeneration or fibrosis were observed in samples belongs to group I, II and III.

LUNG

Light microscopic examination of lung revealed normal alveoli and alveolar sac with no signs of infiltration in both control and treated rats.

STOMACH

The continuity of mucosa was normal with no evidence of ulceration. Lumina of blood vessels appears normal. Appearance of glandular lumen was normal in sample belongs to group I, II and III.

LIVER

Appearance of portal triad was normal with no signs of inflammatory cell infiltration. Liver parenchyma appears normal with no evidence of necrosis were observed in sample belongs to group I, II and III.

KIDNEY

Appearance of proximal and distal convolutes tubules was normal with no evidence of atrophy. Junction between cortex and medulla appears distant in sample belongs to group I,II and III.

SPLEEN

Erythropoietic cells (EP) are scattered throughout the red pulp of both the samples. No abnormalities found in lymph nodes of sample belongs to group I, II and III.

TESTES

Normal sertoli cell aligned properly on the basement membrane with oval dome shaped nucleus shows the normal morphology of the seminiferous tubule were observed in sample belongs to group I,II and III.

UTERUS

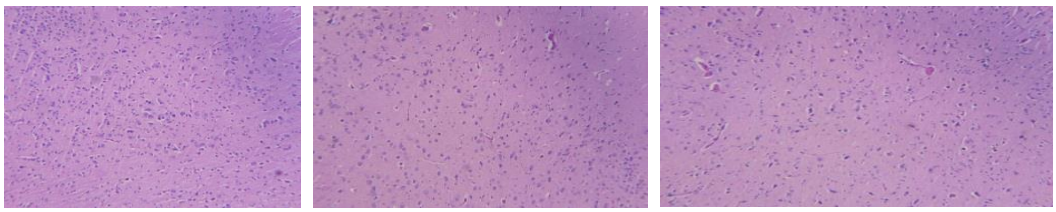
Appearance of endometrium, myometrium and uterine glands was normal. Arrangement of stratum basale, functionale and surface epithelium seems normal in samples belongs to group I,II and III.

OVARY

Histopathological analysis of ovary showing normal corpus luteum (CL) and Primordial follicles with few mature ovarian follicles with no signs of abnormality. Appearance of antral follicle, primary oocyte and secondary follicles are normal in sample belong grouI,II and III.

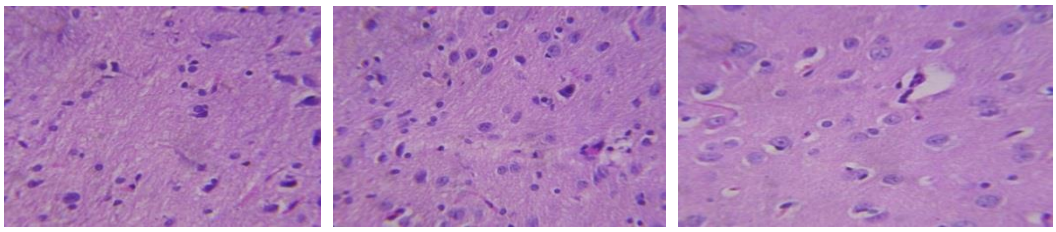
Histopathology of Brain (Male Rat) in Sub-acute toxicity Study

Low Power Magnification 10X



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

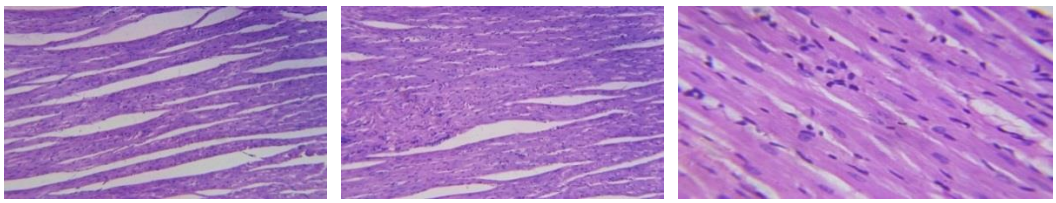
High Power Magnification 40X



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

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

Low Power Magnification 10X



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

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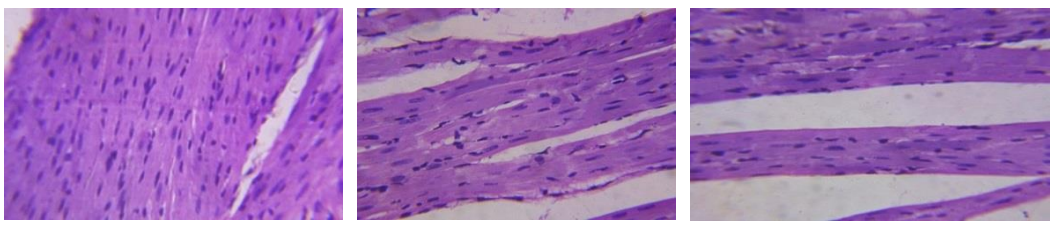
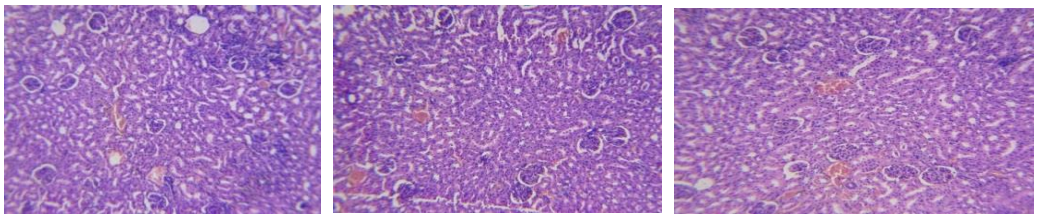


GROUP I **GROUP II** **GROUP III**

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

Low Power Magnification 10X



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

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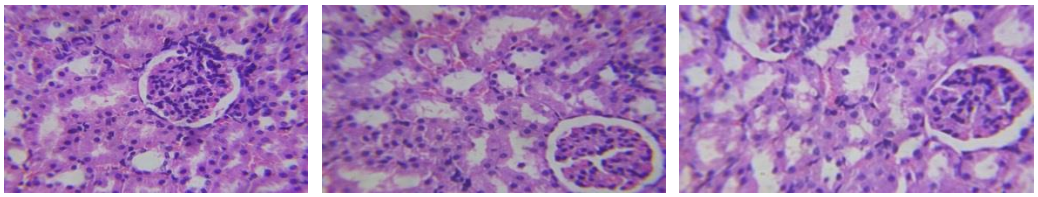
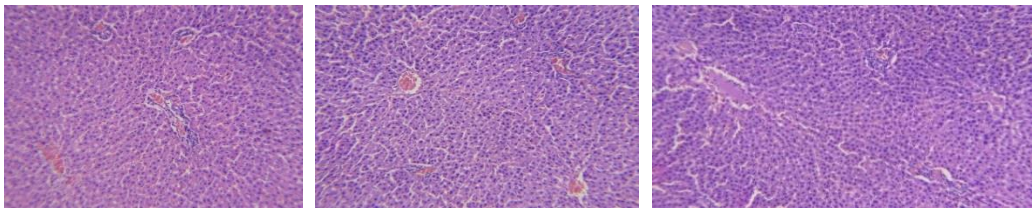


GROUP I **GROUP II** **GROUP III**

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

Low Power Magnification 10X



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

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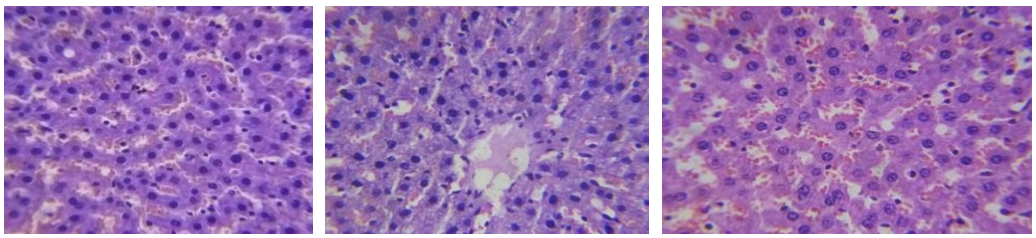
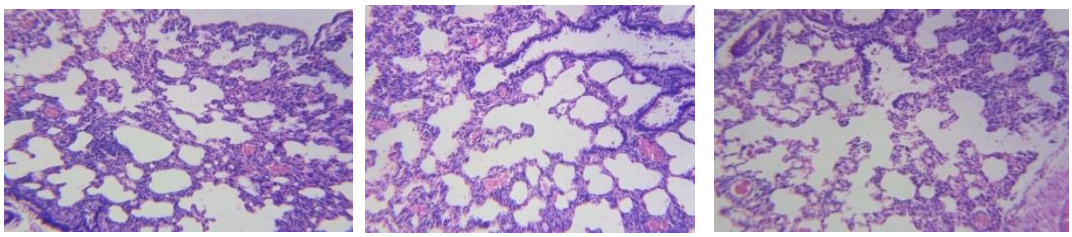


GROUP I **GROUP II** **GROUP III**

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

Low Power Magnification 10X



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

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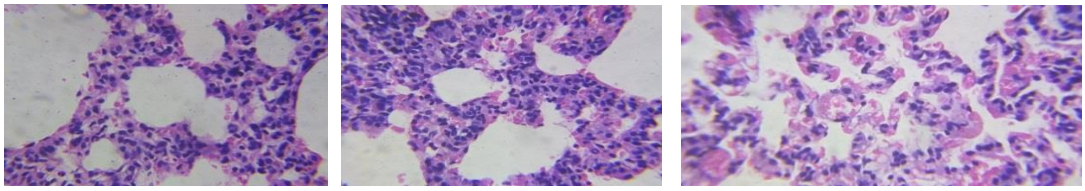
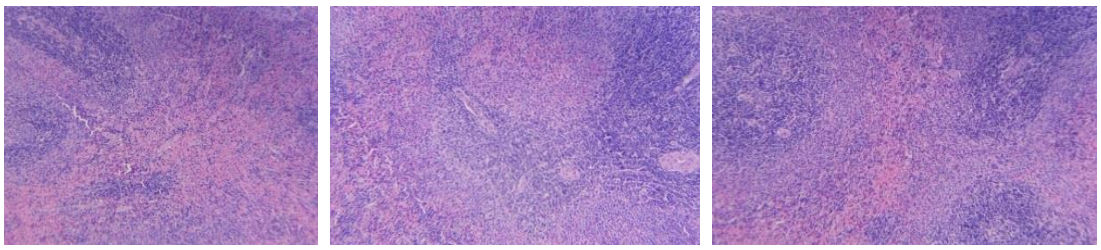


GROUP I **GROUP II** **GROUP III**

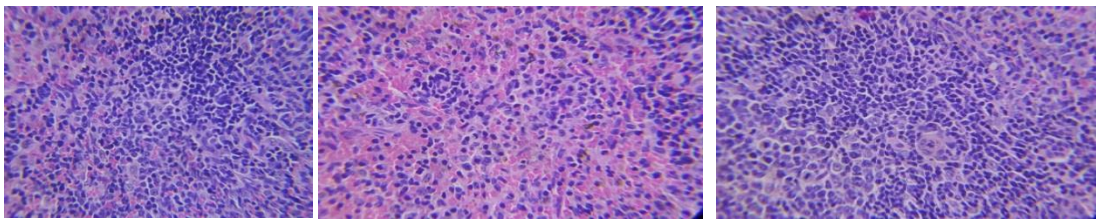
Histopathology of Spleen (Male Rat) in Sub-acute toxicity Study

Low Power Magnification 10X



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

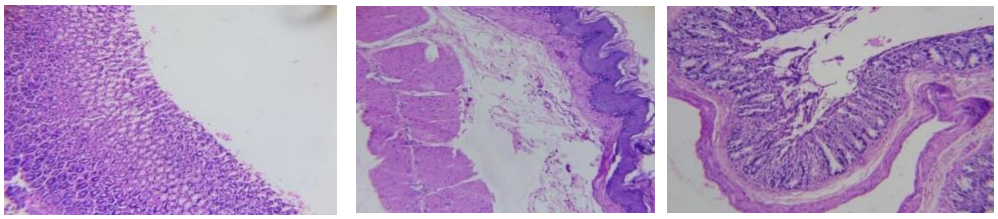
High Power Magnification 40X



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

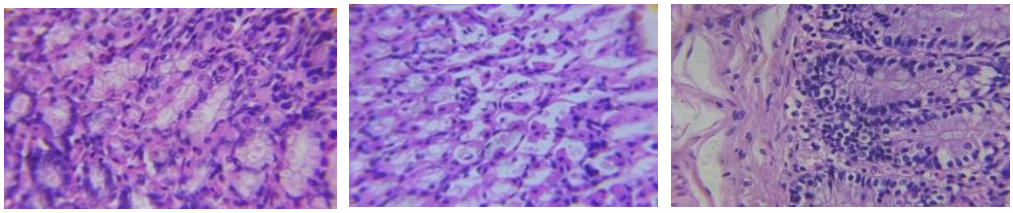
Histopathology of Stomach (Male Rat) in Sub-acute toxicity Study

Low Power Magnification 10X



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

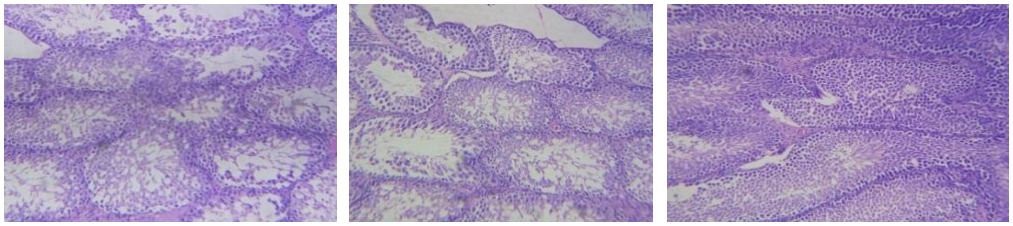
High Power Magnification 40X



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

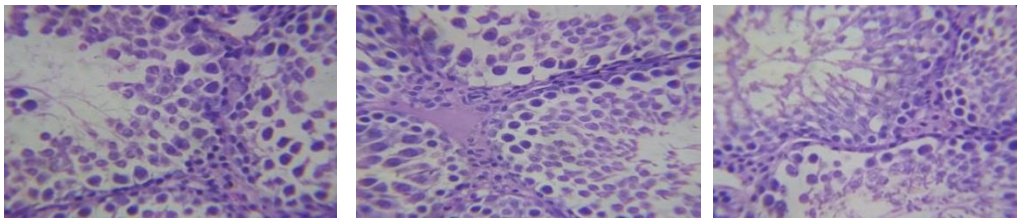
Histopathology of Testes (Male Rat) in Sub-acute toxicity Study

Low Power Magnification 10X



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

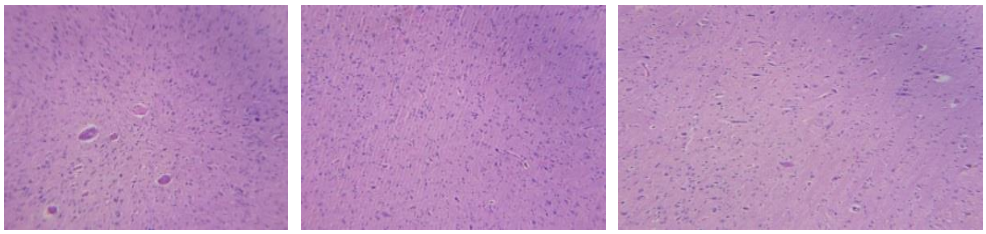
High Power Magnification 40X



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

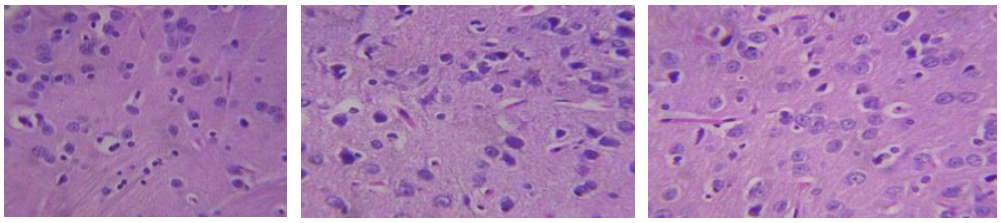
Histopathology of Brain (Female Rat) in Sub-acute toxicity Study

Low Power Magnification 10X



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

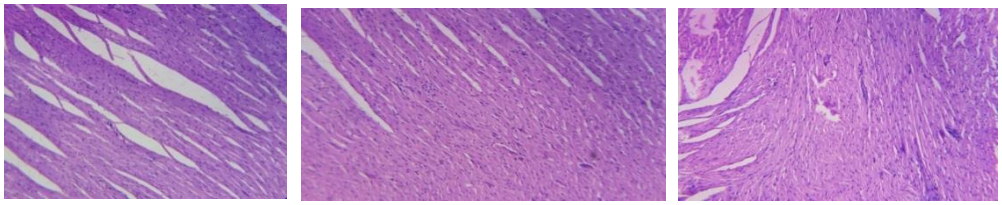
High Power Magnification 40X



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

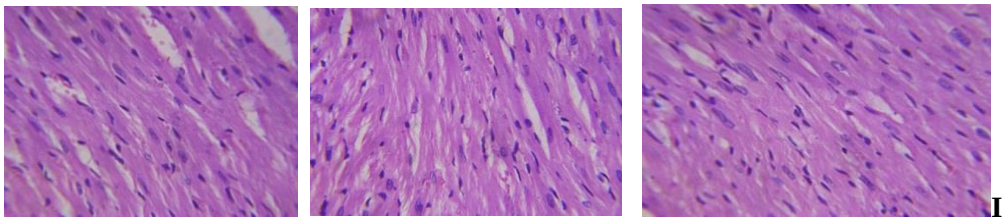
Histopathology of Heart (Female Rat) in Sub-acute toxicity Study

Low Power Magnification 10X



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

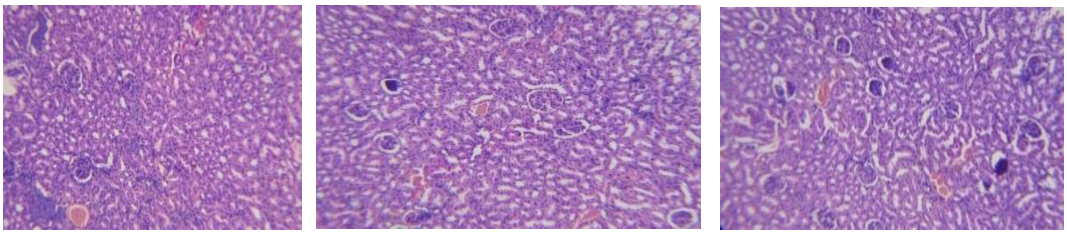
High Power Magnification 40X



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

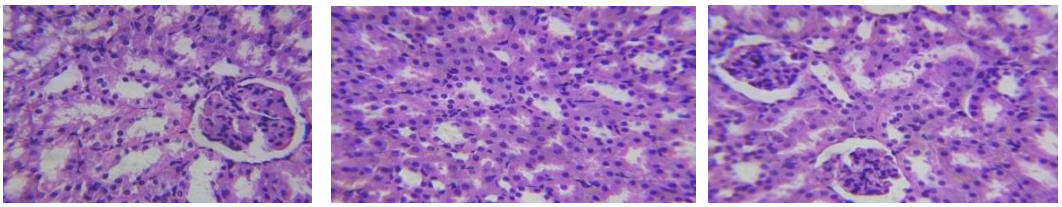
Histopathology of Kidney (Female Rat) in Sub-acute toxicity Study

Low Power Magnification 10X



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

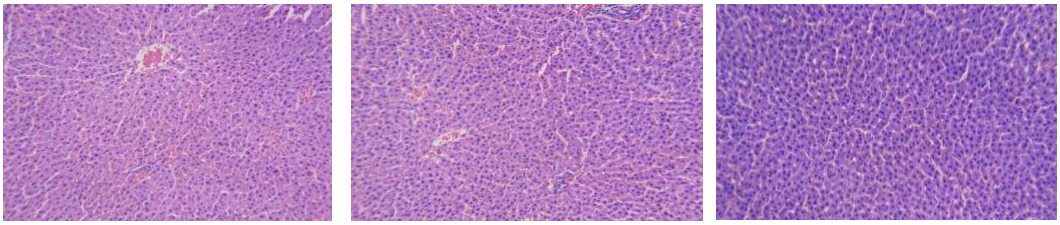
High Power Magnification 40X



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

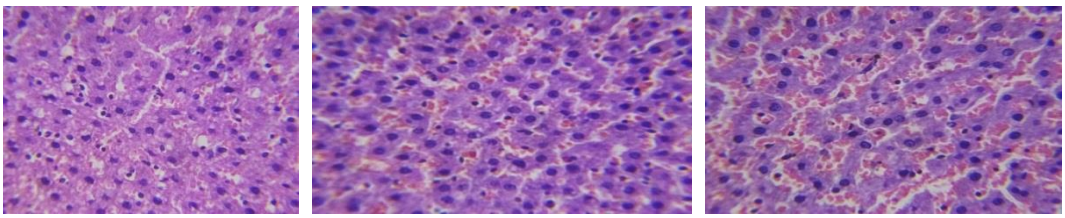
Histopathology of Liver (Female Rat) in Sub-acute toxicity Study

Low Power Magnification 10X



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

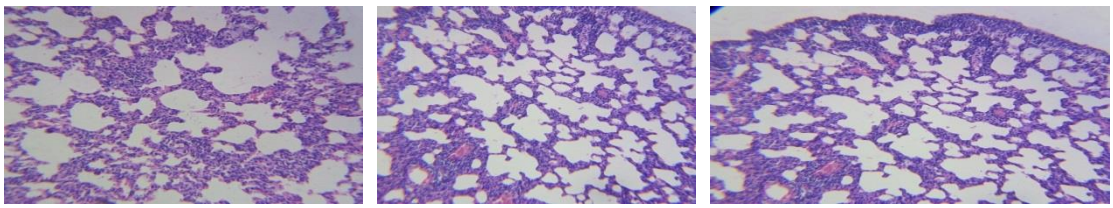
High Power Magnification 40X



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

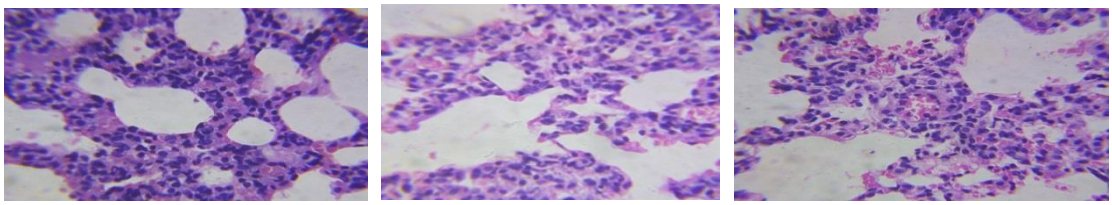
Histopathology of Lung (Female Rat) in Sub-acute toxicity Study

Low Power Magnification 10X



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

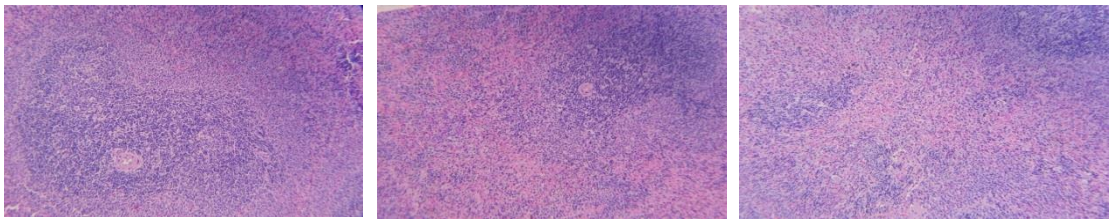
High Power Magnification 40X



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

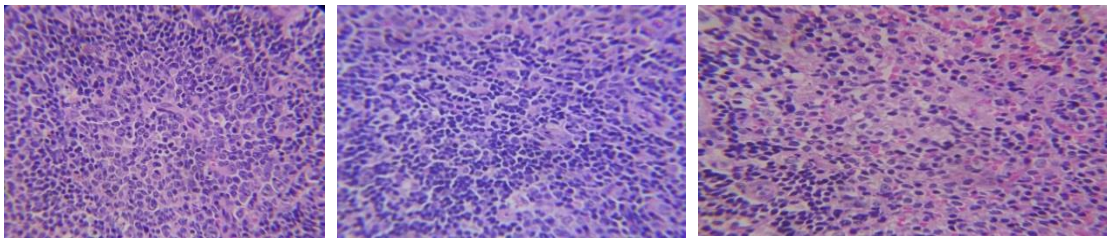
Histopathology of Spleen (Female Rat) in Sub-acute toxicity Study

Low Power Magnification 10X



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

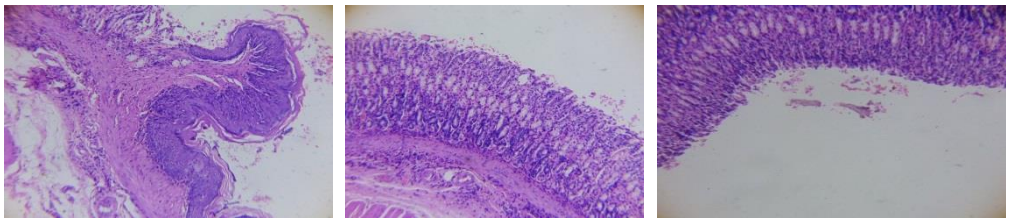
High Power Magnification 40X



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

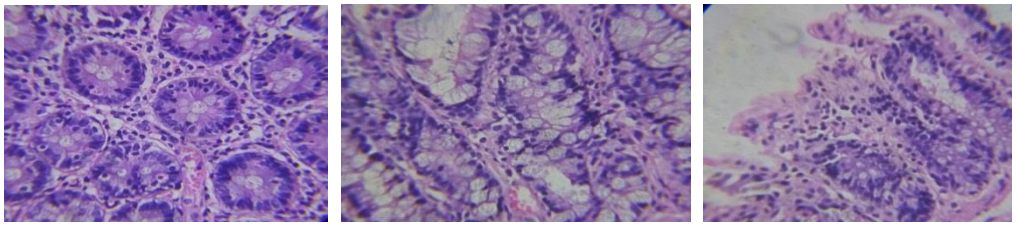
Histopathology of Stomach (Female Rat) in Sub-acute toxicity Study

Low Power Magnification 10X



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

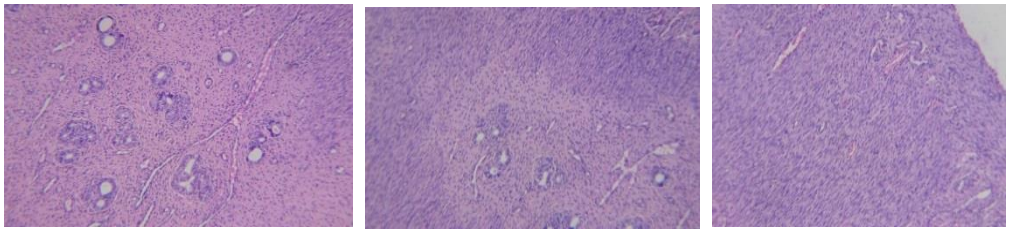
High Power Magnification 40X



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

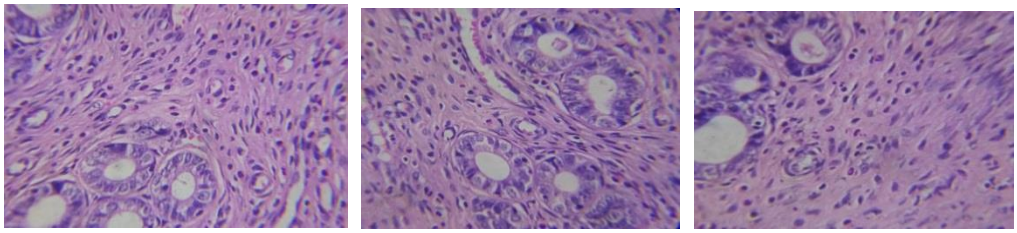
Histopathology of Uterus (Female Rat) in Sub-acute toxicity Study

Low Power Magnification 10X



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

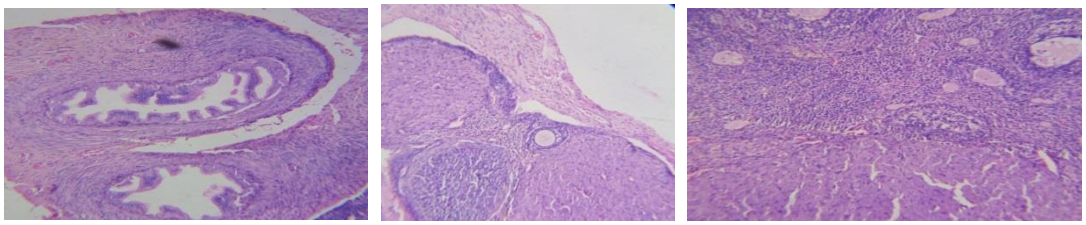
High Power Magnification 40X



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

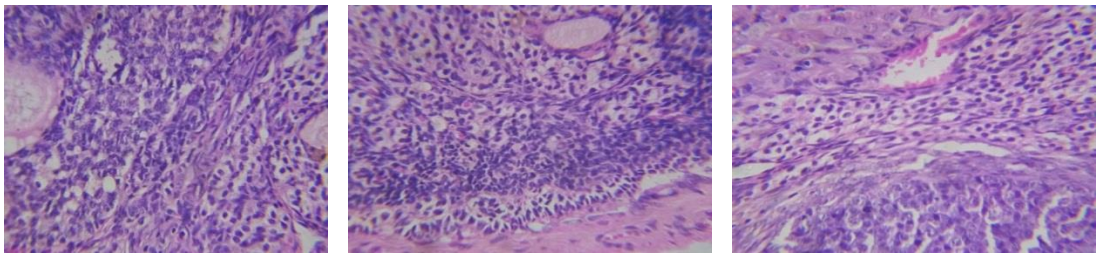
Histopathology of Ovary (Female Rat) in Sub-acute toxicity Study

Low Power Magnification 10X



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

High Power Magnification 40X



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

Pharmacological Evaluation of styptic activity of *Naaval nei* on Aspirin induced bleeding time prolongation in rats.

Name: Dr.S.Jayapriya

IAEC: SU/CLATR/IEAC/VII/049/2016

Animals

Healthy adult Wistar albino female rats weighing between 220-240 g were used for the study. The animals were housed in poly propylene cages and were kept in well ventilated with 100% fresh air by air handling unit. A 12 light / dark cycle were maintained .Room temperature was maintained between 22 $\pm$ 2^{o} C and relative humidity 50–65%. They were provided with food (Sai feeds, Bangalore, India) and water *ad libitum*. All the animals were acclimatized to the laboratory for 7 days prior to the start of the study. The experimental protocol was approved by The Institutional Animal Ethics Committee of Sathyabama University, Chennai, Tamil Nadu, India.

IAEC: SU/CLATR/IEAC/VII/049/2016

Experimental Methodology

The animals were grouped into four groups of 6 animals each. Group I (Control group) -received normal saline 5ml/kg, Group II – Aspirin control received 5mg/kg of aspirin, p.o. for 35 days. Group III - Received Aspirin (5mg/kg) for 21 days and then treated with 200mg/kg *Naaval nei*, p.o weight equivalent to 0.05ml, one hour prior to Aspirin administration from day 22 to 35. Group III - Received Aspirin (5mg/kg) for 21 days and then treated with 400mg/kg *Naaval nei* ,p.o weight equivalent to 0.1ml, one hour prior to Aspirin administration from day 22 to 35.

Bleeding time prolongation in rats

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

Determination of Bleeding Time

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

Determination of Clotting Time

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

Prothrombin time (PT)

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

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

Group I	**Bleeding Time in Sec**	**Clotting Time in Sec**	**Prothrombin time in Sec**
Mean	125	102.5	10
Std. Deviation	15.49	17.54	0.8944
Std. Error	6.325	7.159	0.3651
Group II	**Bleeding Time in Sec**	**Clotting Time in Sec**	**Prothrombin time in Sec**
Mean	417.5	325	14.83
Std. Deviation	22.08	26.27	1.941
Std. Error	9.014	10.72	0.7923
Group III	**Bleeding Time in Sec**	**Clotting Time in Sec**	**Prothrombin time in Sec**
Mean	335	267.5	13.33
Std. Deviation	18.17	22.08	1.211
Std. Error	7.416	9.014	0.4944

Group IV	Bleeding Time in Sec	Clotting Time in Sec	Prothrombin time in Sec
Mean	277.5	262.5	13
Std. Deviation	22.75	36.43	1.095
Std. Error	9.287	14.87	0.4472

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

20.1.2017

CERTIFICATE

Name of the student: Dr. S. Jayapriya, II year PG student, Pothu Maruthuvam, Government Siddha Medical College, Arumbakkam, Chennai-600 106.

Name of the sample: Naaval Nei

Name of the Experiment	**I**	**II**	**Mean**
Loss on drying(at 105°C)	31.315 %	31.44 %	31.378 %
Total ash	4.285 %	4.015 %	4.15 %
Water soluble ash	2.23 %	2.18 %	2.205 %
Acid insoluble ash	0.765 %	0.465 %	0.615 %
Water soluble extractive	15.33 %	14.79 %	15.06 %
Alcohol soluble extractive	2.19 %	2.14%	2.165 %
Acid value	23.0	23.0	23.0
Saponification value	244	244	244
Iodine value	28.0	28.0	28.0
Peroxide value	0.2006	0.2006	0.2006
pH value (10%)	6.51		
TLC/HPTLC	Report Enclosed		

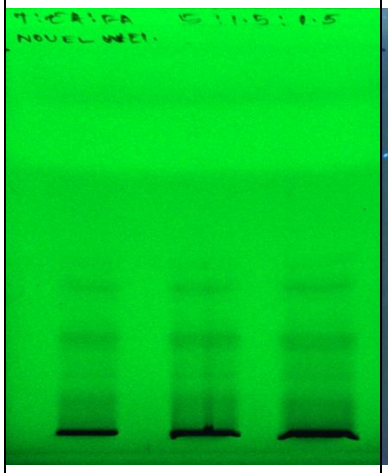
(R. Shakila)
Research Officer (Chemistry) & Head,
Department of Chemistry

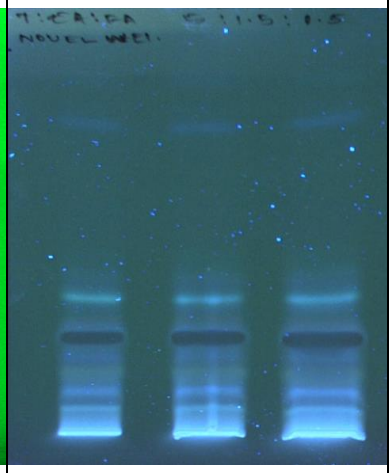
(Dr. P. Elankani) 21/01/17
Research Officer (Scientist II) (Siddha)
for Assistant Director (Siddha) I/c

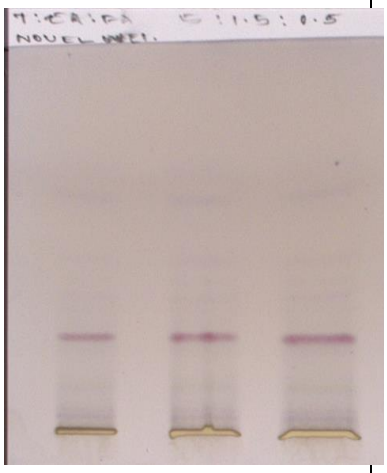
Sample Name/ID – SCRI-Novel Nei-2016-17

Stationary Phase - Silica Gel 60 F_{254}

Mobile Phase - Tolune : Ethyl Acetate : Formic Acid (5:1.5:0.5 v/ v/v)

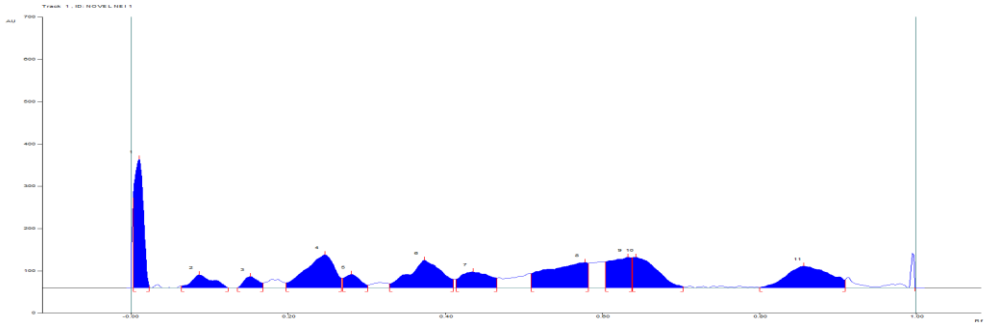






λ = 254 nm		**λ = 366 nm**		**White light**	
Color	**R_f value(s)**	**Color**	**R_f value(s)**	**Color**	**R_f value(s)**
Dark	0.15	Blue	0.06	Brown	0.04
Dark	0.24	Blue	0.11	Pink	0.24
Dark	0.38	Green	0.15	Light Pink	0.62
		Dark	0.24		
		Light Blue	0.35		
		Blue	0.81		

HPTLC Chromatogram @ 254 nm:

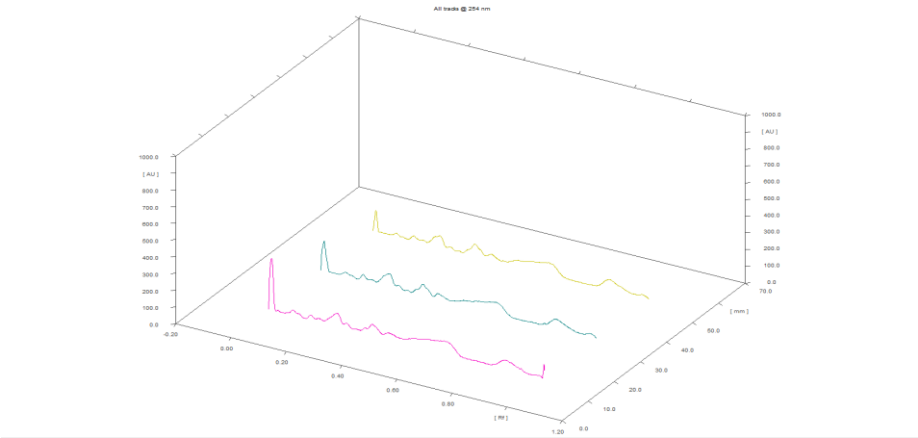


Peak Table @ 254 nm:

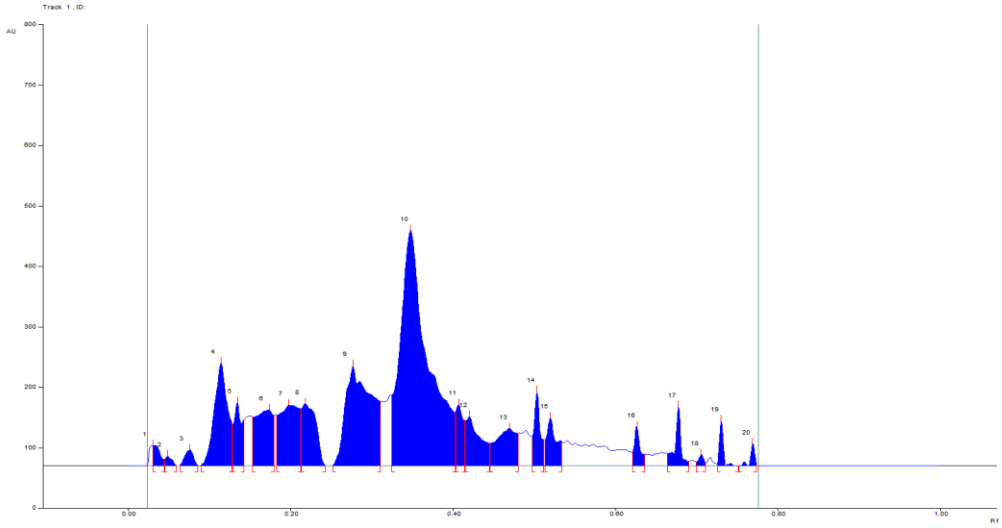
Track 1, ID: NOVEL NEI 1

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	0.00 Rf	213.1 AU	0.01 Rf	304.4 AU	36.70 %	0.02 Rf	3.4 AU	3418.7 AU	15.70 %
2	0.06 Rf	4.4 AU	0.09 Rf	30.4 AU	3.67 %	0.12 Rf	0.3 AU	797.3 AU	3.66 %
3	0.14 Rf	0.2 AU	0.15 Rf	26.7 AU	3.21 %	0.17 Rf	11.4 AU	457.9 AU	2.10 %
4	0.20 Rf	11.8 AU	0.25 Rf	78.0 AU	9.40 %	0.27 Rf	22.6 AU	2758.9 AU	12.67 %
5	0.27 Rf	22.6 AU	0.28 Rf	31.4 AU	3.79 %	0.30 Rf	6.1 AU	607.8 AU	2.79 %
6	0.33 Rf	9.9 AU	0.37 Rf	65.1 AU	7.85 %	0.41 Rf	20.4 AU	2570.0 AU	11.80 %
7	0.41 Rf	20.3 AU	0.44 Rf	37.7 AU	4.55 %	0.47 Rf	23.2 AU	1362.0 AU	6.25 %
8	0.51 Rf	33.6 AU	0.58 Rf	59.9 AU	7.22 %	0.58 Rf	58.3 AU	2993.1 AU	13.74 %
9	0.60 Rf	61.2 AU	0.63 Rf	72.4 AU	8.73 %	0.64 Rf	71.0 AU	1948.2 AU	8.94 %
10	0.64 Rf	71.2 AU	0.64 Rf	72.3 AU	8.72 %	0.70 Rf	3.0 AU	2137.4 AU	9.81 %
11	0.80 Rf	0.9 AU	0.86 Rf	51.2 AU	6.17 %	0.91 Rf	18.4 AU	2730.2 AU	12.53 %

3D Chromatogram @ 254 nm:



HPTLC Chromatogram @ 366 nm:

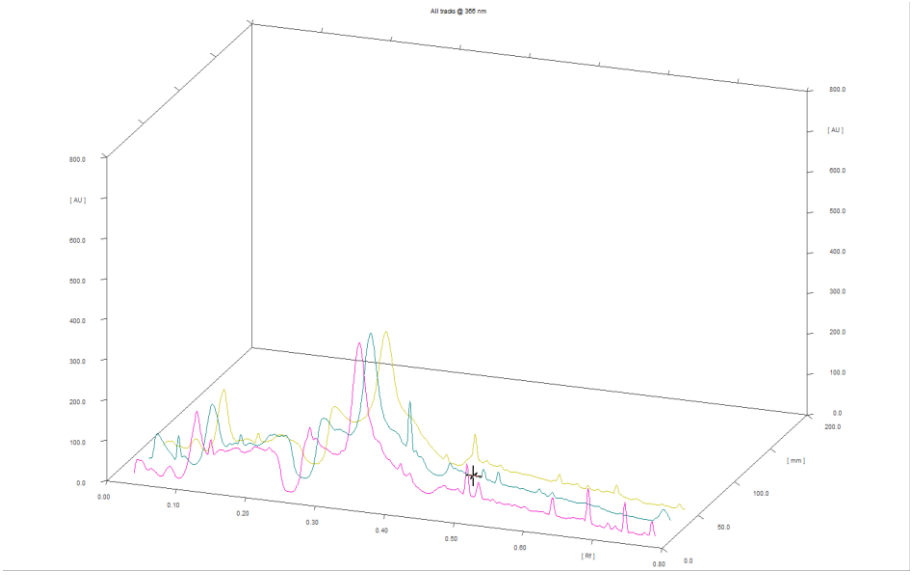


Peak Table @ 366 nm:

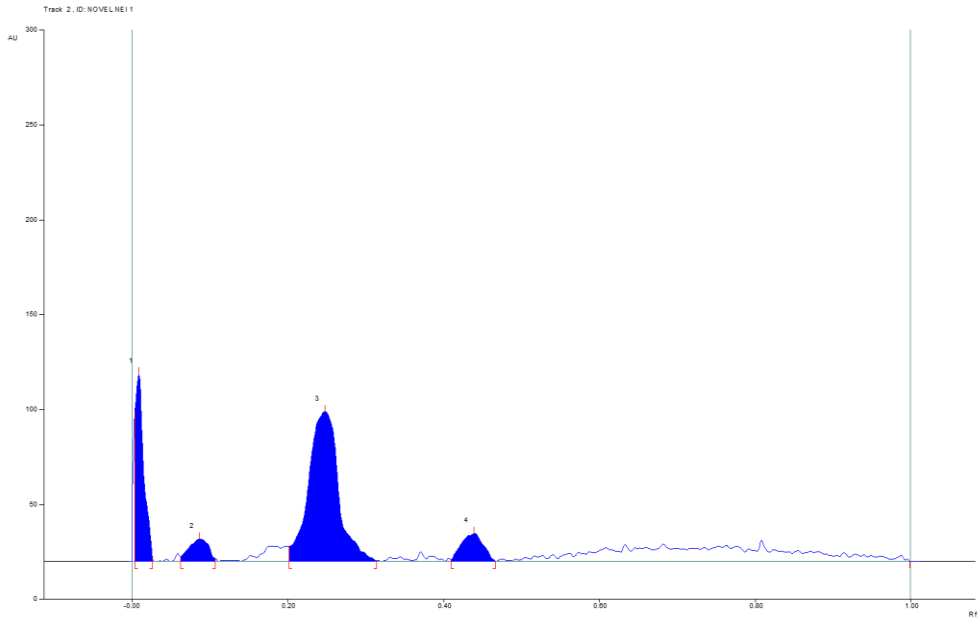
Track 1, ID:

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	0.03 Rf	33.1 AU	0.03 Rf	33.1 AU	1.71 %	0.04 Rf	10.4 AU	314.7 AU	0.86 %
2	0.04 Rf	11.4 AU	0.05 Rf	15.7 AU	0.81 %	0.06 Rf	0.3 AU	124.6 AU	0.34 %
3	0.06 Rf	0.7 AU	0.08 Rf	25.7 AU	1.33 %	0.08 Rf	1.0 AU	266.1 AU	0.73 %
4	0.09 Rf	0.6 AU	0.11 Rf	169.8 AU	8.77 %	0.13 Rf	71.5 AU	2693.8 AU	7.40 %
5	0.13 Rf	67.8 AU	0.13 Rf	104.2 AU	5.38 %	0.14 Rf	76.0 AU	1045.0 AU	2.87 %
6	0.15 Rf	80.1 AU	0.17 Rf	92.7 AU	4.79 %	0.18 Rf	82.9 AU	1985.5 AU	5.45 %
7	0.18 Rf	83.1 AU	0.20 Rf	100.2 AU	5.18 %	0.21 Rf	94.2 AU	2430.5 AU	6.68 %
8	0.21 Rf	94.5 AU	0.22 Rf	102.5 AU	5.30 %	0.24 Rf	0.3 AU	1766.1 AU	4.85 %
9	0.25 Rf	0.3 AU	0.28 Rf	165.6 AU	8.56 %	0.31 Rf	06.1 AU	5245.8 AU	14.41 %
10	0.32 Rf	116.6 AU	0.35 Rf	388.5 AU	20.07 %	0.40 Rf	87.7 AU	13037.0 AU	35.80 %
11	0.40 Rf	89.9 AU	0.41 Rf	101.6 AU	5.25 %	0.41 Rf	75.0 AU	881.4 AU	2.42 %
12	0.42 Rf	74.1 AU	0.42 Rf	81.4 AU	4.20 %	0.44 Rf	37.0 AU	1441.6 AU	3.96 %
13	0.45 Rf	37.0 AU	0.47 Rf	61.8 AU	3.19 %	0.48 Rf	53.6 AU	1522.0 AU	4.18 %
14	0.50 Rf	46.8 AU	0.50 Rf	122.3 AU	6.32 %	0.51 Rf	43.4 AU	917.7 AU	2.52 %
15	0.51 Rf	42.5 AU	0.52 Rf	79.4 AU	4.10 %	0.53 Rf	40.3 AU	966.9 AU	2.66 %
16	0.62 Rf	21.8 AU	0.63 Rf	64.4 AU	3.33 %	0.64 Rf	18.9 AU	479.8 AU	1.32 %
17	0.66 Rf	19.9 AU	0.68 Rf	97.7 AU	5.05 %	0.69 Rf	6.6 AU	681.2 AU	1.87 %
18	0.70 Rf	6.5 AU	0.71 Rf	18.2 AU	0.94 %	0.71 Rf	4.4 AU	115.6 AU	0.32 %
19	0.73 Rf	1.3 AU	0.73 Rf	74.8 AU	3.87 %	0.75 Rf	0.1 AU	325.3 AU	0.89 %
20	0.75 Rf	0.2 AU	0.77 Rf	36.2 AU	1.87 %	0.77 Rf	1.6 AU	170.7 AU	0.47 %

3D Chromatogram @ 366 nm:



HPTLC Chromatogram @ 554 nm:

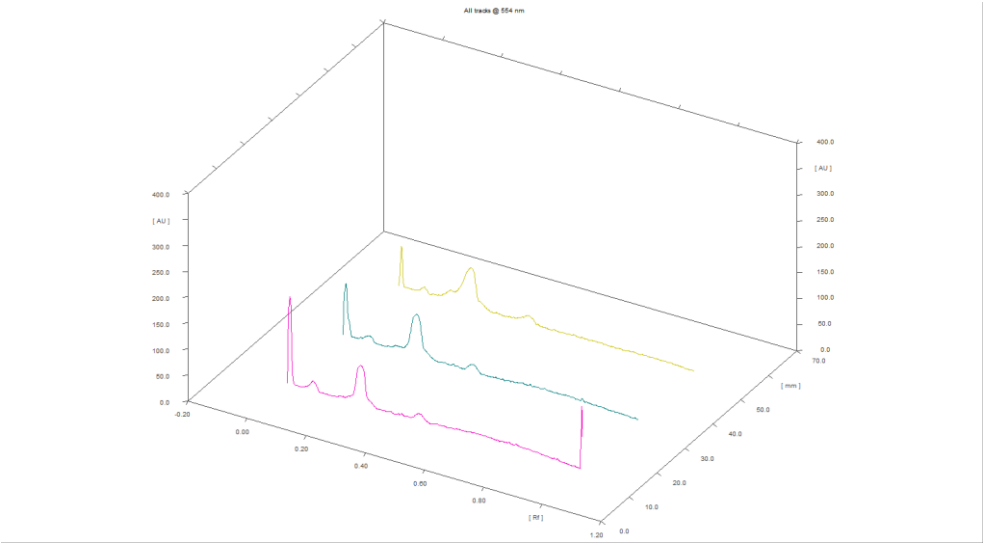


Peak Table @ 554 nm:

Track 2, ID: NOVEL NEI 1

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	0.00 Rf	79.2 AU	0.01 Rf	98.6 AU	48.38 %	0.03 Rf	1.3 AU	1018.9 AU	21.96 %
2	0.06 Rf	2.4 AU	0.09 Rf	11.7 AU	5.76 %	0.11 Rf	1.6 AU	286.6 AU	6.18 %
3	0.20 Rf	7.7 AU	0.25 Rf	78.9 AU	38.71 %	0.31 Rf	0.2 AU	2932.8 AU	63.21 %
4	0.41 Rf	0.9 AU	0.44 Rf	14.6 AU	7.15 %	0.47 Rf	0.1 AU	401.7 AU	8.66 %

3D Chromatogram @ 554 nm:



BIO-CHEMICAL ANALYSIS OF TRIAL MEDICINE

Preparation of Sodium Carbonate extract:

2 gm of the sample drug is mixed 5 gm of Sodium carbonate and taken in a 100 ml beaker and 20 ml of distilled water is added. The solution is boiled for 10 minutes, cooled and then filtered. The filtrate is called sodium carbonate extract.

S.No	EXPERIMENT	OBSERVATION	INFERENCE
I	**TEST FOR ACID RADICALS**		
1a	**Test for Sulphate** 2 ml of the above prepared extract is taken in a test tube. To this add 2ml of 4% Ammonium oxalate solution.	Absence of White Precipitate	Absent
b	2ml of extract is added with 2ml of dilute hydrochloric acid until the effervescence ceases off. Then 2ml barium chloride solution is added.	Absence of White Precipitate	Absent
2	**Test for Chloride:** 2ml of extract is added with dilute nitric acid till the effervescence ceases. Then 2ml of silver nitrate solution is added.	Absence of white precipitate	Absent
3	**Test for Phosphate** 2ml of the extract is treated with 2 ml of Ammonium molybdate solution and 2ml of concentrated nitric acid.	Yellow precipitate obtained	Absent

4	**Test for Carbonate:** 2ml of the extract is treated with 2ml of magnesium sulphate solution.	Absence of white precipitate	Absent
5	**Test for Sulphide:** 1 gm of the substance is treated with 2ml of concentrated Hydrochloric acid	Absence of Rotten egg smelling	Absent
6	**Test for Nitrate:** 1gm of the substance is heated with copper turnings and concentrated sulphuric acid and viewed the test tube vertically down.	Absence of reddish brown gas.	Absent
7a	**Test for Fluoride and oxalate** 2ml of the extract is added with 2ml of dilute acetic acid and 2ml of calcium chloride solution and heated.	Absence of White precipitate	Absent
b	5 drops of clear solution is added with 2ml of dilute sulphuric acid and slightly warmed to this, 1 ml of dilute potassium permanganate solution is added.	Absence of KMNO4 solution Discolourisation obtained	Absent
8	**Test for Nitrite** 3 drops of the extract is placed on a filter paper. On that, 2 drops a Acetic Acid and 2 drops of Benzidine solution is placed.	Absence of yellowish red colour	Absent
9	**Test for Borate**	Absence of Green	Absent

	2 pinches of the substance is made into paste by using Sulphuric acid and Alcohol (95%) and introduced into the blue flame.	tinged flame	
II	**TEST FOR BASIC RADICALS**		
10	**Test for lead** 2 ml of the extract is added with 2 ml of Potassium iodide solution.	Absence of Yellow precipitate	Absent
11a	**Test for Copper** One pinch of substance is made into paste with concentrated Hydrochloric acid in a watch glass and introduced into the non luminous part of the flame.	Absence of Bluish green coloured flame.	Absent
b	2ml of the extract is added with excess of Ammonia solution	Absence of deep blue	Absent
12	**Test for Aluminium** To the 2 ml of extract. Sodium Hydroxide solution is added in drops to excess.	Absence of White Precipitate.	Absent
13a	**Test for Iron** To the 2 ml of extract, 2 ml of Ammonium Thiocyanate Solution is added.	Blood red colour	Present
b	To the 2 ml of extract, 2 ml of Ammonium Thiocyanate solution and 2 ml of concentrated HNO_3 is added.	Blood red colour obtained	Present
14	**Test for Zinc** To the 2 ml of extract Sodium	Absence of White precipitate.	Absent

	Hydroxide solution is added in drops to excess.		
15	**Test for Calcium** 2 ml of the extract is added with 2 ml of 4% Ammonium Oxalate solution.	White precipitate Obtained	Present
16	**Test for Magnesium** 2ml of extract, Sodium Hydroxide solution is added in drops to excess.	Absence of White precipitate.	Absent
17	**Test for Ammonium** 2 ml of extract few ml of Nessler's Reagent and excess of Sodium Hydroxide solution are added.	Absence of Reddish brown precipitate	Absent
18	**Test for Potassium** A pinch of substance is treated with 2 ml of Sodium Nitrite solution and then treated with 2 ml of Cobal Nitrate in 30% glacial Acetic acid.	Absence of Yellow precipitate	Absent
19	**Test for Sodium** 2 pinches of the substance is made into paste by using Hydrochloric acid and introduced into the blue flame.	Absence of Yellow colour flame	Absent
20	**Test for Mercury** 2 ml of the extract is treated with 2 ml of Sodium Hydroxide solution.	Absence of yellow precipitate	Absent
21	**Test for Arsenic** 2 ml of extract is treated with 2 ml of silver Nitrate solution	Absence of Yellow precipitate	Absent

22	**Test for Starch** 2ml of extract is treated with weak iodine solution.	Absence of Blue colour	Absent
23	**Test of reducing Sugar** 5ml of Benedicts qualitative solution is taken in a test tube and allowed to boil for 2 minutes and added 10 drops of the extract and again boiled for 2 minutes. The colour changes are noted.	Green colour obtained	Present
24	**Test of the alkaliods** 2ml of the extract is treated with 2ml of potassium lodide solution.	Absence of Red colour	Absent
25	**Test of the proteins** 2ml of the extract is treated with 2ml of 5% NaOH ,mix well and add 2 drops of copper sulphate solution.	Absence of Violet colour	Absent

RESULTS:

The given sample (Naaval Nei) contains

Iron

Calcium

Reducing sugar.

GOVERNMENT SIDDHA MEDICAL COLLEGE

Arumbakkam, Chennai-106

Communication Of The Decision Of Institutional Ethics Committee (IEC)

IEC No: GSMC-CH-ME-4/2015/005

Protocol title: A CLINICALSTUDY ON PITHA PERUMBADU (MENORRHAGIA) WITH THE EVALUATION OF SIDDHA DRUG NAAVAL NEI
Principal Investigator: DR.S. JAYAPRIYA
Name & Address of Institution : Government siddha medical college, Arumbakkam, Chennai-106
☐ New Review ☐ Revised Review ☐ Expedited Review
Date of review (DD/MM/YY): 26-03-2015 Date Of Previous Review, If Revised Application :
Decision of the IEC ☑ Recommended ☐ Recommended with suggestions ☐ Revision ☐ Rejected
Suggestions / Reasons / Remarks : 1. Duration of treatment should be 48 days (1 mandalam) Instead of 4 days of 3 Consecutive months.
Recommended for a period of 1 year from date of completion of preclinical studies:

Please Note:

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

Dr.P.Jeyaprakashnarayanan
Chairman

Dr.V. Banumathi
Member Secretary

INSTITUTIONAL ETHICS COMMITTEE

Date:

Sub: IEC review of research proposals.

Ref:Your letter dated

MEMBERS	PARTICIPATION	SIGNATURE
DR.P.JEYAPRAKASH NARAYANAN M.D(S)., Chairman		
DR.V.BANUMATHI M.D(S)., Member Secretary		26/03/15
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DR.P.SATHIYA RAJESWARAN M.D(S)., Clinician- Siddha	✓	26/3/15
DR.G.AADINAAATH REDDY,M.Pharm, Ph.D., Pharmacologist	✓	26/03/15
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DR.P.VIDYA M.B.B.S., DMRD., Modern Medicine Expert	✓	
MR.P.SARAVANAN., Public Person	✓	

26/3/15

Dr.P.Jeyaprakashnarayanan
Chairman.

26/03/15

Dr. V. Banumathi
Member Secretary

BIO – STATISTICS

CLINICAL PROGNOSIS

Treatment for Pitha Perumbadu:

The most popular non parametric statistical tool, namely, McNemar Test analysis has been employed to analyses the effectiveness with the help of a hypothesis.

S. No	Signs&Symptoms	Before Treatment	After Treatment
		n%	n%
1.	Excessive Menstruation	20(100)	1(5)**
2.	Prolonged Menstruation	20(100)	0(0)**
3.	Presence Of Blood Clots	20(100)	0(0)**
4.	Lower Abdominal Pain	15(75)	1(5)**
5.	Low Back Ache	10(50)	1(5)**
6.	Tiredness	20(100)	0(0)**
7.	Giddiness	13(65)	1(5)**
8.	Head Ache	3(15)	0(0)**

McNemat test, C.I: 95%, *P<0.05; **P<0.01

Software: spss17 version

Number of cases: 20

Inference:

Since the p value is significant in all signs and symptoms. So there is significant reducing of signs & symptoms among the patients for the treatment of Pitha Perumbadu (Menorrhagia). Hence it is concluded that the treatment was effective and **significant.**

NUMBER OF PADS USED BY THE PATIENTS

BEFORE AND AFTER TREATMENT

Effect of Naaval Nei on number of pads used by the patients

S. no	Number of Pads for a cycle	
	Before Treatment	**After Treatment**
1.	16	10
2.	22	13
3.	14	10
4.	10	7
5.	15	10
6.	13	8
7.	18	11
8.	14	10
9.	26	21
10.	11	8
11.	22	13
12.	13	9
13.	15	10
14.	15	11
15.	16	11
16.	20	12
17.	12	8
18.	14	10
19.	13	9
20.	15	10

Software: spss17 version

Variables: Number of Pads– before treatment, after treatment

Number of cases: 20

Test: Paired t test

Confidence Interval: 95%

Correlation coefficient (r): 0.918

Before and after treatment Mean difference ±SEM: 5.15±0.40.

P Value (2 tailed): p<0.01.

Inference: Since the P value is highly significant (<0.01), The hypothesis is **not** accepted. So the treatment was significantly reducing the number of pads used by the patients for the treatment of Pitha Perumbadu.

HAEMOGLOBIN LEVEL:

Effect of Naaval Nei on Hb level (gm/dl)in pitha perumbadu cases

S. no	Haemoglobin level in gms/100ml of blood	
	Before Treatment	After Treatment
1.	8.0	9.1
2.	6.4	8.3
3.	8.1	9.5
4.	9.0	10.2
5.	9.6	10.5
6.	10.0	10.8
7.	9.2	10.5
8.	9.8	10.5
9.	7.0	7.9
10.	10.8	11.4
11.	9.4	10.6
12.	9.8	10.5
13.	9.4	10.2
14.	9.2	10.2
15.	10.6	11.2
16.	8.0	9.4
17.	9.0	10.2
18.	9.7	10.6

19.	8.3	9.1
20.	8.5	10.3

Software: spss17 version

Variables: Hb level (gm/dl)– before treatment, after treatment

Number of cases: 20

Test: Paired t test

Confidence Interval: 95%

Correlation coefficient (r): 0.955

Before and after treatment mean difference: 1.06 ± 0.08.

P Value (2 tailed): p<0.001.

Inference:

Since the P value is highly significant (<0.001), The hypothesis is **not** accepted. So the treatment was significantly improving the Hb level among the patients for the treatment of Pitha Perumbadu.

BLEEDING TIME:

Effect of Naaval Nei on bleeding time in pitha perumbadu cases

S. no	**Bleeding Time(min)**	
	Before Treatment	**After Treatment**
1.	2.90	2.30
2.	2.17	1.36
3.	3.17	2.90
4.	2.20	2.17
5.	3.45	2.73
6.	2.60	1.17
7.	3.45	2.17
8.	2.17	1.17
9.	3.13	2.97

10.	2.70	2.67
11.	1.80	1.30
12.	2.67	1.13
13.	3.60	2.17
14.	2.17	1.90
15.	2.90	2.10
16.	2.17	1.77
17.	3.15	2.07
18.	2.40	2.03
19.	2.90	1.98
20.	2.92	2.03

Software: spss17 version

Variables:bleeding time(min)– before treatment, after treatment

Number of cases: 20

Test: Paired t test

Confidence Interval: 95%

Correlation coefficient (r): 0.617

Before and after treatment mean difference ± SEM: 0.73 ± 0.10.

P Value (2 tailed): $p<0.001$.

Inference:

Since the P value is significant (<0.001), The hypothesis is **not** accepted. So the treatment was significantly reducing the bleeding time among the patients for the treatment of Pitha Perumbadu.

CLOTTNG TIME:

Effect of Naaval Nei on clotting time in pitha perumbadu cases

S. no	Clotting Time(min)	
	Before Treatment	After Treatment
1.	4.80	5.20
2.	4.80	4.23
3.	4.91	4.28
4.	6.70	5.67
5.	6.03	6.68
6.	4.87	5.42
7.	5.40	4.30
8.	5.73	5.17
9.	6.57	6.03
10.	5.63	4.85
11.	5.37	5.53
12.	4.60	3.83
13.	5.73	5.17
14.	3.92	3.17
15.	3.40	3.33
16.	5.17	4.85
17.	5.80	5.27
18.	5.67	4.65
19.	6.40	5.25
20.	6.17	5.65

Software: spss17 version

Variables: clotting time(min)– before treatment, after treatment

Number of cases: 20

Test: Paired t test

Confidence Interval: 95%

Correlation coefficient (r): 0.808

Before and after treatment mean difference ± SEM: 0.46 ± 0.12.

P Value (2 tailed): $p<0.01$.

Inference:

Since the P value is significant (<0.01), The hypothesis is **not** accepted. So the treatment was significantly reducing the clotting time among the patients for the treatment of Pitha Perumbadu.

CONSENT FORM

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

CLINICAL STUDY ON **"NAAVAL NEI"** IN THE TREATMENT OF

"PITHA PERUMBADU" (MENORRHAGIA).

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

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

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

Date:

Station:

Signature of participant:

Signature of the Guide: Signature of the Investigator:

அரசினர் சித்த மருத்துவக் கல்லூரி,சென்னை 106.

அறிஞர் அண்ணா மருத்துவமனை, சென்னை 106

பித்த பெரும்பாடு நோய்க்கான சித்த மருந்தின் (நாவல் நெய்) பரிகரிப்பு திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான நோயாளியின் ஒப்புதல் படிவம்.

ஆய்வாளரால் சான்றளிக்கப்பட்டது:

நான் இந்த ஆய்வை குறித்த அனைத்து விபரங்களையும் நோயாளிக்குப் புரியும் வகையில் எடுத்துரைத்தேன்.

தேதி: கையொப்பம்:

இடம்: பெயர்:

நோயாளியின் ஒப்புதல்

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

நான் இந்த மருத்துவ ஆய்வின் போது , காரணம் எதுவும் கூறாமல், எப்போது வேண்டுமானாலும் இந்த ஆய்விலிருந்து என்னை விடுவித்துக் கொள்ளும் உரிமையை தெரிந்திருக்கிறேன். நான் என்னுடைய சுதந்திரமாக தேர்வு செய்யும் உரிமையைக் கொண்டு பித்த பெரும்பாடு நோய்க்கான நாவல் நெய் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கு என்னை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி: கையொப்பம்:

இடம்: பெயர்:

உறவுமுறை: சாட்சிக்காரர் கையொப்பம்:

தேதி: பெயர்:

இடம்:

துறைத்தலைவர் கையொப்பம் ஆய்வாளர் கையொப்பம்

CASE SHEET PROFORMA

GOVT.SIDDHA MEDICAL COLLEGE & HOSPITAL, CHENNAI-106

POST GRADUATE DEPARTMENT BRANCH –I MARUTHUVAM

CASE SHEET PROFORMA FOR PERUMBADU

OP No / IP No : **Nationality : Indian**

Ward No : **Religion :**

Bed No : **D.O.A :**

Name : **D.O.D :**

Age :

Sex : Female **Diagnosis :**

Occupation :

Income :

Permanent Address :

Temporary Address : Govt.Siddha Medical college,
Chennai-600106

1. Complaints and duration :

2. History of present illness :

3. History of past illness :

4. Personal history :

5. Occupational history :

6. Menstrual history :

a) Regularity of cycle : Regular / Irregular

b) Length of cycle (days) :

c) Duration of flow (days) :

d) Level of flow : Low/ Moderate /Heavy

e) Abdominal pain : Nil/ Mild/ Moderate/ Severe

f) LMP :

g) Number of pads used per cycle :

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

8. Family History :

9.Obstetric History :

GENERAL EXAMINATION

Patient consciousness :

Body Built :

Nourishment :

Anaemia :

Jaundice :

Cyanosis :

Clubbing :

JVP :

Tracheal deviation :

Pedal oedema :

Lymph adenopathy :

VITAL SIGNS

Heart rate :

Pulse rate :

Respiratory rate :

Blood Pressure :

Body Temperature :

Weight :

Height :

SIDDHA ASPECT

NILAM

Kurinchi :

Mullai :

Marutham :

Neithal :

Palai :

PARUVAKAALAM

Kaar kalam :

Koor kalam :

Munpani kalam :

Pinpani kalam :

Elavenil kalam :

Muduvenil :

YAAKKAI (Udal)

Vaatham :

Pitham :

Kabam :

Kalappu :

GUNAM

Satthuvam :

Rajotham :

Thamasam :

PORI/PULANGAL (SENSORY ORGANS)

Mei (Sensation) :

Vaai (Taste) :

Kan(Vision) :

Mooku (Smell) :

Sevi (Hearing) :

KANMENTHRIYAM/KANNMAVIDAYAM [MOTOR ORGANS]

Kai (Dhaanam) :

Kaal (Kamanam) :

Vaai (Vasanam) :

Eruvaai(Visarkkam) :

Karuvaai (Aanantham) :

UYIR THATHUKKAL

VATHAM

Praanan :

Abanan :

Viyanan :

Udanan :

Samanan :

Nagan :

Koorman :

Kirukaran :

Devathathan :

Thananjeyan :

PITHAM

Anar pitham :

Ranjaga pitham :

Saathaga pitham :

Pirasaga pitham :

Alosaga pitham :

KAPAM

Avalambagam :

Kilethagam :

Pothagam :

Tharpagam :

Santhigam :

UDALTHAATHUKKAL

Saaram :

Senner :

Oon :

Kozhuppu :

Enbu :

Moolai :

Suronitham :

ENVAGAI THERVUGAL

1. Naa :

2. Niram :

3. Mozhi :

4. Vizhi :

5. Sparisam :

6. Malam :

7. Naadi :

8. Moothiram

a) Neer Kuri :

Niram :

Manam :

Edai :

Nurai :

Enjal :

b) Nei Kuri :

MODERN ASPECT

Sytemic Examination

Inspection :

Palpation :

Percussion :

Auscultation :

Others Systems

Cardio Vascular System :

Respiratory system :

Central nervous system :

Genito urinary system :

Endocrine system :

CLINICAL SIGN AND SYMPTOMS OF PERUMBADU

Symptoms	Before Treatment	After Treatment				
		I 7 days	II 9 days	III 12 days	IV 30 days	V 48days
1.Vaginal Bleeding No of pads						
2. Vaginal Bleeding No of days						
3.Passing blood clots						
4. Abdomen pain						
5. Loss of appetite						
6. Anaemia						
7.Myalgia						
8.Tiredness						
9. Head ache						
10. Giddiness						

INVESTIGATIONS

1.BLOOD INVESTIGATIONS :

BLOOD INVESTIGATIONS		BEFORE TREATMENT	AFTER TREATMENT
Hb (gms/dl)			
T.RBC(millions cells/cu.mm)			
ESR (mm)	½ hr		
	1 hr		
T.WBC (cells/cu.mm)			
Differential Count (%)	Polymorphs		
	Lymphocytes		
	Eosinophils		

BLOOD INVESTIGATIONS	BEFORE TREATMENT	AFTER TREATMENT
Bleeding time		
Clotting time		
Blood glucose (mg/dl) (R)		
Blood urea		
Serum cholesterol		

2.URINE INVESTIGATION

URINE INVESTIGATION	BEFORE TREATMENT	AFTER TREATMENT
Albumin		
Sugar		
Desposits		

3. SONOGRAPHY

USG Abdomen and Pelvis

4.SMEAR STUDY

PAP smear

CASE SUMMARY

DIAGNOSIS **: PITHA PERUMBADU**

TRIAL DRUG **: NAAVAL NEI**

Dose **:** 5 gm; Thrice a day after food .

Duration of Treatment **:** For 1 mandalam (48 days)

REPORTS :

DATE	WEEKLY REPORTS	MEDICINE

ADVICE

DO'S

Take balanced and healthy food.

Take rest in comfort bed

Use sanitary pads.

DON'TS

Don't travel

Don't do heavy work

PROGNOSIS AT THE END OF THE TREATMENT :

Reducing in clinical symptoms and by comparing the following parameters before and after treatment.

1.Number of pads used for a cycle

2.Haemoglobin level.

Medical Officer Signature: **HOD**

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