A CLINICAL STUDY ON

"SWASAKASAM" (BRONCHIAL ASTHMA) WITH THE

EVALUATION OF SIDDHA DRUG

SOMBU THEENEER

The dissertation Submitted by

Dr. R.KALPANA Reg. No.321411105

Under the Guidance of

ASST.LEC.DR.U.CHITHRA, M.D(S)

THE TAMILNADU DR. MGR MEDICAL UNIVERSITY

In partial fulfillment of the requirements

For the award of the degree of

SIDDHA MARUTHUVA PERARIGNAR DOCTOR OF

MEDICINE (SIDDHA) BRANCH-I MARUTHUVAM

POST GRADUATE DEPARTMENT OF MARUTHUVAM

THE GOVERNMENT SIDDHA MEDICAL COLLEGE

CHENNAI – 106

OCTOBER - 2017

CERTIFICATE

This is to certify that this dissertation entitled " **A CLINICAL STUDY ON "SWASAKASAM" (BRONCHIAL ASTHMA)** is a bonafide work done by **Dr. R.KALPANA** Government Siddha Medical College, Chennai-106 in partial fulfillment of the University rules and regulations for award of **SIDDHA MARUTHUVA PERARIGNAR** under my guidance and supervision during the academic year 2014 - 2017.

Name & Signature of the Guide: **Name & Signature of the HOD:**

Name & Signature of the Dean/ Principal:

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ACKNOWLEDGEMENT

TOXICOLOGICAL STUDY

Project Report on Toxicity Profiling of Sombu Theeneer

Name	Dr. R. Kalpana
IAEC	SU/CLATR/IAEC/IV/024/2016
Name of the Formulation	Sombu Theeneer
Abbreviation	ST

ACUTE TOXICITY STUDY

Acute toxicity study of the study drug *Sombu Theeneer* 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 ± 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 [1]. The animals were fasted overnight with free access to water. The study was conducted with single oral dose administration of *Sombu Theeneer*.

IAEC SU/CLATR/IAEC/IV/024/2016

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 2.5ml per rat equivalent to ten times higher than he human therapeutic dose (60 ml per adult).

Animal Grouping

GROUP I : Animals received Test drug 2.5ml (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 *Sombu Theeneer* 2.5ml (p.o) per rat .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 [2].

The dose utilized for evaluation of Sub-acute toxicity study is about 0.25 ml for low and 0.5 ml for high dose as derived from the acute toxicity study.

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/024/2016

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 0.25 ml (p.o)

GROUP III   **:** Animals received high dose of test drug 0.5 ml (p.o)

The animals were randomly divided into control group and drug treated groups for two different doses viz. low dose 0.25 ml and high dose 0.5 ml 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 *Sombu Theeneer* 0.25 ml (p.o) and group III received high dose of *Sombu Theeneer* 0.5ml (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 28th day, the animals were fasted for overnight with free access to water. On 29th 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.

Haematological analysis

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

Biochemical analysis[3]

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

Histopathological evaluation[4]

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

Statistical analysis

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

FECAL PELLET ANALYSIS

Methodology

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

Acute Toxicity Study

Analysis	Group I
Consistency	Soft
Shape	Pointed Head
Colour	Greenish brown
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
Shape	Oblong	Pointed Head	Pointed Head
Colour	Greenish brown	Greenish brown	Greenish brown
Mucous Shedding	Absence	Absence	Absence
Blood Cells	Absent	Absent	Absent
Signs of Infection	None Observed	None Observed	None Observed

Muscle Grip Strength Analysis

Methodology

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

Metabolic Cage for Urine Collection

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

Retro Orbital Sinus Puncture

RESULTS

Assessment of clinical signs in rats treated with *Sombu Theeneer* on Acute toxicity study

Parameter	Group I
Clinical Signs Parameters for the duration of 14 days	Test Drug 1.25 ml
Number of animals observed	6 Female
Lacrimation	Absence
Salivation	Absence
Animal appearance	Normal
Tonic Movement	Absence
Clonic Movement	Absence
Laxative action	Absence

Touch Response	Normal
Response to Sound	Normal Response
Response to Light	Normal Response
Mobility	Normal Response
Respiratory Distress	Nil
Skin Color	Normal
Stereotype behaviour	Absence
Pilo erection	Absence
Limb Paralysis	Absence
Posture	Normal
Open field behaviour	Normal
Gait Balancing	Normal
Freezing Behaviour	Absent
Sings of Stress and Anxiety	None Observed
Muscular coordination	Normal
Muscle grip	Normal
Sedation	Absence
Social Behaviour	Normal
Urine Analysis	No Abnormality
Urine Colour	Pale Yellow
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 *Sombu Theeneer* in Acute toxicity study

Group I	Before Treatment Weight in Gms	After Treatment Weight in Gms
Mean	182.5	187.5
Std. Deviation	6.716	5.612
Std. Error	2.742	2.291

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 *Sombu Theeneer* on Sub-Acute toxicity study

Parameter	Group I	Group II	Group III
Clinical Signs Parameters for the duration of 28 days	Control	Test Drug 0.25 ml/ rat	Test Drug 0.5 ml/ rat
Number of animals observed	3 Male and 3 Female	3 Male and 3 Female	3 Male and 3 Female
Lacrimation	Absence	Absence	Absence
Salivation	Absence	Absence	Absence
Animal appearance	Normal	Normal	Normal
Tonic Movement	Absence	Absence	Absence
Clonic Movement	Absence	Absence	Absence
Laxative action	Absence	Absence	Absence
Touch Response	Normal	Normal	Normal
Response to Sound	Normal Response	Normal Response	Normal Response
Response to Light	Normal Response	Normal Response	Normal Response
Mobility	Normal	Normal	Normal

Respiratory Distress	Nil	Nil	Nil
Skin Color	Normal	Normal	Normal
Stereotype behaviour	Absence	Absence	Absence
Pilo erection	Absence	Absence	Absence
Limb Paralysis	Absence	Absence	Absence
Posture	Normal	Normal	Normal
Open field behaviour	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 Behaviour	Normal	Normal	Normal
Urine Analysis	No Abnormality	No Abnormality	No Abnormality
Urine Colour	Yellowish	Pale yellowish	Pale yellowish
Urine pH	6	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 *Sombu Theeneer* on Body weight of Rats in Sub-acute toxicity study

Group I	Before Treatment Weight in Gms	After Treatment Weight in Gms
Mean	177.3	184.5
Std. Deviation	5.82	6.348
Std. Error	2.376	2.592
Group II	**Before Treatment Weight in Gms**	**After Treatment Weight in Gms**
Mean	179.7	192.2
Std. Deviation	6.377	7.494
Std. Error	2.603	3.06
Group III	**Before Treatment**	**After Treatment Weight in Gms**
Mean	178.3	208.5
Std. Deviation	5.046	42.69
Std. Error	2.06	17.43

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 *Sombu Theeneer* for 28 days in Sub-acute toxicity study

GROUP I	Food intake	Water intake
Mean	17.75	29.92
Std. Deviation	0.5693	0.9574
Std. Error	0.2846	0.4787
GROUP II	**Food intake**	**Water intake**
Mean	19.92	39.5
Std. Deviation	1.596	2.203
Std. Error	0.7979	1.101
GROUP III	**Food intake**	**Water intake**
Mean	18.5	39.25
Std. Deviation	1.552	0.8767
Std. Error	0.7758	0.4383

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 *Sombu Theeneer* on Haematology profile of rats in sub-acute toxicity study

GROUP I	WBC count ($\times 10^3$ μl)	RBC ($\times 10^6$ μl)	PLT ($\times 10^3$ μl)	MCV (fl)	MCH (pg)	MCHC (g/dl)	HGB (g/dl)
Mean	12.23	5.817	918.7	60.92	19.82	31.42	11.07
Std. Deviation	2.719	0.9683	71.46	2.062	2.04	1.292	1.507
Std. Error	1.11	0.3953	29.17	0.842	0.8328	0.5275	0.6152
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	11.27	6.383	767.3	60.75	20.7	33.08	12.35
Std. Deviation	2.079	0.6616	369.5	4.138	2.007	1.541	1.772
Std. Error	0.8488	0.2701	150.9	1.69	0.8193	0.629	0.7233
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	11.12	6.183	829.2	61.57	18.93	30.27	13.17
Std. Deviation	1.943	0.8377	94.93	6.125	2.353	3.204	1.671
Std. Error	0.7931	0.342	38.76	2.5	0.9604	1.308	0.682

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 *Sombu Theeneer* 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	69.98	2.633	2.083	1.283	0.3333	6.483
Std. Deviation	3.602	1.102	0.9453	0.2639	0.5164	1.003
Std. Error	1.47	0.4499	0.3859	0.1078	0.2108	0.4094
GROUP II	Lymph (%)	Mon (%)	Neutrophils (X 10^3/mm^3)	Eosinophils (%)	Basophils (%)	MPV (fl)
Mean	78.23	2.75	2.233	1.3	0.3333	4.583
Std. Deviation	6.539	1.329	0.7581	0.1673	0.5164	1.379
Std. Error	2.67	0.5427	0.3095	0.06831	0.2108	0.563
GROUP III	Lymph (%)	Mon (%)	Neutrophils (X 10^3/mm^3)	Eosinophils (%)	Basophils (%)	MPV (fl)
Mean	76.12	3.617	2.4	1.6	0.5	5.6
Std. Deviation	7.279	1.242	0.8989	0.1789	0.5477	1.39
Std. Error	2.972	0.5069	0.367	0.07303	0.2236	0.5675

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 *Sombu Theeneer* 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	82.33	19.67	0.7167	122.7	74.5	59.17	55	14.43
Std. Deviation	13.75	2.338	0.2927	6.088	10.41	15.88	7.849	3.189
Std. Error	5.613	0.9545	0.1195	2.486	4.249	6.483	3.204	1.302
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	78.33	15.17	0.9	110.2	83.83	71.67	48.33	15.13
Std. Deviation	13.22	3.971	0.2098	23.13	14.15	16.21	5.086	2.068
Std. Error	5.395	1.621	0.08563	9.443	5.776	6.616	2.076	0.8441
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	81.17	14.33	0.8	128.7	75.33	68.17	27.17	14.07
Std. Deviation	10.11	2.422	0.2098	10.56	12.01	12.86	4.708	1.555
Std. Error	4.126	0.9888	0.08563	4.31	4.904	5.25	1.922	0.6349

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 *Sombu Theeneer* 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	5.483	2.75	101.3	20.5	139.2
Std. Deviation	1.08	0.5648	20.53	2.881	58.25
Std. Error	0.4408	0.2306	8.381	1.176	23.78
GROUP II	Serum total protein (g/dl)	Serum albumin (g/dl)	(AST) (IU/ml)	(ALT) (IU/L)	(ALP) (IU/L)
Mean	5.367	3.067	102.7	20.17	132.5
Std. Deviation	1.148	0.9771	7.033	3.601	67.78
Std. Error	0.4688	0.3989	2.871	1.47	27.67
GROUP III	Serum total protein (g/dl)	Serum albumin (g/dl)	(AST) (IU/ml)	(ALT) (IU/L)	(ALP) (IU/L)
Mean	5.833	2.833	123.7	33.33	202.7
Std. Deviation	0.568	1.031	4.761	7.685	38.43
Std. Error	0.2319	0.4208	1.944	3.138	15.69

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

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

Treatment Female

Treatment Male

Quantitative data on absolute organ weight of rats treated with *Sombu Theeneer* 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	0.65	6.178	1.437	0.6	1.567	1.783	1.283	3.867	1.4
Std. Deviation	0.1467	0.5603	0.2587	0.1673	0.1862	0.3189	0.3869	0.4041	0.1
Std. Error	0.05989	0.2288	0.1056	0.06831	0.07601	0.1302	0.1579	0.2333	0.05774
GROUP II	HEART (gms)	LIVER (gms)	KIDNEYS (gms)	SPLEEN (gms)	BRAIN (gms)	LUNG (gms)	STOMACH (gms)	TESTES (gms)	UTERUS & OVARY (gms)
Mean	0.6267	5.588	1.427	0.6333	1.6	1.517	1.483	3.333	1.533
Std. Deviation	0.1666	0.8175	0.2526	0.1366	0.1414	0.1941	0.1472	0.8386	0.05774
Std. Error	0.068	0.3337	0.1031	0.05578	0.05774	0.07923	0.06009	0.4842	0.03333
GROUP III	HEART (gms)	LIVER (gms)	KIDNEYS (gms)	SPLEEN (gms)	BRAIN (gms)	LUNG (gms)	STOMACH (gms)	TESTES (gms)	UTERUS & OVARY (gms)
Mean	0.6633	5.333	1.278	0.6167	1.567	1.883	1.467	4.067	1.333
Std. Deviation	0.08262	1.05	0.1635	0.1722	0.1862	0.2787	0.3445	0.4163	0.1528
Std. Error	0.03373	0.4286	0.06675	0.07032	0.07601	0.1138	0.1406	0.2404	0.08819

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[57].

Histopathology of Brain (Male Rat) in Sub-acute toxicity Study
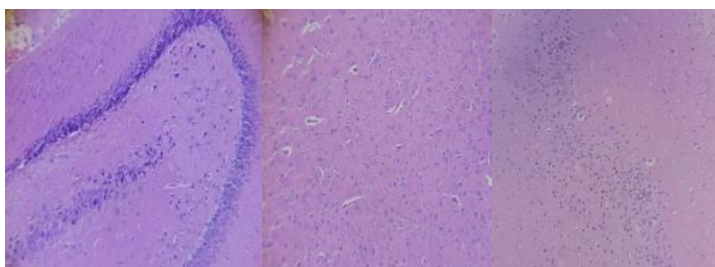
Low Power Magnification 10X

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**

High Power Magnification 40X

GROUP I GROUP II GROUP III

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

Low Power Magnification 10X

GROUP I GROUP II GROUP III

High Power Magnification 40X

GROUP I GROUP II GROUP III

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

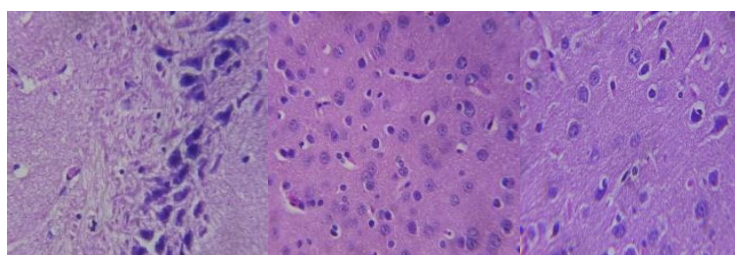**Low Power Magnification 10X**

| GROUP I | GROUP II | GROUP III |

High Power Magnification 40X
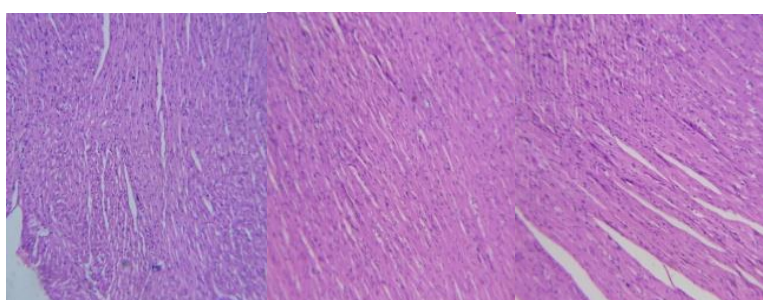

GROUP I   GROUP II   GROUP III

Histopathology of Liver (Male Rat) in Sub-acute toxicity Study
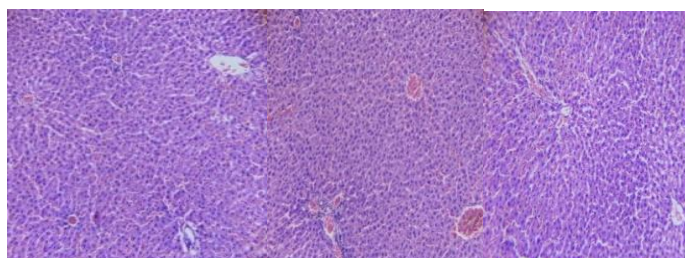
Low Power Magnification 10X

GROUP I   GROUP II   GROUP III

High Power Magnification 40X

GROUP I   GROUP II   GROUP III

Histopathology of Spleen(Male Rat) in Sub-acute toxicity Study
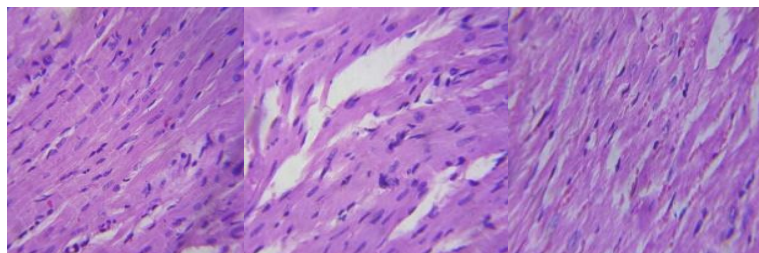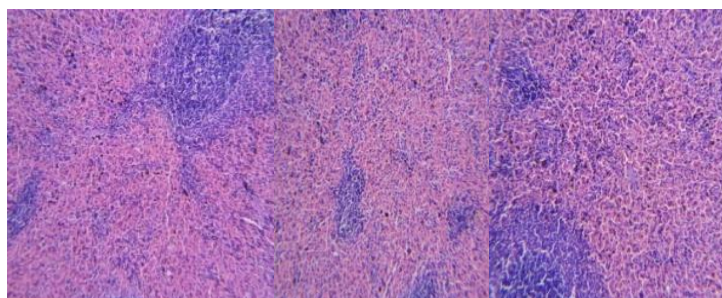
Low Power Magnification 10X

GROUP I   GROUP II   GROUP III

High Power Magnification 40X
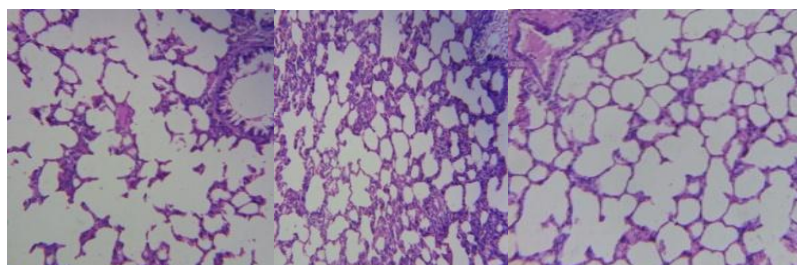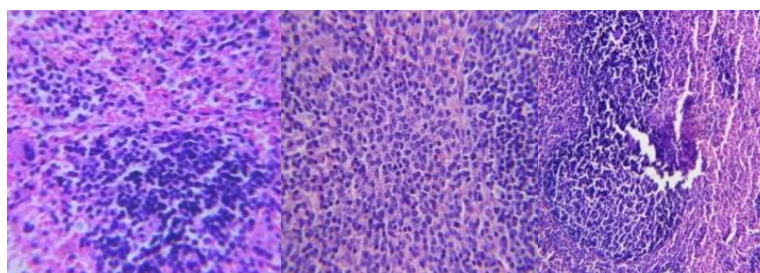

GROUP I   GROUP II   GROUP III

Histopathology of Testes (Male Rat) in Sub-acute toxicity Study
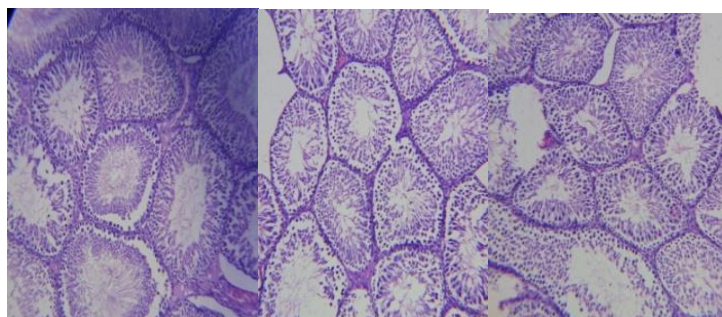
Low Power Magnification 10X
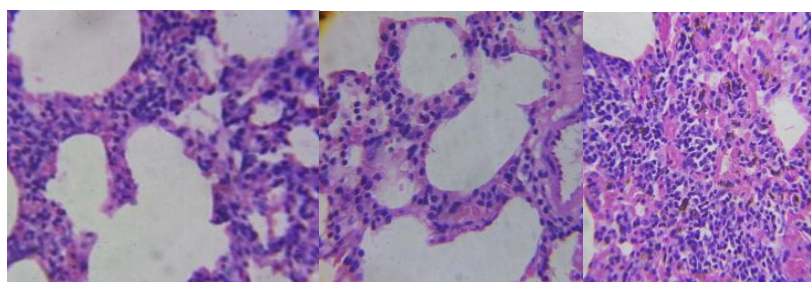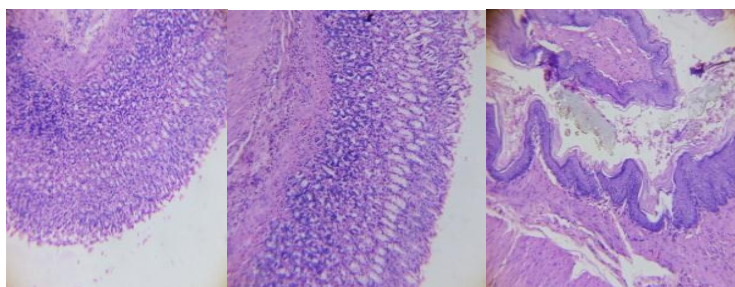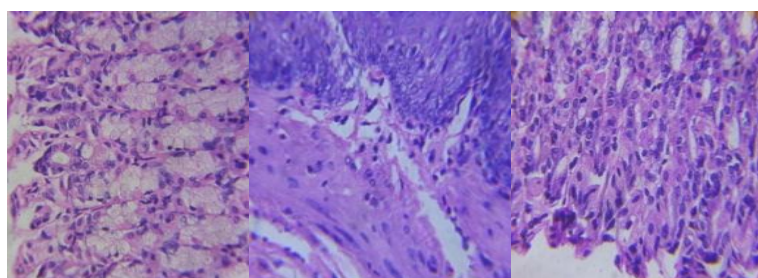

GROUP I   GROUP II   GROUP III

High Power Magnification 40X
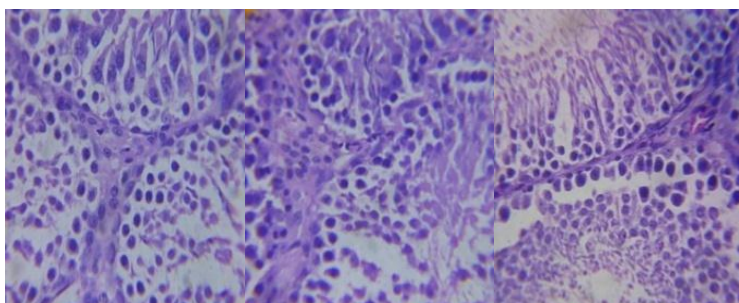
GROUP I   GROUP II   GROUP III

Histopathology of Brain (Female Rat) in Sub-acute toxicity Study
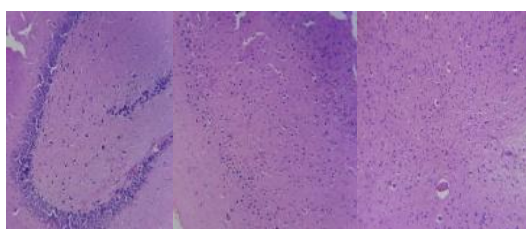
Low Power Magnification 10X   **High Power Magnification 40X**

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

Histopathology of Heart (Female Rat) in Sub-acute toxicity Study
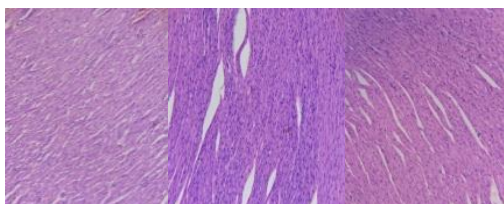
Low Power Magnification 10X   **High Power Magnification 40X**

GROUP I   GROUP II   GROUP III   GROUP I   GROUP II   GROUP III
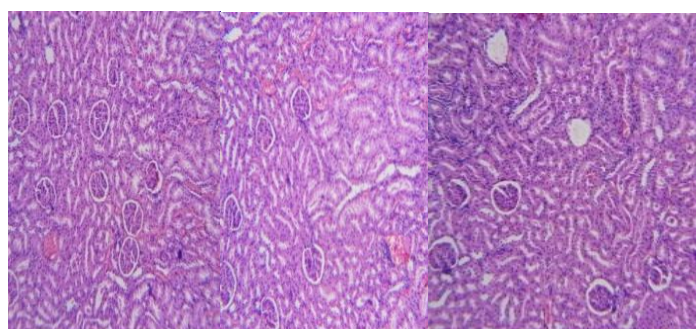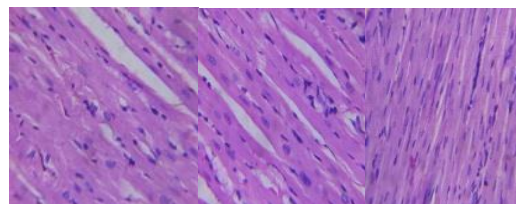
Histopathology of Kidney (Female Rat) in Sub-acute toxicity Study
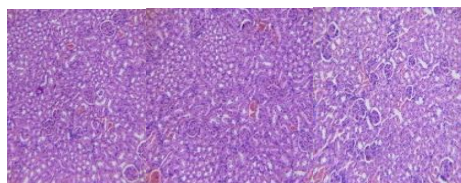
Low Power Magnification 10X   **High Power Magnification 40X**

GROUP I   GROUP II   GROUP III   GROUPI   GROUP II   GROUP III
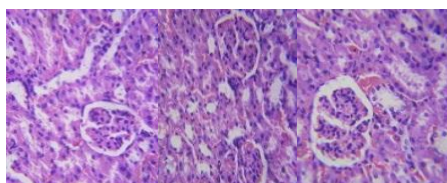
Histopathology of Liver (Female Rat) in Sub-acute toxicity Study
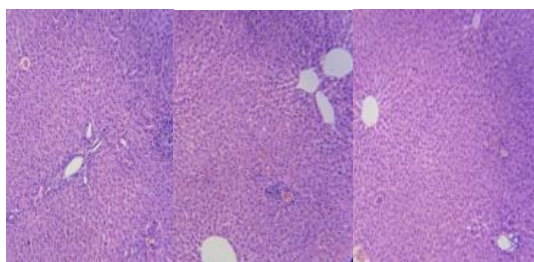
Low Power Magnification 10X   **High Power Magnification 40X**

GROUP I   GROUP II   GROUP III   GROUP I   GROUP II   GROUP III
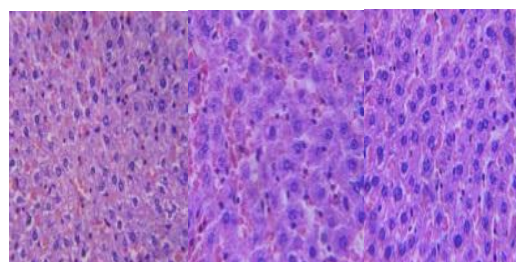
Histopathology of Lung (Female Rat) in Sub-acute toxicity Study
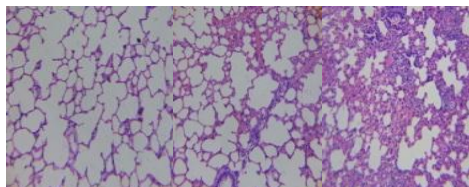
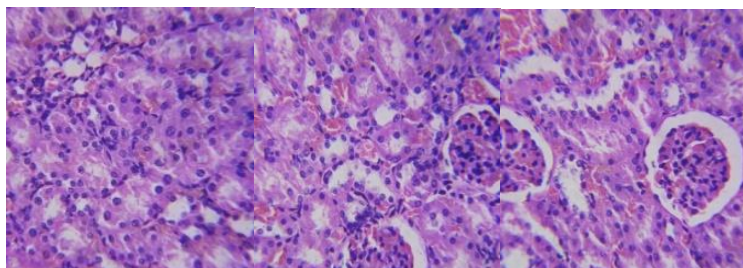**Low Power Magnification 10X**   **High Power Magnification 40X**

GROUP I   GROUP II   GROUP III   GROUP I   GROUP II   GROUP III
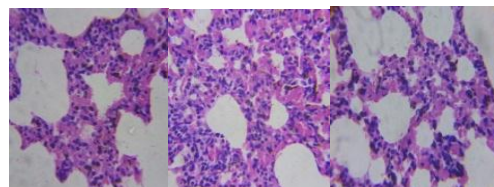
Histopathology of Stomach (Female Rat) in Sub-acute toxicity Study
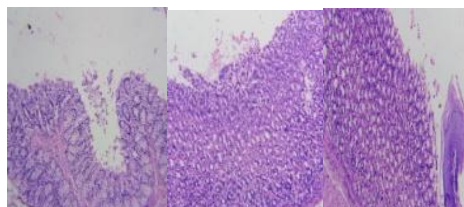
Low Power Magnification 10X   **High Power Magnification 40X**

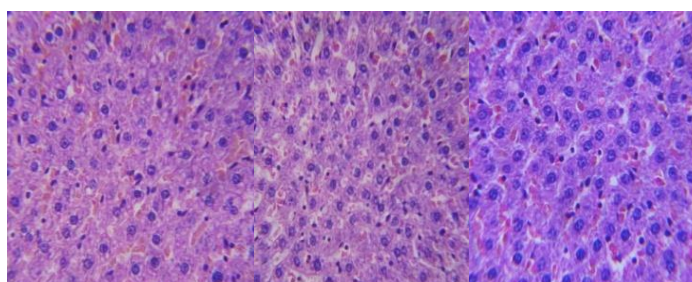**GROUP I   GROUP II   GROUP III   GROUP I   GROUP II GROUP III**
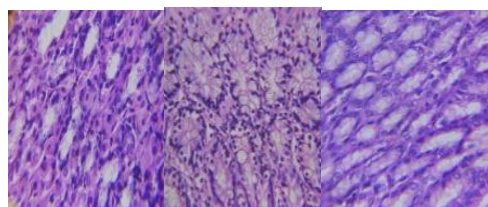
Histopathology of Spleen (Female Rat) in Sub-acute toxicity Study
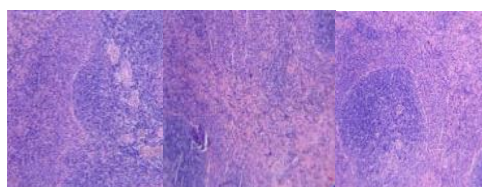
Low Power Magnification 10X   **High Power Magnification 40X**

GROUP I   GROUP II   GROUP III   GROUP I GROUP II   GROUP III
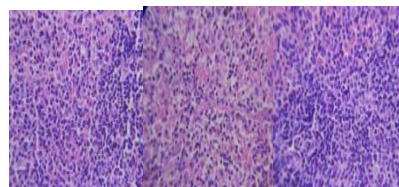
Histopathology of Uterus (Female Rat) in Sub-acute toxicity Study
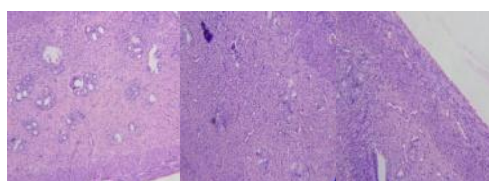
Low Power Magnification 10X   **High Power Magnification 40X**

GROUP I   GROUP II   GROUP III   GROUP I   GROUP II   GROUP III
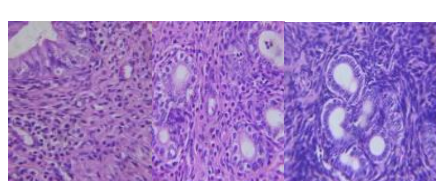
Histopathology of Ovary (Female Rat) in Sub-acute toxicity Study

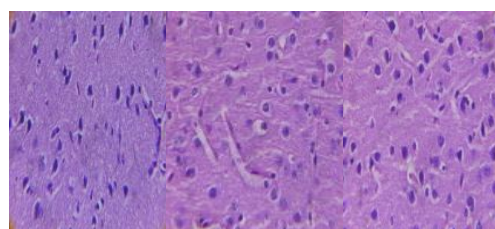**Low Power Magnification 10X**   **High Power Magnification 40X**
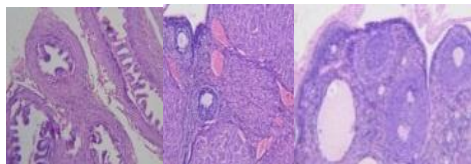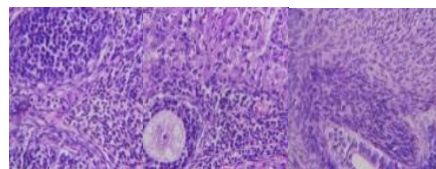
GROUP I   GROUP II GROUP III   **GROUP I   GROUP II GROUP III**

AIM

The aim of this dissertation study is to analyze the safety and efficacy of the *Siddha* medicine **SOMBU THEENEER** for the treatment of **Swasakasam** through preclinical and clinical study.

OBJECTIVE

1. To study the efficacy of the trial drug *SOMBU THEENEER* by clinically.

2. To observe the incidence of the disease with age, occupation, habits, climatic conditions and economical status.

3. To obtain the literature   of both Siddha and modern aspect of the disease *Swasakasam.*

4. To study the clinical course of the disease with observation on aetiology, classification, pathology, complication, differential diagnosis, prognosis and treatment by Siddha aspect.

5. To elicit the diagnostic methods clinically mentioned by *Siddhars* through *Mukkutram, Pori*, *Pulangal and Ezhuudalthathukkal.*

6. To confirm the diagnosis and prognosis of the disease through modern parameters.

7. To evaluate the

- ❖ Physio-chemical analysis
- ❖ Toxicological (Acute and Sub-Acute)
- ❖ Pharmacological activity Broncho-dilator (Milk induced leucocytosis and eosinophilia in mice model)
- ❖ Bio-Statistical analysis of the trial medicine.

SIDDHA ASPECT

<u>சுவாசகாசம்</u>: காசம், ஈளை

DEFINITION:

It is the sound produced by natural stimulation to expel the phlegm and mucous secretions which is excessively secreted by the inflammatory conditions at the nose, throat and lungs due to the accumulation of deranged pitham and kabam.

யூகிமுனிவரின் கூற்று படி,

"வண்மையாய்க் கோழைகட்டி இருமிவிழும்

மாநாகம் போலவே வாங்குஞ் சுவாசம்

திண்மையாய்ச் செருமலுண்டா மடிக்குடிக்குச்

சீரண்மில்லாமலே வயிறு மூதும்

நன்மையாய் நாசியது தணல் போலாகும்

நலிந்துடம்பு வற்றிவருங் குரலுங் கம்மும்

உண்மையா யுண்ணாக்கி லூறுங்கேணி

யுழந்துமே சுவாசகாசத்தி னொப்பே"

- யூகி வைத்திய சிந்தாமணி 800.

The following symptoms are as follows:

- Cough with expectoration
- Difficulty in breathing
- Indigestion
- Flatulence
- Loss of weight
- Hoarseness of voice[8].

நோய் வரும் வழி:

யூகிமுனிவரின் கூற்று படி,

"பாணத்தால் பரமாக்கினி மிகுக்கையாலும்

பராமா மாமிசங்கள் புசிக்கையாலும்

தாணத்தாற் சஞ்சாரந் தவிர்கையாலும்

சரிப்படாப் பதார்த்தங்கள் புசித்தாலும்

தீணத்தாற் பொசியாமலிருக்கையாலும்

சேயிழையார் மேலின்பஞ் சிதைவதலும்

மாணத்தால் மாதுக் கமடைதலாலும்

மதத்தாலும்ஞ் சுவாசமது மருவுகங் காணே".

-   **யூகி வைத்திய சிந்தாமணி** 800.

The following reasons are as follows:

- ❖ Excessive intake of cold drinks
- ❖ Excessive intake of meat, fish..etc
- ❖ Unhealthy food habits ,starvation
- ❖ Excessive or less sexual indulgence
- ❖ Mental disturbances[7].

In Para Rasasekar text the following described as,

"புகைமிகக் குடித்தலாலும் புரையெறிந்தாலும் பேய் வந்

திகலவே நடக்கையாலு மியம்புட் டணத்தினாலும்

தகைபசித் திருக்கை யாலுஞ் சலமலங்கழியா தாலும்

அகமுறப் பிராணவாயு வகன்றுமே னோக்குந்தானே

ஆனதோரையும் பித்துமதை விளைத் திருமித் தள்ளிக்

கானமாங் குழலாய் கம்மிக் கனத்துறு மிடறுங் காதும்

தானது தினவாயன்னந் தன்னையு மறப்பித் தேதான்

ஊனமாங் காசநோய்வந் துறுமென உரைத்திடீரே."

- பராராசேகரம்.

The following symptoms are as follows:

- ❖ Excessive smoking
- ❖ Excessive walking
- ❖ Excessive heat
- ❖ Starvation
- ❖ Improper excretion of urine and faeces[27].

In Dhanvanthri the following quote described as,

"அரசரோ கந்தனக்கே யமைச்சராங் காசரோகம்

தரை மிசை மாந்தர் தம்மை சார்ந்திடும் வகையோ தள்ளி

லூர மிசை கிலேசந் மங்கு முறுதுய ராலு மாதர்

தருமயளாலுந் தூமஞ் சார்துகள் முகர்ந்ததாலும்

- தன்வந்திரி வைத்தியம்

- ❖ Sexual indulgence
- ❖ Stress
- ❖ Inhalation of dust particles.[10]

In Theraiyar Vagadam the following quotes described as

வந்திடும் வெள்ளொக்காளம் வாயது தித்திப்பாகும்

நொந்திடும் பிடரி மண்டை மந்தமும் மிளைப்பி னோங்கும்

முந்தவே தலை னொந்து சரீரமு முகமுங் குத்தும்

கந்தரந் தொண்டை நாசி கர கரன்றுடானே தும்மல்

தும்மலு மிருமலும் தோன்றுங் காசநோய்

நன்மையாய் வியாதி தீர்ந்தொழிய நல்குவார்."

- தேரையர் வாகடம்.

The following symptoms are as follows:

- ❖ Belching
- ❖ Sweet taste
- ❖ Loss of appetite
- ❖ Headache
- ❖ Pain all over the body especially neck and face
- ❖ Soreness of throat
- ❖ Cough.[19]

நோய் எண் யூகிமுனிவரின் கூற்று படி, காசம் 12 வகையாக பிரிக்கபட்டுள்ளது.

"தானான காசமது பன்னிரண்லடாகுந்

தாக்கான மந்தார காசந்தோடு

பானான பக்கமந்தார காசம்

பாங்கான சுடர் காசம் வாத காசம்

பேனான பித்தமாங் காசத்தோடு

பேர்பெரிய் சுவாசகாசத்தோடொக்க

ஏனான இரத்தமாங் காசத்தோடு

இரைப்பான சிலேத்ம காசத்தானமே

ஆகின்ற பீனிசத்தின் சுவாசகாசம்

அழிவாத பித்ததின் காசமாகுகம்

போகின்ற பித்தசிலேத்தும காசந்தானே

புகழ்பெரிய தொந்தமாங் காசத்தோடு

தேகின்ற காசமது பனிரண்டாகும்

தெளிவாக பிதனுடைய செயலைக் கேளாய்

வேகின்ற வதிகமாம் புகையினாலும்

மீறுகின்ற பாணத்தால் மிகுக்குந் தானே"

- யூகிவைத்திய சிந்தாமணி 800

The following types are as follows:

1. Manthaara Erumal
2. Pakk Erumal
3. Sudar Erumal
4. Vali Erumal
5. Azhal Erumal
6. Iyya Erumal
7. Ratha Erumal
8. Peenisa Erumal
9. Vali Azhal Erumal
10. Azhal Erumal
11. Mukkutra Erumal
12. Swasa Erumal.[7]

In Dhanvanthri Vaithiyam the following quotes described as

"இயங்கிய பிராணவாயு மேனோக்கி இருமலுண்டாய்

தீங்கிய வாதகாசம் பைத்தியஞ் சேர்ந்த காசந்

தயங்கிய சிலேற்ப காசஞ் ஷதகாசஞ் சயகாசந்தான்

பயன்பெறுங் காசமஞ்சும் பிறந்திடும் பகுதிதானே".

- தன்வந்திரி வைத்தியம்.

The following classification as follows:

1. Vatha Kasam
2. Pitha Kasam
3. Kabha Kasam
4. Satha Kasam
5. Saya Kasam
6. Dhondha Kasam

7. Manthaara kasam
8. Vega Kasam
9. Pakka Manthara Kasam
10. Sura Kasam.[10]

In Roganirnayathil 5 types have described

ரோகநிர்ணய சாரத்தில் 5

1. Vatha Kasam
2. Pitha Kasam
3. Silethuma Kasam
4. Ratha Kasam
5. Saya Kasam

In Agathiyar 2000 the following quotes described as

அகத்தியர் 2000த்தில் காசரோக குறிகள்

" இருமியே செயலுங்க கெட்டுயிடை சுரமும் தோன்றி

யருவியே மிடருங் கண்ணு மற்பமே வாந்தியாகி

மருவியே அசனந்தாறு மறுத்துள்ளந் தாளும் வற்றிக்

கருவியே குறைத்து வாடும் காசரோக மென்னலாமே"

அகத்தியர் 2000

The Symptoms are as follows:

❖ Cough
❖ Fever
❖ Vomiting
❖ Mental depression
❖ Fatigue
❖ Loss of appetite
❖ Loss of weight[49].

In Kasa Roga Lakshanangal Describes,

<u>காசரோக லட்சணங்கள்</u>

விண்ணிற் சுழந்துயிரமிகு வெளுந்து வத்தித்திமிர்த் தெங்குமங்

கண்ணைப்பார்க்க மஞ்சணித்துக் களைத்தழுகமும் வெளுந்ததனால்

லெண்ணிய கரும மொண்ணுசெய்யி லிளைப்புமுட்டுத் துயருண்டாய்

நண்ணிய பெரிய தாதுகெடும் நவிலுங் காச ரோக மிதே."

-    அகத்தியர் 2000

The Symptoms are as follows:

- ❖ Giddiness
- ❖ Pallor of the skin
- ❖ Numbness
- ❖ Yellowish conjunctiva
- ❖ Dyspnoea[49].

In Kaiyezhuthu Prathiyil describes

கையெழுத்து பிரதியில்,

"கட்டியே கோழை இருமவே வீழ்ந்து

கச்செவி சீறுதல் போல

முட்டியே மூச்சு வன்மையாய்ச் செருமி

மூக்கழல் எய்தியே யுடலம்

வற்றியே மெலிந்துண்ணாவர நீரும்

வரட்சீரண மிகுவியர்வை

கட்டிபோல் வயிறு மூதிலிரைப்பா

மிருமலென ரோதுவர் காணே"

- நோய் நாடல் திரட்டு - II

The symptoms are as follows:

- ❖ Cough with expectoration
- ❖ Dyspnoea
- ❖ Loss of body weight
- ❖ Loss of appetite
- ❖ Indigestion with excessive sweating
- ❖ Pricking pain in the chest[17].

தீரும் தீராதவை:

1. Vali Erumal
2. Iyya Erumal
3. Vali Iyya Erumal
4. Azhal Iyya Erumal
5. Mukkutra Erumal

இவைகள் அனைத்தும் தீராது.

MUKKUTRA VERUPAADUGAL:

According to Siddha system, Body is constituted by 96 Thatuvas. Normal structural and physiological state of the body is maintained by equilibrium with Mukkutram and Several Udarkattugal.

As the udarkattugal 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 Udarkattugal and Mukkutram, it results in incoordination of functions. Thereby the disease manifest and expose its clinical features.

In Swasakasam, the clinical condition is due to the imbalance of IYYAM. Iyyam is primarily deranged leads to the derangement of udhanan which in the turn cause the disease. The pathogenesis of the disease depends upon the affected Iyyam.

நாடி நடை:

பாங்கான வாதத்தில் சேத்தும நாடி

  பரிசித்தால் திமிர்மேவு முளைச்ச லாகும்

தீங்கான இருமலலுடன் சந்நி தோடம்

  சேர்ந்தவிடம் வெடிசூலை இருத்ரோகம்

வாங்காத ஈளையுமந் தார காசம்

  வலியுடனே புறவீச்சு உள்வீச்சு வீக்கம்

ஓங்கானும் சுரமுடனே சுவாசகாசம்

  உண்டாகும் வெகுநோய்க்கு முறுதிதானே"

                    - சதக நாடி

UYIR THATHUKKAL:

MukkutraIyal:

In siddha system of medicine,the manifestations of all diseases are due derangement of mukkutrams. Namely

- Vali – (Kaattru + Veli)
- Azhal – (Thee)
- Iyyam – (Neer + Mann)

The alterations of three thathu in their reaction to extrinsic or intrinsic factors results in disease.

FUNCTIONS OF VALI:

"ஒழுங்குடன் தாதேழ்மூச் சோங்கி இயங்க

எழுச்சிபெற எப்பணியுமற்ற -எழுந்திரிய

வேகம் புலன்களுக்கு மேவச் சுறுசுறுப்பு

வாகளிக்கும் மாந்தர்க்கு வாயு"

- மருத்துவ தனிப்பாடல் பக்கம்

According to the physiological function, vali is classified into ten types. They are

S.NO	VATHAM	GENERAL FEATURES	CHANGES IN SWASAKASAM
1.	Piranan (UyirKaal)	Responsible for respiration and it is necessary for proper digestion	Affect
2.	Abanan (Kizhnokkumkaal)	Responsible for all download forces such as voiding of urine, stools, semen, menstrual flow	Normal
3.	Viyanan (paravukkaal)	Dwells in the skin and is concerned with the sense of touch extension and flexion of the parts of the body and distribution,of the nutrients to various parts of the body	Normal
4.	Uthanan (Melnokkukaal)	Responsible for all kinds of upward motion such as nausea, vomiting…etc..	Normal
5.	Samanan (nadukkaal)	Considered essential for proper digestion, assimilation and carries the digested nutrients to each and every organ	Normal
6.	Nagan	Helps in opening and closing of eyelids	Normal
7.	Koorman	Responsible for vision, lacrimation and yawning	Normal
8.	Kirugaran	Induces appetite, salivation, all secretions in the body including nasal secretion and sneezing	Affect

9.	Thevathathan	Induces and stimulates a person to become alert, get anger to quarrel to sleep etc.	Affect
10.	Dhananjeyan	Resides in the cranium and produces bloating of the body after death. This leaves from the body after 3days of death forming a way through the skull.	_

In SwasakasamPrananan, Kirugaran andDevathathan will be mainly affected[23].

FUNCTIONS OF AZHAL:

" பசிதாகம் ஓங்கொளிகண் பார்வைபஞ்ச டைத்து

ருசிதெரிசத்திவெம்மை வீரம்- உசித

மதிகூர்த்த புத்திவனப் பளித்துக் காக்கும்

அதிகாரி யாங்கா னழல்"

- மருத்துவ தனிப்பாடல் பக்கம்

S.NO	PITHAM	NORMAL FEATURES	CHANGES IN SWASAKASAM
1.	Anarpitham	Peps up the appetite and aids in digestion.	Normal
2.	Ranjagapitham	Responsible for the color and contents of blood .	Normal
3.	Sathagapitham	Controls the whole body and is held responsible for fulfilling a purpose.	Affect
4.	Pirasagapitham	Dwells in the skin and concerned with the shine glow texture and its complexion.	Normal
5.	Alosagapitham	Responsible for the perception of vision.	Normal

In Swasakasam , Sathagapitham will be mainly affected.

FUNCTIONS OF IYAM:

"திடமீயு மென்பிணைப்புத் திண்மையுற்ற யாப்பும்

அடலேர் வழுவழுப்பும் ஆக்கைக் -கிடர்க்கு

வெருவாப் பொறுமையும் மேலான காப்பாம்

பெருமைத்தா மையமெனப் பேசு"

-   மருத்துவ தனிப்பாடல்

S.NO	KABAM	GENERAL FEATURES	CHANGES IN SWASAKASAM
1.	Avalambagam	Lies in the respiratory organs, exercises authority over other khabhas and controls the heart and circulatory system.	Affect
2.	Kilethagam	Found in stomach as its seat, moistens the food , softens and helps to be digested.	Normal
3.	Pothagam	Hold responsible for the sensory perception of taste.	Normal
4.	Tharpagam	Presents in the head and is responsible for the coolness of the eyes, sometimes may be referred to as cerebrospinal fluid.	Normal
5.	Santhigam	Necessary for the lubrication and the free movement of joints[21].	Normal

UDAL KOORUGAL (SEVEN PHYSICAL CONSTITUENTS):

"இரசமிரத் தந்தசை நெய் நிண்மென்புமச்சைவிந்தென் றேழும் முறையே

சரதமொடு மெய்மனத்து நிறைவுதரும் உயிருட் தாங்கியிருக்கும்

உரமுதவும்மேடுபள்ளம் நிரவும் நெய்ப்பசையூட்டும் ஓங்கிநிறுத்தும்

பரந்தென்பின் துளைகடொறும் நிரம்பிடுங்கள் முளைத்தோன்றபப்

பண்ணும்தெரிவாய்"

- சித்தமருத்துவாங்கச் சுருக்கம்

S.NO	UDAL KATTUGAL	GENERAL FEATURES	CHANGES IN SWASAKASAM
1.	Saaram (digestive essence)	Responsible for the growth &development. It keeps the individual in good temperament and it enriches the blood.	Affect
2.	Senneer (Blood)	Responsible for the colour of blood and for the intellect, nourishment, strength, vigour and valour of the body.	Affect
3.	Oon (Muscle)	Gives notable contour to the body as needed for the physical activity. It feed the fat next day and gives a sort of plumpness to the body.	Normal

4.	Kozhuppu (Fat)	Lubricates the organs to facilitate frictionless functions.	Normal
5.	Enbu (Bones)	Supports and protects the vital organs, gives the definite structure to the body and responsible for the posture and movements of the body.	Normal
6.	Moolai (Bone marrow)	Nourishes the bone marrow and brain which is the centre that controls other systems of body.	Normal
7.	Sukkilam/Suronitham (Sperm/Ova)	Responsible for reproduction	Normal

In Swasakasam , Saaram and Senneer will be affected.

KAALA MARUBADUGAL:

PARUVAKALAM (SEASONS):

According to ancient tamilians, a year is divided into six seasons and each season consists of two months and the year starts from Margazhi.

S.NO	KAALAM	TAMIL MONTHS	MUKKUTTRA MARUPAADUGAL
1.	Kaar Kaalam	Aavani & Purattasi Aug 16 To Oct 15	VATHAM – Vetrunilai Valarchi PITHAM - Thanilai valarchi
2.	Koothir Kaalam	Iypasi & Karthigai	VATHAM – Thanilai Valarchi

		Oct 16 To Dec 15	PITHAM - Vetrunilai Valarchi
3.	Munpani Kaalam	Margzhi & Thai Dec 16 To Feb 15	PITHAM - Thanilai Valarchi
4.	Pinpani Kaalam	Masi & Panguni Feb 16 To April 15	KABAM - Thanilai Valarchi
5.	Elavenir Kaalam	Chithrai & Vaikasi April 16 To June 15	KABAM - VetrunilaiValarchi
6.	Mudhuvenir Kaalam	Aani & Aadi June 16 To Aug 15	VATHAM – Thanilai Valarchi

Swasakasam is more prevalent in Pinpani and Elavenir Kaalam due to vitiation of Kabham.

THENAI (LAND):

Siddhars classified the lands into five types. They are,

> ➢ Kurunchi   - Mountain range
> ➢ Mullai   - Pastoral area of the forest
> ➢ Marudham - The fertile river bed
> ➢ Neidhal   - The coastal region
> ➢ Paalai   - Arid desert

Prevalence of the disease Swasakasam is more comman in Kurunchi and Paalainilam. Pitha disease occurs in Mullailand. Vadha disease occurs in Neidhal land. Marudham land is the fertile area where no disease will occurs[25].

RELATIONS BETWEEN MUKKUTRAM, KAALANGAL AND THINNAIGAL:

PARUVAKAALAM (SEASONS)

MUKKUTRAM	Thannilai Vazharchi (Accumulation)	Vetrunilai Vazharchi (Aggravation)	Thannilai Adaithal (Alleviation)	THINAI
VATHAM	Mudhuvenil kaalam	Kaar kaalam	Koothir kaaalam	Vatha disease is more prevalent in NEIDHAL land
PITHAM	Kaar kaalam	Koothir kaaalam	Munpani	Pitha disease is more prevalent in MULLAI land
KAPHAM	Pinpani	Elavenil kaalam	Mudhuvenil kaalam	Kapha disease is more prevalent in KURUNCHI land

PINIYARI MURAIMAI (DIAGNOSIS):

"மதித்திடற் கருமை வாய்ந்த

மாண்பரிகார மெல்லாந்

துதித்திட வுணர்ந்தானேனுந்

துகளறப் பணியின்றன்மை

பதித்திட வுணரானாகிற்

பயனுறானாகாலனே

விசித்திடு பிணிதிறத்தை

விளம்புது முதற்கண் மன்னோ."

- சிகிச்சா ரத்தின தீபம்

Four steps are followed in diagnosing the disease. They are,

i) Poriyaalarithal
ii) Pulanaaltherthal
iii) Vinaathal
iv) Envagaithervu

In detail,

i) Poriyaalarithal:

In this the physician should carefully observe the changes that occur in the five sensory organs [Porigal] of the patient.

ii) Pulanaaltherthal:

The physician carefully applies his five senses of perception, smell, taste, vision, touch, and sound to understand the condition of the patient.

iii)   Vinaathal:

The physician should interrogate about the patients name, age, occupation, socio economic status, food habits, history of past illness, history of present illness, family history, martial status, menstrual history and frequency of pain.

iv)   Ennvagai thervukal:

Siddhars have developed a unique method of diagnosing the disease by "EnvagaiThervugal"[16].

" நாடிப்பரிசம் நாநிறம் மொழி விழி

மல மூத்திரம்மிவை மருத்துவராயுதம்"

- நோய் நாடல் நோய்முதல் நாடல்

.

The diagnosis is made based on the following:

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

1. **NAA:**

   Signs and symptoms in the tongue are noted here. Colour, Salivary secretion, ulcers, coating, inflammation, taste changes, deviation and its nature are generally noted. In **Swasakasam,** naa will be affected due to dryness of tongue.

2. **NIRAM:**

   The colour of the skin is noted here.In **Swasakasam,** niram will be normal.

3. **MOZHI:**

   Character of the speech is noted, mainly urathaolli(high pitched), thazhnthaolli(low pitched), or resembles the sound of any instrument.In **Swasakasam**, mozhi will be affected due to breathlessness.

4. **VIZHI:**

   Character of the eye is noted. Color, warm, burning sensation, irritation, visual perception. In **Swasakasam,** vizhi will be normal.

5. **MALAM:**

   The stools are examined for quantity, hardening(malakattu),loose motion(bethi), colour and smell. In **Swasakasam,** malam will be normal.

6. **MOOTHORAM:**

   i)   **NEERKURI:**

   The urine is examined for its colour, odour, volume, froth, and weight. In Swasakasam**,** moothiram will be normal.

   ii)   **NEIKURI:**

   "அருந்துமாறி ரதமும் அவிரோதமதாய்

   அக்கல் அலர்தல் அகாலவூன் தவிர்தழற்

குற்றளவருந்தி உறங்கி வைகறை

ஆடிக்கலசத் தாவியே காதுபெய்

தொருமுகூர்த்தக் கலைக்குட்படு நீரின்

நிறக்குறி நெய்குறி நிருமித்தல் கடனே"

- சித்தமருத்துவாங்கச் சுருக்கம்

The early morning urine of the patient is analysed by dropping a drop of gingley oil on the surface of the urine sample. The accumulation, formation, changes, and dispersal under the sunlight without any external disturbances of the urine sample should be noted[22].

➢ Vathaneer – The oil spreads like snake
➢ Pithaneer - The oil spreads like ring
➢ Kabhaneer - The oil spreads like pearl
➢ If the oil spreads gradually, it indicates good prognosis
➢ If the oil spreads fast or gets mixed completely with urine or sinks in urine, it suggests bad prognosis[22].

Since **Swasakasam** is due to the derangement of vatham and kapham, the neikuri will be vatha or kabhaneer.

7. NAADI:

Naadi is a unique Siddha Pulse reading method and it should be felt and not read. Different gaits of Vazhi, Azhal, Iyam like branching, jumping, mixing, rotating and compression can be identified.

NAADINADAI:

IDENTIFICATION (FINGER)		INDEX	MIDDLE	RING
STRENGTH (IN UNIT)		1	1/2	¼
PATTERN	MALE	HEN	TORTOISE	SNAKE
	FEMALE	SNAKE	FROG	SWAN

8. **PARISAM:**

Observation such as touch, temperature, sensory impairment, masses, nodes, swelling and texture of the skin, pain, hardness, oedematous, and dullness shall be noted. In **Swasakasam,** the patient's body may be either heat or cold.

LINE OF TREATMENT

In Siddha system, the main aim of the treatment is to cure udalnoi and mananoi. Treatment is given not only for complete healing but also for the prevention and rejuvenation. It consist of

- Kaapu (Prevention)
- Neekam (Treatment)
- Niraivu (Reastoration)

   1. **MEDICINE:**

SOMBU THEENEER - 15ml with 30ml of warm water, twice daily.

   2. **ADVICE:**
- To follow good personal hygiene
- Avoid chill and cold weather
- To find out allergens and avoid them
- To avoid exposure to dust, Fumes and smokes
- To avoid smoking
- Advised to practice pranayamam and asanas

3. YOGA PRACTICE:

Yogasanas are designed to promote a state of mental and physical wellbeing. It consists of relaxation, breathing exercise and physical posture. In can help circulation and breathing, posture and hormonal balance. They will improve the strength of the muscles involved in respiration.

- Pranayama
- Pujangasanam
- Patchimotasana
- Salabasana
- Machasana.

PRANAYAMAM

ASANAS FOR BRONCHIAL ASTHMA

SALABASANAM

PUYANGASANAM

ARTHA CHAKRASANAM

DHANURASANAM

MACHASANAM

MODERN ASPECT

MODERN ASPECT

ANATOMY AND PHYSIOLOGY OF RESPIRATORY SYSTEM:

Developmentally the respiratory system is an outgrowth from the ventral wall of the foregut .The organs of the respiratory system are nose, pharynx, larynx, trachea, two bronchi(one bronchus to each lung), bronchioles and smaller air passages, two lungs and their coverings- the pleura, muscles of respiration –the intercostal muscles and the diaphragm. The upper respiratory tract includes the nose, naso-pharynx and larynx. It is lined by vascular mucous membranes with ciliated epithelium on their surfaces.

The lower respiratory tract includes the trachea and bronchi. These form an inter connecting tree of the conducting airways eventually joining, via around 64000 terminal bronchioles, with the alveoli to form the acini. The lower respiratory tract is lined with ciliated epithelium as far as the terminal bronchioles.[35]

TRACHEA:

The trachea is a wide tube lying more or less in midline, in the lower part of the neck, which serves to conduct air to both lungs for respiration. It starts at the lower border of the cricoid cartilage and ends at the level of the upper border of the thoracic vertebra by dividing into two bronchi, right and left.

FUNCTIONS:

- Support and patency
- Muco-ciliary escalator
- Cough reflex

ARTERIAL SUPPLY:

Inferior thyroid arteries

VENOUS DRAINAGE:

Into the left brachio-cephalic vein

LYMPHATIC DRAINAGE:

To the pretracheal and paratracheal nodes.

BRONCHI:

The two bronchi are formed when the trachea divides, i.e at the level of the 4th thoracic vertebra. The right bronchus is a wider, shorter tube than the left bronchus and it lies in a more vertical position. After entering the right lung at the hilum, it divides into three branches, one of which passes to each lobe. Each branches then subdivided into numerous smaller branches. The left bronchus is narrower than the right. After entering the left lung at the hilum, it divides into two branches, one of which goes to each lobe. Each branch then subdivides progressively into smaller tubes within the lung substance.

FUNCTIONS:

- Warming and humidifying
- Support and patency
- Removal of particulate matter
- Cough reflex

LUNGS:

The lungs are indegeniously constructed to carry out their cardinal function i.e. the exchange of gases between inspired air and blood. The lungs are pair of respiratory organs situated in the thoracic cavity. They are spongy in texture. In the young the lungs are brown or grey in colour. Gradually they become mottled black because of the deposition of inhaled carbon particles.[37]

LOBES AND FISSURES:

RIGHT LUNG:

The right lung is slightly larger than the left is divided by the oblique and horizontal fissures into three lobes, the upper, middle and lower lobes.

LEFT LUNG:

The left lung is divided by a similar oblique fissure into lobes. The upper and the lower lobes. There is no horizontal fissure in the left lung. The Broncho pulmonary segments are the anatomical, functional and surgical units of the lungs. Each lobar bronchus which passes to a lobe of the lung gives off branches called segmental bronchi .Each segmental bronchus then enters a Broncho pulmonary segment. The main Broncho pulmonary segments are as follows:

RIGHT LUNG

SUPERIOR LOBE

- Apical
- Posterior
- Anterior

MIDDLE LOBE

- Lateral
- Middle

INFERIOR LOBE

- Superior(Apical)
- Medial Basal
- Anterior Basal
- Lateral Basal
- Posterior Basal

LEFT LUNG

SUPERIOR LOBE

- Apical
- Posterior
- Anterior
- Superior Lingual
- Inferior Lingula

INFERIOR LOBE

- Superior (Apical)
- Medial Basal
- Anterior Basal
- Lateral Basal
- Posterior Basal

ROOT OF THE LUNG:

Root of the lung is a short, broad pedicle which connects the medial surface of the lung to the mediastinum. It is formed by structures which either enter or come out of the lung at the hilum (latin depression). The roots of the lung lie opposite the bodies of the fifth, sixth and seven thoracic vertebrae.

CONTENTS:

The root is made up of the following structures.

1. Principle bronchus on the left side, and eparterial and hypaterial bronchi on the right side.

2. One pulmonary artery.

3. Two pulmonary veins, superior and inferior.

4. Bronchial arteries, one on the right side and two on the left side.

5. Bronchial veins.[31]

6. Anterior and posterior pulmonary plexuses of nerves.

7. Lymphatics of the lung.

8. Broncho pulmonary lymph nodes.

9. Areolar tissue.

BLOOD SUPPLY:

The bronchial arteries supply nutrition to the bronchial tree and to the pulmonary tissue. These are small arteries that vary in number, size and origin, but usually they are as follows;

- On the right side, there is one bronchial artery which arises from the third right posterior intercostal artery.
- On the left side, there are two bronchial arteries both of which arise from the descending thoracic aorta.

Deoxygenated blood is brought to the lungs by the two pulmonary arteries and oxygenated blood is returned to the heart by the four pulmonary veins.

VENOUS DRAINAGE:

The venous blood from the first and second divisions of the bronchi is carried by bronchial veins. Usually there are two bronchial veins on each side.

- The right bronchial veins drain into the azygos vein.
- The left bronchial veins drain into the hemiazygos vein.

The greater part of the venous blood from the lungs is drained by the pulmonary vein[29].

LYMPHATIC DRAINAGE:

There are two sets of lymphatics, both of which drain into the bronchopulmonary nodes.

1. Superficial vessels drain the peripheral lung tissue lying beneath the pulmonary pleura. The vessels pass round the borders of the lung and margins of the fissure to reach the hilum.
2. Deep lymphatics drain the bronchial tree, the pulmonary vessels and the connective septa. They run towards the hilum where they drain into the bronchopulmonary node.
3. The superficial and deep lymph vessels communicate with each other.

NERVE SUPPLY:

1. Parasympathetic nerves are derived from vagus. These fibers are
   a. Motor to the bronchial muscles and on stimulation cause bronchospasm.
   b. Secretomotor to the mucous glands of the bronchial tree.
   c. Sensory fibres are responsible for the stretch reflex of the lungs, and for the cough reflex[32].
2. Sympathetic nerves are derived from second to fifth sympathetic ganglia. These are inhibitory to the smooth muscle and glands to the bronchial tree. That is how sympathomimetic drugs, like adrenalin, cause broncho dilatation and relieve symptoms of bronchial asthma.

RESPIRATORY UNIT:

Respiratory unit is the terminal portion of respiratory tract. The exchange of gases occurs only in this part. It starts from the respiratory bronchioles. Each respiratory bronchiole divides into alveolar ducts. Each alveolar ducts enters an enlarged structure called alveolar sac. The space inside the alveolar sac is called antrum. The wall of the antral sac contains the alveoli.[41]

RESPIRATORY MEMBRANE:

Respiratory membrane is the membranous structure through which the exchange of gases occurs. The blood vessels in the lungs form a capillary network beyond the terminal bronchiole. The capillaries are formed by endothelial cells. The alveolar membrane and the capillary membrane together form the respiratory membrane. The respiratory membrane separates air in the alveoli from the blood in capillary. Respiratory membrane has a surface area of 70 sq. meters and thickness of 0.5 microns.

DEFENCE MECHANISM IN THE LUNGS

The dust particles, which enter the nostrils, are prevented from reaching the lungs by filteration action of the hairs in the mucus membrane. The small particles, which escape the hairs, are held by the mucus secreted by the nasal mucous membrane. Those dust particles, which escape the nasal hairs and nasal mucous membrane, are removed by the phagocytic action of the macrophages in the alveoli. The particles which escapes the protective mechanisms in nose and alveoli are thrown out by cough and sneezing reflex.

1. **LUNGS OWN DEFENCES:**

The epithelial cells lining the air passage secrete some innate immune factors called defencins and cathelicidins. These substances are the antimicrobial peptides which play an important role in lungs own defences.

2. **LEUKOCYTES:**

The leukocytes, particularly the neutrophils and lymphocytes present in the alveoli of lungs play their role in the defense mechanism against bacteria and virus. The neutrophils kill the bacteria by phagocytosis. Lymphocytes are responsible from the development of immunity against bacteria.

3. MACROPHAGES:

Macrophages engulf the dust particles and pathogens, which enter the alveoli and thereby acts as scavengers in lungs. Macrophages are also involved in the development of immunity by functioning as antigen presenting cells. When foreign organisms invade the body, the macrophages and other antigen presenting cells kill them. Later the antigen from the organisms is digested to polypeptides. The polypeptide products are presented to T lymphocytes and B lymphocytes by the macrophages. Macrophages secrete interleukins, tumour necrosis factors and chemokines. Interleukins and TMF activate the general immunity system of the body. Chemokines attract the white blood cells towards the site of inflammation.

4. MAST CELL:

Mast cell is a large tissue resembling the basophil. It produces the hypersensitivity reactions like allergy and anaphylaxis. It secretes heparin, histamine, serotonin and hydrolytic enzymes.

5. NATURAL KILLER CELLS (NK)

Natural killer cell is a large granular cell, considered as the third type of lymphocyte. Usually NK cell is present in lumgs and lymphoid organs. Its granules contain hydrolytic enzymes, which destroy the microorganisms. NK is said to be the first line of defence in specific immunity particularly against viruses.

6. DENTRITIC CELLS:

Dendritic cells in the lungs play important role in immunity. Along with macrophages, these cells function as antigen presenting cells[40].

RESTRICTIVE AND OBSTRUCTIVE RESPIRATORY DISEASES:

The diseases of the respiratory tract are classified into two types:

1. Restrictive respiratory disease

2. Obstructive respiratory disease

These two types of respiratory diseases are determined by lung function tests, particularly FEV. In restrictive diseases, the PEFR is 200litres/min and in obstructive disease, it is only 100litre/min. Hence, the reduction is more significant in obstructive diseases than in restrictive diseases[41].

RESTRICTIVE RESPIRATORY DISEASE

Any abnormal respiratory condition, which makes it difficult to get the air into the lungs (inspiration) is called restrictive respiratory disease. The expiration is not affected. Restrictive respiratory disease may be because of abnormality of lungs, thoracic cavity or nervous system. Some of the restrictive respiratory diseases are,

- Polio
- Myasthenia gravis
- Flial chest
- Paralysis of diaphragm
- Pleural effusion

OBSTRUCTIVE RESPIRATORY DISEASE

Any abnormal respiratory condition, which makes it to difficult to push the air outside the lungs (expiration) is called Obstructive respiratory disease. Some of the Obstructive respiratory diseases are,

- Bronchial asthma
- Chronic bronchitis

- Emphysema
- Cystic fibrosis

BRONCHIAL ASTHMA

DEFNITION:

Bronchial asthma is characterised by chronic airway inflammation and increased airway hyper-responsiveness leading to symptoms of wheeze, cough, chest tightness, and dyspnoea. It is characterised functionally by the presence of airflow obstruction which is variable over short periods of time, or is reversible with treatment.[38]

EPIDEMOLOGY:

The prevalence of asthma increased steadily over later part of the last century in countries with western lifestyle and is also increasing in developing countries. Current estimates suggest that 300 million people world-wide suffer from asthma and an additional100 million may be diagnosed with asthma by 2025. In childhood, asthma is more common in boys, but following puberty females are more frequently affected. The socio-economic impact of asthma is enormous, particularly when poor control leads to days lost from school or work, hospital admission and for some patients, a premature death[42].

TYPES:

Based on the stimuli initiating bronchial asthma, two broad aetologic types are described

1. Extrinsic (allergy, atopic)

2. Intrinsic (Idiosyncratic, non-atopic)

ATOPIC OR ALLERGIC ASTHMA

This most common type of asthma usually begins in childhood. The disease is triggered by environmental antigens such as dusts, pollens, animal dander and foods, but potentially any antigen is implicated. A positive family history of atopy is common and asthmatic attacks are often preceded by

allergic rhinitis, urticarial or aczema, serum IgE levels are raised. A skin test with the offending antigen results in an immediate wheal and flare reaction, a classic example of type 1IgE mediated hypersensitivity reaction.
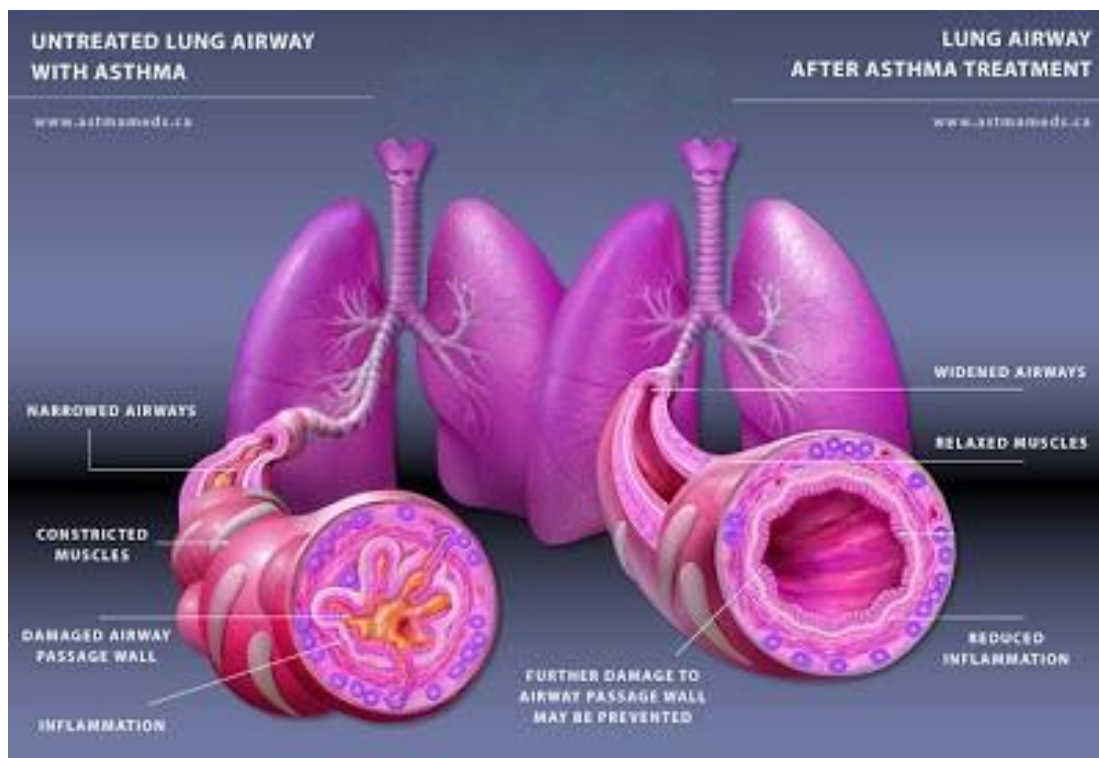
NONATOPIC ASTHMA

The second large group is non atopic variety of asthma which is not frequently triggered by respiratory infections, viruses(eg Rhinovirus, parainfluenza virus) rather than bacteria are the most common provokers. A positive family history is uncommon, serum IgE levels are normal and there are no other associated allergies. In these patients skin test results are usually negative and although hypersensitivity to microbial antigens may play a role, present theories play more stress on hyperirritability of the bronchial tree. It is although that virus induced inflammation of the respiratory mucosa lowers the threshold of the subepitheial vagal receptors to irritants. Inhaled air pollutants such as SO2, Ozone and nitrogen dioxide may also contribute to the chronic airway inflammation and hyper reactivity present in some cases.

DRUG INDUCED ASTHMA

Several pharmacological agents provoke asthma. Aspirin sensitive asthma is a somewhat fascinating type occurring in patients with recurrent rhinitis and nasal polyps. These individuals are exquisitely sensitive to very small doses of aspirin and they experience not only asthmatic attacks but also urticarial. It is probable that aspirin triggers asthma in those patients by inhibiting COX pathway of arachidonic acid metabolism without affecting LOX pathway thus tipping the balance towards elaboration of Broncho constrictor leukotrienes.

OCCUPATIONAL ASTHMA

This form of asthma is stimulated by fumes (epoxy resins, plastics) organic and chemical dusts (wood, cotton, platinum), gases (toluene) and other chemicals (formalin, penicillin products).Very minute quantities are required to induce the attack which usually occurs after repeated exposure. The underlying mechanisms vary according to stimulus and induced type IgE mediated reactions, direct liberation of Broncho constrictor substances and hypersensitivity responses of unknown origin[43].

PATHOPHYSIOLOGY

- Chronic airway inflammation as evidenced by cellular infiltration of airways by activated eosinophils, mast cells, macrophages, and T-lymphocytes
- Released mediators from the above cells cause bronchial smooth muscle contraction
- Denudation and desquamation of the epithelium forming mucous plugs that obstruct the airway
- Airway remodelling is evidenced by

i. Smooth muscle hypertrophy and hyperplasia

ii. Goblet cell and sub-mucosal gland hypertrophy leading to mucous hypersecretion.

iii. Collagen deposition causing thickening of lamina reticularis

iv. Cellular infiltration, oedema and possible airway wall thickening[44]

FACTORS PRECIPTATING ASTHMA:

- Cold air
- Tobacco smoke
- Dust, acrid fumes
- Emotional stress
- Respiratory infections (Viral, bacterial)
- Exercise
- Drugs
    i) NSAIDs especially aspirin
    ii) β-blockers
- Chemicals

    Sulphating agents like Na or K bisulphate, Sulphur dioxide etc.
- Allergens
    i. Ingested (fish, nuts, strawberries)
    ii. Inhaled (dust, pollen, house dust mite)
    iii. Food additives (atrazine, metabisufite preservatives, monosodium glutamate or ajino-moto)
    iv. Occupational allergens (grain-dust, wood-dust)[45]

CLINICAL FEATURES:

- Wheezing
- Widespread polyphonic, high pitched wheezes are heard.
- Expiratory wheeze is heard with mild Broncho-constriction
- Inspiratory and expiratory wheezes are heard in moderate Broncho-constriction.
- Inspiratory wheeze is heard in severe Broncho-constriction
- In near fatal asthma, the chest is silent.
- Chest tightness
- Breathlessness
- Cough with mucoid tenacious sputum[46]

NOCTURNAL ASTHMA:

Nocturnal asthma is defined as an overnight fall of more than 20% in the FEV1 or PEFR it may the sole manifestation of asthma. This is presumed due to:

i. Early morning fall in circulating, adrenaline.
ii. Overnight change in vagal tone (increased vagal tone in the morning).
iii. Airway cooling at night.
iv. Circulation changes in plasma cortisol concentration (midnight to early morning fall in cortisol level).

GASTRIC ASTHMA:

Worsening of asthma after meals or dyspnea occurring only after meals is due to gastro-esophageal reflux. This is treated by avoiding oral bronchodilators and instituting anti reflux therapy.

EXERCISE INDUCED ASTHMA:

Asthma is induced by exercise and inhaled bronchodilators should be given before exercise. Usual therapy is with pre exercise bronchodilators or sodium-chromoglycate.

EPISODIC ASTHMA:

Patient has no respiratory symptoms between episodes of asthma.

CHRONIC ASTHMA:

Symptoms may be chronic unless controlled by appropriate therapy. It may stimulate chronic bronchitis.

CLASSIFICATION OF SEVERITY:

	SYMPTOMS	**NIGHT TIME - SYMPTOMS**	**PEF**
Step 1 Intermittent	<1 time a week Asymptomatic and normal PEF between attacks	≤ 2times a month	≥ 80% predicted variability <20%
Step 2 Mild persistent	≥ 1 time a week but < 1 time a day	>2 times a month	≥ 80% predicted variability <20-30%
Step 3 Moderate persistent	Daily use β2 agonist, daily attacks affect activity	>1 time a week	<80% predicted variability >30%
Step 4 Severe persistent	Continuous limited physical activity	Frequent	≤ 60% predicted Variability >30%

ACUTE SEVERE ASTHMA (STATUS ASTHMATICUS)

It is a medical emergency. Patient is hypoxic and cyanosed due to severe bronchospasm. It is characterized by tachycardia (pulse rate > 120), tachypnea (respiratory rate > 30/min), sweating, pulsusparadoxus, altered level of consciousness, and inspiration- expiration ratio 1:3 or 1: 4.[46]

Life threatening features:

- Patient cannot speak
- Central cyanosis
- Exhaustion, confusion, altered consciousness
- Bradycardia
- Silent chest
- Unrecordable peak flow

- Severe hypoxaemia (8 kpa)
- A normal or high co2 tension (5-6 kpa)
- A low ph or high H+.

DIAGNOSIS AND SPECIAL INVESTIGATION:

Blood

Slight eosinophilia is present but the absolute count is less than 1000/mm3 other blood changes are elevated IgE.

Sputum

It shows eosinophils, charcotleyden crystals, crucians spirals and Laennec's pearls and creoles bodies apart from infective agents**.**

X-ray Chest

It shows over inflation of lungs in acute attack but may show emphysematous changes in late stages.

Pulmonary function test

The degree of airway obstruction can be measured by FEV1 and FEV1/FVC ratio both of which are reduced and improves after the use of bronchodilators. The diffusing capacity is usually normal**.**

Blood gas analysis

It shows diminished po2 and raised paco2 in status asthmaticus but normal in mild attacks. In earlier states respiratory alkalosis is present but in severe late stages respiratory acidosis results.

Skin tests

By pricking test hypersensitivity reaction to various antigens can be obtained

ECG

It shows normal features except tachycardia. But sometimes P.pulmonale, Right axis or RBBB pattern may be observed

COMPLICATION

- Status asthmatics
- Secondary infection-bronchitis, tuberculosis
- Emphysema of lungs
- Right heart failure in late stages called chronic corpulmonale
- Bronchiectasis
- Pneumothorax, pneumo mediastinum

DIFFERENTIAL DIAGNOSIS:

1. Chronic bronchitis

2. Emphysema

3. Cystic fibrosis

4. Cardiac failure

5. Allergic Broncho-pulmonary aspergillosis.

TRIAL DRUG

TRIAL DRUG

PREPARATION AND PROPERTIES OF TRIAL MEDICINE

SOMBU THEENEER

INGREDIENTS:

- *Sombu* - 300 gms
- Water   - 10 litres

STANDARD OPERATIVE PROCEDURE

SOURCE OF RAW DRUGS:

The required raw drugs are procured from a well reputed indigenous drug shop. The raw drugs taken for study will be authenticated by the Pharmacognosist of Siddha Central Research Institute, Chennai.

PREPARATION:

The above said drug *Sombu* is grounded coarsely and immersed in water for about 8hrs then it is distillate into the distillation apparatus finally 5 litres of *THEENEER* is collected.

DRUG STORAGE:

The trial drug is stored in clean dry air tight container and it is given to the patients in diluted form.

DOSAGE:

30 – 60 ml with equal quantity of water twice daily

DURATION:

30 days

REFERENCE-*SIDDHA VAITHIYA THIRTTU* [6]

REVIEW OF LITERATURE FOR TRIAL MEDICINE

சோம்பின் பொதுகுணம்:

யோனிநோய் குன்மம் உரூட்சைமந் தம்பொருமல்

பேனமுறு காசம் பீலிகமிரைப் - பீனஉரை

சேர்க்கின்ற வாதமுபோஞ் சீர்பெரிய சீரகத்தால்

மூக்குநோ யில்லை மொழி.

- அகத்தியர் குணவாகடம்.

MEDICINAL USES :

It is given to cure Asthma, Fever, indigestion, Liver diseases, cough, rhinitis, abdominal pain.[12]
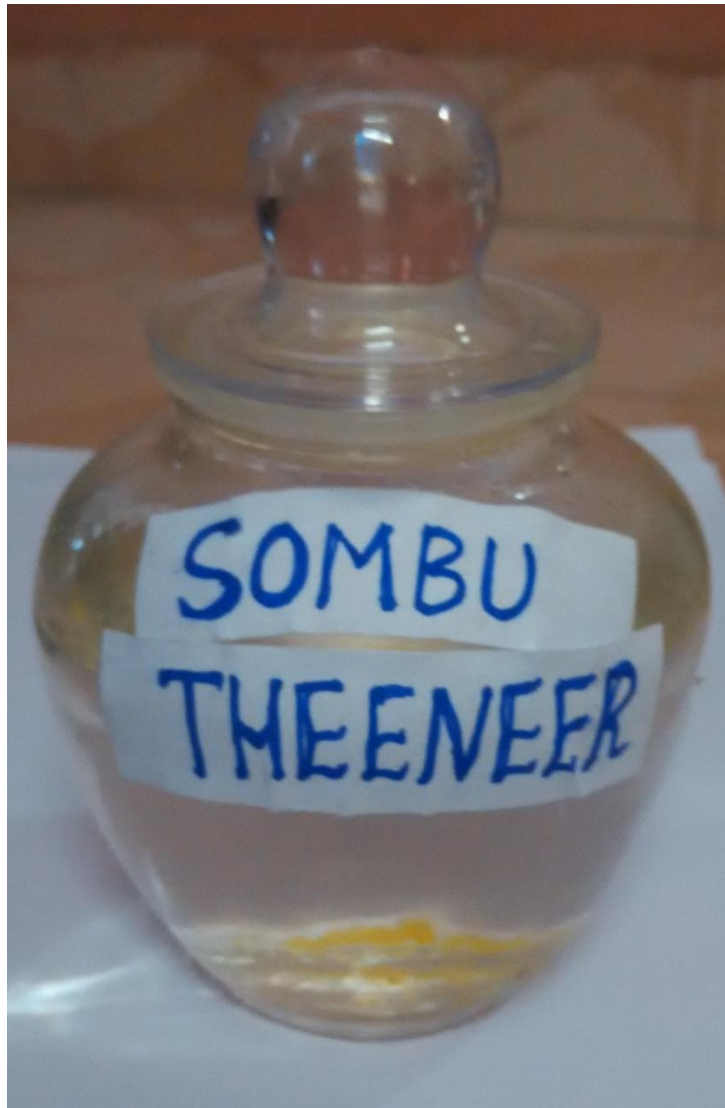
INGREDIENT OF SOMBU THEENEER

SOMBU – Pimpenella anisum

DHRAVAGA IYANDHIRAM

TRIAL MEDICINE

SOMBU THEENEER

MATERIALS &

METHODS

MATERIALS AND METHODS

STUDY DESIGN:

The open clinical trial on *SWASA KASAM* was conducted at the OPD section of **POST GRADUATE, MARUTHUVAM DEPARTMENT** attached to **ARIGNAR ANNA HOSPITAL OF INDIAN MEDICINE**, Chennai-106 during the period 2015-2017.

POPULATION AND SAMPLE:

The population consists of all patients satisfying the inclusion and exclusion criteria mentioned below. Sample consists of *Swasakasam* patients attending the OPD of Arignar Anna Hospital, Arumbakkam, Chennai-106.

SAMPLE SIZE:

The sample size will be 40 patients.

INCLUSION CRITERIA:

> ➢ Age: between 13-60years.
> ➢ Symptoms of Bronchial asthma-breathlessness, cough, wheeze and chest tightness.
> ➢ Willing to give specimen of blood for investigation when required.
> ➢ Willing to attend the OPD once in 7 days.
> ➢ Willing to participate in the trial and sign in consent form.

EXCLUSION CRITERIA:

> ➢ Status asthmatics
> ➢ Drug induced bronchospasm (beta blockers and NSAIDS)
> ➢ History of congestive cardiac failure
> ➢ History of Bronchiectasis
> ➢ History of Bronchogenic carcinoma
> ➢ Chronic bronchitis
> ➢ Vulnerable population like Pregnant and Lactating women, HIV Positive individuals, Diabetic and TB individuals.

WITHDRAWAL CRITERIA:

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

EVALUATION OF CLINICAL PARAMETERS:

Patients are clinically evaluated using following parameters.

HISTORY TAKING:

Age, occupation, socio economic status, complaints and duration, previous illness, family history, Personal habits were recorded in the case sheet for every patient during his/her first visit to OP.

INVESTIGATIONS:

BLOOD:

- • TC
- • DC
- • ESR
- • Hb
- • Blood Sugar (F) & (PP)
- • Blood Urea
- • Serum Cholesterol

URINE:

- • Albumin
- • Sugar
- • Deposits
- ➢ X-ray Chest PA View
- ➢ PEFR (peak expiratory flow rate)
- ➢ Absolute eosinophil count.

CLINICAL DIAGNOSIS BASED ON SIDDHA SYSTEM:

The parameters used to diagnosis the disease *Swasa kasam* based on Siddha system are:

- Poriaalaridhal
- Pulanaalaridhal
- Vinaadhal
- Uyirthathukkal
- Udalthaukkal
- Envagaithervu

    Naa, Niram, Mozhi, Vizhi, Sparisam, Malam, Moorthiram, Naadi.

- Neerkuri:

    Niram, Manam, Nurai, Enjal, Edai

- Neikuri

RESULTS AND OBSERVATION

RESULTS AND OBSERVATION

The study on Swasakasam was carried out in 40 patients in the Department of Pothumaruthuvam, Government Siddha medical College, Chennai-106 attached to Arignar Anna Hospital during 2015-2017 were analysed. The observation were made and tabulated with following criteria.

- Sex Distribution
- Age Distribution
- Socio-Economic status
- Occupational Reference
- Personal habits Distribution
- Diet Distribution
- Kaalam Distribution
- Paruvakaalam Distribution
- Thinai Reference
- Duration of illness
- Mukkutram
- Ezhu udal kattugal Reference
- Envagai Thervugal Reference
- Neikuri Reference
- Clinical features
- Clinical Prognosis
- Peak Expiratory flow Rate
- Grading of results.

1. SEX DISTRIBUTION:

Sex	No of cases / 40	Percentage
Male	17	42.5%
Female	23	57.5%

SEX DISTRIBUTION
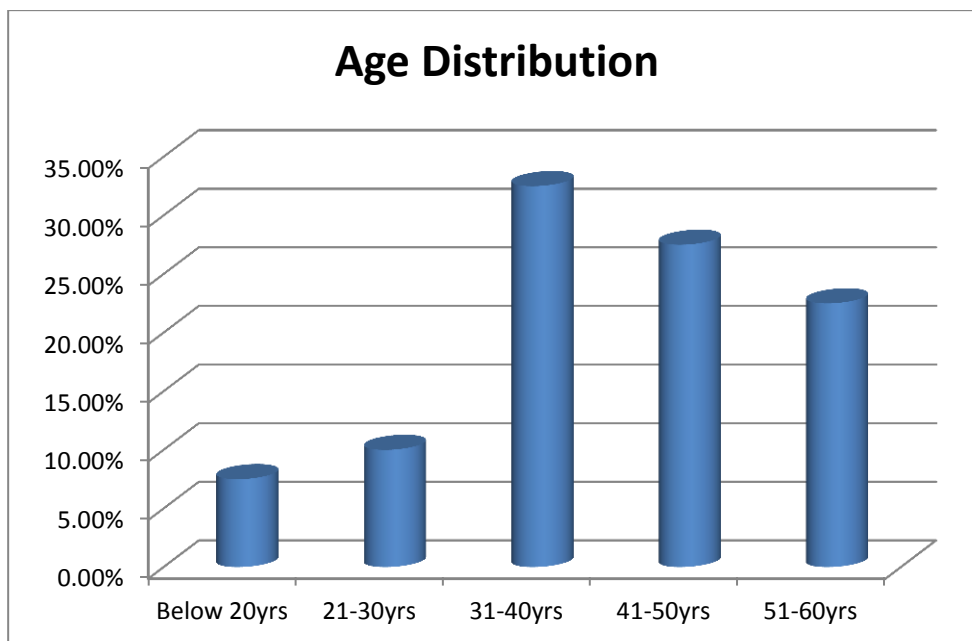
Male 42.5%

Female 57.5%
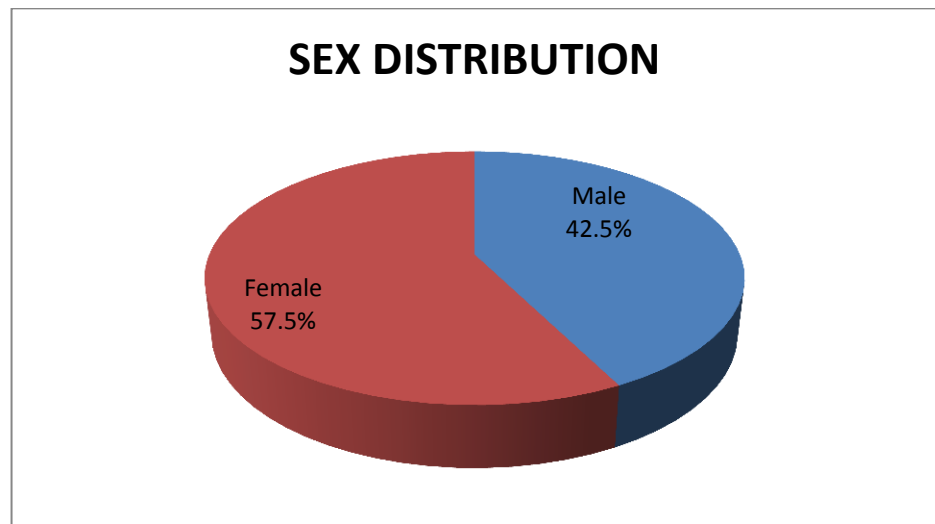
Inference:

Out of 40 patients, 17 cases (42.5%) were male and 23 cases (57.5%) were female.

2. AGE DISTRIBUTION:

| S. No	Age Groups	No of cases/40	Percentage (%)
1.	Below 20 years	3	7.5%
2.	21-30 years	4	10%
3.	31-40 years	13	32.5%
4.	41 -50 years	11	27.5%
5.	50- 60 years	9	22.5%

Age Distribution

Inference:

From selected 40cases, 3 patients (7.5%) were below 20 yrs,4 patients (10%) were between 21-30 yrs, 13 patients (32.5%) were between 31-40yrs, 11 patients (27.5%) were between 41-50 yrs,9 patients (22.5%) were between 51-60 yrs.

3. SOCIO-ECONOMIC STATUS:

| S. No	Socio-Economic Status/Annum	No Of Cases	Percentage (%)
1.	Poor (upto 200,000)	23	57.5%
2.	Middle class (200,000-500,000)	9	22.5%
3.	High class (Above 500,000)	8	20%

SOCIO-ECONOMIC STATUS

■ Poor ■ Middle class ■ High class

20%

22.5%

57.5%
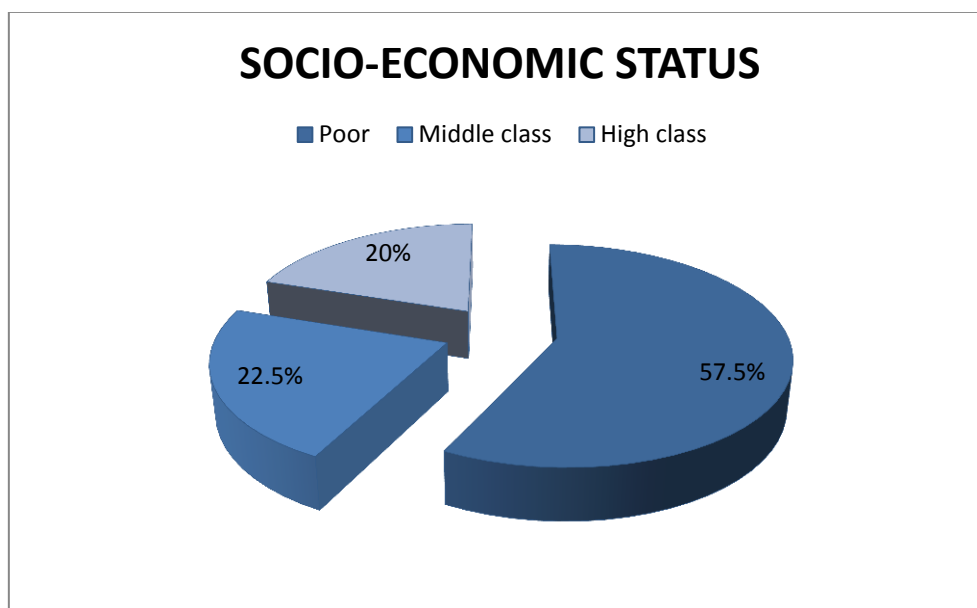
Inference:

Regarding the socio-economic status,23 patients (57.5%) comes under poor category,9 patients (22.5%) comes under middle category, and 8 patients (20%) comes under high class category.

4. OCCUPATIONAL REFERENCE:

| S. No	Occupation	No. Of Cases	Percentage
1.	Business	3	7.5%
2.	Housewife	6	15%
3.	Traffic police	5	12.5%
4.	Student	3	7.5%
5.	Tailor	9	22.5%
6.	Office	14	35%
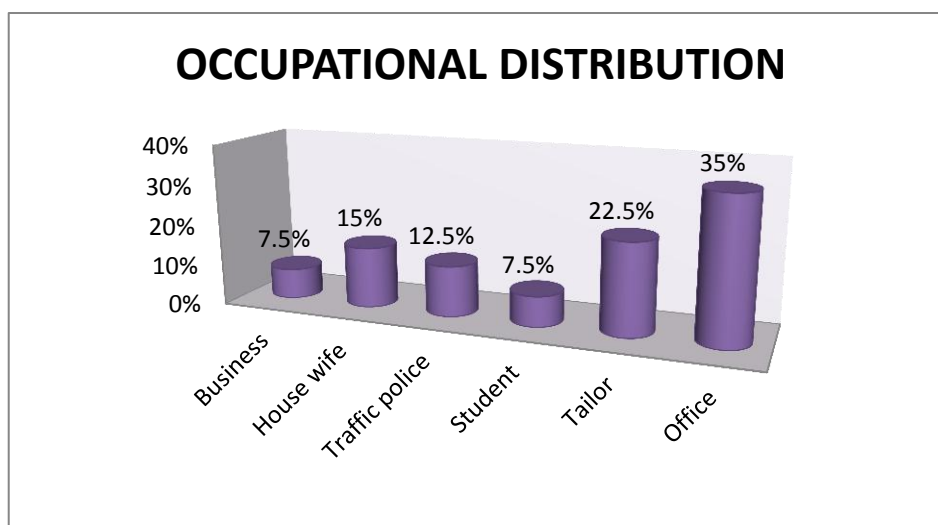
Inference:

Out of 40 patients, 3 patients (7.5%) were business man, 6patients (15%) were housewife, 5 patient(12.5%) was traffic policeman, 3 patient (7.5%) were student, 9 patient (22.5%) was tailor, 14 patient (35%) were office people.

5. PERSONAL HABIT REFRENCE:

| S. No	Personal Habits & Diet	No. Of Cases	Percentage
1.	Smoking	11	27.5%
2.	Alcoholic	4	10%
3.	Both (Smoking & alcoholic)	3	7.5%
4.	Snuff	1	2.5%
5.	Others(Tee totallers)	21	52.5%
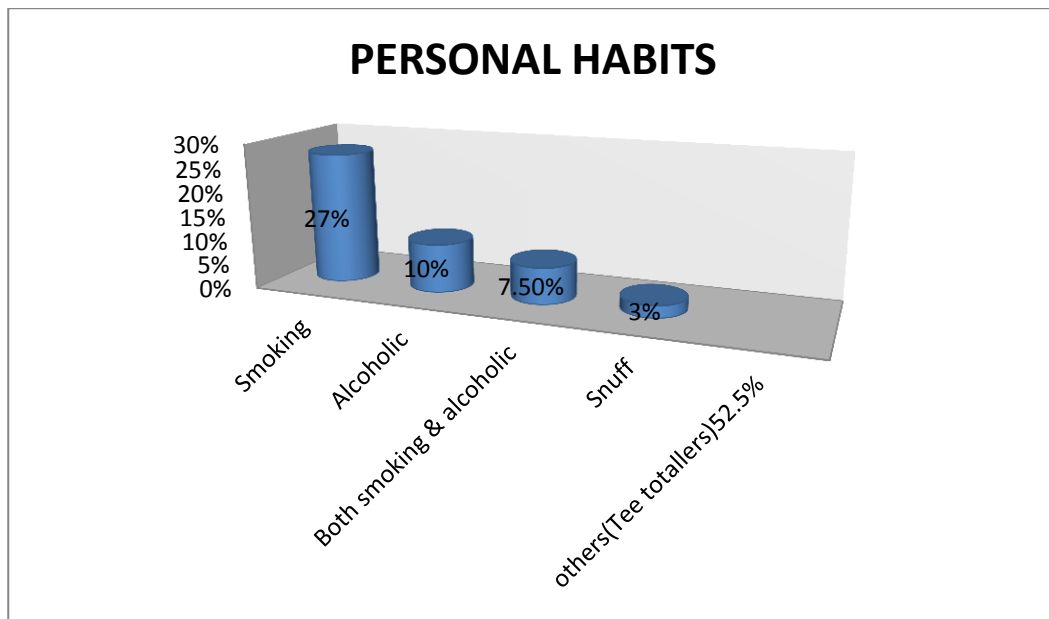
PERSONAL HABITS

Inference:

Regarding personal habits, 11 patients(27.5%) were smokers, 4 patients(10%) were Alcoholic, 3 patients (7.5%) were , 1 patient (2.5%) was a snuff user. Remaining 21 patients(52.5%) were tee tootlers.

6. DIET REFRENCE:

| S. No	Diet	No. Of cases	Percentage
1.	Vegetarian diet	7	17.5%
2.	Mixed diet	33	82.5%
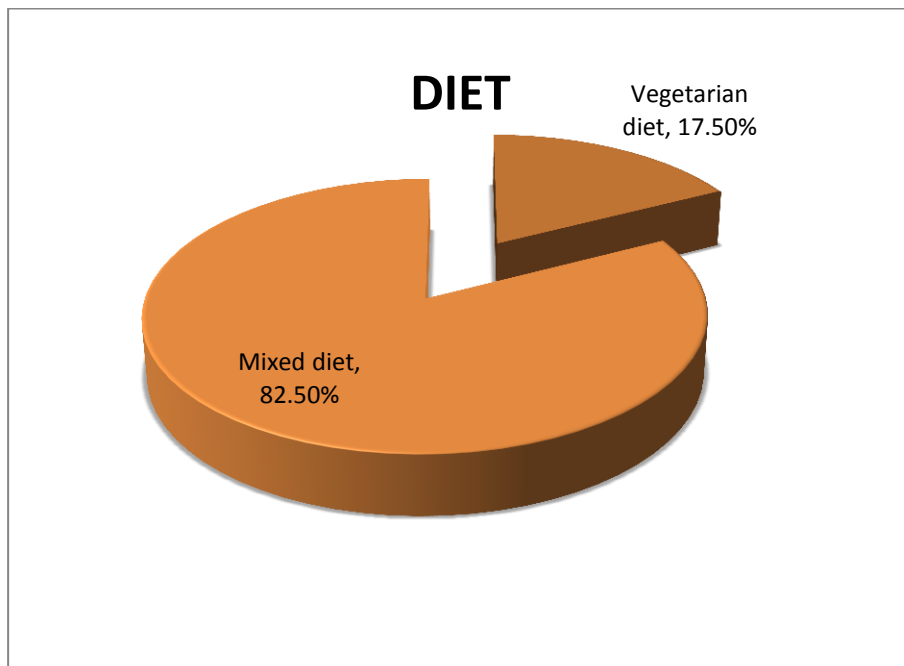
Inference:

Out of 40 patients, 7 patients (17.5%) have Vegetarian diet and 33 patients (82.5%) have mixed diet.

7. **KAALAM DISTRIBUTION:**

| S.No	Kaalam	No. Of Cases / 40	Percentage (%)
1.	Valikaalam (0-33yrs)	15	37.5%
2.	Azhalkaalam(33-66yrs)	25	62.5%
3.	Iyyakaalam(66-100yrs)	-	-

KAALAM DISTRIBUTION

37.50%   62.50%

Vatha kaalam   Pitha kaalam
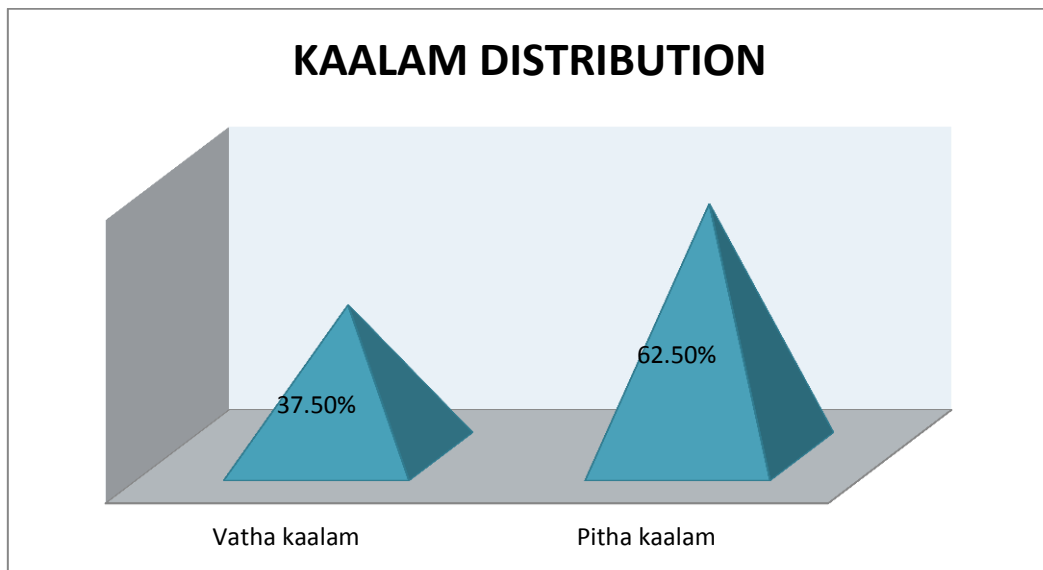
Inference:

Out of 40 patients, 15 patients (37.5%) comes under Valikaalam, 25 patients comes under Azhalkaalam.

8. PARUVAKAALAM:

| S. No	Paruvakaalam	Months	No.of Cases / 40	Percentage
1.	Kaarkaalam	Avani, Puratasi, (Mid Aug- Mid Oct)	16	40%
2.	Koothirkaalam	Iyppasi, Karthigai (Mid Oct - Mid Dec)	9	22.5%
3.	Munpani	Margazhi ,Thai (Mid Dec – Mid Feb)	**7**	17.5%
4.	Pinpani	Maasi,Panguni (Mid Feb- Mid April)	5	12.5%
5.	Elavenil	Chithrai, Vaigasi (Mid April- Mid June)	2	5%
6.	Mudhuvenil	Aani, Aadi (Mid June- Mid Aug)	1	2.5%
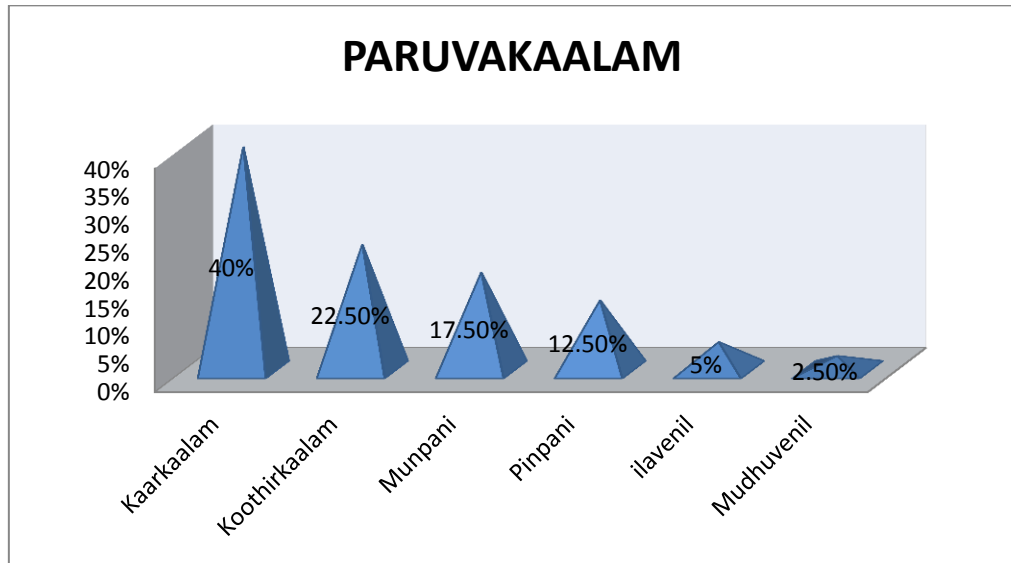
Inference:

From selected 40 patients,16 patients(40%) comes under Kaarkaalam, 9 patients(22.5%) comes under Koothirkaalam,7 patients(17.5%) comes under Munpani,5 patients (12.5%) comes under Pinpani, 2 patinets(5%) comes under Elavenil, 1patient (2.5%) comes under Mudhuvenil.

9. THINAI REFERENCE:

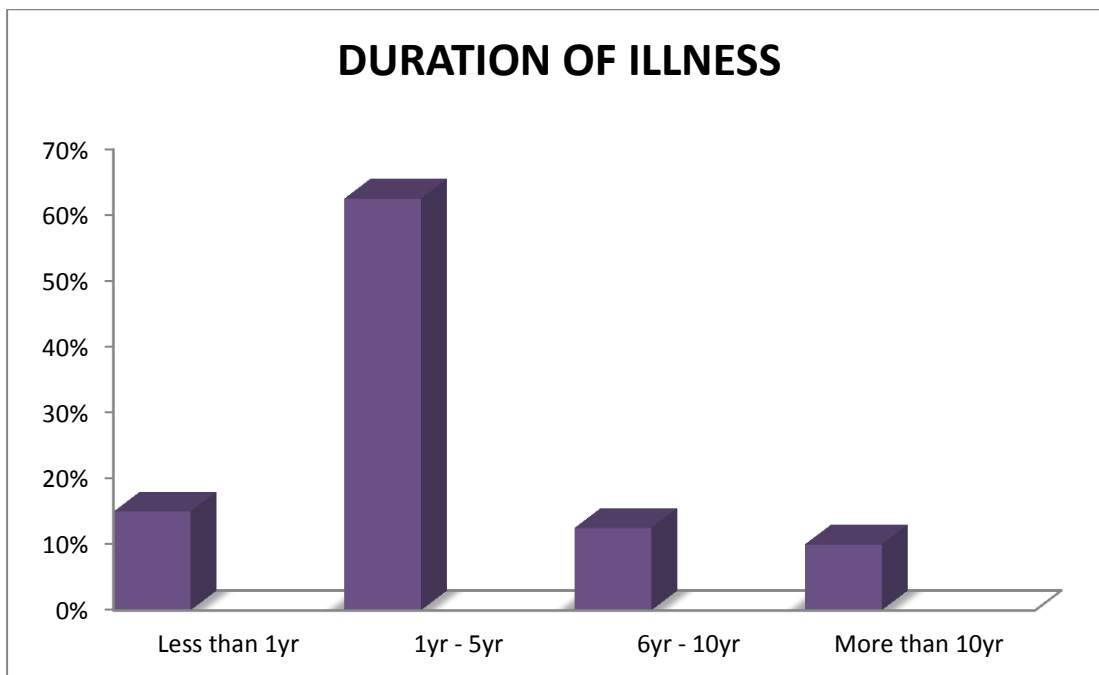| S. No	Thinai	No.of cases/40	Percentage
1.	Kurunji (Hill)	0	0%
2.	Mullai (Forest)	0	0%
3.	Neidhal (Sea)	33	82.5%
4.	Marudham (Fertile)	7	17.5%
5.	Paalai (Desert)	0	0%
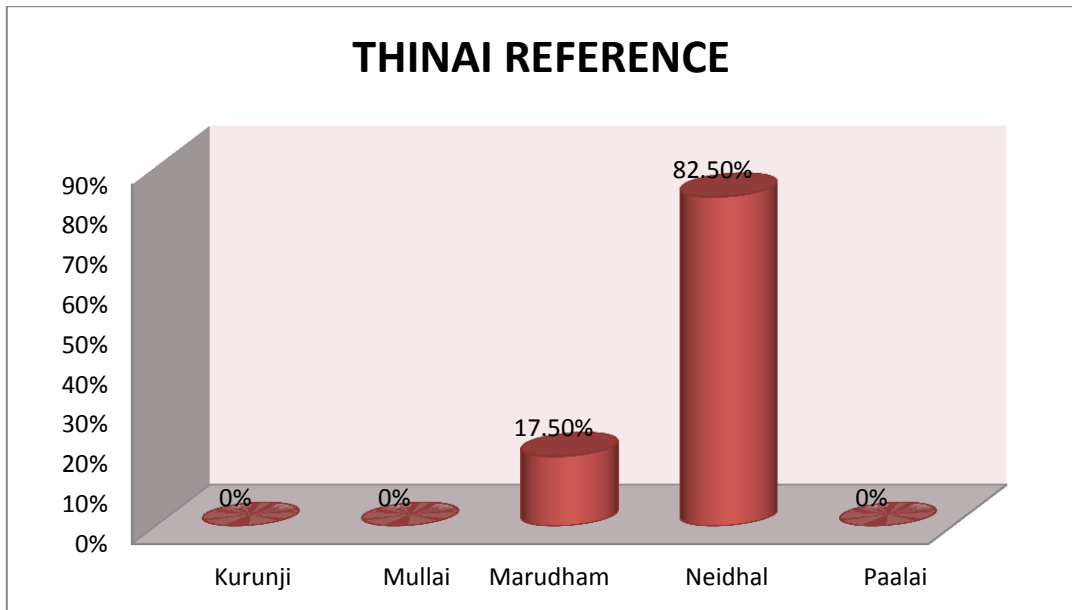
THINAI REFERENCE

Inference:

Out of 40 patients,33 patients (82.5%) comes under Neidhal,7 patients (17.5%) comes under Marudham.

10. DURATION OF ILLNESS:

S. No	Duration of Illness	No. of Cases	Percentage
1.	Less than 1year	6	15%
2.	1 year - 5 years	25	62.5%
3.	6 years – 10 years	5	12.5%
4.	More than 10years	4	10%

DURATION OF ILLNESS

(Bar chart showing percentages: Less than 1yr ~15%, 1yr - 5yr ~62.5%, 6yr - 10yr ~12.5%, More than 10yr ~10%)
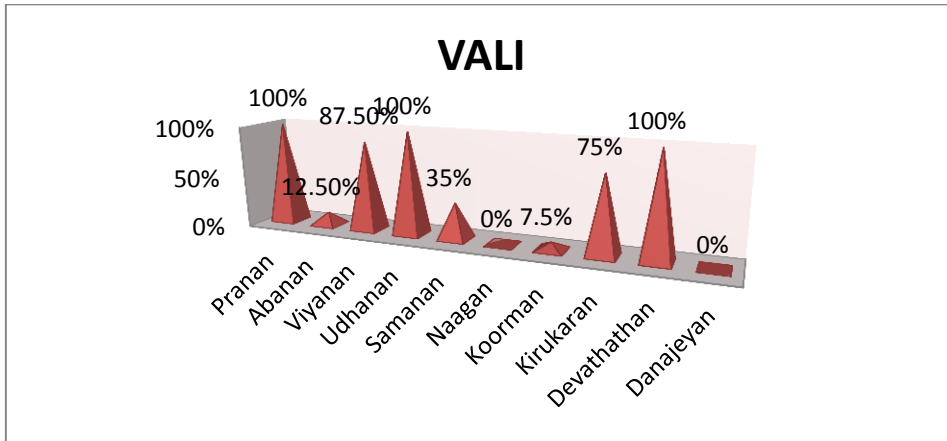
Inference:

Out of 40 patients, 6 pateints(15%) belongs to less than one year duration, 25 patients(62.5%) comes under 1-5 year duration, 5 patients(12.5%) comes under 6-10year duration, and 4 patients (10%) have more than 10 years duration.

11. REFERENCE TO MUKKUTRAM:

I.VALI:

| S.No	Classification of Vali	No.of Cases	Percentage
1.	Pranan	40	100%
2.	Abanan	5	12.5%
3.	Viyanan	35	87.5%
4.	Udhanan	40	100%
5.	Saamanan	14	35%
6.	Naagan	0	0%
7.	Koorman	3	7.5%
8.	Kirugaran	30	75%
9.	Devathathan	40	100%
10.	Dhanjeyan	0	0%

Inference:

From the selected 40 patients, Pranan was affected in 40 patients (100%), Abanan was affected in 5 patients (12.5%), Viyanan was affected in 35 patients (87.5%),Samanan was affected in 14 patients (35%),Koorman was affected in3 patients(7.5%), Kirugaran was affected in 30 patients (75%), Devathathan was affected in 40 patients (100%).

II: AZHAL:

S.No	Classification of Azhal	No. Of cases	Percentage
1.	Analagam	14	35%
2.	Ranjagam	9	22.5%
3.	Saathagam	40	100%
4.	Aalosagam	3	7.5%
5.	Prasagam	0	0%
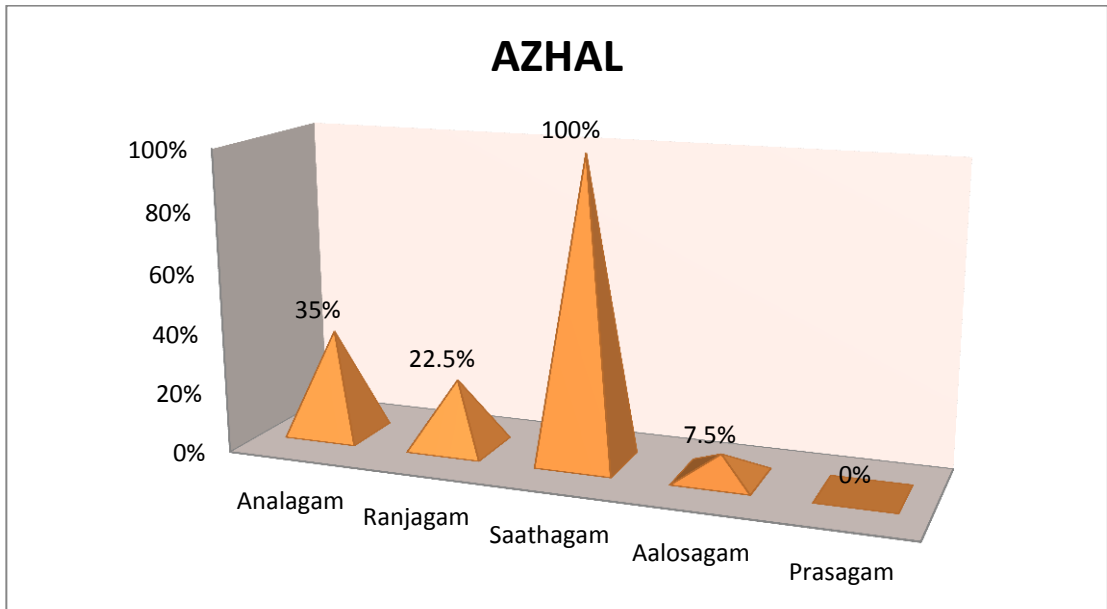
Inference:

Out of 40 patients, Analagam was affected in1 4 patients (35%), Ranjagam was affected in 9 patients (22.5%), Saathagam was affected in 40 patients (100%), Aalosagam was affected in 3 patients (7.5%).

III. IYYAM:

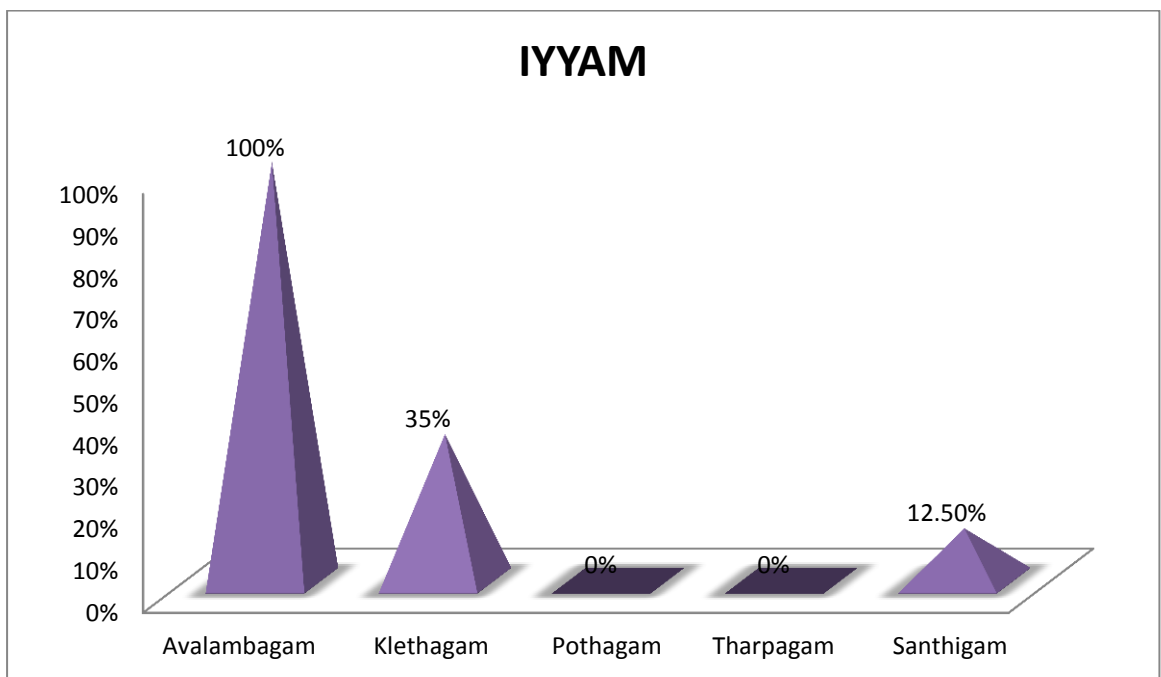| S.No	Classification of Iyyam	No. Of cases	Percentage
1.	Avalambagam	40	100%
2.	Klethagam	14	35%
3.	Pothagam	0	0%
4.	Tharpagam	0	0%
5.	Santhigam	5	12.5%

Inference:

Out of 40 patients, Avalambagam was affected in 40 patients (100%), Klethagam was affected in 14 patients (35%), Santhigam was affected in 5 patients (12.5%).

12. EZHUUDALKATTUGAL:

S. No	Ezhuudalkattugal	No. Of Cases	Percentage
1.	Saaram	40	100%
2.	Seneer	9	22.5%
3.	Oon	0	0%
4.	Kozhuppu	0	0%
5.	Enbu	5	12.5%
6.	Moolai	0	0%
7.	Sukkilam/Suronitham	0	0%
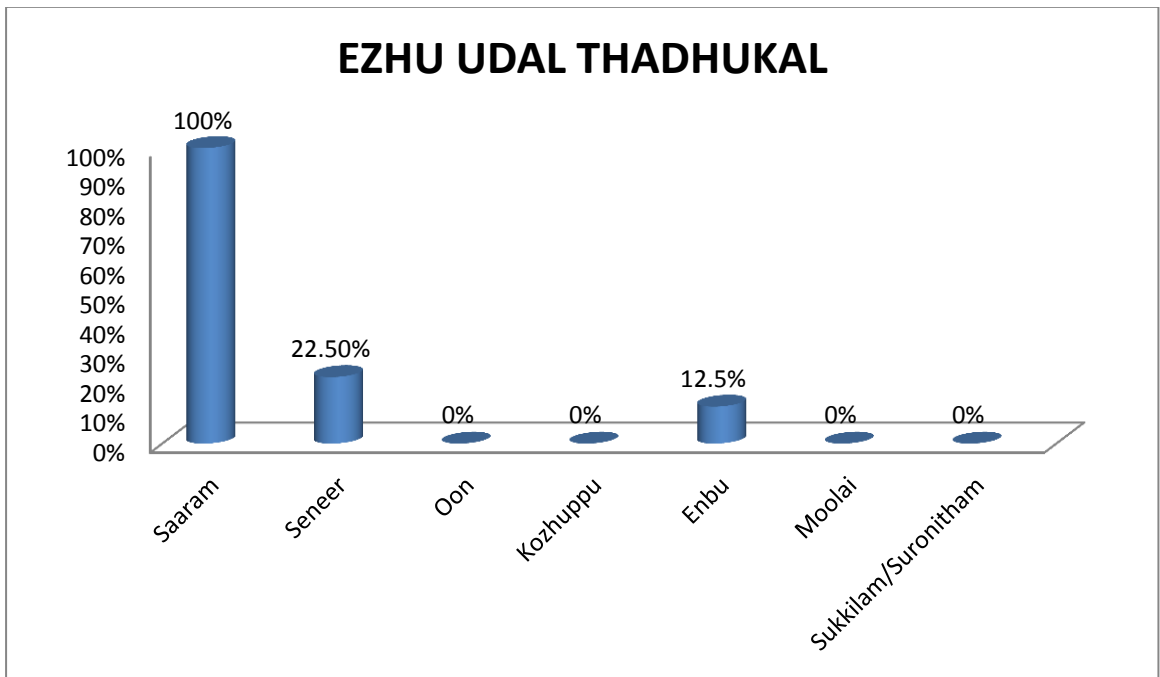
Inference:

Out of 40 cases, Saaram was affected in 40 patients(100%), Seneer was affected in 9 patients(22.5%), Enbu was affected in 5 patients(12.5%).

13. ENVAGAI THERVUGAL REFERENCE:

S.No	Envagai Thervugal	No. Of Cases	Percentage
1.	Naa	9	30%
2.	Niram	0	0%
3.	Mozhi	1	2.5%
4.	Vizhi	9	22.5%
5.	Sparisam	0	0%
6.	Malam	5	12.5%
7.	Moothiram	0	0%
8.	Naadi	40	100%
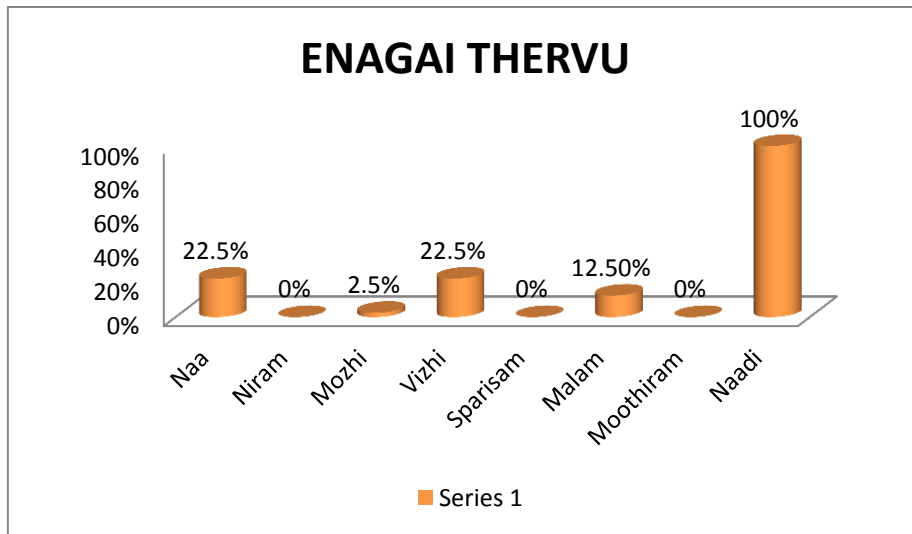
Inference:

Regarding Envagaithervu, Naa was affected in 9 patients(22.5%), Mozhi was affected in 1 patients(2.5%), Vizhi was affected in 9 patients(22.5%), Malam was affected in 5 patients (12.5%), Naadi was affected in 40 patients(100%).

13. NAADI:

S.No	Naadi	No. Of Cases	Percentage
1.	KabhaVatha	31	77.5%
2.	VathaKabha	9	22.5%
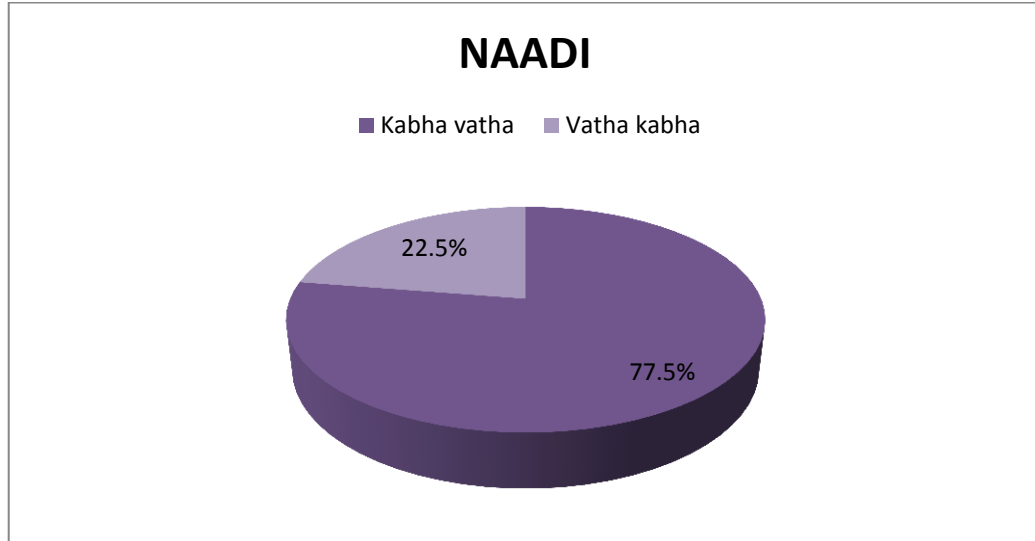
Inference:

Out of 40 patients, 31 patients had Kabhavatha naadi and 9 patients had Vathakabha naadi.

14. NEIKURI:

S. No	Neikuri	Character of Urine	No. Of cases	Percentage
1.	Vathaneer	Spreads like snake	9	22.5%
2.	Pithaneer	Spreads like ring	-	-
3.	Kabhaneer	Spreads like pearl	31	77.5%
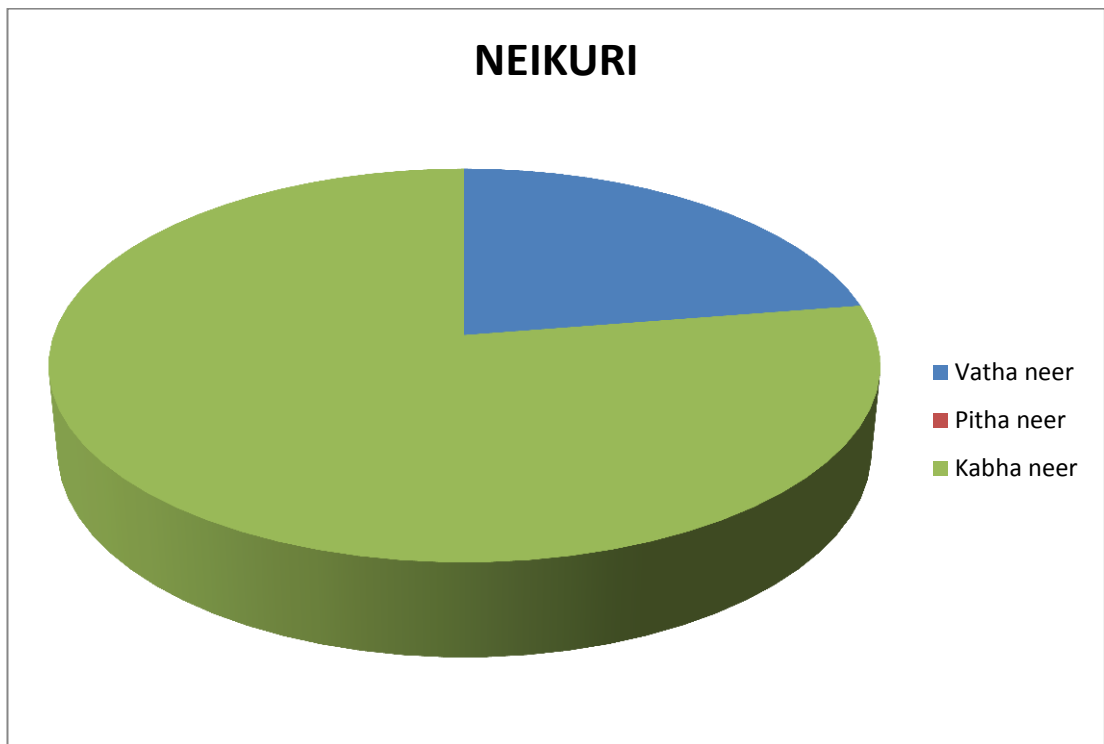
Inference:

Out of 40 patients, 9 patients (22.5%) had Vatha neer,31 patients (77.5%) had Kabha neer.

15. CLINICAL FEATURES:

S. No	Signs & Symptoms	No. Of Cases	Percentage
1.	Dyspnoea	40	100%
2.	Cough without expectoration	30	75%
3.	Wheezing	40	100%
4.	Tightness of chest	35	87.5%
5.	Rhinitis	6	15%
6.	Sneezing	6	15%
7.	Headache	4	10%
8.	Fever	0	0%
9.	Cyanosis	0	0%
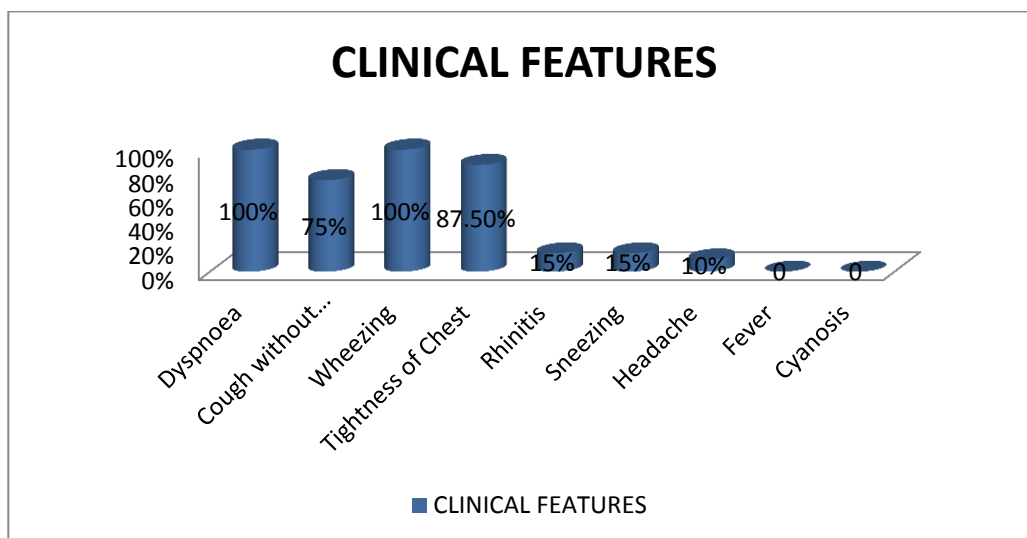
Inference:

Out of 40 patients, 40 patients(100%) had Dyspnoea, 30 patients (75%) had cough with expectoration, 40% patients (100%) had wheezing, 35 patients (87.5%) had tightness of chest, 6 patients (15%) had rhinitis, 6 patients (15%) had Sneezing, 4 patients (10%) had headache.

16. CLINICAL PROGNOSIS:

S. No	Signs & Symptoms	Before Treatment	After Treatment	No. Of Cases	Percentage
		No. Of Cases	Percentage		
1.	Dyspnoea	40	100%	3	7.5%
2.	Cough without expectoration	30	75%	0	0%
3.	Wheezing	40	100%	3	7.5%
4.	Tightness of chest	35	87.5%	0	0%
5.	Rhinitis	6	15%	0	0%
6.	Sneezing	6	15%	0	0%
7.	Headache	4	10%	1	2.5%

Inference:

After treatment, Dyspnoea was present in 3 patients (7.5%), Wheezing was present in 3 patients (7.5%), Headache was present in 1patients (2.5%).

GRADING OF RESULTS:

Result = no. of patients after treatment

_____ X 100

no. of patients before treatment

Thus out of 40 patients before treatment, after treatment 75% of cases showed good result, 25% of the cases showed Moderate result.
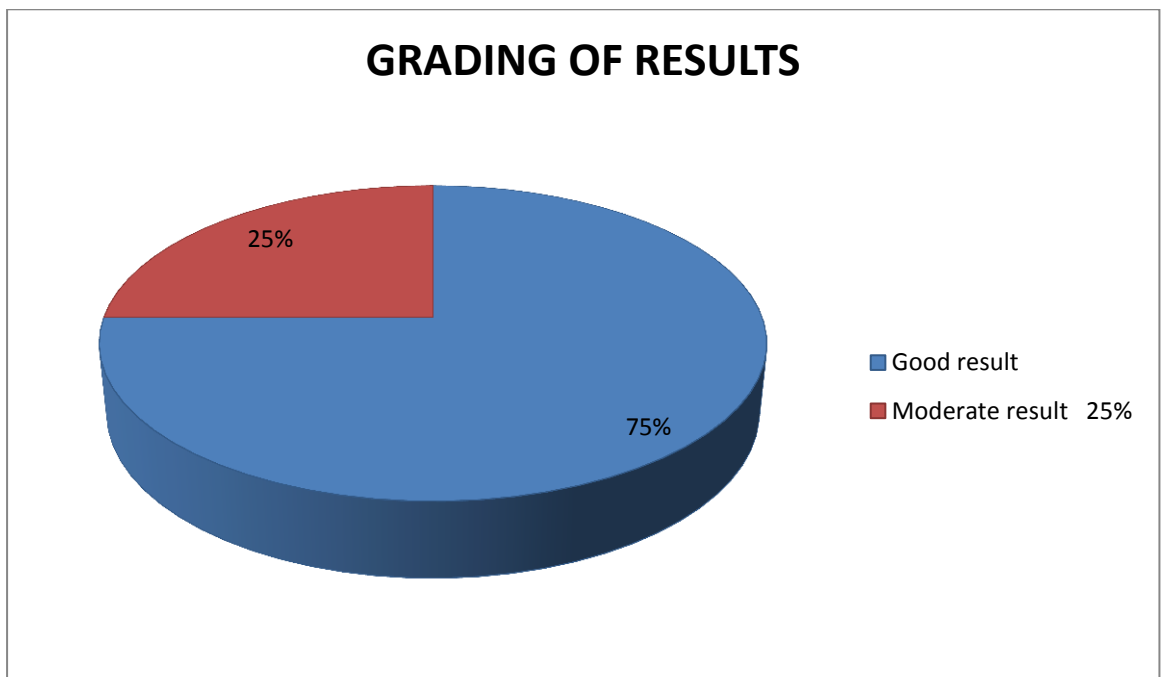
Peak Expiratory Flow Rate

S. No	BT	AT
1.	100	230
2.	350	450
3.	270	350
4.	150	250
5.	170	240
6.	190	260
7.	100	220
8.	180	310
9.	160	220
10.	260	350
11.	250	400
12.	250	340
13.	330	400
14.	80	200
15.	200	320
16.	280	340
17.	220	280
18.	210	330
19.	70	150
20.	150	260
21.	170	240
22.	150	220
23.	190	260
24.	240	300
25.	180	240
26.	70	160
27.	100	210
28.	130	350
29.	250	400

30.	230	340
31.	200	350
32.	260	350
33.	170	260
34.	190	280
35.	130	310
36.	250	340
37.	280	360
38.	350	420
39.	180	280
40.	120	200

BT – Before Treatment ; AT – After Treatment

SL NO.	OP NO	AGE/SEX	HEMATOLOGICAL REPORT															URINE ANALYSIS						RFT			
			BEFORE TREATMENT				AFTER TREATMENT				ESR				HB(gm)		BT			AT			BT		AT			
			TC(Cu/mm)	DC			TC(Cu/mm)	DC			BT		AT															
				P	L	E		P	L	E	½ Hr	1 Hr	½ Hr	1 Hr	BT	AT	Alb	Sug	Dep	Alb	Sug	DEp	Urea	Cre	Urea	Cre
1.	3205	52/F	8400	60	34	6	8600	61	38	1	3	7	2	5	13	13.2	-	-	OEC	-	-	OEC	22	0.7	26	0.6
2.	3293	55/F	9000	54	38	8	9200	55	39	6	12	20	8	12	12	12.4	-	-	OEC	-	-	OEC	24	0.6	26	0.6
3.	3303	49/F	9200	51	40	9	9100	60	38	2	6	14	3	7	12	12.4	-	-	OEC	-	-	OEC	21	0.8	24	0.7
4.	4406	46/F	8600	55	39	6	8900	61	36	3	5	20	4	15	12.4	12.8	-	-	OEC	-	-	OEC	33	0.6	28	0.6
5.	4407	51/F	9100	58	36	6	9200	59	37	4	3	29	2	5	14.2	13.6	-	-	OEC	-	-	OEC	34	0.6	29	0.7
6.	4352	13/F	8700	57	36	7	8600	60	38	2	6	15	7	14	13.5	13.4	-	-	OEC	-	-	OEC	32	0.7	28	0.6
7.	4496	45/F	9800	64	30	6	9200	61	36	3	5	8	4	6	10.6	11.6	-	-	OEC	-	-	OEC	30	0.7	26	0.6
8.	6031	32/F	9000	54	38	8	8900	56	40	4	10	21	5	15	11	13	-	-	OEC	-	-	OEC	27	0.7	28	0.6
9.	6143	24/M	9100	56	36	8	900	60	38	2	5	10	2	5	13	13.4	-	-	OEC	-	-	OEC	24	0.6	26	0.5
10.	5998	21/F	8700	60	34	6	8600	59	37	4	8	22	3	13	10.2	10.4	-	-	OEC	-	-	OEC	19	0.6	23	0.6
11.	6106	48/M	8300	59	36	5	8200	60	36	4	2	5	2	5	12	12.2	-	-	OEC	-	-	OEC	23	0.7	27	0.6
12.	6344	15/F	10100	59	32	9	9800	55	38	7	10	22	6	14	13	13	-	-	OEC	-	-	OEC	22	0.6	25	0.6
13.	6312	44/M	7900	55	37	8	8200	62	34	4	5	15	4	9	10.6	11	-	-	OEC	-	-	OEC	21	0.7	24	0.7
14.	7316	45/F	9500	58	36	6	9100	52	42	6	4	6	2	5	11	11	-	-	OEC	-	-	OEC	30	0.6	28	0.7
15.	7765	36/M	9000	53	40	7	9200	54	42	4	6	14	3	7	13	13.4	-	-	OEC	-	-	OEC	32	0.6	28	0.7
16.	8023	24/M	9100	52	40	8	8900	55	42	3	7	20	7	14	12	12.2	-	-	OEC	-	-	OEC	20	0.8	24	0.6
17.	8810	51/M	10200	61	33	6	10100	60	38	2	20	46	5	15	11	12.4	-	-	OEC	-	-	OEC	24	0.7	22	0.6
18.	8923	42/M	9300	62	30	8	9200	58	38	4	6	8	3	5	12.6	13	-	-	OEC	-	-	OEC	21	0.7	26	0.6
19.	9535	19/F	8100	58	33	9	8400	55	39	2	4	15	3	8	10.5	11.6	-	-	OEC	-	-	OEC	30	0.6	29	0.7
20.	9904	40/F	8800	58	36	6	8600	55	42	3	2	6	2	5	12	12.8	-	-	OEC	-	-	OEC	31	0.6	27	07
21.	1519	36/F	8000	59	33	8	8200	57	40	3	8	18	5	13	13.2	13.4	-	-	OEC	-	-	OEC	32	0.6	28	0.6
22.	1462	33/F	8200	60	32	8	8400	59	39	2	7	7	3	6	14	12.6	-	-	OEC	-	-	OEC	27	0.7	28	0.6

23.	2498	30/M	9300	57	35	8	9000	60	38	2	10	24	8	18	13	13	-	-	OEC	-	-	OEC	24	0.7	26	0.6
24.	6677	42/F	9700	58	36	6	9500	59	38	3	12	35	8	18	10	10	-	-	OEC	-	-	OEC	26	0.6	27	0.7
25.	6678	55/M	9100	62	31	7	9200	63	33	4	6	13	4	7	11	11.2	-	-	OEC	-	-	OEC	33	0.6	28	0.6
26.	6549	40/F	9300	60	31	9	9100	55	42	3	11	23	2	5	12	12.4	-	-	OEC	-	-	OEC	30	0.7	28	0.7
27.	6576	33/F	8600	55	39	6	8500	58	40	2	5	7	5	9	12	12.2		-	OEC	-	-	OEC	22	0.8	20	0.6
28	6479	34/M	8100	57	36	7	8600	59	38	3	5	20	3	15	11	11	-	-	OEC	-	-	OEC	21	0.6	24	0.6
29.	6921	37/M	9600	58	34	8	9300	61	35	4	6	14	3	9	13	13	-	-	OEC	-	-	OEC	28	0.5	26	0.7
30.	8504	54/M	8300	61	30	9	8500	60	38	2	12	26	6	12	13	13.4	-	-	OEC	-	-	OEC	18	0.6	20	0.6
31.	8492	58/F	8500	56	37	7	8700	61	37	2	8	10	3	9	12.4	12.8	-	-	OEC	-	-	OEC	25	0.8	22	0.7
32.	8493	58/F	10,000	60	32	8	10100	61	36	3	12	25	7	14	9.2	11	-	-	OEC	-	-	OEC	22	0.6	20	0.6
33.	9836	39/F	8900	46	46	8	9000	52	46	2	32	65	8	20	12.7	12	-	-	OEC	-	-	OEC	21	0.7	24	0.7
34.	595	37/F	7800	55	39	6	8300	57	39	4	8	20	5	15	12.6	14	-	-	OEC	-	-	OEC	26	0.6	24	0.6
35.	603	48/M	8600	55	36	9	8400	57	38	5	7	15	3	6	12.4	13	-	-	OEC	-	-	OEC	28	0.7	23	0.7
36.	513	55/M	9200	51	42	7	9000	55	42	3	20	40	5	9	14.2	15	-	-	OEC	-	-	OEC	21	0.6	25	0.6
37.	1653	48/F	9000	61	33	6	9200	57	36	7	5	10	3	7	12	12.8	-	-	OEC	-	-	OEC	26	0.8	23	0.7
38.	1651	40/F	8400	54	40	6	8300	56	41	3	8	22	5	15	13.5	13.4	-	-	OEC	-	-	OEC	25	0.6	22	0.6
39.	3726	38/M	8200	62	31	7	8600	65	33	2	12	20	2	5	10	11.6	-	-	OEC	-	-	OEC	28	0.7	26	0.7
40.	8012	42/F	8700	56	38	6	8900	58	36	6	5	15	4	6	11	11.8	-	-	OEC	-	-	OEC	22	0.8	20	0.5

BT – Befor Treatment, AT – After Treatment, TC – Total Count, DC – Differential Count, P – Polymorphs, L – Lymphocyte,

E – Eosinophils, HB – Hemoglobin,   OEC – Occasional Epithelial Cells, RFT – Renal Function Tests, Cre – Creatinine.

SPECIFIC INVESTIGATION OF THE PATIENT

S. NO	OP NO	AGE/SEX	OCCUPATION	Abs.Eosin.Count		X ray chest PA View	
				BT	AT	BT	AT
1.	3205	52/F	House wife	550	260	Normal	Normal
2.	3293	55/F	House wife	400	180	Normal	Normal
3.	3303	49/F	House wife	720	350	Normal	Normal
4.	4406	46/F	House wife	500	310	Normal	Normal
5.	4407	51/M	Office	900	420	Normal	Normal
6.	4352	13/F	Student	240	180	Normal	Normal
7.	4496	45/F	House wife	680	280	Normal	Normal
8.	6031	32/F	House wife	640	320	Normal	Normal
9.	6143	24/M	Office	300	170	Normal	Normal
10.	5998	21/M	Office	320	270	Normal	Normal
11.	6106	48/F	House wife	700	340	Normal	Normal
12.	6344	15/F	Student	200	160	Normal	Normal
13.	6312	44/M	Traffic police	640	270	Normal	Normal
14.	7316	45/F	House wife	280	200	Normal	Normal
15.	7765	36/M	Business	620	310	Normal	Normal
16.	8023	24/M	Office	340	270	Normal	Normal
17.	8810	51/M	Office	680	300	Normal	Normal
18.	8923	42/M	Tailor	720	320	Normal	Normal
19.	9535	19/F	Student	430	350	Normal	Normal
20.	9904	40/F	House wife	850	380	Normal	Normal
21.	1519	36/F	House wife	460	210	Normal	Normal
22.	1462	33/F	House wife	320	220	Normal	Normal
23.	2498	30/M	Office	300	260	Normal	Normal
24.	6677	42/F	Office	670	280	Normal	Normal
25.	6678	55/M	Office	820	360	Normal	Normal
26.	6549	40/F	House wife	600	310	Normal	Normal
27.	6576	33/F	House wife	350	230	Normal	Normal
28	6479	34/M	Office	220	100	Normal	Normal
29.	6921	37/M	Office	620	310	Normal	Normal
30.	8504	54/M	Office	380	190	Normal	Normal
31.	8492	58/F	House wife	460	200	Normal	Normal
32.	8493	58/F	House wife	350	240	Normal	Normal
33.	9836	39/F	House wife	300	210	Normal	Normal
34.	595	37/F	House wife	250	160	Normal	Normal
35.	603	48/M	Office	850	380	Normal	Normal
36.	513	55/M	Business	720	340	Normal	Normal
37.	1653	48/F	House wife	440	300	Normal	Normal
38.	1651	40/F	House wife	380	220	Normal	Normal
39.	3726	38/M	Office	560	240	Normal	Normal
40.	8012	42/F	House wife	680	280	Normal	Normal

BT – Before Treatment ; AT – After Treatment

DISCUSSION

DISCUSSION

Bronchial asthma is characterised by chronic airway inflammation and increased airway hyper-responsiveness leading to symptoms of wheeze, cough, chest tightness, and dyspnoea. It is characterised functionally by the presence of airflow obstruction which is variable over short periods of time, or is reversible with treatment.

Swasakasam is a clinical entity described by *Yugimunivar* in his *Yugi Vaidhya Chinthamani 800*. The classical symptoms are dyspnoea, cough, tightness of chest and wheezing. These clinical features can be well compared with Bronchial Asthma.

As per Siddha literature *Sombu Theeneer* was selected for *Swasakasam* from the *Siddha Vaithyathirattu*.

AUTHENTICATION:

Based upon the organoleptic characters, microscopic and macroscopic examination of market sample Sombu (*Pimpinella anisum)* belongs to the family Apiaceae was done and authenticated by the Botanist, Department of Medicinal Botany, Govt. Siddha Medical College, Arumbakkam, Chennai-600106.

PHYSIO CHEMICAL ANALYSIS:

The *Sombu Theeneer* was evaluated for various physiochemical parameters and the mean value of volatile matter-0.049%, total solids – nil, Specific gravity – 0.95, and p^H value (10%) – 6.5 was analysed.

TOXICITY STUDY:

The experimental protocol was approved by The Institutional Animal Ethics Committee of Sathyabama University, Chennai, Tamil Nadu, India. IAEC Reference No**:** SU/ CLATR/IAEC/IV/024/2016

Acute oral toxicity study followed as per OECD 423 guidelines and dose used was 2.5ml/kg body weight and Sub-acute oral toxicity study done as per OECD 407 guide

lines, here dose utilized was 0.25ml for low and 0.5ml for high dose. These toxicity studies revealed no toxicity in *Sombu Theeneer*. The results of haematological analysis, biochemical analysis revealed no significant changes in the values when compared with those of respective controls. Then the histo-pathological examination of animals in control as well as the treated groups did not reveal any abnormalities.

PHARMACOLOGICAL EVALUATION:

The experimental protocol was approved by The Institutional Animal Ethics Committee of Sathyabama University, Chennai, Tamil Nadu, India. IAEC: IAEC: SU/CLATR/IEAC/VII/054/2016.The pharmacological activity of *Sombu Theeneer* was screened against milk induced eosinophilia in mice model. This proves that *Sombu Theeneer* has Bronchodilator activity.

BIO CHEMICAL ANALYSIS:

Biochemical assays are needed to evaluate disease models and to drive biomarker analysis in translational medicine and clinical research.

Based on the analysis *Sombu Theeneer* exhibits the properties of alkaloids, Potassium and Chloride.

IEC AND CTRI:

IEC has approved my *Sombu Theenee*r with the allowed sample size of 40 patients with combined gender IEC NO: GSMC-CH-ME-4/2015/006.
The global mandate is to register all clinical trials prospectively, i.e. before the enrolment of the first patient I had successfully registered my trial drug by submitting the details and scientific data's to CTRI. CTRI NO: REF/2016/12/012911

CLINICAL STUDY:

Clinical studies were conducted followed by CTRI registration with the sample size of 40 patients. In my study, 40 patients with *Swasakasam* were selected in the Department of Maruthuvam, Government Siddha Medical College, attached to Arignar Anna Govt Hospital for Indian Medicine, Arumbakkam, Chennai -106.All necessary investigations were carried out to all patients and trial medicine was given. The results of before and after treatment of all the patients were analysed and discussed below.

AGE DISTRIBUTION:

Out of 40 patients, high incidence of cases were noted in age group ranging from 31–40 years

SEX DISTRIBUTION:

Out of 40 patients, 17 cases (42.5%) were male and 23 cases (57.5%) were female. Recent studies show that more women are Asthmatic than men.

OCCUPATIONAL STATUS:

Out of 40 patients, 3 patients (7.5%) were business man, 6 patients (15%) were housewife, 5 patient(12.5%) was traffic policeman, 3 patient (7.5%) were student, 9 patient (22.5%) was tailor, 14 patient (35%) were office people..

SOCIO-ECONOMIC STATUS:

Regarding the socio-economic status, 23 patients (57.5%) comes under poor category,9 patients (22.5%) comes under middle category, and 8 patients (20%) comes under high class category.

DIETARY HABITS:

Out of 40 patients, 7 patients (17.5%) have Vegetarian diet and 33 patients (82.5%) have Mixed diet.

PARUVAKAALAM:

From selected 40 patients,16 patients (40%) comes under Kaarkaalam, 9 patients (22.5%) comes under Koothirkaalam,7 patients(17.5%) comes under Munpani,5 patients (12.5%) comes under Pinpani, 2 patinets(5%) comes under Elavenil, 1patient (2.5%) comes under Mudhuvenil.

Kaarkaalam, koothirkaalam and munpani seasons have a great impact on Swasakasam.

THINAI:

Out of 40 patients, 33 patients (82.5%) comes under Neidhal,7 patients (17.5%) comes under Marudham.

DURATION OF ILLNESS:

Out of 40 patients, 6 patients(15%) belongs to less than one year duration, 25 patients(62.5%) comes under 1-5 year duration, 5 patients(12.5%) comes under 6-10year duration, and 4 patients (10%) have more than 10 years duration.

MUKKUTRAM CLASSIFICATION:

In Vatham:

From the selected 40 patients

  i. Pranan was affected in 40 patients (100%), reflected as difficulty in breathing
  ii. Udhanan was affected in 40 patients (100%), reflected as cough
  iii. Abanan was affected in 5 patients (12.5%) reflected as constipation
  iv. Viyanan was affected in 35 patients (87.5%), reflected as body pain
  v. Samanan was affected in 14 patients (35%), reflected as loss of appetite
  vi. Koorman was affected in3 patients(7.5%), reflected as cough and sneezing
  vii. Devathathan was affected in 40 patients (100%) resulting in fatigue

In Pitham:

   Out of 40 patients

  i. Analagam was affected in 14 patients (35%), producing loss of appetite
  ii. Ranjagam was affected in 9 patients (22.5%), resulting in pallor of tongue.
  iii. Saathagam was affected in 40 patients (100%), producing fatigue in routine work

In Kabham:

   Out of 40 patients

  i. Avalambagam was affected in 40 patients (100%) reflected as difficulty in breathing.
  ii. Klethagam was affected in 14 patients (35%) results in loss of appetite.
  iii. Santhigam was affected in 5 patients (12.5%) results in joint pain.

EZHU UDAL THATHUKKAL

1. Saaram affected in all patients (100%) results in tiredness, general debility.

2. Senneer affected in all cases (22.5%) causing pallor, dryness.

3. Enbu affected in 26 patients (12.5%) causing back pain and joint pain.

ENVAGAITHERVUGAL:

1. Naa affected in all 9 patients(30%) results in palor of tongue

2. Mozhi affected in 1 patients (2.5%) results difficult to speak.

3. Vizhi affected in 9 patients(22.5%) pallor of lower eyelids.

4. Malam affected in 5 patients (2.5%) results in constipation.

5. Nadi affected in 40patients (100%) .

Naadi:

Out of 40 patients, 31 patients had Kabhavatha naadi and 9 patients had Vathakabha naadi.

வாத சேத்தும நாடி:

"பாங்கான வாதத்தில் சேத்தும நாடி"

- சுவாசகாசம்

Neikuri:

Out of 40 patients, 9 patients (22.5%) had Vatha neer, 31 patients (77.5%) had Kabha neer.

Signs and symptoms:

Out of 40 patients, 40 patients (100%) had Dyspnoea, 30 patients (75%) had cough with expectoration, 40% patients (100%) had wheezing, 35 patients (87.5%) had tightness of chest, 6 patients (15%) had rhinitis, 6 patients (15%) had Sneezing, 4 patients (10%) had headache.

Clinical prognosis:

Out of 40 patients,

Before treatment 40 patients had dyspnoea, wheezing, 35 patients had tightness of chest, 30 patients had cough with expectoration, treatment 6 patients had rhinitis and sinusitis and 4 patients had headache, after treatment 37 patients cured, only 3 patients had dyspnoea and wheezing and one had headache. Rest all had no symptom.

Laboratory assessment:

Before treatment in the blood parameters ESR, Polymorphs, Leucocytes, Eosinophil were elevated and after treatment all these parameters reduced to their normal limits. Before treatment Absolute eosinophil count was above 400 of patient and after treatment the absolute count reduced to normal range 350 and eosinophil reduced to normal 5.

Peak expiratory flow rate:

Before treatment 40 patients had abnormal peak flow rate, after treatment (75%) got good results and 10 patients (25%) got moderate results.

Suvai mukkuttra theory:

Swasakasm is primarily due to deranged of *vatham* and *iyya kuttram*. The ingredient *Sombu* have the property *kaarpu suvai* of neutralizing the deranged *iyya kutram*.

Bio Statistics:

Since the p value $P<0.01$ is significant in all signs and symptoms. So there is significant reducing of signs & symptoms among the patients for the treatment of *Swasakasam*. Hence it is concluded that the treatment was effective and significant.

Since the P value is highly significant (<0.001). So there is significant increasing of Peak Expiratory Flow Rate among the patients for the treatment of *Swasakasam*. Hence it is concluded that the treatment was effective and significant.

Grading of results:

$$\text{Results} = \frac{\text{No. of patients after treatment}}{\text{No. of patients before treatment}} \times 100$$

Thus out of 40 patients before treatment, after treatment 75% of cases showed good result, 25% of the cases showed Moderate result.

SUMMARY

SUMMARY

The clinical study on Swasakasam was carried out on Post graduate department of Maruthuvam, Government Siddha Medical College, Arignar Anna Hospital, Chennai-106 during the period of 2015 -2017.

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

All patients were treated with SOMBU THEENEER (15ml bid with equal amount of warm water) for duration of 30 days.

➢ The peak incidence of Swasakasam was found to be in 31-40 years of age group of both sexes.

➢ The prevalence of the disease was high among Lower class populations 57.5% followed by Middle class 22.5% and High class population 20%.

➢ Out of 40 patients, 9 patient (22.5%) was tailor, 14 patient (35%) were office people, 5patient (12.5%) was traffic policeman, 3 patients (7.5%) were business man, 6 patients (15%) were housewife, 3 patient (7.5%) were student.

➢ Regarding personal habits 11 patients were smokers, 4 patients were alcoholic, 3 patients were both smoking and alcoholic, 1 patient was a snuff user. Remaining 21 patients were tee tootlers.

➢ Among the dietary patterns, 82.5% consume mixed diet and 17.5% are purely vegetarian.

➢ Out of 40 patients, 37.5% comes under Vatha kaalam, 62.5% comes under Azhal kaalam.

➢ From selected 40 patients,16 patients(40%) comes under Kaarkaalam, 9 patients(22.5%) comes under Koothirkaalam,7 patients(17.5%) comes under Munpani,5 patients (12.5%) comes under Pinpani, 2 patients(5%) comes under Elavenil, 1patient (2.5%) comes under Mudhuvenil.

➢ Out of 40 patients, 33 patients (82.5%) comes under Neidhal,7 patients (17.5%) comes under Marudham.

- From the selected 40 patients, Pranan was affected in 40 patients (100%), Abanan was affected in 5 patients (12.5%), Viyanan was affected in 35 patients (87.5%),Samanan was affected in 14 patients (35%),Koorman was affected in3 patients(7.5%), Kirugaran was affected in 30 patients (75%), Devathan was affected in 40 patients (100%).

- Out of 40 patients, Analagam was affected in1 4 patients (35%), Ranjagam was affected in 9 patients (22.5%), Saathagam was affected in 40 patients (100%), Aalosagam was affected in 3 patients (7.5%).

- Out of 40 patients, Avalambagam was affected in 40 patients (100%), Klethagam was affected in 14 patients (35%), Santhigam was affected in 5 patients (12.5%).

- Out of 40 cases, Saaram was affected in 40 patients (100%), Seneer was affected in 9 patients(22.5%), Enbu was affected in 5 patients(12.5%).

- Regarding Envagaithervu, Naa was affected in 9 patients(22.5%), Mozhi was affected in 1 patients(2.5%), Vizhi was affected in 9 patients(22.5%), Malam was affected in 5 patients (12.5%), Naadi was affected in 40 patients(100%).

- Out of 40 patients, 31 patients had Kabhavatha naadi and 9 patients had Vathakabh anaadi.

- Out of 40 patients, 9 patients (22.5%) had Vatha neer, 31 patients (77.5%) had Kabhaneer.

- Regarding peak expiratory flow rate (75%) got good results and 10 patients (25%) got moderate results.

- The ingredient Sombu has the property kaarpu suvai of neutralizing the deranged iyya kutram.

- The toxicity studies revealed no toxicity in SombuTheeneer.

- The pharmacological activity of SombuTheeneer shows Bronchodilator activity.

- The Biostatsistical report of the clinical trial significant p value P<0.01 and concluded that the treatment was effective and significant.

- Thus out of 40 patients before treatment, after treatment 75% of cases showed good result, 25% of the cases showed Moderate result.

CONCLUSION

CONCLUSION

Swasakasam is primarily due to the derangement of Iyyam and Vatha kutram.

▪ The ingredients of the trial medicine have the properties of neutralizing the deranged kutrams.

▪ From the preclinical toxicity studies, the trial medicine revealed no toxicity and proved to be safe.

▪ From the preclinical pharmacological studies, it is evident that *SOMBU THEENEER* have Bronchodilator activity.

▪ No contraindication was reported during the course of the treatment.

▪ The *SOMBU THEENEER* gave maximum relief from the symptoms of Swasa kasam.

▪ The reduces *SOMBU THEENEER* the frequency of wheeze attacks.

▪ The *SOMBU THEENEER* is economical and easily palatable.

Therefore I conclude that, can give a *SOMBU THEENEER* will be the best remedie for asthma sufferers both curative and preventive.

ANNEXURES

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

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

This Certificate is awarded to Dr/Mr/Mrs .... R. Kalpana ....

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.

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

Prof. Dr.P.ARUMUGAM, M.D.,
REGISTRAR i/c

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

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,
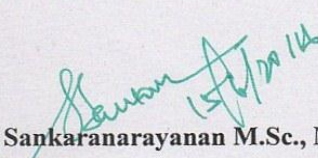Tamil Nadu 600106.

AUTHENTICATION CERTIFICATE

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

Binomial name	Family	Regional names
Pimpinella anisum Linn. Syn *Foeniculum vulgare* Mill.	Apiaceae (Umbelliferae)	Sombu

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-12/2016

Date:15.06.2016

<u>CERTIFICATE</u>

This is to certify that the project entitled "TOXICITY EVALUATION OF *SOMBU THEENEER* 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/024/2016**

Animal Sanctioned: *Rattus norvegicus* / Wistar albino rats

Male: 6; Female: 12; Total: 18 (Eighteen)

Date: 5.3.2016

DR.B.SHEELA RANI

Chair Person

DR. R. ILAVARASAN

CPCSEA Main Nominee

<u>CERTIFICATE</u>

This is to certify that the project entitled "**PHARMACOLOGICAL EVALUATION OF BRONCHODILATORY ACTIVITY OF SOMBU THENEER AGAINST MILK INDUCED EOSINOPHILIA IN MICE**" has been approved by the Institutional Animal Ethics Committee of Sathyabama University, Chennai.
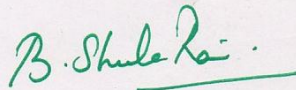
IAEC Approval No.: **SU/CLATR/IAEC/VII/054/2016**

Principal Investigator: Dr. R. Kalpana

Animal Sanctioned: *Mus musculus* / Swiss mice

Male: 24; Total: 24 (Twenty Four)
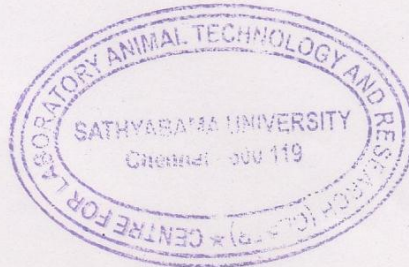
Date: 05.10.2016

DR. B. SHEELA RANI

Chairperson

DR. R. ILAVARASAN

CPCSEA Nominee

PHARMACOLOGICAL

STUDY

PHARMACOLOGICAL STUDY

Pharmacological Evaluation of Bronchodilatory activity of *Sombu Theeneer* against milk induced eosinophilia in mice.

Name : Dr.R.Kalpana

IAEC: SU/CLATR/IEAC/VII/054/2016

Experimental Animals

Healthy Swiss albino male mice weighing between 20-25 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 ± 2^0 Cand 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/054/2016

Experimental Methodology

Animals were randomly divided in four group of 6 male mice each (one normal control, second milk intoxicated, three and four treatment groups).Animal belongs to group I received normal saline 0.1ml. Group II mice received boiled and cooled milk (4 mL/kg, s.c.) from day 1 to 5. Animal belongs to group III received milk (4 mL/kg, s.c.) and treated with 0.05 ml of *Sombu Theeneer* (p.o) 1 hr before milk injection for five days. Animal belongs to group IV received milk (4 mL/kg, s.c.) and treated with 0.1 ml of *Sombu Theeneer* (p.o) 1 hr before milk injection for five days.

Induction of Leukocytosis

Swiss albino male mice were used for this study in which boiled and cooled milk (4 mL/kg, s.c.) was injected to the mice results in abnormal increase in Total WBC, Procalcitonin, eosinophil count.

Blood collection

At the end of the study after overnight fast all mice were anesthetized by intra muscular injection with pentobarbital sodium. Blood will be collected by ocular puncture for biochemical estimations of Total WBC, Procalcitonin, eosinophile count.

Histopathology

At the ends of the study all the mice will be sacrificed and lung was harvested and stored in the fixative solution (10% formalin) and cut into 10 μm thickness. Staining was done by using hematoxylin and eosin

Reference:

1. Dnyaneshwar J Taur. Effect of Abrus precatorius leaves on milk induced leukocytosis and eosinophilia in the management of asthma.Asian Pacific Journal of Tropical Biomedicine (2012);S40-S42
2. Parasuraman S, Raveendran R, Kesavan R. Blood sample collection in small laboratory animals. J Pharmacol Pharmacother. 2010;1:87–93.
3. Verley H. Practical Clinical Biochemistry. New Delhi: CBS Publishers; 2003.

Effect of *Sombu Theeneer* on hematology profile of mice challenged against milk induced eosinophilia

GROUP I	WBC count ($\times 10^3$ μl)	Eosinophil's (%)	Neutrophils $10^3/mm^3$	Lymph (%)	Mon (%)	PCT (%)
Mean	3.117	0.4033	1.617	69.18	2.75	0.3957
Std. Deviation	1.412	0.1097	0.4401	5.363	0.6317	0.201
Std. Error	0.5764	0.04477	0.1797	2.19	0.2579	0.08206

GROUP II	WBC count (×10³ μl)	Eosinophil's (%)	Neutrophils 10³/mm³	Lymph (%)	Mon (%)	PCT (%)
Mean	10.28	2.513	3.467	90.65	6.267	2.655
Std. Deviation	2.184	0.5483	0.6743	3.266	0.8262	0.768
Std. Error	0.8916	0.2238	0.2753	1.333	0.3373	0.3135
GROUP III	WBC count (×10³ μl)	Eosinophil's (%)	Neutrophils 10³/mm³	Lymph (%)	Mon (%)	PCT (%)
Mean	6.433	1.457	2.833	80.38	5.2	1.432
Std. Deviation	1.919	0.218	0.3777	9.439	0.8786	0.4806
Std. Error	0.7834	0.08898	0.1542	3.854	0.3587	0.1962
GROUP IV	WBC count (×10³ μl)	Eosinophil's (%)	Neutrophils 10³/mm³	Lymph (%)	Mon (%)	PCT (%)
Mean	4.183	0.7	2.4	75.05	3.883	0.8655
Std. Deviation	0.9517	0.139	0.4817	4.195	0.5845	0.1425
Std. Error	0.3885	0.05675	0.1966	1.712	0.2386	0.0582

Values are mean ± S.D / S.E (n = 6 per group)

**Effect of *Sombu Theeneer* on Lung weight of mice challenged against milk**

GROUP I	Lung Weight in gms
Mean	0.18
Std. Deviation	0.02098
Std. Error	0.008563
GROUP II	**Lung Weight in gms**
Mean	0.425
Std. Deviation	0.04037
Std. Error	0.01648
GROUP III	**Lung Weight in gms**
Mean	0.33

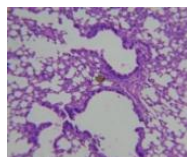| Std. Deviation	0.03347
Std. Error	0.01366
GROUP IV	**Lung Weight in gms**
Mean	0.2283
Std. Deviation	0.03312
Std. Error	0.01352

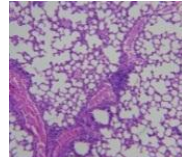**Histopathology of Mice Lung (H&E) Staining**

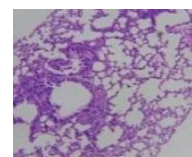**Low Power Magnification 10 X**
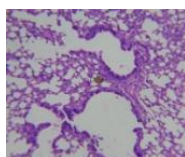
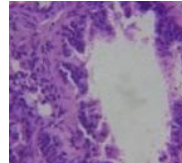| Control Group	Milk alone Treated group	Milk+ Low dose of ST	Milk+ High dose of ST

High Power Magnification 40 X
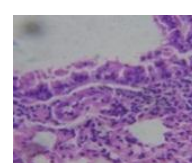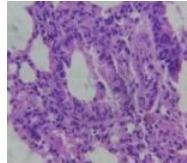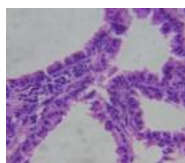
Pathology Report

- Lung parenchyma appears normal with regular arrangement of alveoli and alveolar sac with no signs of lymphocyte infiltration and pulmonary fibrosis

- Mild airway and bronchial secretion with collateral bronchial blood vessels and connective tissue .Evidence of pulmonary edema and vascular congestion was observed in group II sample.

- Massive recruitment of eosinophil's around the airway, blood vessels and bronchoconstriction was observed in sample belongs to group II.

- Mild eosinophilic aggregation around air way with dilated bronchial opening was observed in group III.

- Regular appearance of pulmonary artery, alveolar duct was normal with wide bronchial orifice was observed in group IV.

PHYSICO CHEMICAL ANALYSIS

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

17.02.17

CERTIFICATE

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

Name of the sample: Sombu Theeneer

Name of the Experiment	Mean
Volatile matter	0.049 %
Total solids	Nil
Specific gravity	0.95
pH value (10%)	6.5

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

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

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 add2ml of 4% Ammonium oxalate solution.	Absence of White Precipitate	Absent
b	2ml of extract is added with 2mlof dilute hydrochloric acid until the effervescence ceases off. Then2ml 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.	Presence of white precipitate	**Present**
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** 2 pinches of the substance is made into paste by using Sulphuric acid and Alcohol (95%) and introduced into the blue flame.	Absence of Green tinged flame	Absent
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.	No Blood red colour	Absent
b	To the 2 ml of extract, 2 ml of	Absence of Blood red colour	Absent

	Ammonium Thiocyanate solution and 2 ml of concentrated HNO_3 is added.	obtained	
14	**Test for Zinc** To the 2 ml of extract Sodium Hydroxide solution is added in drops to excess.	Absence of White precipitate.	Absent
15	**Test for Calcium** 2 ml of the extract is added with 2 ml of 4% Ammonium Oxalate solution.	Absence of White precipitate Obtained	Absent
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 Cobalt Nitrate in 30% glacial Acetic acid.	Presence of Yellow precipitate	**Present**
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.	No Green colour obtained	Absent
24	**Test of the alkaloids** 2ml of the extract is treated with 2ml of potassium iodide solution.	Presence of Red colour	**Present**
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 (Sombu Theeneer) contains Chloride, Potassium and Alkaloids.

GOVERNMENT SIDDHA MEDICAL COLLEGE
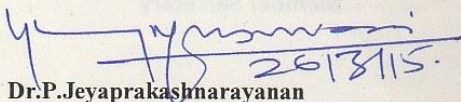### Arumbakkam, Chennai-106

Communication Of The Decision Of Institutional Ethics Committee (IEC)

IEC No: GSMC-CH-ME-4/2015/006

Protocol title:	
A CLINICALSTUDYON SWASA KASAM (BRONCHIAL ASTHMA) WITH THE EVALUATION OF SIDDHA DRUG SOMBU THEENEER	
Principal Investigator:	DR.R. KALPANA
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. In Inclusion criteria, age should be b/w 18 to 60 year.

Recommended for a period of 1 year
from date of completion of preclinical studies:

Please Note:
- Inform IEC immediately in case of any adverse events/serious drug reaction.
- Seek IECapproval in case of any change in the study procedure, site and investigator
- This approval is valid only for period mentioned above
- IEC member have the right to review the trial with prior intimation.
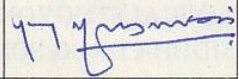
26/3/15.

Dr.P.Jeyaprakashnarayanan
Chairman
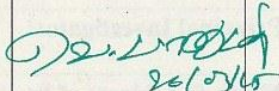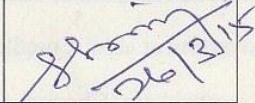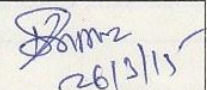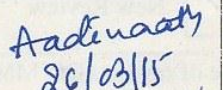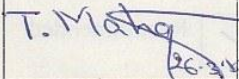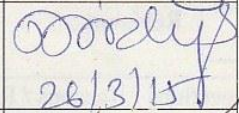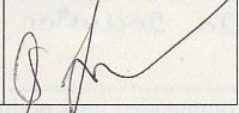
Dr.V. Banumathi
Member Secretary
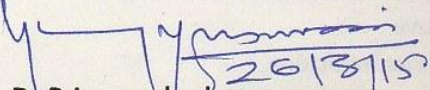
INSTITUTIONAL ETHICS COMMITTEE
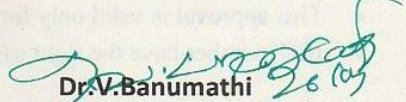
Date:

Sub: IEC review of research proposals.

Ref:Your letter dated

MEMBERS	PARTICIPATION	SIGNATURE
DR.P.JEYAPRAKASH NARAYANAN M.D(S)., Chairman		
DR.V.BANUMATHI M.D(S)., Member Secretary		
DR.N.KABILAN M.D(S)., Clinician- Siddha	✓	
DR.P.SATHIYA RAJESWARAN M.D(S)., Clinician- Siddha	✓	
DR.G.AADINAAATH REDDY,M.Pharm, Ph.D., Pharmacologist	✓	
DR.S.THILAGAVATHY Msc.,Ph.D., Social Scientist	✓	
DR.T.MAHALAKSHMI M.A.,Ph.D., Linguistic Expert	✓	
DR.P.VIDYA M.B.B.S., DMRD., Modern Medicine Expert	✓	
MR.P.SARAVANAN., Puplic Person	✓	

Dr.P.Jeyaprakashnarayanan
Chairman

Dr.V.Banumathi
Member Secretary

BIOSTATISTICAL

ANALYSIS

BIOSTATISTICAL ANALYSIS

CLINICAL PROGNOSIS

Treatment for Swasakasam:

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

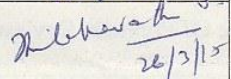| S. No	Signs&Symptoms	Before Treatment	After Treatment
		n%	n%
1.	Dyspnoea	40(100)	3(7.5)**
2.	Cough without expectoration	30(75)	0(0)**
3.	Wheezing	40(100)	3(7.5)**
4.	Tightness of chest	35(87.5)	0(0)**
5.	Rhinitis	6(15)	0(0)*
6.	Sneezing	6(15)	0(0)*
7.	Headache	4(10)	1(2.5)*

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

Software: spss17 version

Number of cases: 40

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 **Swasakasam**.Hence it is concluded that the treatment was effectiveand **significant.**

PEAK EXPIRATORY FLOW RATE BEFORE AND AFTER TREATMENT

Effect of medicineon Peak Expiratory Flow Ratein human subjects

S.No.	BT	AT
1	100	230
2	350	450
3	270	350
4	150	250
5	170	240
6	190	260
7	100	220
8	180	310
9	160	220
10	260	350
11	250	400
12	250	340
13	330	400
14	80	200
15	200	320
16	280	340
17	220	280
18	210	330
19	70	150
20	150	260
21	170	240
22	150	220
23	190	260
24	240	300
25	180	240
26	70	160

27	100	210
28	130	350
29	250	400
30	230	340
31	200	350
32	260	350
33	170	260
34	190	280
35	130	310
36	250	340
37	280	360
38	350	420
39	180	280
40	120	200

Software: spss17 version

Variables: Peak Expiratory Flow Rate – before treatment, after treatment

Number of cases: 40

Test: Paired t test

Confidence Interval: 95%

Correlation coefficient (r): 0.897

Before and after treatment mean difference± SD: 99.48 ± 35.61.

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

Inference:

Since the P value is highly significant (<0.001). So there is significant increasing of Peak Expiratory Flow Rate among the patients for the treatment of **Swasakasam**. Hence it is concluded that the treatment was effective and **significant**

CONSENT FORM

CONSENT FORM

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

DATE :   **SIGNATURE**

NAME:

CONSENT BY THE PATIENT

I have been informed to my satisfaction by the attending physician about the purpose of clinical trial and the nature of the drug treatment and follow up including the lab investigations to be performed to monitor and safeguard my body functions. I am aware of my right to opt out of the trial at any time during the course of the trial without having to give reasons for doing so. I am exercising my free power of choice, and hereby give my consent to be included as a subject in the clinical trial of **SOMBU THEENEER** for the treatment of **SWASAKASAM.**

DATE :   **SIGNATURE**

NAME:

சுவாசகாச நோய்க்கான சித்த மருந்தின் (சோம்பு தீநீர்)பரிகரிப்பு திறனைக் கண்டறியும் மருத்துவ ஆய்வுற்கான தகவல் படிவம்.

ஒப்புதல் படிவம்

ஆய்வாளரால் சான்றளிக்கப்பட்டது

நான் இந்த ஆய்வு குறித்த அனைத்து விபரங்களையும் நோயாளிக்கு புரியும்வகையில் எடுத்துரைத்தேன் என உறுதியளிக்கிறேன்.

தேதி:   கையொப்பம்:

இடம்:   பெயர்:

நோயாளியின் ஒப்புதல்

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

நான் இந்த மருத்துவ ஆய்வின் போது, காரணம் எதுவும் கூறாமல், எப்பொழுது வேண்டுமானாலும் இந்த ஆய்விலிருந்து என்னை விடுவித்து கொள்ளும் உரிமையை தெரிந்திருக்கின்றேன்.நான் என்னுடைய சுதந்திரமாக தேர்வு செய்யும் உரிமையைக் கொண்டுசுவாசகாச நோய்க்கானசோம்பு தீநீர் மருந்தின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கு என்னை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி:   கையொப்பம்:

இடம்:   பெயர்:

தேதி:   சாட்சிக்காரர்
கையொப்பம்:

இடம்:   பெயர்:

உறவுமுறை:

துறைத்தலைவர் கையொப்பம்:   ஆராய்ச்சியாளர்

CASE SHEET

PROFORMA

<p style="text-align:center;">O.P CASE SHEET PROFORMA</p>

<p style="text-align:center;">POST GRADUATE DEPARTMENT, MARUTHUVAM (BRANCH-1)
GOVERNMENT SIDDHA MEDICAL COLLEGE
ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE
CHENNAI – 600 106
CLINICAL STUDY ON "SOMBU THEENEER" IN THE TREATMENT OF
"SWASAKASAM'' (BRONCHIAL ASTHMA)</p>

OP NO: **OCCUPATION:**

NAME: **INCOME:**

AGE: **NATIONALITY:**

SEX: **RELIGION:**

ADDRESS: **DIAGNOSIS:**

CONTACT NO: **MEDICAL OFFICER:**

COMPLAINTS & DURATION:

HISTORY OF PRESENT ILLNESS:

HISTORY OF PAST ILLNESS:

PERSONAL HISTORY AND HABITS:

DIETARY HABIT: FAMILY HISTORY:

GENERAL EXAMINATION:

Consciousness:

Nourishment:

Decubitus: Height (cms):

Weight (kg):

Temperature (°F):

Pulse rate (/min):

Heart rate (/min):

Respiratory rate (min):

Blood pressure (mm/Hg):

Pallor:

Jaundice:

Cyanosis:

Lymphadenopathy:

Pedal edema:

Clubbing:

Jugular vein pulsation:

SIDDHA SYSTEM OF EXAMINATIONS:

1. THEGI: [BODY CONSTITUTION]

    1. Vatha udal

    2. Pitha udal

    3. Kaba udal

    4. Thontha udal

2. NILAM: [LAND WHERE PATIENT LIVED MOST]

    1. Kurinji   (Hilly terrain)

    2. Mullai   (Forest range)

    3. Marutham (Plains)

    4. Neithal   (Coastal belt)

    5. Paalai   (Arid regions)

3. KAALAM:

    1. Kaar kaalam

    2. Koothir kaalam

    3. Munpani kaalam

    4. Pinpani kaalam

    5. Ilavenil kaalam

    6. Muthuvenil kaalam

4. GUNAM:

    1. Sathuvam

    2. Raasatham

    3. Thaamatham

5. IMPORIGAL (SENSORY ORGANS):

1. Mei (Sensation)
2. Vaai (Taste)
3. Kann (Vision)
4. Mukku (Smell)
5. Sevi (Hearing)

6. KANMENDHIRIYAM (MOTOR ORGANS):

1. Kai
4. Kal
5. Vaai
6. Eruvai
7. Karuvaai

7. KOSANGAL:

1. Annamaya kosam
2. Pranamaya kosam
3. Manomaya kosam
4. Vignana maya kosam
5. Anandamaya kosam

8. UYIR THAATHUKKAL: [THREE HUMORS] (VALI, AZHAL, IYAM) A) VALI

1. Pranan
2. Abanan
3. Samanan
4. Uthanan
5. Viyanan
6. Naagan

7. Koorman

8. Kirukaran

9. Devathathan

10. Dhananjayan

B) AZHAL

1. Analakam

2. Ranjakam

3. Sathakam

4. Prasakam

5. Alosakam

C) IYAM

1. Avalambagam

2. Kilethagam

3. Pothagam

4. Tharpagam

5. Santhigam

9. EZHU UDAL THATHUKKAL: (SEVEN SOMATIC COMPONENTS)

1. Saram

2. Senneer

3. Oon

4. Koluppu

5. Enbu

6. Moolai

7. Sukkilam/ suronitham

10. ENVAGAI THERVU:

I. NAADI: [Pulse Perception]

II.   SPARISAM: [Palpation]

III.   NAA: [Tongue]

IV.   NIRAM: [Complexion]

     1. Vadham

     2. Pitham

     3. Kabam

V.   MOZHI: [Voice]

     1. High Pitched

     2. Low Pitched

     3. Medium Pitched

VI.   VIZHI: [Eyes]

VII. MALAM: [Bowel Habits / Stools] Niram

     Irugal

     Ilagal

VIII. MOOTHIRAM [Urine Examination]

NEERKURI:

Niram Manam Edai Nurai Enjal

NEIKKURI

MODERN ASPECTS

EXAMINATION OF RESPIRATORY SYSTEM: Inspection:

1. Shape/ type of the chest:

2. Deformities of chest:

3. Respiratory movements:

4. Type of breathing:

5. Odema of chest wall:

6. Visible pulsations:

7. Distended veins over the chest wall:

8. Wasting:

Palpation:

1. Position of the trachea:

2. Apical impulse:

3. Local swelling:

4. Local tenderness:

5. Enlarged lymphnodes:

6. Vocal fremitus:

Percussion:

1. Over the clavicle:

2. Supra clavicular:

3. Infra clavicular:

4. Axillary:

5. Infra clavicular:

6. Supra clavicular:

7. Inter scapular:

8. Infra clavicular:

Auscultation:

1. Adventitious sounds: Rales:

   Rhonchi:

2. Pleural friction:

3. Vocal Resonance:

Other systems:

    1. Cardio vascular system:

    2. Gastro Intestinal system:

    3. Central Nervous system:

    4. Genito Urinary system

SIGNS AND SYMPTOMS:

S. No	Assessment	Before Treatment	After treatment (week)			
			I	II	III	IV
1.	Dyspnoea					
2.	Cough					
3.	Chest tightness					
4.	Wheezing					
5.	Rhinitis					
6.	Sneezing					
7.	Headache					
8.	Fever					
9.	Cyanosis					
10.	PEFR					

LABORATORY INVESTIGATIONS:

1. **Blood: TC: DC: ESR: Hb: Sugar: Cholesterol: Urea: Creatinine:**
   Urine: Albumin: Sugar: Deposits

2. **PEAK EXPIRATORY FLOW RATE**

3. **ABSOLUTE EOSINOPHIL COUNT**

4. X RAY CHEST PA VIEW CASE SUMMARY

FINAL DIAGNOSIS

MEDICINE:

SOMBU THEENEER- 15ML BD with warm water

MEDICAL ADVICE

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