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Comparative Pilot Study on "Peenisathiri" (Medicated Fumigation Wick) with and Without "Gowri Chinthamani Chenthooram" (Internal) In the Treatment of Kabha Peenisam (Sinusitis)

M. Suganthi[1], H. Vetha Merlin Kumari[*2], Karthika I[3], Shakila M.S[4], K. Manickavasakam[5], V. Banumathi[6]
[1.3,4]PG Scholars, Dept of Maruthuvam, National Institute of Siddha Chennai-47Affiliated to the TN DR M.G.R Medical University, Chennai-32 India
[2]Lecturer, Dept of Maruthuvam, National Institute of Siddha Chennai-47Affiliated to the TN DR M.G.R Medical University, Chennai-32 India
[4]Professor and Head of the Dept of Maruthuvam and Former Director, National Institute of Siddha Chennai-47Affiliated to the TN DR M.G.R Medical University, Chennai-32 India
[5]Director, National Institute of Siddha Chennai-47Affiliated to the TN DR M.G.R Medical University, Chennai-32 India

Original Research Article

***Corresponding author**
H. Vetha Merlin Kumari

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Abstract: In *siddha system* of medicine, diseases of nasal origin are 86. *Kabha Peenisam* is one among them. The signs and symptoms of *Kabha peenisam* mentioned in Siddha literature Yugi *vaithiya chinthamani* such as headache, lacrimation, nasal block, nasal itching, ear discharge, running nose, cough with expectoration, ageusia (absence of taste) may be correlated with SINUSITIS in modern medicine. According to the National Ambulatory Medical care survey (NAMCS) approximately 14 % of adults report having an episode of sinusitis each year and it is the fifth most common diagnosis for which antibiotics are prescribed accounting for 0.4 % of ambulatory diagnosis. Many formulations are being practiced in Siddha system for the treatment of Peenisam. One such external therapy is Peenisa thiri (Medicated fumigation wick). The ingredients present in the formulation are Piper longum.Linn (Thippili), Piper nigrum. Linn (Milagu), Curcuma aromatica. Linn (Manjal) and Tachyspermum ammi. Linn (Omum). Literature evidences had been identified for the Anti histamine activity in each ingredients of this formulations. When this formulation is subjected to pilot study in *Peenisam* (Sinusitis) patients it is found significant result in reducing clinical signs and symptoms of *Kabha peenisam* (Sinusitis)
Keywords: *Kabha Peenisam, Gowri chinthamani chenthooram, Peenisa thiri*, pilot study, *Siddha medicine*.

INTRODUCTION

Gowri chinthamani chenthooram and Peenisa thiri (Medicated fumigation wick) are said for the management of *Kabha Peenisam* (Sinusitis). The objective of the study is to compare the efficacy of *Peenisa thiri* (Medicated fumigation wick) with and without *Gowri chintamani chenthooram* in the treatment of *Kabha Peenisam*.

A well designed study protocol was approved by the Institutional Ethics Committee and the pilot study was conducted in the OPD / IPD of Ayothidass pandithar Hospital of National Institute of Siddha.

Based on the inclusion criteria 10 patients in Group 1 were treated with Peenisa *thiri* and 10 patients in Group 2 treated with *Gowri chinthamani chenthooram* and medicated fumigation wick. Informed consent was obtained from each patient. Medicated fumigation wick was administered to patients according to the severity of the symptoms and asked to use once in 3 days. 200 mg of *Gowri chinthamani chenthooram* with adjuvant *Thirikadugu chooranam* (500mg tablet) was administered orally after food twice a day for a period of 8 days and drug holiday was given from 9th to 16th day where the decoction of *Arugan kattai kudineer* was administered. Then again from 17th to 24th day the drug was administered and advised to follow the prescribed dietary regimen. All the data, laboratory findings and radiological findings were recorded in the Case report form of each patient. The clinical assessment was recorded once in 6 days.

Paired't' test was used to test the significance of treatment using before and after treatment data mainly on Clinical symptoms, Blood investigations (Absolute Eosinophil Count, Erythrocyte Sedimentation rate etc).The level of significance probability 0.05 was used to test the treatment difference and the values are statistically significant.

MATERIALS AND METHODS

The pilot study was conducted by well designed protocol, after obtaining the approval of the Institutional Ethical Committee (IEC) (NIS/IEC/10/2016-17/7-20.05.2016). Then the pilot study was registered in CTRI (Clinical Trial Registry - India). After that the enrolment of patients was started.

CTRI NO: CTRI/2018/04/013132

It is a Comparative Pilot Study on "*PEENISATHIRI"*(Medicated Fumigation Wick) with and without "*GOWRI CHINTHAMANI CHENTHOORAM*" (Internal) in the treatment of *KABHA PEENISAM (SINUSITIS*) conducted in Ayothidoss Pandithar Hospital OPD.NO:1 Dept of Maruthuvam (Medicine),National Institute of siddha, Tambaram Sanatorium, Chennai.

Subject selection

Patients reporting at the OPD of Ayothidoss Pandithar Hospital with symptoms of pain over the face, purulent nasal discharge, headache or heaviness of head, sneezing, fever, tooth ache, nasal block was subjected to screening test and documented by using screening proforma. After screening of 92 patients diagnosed as *kabha Peenisam* (sinusitis), 20 cases were selected to this study -10 patients in Group 1 were treated with Peenisa *thiri* and 10 patients in Group 2 treated with *Gowri chinthamani chenthooram* and medicated fumigation wick. Before enrolment into the trial the informed consent was obtained from all the study participants.

Inclusion criteria

- Age :18-60Yrs
- Sex – Both male & female
- The symptoms of pain over the face, purulent nasal discharge, and headache or heaviness of head, sneezing, fever, tooth ache, and nasal block.
- Patients willing to sign in the informed consent stating that he/she will conscientiously stick to the treatment during 24 days but can opt out of the trial of his/her own conscious discretion.
- Patients who are willing for radiological investigation (X-ray Paranasal sinuses) and provide blood, urine for lab investigation.

Exclusion criteria

- Bronchial asthma
- Chronic obstructive pulmonary disease
- Tuberculosis
- Diabetes mellitus
- Hypertension
- Cardiac diseases

Withdrawal criteria

Intolerance to the drug & development of adverse reactions during trial
Poor patient compliance & defaulters

Patient turned unwilling to continue in the course of treatment.
Increase in severity of symptoms.

Conduct of the study

All the patients were given unique registration card in which patient's Registration number of the study, Address, Phone number, and number etc. All the baseline data, vitals, clinical signs and symptoms of Sneezing, Pain over the face, Headache-Severe frontal, retro orbital pain, pain radiating to occipit, thick purulent nasal discharge, cough with expectoration, fever, heaviness of head while bending forward, tooth ache (most involving upper molar teeth) halitosis , lacrimation, nasal block, redness of eyes, burning sensation of nose, ageusia (absence of taste) and laboratory data(Haematology, biochemistry, lipid profile, LFT & RFT, Urine analysis, X ray para nasal sinuses and envagaithervugal) were recorded in the Case Report Form(CRF) before (ie., 0^{th} day),commencement of the trial.

The trial drug "*PEENISATHIRI*" (Medicated Fumigation Wick) with and without "*GOWRI CHINTHAMANI CHENTHOORAM*" (Internal) will be given continuously for 24 days. *Gowri chinthamani chenthooram* are administered from OPD drugs of Ayothidoss Pandithar Hospital, Chennai. Patient advised to take 200mg of *Gowri chinthamani chenthooram* (internal medicine) twice a day with *THIRIKADUGU CHOORANAM* (500 mg 2 tablets - 1gram for 8 days), drug holiday (9^{th} day to 16^{th} day) – Decoction of Arugan *kattai kudineer* was administered, followed as drug holiday, 17-24 th day drug administration. *PEENISA THIRI* (external medicine) for Fumigation - wick as needed (Evening only – 3 days once). Patients were adviced to visit the hospital once in 6 days. At each visit clinical assessment is done and prognosis is noted by investigator. Laboratory investigations & radiological investigations were also done at the end of the treatment.

Group 1: 5 cases (50%) came under 20-30 years of age group, 4 cases (40%) came under 31-40 years of age group and 1 case (10%) came under the age group 41-50.

Group 2: 2 cases (20%) came under 20-30 years of age group, 6 cases (60%) came under 31-40 years of age

group and 2 cases (20%) came under the age group 41-50.

Table-1: Observation and results-age group

Age group	Group 1		Group 2	
	Number of patients	percentage	Number of patients	Percentage
20-30	5	50%	2	20%
31-40	4	40%	6	60%
41-50	1	10%	2	20%

Table-2: Sex distribution

Groups	Patients	No of cases	Percentage
Group 1	Male	6	60%
	Female	4	40%
Group 2	Male	6	60%
	Female	4	40%

Among 2 groups, 6 cases (60 %) were Male and 4 cases (40%) were Female (Table-2).

Among 2 groups, 3 cases (30%) were cooli in group II, 2 cases (20%) were in IT field in group I & II, 1 case (10%) was civil engineer in group II, 1 case(10%) was supervisor in group I, 1 case(10%) was at Agricultural department in group I, 1 case(10%) was Service manager in group I, 2 cases(20%) were house wife in group I and 1 case(10%) in group II, 1 case(10%) was accountant in group II, 1 case(10%) was student in group II, 3 cases (30%) were self care workers in group I and 1 case(10%) in group II (Table-3).

Among 2 groups, 3(30%) cases were illiterate and 7(70%) cases were literate in Group 1 and Group 2 (Table-4).

Table-3: Occupational history

Occupation	Group I		Group II	
	No of cases	percentage	No of cases	percentage
Building workers /coolly	0	0	3	30%
IT	2	20%	2	20%
Civil engineer	0	0	1	10%
Supervisor	1	10%	0	0
Agricultural department	1	10%	0	0
Service manager	1	10%	0	0
House wife	2	20%	1	10%
Accountant	0	0	1	10%
Student	0	0	1	10%
Self-care workers	3	30%	1	10%

Table-4: Educational status

Groups	Education	No of cases	Percentage
Group 1	Illiterate	3	30%
	Literate	7	70 %
Group 2	Illiterate	3	30 %
	Literate	7	70%

Table-5: Marital status

Groups	Educational status	No of cases	Percentage
Group 1	Married	7	70%
	Unmarried	3	30%
Group 2	Married	8	80%
	Unmarried	2	20%

Among 2 groups, Group 1 -7(70%) cases were male and 3(30%) cases were unmarried. Group 2-8(80%) cases were married and 2(20%) cases were unmarried (Table-5).

Table-6: Economic status

Economic status	Group 1	Percentage	Group 2	Percentage
Poor	0	0	3	30%
Middle	10	100%	7	70%
Higher	0	0	0	0

Among 2 Groups, group 2 -3 cases(30%) were in poor economic status, Group 1-10(100%) cases and Group 2-7 cases (70%) were under middle class family.

All female cases were not yet attained menopause in group I & II.

Table-7: Menopausal status

Menopause	Group 1	Percentage	Group 2	Percentage
Not yet attained	4	40 %	4	40%
Attained	0	0	0	0

Table-8: Family history

Family history	Group 1	Percentage	Group 2	Percentage
Family history	1	10%	0	0%
No family history	9	90%	10	100%

Group 1-1 case (10%) had positive Family history of *kabha peenisam* (sinusitis), 9 cases (90%) in Group 1 and 10 (10%) cases in Group 2 had no positive Family history of sinusitis.

Among 2 groups, all cases (100%) were in non vegetarians.

Table-9: Food habits

Food habits	Group 1	Percentage	Group 2	Percentage
Non vegetarian	10	100 %	10	100%
vegetarian	0	0	0	0

Table-10: Duration of illness

Duration	Group 1	Percentage	Group 2	Percentage
1-6 months	6	60%	3	30%
6 months -1 yr	1	10 %	2	20%
1-2 yrs	1	10%	2	20%
2-3 yrs	1	10%	0	0%
3-4 yrs	0	0%	2	20%
4-5 yrs	1	10%	1	10%

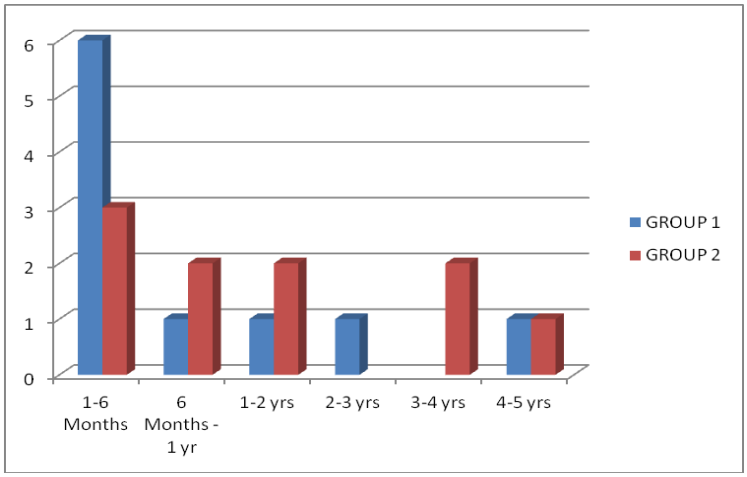

Fig-1

Among 2 groups, 6(60%) cases in Group 1 and 3(30%) cases in group 2 had symptoms within 6 months, 1(10%) case in group 1 and 2(20%) cases in group 2 were between 6 months to 1 year, 1 (10%)case in group 1 and 2 (20%)cases in group 2 were between 1 -2 years,1(10%) case in group 1 were between 2-3 yrs, 2(20%) cases in group 2 were between 3-4 years, 1(10%) case in group 1 and 1 (10%)case in group 2 were between 4-5 years.

Table-10: Kaalam

Kaalam	Group 1	Percentage	Group 2	Percentage
Munpanikaalam	9	90 %	7	70%
Pinpanikaalam	1	10%	3	30%

Among 2 Groups, 9 (90%) cases in Group 1 and 7(70%) cases in Group 2 were affected in Munpanikaalam, 1 case(10%) in Group 1 and 3 (30%) cases in Group 2 were affected in Pinpnikaalam.

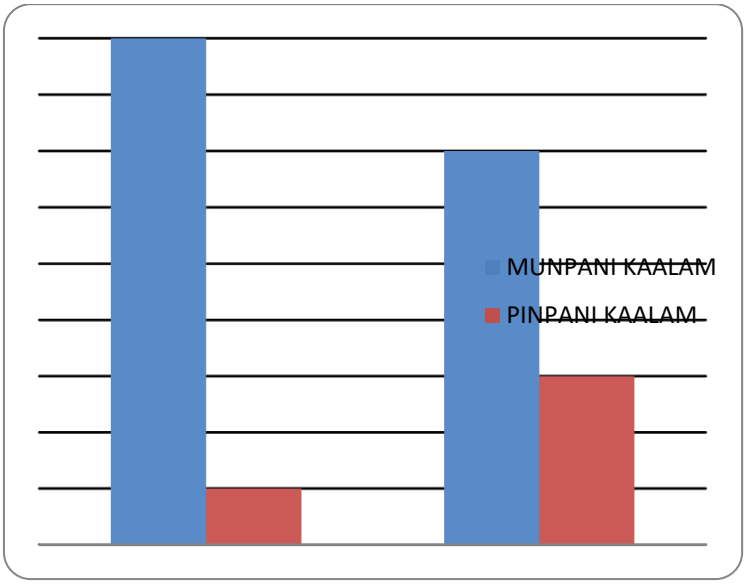

Fig-2

Table-11: Treatmental history

Treatmental history	Group I	Percentage	Group II	Percentage
	5	50%	7	70%

Among 2 groups, 5 cases(50%) in group I and 7 cases(70%) in group II had treatment for sinusitis

OUT COME

(i) Primary outcome Outcome is mainly assessed by clinical symptom
Scoring and laboratory findings

Patient condition: Mild symptom = Upto score 6
Moderate symptom = Upto score 12
Severe symptom = Upto score 18

Outcome:
Good = Any Grade to ≤ grade 2 or Reducing score is 10 or above
Moderate = Reducing score is 9 or below
Poor = No improvement or Deteriorative

Table-12

S.no	Lab & clinical symptoms	Nil	Mild	Moderate	Severe
01	X – ray	0	1	2	3
02	Rhinorrhea	0	1	2	3
03	Nasal obstruction	0	1	2	3
04	Sneezing	0	1	2	3
05	Head ache / facial pain	0	1	2	3
06	Post nasal dripping	0	1	2	3

Table-13: Clinical signs and symptoms

Group 1 patients	Before treatment score	After treatment score	Group 2- patients	Before treatment score	After treatment score
1	16	7	1	18	2
2	13	8	2	14	1
3	16	3	3	12	7
4	15	7	4	12	5
5	13	4	5	12	2
6	16	7	6	14	8
7	13	1	7	17	6
8	16	5	8	15	5
9	15	7	9	17	8
10	15	7	10	16	7

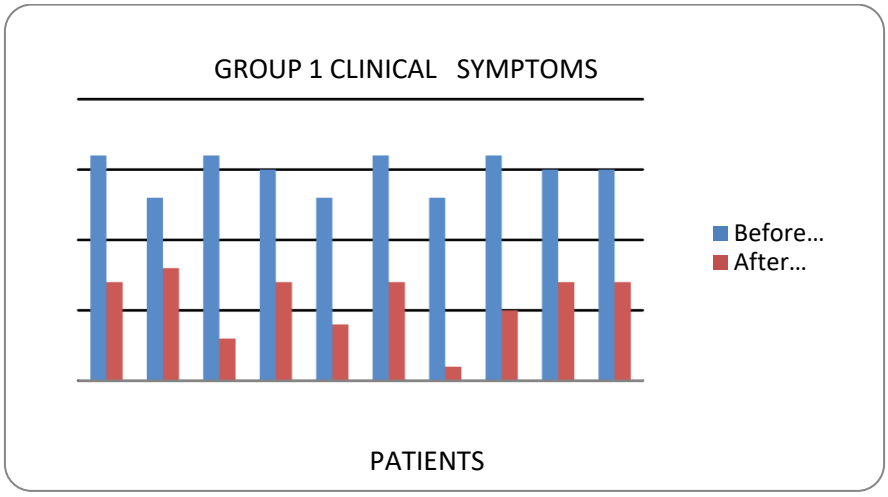

Fig-3

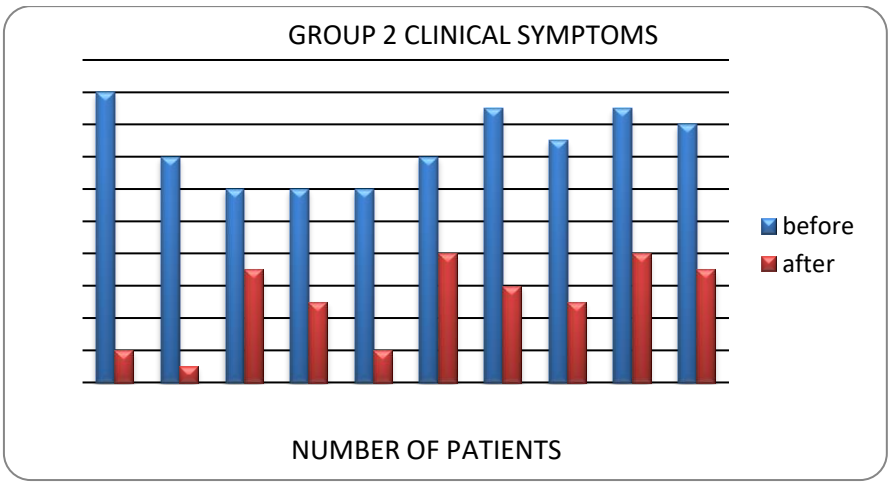

Fig-4

Table-14: Group 1 result

Group 1	Poor result	Moderate result	Good result
Before treatment	10	0	0
After treatment	0	6	4

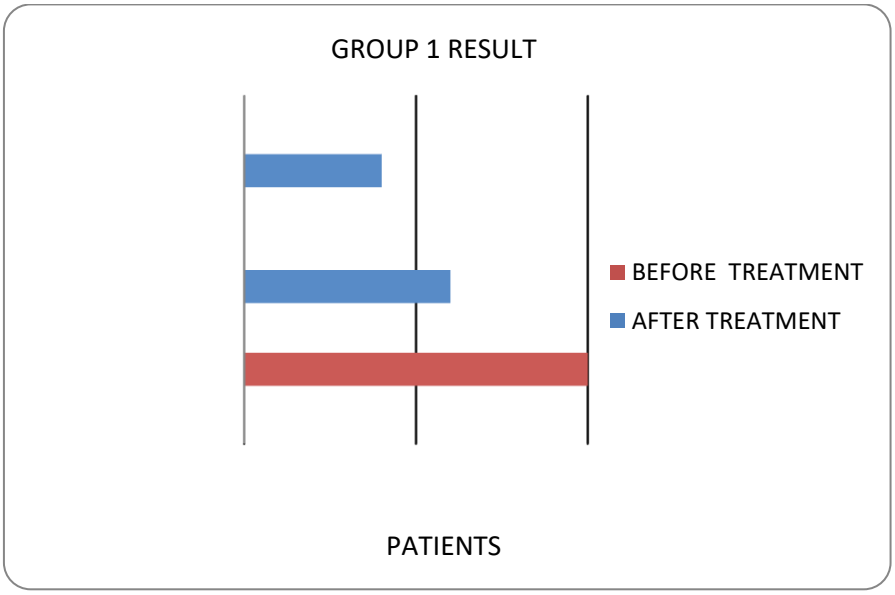

Fig-5

Table-15: Group 2 results

Group 2 result	Poor result	Moderate result	Good result
Before treatment	7	3	0
After treatment	0	5	5

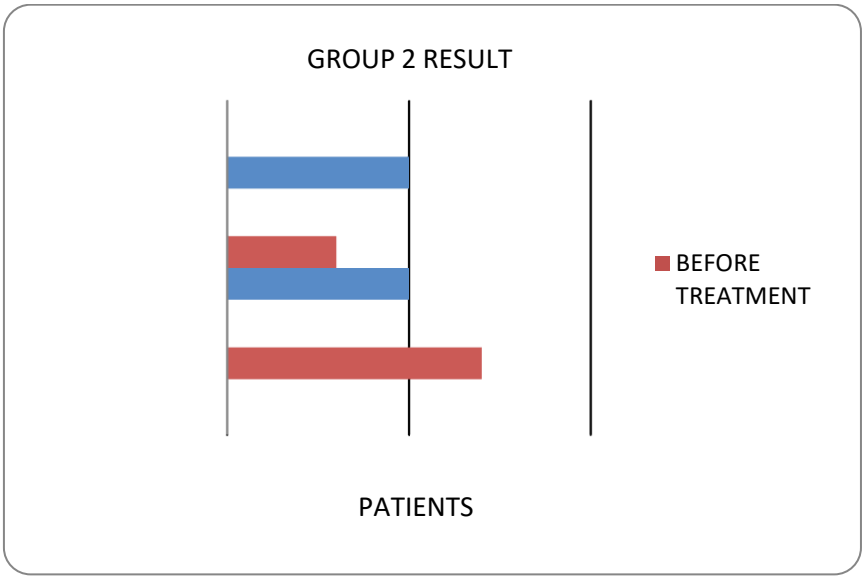

Fig-6

Table-16: Outcome inbetween 2 groups

Outcome	Group 1	Group 2
Good	4 (40%)	5(50%)
Moderate	6(60%)	5(50%)
Poor	0	0

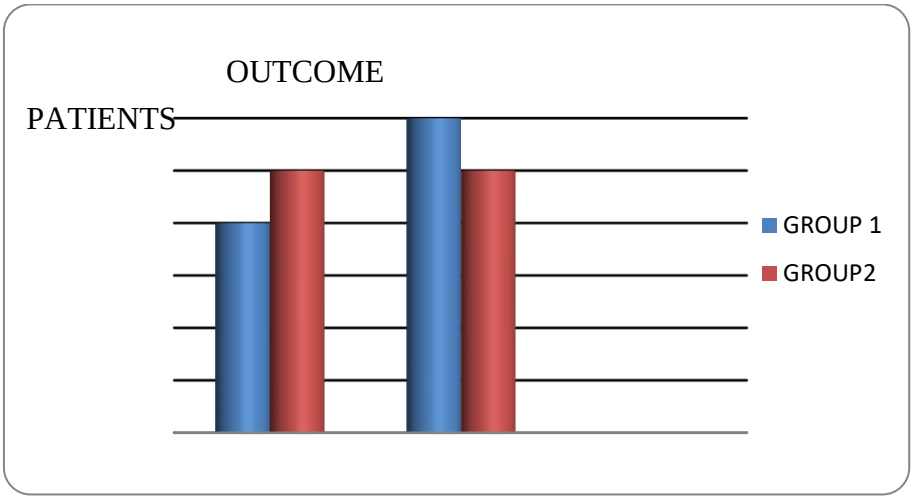

Fig-7

Observation

4 Cases (40%) in Group I and 5 cases (50%) in group II had good result and 6 cases (60%) in group I and 5 cases (50%) in group II had moderate result.

STATISTICAL ANALYSIS

All collected data were entered into computer using MS Excel software. The data entry was cross-checked manually with CRF. The data was analyzed using SPSS version 18.0 software. The probability value 0.05 was taken as significant level.

Table-17: Statistical significance effect of treatment

Parameters	Before/after	Sample	Mean±std	T value	P value
Clinical Symptoms	before after	20 20	14.75±1.80 5.35±2.39	15.22	0.0001(hs)
Absolute Eosinophil count	before after	20 20	395.35±277.75 209.25±130.42	4.54	0.0002(hs)
Erythrocyte Sedimentation rate 1 hr	before after	20 20	20.9±16.3 14.15±10.57	2.56	0.018(ms)
Erythrocyte Sedimentation rate Half hr	before after	20 20	10.4±8.35 6.85±5.89	2.72	0.013(ms)

HS-highly significant; MS-moderate significant

DISCUSSION

The main aim of the study is to compare the efficacy of *Peenisa thiri* (Medicated fumigation wick) with and without *Gowri chinthamani chenthuram* in the treatment of *Kabha Peenisam* (Sinusitis) in which there is derangement of *Pitha thathu* and *kabha thathu*.

Vatham, Pitham, Kabam the three vital humours (*uyir thathukkal*) are responsible for the physiological functions of *udal thathukkal* (7 body constituents).Life style modifications (Food and deeds, stress, mental and physical environmental) causes derangement of vital humours resulting in vitiation of *uyir thathukkal* called *mukkutram* (disease).

Pitham in human organism is nothing but heat as it possesses all the characteristics of external fire such as burning, boiling etc. It produces the internal heat necessary to maintain the integrity of the human body and any increase or decrease in this produces a simultaneous action in the human body.

Kapham supplies the body with moisture even as pitha furnishes it with heat and imparts stability and weight to the body. Its derangement causes excess of thirst, dull appetite, throwing out of phlegm etc.

Siddha literature *THERAN MARUTHUVA BHARATHAM* predicts the fact that we should choose medicines for diseases and not diseases for medicine.

Table-18: Statistical significans between two groups of treatment

Parameters	Group	Sample	Mean±std	T value	P value
Clinical symptoms before	1 2	10 10	14.8±1.31 14.7±2.26	0.120	0.905(ns)
Clinical symptoms after	1 2	10 10	5.6±2.27 5.1±2.60	0.45	0.65(ns)
Erythrocyte Sedimentation rateHalf hr before	1 2	10 10	12.2±10.21 8.6±5.96	0.96	0.34(ns)
Erythrocyte Sedimentation rate Half hr after	1 2	10 10	6.8±6.25 6.9±5.85	0.03	0.97(ns)
Erythrocyte Sedimentation rate 1 hr before	1 2	10 10	23.6±20.08 18.2±12.09	0.72	0.47(ns)
Erythrocyte Sedimentation rate 1 hr after	1 2	10 10	13.4±10.50 14.9±11.16	0.30	0.76(ns)
Absolute Eosinophil count Before	1 2	10 10	346.4±321.28 444.3±233.05	0.78	0.44(ns)
Absolute Eosinophil count After	1 2	10 10	207.6±150.82 210.9±114.72	0.055	0.95(ns)
White blood cells After	1 2	10 10	8193±1722.27 7374.6±1728.2	1.06	0.30(ns)

Siddha system of medicine has its unique perceptions and resultant methodologies for defining and treating human diseases. *Fumigation therapy* is one of the several treatment methods described in *Siddha* whereby fumes produced from defined drug formulations are inhaled by patients. This therapeutic procedure offers promising research opportunities from phyto chemical and ethno pharmacological viewpoints, however it remains under noticed. Considering these facts the review is primarily aimed at introducing *Siddha fumigation therapy* and discussing its scientific gaps and future challenges. *Siddha* recommends fumigation as a method of sterilization and therapeutic procedure for various human diseases including microbial infection and psychological disorders. However it has not gained much attention as prospective field with multiple research opportunities. It is necessary to have a detailed and systemic investigation in order to facilitate the identification of novel bioactive compounds and more effective drug administration methods.

Here we discuss the *fumigation therapy* for Sinusitis which helps in neutralizing deranged *Pitham and Kabham*. The ingredients present in the external medicine Piper longum. Linn (Thippili) possess Anti asthmatic activity, Anti-oxidant and analgesic activity [1].

Curcuma aromatica. Linn (Manjal) possesses Anti-inflammatory and Anti-oxidant activity [2].Tachyspermum ammi. Linn (Omum) possesses Anti-oxidant, Anti nociceptive and broncho dilating actions [3].

Piper nigrum. Linn (Milagu) possesses Anti-inflammatory and Anti-oxidant activity [4]. The ingredients of *Gowri chinthamani chenthooram*: Purified mercury, Purified sulphur, and borax dehydrated.

Gowri chinthamani chenthuram was evaluated for its acute and chronic toxicity studies. Acute toxicity studies at various dose levels did not reveal either mortality or any adverse effects. Study revealed a

maximum dosage of 640mg/100gm b.w. Chronic studies revealed minimum toxic effect with non-specific changes at 40 mg. Long term administration produced renal and hepatic changes at the dose of 160mg [5].

The drug showed significant Anti-oxidant activity [6]. The adjuvant Thirikadugu chooranam consists of Zingiber officinale.Linn (Chukku) consists of Anti-oxidant and Anti-inflammatory activity [7]. Piper longum.Linn (Thippili), Piper nigrum.Linn (Milagu) possess Anti asthmatic and Anti-inflammatory activity [1, 4].

The ingredients of the Adjuvant *Thirikadugu chooranam* possess *Veppa Veeriyam* (Hot potency) naturally and predominantly contains *Kaarpu suvai*(Pungent taste) and *Kaippu suvai* (Bitter taste) . Hence the trial drug expected to balance and rectify the deranged *pitham* and *kabham.*

Arugan kattai kudineer was given during drug holiday. The ingredients of *Arugan kattai kudineer*: Root of Cynodon dactylon and piper nigrum. They were made into decoction and administrated from 9th to 16 th day of trial period to prevent mercury toxicity.

DISCUSSION ON CASE STUDY

AGE

In this study , 5 cases (50%) in Group 1 and ,2 cases (20%) in Group 2 came under 20-30 years of age group,4 cases (40%) in Group 1 and 6 cases (60%) in group II came under 31-40 years of age group and 1 case(10%) in group I and 2 cases(20%) in group II came under the age group 41-50.

Inference

Among 2 groups, most of cases came under 31-40 years of age group. The mean age of patients was 34 years and 70% of patients were suffering from chronic maxillary sinusitis [8].

SEX

Among 2 groups, 6 cases (60 %) were Male and 4 cases (40%) were Female.

Inference

The prevalence was more in males. Highest prevalence in the third and fourth decades of life, with a male preponderance [9].

OCCUPATION

In this study, majority of cases- 3 cases (30%) were Building workers, 4 cases (40%) were IT field workers, 3 cases (30%) were house wife, 4 cases (40%) were self care workers

New Delhi, Cairo or Beijing, where people heat their houses with wood-burning stoves, and factories release pollutants into the air, suggests people are at higher risk of developing chronic sinus problems[10].

There were significantly increased PRs (prevalence ratios) of chronic rhinosinusitis in plant and machinery operators and assemblers, elementary occupations, crafts and related trade workers, and the unemployed [11].

SEASONAL CHANGES

Among 2 Groups, 9 cases (90%) in Group 1 and 7 cases (70%) in Group 2 were affected in *Munpanikaalam*, 1 case (10%) in Group 1 and 3 (30%) cases in Group 2 were affected in *Pinpanikaalam.* Seasonal exposure to cold air causes an increase in the incidence of URTI due to cooling of the nasal airway [12].

EDUCATIONAL STATUS

Among 2 groups, 3 cases (30%) were illiterate and 7 cases (70%) were literate in Group 1 and Group 2

MARRITAL STATUS

Among 2 groups, Group 1 -7(70%) cases were married and 3(30%) cases were unmarried Group 2-8(80%) cases were married and 2(20%) cases were unmarried.

ECONOMIC STATUS

Among 2 Groups, 3 cases (30%) were in poor economic status in group 2, 10 cases (100%) in Group 1 and 7 cases (70%) in Group 2 came under middle class family.

Sinusitis is closely related with the socioeconomic status and is more prevalent in lower middle and lower classes [8].

MENSTURAL HISTORY

All female cases were not yet attained menopause in group I & II

FAMILIAL HISTORY

1 case (10%) had positive Family history of kabha peenisam (sinusitis) in group I and 9 cases (90%) in Group 1 and 10 (10%) cases in Group 2 had no positive Family history of sinusitis. The study revealed that 20% of patients have positive family history of sinusitis [8].

FOOD HABITS

In this study, among 2 groups, all cases (100%) were in non-vegetarians

DURATION OF ILLNESS

Among 2 groups, 6(60%) cases in Group 1 and 3(30%) cases in group 2 had symptoms within 6 months, 1(10%) case in group 1 and 2(20%) cases in group 2 were between 6 months to 1 year, 1 (10%)case in group 1 and 2 (20%)cases in group 2 were between 1

-2 years,1(10%) case in group 1 were between 2-3 yrs, 2(20%) cases in group 2 were between 3-4 years, 1(10%) case in group 1 and 1 (10%)case in group 2 were between 4-5 years.

TREATMENTAL HISTORY

Among 2 groups, 5 cases(50%) in group I and 7 cases(70%) in group II had treatment for sinusitis.

OUTCOME

Before treatment 10 cases (100%) in group I and 7 cases(70%) came under poor result, after treatment 4 Cases (40%) in Group I and 5 cases (50%) in group II had good result and 6 cases (60%) in group I and 5 cases (50%) in group II had moderate result.

STATISTICAL SIGNIFICANCE EFFECT OF TREATMENT

The mean± standard deviation of clinical symptoms before and after treatment were 14.75±1.80 and 5.35±2.39 respectively which is statistically significant ($p<0.001$) The analysis revels that significant reduction of clinical symptoms with the trial drug i.e. there is 63.7% reduction in clinical symptoms compared to start of the treatment.

The mean± standard deviation of Absolute Eosinophil Count before and after treatment were 395.35±277.75 and 209.25±130.42 respectively which is statistically significant ($p<0.001$) The analysis revels that significant reduction of Absolute Eosinophil Count with the trial drug i.e. there is 47.07% reduction in Absolute Eosinophil Count compared to start of the treatment.

The mean ± standard deviation before treatment is 20.9±16.3 and after treatment is 14.15±10.57 for 1 hr. The analysis revels that there is 32.29% reduction in ESR 1 hr compared to start of the treatment.

The mean ± standard deviation before treatment is 10.4±8.35 and after treatment is 6.85±5.89 for half hr. The analysis revels that there is 34.13% reduction in ESR 1/2 hr compared to start of the treatment.

The statistical analysis reveals that there has been a moderate reduction in ESR value after treatment indicating the control over the inflammatory process of the disease.

Statistical significans between two groups of treatment

The mean ± standard deviation clinical symptoms of after treatment in group I is 5.6±2.27 and group II is 5.1±2.60. The analysis revels that among 2 groups, there was no significant changes after the treatment statistically.

The mean ± standard deviation Erythrocyte Sedimentation rate half hr after treatment in group I is 6.8±6.25 and group II is 6.9±5.85. The analysis revels that among 2 groups, there was no significant changes after the treatment statistically.

The mean ± standard deviation Erythrocyte Sedimentation rate half 1 hr after treatment in group I is 13.4±10.50 and group II is 14.9±11.16. The analysis revels that among 2 groups, there was no significant changes after the treatment statistically.

The mean ± standard deviation Absolute Eosinophil Count after treatment in group I is 207.6±150.82 and group II is 210.9±114.72. The analysis revels that among 2 groups, there was no significant changes after the treatment statistically.

The mean ± standard deviation white blood cells after treatment in group I is 8193±1722.27and group II is 7374.6±1728.2 The analysis revels that among 2 groups, there was no significant changes after the treatment statistically.

CONCLUSION

The results of the clinical trial indicates that the trail drug *GOWRI CHINTHAMANI CHENTHURAM AND PEENISA THIRI* is clinically effective, safe and also economical.

On Group 1 and Group 2 patients both the medicines showed reduction in clinical parameters. The mean± standard deviation of clinical symptoms before and after treatment were 14.75±1.80 and 5.35±2.39 respectively which is statistically significant ($p<0.001$) The analysis revels that significant reduction of clinical symptoms with the trial drug i.e. there is 63.7% reduction in clinical symptoms compared to start of the treatment.

But comparing group I and group II there was no significant changes after treatment. The mean ± standard deviation clinical symptoms of after treatment in group I is 5.6±2.27 and group II is 5.1±2.60.

Peenisa thiri play a major role as a main line fumigation therapy for preventive and curative aspects in *Peenisam* (Sinusitis). *Peenisa thiri* has been found economical, easy to perform without any harmful side effects. There were no adverse reactions complained during the trial period.

Because of the encourage clinical outcome, the study may be further carried out with the same drug in large number of cases.

REFERENCES

1. Zaveri M, Khandhar A, Patel S, Patel A. Chemistry and pharmacology of Piper longum L. International

journal of pharmaceutical sciences review and research. 2010 Nov;5(1):67-76.
2. Rikhab C. Srimalb, Industrial Toxicological Research Center, Lucknow, India, Multiple biological activities of curcumin: A short review, Volume 78, Issue 18, 27 March 2006, Pages 2081-2087.
3. Ranjan Bairwa, Trachyspermum ammi, Pharmacogn Rev. 2012 Jan-Jun; 6(11): 56–60.
4. PanelNisarAhmad, Biological role of Piper nigrum L. (Black pepper): A review, Volume 2, Issue 3, Supplement, 2012, Pages S1945-S1953, Asian Pacific Journal of Tropical Biomedicine.
5. Shanmugapriya.P, Toxicological Screening of Gowri Chinthamani Chendooram- A Siddha Metallic Preparation; Pharma Tutor; 2014; 2(9); 119-122.
6. Bharathidasan Ilango, Effect of a mercurial drug of siddha medicine on hematological, biochemical and antioxidant status in rats Article in Indian journal of traditional knowledge 17(3):480-484 • July 2018.
7. Stoilova, Albert krastanov, A Stoyanova , P Denev , SGargova Food chemistry 102(3) , 764-770 , 2007.
8. Abdul k. Dar, azad h. lone, demographic study of sinusitis in patients visiting govt. unani hospital srinagar and ayush centres in Kashmir.
9. Suresh S, Arumugam D, Zacharias G, Palaninathan S, Vishwanathan R, Venkatraman V. Prevalence and clinical profile of fungal rhinosinusitis. Allergy & Rhinology. 2016 Jun; 7(2):ar-2016.
10. Murray Ramanathan MD. Associate professor of otolaryngology - Air pollution may directly affect biology of upper airways to cause chronic sinus problems. http://www.hopkinsmedicine.org/news/media/releases/air_pollution_may_directly_cause_those_year_round_runny_noses_according_to_a_mouse_study.
11. Dong-Hee Koh MD. The relationship between chronic rhinosinusitis and occupation: The 1998, 2001, and 2005 Korea National health and nutrition examination survey (KNHANES) Volume 52, Issue 3 Pages: 179-269, American journal of industrial medicine –Incorporating Environmental and Occupational HealthMarch 2009 ,PMID no:19051236).
12. Johnston F. An Explanation for the Seasonality of Acute Upper Respiratory Tract Viral Infections Pages 183-191 | published online: 08 Jul 2009 Journal Acta Oto-Laryngologica Volume 122, 2002 - Issue 2.