Research Article

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PILOT STUDY ON EFFECTIVENESS OF SIDDHA MEDICINES SOMBU THEENEER (INTERNAL) AND PEENISATHIRKU THAILAM (EXTERNAL) IN THE MANAGEMENT OF PEENISAM (SINUSITIS)

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ABSTRACT

Background: Peenisam (sinusitis) is a widespread condition, and patients are visiting Ayothidass Pandithar Hospital, National Institute of Siddha, to manage this condition. The signs and symptoms of peenisam (sinusitis) are mentioned in Siddha literature Yugi vaithya chinthamani, such as lacrimation, nasal block, headache, rhinorrhea, cough, absence of taste, may be correlated with maxillary sinusitis in biomedicine. Objectives: To evaluate the clinical effectiveness of Siddha formulations Sombu theeneer (internal) and Peenisathirku thailam (external) in the management of sinusitis by using Adelaide Disease Severity Score (ADSS) and to observe changes in clinical lab parameters, total count, differential count, erythrocyte sedimentation rate, absolute eosinophil count and serum immunoglobulin E pre and post-treatment. Methods: An open Non-Randomised clinical trial with a sample size of 10 patients diagnosed with Peenisam within the age limit of 18-60 years. The approval was obtained from Institutional Ethical Committee for conducting this clinical study with the IEC No: (25/11/2021; NIS/IEC/2021/MP-3). It was registered prospectively in the Clinical Trail Registry of India (CTRI Reg No: CTRI/2022/01/051045). The trial drug Sombu theeneer (internal) 30 ml BD with water after food and Peenisathirku thailam (external) were given for 48 days and two months follow up without the trial drug. Results: Biostatistical reports of ADSS scores and lab investigations before and after treatment were statistically analysed using paired t-tests. There was a significant reduction in both the ADSS (p-value<0.001) and lab investigations like Erythrocyte sedimentation rate, Absolute eosinophil count and serum Immunoglobulin E levels (p-value <0.05). Conclusion: The trial drug therapeutically effectively treats Peenisam (sinusitis).

Keywords: Sombu theeneer, Peenisathirku thailam, Peenisam, Sinusitis, Siddha medicine.

INTRODUCTION

The mucosal inflammation of the paranasal sinuses may be an acute or chronic process. It is usually the maxillary sinus which gets involved. However, inflammation of all the sinuses is involved, resulting in pansinusitis. In maxillary sinusitis, the pain is felt in the cheeks below the eyes; it may be referred to the teeth or along the distribution of the superior orbital nerve. Pain is aggravated by stooping or coughing. In ethmoiditis, the pain is localised over the nasal bridge, inner canthus and behind the eye. In frontal sinusitis, the pain is localised over the forehead and the patient complaints of headache. The pain is severe in the morning and gradually subsides towards noon as the infected material drains from the sinus. In sphenoidal infection, the pain is usually referred to as the vertex or occiput. Inflammation of more than one sinus is marked by pain over all the sinuses. Besides the pain, other symptoms of acute sinusitis include nasal blockage and excessive mucopurulent nasal discharge. The X-ray examination of paranasal sinuses, occipitomental view (Water's view), helps reveal the condition of the sinuses. The sinuses appear hazy and may show a fluid level. CT sinuses are diagnostic[1].

Siddha perspective

Yugi Muni says sinusitis is clinically correlated with Peenisam or Mookadaipu Noi in Siddha literature. Intake of cold water, exposure to chillness, inhalation of smoke, harmful and offensive gases, insomnia, speaking in a loud voice, using contaminated water for a bath, suppression of 14 natural urges (particularly vomiting and tears), improper yoga practice, which increases the body heat are the triggering factors to cause this disease[2].

Sombu theeneer (internal) and Peenisathirku thailam (external) are specified for treating sinusitis[3,4]. The objectives of the study were to evaluate the clinical effectiveness of Sombu theeneer (internal) and Peenisathirku thailam (external) in the management of sinusitis by using Adelaide Disease Severity [5] and to observe changes in clinical lab parameters total count, differential count, erythrocyte sedimentation rate, absolute eosinophil count and serum immunoglobulin E pre- and post-treatment.

MATERIALS AND METHODS

The study was conducted with a well-defined protocol and case report forms after the approval of the Institutional Ethical

Committee (25/11/2021; NIS/IEC/2021/MP-3). It was registered prospectively in the Clinical Trial Registry of India (CTRI Reg No: CTRI/2022/01/051045).

Study methodology

Study design: Case series
Study place: OPD of Ayothidoss pandithar hospital, National Institute of Siddha, Tambaram Sanatorium, Chennai, Tamil Nadu, India.
Study period: 6 months
Sample size: 10 patients

Inclusion criteria

- Age: 18-60 years.
- Men and Women, Transgender.
- The patient, willing to give informed consent.
- The patient having headaches, sneezing, nasal congestion, rhinorrhea, postnasal drip, facial pain, and anosmia.
- The patient having pain and tenderness over para nasal sinuses.
- The patient having radiological evidence of sinusitis.
- The patient who had Adelaide Disease Severity Score above 12.

Exclusion criteria

- K/C/O Migraine.
- The patients who were not willing to participate in the study will be excluded.

Withdrawal criteria

- Intolerance to the drug and development of any profound adverse effect during the trial.
- Poor patient compliance and defaulters.
- The patient, unwilling to continue the course of clinical study.

Criteria for assessment

The outcome was mainly assessed by reducing clinical symptoms after the treatment using an Adelaide Disease severity score below 12 and observing changes in clinical laboratory parameters.

Table 1: Adelaide Disease severity score

Symptoms	No symptoms	Mild	Moderate	Severe	Extreme
Nasal obstruction	1	2	3	4	5
Rhinorrhea	1	2	3	4	5
Postnasal drip	1	2	3	4	5
Headache or facial pain	1	2	3	4	5
Sense of smell	1	2	3	4	5

Out of 25	
0-5	No symptoms
6-10	Mild
11-15	Moderate
16-20	Severe
21-25	Extreme

Case description

Written consent was obtained from each patient for publishing their clinical data through patient information sheets and consent forms in a regional language.

Case 1
Op no: 241961
Name: X1
Age/sex: 28/F
A 28 years old female patient visited our hospital to treat sinusitis with complaints of recurrent sneezing, rhinorrhea, nasal congestion and headache for six months. Though she consulted many physicians, she got temporary relief only. After quitting those medicines, symptoms came again.
History of past illness: Not a known case of Diabetes mellitus, hypertension, tuberculosis, chronic kidney disease, migraine.
The clinical findings based on Adelaide Disease Severity Score for sinusitis were 17, along with laboratory investigation and radiological views of the participant's paranasal sinus (PNS) confirmed the diagnosis of bilateral maxillary sinusitis.

Case 2
Op no: 241821
Name: X2
Age/sex: 33/F
Complaints and duration: Recurrent sneezing, rhinorrhea, nasal congestion and headache for three months.
History of past illness: Not a known case of Diabetes mellitus, hypertension, tuberculosis, chronic kidney disease, migraine.
The clinical findings based on Adelaide Disease Severity Score for sinusitis were 21, along with radiological views of the participant's paranasal sinus (PNS) confirmed the diagnosis of bilateral maxillary sinusitis with right turbinate hypertrophy.

Case 3
Op no: 216833
Name: X3
Age/sex: 29/F
Complaints and duration: Recurrent sneezing, rhinorrhea, nasal congestion and headache for eight months.
History of past illness: Not a known case of Diabetes mellitus, hypertension, tuberculosis, chronic kidney disease, migraine.
The clinical findings based on Adelaide Disease Severity Score for sinusitis were 16, along with radiological views of the participant's paranasal sinus (PNS) confirmed the diagnosis of bilateral maxillary sinusitis and frontal and ethmoidal sinusitis.

Case 4
Op no: 243970
Name: X4
Age/sex: 40/M
Complaints and duration: Recurrent sneezing, rhinorrhea, nasal congestion and headache for three months.
History of past illness: Not a known case of Diabetes mellitus, hypertension, tuberculosis, chronic kidney disease, migraine.
Personal habits: Smoker since 8 years(one pack/week)
The clinical findings based on Adelaide Disease Severity Score for sinusitis were 16, and radiological views of the participant's paranasal sinus (PNS) confirmed the diagnosis of right maxillary

sinusitis with right turbinate hypertrophy.

Case 5
Op no: 240969
Name: X5
Age/sex: 40/F
Complaints and duration: Recurrent sneezing, rhinorrhea, nasal congestion and headache for three months.
History of past illness: Not a known case of Diabetes mellitus, hypertension, tuberculosis, chronic kidney disease, migraine.
The clinical findings based on Adelaide Disease Severity Score for sinusitis were 17, along with radiological views of the participant's paranasal sinus (PNS) confirmed the diagnosis of bilateral maxillary sinusitis with right turbinate hypertrophy.

Case 6
Op no: 241340
Name: X6
Age/sex: 25/M
Complaints and duration: Recurrent sneezing, rhinorrhea, nasal congestion and headache for one year.
History of past illness: Not a known case of Diabetes mellitus, hypertension, tuberculosis, chronic kidney disease, migraine.
The clinical findings based on Adelaide Disease Severity Score for sinusitis were 19, along with radiological views of the participant's paranasal sinus (PNS) confirmed the diagnosis of bilateral maxillary sinusitis with left turbinate hypertrophy.

Case 7
Op no: 192845
Name: X7
Age/sex: 28/F
Complaints and duration: Recurrent sneezing, rhinorrhea, nasal congestion and headache for three months.
History of past illness: Not a known case of Diabetes mellitus, hypertension, tuberculosis, chronic kidney disease, migraine.
The clinical findings based on Adelaide Disease Severity Score for sinusitis were 20, along with radiological views of the participant's paranasal sinus (PNS) confirmed the right maxillary sinusitis diagnosis.

Case 8
Op no: 193606
Name: X8
Age/sex: 40/F
Complaints and duration: Recurrent sneezing, rhinorrhea, nasal congestion and headache for three months.
History of past illness: Not a known case of Diabetes mellitus, hypertension, tuberculosis, chronic kidney disease, migraine.
The clinical findings based on Adelaide Disease Severity Score for sinusitis were 18, along with radiological views of the participant's paranasal sinus (PNS) confirmed the diagnosis of left maxillary sinusitis.

Case 9
Op no: 246428
Name: X9
Age/sex: 46/M
Complaints and duration: Recurrent sneezing, rhinorrhea, nasal congestion and headache for ten months.
History of past illness: Not a known case of Diabetes mellitus, hypertension, tuberculosis, chronic kidney disease, migraine.
The clinical findings based on Adelaide Disease Severity Score for sinusitis were 23, and radiological views of the participant's paranasal sinus (PNS) confirmed the right maxillary sinusitis diagnosis.

Case 10
Op no: 246864
Name: X10
Age/sex: 48/M
Complaints and duration: Recurrent sneezing, rhinorrhea, nasal congestion and headache for ten months.
History of past illness: Not a known case of Diabetes mellitus, hypertension, tuberculosis, chronic kidney disease, migraine.
The clinical findings based on Adelaide Disease Severity Score for sinusitis were 23, and radiological views of the participant's paranasal sinus (PNS) confirmed the diagnosis of bilateral maxillary and frontal sinusitis.

Table 2:Interventions

Drugs	Dosage	Ingredients	Botanical name	Ratio
Sombu theeneer (internal)	30 ml with an equal quantity of water twice a day daily after food for 48 days[6]	Sombu Water	*Pimpinella anisum* Linn	560 gm (2 ser) 10.7 litres (1 padhaku)
Peenisathirku thailam (external)	External use for an oil bath, once in three days[7]	Notchi juice Gingelly oil Eerulli	*Vitex negundo* Linn *Sesamum indicum* Linn *Allium cepa* Linn	1.34 L (1 padi) 1.34 L (1 padi) 70 gm (2 sirangai alavu)[8]

OBSERVATIONS AND RESULTS

For the clinical trial, 10 patients were selected and treated in OPD Maruthuvam, Ayothidoss Pandithar Hospital, National Institute of Siddha, Chennai, Tamil Nadu, India. Results were observed for the following criteria.

Gender Distribution: Among 10 cases, the disease's prevalence was higher in females (6 cases, 60%). (Graph 1)

Age Distribution: From selected 10 cases, 4 patients (40%) were 21-30 years, another 4 patients (40%) were 31-40 years, and 2 patients (20%) were 41-50 years. (Graph 2)

Diet habit: Among the 10 cases, 60% (6 cases) were non-vegetarian and 40% (4 cases) were vegetarian. (Graph 3)

Udal Thathukkal-Vatham (influenced by air and space): among 10 cases, before treatment, all of them were affected with pranan (due to recurrent sneezing), samanan (due to pranan affected), kirukaran (due to recurrent sneezing), 10% of cases were affected with abanan (due to constipation), viyanan (due to tiredness). After treatment, 10% of cases were affected with pranan, samanan 20% of cases were affected with aran. (Graph 4)

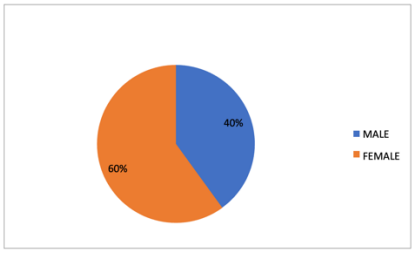
Udal Thathukkal-Pitham (influenced by fire and water): Among 10 cases, 40% of patients were affected with Aalosaga pitham (due to itching and watery discharge from the eyes) before treatment. After treatment, only 20% of patients were affected with Aalosagapitham. (Graph 5)

Udal Thathukkal-Kabam (influenced by water and earth): Among 10 cases, 100% of cases were affected with avalambagam (due to recurrent sneezing, rhinorrhea, nasal congestion, headache, anosmia), and 30% of cases were affected with

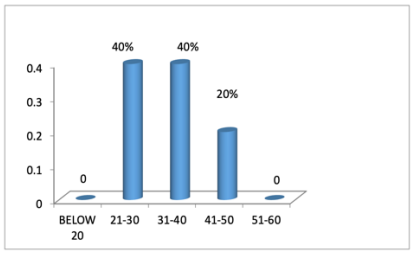
tharpagam (watery discharge from eyes) in before treatment. After treatment, 30% of patients were affected with avalambagam and 10% with tharpagam. (Graph 6)

Udal kattugal (body constituents): Among 10 cases, 100% of patients were affected with saaram (due to the physical and mental tiredness), 100% of patients were affected with senneer (due to the abnormal blood investigations like TC, DC, ESR, AEC, serum IgE) in before treatment. After treatment, 30% of patients were affected with saaram and 20% of cases were affected with senneer. (Graph 7)

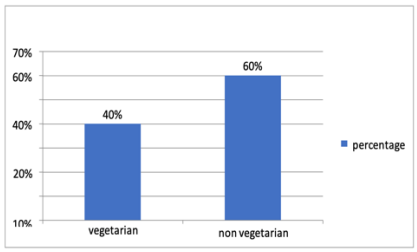
Envagai Thervugal (Siddha diagnostic methods): Among 10 cases, 20% of patients were affected with naa (due to dryness of tongue) and vizhi (due to itching and watery discharge from eyes), 10% were affected with mozhi (due to breathlessness) and malam (due to constipation) in before treatment. After treatment, 10% of patients were affected with vizhi, naa and mozhi. (Graph 8)



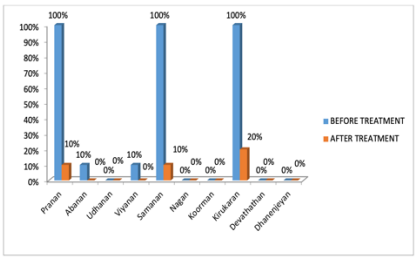
Graph 1: Gender Distribution



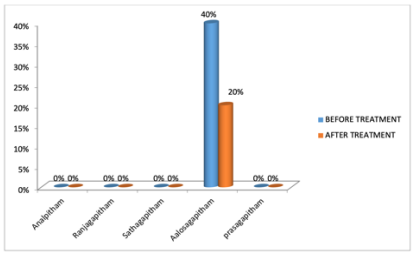
Graph 2: Age Distribution



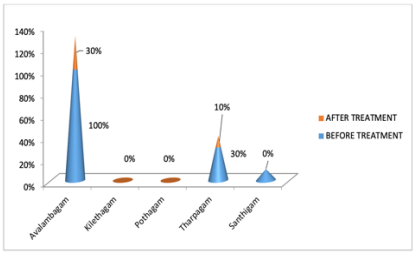
Graph 3: Diet habit



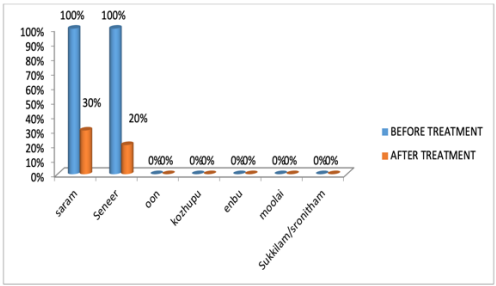
Graph 4: Udal Thathukkal-Vatham (influenced by air and space)



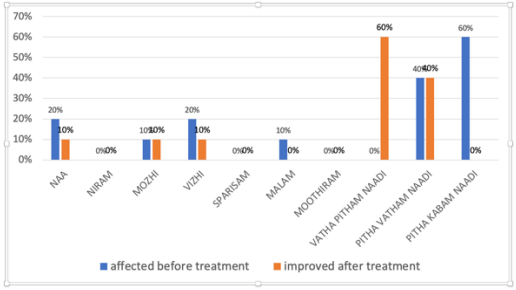
Graph 5: Udal Thathukkal-Pitham (influenced by fire and water)



Graph 6: Udal Thathukkal-Kabam (influenced by water and earth)



Graph 7: Udal kattugal (body constituents)



Graph 8: Envagai Thervugal (Siddha diagnostic methods)

Table 3: Neikuri (an antique method of urine examination based on the distribution of oil drops in urine), Before and After treatment

Neikuri	Before treatment		After treatment	
	Number of cases	Percentage	Number of cases	Percentage
Vatha Neer	5	50%	6	60%
Pitha Neer	2	20%	2	20%
Kaba Neer	3	30%	2	20%

PRIMARY OUTCOME

Table 4: Adelaide Disease Severity Score: Before and After Treatment

	Before Treatment						After Treatment					
OP NO	Nasal obstruction	Rhinorrhea	Postnasaldrip	Headache/ facial pain	Sense of smell	Total score	Nasal obstruction	Rhinorrhea	Postnasal drip	Headache/ facial pain	Sense of smell	Total score
241961	4	4	3	4	2	17	1	2	2	1	1	7
241821	5	5	4	4	3	21	3	2	2	2	1	10
216833	4	3	3	4	2	16	1	1	1	1	1	5
243970	4	4	3	3	2	16	2	2	2	2	1	9
240969	5	4	3	3	2	17	2	2	2	2	1	9
241340	4	4	4	4	3	19	2	2	1	2	1	8
192845	4	4	4	4	4	20	3	1	2	2	1	9
193606	4	4	3	4	3	18	2	2	2	1	1	8
246428	4	4	4	4	3	23	2	2	1	2	1	10
246864	4	5	4	4	3	20	1	1	3	2	2	9

Reduction in scores, moving forward from high levels to low levels, from the above Adelaide Disease Severity Score,

- In (7 cases) 70% - of symptoms reduced well, and those patients were improved from severe to mild.
- In (2 cases), 20% - of symptoms reduced well, and those patients were improved from extreme to mild.
- In (1 case) 10% - symptoms were completely relieved. (Table 4)

Null hypothesis: There is no statistical difference in Adelaide Disease Severity Score before and after treatment.

Alternate Hypothesis: A statistically significant difference exists in Adelaide Disease Severity Score beforeand after treatment.

Since the P value is less than 0.001, a statistically highly significant difference exists on the Adelaide Disease Severity Score. (Table 5)

Since the p-value is less than 0.05, we reject the Null hypothesis that there is a statistical difference in the parameters before and after treatment. (Table 8)

Table 5: Statistical significance effect of treatment

Score	Before mean	After mean	Standard deviation	t value	p-value
ADSS	18.7	8.4	1.7	19.1	<0.001

SECONDARY OUTCOME

Table 6: Observation of clinical laboratory investigations, Before treatment

OPNO.	Total WBC count (Cells/µl)	Differential Count					ESR (mm) 1/2 hour	ESR (mm) 1 hour	AEC (cells/cu.mm)	IgE (UI/ml)
		P	L	M	E	B				
241961	8870	57	30	7	6	0	6	12	532	672.1
241821	9000	51	31	10	8	0	12	24	728	252.6
216833	9070	50	40	5	5	0	14	28	430	873.7
243970	9040	59	26	9	6	0	3	5	542	44.2
240969	7500	66	27	7	7	0	8	14	211	739.6
241340	7400	57	32	2	9	0	12	24	877	260
192845	8330	50	32	7	11	0	4	8	910	614.1
193606	7320	53	37	6	4	0	13	25	450	150
246428	8330	43	45	5	7	0	6	12	580	1400.4
246864	8500	45	38	8	5	0	5	10	450	950

Table 7: Observation of clinical laboratory investigations, After treatment

OPNO.	Total WBC count (Cells/µl)	Differential Count					ESR (mm) 1/2 hour	ESR (mm) 1 hour	AEC (cells/cu.mm)	IgE (UI/ml)
		P	L	M	E	B				
241961	8000	50	28	5	5	0	5	10	500	550.1
241821	8000	49	28	7	5	0	10	22	600	250
216833	8900	50	38	4	4	0	6	12	250	600
243970	7500	45	23	6	4	0	3	4	350	43.1
240969	5500	55	23	4	3	0	4	8	180	500
241340	6500	49	28	2	4	0	10	18	650	220
192845	8000	48	30	6	9	0	4	8	890	600
193606	6900	48	30	5	3	0	10	20	400	148
246428	7800	40	41	5	6	0	5	10	570	1153.3
246864	8000	40	38	7	4	0	5	9	398	800

Table 8: Statistical significance effect of treatment in laboratory investigations

		Before mean	After mean	Standard deviation	t value	p-value
Total WBC Count		8336	7510	573.5697	-4554	0.001378
Differential Count	P	53.1	47.4	4.3729	-4.122	0.00259
	L	33.8	30.7	1.8529	-5.2906	0.005
	M	6.6	5.1	1.1785	-4.0249	0.002996
	E	6.8	4.7	1.4491	-4.5826	0.001323
ESR 1/2 hour		8.3	6.2	2.4698	-2.6888	0.02485
ESR 1 hour		16.2	12.1	4.7011	-2.758	0.02219
AEC		571	478.8	81.5527	-3.5751	0.005976
IgE		595.7	486.4	112.191	-3.0785	0.01317

Table 9: Observations of Erythrocyte sedimentation rate, Absolute eosinophil count and Serum Immunoglobulin E values, Before and After Treatment

OP. NO	ESR (mm) 1/2 hour		ESR (mm) 1 hour		AEC (cells/cu.mm)		IgE (UI/ml)	
	Before	After	Before	After	Before	After	Before	After
241961	6	5	12	10	532	500	672.1	550.1
241821	12	10	24	22	728	600	252.6	250
216833	14	6	28	12	430	250	873.7	600
243970	3	3	5	4	542	350	44.2	43.1
240969	8	4	14	8	211	180	739.6	500
241340	12	10	24	18	877	650	260	220
192845	4	4	8	8	910	890	614.1	600
193606	13	10	25	20	450	400	150	148
246428	6	5	12	10	580	570	1400.4	1153.3
246864	5	5	10	9	450	398	950	800

The erythrocyte sedimentation rate increased in 1 case (10%) before and significantly reduced after treatment.

Absolute eosinophil counts AEC increased in 9 cases (90%) before treatment and significantly reduced in all cases after treatment.

Serum Immunoglobulin E increased in 8 cases (80%) before treatment and significantly reduced in all cases after treatment.

DISCUSSION

Based on Siddha literature, *Pimpenella anisum* Linn *(*sombu) plays a vital role in the management of sinusitis[9]. It has an acrid with a sweet taste and hot potency, which neutralise the kabam humour (fluid of the body and represents the control and stability of the organism). It reduces the signs and symptoms of sinusitis in the Siddha system of medicine[9]. It has anti-inflammatory, carminative, and stomachic activity and also plays a vital role in the management of sinusitis[10]. *Vitex negundo* Linn (nochi) has antimicrobial, anti-histamine, anti-inflammatory, analgesic, astringent and anti-tumour activity[11]. *Allium cepa* Linn (Eerulli) has antimicrobial, antioxidant, anti-inflammatory, anti-allergic and immune modulatory activities[12]. In laboratory investigations, the erythrocyte sedimentation rate was increased in 1 case (10%) before and significantly reduced after treatment. The absolute eosinophil count was increased in 9 cases (90%) before treatment and significantly reduced in all cases after treatment. Serum Immunoglobulin E was increased in 8 cases (80%) before treatment and significantly reduced in all cases after treatment. Since the p-value is less than 0.05, there is a statistical difference in the mean value of the parameters before and after treatment. In Adelaide Disease Severity Score, (7 cases) 70% - symptoms reduced well and those patients were improved from severe to mild; in (2 cases) 20% - symptoms reduced well, those patients were improved from extreme to mild level and in (1 case) 10% - symptoms were completely relieved. Since the P value is less than 0.001, a statistically highly significant difference exists on the Adelaide Disease Severity Score (ADSS).

CONCLUSION

The trial drugs provided statistically significant results ($P < 0.001$) on comparing the Adelaide Disease Severity Score before and after treatment, particularly in nasal obstruction, rhinorrhea, postnasal drip, headache, and sense of smell. The trial drugs effectively lowered the erythrocyte sedimentation rate, absolute eosinophil count and serum Immunoglobulin E levels within the treatment period of 48 days. There were no adverse drug reactions reported during the trial period. Because of the encouraging clinical outcome, the study may be further carried out with the same drug, “Sombu theeneer (internal) and Peenisathirku thailam (external)”, in a larger clinical population.

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