Research Article

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AN OPEN NON-RANDOMIZED CLINICAL TRIAL TO EVALUATE THE EFFECTIVENESS OF SIDDHA FORMULATION THOOTHUVALAI NEI IN THE MANAGEMENT OF SWASAKAASAM (BRONCHIAL ASTHMA)

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ABSTRACT

Background: Bronchial Asthma (Swasakaasam) is a widespread condition, and patients are visiting Ayothidoss Pandithar Hospital, National Institute of Siddha to manage this condition. Bronchial asthma is a heterogeneous pulmonary disorder characterized by recurrent episodes of cough, breathlessness and wheezing, which may resolve spontaneously or after the use of bronchodilator medication. This research article focuses on 10 cases of Bronchial Asthma (Swasakaasam) treated with Siddha Sastric herbal formulation Thoothuvalai Nei. Objective: To assess the therapeutic effectiveness of siddha formulation "Thoothuvalai nei" in the management of Swasakaasam patients by using Pulmonary function test, to observe the changes in clinical symptoms by Asthma control questionnaire and to evaluate the clinical lab parameters such as IgE, AEC, ESR before and after treatment. Methods: This clinical trial was conducted after getting IRRB and institutional Ethical Committee clearance (IEC NO.12/07/2023; NIS/24/IEC/2023/MP/41) and the clinical trial was also registered in CTRI (CTRI/2023/09/057541) Totally 25 patients were screened by using inclusion and exclusion criteria. Among these, the clinical trial was done in total 10 patients diagnosed as Swasakaasam within the age limit of 18-60 years. The trial drug Thoothuvalai nei 4ml with hot water, two times a day, after food were given once in 7 days for 48 days. The clinical improvement was documented by using Asthma control questionnaire. Results: FEV1(L) value, Serum IgE, AEC, ESR and Asthma control questionnaire before and after treatment were statistically analysed using Paired T test. There was a significant reduction in Serum IgE (P value-0.020), AEC (P value-0.002), ESR (P value-0.001) and Asthma control questionnaire (p value<0.05) and significant improvement in FEV1 value (Pvalue-0.028). "Thoothuvalai Nei" plays significant role in reducing the symptoms among the patients with Swasakaasam.

Keywords: Swasakaasam, Bronchial Asthma, Thoothuvalai nei, Siddha formulation.

INTRODUCTION

Asthma is a clinical syndrome to denote any form of dyspnoea of expiratory type occurring in paroxysms. True or bronchial asthma is paroxysmal in nature and often seen in patients of neuropathic inheritance. The nature of this expiratory dyspnoea has been described to excessive vagal discharges as a result of peripheral irritation, caused by inhalation of sensitising agents, or ingestion of sensitising food, by sensitisation with bacterial protein or under the influence of any psychosomatic cause (emotion); the last one often acts as a secondary exciting factor.

Asthma is a disorder characterized by increased responsiveness of the airways to various stimuli as manifested by episodes of wheezing and increased resistance to expiratory air flow. The stimuli vary and include antigens, infection, air pollutants, respiratory irritants, exercise, and emotional factors. In asthmatic patients, the lungs are voluminous and emphysematous. Plugs of mucus in the bronchi and bronchioles contribute greatly to the respiratory difficulty and distress. There is emphysema with formation of bullae due to extreme strain on the part of the pulmonary tissue.

Striking feature in many cases is the great hyaline thickening of the basement membrane of the bronchial mucosa. The walls are infiltrated with chronic inflammatory cells, mostly eosinophils and a large number of lymphocytes. The mucus secretion contains Crusschmann's spirals and Char cot-Leyden crystals. In the stage of emphysema, the walls of many of the alveoli are seen ruptured due to over distension of alveoli.

Yugi Muni says Bronchial asthma is clinically correlated with Swasakaasam in Siddha literature. Exposure to cold weather, over strain in hot climate, in-taking of cold and hot foods, singing/speaking in high pitched voice, irritants caused by following dust, mud, lime etc..., inhalation of pleasant/irritable odour are the triggering factors to cause this disease. Thoothuvalai nei (internal) are specified for treating Bronchial asthma. The objectives of the study were to evaluate the clinical effectiveness of Thoothuvalai nei (internal) in the management of Bronchial asthma by using Pulmonary Function Test, Asthma Control Questionnaire, and to observe the 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 in Ayothidoss Pandithar Hospital, National Institute of Siddha. This clinical trial was conducted after getting IRRB and institutional Ethical Committee clearance (IEC NO.12/07/2023; NIS/24/IEC/2023/MP/41) and the clinical trial was also registered in CTRI (CTRI/2023/09/057541). Totally 25 patients were screened by using inclusion and exclusion criteria. Among these, the clinical trial was done in total 10 patients diagnosed as Swasakaasam within the age limit of 18-60 years. The trial drug Thoothuvalai nei 4 ml with hot water, two times a day, after food were given once in 7 days for 48 days.

The ingredients of the trial drug are

Vernacular Name	Botanical Name	Quantity	Parts used
Thoothuvalai Ver	*Solanum trilobatum*	120 gm	Root
Neermulli Ver	*Hygrophila auriculata*	120 gm	Root
Kandangkathiriver	*Solanum surattense*	120 gm	Root
Adathodai Ver	*Justicia beddomei*	120 gm	Root
Siru Kanjori Ver	*Tragia involucrate*	120 gm	Root
Milagu	*Piper nigrum*	120 gm	Dried fruit
Thipilli	*Piper longum*	120 gm	Dried fruit
Kadukkai Thol	*Terminalia chebula*	120 gm	Dried fruit flesh
Peru Kanjori Ver	*Tragia involucrate*	120 gm	Root
Thaneer	Water	24 liters	-
Pasum Paal	Cow's milk	3 kg	-
Pasu Nei	Cow's ghee	3 kg	-
Chukku	*Zingiber officinale*	30 gm	Rhizome
Milagu	*Piper nigrum*	30 gm	Dried fruit
Thipilli	*Piper longum*	30 gm	Dried fruit
Kadukai	*Terminalia chebula*	30 gm	Dried fruit flesh
Nellikai	*Phyllanthus emblica*	30 gm	Dried fruit flesh
Thaanrikai	*Terminalia bellirica*	30 gm	Dried fruit flesh
Thaleesam	*Abies spectabilis*	30 gm	Leaves
Akirakaaram	*Anacyclus Pyrethrum*	30 gm	Root
Vaaividangam	*Embelia ribes*	30 gm	Dried berry
Seeragam	*Cuminum cyminum*	30 gm	Dried seed
Koshtam	*Costus speciosus*	30 gm	Root
Omam	*Trachyspermum roxburghianum*	30 gm	Dried fruit
Vaal Milagu	*Piper Cubeba*	30 gm	Dried fruit
Citrarathai	*Alpinia officinarum*	30 gm	Root
Perarathai	*Alpinia galanga*	30 gm	Root
Ellam	*Elettaria cardamomum*	30 gm	Rhizome
Kirambu	*Syzygium aromaticum*	30 gm	Dried flower
Saathikai	*Myristica fragrans*	30 gm	Dried fruit flesh
Saathipatri	*Myristica fragrans*	30 gm	Dried husk

Method of Preparation

Make coarse powder of first 9 drugs and put them in water, reduce it to 1.5 liters by boiling, add ghee to this decoction. Grind the other drugs well with cow's milk. And boil it well and filter.

Dispensing

The trial medicine was purchased from a well reputed and GMP certified Pharma IMPCOPS (Indian medical practitioners Co-operative pharmacy and stores Ltd). 56 ml of Thoothuvalai Nei was dispensed in airtight container and were given to patients once in 7 days for 48 days.

RESULTS

The clinical study was conducted on bronchial asthma patients with the trial medicine "Thoothuvalai nei" which was carried out in OPD of Maruthuvam Department, National Institute of Siddha, chennai-47. A total number of 10 patients were treated with the trial medicine for 48 days. Both clinical and pathological assessment were carried out on the basis of siddha and modern aspects before and after treatment. Among 10 cases, Swasakaasam was found to be high in in female 7 cases (70%) when compared to male (Chart 1). Different age group were included in this study, among 10 cases the maximum age distribution of Swasakaasam was under 31-40 age - 6 cases (60%) (Chart 2). Out of 10 cases, 5 cases (50%) are unemployed, 4 cases (40%) are doing professional works, and 1 case (10%) is a daily wager (Chart 3). Out of 10 patients, 8 cases (80%) were non vegetarian and only 2 cases (20%) were vegetarian (Chart 4). The incidence of Swasakaasam was found to be high in patients taking non vegetarian diet. All of the 10 cases (100%) have no family history of bronchial asthma. (Table 1). Out of 10 cases, 1 case (10%) had bronchial asthma for 6 months - 1 year, 2 cases (20%) had bronchial asthma for less than 6 months, 2 cases (20%) had bronchial asthma for 1-2 years, 4 cases (40%) had bronchial asthma for 2-3 years and 1 case (10%) had bronchial asthma for 3-4 years (Chart 5). Out of 10 cases 6 cases (60%) are Kapha thegi, 3 cases (30%) are in Vatha thegi and 1 case (10%) is thontha udal (Chart 6). Out of 10 cases, 5 cases (50%) were from neithal nilam, 4 cases (40%) were from marutham nilam and 1 case (10%) were from kurunji nilam (Chart 7). Among 10 patients, 6 cases (60%) patients were affected in the season of Kaarkaalam (Chart 8). Majority of Swasakaasam cases were recorded on Kaar kalam (Avani, Puratasi) which is the rainy season. The chillness during rainy season aggravates in the body which is the main cause of Swasakaasam. In Swasakaasam, out of 10 patients Saram, seneer were affected in 80% of the cases, Kozhuppu, Enbu were affected in 30% of the cases. So, majority of the cases Saram and seneer were affected (Table 2). In Swasakaasam patients, Pranan, Udhanan, Samanan were affected in all patients (100%), Kirukaran and Abanan affected in 30% of the cases and Viyanan was affected in (10%) Naagan, Koorman,

Devadhathan, and Dhananjayan were not affected (Chart 9). Among 10 cases, Analakam (30% cases), Ranjagam (50% cases), Sathagam (70% cases) were affected. Prasagam and Alosagam were not affected. In Swasakaasam, Sathagam and Ranjagam were affected in most of the patients (Chart 10). Out of 10 cases, Avalambagam 10 cases (100%) were affected, Kilethagam 3 cases (30%) and Santhigam 2 cases (20%) were affected. Bothagam and Tharpagam were not affected before and after treatment. In Swasakaasam, Avalambagam were affected in most of the cases (100%) (Chart 11). ESR (Erythrocyte Sedimentation Rate), Serum Ig E and AEC (Absolute eosinophil count) were raised in before treatment and after treatment, it was moderately reduced. Absolute eosinophil count and Serum IgE, ESR investigations exist with significant difference in before and after Treatment (Table 5) (Chart 15-17). Before treatment 10 patients had abnormal Fev1 value, after treatment seven patients got good results, two patients got moderate results, and one patient got mild improvement (Table 3) (Chart 14).

Since the P value $P<0.05$ is highly significant. So, there was mild improvement in signs & symptoms among the patients for the treatment of Swasakaasam (Table 4).

Table 1: Family history

Family History	No. of Patients	Percentage %
Yes	0	0
No	10	100

Table 2: Udal thathukkal

Udal Thathukkal	Before treatment				After treatment			
	Affected		Normal		Affected		Normal	
	No. of cases	%	No. of cases	%	No. of cases	%	No. of cases	%
Saram	8	80%	2	20%	0	0	10	100%
Seneer	8	80%	2	20%	0	0%	10	100%
Oon	0	0%	10	10%	0	0%	10	100%
Kozhuppu	3	30%	7	70%	0	0%	10	100%
Enbu	3	30%	7	70%	3	30%	7	70%
Moolai	0	0%	10	10%	0	0%	10	100%
Sukkilam / Suronitham	0	0%	0	0%	0	0%	0	0%

Table 3: Primary Outcome Pulmonary Function Test

PFT-FEV1%	
Before	After
68	69
71	96
72	81
70	81
74	63
53	50
66	91
80	95
71	83
51	61

Table 4: Statistical Analysis of PFT

Paired T-test				
Variable	Pre treatment (Mean ± S.D)	Post treatmen (Mean ± S.D)	T-value	P-Value
PFT-FEV1	67.6 ± 9.03	77 ± 15.61	-2.609	0.028

$p<0.05$- Significant, Otherwise not significant

Table 5: Secondary Outcome

				ESR (mm)			
Serum IgE (IU/ml)		AEC (cells/micro liter)		1/2 hour		1 hour	
Before	After	Before	After	Before	After	Before	After
595.01	719	662	516	8	5	20	10
1782	765	562	382	5	4	10	9
423	403	307	240	8	5	18	10
423	354	94	80	9	5	20	15
1177	812	387	216	36	20	16	8
1490	980	1058	728	11	9	30	27
1643	643	651	353	8	5	28	19
566	402	439	313	12	5	24	12
2263	1111	539	500	8	6	14	10
484	419	253	169	18	16	26	24

Table 6: Statistical Analysis of secondary outcome

Paired T-test				
Variable	Pre treatment (Mean ± S.D)	Post treatment (Mean ± S.D)	T-value	P-Value
Serum Ige	1084.6 ± 675.32	660.8 ± 264.16	2.836	0.020
AEC	495.2 ± 267.73	349.7 ± 191.79	4.407	0.002
ESR 1/2 hour (mm)	12.3 ± 9.03	8 ± 5.52	3.074	0.013
ESR 1 hour (mm)	20.6 ± 6.4	14.4 ± 6.72	5.291	0.001

p<0.05- Significant, Otherwise not significant

Asthma Control Questionnaire

Table 7: Wilcoxon Signed Ranks Test

Variable		N	Mean Rank	Sum of Ranks	Test Value	P-Value
How often were you woken by your asthma during night? (after - before)	Negative Ranks	7	4.86	34.00	-2.263	0.024
	Positive Ranks	1	2.00	2.00		
	Ties	2				
	Total	10				
How bad were your asthma symptoms when you woke up in the morning? (after - before)	Negative Ranks	8	5.38	43.00	-2.461	0.014
	Positive Ranks	1	2.00	2.00		
	Ties	1				
	Total	10				
How limited were you in your activities because of your asthma? (after - before)	Negative Ranks	8	5.25	42.00	-2.333	0.02
	Positive Ranks	1	3.00	3.00		
	Ties	1				
	Total	10				
How much shortness of breath did you experience because of your asthma? (after - before)	Negative Ranks	8	4.50	36.00	-2.636	0.008
	Positive Ranks	0	0.00	0.00		
	Ties	2				
	Total	10				
How much of the time did you wheeze? (after - before)	Negative Ranks	9	5.00	45.00	-2.687	0.007
	Positive Ranks	0	0.00	0.00		
	Ties	1				
	Total	10				
How many puffs of short-acting bronchodilator have you used each day? (after - before)	Negative Ranks	8	4.50	36.00	-2.714	0.007
	Positive Ranks	0	0.00	0.00		
	Ties	2				
	Total	10				

Table 8: Wilcoxon Signed Ranks Test

Variable		N	Mean Rank	Sum of Ranks	Test Value	P-Value
Cough With or without Expectoration (after - before)	Negative Ranks	0	0.00	0.00	-2.714	0.007
	Positive Ranks	8	4.50	36.00		
	Ties	2				
	Total	10				
Wheezing (after - before)	Negative Ranks	0	0.00	0.00	-2.251	0.024
	Positive Ranks	6	3.50	21.00		
	Ties	4				
	Total	10				
Dyspnoea (after - before)	Negative Ranks	0	0.00	0.00	-2.530	0.011
	Positive Ranks	7	4.00	28.00		
	Ties	3				
	Total	10				
Tightness of chest (after - before)	Negative Ranks	0	0.00	0.00	-2.000	**0.046**
	Positive Ranks	4	2.50	10.00		
	Ties	6				
	Total	10				
H/o Wheezing min. 2 episodes per week (after - before)	Negative Ranks	0	0.00	0.00	-3.000	**0.003**
	Positive Ranks	9	5.00	45.00		
	Ties	1				
	Total	10				

P<0.05 Significant, Otherwise not significant

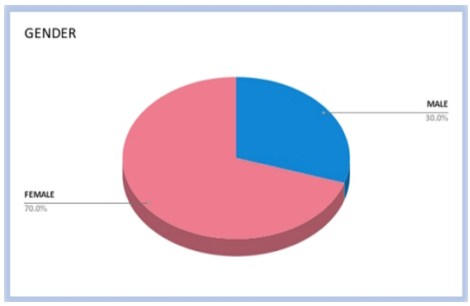

Chart 1: Gender

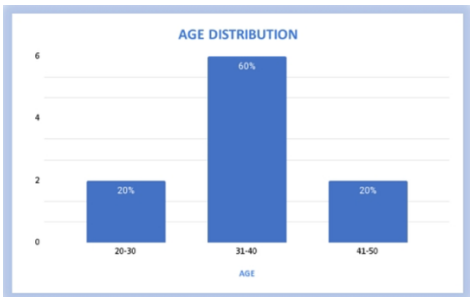

Chart 2: Age

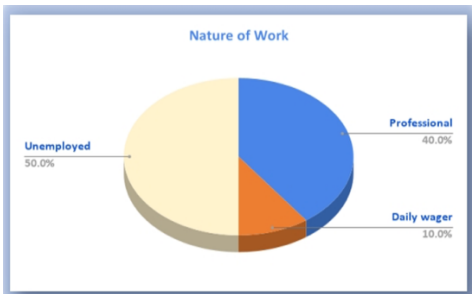

Chart 3: Nature of Work

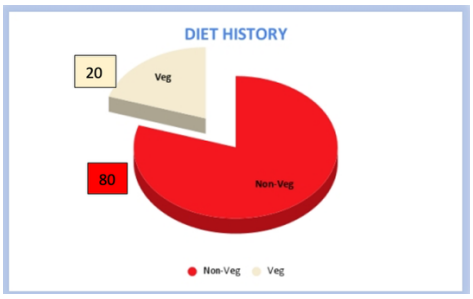

Chart 4: Diet

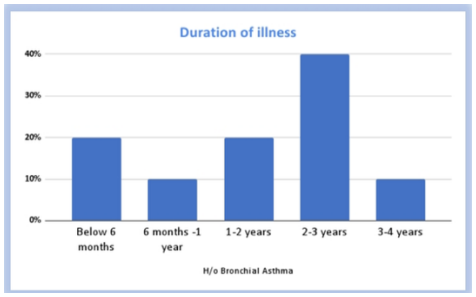

Chart 5: Duration of Illness

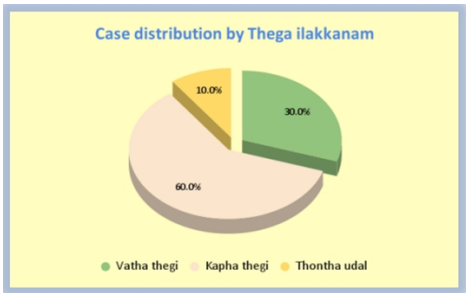

Chart 6: Thega ilakkanam

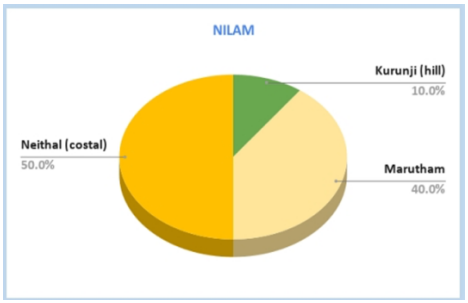

Chart 7: Nilam

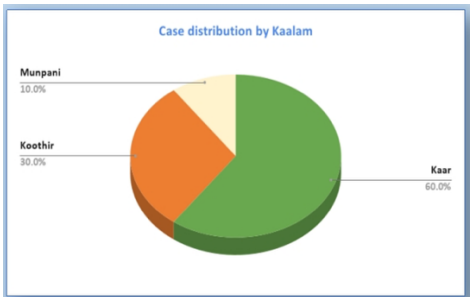

Chart 8: Kaalam

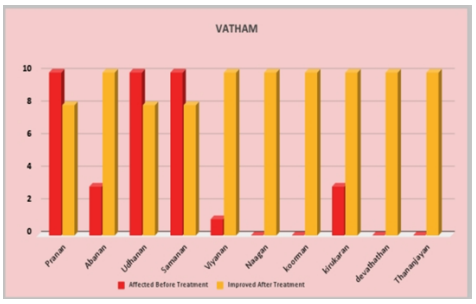

Chart 9: Uyir Thathukkal Vatham

Chart 10: Pitham

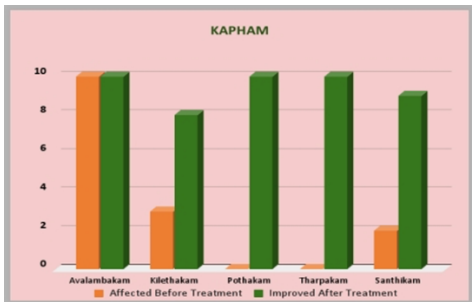

Chart 11: Kapham

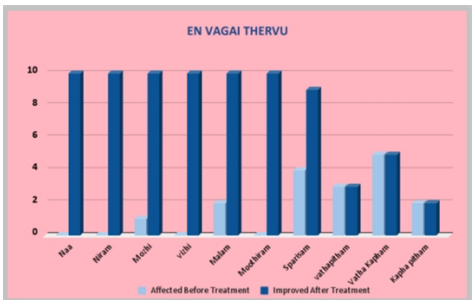

Chart 12: Envagai thervu

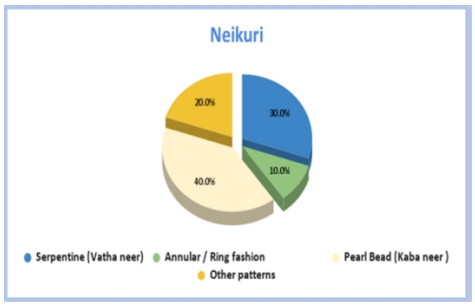

Chart 13: Neikuri

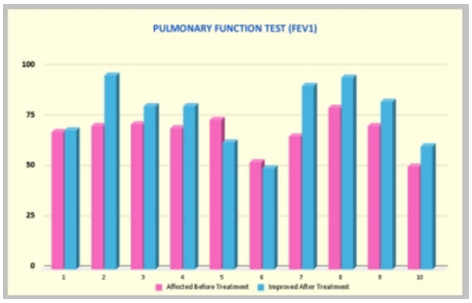

Chart 14: Pulmonary Function Test

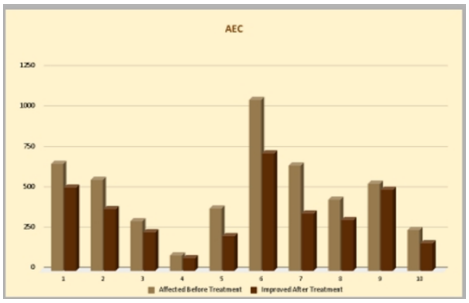

Chart 15: Absolute eosinophil count

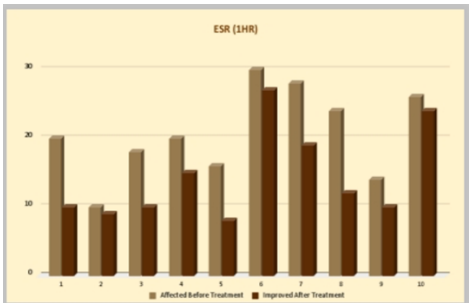

Chart 16: Erythrocyte Sedimentation Rate

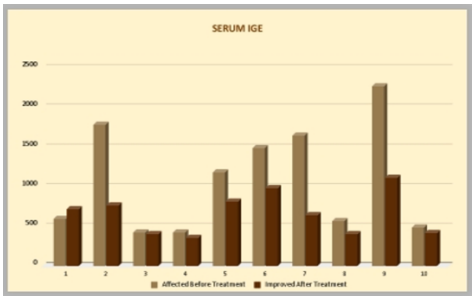

Chart 17: Serum Immunoglobulin E

DISCUSSION

Based on Siddha literature 'Agathiyar Vaidya Rathina Churukkam 360' Thoothuvalai Nei plays a vital role in the management of Swasakaasam. This disease occurs mostly in chill climate; this study reveals that the incidence of Swasakaasam is high during Kaarkaalam. Kapham is dominant in the body during kaarkaalam, to balance this Kapham all the patients were asked to take Veppa veeriyam diet as a prevention. Most of the ingredients present in this polyherbal formulation (Thoothuvalai nei) has pungent taste and hot potency which neutralizes the Kapha and Vatha humour. In Thoothuvalai Nei, the ingredients such as *Solanum trilobatum, Hygrophila auriculata, Solanum surattense, Justicia beddomei, Tragia involucrate, Piper nigrum, Piper longum, Terminalia chebula,* and *Tragia involucrate* are present in four-fold increased proportion than other drugs and these drugs have anti-inflammatory, antioxidant, antihistamine activity, bronchodilator, anti-asthmatic and expectorant activities. Some studies on *Solanum trilobatum* have suggested that its bioactive compounds such as alkaloids, flavonoids and saponins may play a major role in reducing airway inflammation and improving lung function. This study also reveals that administration of Thoothuvalai Nei has reduced the frequency of asthma attacks, improved respiratory function and decreased the usage of other conventional asthma medications like inhalers and

corticosteroids. Besides this, they also have the potency to act in Kaasam disorders.

In Erythrocyte Sedimentation Rate, there is a significant reduction in 6 cases (60%), moderate reduction in 3 cases (30%) and mild reduction in 1 case (10%) (P value - 0.001). In Absolute Eosinophil Count, there is a significant reduction in 5 cases (50%), moderate reduction in 3 cases (30%) and mild reduction in 2 cases (20%) (P value - 0.002). In Serum IgE, there is a significant reduction in 5 cases (50%), moderate reduction in 2 cases (20%) and mild reduction in 2 cases (20%) (P value - 0.020) (Table 5-6).

There is a reduction in ACQ scores from all patients in (30%) 3 cases, symptoms were well controlled, in (30%) 3 cases, symptoms were reduced from poor to mild. In (40%) 4 cases, symptoms were reduced from moderate to mild. (P value <0.05). Before treatment 10 patients (100%) had abnormal Fev1(%) value, after treatment 6 patients (60%) got good results, 2 patients (20%) got moderate results, and 2 patients (20%) has no improvement (P value - 0.028) (Table 7-8).

Of the 10 cases, 5 cases were on inhalers at the onset of the treatment, the frequency of usage of the inhaler was gradually decreased and withdrawn after 3 weeks. So it is a very effective drug in the management of Swasakaasam. The regular practice of pranayama and yoga therapies such as trikonasana and salabasana helps to strengthen the immune system and improves the function of lungs, patients with bronchial asthma were advised to do the above yoga poses and pranayama every day.

CONCLUSION

In Siddha literature, there are lot of medicine but this "Thoothuvalai Nei" Plays a significant role in Bronchial Asthma as a bronchodilator. There was a significant reduction in the symptoms and laboratory investigation. i.e., dyspnoea, cough with or without expectoration, rhinitis, sneezing, wheeze, and tightness of chest. As per PFT (Fev1) value among 10 cases, 7 cases (70%) showed good improvement (Fev1 value increased). Majority of the Swasakaasam (Bronchial asthma) cases proven the effectiveness of Thoothuvalai Nei. In the pulmonary function test, statistically significant improvement was observed with the significant (p value - 0.028). The statistically significant improvement was also observed symptomatically in asthma control questionnaire with the significant (p value < 0.05). Thoothuvalai Nei was therapeutically effective in lowering the erythrocyte sedimentation rate (p value - 0.001), absolute eosinophil count (p value - 0.002) and Serum IgE levels (p value - 0.020) within the treatment period. The bio statistical report of the clinical trial significant P value (P < 0.05) and concluded that the treatment was effective and significant. The results of the clinical trial indicate that the trial drug is clinically effective in bronchial asthma. No adverse effects were reported during the course of treatment. This study of Swasakaasam with the evaluation of trial medicine "Thoothuvalai Nei" plays significant role in reducing the symptoms among the patients with Swasakaasam. So, the study may be undertaken with same medicine in a large number of cases, and it may throw new lights for the treatment of Swasakaasam.

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