

PRE CLINICAL AND CLINICAL STUDY ON SWASAKASAM (BRONCHIAL ASTHMA) AND THE DRUG OF CHOICE IS THUTHUVALAYATHY CHOORANAM

Banu.G¹, *Nalini Sofia.H², Vetha Merlin Kumari .H², Manickavasakam.K²

¹Siddha physician, Pune, ²Department of Maruthumam, National Institute of Siddha, Chennai.

*Corresponding Author Email: dr.h.nalinisofia@gmail.com

ABSTRACT

This is an open clinical trial conducted in OPD/IPD of Ayothidoss pandithar Hospital of National Institute of Siddha Chennai-47. 40 patients diagnosed as Swasakasam (Bronchial asthma) were enrolled for this study to estimate the efficacy of Thuthuvalayathychooranam a herbomineral Siddha formulation. The study was conducted in accordance with the standard study protocol approved by the Institutional Ethics Committee. Informed consent was obtained from each patient before study initiation. 1.5gm of Thuthuvalayathy Chooranam was administered internally twice a day with honey for a period of 24 days and advised to follow the prescribed dietary regimen. All the baseline data, Laboratory investigations before (0th day) and after treatment (24th day) and clinical assessment once in 7 days were recorded in the prescribed Case Report Form of each patient. All the patients were put under observation for 2 months follow up period without the trial drug treatment. Paired 't' test was used to test the significance of treatment using before and after treatment data on PEFR, Clinical symptoms, Eosinophil and ESR and Grading of asthma. The level of significance probability 0.05 was used to test the treatment difference and the values are statistically significant.

KEY WORDS

Clinical trial, Siddha medicine, Bronchial asthma, Thuthuvalayathy Chooranam, National Institute of Siddha

INTRODUCTION

Siddha system is one of the ancient systems of medicine in India. Siddha system of medicine doesn't consider treatment and prevention separately. The main aim of this system is prevention of disease as it is well said that "Prevention is better than cure." Siddha system based on five elements, 96 thathuvam and three life factors vatha, pitha and kapha. They are the three fundamental principles and essential factors in the composition of human body. In all tissue of the body they exist in different ratio. The three life factor vatha, pitha, kaba, represent the five basic element or Bhuthas.

- Vatha consist of vali and vinn (air and ether)
- Pitham consists of Thee (fire)
- Kabam consists of mann and neer (earth and water)

They all persist in the body in subtle form. There appearance in the body is felt by their special characteristic features and their function in the body. When these three life factors get deranged due to extrinsic and intrinsic factors like diet and habit they bring about disease peculiar to their influence.

One among the 18 Siddhars, Yugi Munivar, says Swasakasam is a disease condition contributed by the following sign and symptoms such as severe cough with or without expectoration, Expiration is like a hiss of a serpent, frequent hemming, sense of heat in both nostrils, Hoarseness of voice, indigestion, flatulence which may be co-related to the disease condition "Bronchial Asthma" in modern science.

Bronchial asthma is a very common disease in the society due to increasing exposure to air pollution and

western life style. It is common in both sex but more prevalent among boys, while during adolescence and adulthood, it affects girls and women more. The prevalence of bronchial asthma has increased significantly since the 1970s. About 300 million people worldwide have asthma and by 2025 it has been estimated that a further 100 million will be affected. In India, it is estimated that 57,000 deaths were attributed to Bronchial Asthma in 2004(WHO 2004) and it was seen as one of the leading cause of morbidity and mortality in rural India (Smith 2000). In 2009 Bronchial asthma caused 250,000 deaths globally.

In order to specify the importance and prevention of this disease, GINA (Global Initiative for Asthma) sponsors World Asthma Day held each year on the 1st Tuesday of month of May to create awareness and graded asthma severity as intermittent, mild, moderate and severe persistent based on the symptoms.

So there is a noticeable increase in health care burden for asthma in several area of the world to change in it epidemiology and symptoms. Since other system of medicine use long term of steroid drug for Bronchial Asthma it is need for hour to explore siddha drug formulations to avoid complication produced by steroid drug. So Author has intended to evaluate the efficacy of the Siddha formulation Thuthuvalayathy chooranam for Swasakasam (Bronchial asthma). The ingredient of this drug said to possess expectorant, stimulant, carminative, antispasmodic action, immune modulator, broncho dilator, anti-oxidant, anti-inflammatory, anti-histamine actions and cost effective treatment.

MATERIALS AND METHOD

The clinical study was conducted in accordance with standard protocol after obtaining the approval of the Institutional Ethical Committee (IEC) (NIS/IEC/2011/3/01 – 24/12/2011). It is an Open Clinical Trial conducted in Ayothidoss Pandithar Hospital OPD.NO:1 Dept of Maruthumam (Medicine), National Institute of Siddha, Tambaram sanatorium, Chennai-47.

Subject selection

As and when patients reporting at the OPD of Ayothidass Pandithar Hospital with symptoms of inclusion criteria will be subjected to screening test and documented by using screening proforma. . After screening of 60 cases diagnosed as Swasakasam (Bronchial asthma) 40 cases were selected for induction to the trial. Before enrollment into the trial the informed consent was obtained from the patients.

Inclusion criteria

- 1) Age 18 to 60 yrs.
- 2) Sex: Both male and female.
- 3) Difficulty in breathing, Tightness of chest, Wheeze - Added sound (Rhonchi), coughs with or without expectoration.
- 4) H/O allergy, sneezing.
- 5) Patients who are willing to take radiological investigation and provide blood sample for laboratory investigation.
- 6) Patients who are willing to estimate volume of air forcibly expired after a deep inspiration by using Mini-Peak flow meter and PEFr below normal range from 250L/min to 150 l/min for men; from 200L/min to 100 L/min for women ,for those patients are included.

[Normal range of PEFr:

Male: young adult: 400-650 L/min; Above 40 yr: 300-500L/min

Female: young adult: 250-450L/min; Above 40 yr: 200-400L/min]

Exclusion criteria:

1. Cardiac disease.
2. Renal disease.
3. Tuberculosis.
4. COPD.
5. Status asthmaticus.
6. Diabetes mellitus.
7. Hyper tension.
8. Pregnancy.
9. Lactation.
10. psychological factor.
11. Worm infestation.

Withdrawal criteria:

1. Intolerance to the drug and development of adverse reactions during drug trail
2. Poor patient compliance and defaulters.

3. Patient turned unwilling to continue in the course of clinical trial.
4. Occurrence of any serious illness

CONDUCT OF STUDY

All these patients were given unique registration card in which patient's Registration number of the study, Address, Phone number and Doctors phone number etc. were given, so as to report easily and report any Adverse effect. The patients were treated with Thuthuvalayathy Chooranam (Internal medicine) at the dose of 1.5gms, twice a day with the adjuvant of honey for a period of 24 days. The Patients were advised to take the trial drug with appropriate dietary regimen. All the baseline data, Laboratory investigations before (0th day) and after treatment (24th day) and clinical assessment once in 7 days were recorded in the prescribed Case Report Form of each patient. All the patients were put under observation for 2 months follow up period without the trial drug treatment.

OBSERVATION:

Age:

Out 40 cases, 26 cases (65%) were Female and 14 cases (35%) were Male.

Sex:

Out 40 cases, 2cases (5%) were in the age group between 18-20, 12 cases (30%) were in the age group between 21-30, 13 cases (32.5%) were in the age group between 31-40, 9 cases(22.5%) were in the age group between 41-50 ,4 cases (10%) were in the age group between 51-60.

Seasonal occurrence:

Among the 40 cases, in 25 cases (62.5%) the incidence of the disease seems to be higher in kaar kalam ie., during early rainy season (Aug 16 – Oct 15), in 13 cases (32.5%) the incidence occurred in Mudhuvani ie., later summer season (Jun 16 –Aug15) and in 2 cases (5%) the incidence occurred in koothir kaalam ie., later rainy season (Oct 16-Dec15).

Occupation:

Out of 40 cases, 14cases (35%) were House wives, 4 cases(10%) Students, 5 cases (12.5%) were Software Engineers, 2 cases (5%) were cook, Tailor, Mill worker and the remaining 2.5% of cases were Gardener, Textile worker, Sales representative, Poultry worker, Diver, Leather Factory worker ,Mechanic, missionary, Farmer, Dhobi and Housemaid.

Diet:

Among 40 cases, 32 cases (80%) were Non-Vegetarian and 8 (20%) were vegetarian.

Family History:

Among 40 cases, 23 cases (57.5%) reported Negative family history of similar illness and 17 cases (42.5%) reported Positive family history of similar illness.

Habit:

Out of 40 cases, 6 cases (15%) were smokers, 4 cases (10%) were Alcoholic and 2 cases (5%) were Betel nut chewer.

Triggering factors:

Among 40 cases, Dust and smoke is a main triggering factor in all 40 cases (100%), cold exposure in 32 cases (80%), food additive in 15 cases (37.5%), emotion in 17 cases (42.5%), occupation in 15cases(37.5%),chemicals in 12 cases (30%),fumes of paints and petrol in 7 cases (17.5%),exercise in 6 cases (15%),detergent in 12 cases (30%), menstruation in 2cases (5%), husks, grains and pollens in 6 cases (15%) and other surrounding environment factor in 5 cases(12.5%).

Clinical assessment:

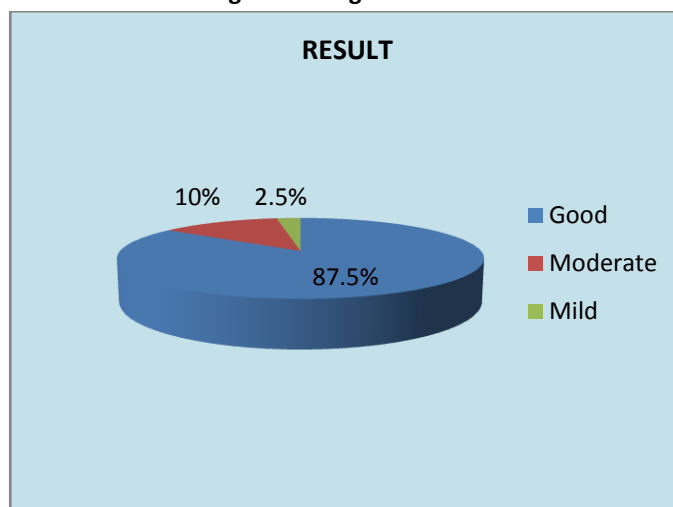
Among 40 cases, before treatment, all the 40 cases (100%) had wheezing, cough, tightness of chest. 36 cases (90%) had breathlessness, 38 cases (95%) had Sleep disturbance, 32 cases (80%) had sneezing and 12 cases (30%) had hoarseness.

Among 40 cases, after completion of the trial all 40 cases (100%) were relieved from breathlessness, tightness of chest and hoarseness. 34cases (85%) were relieved from sneezing, 30 cases (75%) were relieved from cough and 38 cases (95%) were relieved from Sleep disturbance.

RESULTS:

Grading of Asthma:

Fig: 1 Grading of Asthma



0 - None; 1 - Intermittent, 2-Mild; 3 - Moderate; 4 - Severe

0: No day and Night symptoms.1: Daytime symptoms<once a week, Night symptoms-rare 2- Daytime symptoms>once a week, Night symptoms-occasional 3- Daytime symptoms daily, Night symptoms-weekly 4 -Daytime symptoms daily ,Night symptoms-frequent.

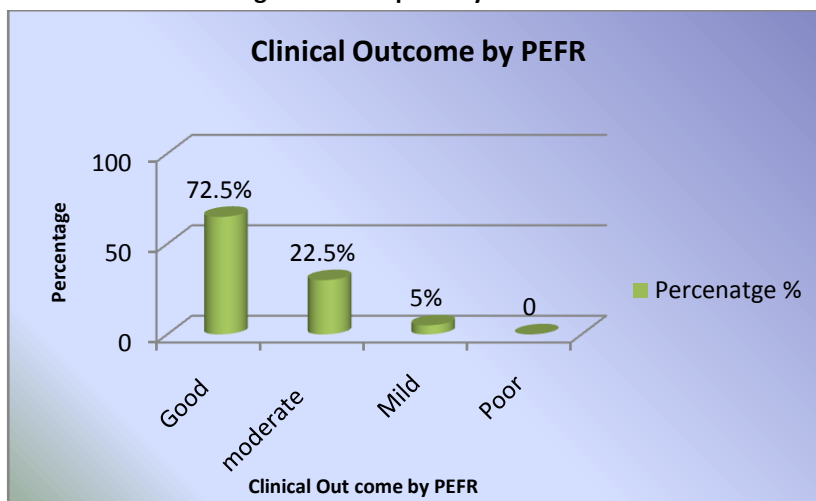
Out of 40 cases, Good improvement were observed in 35 (87.5%) of cases, Moderate improvement was

observed in 4 cases (10%) and only one case had Mild improvement (2.5%).

Peak Expiratory Flow Rate:

Good – PEFR value increased 100 and above 100; Moderate – PEFR value increased 50 - below100; Mild – PEFR value increased 10 – below 50; Poor – No change in PEFR value.

Fig: 2 Peaks Expiratory Flow Rate



Out of 40 cases as per PEFR , 29 cases (72.5%) showed clinically good improvement, 9 cases (22.5%)

) were moderate improvement and 2 cases (5%) were mild improvement.

Statistical analysis

Paired 't' test was used to test the significance of treatment using before and after treatment data on PEFR, Clinical symptoms, Eosinophil and ESR and

Grading of asthma. The level of significance probability 0.05 was used to test the treatment difference and the values are statistically significant.

Table 1: Paired 't' test for Peak Expiratory Flow Rate:

Group	Mean	Std	t value	P Value
Before	170.25	35.84	-16.30	P<0.0001
After	296.25	64.3		

PEFR before treatment is 170.25 and after treatment is 296.25 which is statistically significant ($p < 0.0001$)

Table 2: Paired 't' test for Eosinophilia :

Group	Mean	Std	t value	P Value
Before	6.00	2.428	12.262	P<0.0001
After	2.73	1.432		

Eosinophilia before treatment is 6.00 and after treatment is 2.73 which is statistically significant ($p < 0.0001$).

Table 3: Paired 't' test for ESR ½ Hr:

Group	Mean	Std	t value	P Value
Before	5.42	2.747	-8.977	P<0.0001
After	3.16	1.838		

ESR 1/2 hrs before treatment is 5.42 and after treatment is 3.16 which is statistically significant ($p < 0.0001$).

Table 4: Paired 't' test for ESR 1 Hr:

Group	Mean	Std	t value	P Value
Before	12.00	6.359	10.804	P<0.0001
After	7.21	4.351		

ESR 1 hrs before treatment is 12.00 and after treatment is 7.21 which is statistically significant ($p < 0.0001$).

Table 5 : Paired 't' test for Grading of Asthma:

Group	Mean	Std	t value	P Value
Before	2.65	0.864	15.959	P<0.0001
After	0.35	0.580		

Grading of Asthma before treatment is 2.65 and after treatment is 0.35 which is statistically significant ($p < 0.0001$).

Table 6: Paired 't' test clinical symptoms before and after Treatment:

Variable	Mean	Std. dev	t value	p value
Before	3.55	1.054	15.5	<0.0001
After	0.55	0.959		

Clinical symptoms before treatment is 3.55 and after treatment is 0.55 which is statistically significant ($p < 0.0001$).

DISCUSSION:

Bronchial Asthma (the Greek -"panting") is a bronchial hypersensitivity disorder characterized by reversible airway obstruction, produced by a combination of mucosal edema, constriction of the bronchial musculature and excessive secretion of viscid mucus, causing mucous plugs. Around age 20, the ratio of asthma between men and women is the same. At age 40, i.e. in adult age asthma occurs more in females than males in the ratio of 3:1. Atopic asthma is the most common type of asthma usually begins in childhood. This disease has been thought to be result from sensitization of the bronchial mucosa by tissue specific antibodies. The antibodies produces a specific immunoglobulin IgE (type 1) class and the total Serum IgE levels are usually. Eighty percent of people with asthma have allergies to airborne substances such as tree, grass, and weed pollens, mold, animal dander, dust mites, and cockroach particles. Allergic asthma is dependent on IgE response controlled by T and B lymphocytes and activated by the interaction of antigen with mast cells-bound IgE molecule.

A positive family history of atopy is common, and asthmatic attacks are often preceded by allergic rhinitis, urticaria or eczema. Approximately 50% of asthmatics are of the non atopic (intrinsic) type in which the bronchial reaction occurs in response to non immunological stimuli such as infection, irritating inhalants, cold air, exercise and emotional upset. About 10% of patients become hypersensitive to drugs. Environmental causes of asthma are usually related to climate conditions that promote the concentration of atmospheric pollutants and antigens. These conditions tend to develop heavily industrial or densely populated urban areas and frequently associated with thermal inversion or other situation that cause stagnant air masses. The air pollutants known to have this effect are ozone, nitrogen dioxide & sulphur dioxide.

Broncho constriction can result from working with or being exposed to metal salts, wood and vegetable dust, husk of grains, flour, castor bean, gum acacia, karay gum, tragacanth, pharmaceutical agents e.g.

antibiotics, piperazine and cimetidine, industrial chemicals and plastics, biological enzymes, laundry detergents and pancreatic enzymes, animal & insect dusts, serum and secretions. The most common foods associated with allergic symptoms are: Eggs, Cow's milk, Peanuts, Soy, Wheat, Fish, Shrimp and other shellfish, Salads and fresh fruits. Food preservatives can also trigger asthma. Sulfite additives, such as sodium bisulfite, potassium bisulfite, sodium metabisulfite, potassium metabisulfite, and sodium sulfite, are commonly used in food processing or prepackaging and may trigger asthma in those people who are sensitive.

In Siddha system of medicine the disease Swasakasam (Bronchial asthma) is characterized by severe cough with or without expectoration, expiration is like a hiss of a serpent, frequent hemming and sense of heat in both nostrils, hoarseness of voice, indigestion and flatulence. The causes of the disease as per Siddha text are exposed to excessive smoke, Excessive intake of cold water and food items, Increased acidity, Excessive intake of non-vegetarian diet, Lack of Exercise, Intake of allergy inducing food, Starving on hunger, Taking Improperly cooked food and Excessive Mental Stress.

The herbomineral formulation Thuthuvalayathy Chooranam was prepared by combination of 11 herbal and 2 mineral ingredients. The herbal drugs present in this formulation have expectorant, carminative, stimulant, anti-histaminic, anti-microbial, anti-inflammatory, and anti-spasmodic effect. The qualitative analysis revealed that the drug possess Sulphate, Phosphate, Magnesium, Alkaloid, Iron, Calcium, Ammonium, Silicate, Carbonate, Sodium, Chloride, Tannic acid, Reducing sugar, Copper, Lead and fluoride.

CONCLUSION:

The Siddha medicine Thuthuvalayathy Chooranam was cost effective, safe and therapeutically effective in Swasakasam (Bronchial asthma).

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*Corresponding Author:

Nalini Sofia.H *
Department of Maruthumam,
National Institute of Siddha, Chennai