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A Study on Clinical Efficacy of Thulasi Ennai in Treatment of Childhood Asthma (Sooli Kanam)

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Abstract

In the patient of childhood asthma (Sooli kanam) which is mentioned in the classical Siddha textbook of Bhalavagadam. Thulasi ennai was given at a dose of 5ml once a day orally to 40 patient of either sex in the range of 7 to 12 years with mild to moderate childhood asthma. The respiratory functions were assessed using a peak expiratory flow meter prior to after 40 days of treatment.40 days treatment with the drug showed statistically significant improvement in various parameters of pulmonary function in asthmatic subjects. Also significant improvement was observed in clinical symptoms and severity of asthmatic attacks. None of the patient showed any adverse effects with Thulasi ennai. The results of the present study suggest the usefulness of Thulasi Ennai in patients with bronchial asthma.

Keywords: childhood asthma, Thulasi ennai, pulmonary function test, peak expiratory flow meter.

1. Introduction

Siddha System of medicine is considered to be the ancient documented medical system of the world. The term Siddha means 'achievements' and Siddhars were saintly persons who achieved ‘results’ in medicine. Kuzhandhai Maruthuvam is a specialized branch in Siddha Medicine which deals with the treatment of the disease of children upto 12 years. Asthma is the most common chronic disease of the childhood in the developed world. Current levels of vehicle-related air-pollution are associated with the development of childhood asthma, although some inconsistencies and heterogenecity remain. Asthma prevalence in children has increased to 58% since 1980 mortality has increased by 78%. Sooli kanam is probably correlates with Childhood asthma which is mentioned in the classical Siddha textbook of Bhalavagadam. And thulasi ennai said to be straight medicine for sooi kanam. However, no scientific studies are so far carried out to investigate the efficacy of Thulasi ennai in the treatment of childhood asthma.

2. Materials and Methods

The required drug of Thulasi Ennai would be purchased from a well reputed country shop and raw drugs were authenticated by the medicinal botanist of National Institute of Siddha. The medicine will be prepared in Gunapadam lab of National Institute of Siddha after proper purification. The prepared medicine would also be authenticated by the concerned head of the department for its completeness.

An open label, noncomparative clinical study was carried out on patients of either sex, having childhood asthma and visiting outpatient department of Nation institute of Siddha, Tambaram sanatorium, India. The protocol for carrying out clinical study was approved by Director, Department of National Institute of Siddha, Tambaram sanatorium, India and also by the international ethics of committee for the clinical study. Informed consent was obtained from all parties enrolled in the study.

All patients in the age range 7 to 12 years having mild to moderate childhood asthma by their clinical history commonly absorbed symptoms of bronchial asthma (cough, wheezing, tightness of chest, shortness of breath etc.) and physical examination. Patient having children below 7 years and above 12 years, haemoptysis, pneumonia, congenital heart disease, status asthmaticus. In the patients satisfying the inclusion and exclusion criteria, baseline characteristics were measured and clinical and family history was recorded. Details of duration of bronchial asthma. Patients were given finely Thulasi ennai at a dose of 5 ml twice a day for 40 days.

For patients taking concurrent medicine for childhood asthma, details of the drugs used and their dosages were collected before starting the treatment with Thulasi Ennai and at the end of the study. General physical examination were measured before start of the treatment and at every week after start of the treatment.

Absolute eosinophil's count, total leucocytes count, differential leucocytes count and erythrocytes sedimentation rate were carried out before start of the treatment and at the end of the 40 days of treatment. Patient were given medication supply of 7 days and were asked to report every week. At every weekly visit, patients were asked for occurrence of untoward effect if any and improvement in the symptoms observed. Symptom score was measured for all commonly observed symptoms of bronchial asthma I.e. cough, wheezing, tightness of chest, shortness of breath before starting the treatment and at the end of 40 weeks of treatment. Evoluvation of lung function was done with the help of peak expiratory flow meter. Peak expiratory flow meter was performed before starting the treatment with Thulasi Ennai and at the end of the 40 days of treatment. The value were expressed as mean +/- standard erro of means (S.E.M) Standard significance of the differences in parameters before and after treatment was calculate.

3. Results

Demographic profile:

80 Patients satisfying including the study then I removed 20 cases depend up on my exclusion criteria.12 case use nebulizer acute wheezing at night in the study period of in between 40 days. 8 patients discontinued the study in between due to unknown reason. Finally 40 patients completed the total 40 days of study.

Effect of Thulasi Ennai on commonly observed symptoms of Childhood asthma:

Out of 40 cases, 52.5% of cases showed significant improvement because their sign and symptoms were reduced markly. They were considered as good response Group. About 35% of cases showed moderate improvement. Remaining 12.5% have mild response.

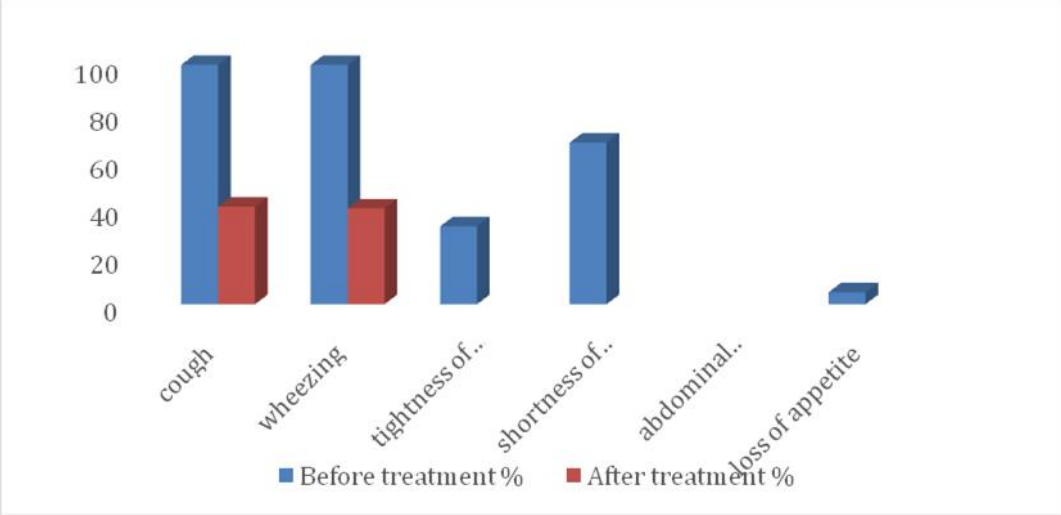
The clinical features of the children in the study are tabulated as follows

Table no: 1.Distribution of Childrens with Sooli kanam according to observation of Clinical features analysis before treatment.

S.No	Clinical features	No of cases	Percentage
1.	Cough	40	100
2.	Wheezing	40	100
3.	Tightness of chest	13	32.5
4.	Shortness of breath	27	67.5
5.	Abdominal bloating	-	-
6.	Loss of appetite	2	5

Table no 2: Distribution of Childrens with Sooli kanam according to observation of Clinical features analysis after treatment

S.No	Clinical features	No of cases	Percentage
1.	Cough	19	47.5
2.	Wheezing	16	40
3.	Tightness of chest	-	-
4.	Shortness of breath	-	-
5.	Abdominal bloating	-	-
6.	Loss of appetite	-	-

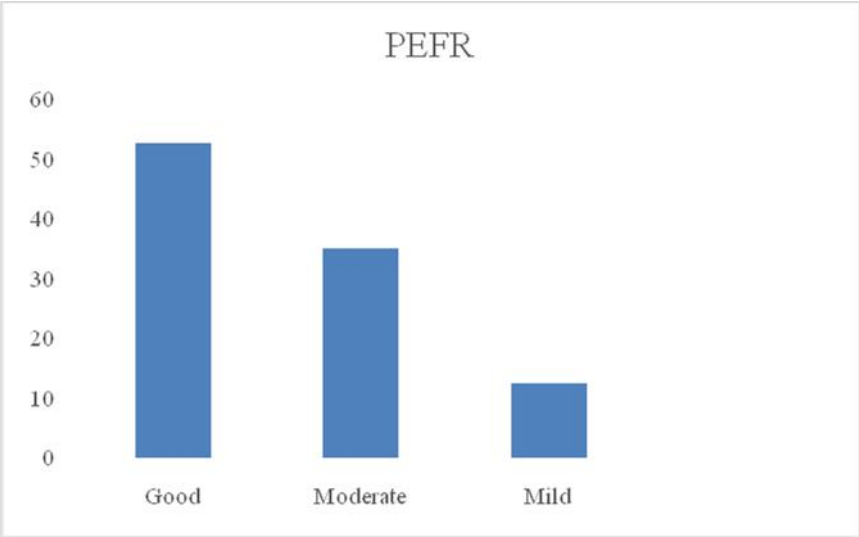


Effect of the Thulasi Ennai on lung function parameters of the Asthmatic patients:

The outcome of this study was clinically observed by PEFR, There is significant difference between before and after treatment ($p < 0.0001$). That is 59% improvement over the start of treatment in PEFR after treatment.

Table no 3: Statistical significance of PEFR Before Treatment and After Treatment

Variable	Obs	Mean±SD	t Value	p Value
Before treatment	40	125.75±17.37	t=13.48	p <0.0001)
After treatment	40	199.75±32.3		



Laboratory investigations were done for all the cases before and after treatment. In AEC, there is moderate significant difference between before and after treatment.

Table no 4: Statistical significance of AEC Before Treatment and After Treatment

Variable	Obs	Mean±SD	t Value	p Value
Before treatment	40	415±360	t=1.99	0.053
After treatment	40	339.8±414		

In ESR-1/2 hr, there is significant difference 28% reduction from the start of treatment. In average 28% reduction after treatment. In ESR-1 hr, there is moderate significant difference 17% reduction from the start of treatment. In average 17% reduction after treatment.

Table no 5: Statistical significance of ESR-1/2 hour Before Treatment and After Treatment

Variable	Obs	Mean±SD	t Value	p Value
Before treatment	40	7.6±5.96	t=3.65	p <0.001)
After treatment	40	5.55±5.19		

Table no 6: Statistical significance of ESR-1 hour Before Treatment and After Treatment

Variable	Obs	Mean±SD	t Value	p Value
Before treatment	40	15.42±12.27	t=2.04	0.004
After treatment	40	12.85±13.0		

4. Discussion

The Siddha system of medicines has certainity with safer medications to treat children. In the present study, the trial drug Thulasi Ennai is treated to the children of age group, 7-12 years who are all diagnosed to have Sooli kanam. The ingredients of Thulasi Ennai are feasible, useful and these compounds may serve as potentially useful drug at a lower cost since most of them had anti-inflammatory, anti-asthmatic, anti-tussive, broncho- dilator, anti-pyritic activity. Clinical results were found to be significant. Good improvement was found in 52.5% of cases, moderate in 35% of cases, mild in 12.5% of cases. Thus the drug is found to be safe and effective in the management of Sooli kanam. The clinical efficacy of the drug was analyzed statistically on all the symptoms mentioned in the Peak expiratory meter, clinical symptoms and laboratory investigations. The observation made during the clinical study showed that the trail drug Thulasi Ennai was clinically effective.

5. Conclusion

The ingredients of Thulasi Ennai are feasible, useful and these compounds may serve as potentially useful drug at a lower cost since most of them had anti-inflammatory, anti-ashmatic, anti-tussive, broncho-dilator, anti-pyritic activity. Clinical results were found to be significant. The present clinical study has established that Thulasi Ennai is having good result in reducing the majority of the symptoms of Sooli kanam. This has inturn provided a further research and opportunity for new drug established in the management of Sooli kanam.

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