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A Comparative Clinical Trial of Yogam and Nilavagai Chooranam in the Management of Eraippu Erumal (Bronchial Asthma)

Muthukumar N.J.^{1*}, Sugasini P.², Keerthika R.³ and Mahalakshmi V.⁴

¹Department of Varma Maruthuvam, National Institute of Siddha, Chennai, India

²Department. of Sirappu Maruthuvam, National Institute of Siddha, Chennai, India

³Pura Maruthuam National Institute of Siddha, Chennai, India

⁴Siddhar Yogam Maruthuam National Institute of Siddha, Chennai, India

*Corresponding Author

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Abstract: The ancient Siddha system of medicine is not only a medicine but a life science of wellness. It is mainly based upon philosophy. Two great sages of ancient India are known to have spread the word about the practice of Yogam –sage Thirumoolar (Father of therapeutic Yogam) and sage Patanjali (known for his spiritual pursuits). Eraippu Erumal may be correlated with Bronchial asthma in modern medicine. It is mainly characterized by cough, chest tightness, difficulty in expiration, and there is characteristic musical sound during expiration (Rhonchi). Nowadays, Eraippu Erumal is very common in society due to increasing exposure to air pollution and lifestyle changes. 30 patients fulfilling the inclusion and exclusion criteria were treated in the OP department of Siddhar Yoga Maruthuvam,. The trial drug Nilavagai chooranam was given for 45 days to Group I patients. Group II patients were taught Yogasanam along with internal drug. Compared two groups treatment Mean value for lung volumes are significantly improved, there exist significant differences ($p < 0.01$) for VC, IC, FEV, and FVCex these parameters before and after treatment. Parameter Ig E, AEC, exist significant ($p < 0.01$) difference before and after treatment. The results of the clinical trial indicate that the trial drug and Yogam is clinically effective in Bronchial asthma. The present study suggests that if the subjects practice yogam regularly for a longer duration, then there may be further improvement in pulmonary functions. Yogam is one of the best treatments for asthma.

Keywords: Nilavagai chooranam, Siddhar Yogam, Bronchial Asthma, Siddha medicine

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Introduction

The ancient Siddha medical system is not only a medical practise, but a way of life dedicated to promoting health and well-being. Its foundation is

mostly philosophical. Siddhars were visionaries, intellectuals, and doers whose lives were dedicated to serving God and mankind. According

to the Siddhars, there are 4,448 different ailments that affect human beings. This number is derived from the Mukkutram, which includes the Vali, Azhal, and Iyyam. Two ancient Indian sages, Sage Thirumoolar (Father of therapeutic Yogam) and Sage Patanjali (author of the Siddha classic writings Thirumandiram), are credited with spreading the information of yogam (known for his spiritual pursuits and author of text yoga sutra) (Muthaliyar, 2004).

Throughout the ages, they have morphed into a whole body workout that tones and strengthens every organ, muscle, and artery. There is evidence that it has been used for at least 4000 years. In contemporary medical practise, there may be a link between Eraippu Erumal and bronchial asthma. Increases in the prevalence of bronchial asthma have been observed all over the world in recent decades (Sambasivam Pillai, 2009). This disease is characterised by chronic bronchial inflammation of varying intensity, which leads to recurrent reversible airflow obstruction and symptoms like coughing, wheezing, shortness of breath, and chest tightness (Anandha Rahasyam, 2003). The World Health Organization reports that in 2019, asthma afflicted 262 million people and caused an estimated 4,55,000 deaths worldwide. Yogam is a priceless contribution to the Siddha medical tradition; while the condition cannot be cured, it may be managed well to alleviate its symptoms and enable patients to lead relatively normal lives. One of the kayalkalpam techniques that helps keep the body and mind healthy is yogam. Yoga and other Indian medical traditions have prioritised quality of life for thousands of years. Doing yoga regularly increases your strength, stamina, and flexibility, and it also helps you be more sociable, compassionate, and in control of your emotions. For India, Yogam is the thirteenth intangible cultural heritage to be recognised by UNESCO. The Indian government recognises an opportunity to profit from yoga's rising profile by sponsoring international events like the International Day of Yoga. Hence, more and more individuals are beginning to recognise its

significance. Due to rising levels of air pollution and shifting social norms, Eraippu Erumal is more prevalent in modern culture. (1) Breathing problems, chest pain, a wheezing additional sound (rhonchi), and a cough that causes chest pain., (2) Sneezing, allergies, (3) A patient who is cooperative with a radiological examination and a blood sample request, (4) Those who are game for a pulmonary function test in which they estimate the amount of air they forcefully exhaled after a deep inhalation.

Materials and Methods

The potential subjects went through a step-wise screening procedure. The inclusion criteria consisted of (1) Age 19 to 60 years, and (2) Sex--Female and Male. Transgender 78 potential subjects was screened, did not meet the above-described eligibility criteria. Of the 42 eligible subjects, only 34 were included in the study at the end of the 1-week run-in period. 30 subjects were allocated by simple random method, yoga (intervention) group (n = 15) and the medicine group (n = 15). However, three subjects in the yoga group, and one subject in the medicine group discontinued midway in the study. The results presented in this study are based on the data collected from only the 30 subjects who completed the study (yoga group, n = 15; medicine group, n = 15).

Siddhar Yoga Maruthuvam OP's department cared for 30 patients who met the inclusion and exclusion criteria. For 45 days, participants in Group I received Nilavagai chooranam, the study medicine. Those in Group II were also given Yogasanam instruction as an internal medicine treatment.

To make Nilavagai chooranam, the necessary raw pharmaceuticals were procured from a reputable drug store and validated by the appropriate agency (Medicinal Botany and Gunapadam Department). Medicine was then manufactured at the Gunapadam laboratory at National Institute of Siddha after the raw pharmaceuticals had been purified independently.

Ethical considerations:

The Clinical trial was approved by the Institutional Ethics Committee (IEC) of National Institute of Siddha, NIS/IEC/14/2018-19/31-20.09.18 and further registered in Clinical Trial Registry of India (Reg NO.CTRI/2019/07/020223). The subjects signed an informed consent form before being enrolled for the study and knew that they were free to withdraw from the study at any stage without assigning any reason.

Statistical analysis:

Microsoft Excel was used to organise the data, with each column representing a distinct variable and each row representing a separate patient. All statistical analysis was done in SPSS. Simple descriptive statistics were run, such as frequency distributions and cross-tabulations. Both quantitative metrics (Mean $\pm$ SD) and qualitative information (percentages) were reported. SPSS version 22 for Windows was used for the statistical analysis (SPSS Inc., Chicago, USA). The Wilcoxon Signed Ranks Test was used to check for skewed data and determine whether or not the variables followed a normal distribution. A paired sample t-test was used to compare the dependent variables from the pre- and post-tests. A t-test was used to compare CON with YOG in terms of the dependent variables. At the level of $p < 0.05$, we recognised differences as meaningful. Mean and standard deviation were used to describe the data (SD)

Results

The values of the outcome measures at different time points during the study are given in Tables 1-4.

There were significant changes in pulmonary function indices in the control group and yoga during the course of the study. In contrast, there was a steady and progressive improvement in the subjects of yoga group during the same period. The change in the yoga group was statistically significant for IC, TV, FEV1, FVCex, PEF, MEF25, MEF25_75 as compared to the corresponding

baseline values (Table 3). In addition, significant group mean differences were observed between yoga and control groups over the study period in PEFR, FEV1, FEV1/FVC and FEF25– 75%. In PEFR, since there is a significant baseline difference, baseline was considered as a constant covariate for between-group comparisons.

There was significant change in IgE, ACE during the study period in both group (Table 4). The IgE, ACE decreased significantly in the yoga group compared to control group, Subgroup analysis in IgE, ACE subjects revealed significant reduction in both yoga and control groups but the amount of reduction observed was more marked in the yoga group than in the control group.

The asthma scores showed an improvement over the study period in both groups (Table 5). But the improvement was achieved relatively earlier and was more complete in the yoga group. At 3 wk, the improvement was statistically significant as compared to the baseline score in the total quality of life as well as each of the four subdomains in the yoga group, but not in the control group. Even by 7-wk, significant improvement was seen in the control group only in symptoms. The asthma score was mean rank yoga group, control group 9.13. Here it is clear that mean rank is less for control group, i.e. medicine group shows more improvement in reduction in scoring. clinically meaningful improvement in quality of life over and above the improvement that the subject would have experienced with conventional treatment alone. Since the p-value is less than 0.05, reject the null hypothesis and accept the alternate hypothesis. That is there is a statistically significant difference in treatment effects of asthma score in both treatment methods. Hence, we compare both methods (Pair 1 and 2) to have the same effect on asthma score.

Here we are using an independent sample t-test for a non-normal sample, that is using Mann Whitney test.

Null Hypothesis: There is no statistically significant

Table 1: Wilcoxon Signed Ranks Test

Wilcoxon Signed Ranks Test					
		Mean	Std. Deviation	Z - score	p-value
GROUP 1	ASTHMA_B_1	26.4667	2.61498	-3.417	0.001**
	ASTHMA_A_1	10.4000	2.22967		
GROUP 2	ASTHMA_B_2	25.4000	1.63881	-3.436	0.001**
	ASTHMA_A_2	4.8000	1.85934		

Table 2: Paired Sample Test (Medicine and Yoga Group)

Paired Samples Test - MEDICINE AND YOGA GROUP								
			Paired Differences				t	Sig. (2-tailed)
Pair	Mean			Std. Deviation	95% Confidence Interval of the Difference			
	Before	After	Difference		Lower	Upper		
VC	2.90	3.13	-0.23	0.68	-0.60	0.14	-1.316	0.209
IC	1.72	2.03	-0.31	0.31	-0.48	-0.14	-3.843	0.002
TV	1.02	1.58	-0.56	0.65	-0.92	-0.20	-3.336	0.005
ERV	1.30	1.73	-0.43	1.07	-1.02	0.16	-1.552	0.143
FEV1	1.97	2.64	-0.67	0.44	-.91	-0.43	-5.942	0.001
FVCex_	2.55	2.82	-0.28	0.27	-0.43	-0.13	-3.982	0.001
FEV1_FVC	77.60	80.73	-3.13	6.75	-6.87	0.60	-1.798	.094
PEF	3.91	4.51	-0.60	1.05	-1.18	-0.01	-2.190	0.046
MEF25	0.96	1.18	-0.22	0.20	-0.34	-0.11	-4.197	0.001
MEF50	2.01	2.12	-0.11	0.44	-0.35	0.14	-.946	0.360
MEF75	3.25	3.73	-0.49	1.13	-1.11	0.14	-1.672	0.117
MEF25_75	1.79	1.98	-0.19	0.34	-0.37	0.00	-2.105	0.054
tex_	3.78	3.74	0.04	0.80	-0.41	0.49	0.193	0.850

Table 3: Summary of Hypothesis Test

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of Asthma_Score is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	<0.001 ¹	Reject the null hypothesis.

Asymptotic significances are displayed. The significance level is 0.05.

¹Exact significance is displayed for this test.

Table 4: Independent Sample Test

Independent Samples Test						
Group		N	Mean	Std. Deviation	T-value	P-Value
IG_E	Medicine Group	15	149.2400	212.35437	-0.343	0.734
	Medicineand Yoga Group	15	172.2000	148.29324		
AEC	Medicine Group	15	203.8667	287.14378	0.672	0.507
	Medicineand Yoga Group	15	142.6667	204.63266		

difference between the median values in asthma scores on different treatment methods “Medicine” and “Medicine and Yogam”.

Alternate Hypothesis: There is statistically significant difference between the median values in asthma score on different treatment methods “Medicine” and “Medicine and Yogam”.

Discussion

This ailment Based on the authorised protocol, 30 patients with Eraippu Erumal were chosen for a clinical investigation using Nilavagai chooranam. The trial was conducted without incident, and no untoward responses to the drugs were reported.

Before and after therapy, haematological parameters and pulmonary function tests were

taken. After therapy, statistical analyses were conducted. No serious side effects were reported throughout the study's time period.

The mean values of the four measures (VC, IC, FEV, and FVCex) have all improved dramatically following therapy, and there are statistically significant changes between the two sets of values (p0). There is a statistically significant (p<0.01) change in the Ig E, AEC parameter between the pre- and post-treatment periods.

When patients in both groups were compared, those in Group I had a statistically significant (p<0.01) improvement in their Asthma score compared to those in Group II (Fig. 1). Clinical symptom improvement before and after therapy showed that the trial medication and yogam were effective in treating symptoms such as shortness

of breath, chest tightness, wheezing, coughing, sneezing, and sleep disturbances. It has been

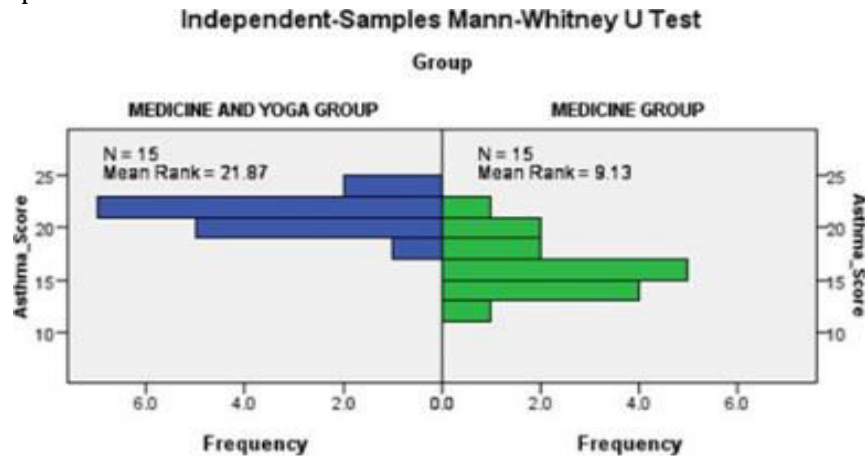


Fig. 1: Independent –Samples Mann-Whitney U Test.

statistically determined that the combination of Nilavagai chooranam and yogam is both effective and significant ($p < 0.01$). Hence, it is efficient in enhancing patients' health, allowing them to engage in everyday activities without assistance.

Our findings of a beneficial impact of yoga on bronchial asthma in various end measures are in line with those of numerous other research. Several of yoga's most accessible and obvious aspects are chosen for their potential to aid in illness prevention and management. As a kind of complementary and alternative medicine, our intervention has made use of yoga.

Yoga and trial medication (group) patients showed statistically and clinically substantial improvements in Asthma symptoms, IgE, and AEC compared to baseline symptoms and control group data.

Conclusion

Based on the results of the current research, it seems that yogam practise may enhance pulmonary functions, and this effect may be

amplified if the individuals engage in yogam for an even longer period of time. One of the most effective therapies for asthma is yoga. It's not drug-based treatment, therefore it is harmless. According to the promising clinical outcomes, a larger scale trial using the same medicine in conjunction with yogam over an extended length of time is warranted, with the potential to provide new insight on the treatment of Eraippu Erumal.

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