

A Clinical Study to Evaluate the Effects of Yogic Intervention on Pulmonary Functions, Inflammatory Markers and Quality of Life in Patients of Bronchial Asthma

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Abstract

Asthma is non-curable disease, the current pharmacotherapy depends on anti-inflammatory agents (corticosteroids) and bronchodilators (beta agonists) which are accompanied by troublesome adverse effects. It is therefore important to explore adjuncts from alternative forms of therapy to complement/supplement the conventional treatment of the disease. The present study evaluated the effects of yogic intervention on pulmonary functions, inflammatory markers and quality of life in patients of bronchial asthma. The study was conducted as per the GCP guidelines and was approved by the Institutional Ethical committee. Patients with clinical diagnosis of mild to moderate bronchial asthma were randomized into two groups, 20 patients in each. In Group I patients were given conventional anti-asthma treatment and in Group II patients received additionally Yoga intervention for 50 minutes daily for 3 months. Pulmonary functions, Fractional exhaled nitric oxide (FeNO), inflammatory marker IL-6 and Quality of Life were assessed in all patients at baseline and after three months of treatment. The results showed a significant improvement in pulmonary function parameters (FEV₁ and FEV₁%), Fractional Exhaled Nitric Oxide (FeNO), and in Quality of life which was accompanied with reduction in Interleukin-6 in Group II. The results suggest that yoga improved the pulmonary functions by reducing the inflammation in the airways. Thus, introducing yoga as adjunct therapy in bronchial asthma can minimize the need for medication which may reduce systemic toxicity of drugs and improve the quality of life.

Keywords: Bronchial Asthma; PFT; FeNO; IL-6 and AQLQ

Introduction

Bronchial asthma is one of the most common chronic inflammatory disease of the respiratory tract. Approximately 300 million people worldwide currently have asthma and its prevalence increases by 50% every decade [1]. There is epidemiological evidence that the disease is progressing rapidly in children and one third of patients with asthma are children under the age of 18 years. As asthma is a chronic disease, patients have to depend heavily on medicines lifelong to keep the disease under control and maintain their daily routine. Current pharmacotherapies for bronchial asthma are mainly aimed at relieving symptoms by bronchodilators (beta agonists, anticholinergics, methylxanthines etc) and controlling asthmatic attacks with anti-inflammatory agents which are mainly steroid dependent. These, most effective therapeutic strategies are associated with several untoward drug effects which negatively affect the compliance to therapy. Adverse effects of these drugs are a major reason for non-compliance and worsening of the disease [2,3]. Further, drug insensitive/refractory cases of asthma are surfacing rapidly. It is therefore important to explore adjuncts from alternative forms of therapy to complement/supplement the conventional treatment of the disease [4,5].

The use of traditional systems of medicine is being encouraged by the Govt. of India because of their easy availability, low cost, and safety. Further, their validation by using a modern scientific methodology is also being promoted. Yoga is an important way of life which has strongly emerged as an alternative form of traditional therapy. It is a generic term for the physical, mental, and spiritual practices or disciplines which originated in ancient India with a view to attain a state of permanent peace. Its benefits are being acknowledged globally, particularly for chronic diseases. The greatest respiratory benefit may come from regular practice of pranayama and selective yoga asanas which work directly on the respiratory system. Regular yoga therapy may strengthen lung muscles, widen the airways and may provide relief from symptoms of asthma viz. coughing, wheezing, shortness of breath, and chest tightness [6-13]. There is some evidence that yoga can be helpful when it is practiced alone or in addition to standard therapeutics for several conditions like anxiety disorders, stress, asthma, high blood pressure, heart disease and depression [6-14]. On the other hand, studies by Cooper, *et al.* [15] and Vedanthan, *et al.* [16] have shown no additional benefit of pranayamic breathing in bronchial asthma. Singh, *et al.* [13] and Thomas [17] had concluded that the usefulness of controlled ventilation exercises in asthmatics should further be investigated. In view of the above, the present study was conducted to investigate the influence of Yoga on pulmonary functions, inflammatory markers and quality of life parameters in patients of bronchial asthma.

Materials and Methods

The present study was a randomized, open label, parallel design, controlled clinical study, conducted in the Department of Pharmacology, Delhi, in collaboration with the outpatients department of the Viswanathan Chest Hospital, V.P. Chest Institute, University of Delhi, Delhi, India. The effects of Yoga intervention has been assessed on pulmonary functions, clinical symptoms, and cellular/molecular markers of inflammation and quality of life parameters, in patients of bronchial asthma.

The study was conducted in accordance with the International Conference on Harmonization-Good Clinical Practice (ICH-GCP) guidelines and had the approval of the Institutional Ethical Committee (IEC). Patients with clinical diagnosis of mild to moderate bronchial asthma from outdoor facilities were enrolled after a written informed consent from them. Exclusion criteria of the study were- any respiratory tract infection, any other systemic disorders, pregnant/lactating females and patients with history of smoking. Inclusion criteria of the study were age group 20 - 60 years, irrespective of gender and relatively stable, ambulatory and cooperative. Patients were randomized into two groups of 20 patients each. The treatment groups were as under:

Group I. Conventional treatment (inhaled corticosteroids with long acting β -agonist)

Group II. Conventional treatment was given along with Yoga therapy for 1 hour.

Both Groups were given SOS I-salbutamol.

After recording the baseline parameters in both Group I and Group II, Group II patients assigned to the yoga group underwent a comprehensive yogic intervention as shown in Table 1. The yogic intervention consisted of physical practices, pranayama (breathing techniques), meditation and shavasana (relaxation techniques) under the guidance of a qualified Yoga teacher. The physical practices consisted of preliminary breathing exercises and loosening exercises followed by asanas under four categories (standing, sitting, prone and supine). Yoga sessions were conducted daily for 1hour in Group II as per Table 1. The patients were given a training of yoga for 1 hour daily for 2 weeks (or more if required by some patients). During the follow-up period, the patients were expected to continue the yoga practice daily. The compliance to yogic intervention was monitored by a diary, which they brought at each visit and on phone calls. Patients doing yoga for at least ≥ 5 times/week were considered compliant and data arising from these patients was used for analysis. After 3 months, patients were physically examined and PFT (spirometry), fractional exhaled nitric oxide (FeNO), IL-6 and quality of life were done.

S.no	Category	Duration	Name of the practice
1.	Yogic Sukshmaryama	10 minutes	Involving most of the joints and body parts (selected yogic practice chosen) Grivasaktivikasak-I and II, chest expansion-I and II, katisakti vikasak-5, jhangasaktivikasak, uddiyanbandha.
2.	Breathing maneuvers	05 minutes	Sectional-abdominal chest breathing
3.	Yogasanas	15 minutes	Bhujangasana, Gomukhasana, Uttanmandukasana, Savasana (Aasanas involving chest expansion)
4.	Pranayama	15 minutes	Nadishodhana- 5 minutes (approx. 30 rounds) Suryabhedan-5 minutes (approx. 40 rounds, avoid in high B.P. and do more nadishodhan) Bhramari- 5 minutes (approx.20 times)
5.	Meditation	05 minutes	Meditation

Table 1: Yogic interventions practiced daily for 50 minutes in Group II.

Pulmonary functions

Respiratory flows and volumes were assessed by Spirometry, which is the most reliable method to assess the lung functions, specifically the amount (volume) and/or speed (flow) of air that can be inhaled and exhaled. It gives the predicted values which are calculated according to the age, height and weight of the patient and compared to the corresponding measured data, customize according to north Indian population with ethnic group correction to measure FEV₁ (forced expiratory volume in 1 second after full inhalation), FVC (forced vital capacity) and FEV₁ %.

Fractional Exhaled Nitric Oxide (FeNO)

Levels of nitric oxide (NO) are known to increase in exhaled air in bronchial asthma, and decrease with appropriate anti-inflammatory treatment [18]. FeNO analyzer was used for measuring NO levels in expired air. Measurement of nitric oxide (NO) levels in expired air is a latest, non-invasive biomarker for bronchial asthma and is correlated with eosinophilic airway inflammation.

Estimation of serum IL-6

IL-6 mediates the changes occurring during inflammation changing from acute to chronic situation [19,20]. The levels of serum cytokines IL-6, was assessed by ELISA by commercially available kits in blood samples of both the Groups: I and II (Diacclone, France).

Asthma Quality of Life Questionnaire (AQLQ)

Permission had been taken by Professor Elizabeth Juniper, Mc Master University, Canada. The Asthma Quality of Life Questionnaire (AQLQ) is an evaluative questionnaire to measure quality of life (QOL) in patients of asthma. It consists of 32 questions which are categorized under sub-domains; symptoms which has 12 questions, activity limitation has 11 questions, emotional function has 5 questions and response to environmental stimuli has 4 questions [21,22].

Ethics

The study was initiated after obtaining the approval of the Institutional Ethical Committee and was conducted according to the ICH-GCP guidelines.

Statistical Analysis

PFT data were analysed by paired t test. FeNO, IL-6 and AQLQ data were expressed as Mean ± SEM and analysed by one way ANOVA followed by Tukey Kramer post-hoc test. A p value <0.05 was used as a level of significance in all statistical tests.

Results

Analysis of data showed that pulmonary functions (FEV₁ and FEV%) were significantly improved in the Groups II after 3 months which was on conventional treatment with yogic intervention. The results are depicted in table 2.

Parameters	Groups	Baseline	After 3 months
FEV ₁ (L)	Group I	2.80 ± 0.83	2.90 ± 1.01
	Group II	2.57 ± 0.88	2.89 ± 0.79*
FVC (L)	Group I	3.62 ± 0.81	3.86 ± 1.13
	Group II	3.51 ± 1.04	3.70 ± 0.90
FEV ₁ /FVC (%)	Group I	74.85 ± 11.16	76.02 ± 8.44
	Group II	72.05 ± 9.34	76.46 ± 8.55*

Table 2: Comparison of Pulmonary function of the Group I (control group) and Group II (Yogic intervention group) at the baseline and after 3 months of study.

Data are expressed as mean ± SD. *P < 0.05, as compared to yoga group at 0 month (paired t- test)

Fractional Exhaled Nitric Oxide (FeNO)

The data showed that FeNO levels were found to be reduced in both the groups, significant reduction of FeNO was found in Group II i.e. 24.8 % after 3 months of conventional treatment with yogic intervention as compared to Group II (yoga) at baseline and in Group I (control) reduction was 8.5% after 3 months of conventional treatment as compared to Group I (control) at baseline. This suggests better control of inflammation in Group II. The results are shown in Figure 1.

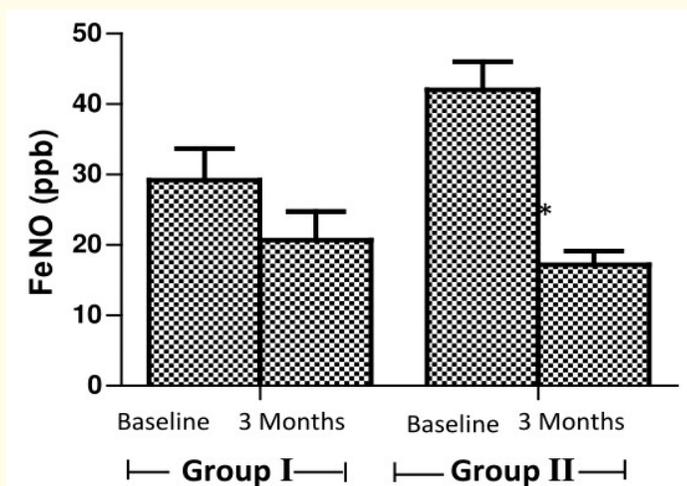


Figure 1: Comparison of FeNO (ppb) between Group I (control) and Group II (yoga) after 3 months of treatment. FeNO: Fractional exhaled nitric oxide. *p < 0.05 vs baseline of Group II (yoga group)

Estimation of serum IL-6

Interleukin-6 (IL-6) levels are associated with inflammation and the progression of obstructive airway diseases. The IL-6 levels were significantly decreased in both groups after 3 months of conventional treatment in Group I and conventional treatment with yogic intervention in Group II ($p < 0.05$). The observed data on of serum IL-6 level for Group I (control) at baseline were was 200 ± 27.35 pg/ml which was reduced to 106.3 ± 22.95 pg/ml after 3 months of conventional drug treatment i.e. the level was decreased by 46.85 %. The level of IL-6 for Group II (yoga) at baseline was 245.9 ± 23.41 pg/ml, after 3 months of conventional treatment with yogic intervention the level of IL-6 was decreased to 67.07 ± 10.10 pg/ml which was decreased by 72.8 %. The results are shown in Figure 2.

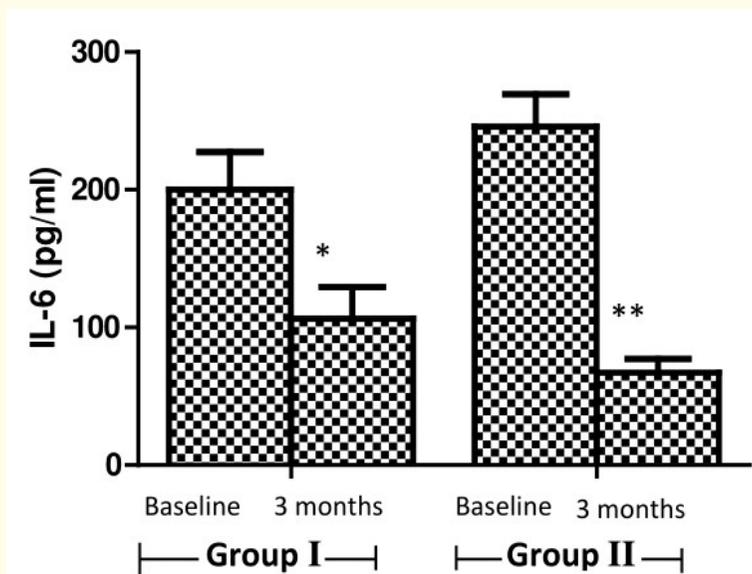


Figure 2: Comparison of IL-6 marker between Group I (control) and Group II (yoga) after 3 months of treatment. IL-6: Interleukin 6. * $p < 0.05$, ** $p < 0.01$ vs respective baseline values at 0 month.

Quality of Life,

The analysis of the data after different treatments showed that the marginal change in AQLQ score was observed in Group I, whereas significant changes were found in Group II in which yogic intervention was given with conventional treatment after 3 months in all sub-domain of questionnaire. The score of the Symptoms Domain (SD) at baseline in Group I (control group) and Group II (yoga group), were 5.23 ± 0.29 and 4.55 ± 0.30 respectively, which was increased, i.e.. 5.81 ± 0.27 and 6.44 ± 0.30 in Group I (control group) and Group II (yoga group) respectively. The Activity Limitation (AL) score at baseline in Group I (control group) and Group II (yoga group), were 5.03 ± 0.36 and 4.23 ± 0.36 respectively, after 3 months the score which was increased i.e. 5.12 ± 0.34 , 5.76 ± 0.22 respectively. Similarly, the score of Emotional Function (EF) at baseline Group I (control) and Group II (yoga), were 4.90 ± 0.34 , 4.43 ± 0.41 which were increased to 5.22 ± 0.39 , 6.43 ± 0.17 respectively after 3 months of respective treatments. Environment Stimuli (ES) in AQLQ, i.e. 3.28 ± 0.68 at baseline Group I (control) was increased to 3.77 ± 0.52 whereas baseline level of 2.28 ± 0.26 in Group II (yoga) was raised to 4.16 ± 0.40 after 3 months of yogic intervention along with conventional treatment. The results are summarized in figure 3.

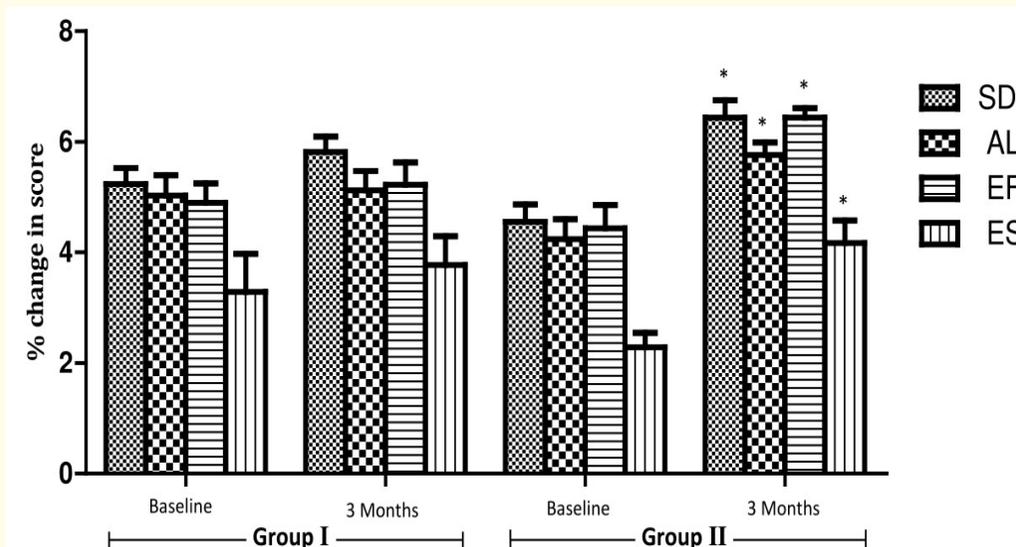


Figure 3: Comparison of Change in AQLQ score between group I (control) and group II (yoga) after 3 months of treatment. AQLQ: Asthma Quality of Life Questionnaire SD: Symptoms Domain, AL: activity limitation, EF: Emotional function, ES: Environmental stimuli. * $p < 0.05$ vs respective baseline values.

Discussion

Interleukin-6 (IL-6) levels are associated with inflammation and the progression of obstructive airway diseases. The measurement of IL-6 in exhaled air can be a useful and sensitive inflammatory marker to assess the modulatory role of therapy. In the present study, we found the reduction in levels of pro-inflammatory cytokines, IL-6 in both the group. However, the reduction in IL-6 was remarkably more in Group II as compared to Group I. Further, the reduction was accompanied with better improvement in the pulmonary functions in group II as evident from FEV1 values. Thus, reduction in IL-6 may be responsible for reducing the inflammation and the greater effect in improving the pulmonary functions.

In subjects with asthma, the levels of Fractional exhaled nitric oxide (FeNO) is shown to have excellent correlation with eosinophilic airway inflammation. It is considered a valid and reproducible non-invasive marker with a high discriminatory capacity and can be used with more than 90% specificity for the diagnosis of asthma in both adults and children [18]. The results of the present study showed that the levels of FeNO were also reduced in both the groups, suggesting, this may be a contributing factor in decreasing the eosinophil counts and thus reduced inflammation, Similar to observed earlier, the magnitude of effect was much more in Group II with yoga as adjunct therapy. The results further corroborate to the findings of anti-inflammatory effects of yogic intervention in asthma.

Although, all the aspects of the Asthma Quality of life Questionnaire, i.e. symptoms, activity limitation, emotional function and response to environmental stimuli were found to be improved, the maximal effect was observed in response to environmental stimuli. The improvement was significantly more in Group II with yoga as adjunct therapy as compared to Group I which was on conventional drug treatment. Taken together, the results suggest that yogic intervention as an adjunct therapy along with conventional drug treatment improves the quality of life by achieving emotional stability which comes with disease Psychophysiology benefits and resilience against environmental stimuli that works on decreasing in symptoms and leads to the efficient pulmonary functions of the body.

Conclusion

Thus, it can be concluded that introducing yoga as adjunct therapy in bronchial asthma can minimize the need for medication, reduce systemic drug toxicity, burden of the cost of drugs on patients and improves the quality of life. However, it needs to be authenticated in a larger group of population.

Conflict of Interest

The authors declare that there is no financial interest or any conflict of interest in this study.

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