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Evaluation of symptoms & spirometry in children treated for asthma

Shobi Anandi, Milind S. Tullu & Keya Lahiri

Department of Pediatrics, Seth G.S. Medical College & KEM Hospital, Mumbai, India

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***Background & objectives*: Spirometry plays an important role in the assessment and long term monitoring of patients with asthma. Difficulty in performing spirometry in children has resulted in a paucity of Indian studies using spirometry regularly for research in the paediatric population. This study was undertaken to assess the clinical improvement and changes in spirometric measurements with treatment in children with newly diagnosed asthma and to compare the changes in the symptom score and spirometric measurements.**

***Methods*: This prospective study included 32 children between 6 to 12 yr of age (enrolled over a period of one year with follow up of six months) who were newly diagnosed as cases of asthma on the basis of symptoms and medical history. Baseline symptom score and spirometric measurements were determined at the first visit. The children were treated and followed up at six weeks, three and six months of initiating treatment. Symptom score and spirometric measurements were repeated at every visit.**

***Results*: Significant improvement in symptom score was evident at six weeks of therapy ($P<0.05$) while the lung function parameters FEV_1 (forced expiratory volume in 1 second) and FVC (forced vital capacity) showed significant improvement at three months of therapy. Peak expiratory flow rate (PEFR) was found to improve at six months. There was a positive linear correlation between the changes in symptom score and FEV_1, FVC and PEFR with treatment.**

***Interpretation & conclusions*: Symptomatic improvement became apparent before the improvement in spirometric parameters in children with asthma (after treatment initiation).**

Key words Airways - asthma - children - GINA guidelines - paediatric - pulmonary functions - spirometry - symptom score

Asthma is a chronic inflammatory disease of airways characterized by bronchial hyper-responsiveness and reversible airway obstruction[1]. Pulmonary function tests, mainly spirometry are gold standard tools for objective evaluation in childhood asthma[2]. Spirometry determines the degree of airway obstruction and its response to treatment.[3] However, most asthmatic children, independent of the disease severity, have been found to have normal forced expiratory volume (FEV) values especially when asymptomatic[4,5]. Hence, the role of pulmonary function tests in short and long term evaluations of childhood asthma remains controversial. Also, reliable spirometric measurements depend on the patient's ability to perform a forceful expiratory maneuver which is difficult in young children. Hence, the clinical picture in terms of signs and symptoms is also of paramount significance[6]. The lung function measurements give information

about the patients' physiology in an objective way, whereas symptoms give more information about how the disease is affecting the patient[6]. Though it is known that with treatment there is improvement in both symptoms and lung function measures, the levels of improvement in each of the parameters are not yet clear. This emphasizes the need for further studies to determine how spirometric measures and the clinical features improve with treatment. Hence we undertook this study to determine the clinical improvement and the changes in the spirometric measurements with treatment in newly diagnosed cases of asthma in children and to compare the change in the symptom score and spirometric measurements.

Material & Methods

The present study was a prospective observational study initiated after the approval of the protocol and the study design by the Institutional Ethics Committee, and conducted at the Paediatric Chest Clinic at KEM Hospital, a tertiary care referral hospital in Mumbai, Maharashtra, India. The study included children between 6 and 12 yr of age who consecutively presented at this clinic over a period of one year (January to December 2010) with signs and symptoms suggestive of asthma (newly diagnosed) and who were able to perform spirometry. Patients who were treated elsewhere, on long term oral steroids, those who could not perform spirometry or refused to give consent were excluded. A total of 37 patients were identified and five were lost to follow up. Only 32 patients were followed up for a period of six months. Written informed consent of the parent/guardian and assent of children above seven years of age were obtained. The children were assessed and classified according to severity of the symptoms as per the Global Initiative for Asthma (GINA) guidelines 2009[7]. The baseline symptom score and spirometric measurements were done. Spirometric readings were obtained on a portable standardized spirometer (spirolab III, MIR, Italy). The symptom score was determined by using the Childhood Asthma Control Test: C-ACT[8]. This test consists of seven questions related to the last four weeks, of which four are to be answered by the child and three by the parents. The total score can range from 0-27. The C-ACT is a validated test to assess asthma control and identify children with inadequately controlled asthma[8]. The children were started on treatment according to GINA guidelines[7]. Metered dose inhaler or rotahaler was used to deliver beta 2 agonists and steroids. The drugs were stepped up/down as required according to the guidelines. The parents were educated about the disease and treatment, the symptoms and signs of acute exacerbation and the importance of avoiding triggering factors. They were trained to use the inhalation devices and the technique was checked at every visit to ensure adequate drug delivery. Regular visits were ensured by giving the date for the next visit and patients who did not turn up on the day of the scheduled visit were reminded telephonically. Thus follow up and treatment compliance was ensured. The children were followed up at six weeks, three and six months of treatment and assessed clinically in terms of symptom score. Spirometric measurements were performed at every visit. The tests were not applied during an acute exacerbation. Spirometry was performed when the patient was not on bronchodilators.

The following lung function parameters were monitored during the study period: FEV_1 (forced expiratory volume in 1 second), FVC (forced vital capacity), FEV_1/FVC ratio, and PEFR (peak expiratory flow rate).

Statistical analysis: The data were tested for normality using D'Agostino-Pearson omnibus normality test[9] and were found to be not normally distributed. The data were analyzed using the 'Wilcoxon signed Rank sum test for the symptom score and paired t test for the lung function parameters. The symptom score and each of the lung function parameters were compared and Pearsons correlation factor was calculated.

Results & Discussion

The mean age of the patients was 8.72 ± 1.95 yr; 20 (62.5%) were males and 12 (37.5%) were females. The male: female ratio was 1.67:1. The height was 125.50 ± 12.23 cm, and the weight was 22.19 ± 6.7 kg. Twenty seven patients belonged to mild persistent type and five were of moderate persistent type of asthma. The mean symptom score, FEV_1, FVC, FEV_1/FVC and PEFR values at each visit and the improvement in the various parameters when compared to baseline are shown in Table I. Significant improvement in the symptom score was evident at six weeks of therapy while the lung function parameters, FEV_1 and FVC showed significant improvement at three months. PEFR was found to show improvement at six months. FEV1/FVC did not show significant improvement during the study period. Table II shows improvement in the various parameters during follow up when compared to the previous visit. Improvement was noticed in all the spirometric parameters at six months follow up. There

was a positive linear correlation between the changes in symptom score and FEV_1, FVC and PEFR (r=0.91, P<0.001; r=0.93, P<0.001; and r=0.88, P<0.001, respectively).

Asthma control and severity have been conventionally assessed using several indices which have included symptoms, level of treatment and lung function[5,6]. It is apparent that no single measure of disease control can encompass all the clinical problems in asthma[6]. It is also known that patients with similar levels of lung function may experience a wide range of severity and morbidity[5]. Thus, there is always a risk of underdiagnosis or overdiagnosis of asthma if only the spirometric measurements (FEV_1) were taken into account since majority of children irrespective of the severity of asthma tend to have a normal FEV_1 when asymptomatic[4,5]. Stout *et al*[10] reported that one third of the children with asthma were reclassified into a more severe asthma category when pulmonary functions were taken into consideration in addition to symptom frequency. Measurements of pulmonary functions require a high degree of patient's cooperation and the readings reflect a onetime measurement of the child's status and so are probably of questionable value[2,3,11]. Serial follow ups and monitoring of the lung function measures are more reliable than a single reading which usually does not convey much meaning[6]. This highlights the need to use multiple parameters in assessing children with asthma[6]. Our study showed that with appropriate treatment and regular follow up, there was a significant improvement in both the symptom score and the lung function measures. The improvement was initially apparent in the symptom score of the patient.

In a study on asthmatic children, where the improvement in symptom score at 2, 4 and 8 wk of starting treatment was determined, the mean symptom score showed a significant change from 57.80 to 49.5 at two weeks, 37.74 and 27.80 at four and eight weeks, respectively (P<0.01)[12]. There was a significant improvement in FEV_1, FVC and PEFR at the same time, showing that improvement in both symptom score and lung function measures[12]. Another study showed that at the end of three months treatment, there was a significant improvement in the symptom score (8.35±0.67 vs 1.76±0.27, P<0.001)[13]. Improvement was also noticed in the lung function parameters- FEV_1 (68.25±2.83 to 76.28±2.47, P<0.002) and PEFR (63.95±3.13 to 75.68±3.66, P<0.001)[13]. Zhang *et al*[11] showed that perception of symptomatic improvement by both parents and children correlated weakly with the changes in pulmonary function parameters during the study period. This was attributed to the fact that the lung function measures represented the pulmonary

Table I. Mean symptom score, and lung function parameters at baseline and upto six months of follow up

	Mean total symptom score	Mean FEV_1 (l)	Mean FVC (l)	Mean FEV_1/FVC	Mean PEFR (l/sec)
Baseline	18.78 ± 3.68	0.96 ± 0.34	1.05 ± 0.40	92.84 ± 8.06	2.49 ± 0.78
6 wk	22.53 ± 2.81*	1.03 ± 0.31	1.14 ± 0.36	91.36 ± 8.34	2.67 ± 0.87
3 months	23.81 ± 1.96*	1.11 ± 0.30*	1.24 ± 0.33*	89.67 ± 7.96	2.79 ± 0.76*
6 months	25.59 ± 1.64*	1.29 ± 0.33*	1.42 ± 0.35*	91.30 ± 5.99	3.32 ± 0.92*

*P<0.05 significant compared to baseline. Values are mean ± SD (n=32)
FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity; PEFR, peak expiratory flow rate

Table II. Improvement in symptom score and lung function parameters at follow up when compared to previous visit

Improvement in parameter compared to previous visit	At 6 wk	At 3 months	At 6 months
Symptom score	P<0.05	P<0.05	P<0.05
FEV_1	NS	NS	P<0.05
FVC	NS	P<0.05	P<0.05
PEFR	NS	NS	P<0.05

FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity; PEFR, peak expiratory flow rate; NS, not significant

functional status at the moment of visit while the symptom score reflected the improvement over a period of time[11]. Planned education interventions reduce the symptom frequency and duration and the need for oral steroid burst therapy[14]. Also, with proper education and follow up, children were found to take their medications more regularly[14].

The improvement was initially evident in the symptom score as early as the six weeks of treatment while the improvement in the lung functions was noticed at three months. It indicates that the subjective improvement precedes improvement in objective parameters. So the symptom score, the FEV_1, FVC and PEFR are all good indicators of response to treatment in asthma. In addition to drug therapy, the role of psychosocial and other environmental factors like avoidance of triggers in the control of asthma cannot be underestimated. The small sample size and the shorter duration of follow up were the main limitations of this study. A long term follow up of the patients would yield valuable information regarding the trends in both symptom score and lung function measures.

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***Conflicts of Interest*:** None.

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Reprint requests: Dr Milind S. Tullu, "Sankalp Siddhi", Block No.1, Ground Floor, Kher Nagar, Service Road, Bandra (East), Mumbai 400 051, Maharashtra, India
e-mail: milindtullu@yahoo.com