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Effectiveness of peak flow meter in management of childhood asthma

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Objective : *To assess the effectiveness of routine use of peak flow meter (PFM) in addition to symptom-based guided self-management of children with asthma.*

Materials and Method : *A prospective randomized controlled trial was performed in patients aged 6 - 15 years with persistent asthma who had been treated with inhaled corticosteroid (ICS) for at least 1 month. The recruited patients were randomized into 2 groups. The first group used PFM in addition to the symptoms assessment in self-management plan (PFM group) while the other group used only symptoms-based management plan (non-PFM group). All patients were evaluated in terms of symptom scores, quality of life scores and pulmonary function test at the beginning, during the 1st or 2nd month and at the end of the 3rd month.*

Result : *Sixty-six patients were studied (male: female 38: 28; mean age 8.9 ± 2.0 years); 87.8% and 12.2% of them had mild and moderate persistent asthma respectively. The average duration*

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of ICS was 3.1 ± 2.1 years. There were no significant differences between the PFM group and the non-PFM group in terms of symptom scores [at 3rd month 0.3 (0 - 4.1) vs. 0.3 (0 - 7); p >0.05], quality of life scores [6 ± 0.7 vs. 6.1 ± 0.8; p >0.05] and pulmonary function. However, the quality of life scores of the PFM group were significantly improved at the end of the 3rd month [5.7 ± 0.9 vs. 6.2 ± 0.7 (p = 0.003)].

Conclusion : *The addition to routine PEFR monitoring to symptom-based guided self management did not result in significant differences from symptom-based guided self management alone in terms of symptom scores, quality of life scores and pulmonary function among children with mild to moderate persistent asthma. However, PFM may be beneficial in those who have been using ICS for 1 -3 years.*

Keywords : *Peak flow meter, asthma, children.*

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ทำนบ ตัณนิติศุภวงษ์, นวลจันทร์ ปราบพาล, จิตลัดดา ดีโรจนวงศ์, สุชาดา ศรีทิพยวรรณ, รุจิภัตต์ สำราญสำรวจกิจ. ประสิทธิภาพของการใช้ peak flow meter ในการดูแลรักษาผู้ป่วยเด็กโรคหืด. จุฬาลงกรณ์เวชสาร 2555 ก.ย. – ต.ค.; 56(5): 545 – 55

วัตถุประสงค์ : *เพื่อศึกษาประสิทธิภาพของการใช้ peak flow meter (PFM) ในการดูแลรักษาผู้ป่วยเด็กโรคหืด*

วิธีการศึกษา : *เป็นการศึกษาแบบ prospective randomized control trial ในผู้ป่วยอายุ 6 –15 ปี ที่ได้รับการวินิจฉัยว่าเป็นโรคหืด ระดับ mild persistent ขึ้นไป โดยแบ่งผู้ป่วยเป็น 2 กลุ่ม กลุ่มแรกใช้ PFM เป็นอุปกรณ์ที่ใช้ในการประเมินความรุนแรงของโรคร่วมกับ อาการเพื่อช่วยในการดูแลรักษาตนเองเป็นเวลา 3 เดือนที่บ้าน กลุ่มที่ 2 จะใช้อาการเพียงอย่างเดียวในการประเมินและให้การรักษา ทั้งสองกลุ่มจะได้รับการเปรียบเทียบกันในเรื่องอาการ (symptom scores), คุณภาพชีวิต (quality of life scores) และผลการตรวจสมรรถภาพปอด เมื่อเริ่มต้นการศึกษา, ในช่วง 1-2 เดือนและเดือนที่ 3*

ผลการศึกษา : *ผู้ป่วยทั้งหมด 66 ราย เพศชาย : หญิง 1.4: 1 อายุเฉลี่ย 8.9 ± 2.0 ปี ร้อยละ 87.8 เป็น mild persistent asthma ระยะเวลาเฉลี่ยของการได้รับ inhaled corticosteroid (ICS) 3.1 ± 2.1 ปี พบว่ากลุ่มที่ใช้ PFM และกลุ่มที่ไม่ใช้ PFM ไม่มีความแตกต่างกันในเรื่องของอาการ, คุณภาพชีวิต, สมรรถภาพปอด และการได้รับยารักษาที่เพิ่มขึ้นตลอดระยะเวลา 3 เดือนของการศึกษา อย่างไรก็ตาม พบว่า ในผู้ป่วยที่ได้รับ ICS 1-3 ปี กลุ่มที่ใช้ PFM มี symptom scores ที่ 1, 2 และ 3 เดือนน้อยกว่ากลุ่มที่ไม่ใช้ PFM อย่างมีนัยสำคัญทางสถิติ (scores ที่ 3 เดือน : 0 vs. 0.2 ; p = 0.02) และquality of life scores ของกลุ่มที่ใช้ PFM สูงขึ้นอย่างมีนัยสำคัญทางสถิติ (5.7 ± 0.9 vs. 6.2 ± 0.7; p = 0.03)*

สรุป : *การใช้ PFM ในการประเมินและดูแลรักษาผู้ป่วยเด็กโรคหืดไม่ทำให้อาการของโรค คุณภาพชีวิต และสมรรถภาพปอดแตกต่างอย่างมีนัยสำคัญทางสถิติ เมื่อเปรียบเทียบกับการใช้อาการและอาการแสดงของผู้ป่วยเพียงอย่างเดียว โดยเฉพาะอย่างยิ่งในรายที่เป็น mild persistent asthma แต่ PFM อาจมีประโยชน์ในรายที่ได้รับยา ICS 1-3 ปี*

คำสำคัญ : *Peak flow meter, โรคหืด, เด็ก.*

Guided self-management is the cornerstone of asthma care for all age groups including children.[1] The use of peak flow meter (PFM) to monitor peak expiratory flow rate (PEFR) is suggested in self-management plan for children with asthma but its effectiveness and necessity is still inconclusive.

A number of previous studies showed that prescribing PFM in addition to giving self-management guidelines to all asthmatic patients was unlikely to improve the outcomes of the disease.[2-6] However, some studies demonstrated the benefit of using PFM in protecting poorly controlled asthmatic patients against severe exacerbations and reduction the inappropriate use of the medications.[7,8] Moreover, compliance with of daily peak expiratory flow assessments was generally poor and unreliable.[9 -11] Most of the subjects recruited in the reported studies were adults and adolescents. There is still limited data in children especially from developing countries.

This study was aimed to assess the effectiveness of routine use of PFM in addition to symptom-based guided self-management of asthmatic children in terms of symptom score, quality of life score and pulmonary functions.

Materials and Methods

This was a prospective, randomized, controlled trial. The patients who were eligible for the study according to the inclusion criteria were randomized into 2 groups. The first group used PFM in addition to the symptoms assessment in their self-management plan (PFM group) while the other group used only symptoms-based plan (non-PFM group). The main outcome measures were mean daily symptom scores,[4] quality of life (QoL) scores[12,13] and pulmonary function test including PEFR, FEV1, $FEF_{25-75\%}$ and FVC. All patients were re-evaluated twice during the follow-up period of 3 months. The study protocol has been approved by the Ethics Committee of the Faculty of Medicine, Chulalongkorn University. Informed consent and assents were obtained from all the studied patients and their caregivers.

The daily symptom scores were obtained by using the same scoring system used in the study of Chan-yeung M, et al.[4] The studied patients or the caregivers were asked to assess the severity of the patients' asthma symptoms everyday by answering 7 questions in the scoring system and recorded the scores in their personal diary books. The score of each question ranged from 0 (no symptoms) to 3 (severe symptoms). A total_daily score would range from 0 - 21. The 7 symptoms which were asked in the scoring system included the presence of daytime cough, nighttime cough, daytime wheeze, nighttime wheeze, dyspnea during daytime, dyspnea during nighttime and dyspnea during exercise.

Concerning the quality of life score, we use the questionnaire in the survey form of Juniper EF, et al[12] which had been translated into Thai version and validated by Poachanukoon O, et al.[13] This questionnaire consisted of 23 questions and the score for each question ranged from 1 to 7.

Study Protocol

Inclusion criteria included: (1) age 6 –15 years; (2) physician-diagnosed asthma; (3) receiving regular and stable treatment with inhaled corticosteroid (ICS) according to the GINA Guidelines for Asthma Management [1] for at least 1 month; (4)

no other respiratory problems and (5) competent for peak flow meter (PFM) usage and were followed up regularly at the pediatric chest clinic of King Chulalongkorn Memorial Hospital during the study period. Those patients who had other respiratory problems or other chronic diseases or unable to use PFM regularly were excluded from the study.

The recruited patients were randomly allocated into one of the two self-management groups: PFM group (based on symptoms plus PFM usage) and non-PFM group (based on symptoms alone). All subjects and their main caregivers were taught self-management in a training session during the first meeting. The content of self-management training included symptoms that needed extra dose of bronchodilator inhalation or ER visit, appropriate exercise and environmental management. The patients in the PFM group were trained how to use PFM correctly and to record the measured PEFR in their diaries. They were asked to use PFM to measure their PEFR twice daily (approximately at the same time in the morning and evening). The PEFR values were recorded in the diary everyday for 3 months. The PEFR values indicating the adjustment of treatment plan were based on the child's previous best PEFR, i.e. continuing the same treatment if PEFR 80-100 % of previous best value; doubled dose of ICS or adding β2-agonist if PEFR 60 – 80 % of previous best and giving oral prednisolone and/or seek medical help if PEFR < 60% of previous best. The symptom scores were also recorded in the diary every morning during the 3-month- study period.

The patients were followed up twice after enrollment in the study, i.e. at the end of the 1st or 2nd month and at the end of the 3rd month. At the time of enrollment (first visit), the demographic data were collected, pulmonary function test were performed and the QoL questionnaires were completed. At the end of the 1st or 2nd month, QoL questionnaires were performed, the recorded daily symptom scores were collected. History of asthma symptoms requiring double doses of usual ICS or addition of oral prednisolone (days), number of ER (emergency room) visits, the frequency and duration of hospitalization for acute exacerbation, number of days of absence from school and parental absence from work. At the end of the 3rd month, daily symptom scores were collected, QoL questionnaires and pulmonary function test were performed.

Analysis

The study outcomes were compared between the 2 groups and the outcome parameters in each group were also compared between the1st and the 3rd month. The statistical analysis including mean $\pm$ SD, median (range), Chi-square test, Student t - test, Mann-Whitney U test and Wilcoxon signed ranks test were applied according to the characteristics of the data. The p-value < 0.05 was considered statistically significant.

Results

Sixty-six patients with asthma having characteristics compatible with the inclusion criteria were studied. There were 38 boys and 28 girls with the mean age of 8.9 $\pm$ 2.0 years. Fifty-eight cases (87.8%) were classified as mild persistent asthma while 8 cases (12.2%) had moderate persistent asthma. The average duration of ICS use before the time of study was 3.1 $\pm$ 2.1 years with average QoL

score of 5.8 ± 0.8. The average values of FVC, FEV_1 and PEFR were in normal ranges except for $FEF_{25-75\%}$ which was lower than normal (47.0 ± 14.7% predicted value).

The 66 patients were equally allocated into PFM group (33 cases) and non-PFM group (33 cases). The baseline demographic data of the two groups were not significantly different (Table 1). Having followed up until the end of the 1st or 2nd month and at the end of the 3rd month, there were no significant differences between the PFM group and the non-PFM group in terms of symptom scores [at 3rd month 0.3 (0 - 4.1) *vs*. 0.3 (0 - 7); $p>0.05$], quality of life scores [6 ± 0.7 *vs*. 6.1 ± 0.8; $p>0.05$], pulmonary function test, the need for increased dose of ICS or ER visit (Table 2). None of the patients in this study was hospitalized due to asthma exacerbation or absence from school due to asthma symptoms during the follow-up period. However, when analyzing in the subgroup of patients who had received ICS for 1-3 years, the symptom scores of the PFM group were significantly lower than the non-PFM group in each follow-up visit (Figure 1) while there was no difference in the follow-up symptom scores between the 2 groups in those who had received ICS for less than 1 year and over 3 years.

When comparing the symptom scores, quality of life scores and pulmonary function tests of the non-PFM group between the 1st month and the 3rd month, there were no significant changes in every measured outcomes (Table 3). These findings were also found in the PFM group (Table 4) except for the quality of life score which significantly improved at the end of 3rd month (5.7 ± 0.9 *vs*. 6.2 ± 0.7; p = 0.003).

Table 1. Demographic data and characteristics of the patients in PFM group and non-PFM group.

	PFM (N = 33)	**Non - PFM (N = 33)**	***p* - value**
Sex (F: M)	15 : 18	13 :20	*ns*
Age at enrollment (years) : mean ± SD	9.3 ± 1.5	8.5 ± 2.3	*ns*
Asthma severity (cases)			
mild persistent	29	29	*ns*
moderate persistent	4	4	*ns*
severe persistent	-	-	*ns*
Duration of ICS use (years) : mean ± SD	3.2 ± 2.2	3.0 ± 2.1	*ns*
ICS < 1 year (case)	6	5	*ns*
ICS 1-3 years (case)	12	14	*ns*
ICS > 3 years (case)	15	14	*ns*

ns = no statistical significance ($p>0.05$)

Table 2. Comparison between the PFM group and non-PFM group during the 3-month - period.

	PFM (N = 33)	Non - PFM (N = 33)	*p* - value
Symptom score 1st	0.4 (0 - 6.8)	0.5 (0 - 4.0)	*ns*
Symptom score 2nd	0.3 (0 - 5.2)	0.3 (0 - 5.2)	*ns*
Symptom score 3rd	0.3 (0 - 4.1)	0.3 (0 - 7.0)	*ns*
QoL score $_{baseline}$	5.7 ± 0.9	5.9 ± 0.8	*ns*
QoL score $_{during}$	6.0 ± 0.6	6.0 ± 0.8	*ns*
QoL score $_{at\ the\ end\ of\ 3^{rd}\ month}$	6.2 ± 0.7	6.1 ± 0.8	*ns*
PFT $_{baseline}$ (%predicted)			
FVC	93.0 ± 12.8	90.0 ± 16.6	*ns*
FEV_1	93.0 ± 15.2	93.6 ± 17.8	*ns*
$FEF_{25-75\%}$	48.6 ± 14.4	47.1 ± 12.0	*ns*
PEFR	97.2 ± 16.1	97.6 ± 19.4	*ns*
PFT $_{at\ the\ end\ of\ 3^{rd}\ month}$			
FVC	97.3 ± 12.1	93.5 ± 17.1	*ns*
FEV_1	98.6 ± 12.5	95.1 ± 17.0	*ns*
$FEF_{25-75\%}$	53.1 ± 12.8	47.9 ± 15.9	*ns*
PEFR	102.8 ± 18.6	98.3 ± 18.9	*ns*
Use of double dose ICS or oral prednisolone (days)	0 (0 - 4)	0 (0 - 3)	*ns*
ER visit (times)	0 (0 - 1)	0 (0 - 1)	*ns*
Hospitalization (days)	0	0	*ns*
Absence from school(days)	0	0 (0 - 2)	*ns*

ns = no statistical significance ($p > 0.05$)

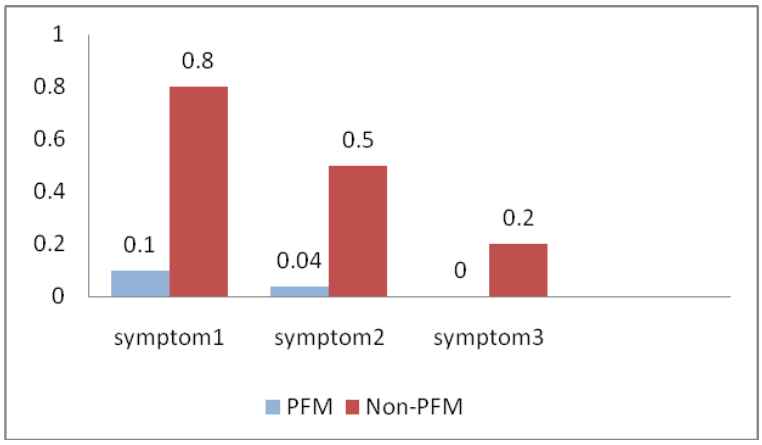

Figure 1. Comparison of symptom scores at 1st , 2nd & 3rd visits (labeled as symptoms1,2,3,respectively) between the PFM group and non-PFM group of the asthmatic patients who had received ICS for 1 - 3 years showed significant differences in every visit ($p < 0.05$).

Table 3. Comparison of outcome measures between the 1st and 3rd months in the PFM group (n = 33).

Outcomes	1st month	3rd month	*p value*
QoL score	5.7 ± 0.9	6.2 ± 0.7	0.003
Symptom score	0.4 (0 - 6.8)	0.3 (0 - 4.1)	ns
PFT			
FVC	93.0 ± 12.8	97.3 ± 12.1	ns
FEV_1	93.0 ± 15.2	98.6 ±12.5	ns
$FEF_{25-75\%}$	48.6 ±14.4	53.1 ± 12.8	ns
PEFR	97.2 ±16.1	102.8 ± 18.6	ns

ns = no statistical significance ($p > 0.05$)

Table 4. Comparison of outcome measures between the 1st and 3rd months in the non-PFM group (n = 33).

	1st month	3rd month	*p value*
QoL score	5.9 ± 0.8	6.1 ± 0.8	*ns*
Symptom score	0.5 (0 - 4.0)	0.3 (0 - 7.0)	*ns*
PFT			
FVC	90.0 ± 16.6	93.5 ± 17.1	*ns*
FEV_1	93.6 ± 17.8	95.1 ± 17.0	*ns*
$FEF_{25-75\%}$	47.1 ± 12.0	47.9 ± 15.9	*ns*
PEFR	97.6 ± 19.4	98.3 ± 18.9	*ns*

ns = no statistical significance ($p > 0.05$)

Discussion

This study could not demonstrate any differences in daily symptom scores, pulmonary function and quality of life scores between the asthmatic children who used self-management plans based on symptoms alone and those who used peak flow meters (PFM) plus symptoms as the guide of their management. These results are consistent with previous findings from clinical trials in adults and most of the reports in children.[2-6] It seemed that PFM did not add any benefit in the management plan for children with persistent asthma. The reasons for the ineffectiveness of PFM might be due to inadequate compliance or adherence to the PEFR measurement schedule and the unreliable results especially in young children.[4, 6, 9-11] However, most of the current guidelines still recommend using pulmonary function test including forced expiratory volume at one second (FEV1) from spirometry and peak expiratory flow rate (PEFR) and its variability measured by using peak flow meter as the diagnostic and monitoring tools for assessing asthma control in addition to symptoms

especially in persistent severe asthma or in those who had poor perception of their symptoms.[1,14,15] Although the results of our study did not favor the use of PFM, there were no complaints about the burden of using this device among the studied patients and their caregivers. Moreover, the majority of our studied patients belonged to the groups of mild to moderate persistent asthma whose symptoms were not very severe and had low risk of asthma exacerbations. This might be the contributing factor leading to inability to demonstrate the usefulness of PFM in improving the outcomes of asthma management when compared to the symptom-based plan alone. In addition, most of the patients and caregivers in this study had good perception of the patients' symptom changes and they stepped up the treatment according to the symptom changes before the PEFR decreased below 80% of their personal best.

Among the asthmatic patients who were treated with ICS for 1-3 years, the symptom scores at the end of 1st, 2nd and 3rd month of the PFM group were significantly lower than those of the non-PFM group, while no difference was observed in those who received ICS less than 1 year or more than 3 years. This might indicate that PFM was probably a useful additional tool for self-management of children with asthma who had received ICS for 1-3 years. There was no previous report and explanations about the association between the duration of controller (ICS) use and the usefulness of PFM in management plan for asthmatic children. Our proposed explanation for this findings was that the patients who were treated with ICS for less than1 year tended to be followed up more frequently and the adjustment of their treatments were mostly decided by the physicians and those who had been treated with ICS for more than 3 years might have more understanding and more experiences of their illness. They might be able to cope with their symptoms without using PFM.

When comparing the measured outcomes between the start of the study and at the end of 3rd month, there was significant improvement in quality of life (QoL) scores among PFM group (5.7 ± 0.9 *vs*. 6.2 ± 0.7; $p = 0.003$) while there was no significant change among the non-PFM group. However, no changes in PFT and symptom scores were observed in both groups. Since the assessment of QoL score was basically subjective,[12, 13] its improvement among the PFM group might be due to the positive perception of the patients and their caregivers on the benefit of PFM in providing the measured value of PEFR that would reassure them on their decision making on treatment plan rather than the benefit of the PFM itself.

Conclusions

The results of this study could not demonstrate the benefit from the addition of PEF monitoring to routine symptom-based guided self-management of childhood asthma especially in those with mild to moderate persistent asthma. These findings also confirmed the unnecessary routine use of PFM among asthmatic children with mild persistent asthma. However, it might play some beneficial role in the improvement of quality of life score and improving symptom scores among asthmatic children who had been receiving ICS for 1-3 years.

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