## The efficacy of a management protocol in reducing emergency visits and hospitalizations in chronic asthmatics

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## ABSTRACT

**Objectives:** To assess whether a simple protocol used in the outpatient's asthma clinic was effective in reducing emergency room (ER) visits and hospitalizations in chronic asthmatics during a year of follow-up, and to evaluate which type of asthmatics, according to severity of asthma, may benefit more from the protocol.

**Methods:** Prospective assessment of a simple protocol (consisted of combined medical and educational aspects in the form of corticosteroids inhalation as a monotherapy and correction of the pitfalls of inhalation technique) in reducing ER visits, and hospitalization in chronic asthmatics. It was performed in the outpatients asthma clinic at King Abdul-Aziz University Hospital, Jeddah, Kingdom of Saudi Arabia. A total of 128 chronic asthmatics were evaluated and followed up for one year between January 1999 and March 2000.

**Results:** Between January 1999 and March 2000 the total number of ER visits, and hospitalizations in 128 chronic asthmatics in the year before the protocol were 269 and 85. This was reduced to 116 ER visits and 27 hospitalizations a year after the protocol, a 55.4%, and

68.2% reduction. While only 25% never attended ER before the protocol, almost 58.6% did not attend ER after the protocol. The proportion that visited ER more frequently (at least 3 times/year) decreased from 50.8-18%, a 65% reduction. Similarly, patients who did not require hospitalization increased from 62.5% up to 85.2%. Moreover, the proportion that was hospitalized more frequently (at least 3 times/year) decreased from 10.2% to as low as 0.8%. Mean paired differences for ER visits were -1.16 ± 1.42 with 95% confidence interval extending from -1.412 to - 0.916 with a P value <0.001. Mean paired differences for hospitalization were -0.453 ± 0.955 with 95% confidence interval extending from -0.620 to -0.286 with a P value <0.001.

**Conclusion:** A simple protocol in outpatient's asthma clinic can significantly reduce ER visits and hospitalizations in chronic asthmatics. All asthmatics, irrespective of severity benefited significantly from the protocol.

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**B** ronchial asthma is a common disease that affects 5-10% of the population worldwide.<sup>1-3</sup> In Saudi Arabia (KSA), the prevalence of asthma is increasing and may exceed 10% in children.<sup>4</sup> In adults, although no studies have yet been carried out, the prevalence is likely to be 5% or more. In Jeddah city, KSA the prevalence of asthma in children is among the

highest in KSA, and may reach up to 13%.<sup>4</sup> In United Kingdom (UK), several studies have shown high prevalence of asthma up to 32.2%.<sup>5.6</sup> This could represent the highest in Europe and may be related to environmental factor.<sup>5</sup> In the United States of America (USA) the prevalence of self reported asthma has increased by 42%,<sup>7</sup> while the annual

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hospitalization rates for asthma were increased by 28%.<sup>8</sup> In KSA, though no statistical data was available, the number of emergency room (ER) visits and hospitalizations in chronic asthmatics have risen sharply during the last years. This may be related to the increase of prevalence and severity of asthma due to environmental and social changes in our society. Among these changes is westernization, rapid civilization, increased exposure to indoor and outdoor allergens and possibly due to increased occupational exposure to pollutants.9 In addition, most asthmatics in KSA were mainly and poorly managed by non specialists with repeated courses of cough syrup, antibiotics, and bronchodilators rather than inhaled anti-inflammatory therapy.<sup>10</sup> Moreover, the minority of asthmatics using inhaled steroid therapy was also on sub-optimal doses. They also tend to have a higher incidence of poor inhalation technique and non-compliance to therapy. Recently, a study from Riyadh, KSA describing the pattern of prescription in 243 asthmatics found that 55% were on regular beta agonists, 30% were on cough mixtures, 26% were on repeated courses of antibiotics, 21% were on theophylline derivatives while only 33% were on inhaled steroids.<sup>10</sup> In the same study, the incidence of poor inhalation technique in asthmatics was also found to be as high as 53%.

In 1995, the health authority in KSA introduced the national protocol for management of asthma.<sup>11</sup> It contains guidelines identical to that found in different international protocols<sup>12-14</sup> that emphasize the importance of using inhaled anti-inflammatory drugs as the main line of therapy in the management of asthma.<sup>11-17</sup> Though 6 years have elapsed since the introduction and the wide dissemination of the national protocol, there were no significant changes in asthma control as the total number of ER visits and hospitalizations in asthmatics is still high. This could be related to the difficulty of applying the recommendations of these guidelines on asthmatics, which consequently has been reflected negatively on the outcome of asthma control. So, to improve asthma control and to simplify the guidelines for asthma management, a simple protocol was designed to be used in the outpatient's asthma clinic on chronic asthmatics. It consisted of 2 aspects (medical, and educational) combined in the form of; steroids inhalation therapy (monotherapy) and regular correction of the pitfalls of inhalation technique.

The aims of this study were to assess whether a simple protocol used in the out-patient's asthma clinic was effective in reducing ER visits and hospitalizations in chronic asthmatics during a year of follow-up, and to evaluate which type of asthmatics, according to severity of asthma, may benefit more from the protocol.

Methods. Description of asthma clinic *protocol.* The protocol consists of 2 aspects: 1. medical therapy in which regular inhaled steroids (budesonide or beclomethasone) were used as the main line of therapy (monotherapy), and 2. Education in which the pitfalls of inhalation technique were regularly checked and corrected in all asthmatics involved in the study. There was no intention to make a comparison between the 2 aspects of the protocol as which one was more effective in reducing ER visits and hospitalizations (if any) in chronic asthmatics. We believe both aspects of this protocol were important and complemented each other in improving asthma control.

**Patients selection criteria for the protocol.** A total of 136 patients fulfilling the American Thoracic Society definition and diagnosis of asthma were included in the study.<sup>18</sup> Eight patients were excluded from the study as they have been lost to follow up. Diagnosis of asthma was based upon clinical history, reversibility of forced expiratory flow (FEV1) >15%, and diurnal variations of peak expiratory flow rate >20%. The inclusion criteria of the study were: asthmatics with one year or more duration of asthma, non smoker, aged 13 years or more, and signed a consent form. Asthmatics were referred to asthma clinic from general practitioners, internists, inpatients, outpatients, and emergency room.

First visit. Role of the pulmonologist. On attendance at the asthma clinic, each asthmatic was interviewed. and clinically evaluated. Α questionnaire that includes personal data (age, sex, nationality, occupation, and duration of asthma) was filled out for each patient. Severity of asthma was measured in each asthmatic and graded into mild, moderate, and severe persistent according to the guidelines on management of asthma.<sup>11-15</sup> Mild asthma was diagnosed if the patient had: intermittent symptoms <one time a week, nocturnal symptoms <2 times a month, was asymptomatic between exacerbation, peak expiratory flow (PEF) >80% predicted, and PEF variability <20%. Moderate asthma was diagnosed if the patient had: nocturnal asthma symptoms >2 times a month, exacerbation >one-2 times a week, PEF 60-80% predicted, and PEF variability >30%. Severe asthma was diagnosed if the patient had: continuous symptoms, frequent nocturnal asthma and frequent or life-threatening exacerbation, PEF <60% of predicted, PEF variability >30%. Each asthmatic was interviewed for one hour divided between the treating physician and the medical educator. All asthmatics were placed only on regular doses of inhaled steroids while the inhaled beta-agonists were used only on as needed basis (PRN). All asthmatics were asked to stop and not to use any of their previous medications once they joined the protocol. The importance of using the inhaled steroid as the only therapy (monotherapy), to

be used regularly at the recommended dose, was stressed to each asthmatic. All asthmatics were instructed not to stop or to reduce the recommended doses of inhaled steroid on their own once they felt better. This should only to be carried out under the supervision of the treating physician on their subsequent visits to the asthma clinic.

Scoring of the total number of emergency room visits and hospitalizations. The total number of ER visits and hospitalizations (if any) due to asthma exacerbation was recorded in each asthmatic for one year before and after the date of starting the protocol. This was scored from zero to 4 in each asthmatic. For ER visit: 0=no visit, 1= one visit, 2= two visits, 3= three visits, 4=four visits. For hospitalization: 0= no 1=one hospitalization, hospitalization, 2=two hospitalizations, 3=three hospitalizations, 4=four hospitalizations. This was double checked against hospital notes to make sure that the sole reasons for ER visits or hospitalizations before and after the protocol was only an asthma exacerbation.

Drugs used in the protocol. The medications used in the protocol were according to the national and international recommendations and guidelines for diagnosis and management of asthma.<sup>11-15</sup> The modification in this protocol was the use of the inhaled steroids as a monotherapy irrespective of asthma severity to improve the patient's compliance and to reduce the cost of therapy. The inhaled steroid used in this study was either Beclomethasone meter dose inhaler (MDI) or Budesonide Turbohaler. The starting dose of inhaled steroids was depended on the severity of asthma. In mild asthma the dose was ranged between 800 µg to 1200 µg/day while in moderate and severe asthma the dose was ranged between 1200 µg to 2000 µg/day according to the guidelines' recommendations. The dose of inhaled beclomethasone ranged from 2 puffs (250 µg/puff) 2-4 times/day (1000-2000 µg/day), while the inhaled budesonide 2 puffs (200 µg/puff) 2-4 times/day (800-1600 µg/day). The beta-agonists used were either salbutamol MDI 2 puffs prn (200 µg/puff), or terbutaline turbohaler one puff prn (500 µg/puff). The selection of the inhaled therapy (beclomethasone versus budesonide or salbutamol versus terbutaline) was based mainly on the availability of the medications in the pharmacy. However, most patients purchase medicine on their own. Prednisone tablets were given to any asthmatic presenting with a severe attack, or having significant drop of PEF <50% of predicted value The starting dose of prednisone was 40 mg/day that reduced by 5-10 mg every 2nd or 3rd day to nil. Non of the asthmatics received oral theophylline or beta 2 agonists tablets during the period of the whole study.

**Role of the medical educator.** A full time nurse interested in asthma education (medical educator) was involved in the whole period of the study. She taught each asthmatic the correct way of inhalation

technique. She checked the inhalation technique step by step according to the types of device used (MDI and or turbohaler). She recorded the pitfalls of inhalation technique in each asthmatic. She checked and corrected these errors in the subsequent visits for each asthmatic. She used the placebo samples of the MDI, and turbohaler for the demonstration. She made sure that all asthmatics were able to use the inhaler devices correctly, and this was carried out by asking each one to demonstrate this before leaving the asthma clinic. In any asthmatic that was unable or failed to use the inhaler devices correctly a space device (Aerochamber or Volumatic), was used from the beginning. Training of using the space device correctly was also provided to any asthmatic in need.

Subsequent visits. Each patient was seen every 6 weeks for the first 2 visits, and then once every 3 months until the end of a year of follow-up. In each visit the dose of inhaled steroid was checked, and adjusted according to the patients' symptoms, and to the peak flow meter readings. Doses of inhaled steroids were reduced gradually when asthmatics became asymptomatic. They were placed on the minimum doses of inhaled steroid that kept them free of symptoms. Doses of inhaled steroid were increased or doubled in any asthmatic with poor control of asthma (presence of recurrent nocturnal symptoms, frequent episodes of chest tightness, increased intake of inhaled beta2 agonists, and or drop of PEF< than 70% of predicted). Asthmatics with acute exacerbation were instructed to report to the asthma clinic without making an appointment. In case of holidays or during closure of the clinic, or if the attack was too severe, from the start they were instructed to report immediately to the ER of King Abdul-Aziz University Hospital, Jeddah, KSA. The decision for hospitalization was left to ER doctor and or to resident on call without interference from the treating physician. All asthmatics were instructed to report any hospitalization or ER visits to the treating physician in the subsequent visit. Asthmatics presenting to the outpatient's asthma clinic with an exacerbation were managed according to the severity of attack. Prednisone orally at a tapered dose was given if the PEF drop < 50% of predicted while if the PEF was between 50-70% the doses of inhaled steroid was doubled, and beta2 agonist was used regularly. Subsequently they were followed up weekly until the symptoms subsided, and peak flow rate return to normal or to the baseline before the attack.

**Data management and statistical analysis.** Data was entered in a data base file and scrutinized for outlier. The analysis was carried out using statistical package for social sciences. Descriptive statistics and frequency distributions were performed to describe the studied variables. Student t-tests, analysis of variance, and paired sample's t-test was used as appropriate. Level of significance was set to be <0.05 through the analysis.

**Results.** A total of 128 asthmatic patients were studied, 74.2% were females and 57.8% were Saudis and the overall mean age was  $39.7 \pm 14.7$  years (minimum 13 and maximum 76). The mean duration of illness was 10.7 ± 10.3 years (minimum 0.4 and maximum 52). Steroid pulses were given for 14 asthmatics. Aerochamber were used by 6 asthmatics. Table 1 shows the main characteristics of the asthmatic patients. Overall there were 269 ER visits/ year before protocol that has been reduced to 116 ER visits/year after, a 55.4% reduction. Similarly, there were 85 hospitalizations per year before protocol that has been reduced to 27 hospitalizations/year, a 68.2% reduction. Table 2 shows the breakdown of these visits by asthma severity with corresponding percentage reduction. Table 3 shows the frequency distribution and mean  $\pm$  (SD) for ER visits and hospitalizations before and after protocol. While only 25% never attended ER before protocol, almost 58.6% did not attend ER after the protocol. In addition, the proportion that visited ER more frequently (at least 3 times) decreased from 50.8% to 18%, a 65 reduction. Similarly, patients who did not require hospitalizations increased from 62.5% up to 85.2%. Moreover, the proportion who was hospitalized more frequently (at least 3 times) decreased from 10.2% to as low as 0.8%. Table 4 shows the parameters of testing paired differences of ER visits and hospitalizations for asthmatics before and after protocol. Mean paired difference for ER visits was  $-1.16 \pm 1.42$  with a 95% confidence interval extending from -1.412 to -0.916 and a P-<0.001. Mean paired difference value for hospitalizations was  $-0.453 \pm 0.955$  with 95% confidence interval extending from -0.620 to -0.286 and a P-value <0.001. Further analysis of these paired differences considering the classification of severity of BA (mild, moderate, and severe) showed statistically significant results (Table 4) indicating a profound effect of protocol for all kinds of patients (Figures 1 & 2).

**Discussion.** This is a prospective study in which the efficacy of a simple protocol on reducing the number of ER visits and hospitalizations in chronic asthmatics has been evaluated. The protocol consists of 2 combined aspects in the form of steroid inhalation therapy (monotherapy) and training of asthmatics on the proper use of the inhaler devices (MDI, and Turbohaler, or both). A total of 128 chronic asthmatics were involved in the study that has shown 2 important findings. First, a simple protocol used in the outpatient's asthma clinic has reduced significantly the number of ER visits and hospitalizations in chronic asthmatics up to 55.4% and 68.2%, in the year of follow-up. Second, the number of ER visits and hospitalizations were significantly reduced in all types of asthmatics with mild to severe asthma. Although mild asthmatics

Table 1 - The main characteristics of the chronic asthmatics (n=128).

Characteristic	Findings n (%)
Age (mean ± standard deviation)	39.7 ± 14.7
Sex Male Female	33 (25.8) 95 (74.2)
<i>Nationality</i> Saudi Non-Saudi	74 (57.8) 54 (42.2)
Duration (years) (mean ± standard deviation)	$10.7 \pm 10.3$
<i>Severity</i> Mild Moderate Severe	72 (56.3) 31 (24.2) 25 (19.5)
<i>Therapy</i> Bronchodilators Salbutamol (as required) Terbutaline (as required) <i>Anti-inflammatory</i> Budesonide	84 (66) 22 (17.2) 52 (40.6) 76 (59.4)

 
 Table 2 - Percentage reduction in number of emergency room visits and hospitalizations by asthma severity before and after protocol.

Asthma severity	r Before	-	Reduction (%)		
<i>ER visits</i> Mild	115	26			
Moderate	83	20 44	(77.4) (47)		
Severe	71	44	(35.2)		
Hospitalization					
Mild	28	7	(75)		
Moderate	24	4	(83)		
Severe	33	16	(52)		
n - 1	number, ER -	emergency	room		

**Table 3** - Frequency distribution and mean  $\pm$  standard deviation for ER visits and hospitalizations before and after the protocol.

Type of visit before and after protocol	Never attended	1	2	3	4	Mean ± standard deviation
ER before	25	16.4	7.8	25	25.8	2.1 ± 1.57
ER after	58.6	17.2	6.3	7.8	10.2	$0.94 \pm 1.37$
H before	62.5	22.7	4.7	6.3	3.9	$0.66 \pm 1.08$
H after	85.2	10.2	3.9	0	0.8	$0.21 \pm 0.58$
ER before - emergency room visits before protocol ER after - emergency room visits after protocol H before - hospitalizations before protocol H after - hospitalizations after protocol						

Type of visit	Paired differences			t-value	n value	95% CI
	Mean	SD	SE	t-value	p-value	95 % CI
ER Hospitalization	-1.164 -0.453	1.42 0.955	0.125 0.084	-9.28 -5.37	<0.001 <0.001	-1.412, -0.916 -0.620, -0.286
<i>ER</i> Mild Moderate Severe	-1.181 -1.258 -1.00	1.387 1.341 1.633	0.163 0.241 0.327	-7.22 -5.22 -3.06	<0.001 <0.001 0.005	-1.507,- 0.854 -1.750, -0.766 -1.674, -0.326
Hospitalization Mild Moderate Severe	-0.292 -0.645 -0.680	0.830 1.112 1.030	0.098 0.20 0.206	-2.98 -3.23 -3.30	0.004 0.003 0.003	-0.487, -0.097 -1.053, -0.237 -1.105, -0.255

Table 4 - Parameters of testing paired differences of ER visits and hospitalizations for asthmatics before and after the protocol.

may not require hospitalization, in this study we found 33% of mild asthmatics were hospitalized. The high incidence of hospitalization in mild asthmatics could be related to either to the severity of asthma exacerbation or to the inadequate response to medical therapy in the emergency room. The current guidelines have stressed the importance of using anti-inflammatory inhaled therapy in the management of chronic asthma.<sup>11-15</sup> In particular inhaled steroid has been recommended for the treatment of all types of asthmatics with mild to severe asthma.11-15 These recommendations were based on the recognition of asthma as an inflammatory airway disease that needs regular antiinflammatory therapy.<sup>16</sup> This was supported by several studies that have shown inhaled steroids have reduced asthma symptoms, decreased asthma exacerbations, and improved pulmonary function.<sup>17-21</sup> In KSA the majority of asthmatics were managed by non specialists with repeated courses of cough mixtures, antibiotics, and bronchodilators rather than inhaled anti-inflammatory therapy. Recently, a single study from Riyadh, KSA describing the pattern of prescription on 243 chronic asthmatics found only 33% were using inhaled steroids and 50% of them were receiving steroids at suboptimal doses.<sup>10</sup> In rural areas of KSA, asthma management is worse as inhaled steroid therapy has hardly ever been used. Several studies have shown significant correlation between the use of inhaled steroids and reduction of hospitalizations.<sup>22-24</sup> A study by Donahue et al,<sup>22</sup> found asthmatics on inhaled steroid were associated with 50% reduction of hospitalization when compared to asthmatics on no inhaled steroid. Moreover, 64% of hospitalized asthmatics were not using inhaled steroid before hospitalization. In the present study, the incidence of no inhaled steroid was not checked in asthmatics whether visited ER or hospitalized before joining the protocol. However, from our observation we believe most of our

asthmatics were not using inhaled steroid therapy before hospitalization. Another study by Gottlieb et al<sup>23</sup> has also found an inverse relationship between the frequency of dispensing inhaled steroid and asthma hospitalization. Dales et al<sup>24</sup> has shown that 50% of asthmatics visiting ER were not taking inhaled steroids. A study in pediatrics has shown that the use of anti-inflammatory therapy was responsible for the reduction of hospitalizations among children.<sup>25</sup> The finding in the present study has proved the efficacy of the protocol in reducing ER visits and hospitalizations in chronic asthmatics using inhaled steroid as a monotherapy and it was comparable with previous studies. The total number of asthmatics received steroid pulses at the asthma clinic was 14 patients during the duration of study. This could be another advantage of the protocol. Patient's education has also been considered to be an essential part in the management of asthma. The guidelines for asthma management have also stressed the importance of education in each asthmatic.<sup>11-15</sup> Asthma education has included a wide range of recommendations that may or may not be suitable to each asthmatic. The importance of education is to provide asthmatics with appropriate simple facts regarding the nature of asthma, to correct any sociocultural misconceptions regarding asthma, and to educate asthmatics clearly in when and how to use the inhaled therapy and how the inhaler devices can be used correctly.<sup>11-15</sup> Though education is important each asthmatic in general, it should be in individualized according to the patient's requirements that could differ from one individual to another and from one community to another. In fact, most of asthmatics in KSA have difficulty in using the inhaler devices properly. For instance, in Rivadh, KSA the incidence of poor inhalation technique was high and up to 53%<sup>10</sup> while in Jeddah, KSA, though no data was available we believe from our observation it is much higher. Therefore, the delivery

of inhaled medications to the lung was insufficient. This may explain in why asthma was poorly controlled and why the ER visits and hospitalizations were increasing. So in this protocol we concentrated mainly on educating the asthmatics on how they become competent in using their inhaler devices. So, they were trained regularly in the outpatients under direct supervision of the medical educator. The advantage of this method of education was to establish a direct relationship between patient, nurse, and doctor that could reflect positively on asthma control.

Several studies using different methods of education have shown significant reduction in asthma symptoms, ER visits and hospitalizations.<sup>26-28</sup> An Australian study by Yoon et al<sup>26</sup> was aimed to improve the inhaler skill. They educated asthmatics on how to adjust drug doses according to their PEF measurements. They have shown significant reduction in the rate of re-admission in the educated group up to one 7th when compared with control group over period of 10-months.

Another study by Osman et al<sup>27</sup> in which they made a comparison between asthmatics taking part in enhanced education program and conventional oral education. The program consisted of 4 printed booklets on asthma management covering both regular control and action in acute episode, and was sent to the patients by post. They found 54% reduction in hospitalizations in asthmatics receiving enhanced educational program than did the control group over the study year. Wilson et al<sup>28</sup> compared asthmatics receiving self-management education program (individual teaching, small group education, and work book education) with a control group (no formal asthma education). They found asthmatics with self management education program have significant improvement in control of asthma symptoms, and MDI technique. The improvement in MDI technique was also positively correlated with improved control of symptoms. In the present study the significant reduction in ER visits and hospitalizations could also be related to the improvement of the inhalation technique and it was comparable with the previous studies. However, in the previous studies the role of education was separate from the medical therapy and the education was self dependent while in our study the protocol used combined medical therapy with education. Mayo et al<sup>29</sup> using an out-patients protocol based on teaching moderate and severe asthmatics an aggressive self-management strategy in case of acute asthma exacerbation has resulted in 3-fold reductions in the re-admission rate and 2-fold reductions in hospital stay use during a 32 month follow-up period. The long term effect of their protocol was found to sustained in reducing ER he visits and hospitalizations.<sup>29</sup> In the present study the long term

efficacy of the protocol used has not vet been evaluated. However, we believe that it will have a sustained effect as long as asthmatics are using their inhaled therapy regularly and correctly. The absence of a control group of asthmatics not using the protocol was one of the drawbacks of the study. However, the use of the same group of asthmatics before and after the protocol could over come this drawback.

In conclusion, this study supports the view that a simple outpatient protocol consisting of combined steroid inhalation therapy and regular education on the proper use of inhalation technique can significantly reduce the number of ER visits and hospitalization in chronic asthmatics. Due to the simplicity and efficacy of the protocol we recommend its use in the outpatient asthma clinic. The long term efficacy of the protocol on reducing ER visits and hospitalizations needs to be evaluated.

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