

A descriptive study on usage of inhaled steroids in children

G M Bandaranayake¹, A P Wijesuriya²

Sri Lanka Journal of Child Health, 2010; **39**: 128-132

(Key words: Corticosteroids, beclomethasone, inhaler device, bronchial asthma)

Abstract

Objective To determine the use of inhaled corticosteroids in a cohort of children at Lady Ridgeway Hospital (LRH), Colombo.

Method A cross-sectional descriptive study was carried out on all clinic and in-ward patients of ward 4 LRH receiving inhaled corticosteroids for more than 6 months. A pre-tested, structured interviewer administered questionnaire was used to collect data on the demography, type of drug and device, adherence and response to therapy.

Results The study population comprised 185 children, 55% of whom were males and 35% in the 2-5 year age group. In 90% the inhaled steroid was beclomethasone. Metered dose inhaler was used by 64% and dry powder inhaler by 36% for steroid delivery. Ninety six percent of the study population used the correct inhaler device for their age group. The commonest indication for inhaled steroid was moderate persistent bronchial asthma. The technique was demonstrated at initiation to 99.5% of the users by the prescriber. Eighty four percent of the study population practised a 'good' technique. Nearly 80% of the patients adhered to the therapy daily and attended the clinic regularly. Around 15% needed hospitalisation. About 96% showed restricted lifestyles, mainly consumption of iced food. Inhaler technique of the patient had a significant effect on the clinical response to therapy ($p < 0.05$).

Conclusions Beclomethasone was the most commonly used inhaled corticosteroid in the study. Ninety six percent used the correct inhaler device for their age group. Inhaler technique had a significant effect on the clinical response. About 96% had restricted lifestyle despite optimal control.

¹Senior Registrar in Paediatrics, ²Consultant Paediatrician, Lady Ridgeway Hospital, Colombo

(Received on 10 September 2009. Accepted on 19 December 2009)

Introduction

Bronchial asthma is a common respiratory illness with long term morbidity among children. According to the International Study of Asthma and Allergies in Childhood (ISAAC), prevalence rates of childhood asthma in Sri Lanka can be as high as 30-40%¹. It is also a common cause of school absenteeism^{1,2,3}. Denial of the disease, reluctance to use inhalers, myths regarding inhalers and poor compliance^{1,3,4,5} further aggravate the issue. Despite many clinical trials, introduction of newer potent treatment modalities and management guidelines^{1,6,7}, doctors and parents encounter many practical difficulties and asthma retains a considerable respiratory morbidity among children. It is accepted worldwide that inhaled steroids have become the cornerstone of long-term prophylaxis imparting better control of the disease^{3,8}. It is evident that in recommended dosages steroids are safe and effective in infants and younger children with asthma^{3,8,9,10}.

Childhood asthma directly and indirectly leads to many complications including growth failure, chest deformities, restricted physical activity, recurrent hospitalizations and school absenteeism. Prophylactic inhaled corticosteroids have been shown to reduce mortality⁸, morbidity, improve lung function, reduce acute exacerbations and ensure near normal life in children^{6,8}. However, availability, accessibility and affordability have become limitations in gaining maximum benefit. Inhaled corticosteroids are currently available in some Sri Lankan Public Health Sector hospitals free of charge. It is widely accepted and proven that proper technique and good adherence are essential for it to be most cost effective^{9,10}.

Objective

To determine the usage of inhaled corticosteroids in a cohort of children managed at Lady Ridgeway Hospital for Children, Colombo.

Specific Objectives:

- To describe the aspects of prescription of inhaled corticosteroids
- To evaluate the compliance of the patients towards inhaled corticosteroids
- To determine the response to inhaled corticosteroid therapy
- To assess the impact on the life style of these children
- To describe the factors associated with the clinical response to inhaled corticosteroids

Method

A cross-sectional descriptive study was carried out on all clinic and in-ward patients of ward 4, Lady Ridgeway Hospital (LRH) on inhaled corticosteroids for more than 6 months. The study was carried out for three months commencing 1st April, 2009. As most of them attended the clinic on a monthly basis, measures were taken to avoid duplication. Children were excluded from the study if the parents refused consent, were mentally subnormal or were unable to understand the questionnaire in Sinhala or English. However, none of the patients were excluded during the study period.

A pre-tested, structured interviewer administered questionnaire was used to collect data. This questionnaire assessed:

- (a) Demographic data
 - i. age
 - ii. gender
- (b) Indication for therapy, the device and the drug used
- (c) Who prescribed the therapy and whether the technique had been demonstrated by the prescriber
- (d) Assessment of the technique
- (e) Adherence
 - i. Adherence to therapy
 - ii. Clinic attendance
- (f) Response to therapy
 - i. School absence
 - ii. Use of rescue medication
 - iii. Details of hospitalisation
 - iv. Restriction of normal life style

During the study period the principal investigator personally reviewed the patients. Child and parents / caregivers were given explanations about the study, informed consent was obtained and patients were serially enrolled. At the end of interview, child and parent were requested to demonstrate the inhaler

technique, and any wrong technique was rectified by demonstrating the correct method.

Results

Demographic data is shown in Table 1.

Table 1
Demographic data

Variable	Number (%)
Gender: Male	101 (55)
Female	84 (45)
Age: <2 years	24 (13)
2-5 years	64 (35)
>5-<8years	42 (22)
8 years or >	55 (30)

Of the study population 78 (42%) had moderate persistent asthma, 72 (39%) mild persistent asthma, 48 (26%) nocturnal cough as the *main* symptom, 28 (15%) acute severe asthma, 15 (8%) severe persistent asthma and 03 (1.6%) exercise induced asthma. Some children shared more than one state. None used inhaled corticosteroids following chronic lung disease.

Beclomethasone was the inhaled corticosteroid used in 167 (90%) children and 18 (10%) children were on combined preparations.

Corticosteroids were delivered via a dry powder inhaler (DPI) in 36% of cases (*DP haler* 35%, *Cyclohaler* 1%). The metered dose inhaler (MDI) was used for steroid delivery in 64% cases, 25% using the volumatic spacer without a mask, 23% the babyhaler spacer device and 16% the volumatic spacer with a mask. Ninety six percent of the study population used the appropriate device for their age group (Table 2).

Table 2
Device for the respective age groups

Device	<2yrs	2-5 yrs	>5 to <8yrs	8yrs & >	Total
Dry powder inhaler	0	3	27	36	67
Babyhaler	21	21	0	0	42
Spacer	1	19	20	7	47
Spacer and mask	3	26	0	1	30
Total	25	69	47	44	185

Of the inhaled corticosteroids 180 (97%) were prescribed by paediatricians in the government

sector, 03 (2%) by paediatricians in the private sector and 02 (1%) by general practitioners.

Demonstration of the technique was done at the initiation of the therapy in 184 (99.5%) of the users. Further demonstration of the technique was done in between therapy in 150 (80%). In one of the users the technique was not demonstrated at any stage.

Among 84% of the study population, practice of the technique was 'good' and in 16% 'moderate'. The criteria used for assessment were as follows:

For MDI with spacer (with or without mask)

1. Removal of cap
2. Spacer compatible with MDI
3. Shake the inhaler
4. Insert the mouthpiece into the socket provided at the end of spacer
5. Place the mouth piece of spacer into the mouth and close lips tightly around it
6. Release medication and breath in and out normally through the mouth 3-5 times
7. Minimal delay between MDI actuation and inhalation
8. Hold breath
9. Breath released slowly
10. Wait before taking next puff

For DPI

1. Loading the drug substance properly
2. Exhale before firing
3. Correct rotation
4. Take the mouthpiece into the mouth and close lips tightly around it
5. Tilt the head back slightly
6. Inhale forcefully and deeply
7. Hold breath for 10 seconds or more
8. Check for any remaining drugs
9. Repeat steps 4-7 to allow delivery of remaining powder
10. Wash mouth and gargle the throat with water and spit the water out

Overall assessment was done as

1. Good knowledge (7-10)
2. Moderate knowledge (4-6)
3. Poor knowledge (<4)

The most overlooked steps in MDI use were holding the breath after inhaling the drug (48%) and slowly releasing the breath after the inhalation of the drug (47%). DPI users overlooked tilting the head slightly while inhaling the drug (42%) and holding the breath after inhaling the drug (25%).

Compliance of patients towards inhaled steroids was assessed by noting the adherence to therapy and clinic attendance. This is shown in Table 3.

Table 3
Adherence

Variable	Number (%)
<i>Adherence to therapy</i>	
Daily	152 (82)
Always	14 (08)
Mostly	12 (06)
Seldom	07 (04)
<i>Clinic Attendance</i>	
Always regular	147 (80)
Sometimes regular	29 (15)
Infrequent	05 (03)
Buys drugs from pharmacy	04 (02)

Changing of therapy

Of the study population 19 (10%) changed therapy at least once for the past 6 months. Among them, 11 (58%) changed during past 3 months, 05 (26%) changed during past 1 month and 03 (16%) during past 6 months. Among those who needed to change therapy 09 (47%) changed their drugs, 07 (37%) changed the dosage, 02 (10.5%) had the device changed and 02 (10.5%) had the frequency adjusted. Most common (97%) reason to change the therapy was poor response while 02 (10.5%) changed therapy due to improvement of the condition.

Response to therapy

Response to the therapy was measured using multiple parameters such as school absence, use of rescue medication, duration and treatment received during hospital stay and life style restriction.

Among the 97 school attending children there was no school absence in 60 (62%) for the past 3 months, 24 (25%) had not attended school for 1-4 days, 09 (9%) lost 5-10 school days and 04 (4%) missed school for more than 10 days.

Thirty two (17.3%) children needed inhaled bronchodilator therapy during the past 3 months while 59 (32%) needed nebulisation. Among those who needed nebulisation 45 (77%) came to the outpatient department (OPD) of a government hospital, 12 (20%) went to the private sector and 02 (3%) were nebulised at home.

Overall control of the disease without considering hospitalization was very good in 101 (55%), good in 23 (12%), moderate in 03 (2%) and poor in 58 (31%)

among the population. Here the school absenteeism and the need for rescue medication were considered.

- *Very good:* No school absenteeism and no rescue medication used.
- *Good:* <5 days of school absence during last 3 months or needed bronchodilator inhaler therapy.
- *Moderate:* 5 -10 days of school absence for the last 3 months or needed home nebulisation.
- *Poor:* >10 days of school absence during last 3 months or nebulisation at OPD/ private sector.

Of the study population 30 (16%) needed hospitalization during the past 6 months. Of those admitted to hospital 14 (45%) stayed for 3-4 days, 12 (43%) stayed less than 3 days, 02 (6%) stayed 5-6 days and another 02 (6%) stayed for more than 1 week in the hospital. All patients needed nebulisation during their hospital stay, while 27 (91%) received oral steroids. Only 03 (11%) needed IV steroids and none needed IV aminophylline, IV magnesium sulphate or ICU care during the study period.

Response to therapy in patients who needed hospitalization was very good in 25 (83%), good in 04 (14%), and moderate in 01 (3%). This was assessed by the following criteria:

- *Very good:* No hospitalizations.
- *Good:* 1-2 hospitalizations for the last 6 months and duration of hospital stay <4 days and needed only nebulisation and oral steroids as treatment.
- *Moderate:* 3-5 hospitalisations for the last 6 months or duration of stay 5-7 days or needed IV Steroids as treatment.
- *Poor:* >5 hospitalisations for the past 6 months or duration of stay >7 days or needed IV aminophylline or IV magnesium sulphate as treatment.
- *Very poor:* >5 hospitalisations for the past 6 months duration of stay >7 days and needed ICU care.

Of the study population 178 (96%) had lifestyle restrictions where 74 of 97 (76%) had restricted participation of sports at school, 78 of 97 (80%) had restriction of sports outside the school, 147 (80%)

were deprived of iced food and 44 (24%) had sleep disturbances.

Factors associated with clinical response to inhaled corticosteroids

A significant difference was observed in the technique of using the inhaler device between the patients who had been demonstrated and had not been demonstrated the technique in between therapy ($\chi^2=6.373$, $df=1$, $p<0.05$) while demonstrating the technique at the initiation of the therapy had not changed the technique significantly.

There was a significant difference of the clinical response (without considering hospitalization) between patients who practised a 'good' technique and a 'poor' technique ($\chi^2=5.471$, $df=1$, $p<0.05$) and who had 'good' adherence to therapy and 'poor' adherence to therapy ($\chi^2=4.868$, $df=1$, $p<0.05$) while there was no significant difference of the clinical response (without considering hospitalization) in relation to the clinic attendance.

The clinical response in relation to hospitalization was significantly different between patients who practised 'good' technique compared to the patients who had a 'poor' technique ($\chi^2=4.732$, $df=1$, $p<0.05$) while adherence to therapy and clinic attendance did not affect significantly to the clinical response in relation to hospitalization.

A significant difference of the lifestyle restriction was observed between the patients who practised a 'good' technique and a 'poor' technique ($\chi^2=4.066$, $df=1$, $p<0.05$) and adherence to therapy and clinic attendance had no significant impact on lifestyle restriction. Appropriateness of the inhaler device made no significant difference in the clinical response or lifestyle restriction.

Discussion

In this study moderately persistent asthma was the commonest indication for prophylaxis and a significant proportion only had nocturnal cough as their presentation prior to starting prophylaxis. Majority of patients were on an appropriate device for their respective age groups. Both these fall in line with the Sri Lanka Medical Association guidelines¹. Although change of therapy was observed in a minority, it was predominantly due to unsatisfactory response. The inhaled steroid therapy was prescribed mainly by the paediatricians attached to the government sector. Almost all recipients (99.5%) were demonstrated the correct technique by the

prescriber and in the majority it was reinforced in between the follow up care and our results showed better values than other studies⁴. Most of the users' compliance and clinic attendance were satisfactory.

In contrast to the common belief of near normal activity following inhaled steroids, in our study it was revealed that the majority of parents denied their children iced food (in spite of optimal asthma control) and restricted physical activities. Although acute severe asthma management may require intravenous (IV) aminophylline, IV magnesium sulphate or even intensive care unit admission, none of our patients needed them probably due to better long-term control achieved by inhaled steroids. This fact was proven by many studies^{3,6}. All admitted patients required nebulisation and most of them also required oral steroids. It was clearly observed that the clinical response and reduction of hospitalization directly depended upon the proper technique.

Conclusions

- Beclomethasone was the most commonly used inhaled corticosteroid in the study.
- Ninety six percent used the correct inhaler device for their age group.
- Inhaler technique had a significant effect on the clinical response.
- About 96% had restricted lifestyle despite optimal control.

Recommendations

It is vital to educate the parents and children that asthmatic children can lead a normal life by adhering to optimal asthma therapy. Restriction of food especially iced products is not necessary in most patients. We should not ignore the fact that repeat re-enforcement of inhaler technique during clinic visits is of immense benefit to the patient for a better life style and long-term outcome.

Acknowledgements

We thank Dr A B P Perera, Relief House Officer, Lady Ridgeway Hospital, Colombo for continuous support and assistance, Dr S Sri Ranganathan, Senior Lecturer in Pharmacology and Consultant Paediatrician, Faculty of Medicine, University of Colombo for invaluable guidance, Dr N Gunawardena, Senior Lecturer, Department of

Community Medicine, Faculty of Medicine, University of Colombo for advice and guidance.

References

1. SLMA Guidelines on the Management of Asthma 3rd ed. Expert Committee on Asthma. Colombo: Sri Lanka Medical Association; 2005.
2. Doull IJ, Williams AA, Freezer NJ, Holgate ST. Descriptive study of cough, wheeze and school absence in childhood. *Thorax* 1996; **51**(6): 630-1.
3. British Guideline on the Management of Asthma – a national clinical guideline- May 2008. Available from: <http://www.guidelines.gov/content.aspx?id=15073>
4. Lim SH, Goh Dyt, Tan Ays, Lee BW. Parents' perceptions towards their child's use of inhaled medications for asthma therapy. *Journal of Paediatrics & Child Health* 1996; **32**(4):306-9.
5. Cochrane GM, Horne R, Chanez P. Compliance in asthma. *Respiratory Medicine* 1999; **93**(11): 763-9.
6. Rowe, BH, Spooner, CH, Ducharme, FM, et al. Corticosteroids for preventing relapse following acute exacerbations of asthma. *Cochrane Database Syst Rev* 2000; CD000195.
7. Cochrane MG, Bala MV, Downs KE, Mauskopf J, Ben-Joseph RH. Inhaled corticosteroids for asthma therapy – patient compliance, devices and inhalation technique. *Chest* 2000; **117**:542-50.
8. Behrman RE, Kliegman RM, Jenson HB, editors, Nelson Text Book of Paediatrics 18th ed. Chapter 143. Philadelphia: W B Saunders;2007
9. Powell CV, Everard ML. Treatment of childhood asthma: Options and rationale for inhaler therapy.
10. Pereira LMP, Clement Y, McIntosh D, Simeon DT. Understanding and use of inhaler medication by asthmatics in Specialty Care in Trinidad. *Chest* 2002; **121**:1833-40.
11. Guilbert TW, Morgan WJ, Zeiger RS, et al. Long-term inhaled corticosteroids in preschool children at high risk for asthma. *N Engl J Med* 2006; **354**(19): 1985-97.