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Original Research Article

Exploring the role of inhaled corticosteroid/betamethasone for managing recurrent respiratory illness in infants and young children

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ABSTRACT

Background: Recurrent respiratory illnesses (RRIs) are frequent respiratory tract infections, particularly common in fall-winter and during seasonal changes. RRIs primarily affect children aged 2-7 years and the elderly, with respiratory viruses causing about 80% of cases. They interfere significantly with children's well-being and incur substantial medical and social costs. The study aim was to assess the effectiveness of inhaled corticosteroids (ICS) in infants and young children with recurrent respiratory symptoms.
Methods: This prospective observational study took place over one year at the department of pediatrics, Cox's Bazar medical college, Bangladesh, from June 1, 2014, to May 31, 2015.
Results: The study involved 210 children with recurrent respiratory symptoms, mostly males (57.62%) and predominantly aged 1-3 years (55.71%). Atopy was present in 16.67%, and eczema in 30.48%. Only 2.38% of mothers smoked during pregnancy, and 20.48% of children were exposed to passive smoke. Salbutamol use was high (80.48%), and 32.86% used ICS. Symptoms ranged from mild (13.81%) to severe (23.81%). After six months, daytime cough reduced from 52.38% to 1.43%, and nighttime cough from 66.19% to 0%. Symptom-free days increased, and hospital admissions decreased from 90.95% to 9.05%. Common adverse events included worsening symptoms (13.81%) and fever (13.33%).
Conclusions: Inhaled corticosteroid/betamethasone therapy significantly improved symptoms in infants and young children with RRIs over six months, reducing coughing, wheezing, shortness of breath, and hospital admissions, while increasing symptom-free days. Adverse events were mild and infrequent, suggesting ICS is effective and safe. Further research is needed to optimize treatment.

Keywords: Inhaled corticosteroid, Betamethasone, RRIs, Infants and young children

INTRODUCTION

Recurrent respiratory illness or infections (RRIs) are a common respiratory condition characterized by multiple episodes of respiratory tract infections that recur several times during the year, particularly in the fall-winter period and during seasonal changes.[1] These infections can affect various parts of the respiratory system, including the upper and lower airways, leading to symptoms such as coughing, wheezing, and difficulty breathing. RRIs are prevalent in children aged 2 to 7 years and the elderly, with respiratory viruses being the main infectious agents responsible for about 80% of cases, rather than pathogenic bacteria requiring antibiotic therapy.[2,3]

Approximately 25% of children under 1 year and 6% of children during the first 6 years of life experiencing RRIs. Despite being a benign condition that tends to improve by the age of 12, RRIs significantly interfere with the child's well-being and result in substantial medical and social costs.[1] For children under the age of 5, it is especially challenging to differentiate between those with temporary symptoms, such as viral wheeze, and those with ongoing symptoms, such as asthma.[3,5] At present, it is not possible to determine which infants with respiratory symptoms will go on to develop asthma and which will not. Additionally, it remains uncertain which children with respiratory symptoms may need ongoing asthma maintenance therapy.[6,7] Currently, treatment decisions are not based on solid evidence, which can lead to both undertreatment and overtreatment in these patients. ICS such as betamethasone, have been widely used in the management of chronic respiratory conditions in older children and adults due to their anti-inflammatory properties.[8,9] These medications help to reduce airway inflammation, mucus production, and hyperresponsiveness, which can improve breathing and decrease the frequency and severity of respiratory symptoms. As a result, ICS are considered a cornerstone of treatment for asthma and other chronic respiratory conditions.[10] While the benefits of ICS in managing chronic respiratory conditions in older children and adults are well-established, their role in infants and young children with RRIs remains less clear.[11] Concerns have been raised about the potential side effects of corticosteroids on growth and development, particularly in young children. Therefore, exploring the safety and efficacy of ICS in managing recurrent respiratory illnesses in infants and young children is crucial.[12]

However, there is limited data on the appropriate dosing, duration of treatment, and long-term effects of inhaled betamethasone in infants and young children. The study aim was to assess the effectiveness of ICS in infants and young children with recurrent respiratory symptoms.

METHODS

This prospective observational study was conducted at the department of pediatrics, Cox's Bazar medical college, Bangladesh. The study duration was one year from 1st June 2014 to 31st May 2015. Before collecting data, a consent from was taken from every participant.

Inclusion criteria

Infants and young children of 2 months to 5 years of age, history of respiratory symptoms at least 3 times in last 6 months were included in study.

Exclusion criteria

Data with incomplete documentation, critically ill infants and young children and patient came with respiratory symptoms for the first time were excluded from study.

The study protocol was approved by ethics committee of the institution. Data will be collected using a structured questionnaire form containing all the variables of interest. The questionnaire will be finalized following pre-testing. Data collected were organized into tables or graphs based on relevance, with each presentation accompanied by a clear, descriptive explanation.

Statistical analysis was performed using the statistical package for the social sciences (SPSS) software on the Windows platform.

RESULTS

The study included 210 children with recurrent respiratory symptoms. The gender distribution reveals a higher proportion of males (57.62%) compared to females (42.38%). Most children are between 1-3 years old (55.71%), followed by those aged 3-5 years (32.86%) and 0-1 years (11.43%). Atopy is present in 16.67% of the children, while 30.48% have eczema. Only 2.38% of mothers smoked during pregnancy and passive smoke exposure affects 20.48% of the children (Table 1). The use of salbutamol during the run-in period is prevalent, with 80.48% of the children having used this bronchodilator. Additionally, 32.86% have a history of using ICS. 13.81% of children experiencing mild symptoms, 62.38% moderate, and 23.81% severe symptoms (Table 1).

The frequency of daytime cough decreases from 52.38% after one month to 1.43% after six months of treatment. Similar to daytime cough, nighttime cough also shows a reduction from 66.19% to 0%. Wheezing episodes and shortness of breath decrease steadily over the treatment period, with no instances reported after six months. The number of symptom-free days increases from 20 to 29. No exacerbation days were reported after six months (Table 2).

Following one month of treatment, the total symptom score decreased to a range of 1.40 to 2.15, with a mean score of 1.58. At the six-month mark, the total symptom score was 1.36. Total Day-time symptom and night-time symptom score were reduced to 0.75 and o.58 after the period of 6 months (Table 3).

Table 4 shows that the most common adverse events were worsening respiratory symptoms (13.81%) and fever (13.33%). Upper respiratory tract infections were also relatively common, occurring in 10.95% of the study population. Less common but notable were cases of otitis media (3.81%), rash (3.33%), bacterial skin infections (2.38%), and fungal infections (1.90%).

Before the initiation of therapy, hospital admission was needed for 90.95% cases, whereas 9.05% cases needed this after initiation of therapy (Figure 1).

Table 1: Baseline characteristics of children with recurrent respiratory symptoms, (n=210).

Characteristics	N	Percentage (%)
Gender distribution		
Male	121	57.62
Female	89	42.38
Age distribution (in years)		
2 months-1	24	11.43
1-3	117	55.71
3-5	69	32.86
Atopy (Positive phadiatop)		
Yes	35	16.67
No	175	83.33
Eczema		
Yes	64	30.48
No	146	69.52
Mother smoked during pregnancy		
Yes	6	2.38
No	204	97.62
Passive smoke exposure		
Yes	43	20.48
No	167	79.52
Use of salbutamol during run-in period		
Yes	169	80.48
No	41	19.52
Use of ICS in past		
Yes	69	32.86
No	141	67.14
Severity of symptoms		
Mild	29	13.81
Moderate	131	62.38
Severe	50	23.81

Table 2: Diary record cards analysis of symptoms for 6 months, (n=210).

Characteristics	After 1 month treatment		After 3-month treatment		After 6-month treatment	
	N	%	N	%	N	%
Day cough	110	52.38	36	17.14	3	1.43
Day wheeze	17	8.10	4	1.90	0	0.00
Night cough	139	66.19	53	25.24	0	0.00
Night wheeze	71	33.81	17	8.10	7	3.33
Shortness of breath in day	25	11.90	19	9.05	0	0
Shortness of breath in night	78	37.14	55	26.19	0	0.00
Symptom free days	20		27		29	
Exacerbation days	5		2		0	

Table 3: Symptom scores (DRC) at baseline and at 1, 3, and 6 months, (n=210).

Base line	After 1 month treatment	After 3-month treatment	After 6-month treatment
Total symptom score, range (0-18)	1.58 (1.40-2.15)	1.45 (0.98-1.82)	1.36 (0.95-1.78)
Total day-time symptom score, range (0-9)	0.96 (0.76-1.18)	0.77 (0.52-1.01)	0.75 (0.53-.97)
Total night-time symptom score, range (0-9)	0.81 (0.64-0.99)	0.62 (0.43-0.81)	0.58 (0.42-0.86)

Table 4: Adverse events for study population, (n=210).

Adverse events	N	Percentage (%)
Worsening respiratory symptoms	29	13.81
Upper respiratory tract infection	23	10.95
Fever	28	13.33
Otitis media	8	3.81
Varicella zoster	4	1.90
Rash	7	3.33
Fungal infection	4	1.90
Bacterial skin infection	5	2.38
Enteriobiasis	3	1.43
Conjunctivitis	2	0.95
Pain in legs	4	1.90

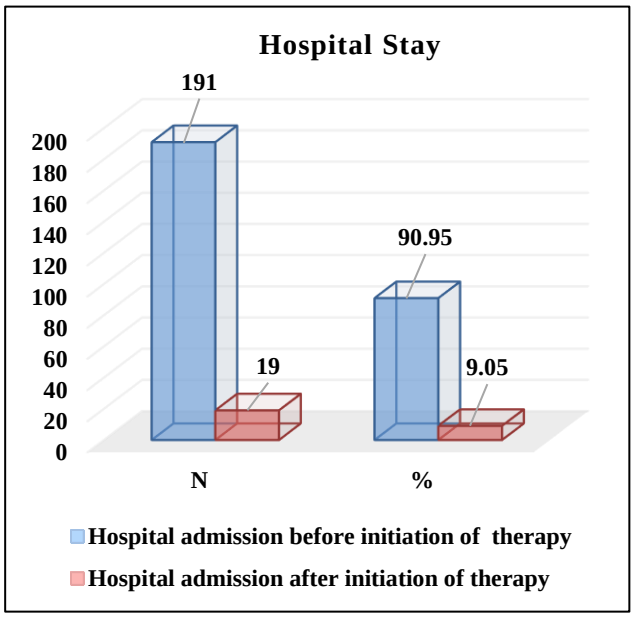

Table 5: Need to hospital stay for study population, (n=210).

DISCUSSION

This study explores the efficacy of inhaled corticosteroid/betamethasone in managing RRIs in infants and young children. The results indicate an improvement in symptoms over the six-month treatment period. ICS use in childhood asthma has been the focus of many studies performed in pediatric outpatient populations. Research in general practice is scarce although a previously performed pilot study in primary care also failed to demonstrate the benefits of ICS in children with symptoms suggestive of asthma.[13] Nevertheless, our findings support a number of results generated in hospital-based studies whilst simultaneously contradicting studies in which a beneficial effect of ICS has been demonstrated.[14-17] A study in young children (1-3 years of age) with moderate to persistent asthmatic symptoms which confirmed the efficacy of ICS within a pediatric dose range (100-200 mcg daily), is often cited in discussions about ICS use in children in favor of the use of ICS.[14] The study's demographic data provide additional insights. A slightly higher proportion of males (57.62%) participated in the study compared to females (42.38%). The age distribution shows that the majority of participants were between 1-3 years old (55.71%). A notable finding is the high percentage of children with a history of atopy (16.67%) and eczema (30.48%), conditions often associated with recurrent respiratory issues. Additionally, exposure to smoke, both prenatal (2.38%) and passive (20.48%), is a significant factor, suggesting environmental influences on respiratory health. These findings of the demographic study of our study are comparable with the result of Schokker et al.[11] In our study, the diary record cards (Table 2) reveal a substantial decrease in respiratory symptoms. Cough, wheezing, and shortness of breath, both during the day and at night, showed marked reductions, indicating that the treatment effectively alleviates both day and nighttime symptoms. The increase in symptom-free days and the decrease in exacerbation days further corroborate the efficacy of the treatment. A Cochrane review of studies in children with viral-induced wheeze demonstrated no effect of ICS.[15] On the other hand, in children who were more likely to have asthma, ICS seems to be effective.[18] Consequently, the need to predict who will respond to treatment, and who will not, is cardinal. ICS may have a more pronounced effect in children with frequent symptoms and children with a positive family history of asthma, which has also been reflected in a recent study in infants (6-24 months of age), including only children with a positive first-degree family history for asthma or atopy, showing a beneficial effect of ICS.[17,1] According to our study, symptom scores at baseline and during the treatment period demonstrate improvement. The total symptom score decreased from 2.74 at baseline to 1.36 after six months. Both daytime and nighttime symptom scores showed similar trends of reduction, reinforcing the effectiveness of the inhaled corticosteroid/betamethasone in managing respiratory symptoms. The study also monitored adverse events to assess the safety of the treatment. The most common adverse events were worsening respiratory symptoms (13.81%), fever (13.33%), and upper respiratory tract infections (10.95%). Other adverse events included otitis media, rash, and various infections, each with lower incidence rates. Importantly, the incidence of serious adverse events was low, and no new safety concerns emerged during the study period. The frequency of adverse effects is similar to another study.[11] Before initiating therapy, a significant 90.95% of cases required hospital admission, which dropped dramatically to 9.05% post-therapy. This reduction underscores the effectiveness of the treatment in not only managing symptoms but also in preventing severe exacerbations that necessitate hospitalization. A study reported that regular use of low dose ICS prevents a large proportion of hospital admissions with asthma, both early and later on in the course of the disease.[20] There is therapeutic dilemma, the challenge faced by healthcare providers in

pediatric respiratory medicine in deciding which children with recurrent respiratory symptoms should be treated as if they have asthma. This difficulty arises because symptoms of asthma, such as coughing, wheezing, and shortness of breath, can overlap with other respiratory conditions common in infants and young children. More research is needed to disentangle the diagnostic difficulties in children with respiratory symptoms, in order that we can more appropriately target treatment with ICS to the right children, i.e. children with persistent symptoms. The development of diagnostic tools for asthma in children is fundamental and would be helpful in the clinical setting as well as for research purposes. The study provides compelling evidence that inhaled corticosteroid/betamethasone therapy can be effective in managing RRIs in infants and young children.

Limitations

This study has several limitations. The sample size is relatively small and drawn from a single medical institution, which may limit the generalizability of the findings. Also, the study's observational design lacks a control group, which weakens the ability to establish causality. Data on the long-term effects of inhaled corticosteroid use in this age group remain sparse, making it difficult to assess potential growth and developmental impacts. Additionally, the study relies on parental reporting for symptom tracking, which could introduce reporting bias.

CONCLUSION

This study demonstrates that inhaled corticosteroid/ betamethasone therapy significantly improves symptoms in infants and young children with recurrent respiratory illnesses. Over a six-month period, there was a marked reduction in daytime and nighttime coughing, wheezing, and shortness of breath, with a corresponding increase in symptom-free days. The need for hospital admissions also significantly decreased post-therapy. Adverse events were relatively mild and infrequent. These findings suggest that ICS can be an effective and safe treatment for managing recurrent respiratory symptoms in young children. Further research is necessary to refine diagnostic criteria and optimize treatment protocols in this population.

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