DOI: https://doi.org/10.53350/pjmhs2023174663

ORIGINAL ARTICLE

Effects of Short-Acting Beta-Agonist (SABA) Alone and SABA with Inhaled Corticosteroids in the Management of Asthma among Children

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ABSTRACT

Introduction: However, the comparative efficacy of SABA alone vs SABA in conjunction with ICS in the treatment of childhood asthma remains an important topic of research. Understanding the comparative efficacy of SABA alone versus SABA in conjunction with ICS in the treatment of childhood asthma is critical for evidence-based decision-making.

Methodology: This randomized controlled study (RCT) included 80 children aged 6 to 12 years who were diagnosed with mild chronic asthma. The participants were separated into two groups: SABA alone and SABA plus ICS. For symptom alleviation, the SABA alone group got as-needed treatment with a short-acting beta-agonist (SABA). The SABA with ICS group got SABA therapy on a regular basis for symptom alleviation, as well as daily inhaled corticosteroid (ICS) therapy for maintenance. To compare the outcomes of the two groups, statistical analysis was done using an independent t-test. A statistically significant p-value of less than 0.05 was evaluated.

Results: Spirometry measures were taken to quantify vital capacity (VC), forced expiratory volume at one second (FEV1), and the FEV1/VC ratio. Both groups had lower baseline values for these measures, indicating decreased lung function. However, both groups' lung function improved significantly following the intervention ($p<0.05$).

Practical Implication: The findings of this study can not only educate clinical practice, but also assist healthcare practitioners in making informed treatment decisions in order to enhance asthma management and outcomes for patients.

Conclusion: According to the data, combining these drugs can enhance symptom management and lung function in children with moderate chronic asthma.

Keywords: Asthma, Lung Function test, Forced expiratory volume, Short Acting Beta Agonist, Inhaled Corticosteroids, Children.

INTRODUCTION

Asthma is a chronic respiratory condition that has a substantial influence on the quality of life for people of all ages, particularly children who may face lengthy periods of poor health.[1,2] According to 2019 estimates, more than 260 million people worldwide suffer with poorly managed asthma, with a disproportionately high burden of disability and early death in low- and middle-income countries (LMICs).[3] Age, gender, maternal education, indoor smoking exposure, pet ownership, excessive usage of short-acting 2-agonists, inappropriate inhaler technique, poor adherence to medicine, and the existence of co-existing disorders all impact asthma in children.[4-6] Atopic disorders such as food allergy, allergic rhinitis, atopic dermatitis, and recurrent respiratory tract infections are also common in children with asthma. These atopic comorbidities and recurring infections add greatly to the morbidity associated with asthma.[7-10] Children with both asthma and food allergies, for example, may have more severe asthma symptoms and worse lung function than those without food allergies. Similarly, children with asthma and allergic rhinitis have worse asthma control, and the presence of allergic rhinitis increases the likelihood of exacerbations, emergency visits, and hospitalizations.[11-13] Hence, effective asthma care is critical for reducing symptoms, preventing exacerbations, and improving quality of life. Short Acting Beta Agonist (SABAs) are often used as a quick-relief medicine to offer instant alleviation of asthma symptoms by relaxing the smooth muscles of the airway.[14] Long-term asthma therapy, on the other hand, necessitates the use of controller drugs, such as inhaled corticosteroids (ICS), which help lower airway inflammation and avoid symptoms and exacerbations. The best treatment strategy for children with asthma is still being researched and debated.[15,16] While SABAs give immediate relief, their long-term efficacy in managing asthma and avoiding exacerbations as monotherapy is unknown. The inclusion of inhaled corticosteroids (ICS) to the therapy regimen seeks to target the underlying airway inflammation and enhance asthma control.[17] However, the comparative efficacy of SABA alone vs SABA in conjunction with ICS in the treatment of childhood asthma remains an important topic of research. Understanding the comparative efficacy of SABA alone versus SABA in conjunction with ICS in the treatment of childhood asthma is critical for evidence-based decision-making. It can give useful insights into the possible advantages of combination therapy in terms of symptom control, exacerbation reduction, quality of life improvement, and lung function preservation. Furthermore, such study can aid in determining the best treatment plan for various subgroups of p patients, taking into consideration aspects such as illness severity, age, and individual patient features. By addressing this critical research topic, we hope to add to existing information and overcome the present gap in knowing the best treatment strategy for children with asthma. The findings of this study can not only educate clinical practice, but also assist healthcare practitioners in making informed treatment decisions in order to enhance asthma management and outcomes for patients.

METHODOLOGY

Study Setting: This research was carried out at the Memon Charitable Trust Hospital in Hyderabad.

Target Population: This randomized controlled study (RCT) included 80 children aged 6 to 12 years who were diagnosed with mild chronic asthma. The participants were chosen from the hospital's paediatric outpatient department. Prior to the children's inclusion in the research, their parents or legal guardians provided informed permission.

Randomization: By using a computer-generated randomization sequence, the patients were randomly allocated to one of two groups. An independent researcher who was not engaged in the study carried out the randomization method. The distribution was hidden in sealed envelopes, and each participant was given a unique identifying number.

Treatment: The participants were separated into two groups: SABA alone and SABA plus ICS. For symptom alleviation, the SABA alone group got as-needed treatment with a short-acting beta-agonist (SABA). The SABA with ICS group got SABA therapy on a regular basis for symptom alleviation, as well as daily inhaled corticosteroid (ICS) therapy for maintenance. The amount and frequency of the drugs were calculated using normal clinical

standards based on the participants' age, weight, and severity of asthma.

Outcome Measures: The effects of intervention were assessed on two parameters that included asthma symptom control and lung function that were measured twice at baseline and after completion of eight weeks of intervention

Data Analysis: Participants' baseline demographic and clinical data were collected. Throughout the trial, data on outcome measures were gathered at regular intervals. To compare the outcomes of the two groups, statistical analysis was done using an independent t-test. A statistically significant p-value of less than 0.05 was evaluated.

Ethical Considerations: The Institutional Review Board authorized the research protocol, which was given the number IRB/MCH/OPD/24/22, Dated 12-02-2022.

The research was carried out in conformity with the Helsinki Declaration's ethical guidelines. Throughout the study, the confidentiality and privacy of the participants' information were rigorously preserved. Any possible hazards or adverse events related with the interventions were rigorously evaluated, and necessary precautions to guarantee participant safety were implemented.

RESULTS

A total number of n=80 participants were divided into two groups n=40 participants in each group with equal number of male (n=20) and female (n=20) in each group. The demographics description included average age and male and female percentages. The average age of participants included in the study was 10.2±1.2 years. Detail analysis was provided in table 1.

Table 1: Descriptive analysis of participants included in the study.

Variables	Age in years ±SD	Frequency of male participants (%)	Frequency of female participants (%)
SABA group	10.3±1.4	20(25%)	20(25%)
SABA+IC group	10.1±1.1	20(25%)	20(25%)
Total (Combine group)	10.2±1.2	40(50%)	40(50%)

Asthma Symptom Control: Asthma symptoms Control was evaluated using an asthma control test (ACT) questionnaire. The questionnaire has a test-retest reliability of 0.77 and an internal consistency of 0.84. The findings had revealed that at baseline participants in both the groups had a lower ACT value of 10.5±3.8 in SIBA group and 10.3±2.8 in SIBA+IC group that had improved significantly p<0.001 after eight weeks of intervention with more effective results were obtained in SIBA+IC group p<0.05 than SIBA alone. The analysis was provided in table 2.

Table 2: Effects of intervention on Asthma Symptom Control (Paired t test).

Variables	Pre ± SD	Post ± SD	t-test	Level of significance
SABA	10.5±3.8	18.5±2.1	6.53	p<0.001
SABA+IC	10.3±2.8	20.12±1.9		
Efficacy of treatment SIBA and SIBA+IC (Independent t test)				
Variables	Post intervention ± SD	t-test	Level of significance	
SABA	18.5±2.1	3.2	p<0.005	
SABA+IC	20.12±1.9			

Table 3: Effects of intervention on Lung Function Test.

Variables	Pre ± SD		Post ± SD	t-test	Level of significance
Short Acting Beta Agonist (SABA)					
VC	70.5±3.8		78±2.5	7.9	p<0.001
FEV1	78.56±2.5		85.3±1.9		
FEV1/VC	75.56±3.9		80.2±1.3		
SABA+IC group					
VC	60.8±4.1		82.5±5.5	12.5	p<0.001
FEV1	75.3±1.5		89.4±4.2		
FEV1/VC	77.8±2.4		86.52±2.99		
Efficacy of treatment SIBA and SIBA+IC (Independent t test)					
Variables	SABA	SABA+IC	t-test	Level of significance	
VC	78±2.5	82.5±5.5	4.5	p<0.005	
FEV1	85.3±1.9	89.4±4.2	2.5		
FEV1/VC	80.2±1.3	86.52±2.99	3.6		

Lung Function Test: Lung function test was analyzed using a spirometry, the values of vital capacity, forced expiratory reserved volume at one second (FEV1) and the ratio of FEV1/VC was reduced among participants in both the group at baseline that had improved significantly p<0.05 after intervention. Further between group analysis had revealed that combine SABA+IC based intervention had shown efficacy over SABA alone p<0.05 (Table 3).

DISCUSSION

The study comprised a total of 80 individuals, with 40 in each group (SABA alone and SABA plus ICS), with males and females evenly divided. The participants' average age was 10.2±1.2 years. The Asthma Control Test (ACT) questionnaire was used to measure the participants' asthma symptom control in the research. Both groups had lower ACT scores at the start, indicating worse asthma symptom management. However, after eight weeks of intervention, both groups showed considerable gains. When compared to the SABA alone group, the SABA + ICS group produced more beneficial outcomes (p<0.05). Spirometry measures were taken to quantify vital capacity (VC), forced expiratory volume at one second (FEV1), and the FEV1/VC ratio. Both groups had lower baseline values for these measures, indicating decreased lung function. However, both groups' lung function improved significantly following the intervention (p<0.05). Importantly, as compared to the SABA alone group, the SABA plus ICS group displayed higher effectiveness (p<0.05). Higher values for VC, FEV1, and FEV1/VC ratio were seen in the SABA with ICS group, indicating enhanced airflow and lung capacity. The findings were according to the findings of a review that were performed with the aim to evaluate the efficacy of reliever drugs combining inhaled corticosteroids (ICS) to short-acting 2-agonists (SABA) as relievers or when combination with maintenance ICS and SABA as relievers in patients with moderate asthma[18]. Nine trials were reviewed, including four recent studies that evaluated the combination of ICS/formoterol as a relief versus SABA alone. The data demonstrated that ICS-containing reliever drugs outperformed SABA alone as relievers and were equivalent to maintenance ICS and SABA as relievers, especially in terms of lowering the incidence of severe asthma exacerbations. As a result, utilizing SABAs as pain medications without ICS was not advised. In moderate asthma patients, the worry over patient adherence to maintenance ICS justified the advice that ICS/formoterol be evaluated as a therapeutic option rather than maintenance ICS alone. This method would reduce the danger of patients relying entirely on SABA for asthma control.[18] Similarly in another study that was aimed to determine the safety and tolerability of short-acting 2-agonist (SABA) reliever monotherapy in adults and adolescents with asthma. The study compared SABA monotherapy to inhaled corticosteroid (ICS) monotherapy using randomized controlled trials (RCTs). According to the findings of a meta-analysis of 24 RCTs, fatalities with SABA reliever monotherapy were uncommon, and the rates of serious adverse events (SAEs) and discontinuation owing to adverse events (DAEs) were comparable between SABA reliever and ICS treatment groups. SAE risk was comparable for SABA and ICS therapies. As a result, when taken as directed, SABA reliever treatment does not lead to increased mortality, SAEs, or DAEs.[19]

However the current study has some strength and weaknesses. The randomized controlled design of this study helps to minimize bias and demonstrate a cause-effect link between the treatments and outcomes. The research also had a large enough sample size of 80 individuals to allow for more credible statistical analysis. Furthermore, the study included established outcome measures, such as the asthma control test questionnaire and spirometry, which improves the study's validity and reliability. Furthermore, the study evaluated two therapy modalities, SABA alone and SABA with ICS, offering important insights into the relative effectiveness of both therapies. There are, however, some constraints to consider. For starters, the study was limited to a

single hospital, which may restrict the findings' applicability to other contexts. Second, because the trial was only eight weeks long, it may not have captured long-term impacts and results of the therapies. The study also relied on self-report measures, which may add subjectivity and recall bias. Furthermore, the trial lacked a placebo control group, which would have allowed for a more accurate comparison of the therapies. Finally, the study did not analyze the therapies' possible adverse effects or safety outcomes, which might be crucial concerns in asthma therapy.

CONCLUSION

This study adds to the current body of knowledge by providing data that supports the use of SABA + ICS as an effective treatment approach for pediatric asthma. According to the data, combining these drugs can enhance symptom management and lung function in children with moderate chronic asthma. This data can help healthcare providers make more educated treatment decisions and improve asthma management and outcomes for their patients. More study is required to investigate long-term impacts, safety concerns, and the application of these findings in various healthcare settings.

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