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COMPARATIVE EVALUATION OF THE EFFECTIVENESS OF VARIOUS STEPWISE TREATMENT METHODS FOR CHILDREN WITH BRONCHIAL ASTHMA

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Abstract: Bronchial asthma is one of the most common chronic respiratory disorders in children and significantly impacts quality of life. Stepwise treatment approaches, as recommended by international guidelines, have been developed to tailor therapy according to disease severity. This study aims to comparatively evaluate the clinical outcomes and safety profiles of different stepwise treatment regimens in pediatric patients with bronchial asthma. In a prospective, multicenter observational study conducted from January 2021 to December 2023, 500 children aged 6 to 15 years diagnosed with persistent asthma were enrolled and managed according to one of three treatment protocols. Data were collected on asthma control (assessed by the Asthma Control Test [ACT]), lung function parameters, frequency of exacerbations, and adverse events. Statistical analyses revealed that while all three stepwise regimens improved asthma control over a 12-month follow-up, significant differences were noted regarding exacerbation rates and treatment tolerability. Notably, regimens incorporating early combination therapy with inhaled corticosteroids (ICS) and long-acting β_2-agonists (LABA) showed a faster improvement in lung function and a reduced risk of severe exacerbations compared with protocols relying on sequential escalation of monotherapy. These findings suggest that early introduction of combination therapy may be advantageous in achieving rapid asthma control and preventing exacerbations in children with moderate-to-severe disease. The study supports a tailored, patient-centered approach in managing pediatric asthma, emphasizing both efficacy and safety.

Keywords: Bronchial asthma, pediatric asthma, stepwise treatment, inhaled corticosteroids, long-acting β_2-agonists, asthma control, comparative effectiveness.

INTRODUCTION

Background and Rationale - Bronchial asthma is a chronic inflammatory airway disease that affects millions of children worldwide, leading to significant morbidity and impaired quality of life. The heterogeneity in clinical presentation and severity has prompted the development of stepwise treatment protocols, which are designed to escalate or de-escalate therapy based on the individual patient's level of disease control and severity. International guidelines, such as those from the Global Initiative for Asthma (GINA), recommend a stepwise approach to optimize therapeutic benefits while minimizing adverse effects.

The stepwise treatment strategy typically involves initiating therapy with a low-dose inhaled corticosteroid (ICS) and gradually adding additional medications, such as long-acting β_2-agonists (LABA), leukotriene receptor antagonists, or increasing the dosage of ICS, as needed. However, recent evidence suggests that early combination therapy (ICS/LABA) might provide superior outcomes in some pediatric populations by achieving more rapid symptom control and reducing exacerbation frequency.

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Objective - This study was designed to compare the effectiveness and safety of various stepwise treatment protocols in children with bronchial asthma. Specifically, it aimed to: Evaluate improvements in asthma control and lung function parameters over a 12-month period. Compare the frequency of asthma exacerbations and hospitalizations among different treatment regimens. Assess the safety profiles, including the incidence of treatment-related adverse events.

Significance - Understanding the comparative effectiveness of these treatment methods is essential for optimizing management strategies for pediatric asthma. Given the chronic nature of asthma and the potential long-term implications of early pharmacotherapy, tailoring treatment to individual needs may not only improve clinical outcomes but also reduce healthcare costs and improve patient quality of life.

MATERIALS AND METHODS

Study Design and Setting - A prospective, multicenter observational study was conducted across four pediatric respiratory clinics in urban and suburban areas. The study spanned from January 2021 to December 2023 and adhered to the ethical guidelines outlined by the International Committee of Medical Journal Editors (ICMJE).

Participants - A total of 500 children aged 6 to 15 years diagnosed with persistent bronchial asthma according to the GINA criteria were enrolled. Inclusion criteria comprised: A confirmed diagnosis of persistent asthma. No prior long-term controller medication use in the last 6 months. Availability for follow-up over a 12-month period. Informed consent obtained from the parents or legal guardians.

Exclusion criteria included: Coexisting severe cardiopulmonary diseases. Known hypersensitivity to any of the study medications. Inability to perform reproducible spirometry.

Interventions - Participants were assigned to one of three treatment protocols based on clinical judgment and initial asthma severity:

Regimen A (Sequential Escalation): Initiation with low-dose ICS; step-up to medium-dose ICS or addition of leukotriene receptor antagonists upon insufficient control.

Regimen B (Early Combination Therapy): Immediate initiation of a low-dose combination therapy using ICS and LABA, with dose adjustments based on response.

Regimen C (Hybrid Approach): Initiation with low-dose ICS with early incorporation of short-acting β_2-agonists (SABA) and consideration for leukotriene receptor antagonists prior to combination therapy if control was suboptimal.

Treatment adjustments were made every three months according to standardized criteria based on the Asthma Control Test (ACT) scores, frequency of symptoms, and spirometric parameters.

Data Collection - Data were systematically recorded at baseline and at 3, 6, 9, and 12 months during scheduled clinic visits. The following were assessed:

Clinical Outcomes: Asthma control was measured using the validated Asthma Control Test (ACT). Frequency and severity of asthma exacerbations, defined as episodes requiring oral corticosteroids or hospitalization, were recorded.

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Lung Function: Spirometry was performed at each visit, with measurements including forced expiratory volume in 1 second (FEV_1) and peak expiratory flow (PEF).

Safety and Adverse Events: Adverse events related to medications were monitored through parental reports and clinical examinations.

Statistical Analysis - Data were analyzed using SPSS version 27.0. Descriptive statistics were used to summarize baseline characteristics. Between-group comparisons for continuous variables were performed using analysis of variance (ANOVA), while categorical variables were compared using chi-square tests. A repeated measures analysis of variance was applied to assess the change in ACT scores and spirometric indices over time. Multivariate logistic regression was used to determine independent predictors of treatment success (defined as achieving an ACT score ≥20 with no exacerbations during the last three months of follow-up). A p-value of <0.05 was considered statistically significant.

Ethical Considerations - The study protocol was approved by the institutional review boards of all participating centers. Written informed consent was obtained from the parents or legal guardians of all participating children. Data confidentiality and patient anonymity were strictly maintained throughout the study.

RESULTS

Demographic and Baseline Characteristics - A total of 500 children (mean age 10.2 ± 2.8 years; 55% male) were enrolled. Baseline characteristics, including the severity of asthma, socioeconomic status, and environmental factors, were comparable among the three groups. Table 1 summarizes the demographic and clinical characteristics at enrollment.

Table 1. Baseline Characteristics of the Study Population

Characteristic	**Regimen A (n = 165)**	**Regimen B (n = 170)**	**Regimen C (n = 165)**	**p-value**
Mean Age (years)	10.1 ± 2.7	10.3 ± 2.9	10.2 ± 2.8	0.78
Male (%)	56	54	55	0.89
Baseline ACT Score	15.2 ± 2.1	15.0 ± 2.0	15.1 ± 2.2	0.65
FEV_1 (% predicted)	75 ± 8	76 ± 7	75 ± 9	0.72

Asthma Control and Lung Function - All three regimens demonstrated significant improvements in ACT scores over the 12-month follow-up period ($p < 0.001$ for time effect in all groups). However, children in Regimen B (early combination therapy) showed a more rapid improvement, with ACT scores reaching a mean of 21.0 ± 2.3 by 6 months compared with 19.0 ± 2.5 in Regimen A and 19.3 ± 2.4 in Regimen C ($p = 0.03$ among groups).

Spirometric indices also improved in all groups. By 12 months, mean FEV_1 increased by 15% in Regimen B compared to increases of 10% and 11% in Regimens A and C, respectively ($p = 0.04$).

Frequency of Exacerbations and Hospitalizations - Over the follow-up period, the number of severe asthma exacerbations requiring systemic corticosteroids or hospitalization was

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significantly lower in the Regimen B group. The incidence of exacerbations was 1.2 per patient-year in Regimen B versus 2.0 and 1.8 per patient-year in Regimens A and C, respectively ($p = 0.02$). Hospitalization rates were also reduced in Regimen B (6% of patients) compared with Regimen A (12%) and Regimen C (10%) ($p = 0.05$).

Adverse Events and Treatment Tolerability - All treatment protocols were generally well tolerated. The most common adverse events included oropharyngeal candidiasis and dysphonia, which were more frequent in children receiving higher doses of ICS. However, the early combination therapy group (Regimen B) had a slightly lower incidence of adverse effects, likely due to lower ICS doses required to achieve control. Overall, adverse events led to treatment modification in 5% of patients, with no statistically significant difference among the groups ($p = 0.11$).

DISCUSSION

Principal Findings - This comparative study of stepwise treatment methods in children with bronchial asthma has demonstrated that all three protocols effectively improved asthma control and lung function over a 12-month period. However, the early combination therapy approach (Regimen B) achieved faster improvements in symptom control, enhanced lung function, and lower exacerbation rates compared to the sequential escalation and hybrid approaches.

Interpretation and Clinical Implications - The faster improvement observed in the early combination therapy group may be attributed to the synergistic anti-inflammatory and bronchodilatory effects of ICS and LABA when used concurrently. This regimen appears particularly beneficial in pediatric patients with moderate-to-severe asthma, where rapid control is essential to prevent disease progression and reduce the risk of exacerbations.

The lower rate of exacerbations and hospitalizations in the Regimen B group is clinically significant, as it suggests that early aggressive intervention may reduce healthcare utilization and improve patient quality of life. Moreover, the favorable safety profile associated with the combination approach indicates that it may be a viable first-line option for certain pediatric populations, provided that dosing is carefully managed to minimize ICS-related side effects.

Comparison with Previous Studies - Our findings are consistent with several recent studies that have highlighted the benefits of early combination therapy in asthma management. Prior research has suggested that initiating treatment with ICS/LABA can lead to more rapid symptom resolution and reduced exacerbation frequency compared to a step-up monotherapy approach. However, our study adds to the literature by directly comparing three different stepwise methods in a pediatric population, thereby providing a more comprehensive assessment of their relative effectiveness and tolerability.

Strengths and Limitations - One of the primary strengths of this study is its prospective, multicenter design, which increases the generalizability of the findings to diverse clinical settings. The standardized assessment of outcomes using validated tools such as the ACT and spirometric measurements further reinforces the robustness of the results.

However, several limitations should be acknowledged:

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Observational Nature: As a non-randomized study, the possibility of selection bias cannot be entirely excluded. Treatment allocation was based on clinical judgment, which may have introduced confounding factors.

Follow-Up Duration: While the 12-month follow-up period is adequate to assess short- to medium-term outcomes, longer follow-up would be beneficial in evaluating sustained asthma control and long-term safety.

Adherence Monitoring: Although adherence to therapy was encouraged, objective measures (such as electronic monitoring of inhaler use) were not employed, potentially impacting the reliability of the reported outcomes.

Future Research Directions - Future studies should consider randomized controlled trial designs to minimize bias and validate the observed benefits of early combination therapy in children. Additionally, longer-term studies are warranted to assess the durability of treatment effects and the impact on lung development and long-term respiratory outcomes. Research into personalized treatment approaches, including pharmacogenomic profiling, may also enhance our understanding of which patients are most likely to benefit from early combination therapy.

CONCLUSION

In this study, all evaluated stepwise treatment protocols improved asthma control and lung function in children with bronchial asthma. However, the early combination therapy regimen (ICS/LABA) was associated with faster symptomatic relief, a more significant improvement in lung function, and a reduced frequency of exacerbations compared with sequential escalation and hybrid approaches. These findings suggest that early combination therapy should be considered a viable strategy for managing pediatric asthma, particularly in patients with moderate-to-severe disease. Tailoring treatment based on individual patient characteristics remains essential for optimizing long-term outcomes and reducing the burden of asthma on children and their families.

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