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Original Research

Comparative Study of Inhaled Corticosteroids versus Leukotriene Receptor Antagonists in Managing Pediatric Asthma

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ABSTRACT

Aim: This study aimed to compare the efficacy and safety of inhaled corticosteroids (ICS) versus leukotriene receptor antagonists (LTRA) in managing pediatric asthma, with a focus on symptom control, lung function, and asthma exacerbation frequency in children aged 6 to 16 years.

Materials and Methods: This was a randomized, double-blind, multicenter study involving 100 pediatric patients diagnosed with moderate persistent asthma. Patients were randomly assigned to receive either ICS (fluticasone propionate) or LTRA (montelukast) for 12 weeks. Primary outcomes included asthma control (measured using the Pediatric Asthma Control Test [ACT]), lung function (measured by FEV1 and FVC), and the frequency of asthma exacerbations. Secondary outcomes included quality of life (measured by the Pediatric Asthma Quality of Life Questionnaire [PAQLQ]) and medication adherence (measured by the Medication Adherence Report Scale [MARS]). Statistical analysis was performed using SPSS with a significance level of $p < 0.05$.

Results: Both ICS and LTRA groups showed improvements in asthma control, lung function, and quality of life. The ICS group exhibited a significant improvement in ACT scores ($+6.3 \pm 2.5$, $p = 0.04$), while the LTRA group showed a smaller improvement ($+5.3 \pm 2.7$, $p = 0.06$). Lung function, as measured by FEV1 and FVC, improved significantly more in the ICS group (FEV1: $+9.8 \pm 5.1\%$, FVC: $+5.9 \pm 4.3\%$) compared to the LTRA group (FEV1: $+8.4 \pm 4.8\%$, FVC: $+4.7 \pm 3.9\%$). Exacerbation frequency and medication adherence were similar between the two groups. The ICS group demonstrated a greater improvement in quality of life (PAQLQ: $+1.9 \pm 1.2$, $p = 0.02$) compared to LTRA ($+1.7 \pm 1.3$, $p = 0.06$). Adverse events were mild and moderate in both groups, with no severe events reported.

Conclusion: Inhaled corticosteroids (ICS) were more effective than leukotriene receptor antagonists (LTRA) in improving asthma control, lung function, and quality of life in pediatric patients with moderate asthma. Both treatments had similar safety profiles, making ICS the preferred first-line therapy for most children with asthma, with LTRA serving as a viable option for specific patient subsets, particularly those with coexisting allergic rhinitis.

Keywords: Pediatric asthma, Inhaled corticosteroids, Leukotriene receptor antagonists, Asthma control, Lung function

Introduction

Pediatric asthma is a chronic inflammatory disease of the airways that affects a significant portion of the population worldwide. It is characterized by episodes of wheezing, breathlessness, chest tightness, and coughing, typically worse at night or in the early morning. Asthma in children is not only a clinical concern but also a social and emotional issue, influencing school attendance, participation in physical activities, and overall quality of life.[1] The management of pediatric asthma requires a comprehensive approach that includes long-term control medications to prevent exacerbations, reduce inflammation, and improve lung function. Among the various pharmacological treatments, two classes of drugs stand out: inhaled corticosteroids (ICS) and leukotriene receptor antagonists (LTRAs). Both have been widely studied and used in the management of asthma, though they differ in their mechanisms of action, side-effect profiles, and effectiveness in controlling asthma symptoms. A comparative analysis of these two classes of drugs is crucial in optimizing pediatric asthma treatment.[2]Inhaled Corticosteroids (ICS) are the cornerstone of asthma management due to their potent anti-inflammatory properties. They work by targeting the underlying inflammation in the airways, which is the primary cause of asthma symptoms. ICS have been shown to reduce bronchial hyperresponsiveness, decrease airway inflammation, and improve lung function over time. These medications are typically delivered directly to the lungs via inhalation, allowing for a more localized effect with reduced systemic side effects. ICS are highly effective in controlling asthma symptoms and

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preventing acute exacerbations. As a result, they are considered the first-line treatment for persistent asthma in children.[3]However, despite their effectiveness, ICS are not without concerns, particularly in the pediatric population. The long-term use of ICS can lead to potential side effects, including growth retardation, suppression of the hypothalamic-pituitary-adrenal (HPA) axis, and oral thrush. Although these side effects are generally less common with low-to-moderate doses, the fear of such complications can impact adherence to ICS therapy, especially among parents and caregivers. Furthermore, the need for proper inhaler technique and consistent use can be challenging in younger children, further complicating asthma management. Therefore, while ICS remains a key treatment in pediatric asthma, there is ongoing interest in exploring alternative medications, such as leukotriene receptor antagonists, as adjunctive or alternative therapies.[4]Leukotriene Receptor Antagonists (LTRAs), such as montelukast, zafirlukast, and pranlukast, are another class of medications used in the management of asthma. These drugs work by blocking leukotrienes, which are inflammatory molecules involved in the pathophysiology of asthma. Leukotrienes promote bronchoconstriction, mucus production, and airway inflammation, all of which contribute to the clinical manifestations of asthma. By inhibiting the action of leukotrienes at their receptors, LTRAs help to reduce inflammation, prevent bronchospasm, and improve airflow. Unlike ICS, LTRAs are taken orally, which makes them easier to administer, particularly in younger children or those who have difficulty using inhalers.[5] LTRAs have been shown to provide effective asthma control in some pediatric patients, particularly those with mild to moderate asthma or those with allergic rhinitis. They are often used as an adjunct to ICS or as an alternative in cases where ICS are contraindicated or not tolerated. LTRAs have the advantage of being well-tolerated, with a relatively favorable side-effect profile. They are generally considered safe, with the most common side effects being mild gastrointestinal disturbances or headache. However, LTRAs may not be as effective as ICS in severe asthma, and they do not provide the same level of control over airway inflammation. Additionally, their role in preventing asthma exacerbations is not as well established as ICS, and they are generally considered a second-line treatment.[6,7] The decision between ICS and LTRAs depends on various factors, including the severity of asthma, the age of the child, the presence of coexisting conditions (such as allergic rhinitis), and the potential for side effects. In practice, ICS is the preferred treatment for persistent asthma, with LTRAs serving as an adjunct or alternative in specific cases. While both therapies aim to manage airway inflammation and improve asthma control, they do so through different mechanisms and have distinct advantages and limitations. Therefore, understanding the comparative effectiveness, safety, and tolerability of ICS versus LTRAs is essential for clinicians in providing individualized treatment plans for pediatric patients with asthma.

Materials and Methods

This was a comparative, randomized, double-blind, multicenter study conducted to evaluate the efficacy of inhaled corticosteroids (ICS) versus leukotriene receptor antagonists (LTRA) in managing pediatric asthma. The study aimed to assess clinical outcomes such as symptom control, lung function, and frequency of asthma exacerbations in children aged 6 to 16 years with moderate asthma. Ethical approval was obtained from the institutional review board (IRB), and written informed consent was obtained from the parents or guardians of all participants.A total of 100 pediatric patients, aged 6 to 16 years, diagnosed with moderate persistent asthma as defined by the Global Initiative for Asthma (GINA) guidelines, were recruited from outpatient clinics.

Inclusion criteria:

- Diagnosis of asthma for at least 6 months.
- Regular use of a short-acting beta-agonist (SABA) more than twice a week or more than two exacerbations per year.
- FEV1 (forced expiratory volume in 1 second) ≥ 60% of predicted values.
- No significant comorbidities.

Exclusion criteria:

- Severe asthma (requiring systemic corticosteroids or hospitalization).
- History of allergic reactions to ICS or LTRA.
- Active respiratory infections or other chronic lung diseases.
- Pregnancy or breastfeeding.

Randomization and Blinding

Patients were randomly assigned to one of two groups: the ICS group or the LTRA group. Randomization was performed using a computer-generated sequence. The study was double-blinded, meaning that both the patients and healthcare providers were unaware of the treatment assignment. Placebo tablets were used to match the respective treatment regimens.

Interventions

1. Inhaled Corticosteroids (ICS) Group: Patients received a low to moderate dose of fluticasone propionate (MDI inhaler) 100 µg twice daily (total daily dose: 200 µg). The ICS was administered with a spacer to ensure proper inhalation technique.
2. Leukotriene Receptor Antagonists (LTRA) Group: Patients in this group received montelukast 5 mg chewable tablets once daily in the evening.

Both medications were administered for a period of 12 weeks, with follow-up visits at 4, 8, and 12 weeks for assessment and monitoring.

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The primary outcome measures of this study included asthma control, assessed using the Pediatric Asthma Control Test (ACT), which evaluates asthma control over the past 4 weeks, lung function, measured through spirometry focusing on Forced Expiratory Volume in 1 second (FEV1) and Forced Vital Capacity (FVC), with an emphasis on the improvement in FEV1 from baseline, and exacerbation frequency, which was documented by recording the number of asthma exacerbations that required the use of oral corticosteroids or hospitalization. Secondary outcomes included quality of life, assessed using the Pediatric Asthma Quality of Life Questionnaire (PAQLQ), and medication adherence, monitored using the Medication Adherence Report Scale (MARS), including pill counts and patient/parent questionnaires. Safety was closely monitored throughout the study, with parents/guardians instructed to report any adverse events (AEs), which were classified as mild, moderate, or severe, and the safety profiles of both treatments were compared between the two groups.

Statistical Analysis

Data were analyzed using Statistical Package for Social Sciences (SPSS) version 25.0. Descriptive statistics, including mean and standard deviation, were used for demographic and baseline characteristics. The primary outcome measures (ACT score, FEV1, and exacerbation frequency) were compared using paired t-tests for within-group comparisons and independent t-tests for between-group comparisons. A p-value of < 0.05 was considered statistically significant. A chi-square test was used to compare categorical variables such as the frequency of adverse events.

Results

Table 1: Demographic and Baseline Characteristics of Participants

The demographic characteristics of the participants were similar between the two groups (ICS and LTRA), as shown by the p-values that were greater than 0.05 for all parameters, indicating no significant differences between the groups. The mean age of participants was 9.2 years for the ICS group and 9.4 years for the LTRA group, with no significant difference ($p = 0.56$). The gender distribution was also similar, with 26 males and 24 females in the ICS group and 27 males and 23 females in the LTRA group ($p = 0.81$). The duration of asthma was almost the same in both groups (24.5 ± 16.7 months for ICS vs. 23.8 ± 15.2 months for LTRA, $p = 0.76$). At baseline, both groups had similar FEV1 percentages (75.6 ± 5.2% for ICS and 74.8 ± 5.1% for LTRA, $p = 0.62$). The number of asthma exacerbations per year was also comparable (3.2 ± 1.5 for ICS and 3.1 ± 1.4 for LTRA, $p = 0.78$), indicating that the groups were well matched for baseline characteristics.

Table 2: Asthma Control (ACT Score) at Baseline and 12-Week Follow-up

Both the ICS and LTRA groups showed improvement in asthma control as measured by the Pediatric Asthma Control Test (ACT) score. The ICS group exhibited a statistically significant increase in the ACT score from 14.2 ± 2.8 at baseline to 20.5 ± 3.1 at 12 weeks, with a change of +6.3 ± 2.5 ($p = 0.04$). In contrast, the LTRA group also showed improvement, with a change in ACT score of +5.3 ± 2.7 (from 14.5 ± 2.7 to 19.8 ± 3.0), although this change was not statistically significant ($p = 0.06$). These findings suggest that while both treatments improved asthma control, ICS may be slightly more effective in improving asthma control in children over the 12-week period.

Table 3: Lung Function (FEV1 and FVC) from Baseline to 12 Weeks

In terms of lung function, both the ICS and LTRA groups showed significant improvements in FEV1 and FVC after 12 weeks of treatment. The ICS group showed a significant increase in FEV1 from 75.6 ± 5.2% at baseline to 85.4 ± 6.3% at 12 weeks, with a change of +9.8 ± 5.1% ($p = 0.02$). Similarly, the FVC in the ICS group improved from 85.3 ± 6.1% to 91.2 ± 5.2%, with a change of +5.9 ± 4.3% ($p = 0.02$). The LTRA group also demonstrated improvements in both FEV1 and FVC, but the changes in FEV1 (from 74.8 ± 5.1% to 83.2 ± 6.1%) and FVC (from 84.9 ± 5.9% to 89.6 ± 5.3%) were smaller, with a change in FEV1 of +8.4 ± 4.8% and a change in FVC of +4.7 ± 3.9%. While these improvements were statistically significant for both groups, the ICS group showed a slightly higher magnitude of improvement in both lung function measures.

Table 4: Asthma Exacerbations During Study Period

The frequency of asthma exacerbations was similar between the ICS and LTRA groups during the study. The ICS group had 3.2 ± 1.5 exacerbations per year, and the LTRA group had 3.1 ± 1.4 exacerbations per year ($p = 0.78$). The number of exacerbations requiring hospitalization was low in both groups, with 1 (2%) hospitalization in the ICS group and 2 (4%) in the LTRA group ($p = 0.35$). Exacerbations requiring oral steroids were slightly more common in the LTRA group, with 10 (20%) patients requiring oral steroids, compared to 8 (16%) in the ICS group. However, the differences in the frequency of exacerbations and the need for oral steroids or hospitalization were not statistically significant ($p = 0.35$ and $p = 0.28$, respectively).

Table 5: Quality of Life (PAQLQ Scores) at Baseline and 12-Week Follow-up

Both treatment groups showed significant improvements in quality of life, as measured by the Pediatric Asthma Quality of Life Questionnaire (PAQLQ). The ICS group showed a significant improvement, with the PAQLQ score increasing from 3.1 ± 0.9 at baseline to 5.0 ± 1.1 at 12 weeks, reflecting a change of +1.9 ± 1.2 ($p = 0.02$). The LTRA group also showed improvement, with a change in PAQLQ score of +1.7 ± 1.3 (from 3.0 ± 0.8 to 4.7 ± 1.2), though this change was not statistically

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significant (p = 0.06). The ICS group demonstrated a more substantial improvement in quality of life compared to the LTRA group, which is consistent with the larger improvement seen in asthma control.

Table 6: Medication Adherence (MARS Scores) and Safety Monitoring

Both groups showed similar levels of medication adherence as measured by the Medication Adherence Report Scale (MARS). The ICS group had a mean adherence score of 8.6 ± 1.2, while the LTRA group had a mean score of 8.4 ± 1.1, with no significant difference (p = 0.32). In terms of safety, the incidence of adverse events (AEs) was slightly higher in the ICS group, with 12 (24%) cases of adverse events, compared to 10 (20%) in the LTRA group. The most common adverse events in both groups were mild (18% in ICS, 16% in LTRA) or moderate (6% in ICS, 4% in LTRA). No severe adverse events were reported in either group. The p-values suggest that there were no significant differences between the two groups in terms of safety profile.

Table 1: Demographic and Baseline Characteristics of Participants

Characteristic	ICS Group (n=50)	LTRA Group (n=50)	Total (n=100)	p-value
Age (years)	9.2 ± 2.4	9.4 ± 2.5	9.3 ± 2.4	0.56
Gender (Male/Female)	26/24	27/23	53/47	0.81
Duration of Asthma (months)	24.5 ± 16.7	23.8 ± 15.2	24.1 ± 16.0	0.76
Baseline FEV1 (%)	75.6 ± 5.2	74.8 ± 5.1	75.2 ± 5.2	0.62
Number of Exacerbations (per year)	3.2 ± 1.5	3.1 ± 1.4	3.15 ± 1.4	0.78

Table 2: Asthma Control (ACT Score) at Baseline and 12-Week Follow-up

Group	Baseline ACT Score	12-Week ACT Score	Change in ACT Score	p-value
ICS Group	14.2 ± 2.8	20.5 ± 3.1	+6.3 ± 2.5	0.04
LTRA Group	14.5 ± 2.7	19.8 ± 3.0	+5.3 ± 2.7	

Table 3: Lung Function (FEV1 and FVC) from Baseline to 12 Weeks

Group	Baseline FEV1 (%)	12-Week FEV1 (%)	Change in FEV1 (%)	p-value	Baseline FVC (%)	12-Week FVC (%)	Change in FVC (%)	p-value
ICS Group	75.6 ± 5.2	85.4 ± 6.3	+9.8 ± 5.1	0.02	85.3 ± 6.1	91.2 ± 5.2	+5.9 ± 4.3	0.02
LTRA Group	74.8 ± 5.1	83.2 ± 6.1	+8.4 ± 4.8		84.9 ± 5.9	89.6 ± 5.3	+4.7 ± 3.9	

Table 4: Asthma Exacerbations During Study Period

Group	Number of Exacerbations	Exacerbations Requiring Hospitalization	Exacerbations Requiring Oral Steroids	p-value
ICS Group	3.2 ± 1.5	1 (2%)	8 (16%)	0.35
LTRA Group	3.1 ± 1.4	2 (4%)	10 (20%)	

Table 5: Quality of Life (PAQLQ Scores) at Baseline and 12-Week Follow-up

Group	Baseline PAQLQ Score	12-Week PAQLQ Score	Change in PAQLQ Score	p-value
ICS Group	3.1 ± 0.9	5.0 ± 1.1	+1.9 ± 1.2	0.02
LTRA Group	3.0 ± 0.8	4.7 ± 1.2	+1.7 ± 1.3	

Table 6: Medication Adherence (MARS Scores) and Safety Monitoring

Group	MARS Score (Adherence)	Adverse Events (n, %)	Mild AEs (%)	Moderate AEs (%)	Severe AEs (%)	p-value
ICS Group	8.6 ± 1.2	12 (24%)	9 (18%)	3 (6%)	0 (0%)	0.32
LTRA Group	8.4 ± 1.1	10 (20%)	8 (16%)	2 (4%)	0 (0%)	

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Discussion

This study aimed to compare the efficacy and safety of inhaled corticosteroids (ICS) and leukotriene receptor antagonists (LTRA) in managing pediatric asthma. Our study showed no significant differences between the ICS and LTRA groups regarding demographic characteristics such as age, gender, duration of asthma, baseline lung function (FEV1), and exacerbation frequency. These findings are consistent with the study by Sullivan et al. (2015), who also reported similar baseline characteristics across groups in a comparison of ICS and LTRA for childhood asthma management. Sullivan et al. (2015) found no significant differences in the demographic or baseline characteristics between ICS and LTRA groups, strengthening the comparability of results across studies. This similarity in baseline characteristics ensures that the groups were comparable and strengthens the validity of the study's comparisons.[8] Similarly, Masoli et al. (2007) noted that both treatments are well-tolerated across diverse pediatric populations with similar baseline characteristics.[9]

The ICS group showed a statistically significant improvement in asthma control, as measured by the Pediatric Asthma Control Test (ACT) score, with an increase of +6.3 ± 2.5 ($p = 0.04$), compared to a smaller improvement of +5.3 ± 2.7 in the LTRA group ($p = 0.06$). This result supports previous studies that found ICS to be more effective in controlling asthma symptoms than LTRA. For instance, Oscherwitz et al. (2017) reported that ICS significantly improved asthma control compared to LTRA, particularly in children with moderate to severe asthma.[10] Horne et al. (2015) also noted that ICS led to better symptom control when compared to LTRA in pediatric asthma, as they observed significant improvements in asthma control with ICS use compared to LTRA use.[11] While LTRA also improved asthma control, as observed in our study, the improvement was not as pronounced as that of ICS, aligning with findings from Green and Brightling (2014), who concluded that ICS generally provides superior control compared to LTRA in pediatric asthma management.[12]

In terms of lung function, both the ICS and LTRA groups showed significant improvements in FEV1 and FVC after 12 weeks of treatment. The ICS group showed a significant increase in FEV1 from 75.6 ± 5.2% at baseline to 85.4 ± 6.3% at 12 weeks, with a change of +9.8 ± 5.1% ($p = 0.02$). Similarly, the FVC in the ICS group improved from 85.3 ± 6.1% to 91.2 ± 5.2%, with a change of +5.9 ± 4.3% ($p = 0.02$). The LTRA group also demonstrated improvements in both FEV1 and FVC, but the changes in FEV1 (from 74.8 ± 5.1% to 83.2 ± 6.1%) and FVC (from 84.9 ± 5.9% to 89.6 ± 5.3%) were smaller, with a change in FEV1 of +8.4 ± 4.8% and a change in FVC of +4.7 ± 3.9%. These findings align with those from Green and Brightling (2014), who found that ICS generally provides superior improvements in lung function compared to LTRA.[12] Spector et al. (2018) also reported that ICS therapy significantly improved lung function compared to LTRA in children with asthma, supporting the superiority of ICS in this regard.[13] Additionally, the study by Leung and Szefler (2014) highlighted that although both treatments improved lung function, ICS was more effective in achieving greater improvements in both FEV1 and FVC, particularly in children with more severe asthma.[14]

The frequency of asthma exacerbations was similar between the ICS and LTRA groups during the study, with no significant differences in the frequency of exacerbations or the need for hospitalization or oral steroids. The ICS group had 3.2 ± 1.5 exacerbations per year, while the LTRA group had 3.1 ± 1.4 exacerbations per year ($p = 0.78$). The number of exacerbations requiring hospitalization was low in both groups, with 1 (2%) hospitalization in the ICS group and 2 (4%) in the LTRA group ($p = 0.35$). Exacerbations requiring oral steroids were slightly more common in the LTRA group, with 10 (20%) patients requiring oral steroids, compared to 8 (16%) in the ICS group. However, the differences in the frequency of exacerbations and the need for oral steroids or hospitalization were not statistically significant ($p = 0.35$ and $p = 0.28$, respectively). These results are in line with the study by Leung and Szefler (2014), who found no significant differences in exacerbation rates between ICS and LTRA in children with asthma.[14] Boulet et al. (2013) also noted that while ICS is generally more effective at reducing exacerbation frequency, LTRA has a comparable effect in reducing exacerbations in certain subsets of children with asthma.[15]

Both ICS and LTRA treatments showed significant improvements in quality of life, as measured by the Pediatric Asthma Quality of Life Questionnaire (PAQLQ), with the ICS group demonstrating a more substantial improvement. The ICS group showed a significant improvement, with the PAQLQ score increasing from 3.1 ± 0.9 at baseline to 5.0 ± 1.1 at 12 weeks, reflecting a change of +1.9 ± 1.2 ($p = 0.02$). The LTRA group also showed improvement, with a change in PAQLQ score of +1.7 ± 1.3 (from 3.0 ± 0.8 to 4.7 ± 1.2), though this change was not statistically significant ($p = 0.06$). This finding is consistent with the results from Dietz et al. (2016), which showed that ICS therapy leads to a significantly greater improvement in quality of life compared to LTRA.[16] Smellie et al. (2018) also observed that although LTRA improved quality of life in children with asthma, ICS was more effective in enhancing overall asthma-related quality of life.[17]

Regarding medication adherence, both groups exhibited similar adherence levels, with no significant differences in MARS scores. The ICS group had a mean adherence score of 8.6 ± 1.2, while the LTRA group had a mean score of 8.4 ± 1.1, with no significant difference ($p = 0.32$). This finding is consistent with the results from Horne et al. (2015), who reported similar adherence rates between

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children on ICS and LTRA, suggesting that adherence may be influenced more by factors like medication regimen and family support than by the specific type of asthma treatment.[11] In terms of safety, the incidence of adverse events (AEs) was slightly higher in the ICS group, with 12 (24%) cases of adverse events, compared to 10 (20%) in the LTRA group. The most common adverse events in both groups were mild (18% in ICS, 16% in LTRA) or moderate (6% in ICS, 4% in LTRA). No severe adverse events were reported in either group. These findings are consistent with previous studies such as those by Green and Brightling (2014) and Boulet et al. (2013), which noted that while ICS can lead to more adverse effects, these are typically mild and manageable, and LTRA is associated with fewer side effects.[12,15]

Conclusion

In conclusion, both inhaled corticosteroids (ICS) and leukotriene receptor antagonists (LTRA) are effective treatments for pediatric asthma, with ICS showing superior improvements in asthma control, lung function, and quality of life compared to LTRA. While both treatments demonstrated similar safety profiles and medication adherence, ICS was more effective in managing moderate to severe asthma. Our findings support ICS as the first-line therapy for most children with asthma, while LTRA can be considered for specific patient subsets, particularly those with coexisting allergic rhinitis.

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