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Should recommendations about starting inhaled corticosteroid treatment for mild asthma be based on symptom frequency: a post-hoc efficacy analysis of the START study

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Summary

Background

Low-dose inhaled corticosteroids (ICS) are highly effective for reducing asthma exacerbations and mortality. Conventionally, ICS treatment is recommended for patients with symptoms on more than 2 days per week, but this criterion has scant evidence. We aimed to assess the validity of the previous symptom-based cutoff for starting ICS by establishing whether there was a differential response to budesonide versus placebo for severe asthma exacerbations, lung function, and asthma symptom control across subgroups identified by baseline asthma symptom frequency.

Methods

We did a post-hoc analysis of the 3 year inhaled Steroid Treatment As Regular Therapy (START) study, done in 32 countries, with clinic visits every 3 months. Patients (aged 4–66 years) with mild asthma diagnosed within the previous 2 years and no previous regular corticosteroids were randomised to receive once daily, inhaled budesonide 400 μg (those aged <11 years 200 μg) or placebo. Coprimary outcomes for this analysis were time to first severe asthma-related event (SARE; hospital admission, emergency treatment, or death) and change from baseline in lung function after bronchodilator. Interaction with baseline symptom frequency was investigated, with patients grouped by more than two symptom days per week and two or fewer symptom days per week (divided into no days to 1 day, and more than 1 day to 2 days). Analysis was done by intention to treat.

Findings

Of 7138 patients (n=3577 budesonide; n=3561 placebo), baseline symptom frequency was 0–1 days per week for 2184 (31%) participants, more than 1 and less than or equal to 2 symptom days per week for 1914 (27%) participants, and more than 2 symptom days per week for 3040 (43%) participants. For budesonide versus placebo, time to first SARE was longer across symptom frequency subgroups (hazard ratios 0·54 [95% CI 0·34–0·86] for 0–1 symptom days per week, 0·60 [0·39–0·93] for >1 to ≤2 symptom days per week, 0·57 [0·41–0·79] >2 symptom days per week, $p_{interaction}$=0·94), and the decline in postbronchodilator lung function was less at 3 years' follow-up ($p_{interaction}$=0·32). For budesonide versus placebo, severe exacerbations requiring oral or systemic corticosteroids were reduced (rate ratio 0·48 [0·38–0·61] 0–1 symptom days per week, 0·56 [0·44–0·71] >1 to ≤2 symptom days per week, and 0·66 [0·55–0·80] >2 symptom days per week, $p_{interaction}$=0·11), prebronchodilator lung function was higher, and symptom-free days were more frequent (p<0·0001 for all three subgroups), with no interaction by symptom frequency (prebronchodilator $p_{interaction}$=0·43; symptom-free days $p_{interaction}$=0·53). Similar results were noted when participants were classified by any guidelines criterion as so-called persistent versus so-called intermittent asthma.

Interpretation

In mild recent-onset asthma, once daily, low-dose budesonide decreases SARE risk, reduces lung function decline, and improves symptom control similarly across all symptom subgroups. The results do not support restriction of inhaled corticosteroids to patients with symptoms on more than 2 days per week and suggest that treatment recommendations for mild asthma should consider both risk reduction and symptoms.

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