Maintenance plus as needed budesonide plus formoterol was better than fixed dose for severe exacerbations in asthma


Clinical impact ratings GP/FP/Primary care ★★★★★☆ Internal medicine ★★★★★☆ Respирology ★★★★★☆

In patients with asthma, is budesonide (BUD) plus formoterol (FORM) (BUD + FORM) both for maintenance and symptom relief more effective than fixed dosing using BUD + FORM plus a short acting β2 agonist (SABA) or a 4 fold higher dose of BUD plus SABA for reducing the rate of severe asthma exacerbations?

METHODS

**Design:** randomised controlled trial.

**Allocation:** concealed.*

**Blinding:** blinded (patients and healthcare providers).*

**Follow up period:** 1 year.

**Setting:** 246 centers in 22 countries

**Patients:** 2760 outpatients 4–80 years of age (mean age 36 y, 55% female; 12% children 4–11 y of age) with asthma who were using inhaled corticosteroids.

**Intervention:** BUD + FORM (budesonide, 80 µg, plus formoterol, 4.5 µg) both for maintenance and as needed (BUD + FORM for both, n = 925), BUD + FORM for maintenance plus terbutaline, 0.4 mg as needed (BUD + FORM plus SABA, n = 909), or budesonide high dose 320 µg for maintenance plus terbutaline as needed (BUDH plus SABA, n = 926). All maintenance treatments were twice daily for patients 12–80 years of age and once daily for children 4–11 years of age.

**Outcomes:** time to first severe asthma exacerbation (defined as deterioration in asthma resulting in hospital admission or emergency room treatment, oral steroid treatment, or morning peak expiratory flow <70% of baseline on 2 consecutive d).

**Patient follow up:** 99.7% of patients were included in the intention to treat analyses.

*See glossary.

MAIN RESULTS

Time to first severe exacerbation was greater in the BUD + FORM for both group than in the BUD + FORM plus SABA group or BUDH plus SABA group (p values <0.001). Fewer patients in the BUD + FORM for both group than in the BUD + FORM plus SABA group or BUDH plus SABA group had >1 severe asthma exacerbation (table).

CONCLUSION

In patients with asthma, budesonide plus formoterol (BUD + FORM) both for maintenance and symptom relief was more effective than fixed dosing using BUD + FORM plus a short acting β2 agonist (SABA) or a 4 fold higher dose of budesonide plus SABA.

A modified copy of this abstract appears in Evidence-Based Nursing.

<table>
<thead>
<tr>
<th>Outcomes at 1 year</th>
<th>Comparison</th>
<th>Event rates</th>
<th>RRR (95% CI)</th>
<th>NNT (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥1 severe asthma exacerbation</td>
<td>BUD/FORM for both v BUD/FORM plus SABA</td>
<td>16% v 27%</td>
<td>0.41 (0.30 to 0.52)</td>
<td>10 (8 to 13)</td>
</tr>
<tr>
<td></td>
<td>BUD/FORM for both v BUDH plus SABA</td>
<td>16% v 28%</td>
<td>0.43 (0.31 to 0.53)</td>
<td>9 (7 to 12)</td>
</tr>
</tbody>
</table>

*Abbreviations defined in glossary; RRR, NNT, and CI calculated from Cox proportional hazard ratio in article.
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