Inactivated influenza vaccine decreased pulmonary function in asthma except when colds were considered


Question
In patients with asthma, is inactivated influenza vaccine safe when the occurrence of colds is taken into account?

Design
Randomised, double-blind, placebo-controlled crossover trial with follow-up to 2 weeks after the final injection.

Setting
9 respiratory centres and 2 asthma clinics in the United Kingdom.

Patients
299 patients between 18 and 75 years of age (mean age 52 y, 57% women) who had stable asthma. Exclusion criteria were hypersensitivity to eggs, chicken, or influenza proteins; pregnancy; a febrile illness at the beginning of the study; or treatment with an investigational drug during the 30 days before study recruitment. 262 patients (88%) completed the study; 255 (80%) had complete paired data.

Intervention
Patients were allocated in a crossover design to 0.5~mL intramuscular injection of vaccine and placebo separated by 2 weeks.

Main outcome measures
Exacerbation of asthma within 72 hours of injection, defined as a decline in early-morning peak expiratory flow (PEF) of > 20% compared with the lowest of the best 3 early-morning PEF values measured during the 3 days before injection. Secondary outcomes were colds coinciding with exacerbations; β2-agonist, antibiotic, and oral steroid use; and medical consultations and hospital admissions.

Main results
Analysis was by intention to treat. Among 255 patients with paired data, 11 had a decrease in PEF of > 20% after vaccine compared with 3 after placebo (P = 0.03) (Table). 8 patients had a moderate or severe decrease in PEF (> 30%) after vaccine compared with 0 after placebo (P = 0.008) (Table). When patients with colds were excluded, the groups did not differ for a decrease in PEF of > 20% (6 vs 3, P = 0.51) or > 30% (5 vs 0, P = 0.06) (Table). No differences existed between the groups for other secondary outcomes.

Conclusions
Inactivated influenza vaccine led to a decrease in pulmonary function in patients with asthma. However, this decrease was no longer statistically significant when concurrent colds were considered.


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Inactivated influenza vaccine vs placebo at 2 weeks in asthma†

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Vaccine</th>
<th>Placebo</th>
<th>RRI (95% CI)</th>
<th>NNH (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fall in PEF &gt; 20%</td>
<td>4.3%</td>
<td>1.2%</td>
<td>267% (12 to 111)</td>
<td>32 (15 to 289)</td>
</tr>
<tr>
<td>Excluding those with a cold</td>
<td>2.4%</td>
<td>1.2%</td>
<td>100% (--45 to 624)</td>
<td>Not significant</td>
</tr>
<tr>
<td>Fall in PEF &gt; 30%</td>
<td>3.1%</td>
<td>0%</td>
<td>Approaches infinity</td>
<td>33 (20 to 110)</td>
</tr>
<tr>
<td>Excluding those with a cold</td>
<td>2.0%</td>
<td>0%</td>
<td>Not significant</td>
<td>Not significant</td>
</tr>
</tbody>
</table>

HPEF = peak expiratory flow. Other abbreviations defined in Glossary; RRI, NNH, and CI calculated from data in article.

References