Ear drops containing steroids were better than acetic acid for otitis externa


In patients with acute otitis externa, what is the relative effectiveness of ear drops containing acetic acid, steroids and acetic acid, and steroids and antibiotics?

**METHODS**

- **Design:** randomised controlled trial.
- **Allocation:** concealed.
- **Blinding:** blinded (health care providers and patients).
- **Follow up period:** 42 days.
- **Setting:** 47 general practices in the central part of the Netherlands.
- **Patients:** 213 patients (mean age 43 y, 50% men) presenting with signs and symptoms of acute otitis externa. Exclusion criteria: age < 17 years, pregnancy, otitis externa lasting > 3 weeks, furuncle in the external auditory canal, acute otitis media, perforated eardrum, perichondritis, fever, allergy to study drugs, or treatment for acute otitis externa in the past month.
- **Interventions:** 3 ear drops 3 times daily of 7.2 mg of acetic acid per gram of propylene glycol (acetic acid group) (n = 71); 0.66 mg of dexamethasone phosphate sodium, 5 mg of neomycin sulphate, and 10 000 IU of polymyxin B sulphate/ml (steroid plus antibiotic group) (n = 79).
- **Outcomes:** self reported duration of symptoms until recovery. Secondary outcomes were cure rate (proportion of patients recovered according to general practitioner) at 7, 14, and 21 days; and recurrence of symptoms from day 21-42.
- **Patient follow up:** 89% at 21 days.

**MAIN RESULTS**

Analysis was by intention to treat. Duration of symptoms was shorter in patients who received steroids plus acetic acid or steroids plus antibiotics than in those who received acetic acid (mean 7 ± 8 d and 6 ± 8 d, respectively, p<0.001 across 3 groups). The cure rate was greater at 14 and 21 days in patients who were in the steroid plus acetic acid or steroid plus antibiotic groups than those in the acetic acid group (table). Fewer patients in the steroid plus acetic acid group than the acetic acid group had a recurrence of otitis externa at 21–42 days (table).

**CONCLUSION**

Ear drops containing steroids with acetic acid or antibiotics were more effective than acetic acid alone for acute otitis externa.

**Commentary**

A cute otitis externa, an infection of the external auditory canal, is associated with exposure to warm humid climates, swimming, and aggressive cleaning of the ear canal.1 It is a common disease in primary care, usually treated with ear drops containing antibiotics with steroids; however, the optimal treatment has not been established. The study by van Balen et al is the first large study of acute otitis externa that examined cure rates at 7 days and recurrence after symptom resolution. Based on the findings, the authors recommend that acetic acid drops alone should no longer be used to treat adults with acute otitis externa.

Methodological strengths of this study include recruitment of patients from 47 general practices, concealed allocation of patients, blinding of patients and clinicians, training of general practitioners in diagnosing and treating acute otitis externa, and inclusion of important clinical endpoints, such as speed of recovery and symptom recurrence up to 42 days after treatment initiation. Adjustment of the primary and secondary outcomes for differences in baseline characteristics improved the rigour of the study. Confidence intervals around odds ratios reported in the study and around the relative benefit increases and the relative risk reductions reported in the table of the EBN abstract indicate a lack of precision that would have been improved with a larger sample size.

The study makes a strong case for the use of steroids combined with either acetic acid or antibiotics for treatment of acute otitis externa. Caution should be exercised when applying these findings to patients with comorbid conditions because this study predominantly included healthy adults. The results are particularly relevant to nurse practitioners working in primary healthcare and ear-nose-throat clinical settings.


**Table:**

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Comparisons</th>
<th>Event rates</th>
<th>RBI (95% CI)</th>
<th>NNT (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cure rate at 14 days</td>
<td>S+AA v AA</td>
<td>75% ± 57%</td>
<td>33% (4 to 54)</td>
<td>6 (4 to 44)</td>
</tr>
<tr>
<td></td>
<td>S+AB v AA</td>
<td>82% ± 57%</td>
<td>44% (19 to 60)</td>
<td>4 (3 to 10)</td>
</tr>
<tr>
<td>Cure rate at 21 days</td>
<td>S+AA v AA</td>
<td>89% ± 62%</td>
<td>45% (23 to 54)</td>
<td>4 (3 to 7)</td>
</tr>
<tr>
<td></td>
<td>S+AB v AA</td>
<td>86% ± 62%</td>
<td>39% (19 to 31)</td>
<td>5 (4 to 9)</td>
</tr>
</tbody>
</table>

| Recurrence at 21–42 days | S+AA v AA   | 26% ± 45% | 56% (19 to 83) | 4 (3 to 12) |
|                         | S+AB v AA   | 21% ± 45% | 45% (0 to 69) | Not significant |

*Abbreviations defined in glossary; RBI, RRR, NNT, and CI calculated from data in article using odds ratios adjusted for differences at baseline.
†Based on 172 patients who were symptom free at day 21.