An alternative to antibiotics for the symptomatic relief of sore throat – evidence from a randomised controlled study of flurbiprofen lozenges

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INTRODUCTION

- Antibiotics continue to be overprescribed for sore throat.1–4
- In a recent study in a US culture, 10% of patients with sore throat (46% in Denmark) were prescribed antibiotics for their sore throat.5
- Most sore throats (95–99% of adults) are caused by a viral infection, for which antibiotics are ineffective.6
- Bacteria such as group A streptococcus (Strep A) and group C streptococcus (Strep C) can cause sore throat infections, but these are generally self-limiting and complications are rare. Therefore, antibiotics are usually unnecessary.7
- Regardless of the cause, most patients with sore throat want pain relief rather than an antibiotic so they should be offered treatments with effective analgesic action.8
- A lozenging containing a dose (8.75 mg) of the anti-inflammatory drug, flurbiprofen, has been developed for the effective treatment of sore throat symptoms irrespective of whether the cause is streptococcal or non-streptococcal.9,10
- This study aimed to establish the time to onset of analgesia of flurbiprofen 8.75 mg lozenges in patients with and without oropharyngeal infection.

METHODS

Study design

- A randomised, double-blind, placebo-controlled, single-dose, single-centre, parallel-group clinical trial.

Study population

- Study inclusion criteria were: Aged ≥18 years with recent onset (≤4 days) sore throat
- ClinicalTrials.gov identifier: NCT01986361

Study medication

- Patients were randomised to receive one sugar-based flurbiprofen 8.75 mg lozenge or one sugar-based matching placebo lozenge.

Study assessments

- The practitioner conducted several assessments at baseline including the TPA and the Practitioner’s Assessment of Pharyngeal Inflammation (PAIN). A 10-category scale is rated on the extent of pharyngeal inflammation, with a maximum possible score of 31.2
- Table 1. Tonsillo-Pharyngeal Assessment

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Flurbiprofen (N=34)</th>
<th>Placebo (N=8)</th>
<th>Overall (N=322)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral temperature</td>
<td>98.4 (1.5)</td>
<td>98.0 (1.7)</td>
<td>98.1 (1.6)</td>
</tr>
<tr>
<td>Pharyngeal colour</td>
<td>pink</td>
<td>red</td>
<td>red</td>
</tr>
<tr>
<td>PAIN, n (%)</td>
<td>19 (55.9)</td>
<td>3 (37.5)</td>
<td>22 (68.7)</td>
</tr>
<tr>
<td>No PAIN, n (%)</td>
<td>15 (44.1)</td>
<td>5 (62.5)</td>
<td>20 (61.3)</td>
</tr>
<tr>
<td>TPS, mean (SD)</td>
<td>8.8 (6.0)</td>
<td>7.7 (6.4)</td>
<td>8.2 (6.2)</td>
</tr>
<tr>
<td>TPS, n (%)</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Moderate</td>
</tr>
<tr>
<td>Placebo 8.75 mg</td>
<td>10 (29.4)</td>
<td>8 (100.0)</td>
<td>18 (56.3)</td>
</tr>
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RESULTS

Patient population

- A total of 122 patients were randomised to flurbiprofen (n=101) or placebo (n=21). All patients completed the 3-hour study
- Mean age was 19.5 years and 52.8% of the patients were female (Table 2)
- Patients with Strep A/C infection were similar for both treatment groups

Table 2. Baseline demographics and characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Flurbiprofen (N=34)</th>
<th>Placebo (N=8)</th>
<th>Overall (N=322)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), years</td>
<td>19.5 (2.2)</td>
<td>19.6 (1.36)</td>
<td>19.5 (2.92)</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>20 (58.8)</td>
<td>7 (87.5)</td>
<td>27 (84.4)</td>
</tr>
<tr>
<td>Oral temperature, mean (SD), ºF</td>
<td>98.4 (1.5)</td>
<td>98.0 (1.7)</td>
<td>98.1 (1.6)</td>
</tr>
</tbody>
</table>
| Number of oropharyngeal symptoms (absent, present or moderate) | Flurbiprofen 8.75 mg lozenge starts working quickly to relieve sore throat, while antibiotics should be reserved for patients with a serious infection or those with oropharyngeal infection.

DISCUSSION

- Median time to first perceived relief for patients receiving flurbiprofen was 5.2 minutes (95% CI: 2.9, 5.5) for patients with Strep A/C (Figure 1) and 20.7 minutes (95% CI: 13.6, 27.8) for patients with Strep A/C (Figure 2).
- Pain reduction was sustained and later confirmed to be meaningful to patients with or without Strep A/C (Figure 3).
- These findings suggest that flurbiprofen 8.75 mg lozenges provides fast and meaningful relief to adults with acute sore throat, regardless of the cause.
- Flurbiprofen 8.75 mg lozenges can be recommended as an effective first-line treatment for sore throat, while antibiotics should be reserved for patients with a serious infection or those as increased risk of complications.

CONCLUSIONS

- Flurbiprofen 8.75 mg lozenges start working quickly to relieve patients’ sore throat symptoms, providing meaningful relief to those with or without Strep A/C infection.
- Flurbiprofen 8.75 mg lozenges can be recommended as a first-line treatment for sore throat and an alternative to immediate antibiotic prescribing.

REFERENCES


Figure 1. Proportion of Strep A/C patients achieving first perceived relief

Figure 2. Proportion of non-Strep A/C patients achieving first perceived relief

Figure 3. Proportion of Strep A/C patients achieving meaningful relief

Figure 4. Proportion of non-Strep A/C patients achieving meaningful relief

Safety

- Two patients (9.5%) in the flurbiprofen group and one patient (4.8%) in the placebo group reported an AE during the 3-hour observation period (p=0.69 for flurbiprofen vs. placebo).
- There were two AEs in the flurbiprofen group, which were considered to be possibly or probably related to study treatment (abdominal discomfort and throat irritation) (p=0.16 vs. placebo).
- There were no serious AEs and no patient discontinued from the study because of an AE.