Corticosteroids for treatment of sore throat: systematic review and meta-analysis of randomised trials

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WHAT IS ALREADY KNOWN ON THIS TOPIC

Short course corticosteroids are one adjunct treatment option for relief of symptoms in patients with sore throat

Corticosteroids are not commonly prescribed as clinicians are uncertain about the balance of benefits and harms and the applicability of the evidence to patients with less severe disease

WHAT THIS STUDY ADDS

Moderate to high quality evidence suggests the addition of one (or two) dose(s) of corticosteroids reduces the intensity and duration of pain in patients with sore throat with no increase in serious adverse effects

The mean time to complete pain resolution was about 11 hours shorter with corticosteroids, and about 18% more patients experienced complete pain relief at 48 hours

There were no subgroup effects between patients consulting at the emergency departments or primary care family practice

RESULTS

10 eligible trials enrolled 1426 individuals. Patients who received single low dose corticosteroids (the most common intervention was oral dexamethasone with a maximum dose of 10 mg) were twice as likely to experience pain relief after 24 hours (relative risk 2.2, 95% confidence interval 1.2 to 4.3; risk difference 12.4%; moderate quality evidence) and 1.5 times more likely to have no pain at 48 hours (1.5, 1.3 to 1.8; risk difference 18.3%; high quality). The mean time to onset of pain relief in patients treated with corticosteroids was 4.8 hours earlier (95% confidence interval −1.9 to −7.8; moderate quality) and the mean time to complete resolution of pain was 11.1 hours earlier (−0.4 to −21.8; low quality) than in those treated with placebo. The absolute pain reduction at 24 hours (visual analogue scale 0-10) was greater in patients treated with corticosteroids (mean difference 3.9, 95% confidence interval −2.7 to −7.8; moderate quality) than in those treated with placebo (mean difference 2.2, 95% confidence interval −1.9 to −7.8; moderate quality). Nine of the 10 trials sought information regarding adverse events. Six studies reported no adverse effects, and three studies reported few adverse events, which were mostly complications related to disease, with a similar incidence in both groups.

CONCLUSION

Single low dose corticosteroids can provide pain relief in patients with sore throat, with no increase in serious adverse effects. Included trials did not assess the potential risks of larger cumulative doses in patients with recurrent episodes of acute sore throat.

SYSTEMATIC REVIEW REGISTRATION

PROSPERO CRD42017067808

Introduction

Sore throat is among the most common presenting complaints in both emergency departments and outpatient care settings. It is the cause of about 5% of medical visits in children and about 2% of all outpatient visits in adults.1,3 The most common cause of sore throat is acute pharyngitis caused by self limiting viral infections. Pain management with paracetamol (acetaminophen) or non-steroidal anti-inflammatory drugs (NSAIDs) therefore represents the mainstay of care.4 5 These drugs provide limited pain relief but also sometimes cause serious harm.6 7 Treatment of sore throat with antibiotics also provides modest benefit in reduction of symptoms and fever when the infection is bacterial, but their use could contribute to antibiotic resistance.8 9 Although most cases of sore throat have a viral aetiology, and the risk of secondary complications is low, clinicians commonly prescribe antibiotics.4 10 Though this could be because clinicians think that patients seeking care expect a course of antibiotics, in reality pain relief might be more important to them.10

Corticosteroids represent an additional therapeutic option for symptom relief. Randomised control trials

ABSTRACT

OBJECTIVE

To estimate the benefits and harms of using corticosteroids as an adjunct treatment for sore throat.

DESIGN

Systematic review and meta-analysis of randomised control trials.

DATA SOURCES

Medline, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), trial registries up to May 2017, reference lists of eligible trials, related reviews.

STUDY SELECTION

Randomised controlled trials of the addition of corticosteroids to standard clinical care for patients aged 5 or older in emergency department and primary care settings with clinical signs of acute tonsillitis, pharyngitis, or the clinical syndrome of sore throat. Trials were included irrespective of language or publication status.

REVIEW METHODS

Reviewers identified studies, extracted data, and assessed the quality of the evidence, independently and in duplicate. A parallel guideline committee (BMJ Rapid Recommendation) provided input on the design and interpretation of the systematic review, including the selection of outcomes important to patients. Random effects model was used for meta-analyses. Quality of evidence was assessed with the GRADE approach.

RESULTS

CONCLUSION

Single low dose corticosteroids can provide pain relief in patients with sore throat, with no increase in serious adverse effects. Included trials did not assess the potential risks of larger cumulative doses in patients with recurrent episodes of acute sore throat.

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Introduction

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Corticosteroids represent an additional therapeutic option for symptom relief. Randomised control trials
suggest that a short course of low-to-moderate dose corticosteroids probably provides symptomatic benefit to patients with sore throat.\textsuperscript{11,16} Despite this evidence, clinicians do not commonly use steroids. Reasons might include uncertain applicability of the evidence to patients with less severe disease, as the initial studies enrolled only patients with severe sore throat presenting to emergency departments, almost all of whom received antibiotics.

This systematic review is part of the BMJ Rapid Recommendations project, a collaborative effort from the MAGIC research and innovation programme (www.magicproject.org) and BMJ. The aim of the project is to respond to new potentially practice changing evidence and provide a trustworthy practice guideline in a timely manner.\textsuperscript{15} In this case, the stimulus was the recent TOAST (Treatment Options without Antibiotics for Sore Throat) trial, which randomised over 500 patients with sore throat presenting to their primary care clinician who were not initially prescribed antibiotics; the TOAST authors reported beneficial effects of corticosteroids.\textsuperscript{16} In the light of this new potentially practice changing evidence, we updated the latest Cochrane review\textsuperscript{17} dealing with the effectiveness and safety of corticosteroids as an adjunct treatment for sore throat in addition to standard care compared with standard care alone. This systematic review informed the parallel guideline published in a multi-layered electronic format on bmj.com\textsuperscript{17} and MAGICapp (https://www.magicapp.org/goto/guideline/JjXYAL/section/j79pvn).

Methods

Guideline panel and patient involvement

According to the BMJ Rapid Recommendations process,\textsuperscript{15} a guideline panel provided critical oversight to the review and identified populations, subgroups, and outcomes of interest. The panel included clinicians, methodologists, and patients with experience of sore throat. Patients received personal training and support to optimise contributions throughout the guideline development process. The patients on the panel led the interpretation of the results based on what they expected the typical patient values and preferences to be, as well as the variation between patients. Five patient representatives were full members of the guideline panel and contributed to the selection and prioritisation of outcomes, values and preferences assessments, and critical feedback to the protocol for the systematic review and the BMJ Rapid Recommendations manuscript.

Search strategy

We searched Medline, Embase, and the Cochrane Central Register of Controlled Trials (CENTRAL) for relevant published randomised controlled trials based on the strategy reported in the most recent Cochrane systematic review,\textsuperscript{12} modified under the guidance of a research librarian (appendix 1). We limited the search from 1 January 2010, which included a two month overlap with the previous Cochrane review search,\textsuperscript{12} to 1 May 2017. There were no language restrictions. We reviewed reference lists from eligible new trials and related reviews for additional eligible trials and searched ClinicalTrials.gov for ongoing or unpublished trials and for additional data from published trials.

Study selection

Reviewers (BS, RACS, DP, RBP) independently and in duplicate screened the titles and abstracts of all identified studies using a priori selection criteria. Subsequently, the same reviewers independently assessed eligibility of the full texts of potentially eligible studies. Reviewers resolved discrepancies through discussion or, if needed, by adjudication from a third reviewer.

We included randomised controlled trials that compared corticosteroids with standard of care or placebo and enrolled adults and/or children aged 5 and over in emergency departments and primary care settings with a clinical syndrome of sore throat (painful throat, odynophagia, or pharyngitis).

We excluded studies of participants who were admitted to hospital or immunocompromised and those with infectious mononucleosis, sore throat after any surgery or intubation (postoperative sore throat), gastroesophageal reflux disease, croup, or peritonsillar abscess. We also excluded studies that enrolled children aged under 5 because they would not be able to provide trustworthy outcome measurements, especially for self reported pain.

Our outcomes of interest were complete resolution of pain at 24 and 48 hours; mean time to onset of pain relief; mean time to complete resolution of pain; absolute reduction of pain at 24 hours; duration of bad/non-tolerable symptoms (such as problems for eating, drinking, swallowing); recurrence/relapse of symptoms; days missed from school or work; need for antibiotics; and rate of adverse events related to treatment. We included any adverse events reported by the authors.

Data abstraction and risk of bias assessment

Reviewers extracted the following data, independently and in duplicate: general study information (authors, publication year, and study location); study population details (sample size, age, diagnosis, and over in emergency departments and primary care settings with a clinical syndrome of sore throat (painful throat, odynophagia, or pharyngitis)); setting (primary care versus hospital emergency department); details on the intervention and comparison (for example, type, form, duration, and dose of corticosteroids; type of control group); co-interventions (proportion of participants who received antibiotics and/or analgesics); and outcomes as listed above.

In randomised controlled trials with more than two arms, we extracted data from the arm closest to a single dose regimen or data from the arm that received corticosteroid as adjunct treatment to standard of care rather than instead of standard of care. In trials with data for both oral and parenteral corticosteroids, we...
used oral data for the main analysis and intramuscular data for the appropriate subgroup analysis.

Two reviewers independently assessed risk of bias using the modified Cochrane risk of bias instrument, which deals with random sequence generation; allocation concealment; blinding of study participants, healthcare providers, and outcome assessors; incomplete outcome data; and other potential sources of bias. Reviewers classified studies at high risk of bias when they had rated at least one item as high risk of bias.

To assess the quality of evidence, we used the GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) approach that classifies evidence as high, moderate, low, or very low quality based on considerations of risk of bias, consistency, directness, precision, and publication bias. We resolved disagreements between reviewers in data extraction and assessments of risk of bias or quality of evidence by discussion and, if needed, by third party adjudication. We used the MAGICapp platform to generate the GRADE summary of findings table.

### Data synthesis and statistical methods

For continuous outcomes, we calculated the mean difference and its corresponding 95% confidence interval. For dichotomous outcomes, we calculated the relative risk and its corresponding 95% confidence interval. For dichotomous outcomes, we calculated the risk difference and its corresponding 95% confidence interval. For continuous outcomes, we calculated the mean difference and its corresponding 95% confidence interval. For dichotomous outcomes, we calculated the relative risk and its corresponding 95% confidence interval. For continuous outcomes, we calculated the mean difference and its corresponding 95% confidence interval.

Statistical heterogeneity was determined with the Q statistic and I². We used the DerSimonian-Laird random effects model for the meta-analysis of all outcomes. Regardless of the observed statistical heterogeneity, we conducted the following prespecified subgroup analyses when each subgroup was represented by at least two studies: age (children v adults), postulating a larger effect in adults; route of administration of corticosteroids (oral v parenteral), postulating a larger effect for parenteral; presence or absence of positive results on culture for a bacterial pathogen or direct antigen test for group A β haemolytic streptococcus, postulating a larger effect in patients with positive test results; initial setting (emergency departments v family practice), postulating a larger effect in patients consulting the emergency department; and place of subsequent care (admitted to hospital v outpatient), postulating a larger effect among the patients admitted. For subgroup analysis, we tested for interaction using a χ² significance test. We planned to examine publication bias using funnel plots for outcomes for which data from 10 or more studies were available. Data were analysed with STATA software (version 14.2, TX, USA).

### Patient involvement

Five patient representatives were full members of the guideline panel, and contributed to the selection and prioritisation of outcomes, values and preferences assessments, and critical feedback to the protocol for the systematic review and the BMJ Rapid Recommendations manuscript.

### Results

**Description of included studies**

We identified 2349 titles and abstracts through our literature search, of which 46 were potentially eligible and 36 were excluded (19 were not randomised trials; 14 had no patients with sore throat/acute pharyngitis; in three corticosteroids were not among the interventions or were not compared with a placebo/usual care). Figure 1 shows the details of study selection process.

The 10 randomised controlled trials that proved eligible enrolled 1426 individuals. Eight studies recruited patients from hospital emergency departments and two from primary care. Three studies enrolled children, six studies enrolled adults, and one study included both children and adults. Oral dexamethasone (single dose of 10 mg for adults and 0.6 mg/kg, maximum 10 mg for children) was the most common intervention (five studies) followed by single dose intramuscular injection of dexamethasone (three studies). All patients in three trials received both antibiotics and analgesics as the usual care; in two trials, all patients received antibiotics, while analgesics were prescribed at the physician’s discretion. In the five remaining trials, patients in usual care group received antibiotics or analgesics at the physician’s discretion.

Table 1 presents study details.

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**Table 1**

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td>1000</td>
</tr>
<tr>
<td>Children</td>
<td>426</td>
</tr>
<tr>
<td>Total</td>
<td>1426</td>
</tr>
</tbody>
</table>

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**Fig 1** | Selection of studies in review of corticosteroids for treatment of sore throat
Among the included studies, four randomised controlled trials were at high risk of bias.\textsuperscript{23,24,26,28} One study had issues in more than one category of risk.\textsuperscript{26} The three remaining studies had issues in concealment of the treatment allocation, incomplete outcome reporting, and blinding of outcome assessors. Appendix 2 summarises the risk of bias assessments.

Table 2 shows findings for all outcomes. Interactive tables summarising findings are available at https://www.magicapp.org/goto/guideline/JjXYAL/section/j79pvn

### Pain

In the five randomised controlled trials that reported complete resolution of symptoms at 24 hours,\textsuperscript{16,25,29-31} patients who received a single dose of corticosteroids were twice as likely to experience complete symptom resolution than placebo patients (relative risk 2.24, 95% confidence interval 1.17 to 4.29; \(I^2=69\%\), 22.4% vs. 10.0%; moderate quality evidence; fig 2, table 2). All studies reporting this outcome were at low risk of bias. Tests of interaction showed no evidence of any subgroup effect (table A in appendix 3).

In the four trials that reported complete resolution of pain at 48 hours,\textsuperscript{16,29-31} patients treated with corticosteroids were 50% more likely to experience complete resolution (relative risk 1.48, 95% confidence interval 1.26 to 1.75; \(I^2=3\%\), 60.8% vs. 42.5%; high quality; fig 3, table 2). These four studies were all at low risk of bias, and tests of interaction showed no evidence of any subgroup effect (table A in appendix 3).

In the eight studies that reported mean time to onset of pain relief,\textsuperscript{16,23-28,30} patients receiving corticosteroids experienced onset of pain relief on average 4.8 hours earlier than those who received placebo (95% confidence interval −1.9 to −7.8; \(I^2=78\%\); moderate quality; fig 4, table 2). We found no evidence of subgroup effect for this outcome (table A in appendix 3).

Time to complete resolution of pain was reported in six studies.\textsuperscript{16,23,24,27,28,30} On average, patients receiving a single dose corticosteroid experienced complete resolution 11.1 hours earlier (95% confidence interval −0.4 to −21.8; \(I^2=85\%\); low quality; fig 5, table 2). In our subgroup analysis, we found a significantly larger effect among those treated with intramuscular corticosteroids (mean difference −22.4 (95% confidence interval −27.3 to −17.5) and −1.5 (−12.6 to 9.5), for intramuscular and oral corticosteroids, respectively; \(P=0.001\) for interaction); however, the effect modification is suggested by comparison between rather than within studies. We found no other subgroup effect (table B in appendix 3).

Meta-analysis from eight studies that assessed pain with a visual analogue scale (0=no pain, 10=maximum pain) at baseline and after 24 hours\textsuperscript{16,23,24,27,28,30} showed a 1.3 points lower pain score among patients treated with corticosteroids compared with those treated with placebo at 24 hours (95% confidence interval 0.7 to 1.9; \(I^2=65\%\); moderate quality; fig 6, table 2). We

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**Table 1**: Characteristics of studies included in systematic review of corticosteroids for treatment of sore throat

<table>
<thead>
<tr>
<th>Study</th>
<th>Setting</th>
<th>Population</th>
<th>Mean age (years)</th>
<th>Antibiotic use (%)</th>
<th>Analgesic use (%)</th>
<th>Pathogen positive* (%)</th>
<th>Type of steroid</th>
<th>Dose and duration</th>
<th>Interventions</th>
<th>Control</th>
<th>Interventions</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hayward, 2017</td>
<td>Primary care</td>
<td>Adults</td>
<td>34.0</td>
<td>29.3/28.3</td>
<td>29.9</td>
<td>Dexamethasone (oral)</td>
<td>10 mg, single dose</td>
<td>39.9</td>
<td>39.0</td>
<td>77.1</td>
<td>78.9</td>
<td></td>
</tr>
<tr>
<td>Tasar, 2008</td>
<td>ED</td>
<td>Adults</td>
<td>31.3</td>
<td>31/42</td>
<td>NR</td>
<td>Dexamethasone (IM)</td>
<td>8 mg, single dose</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Niland, 2006</td>
<td>ED</td>
<td>Children</td>
<td>7.7†</td>
<td>30/30</td>
<td>100.0</td>
<td>Dexamethasone (oral)</td>
<td>0.6 mg/kg, max 10 mg, single dose</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>Olympia, 2005</td>
<td>ED</td>
<td>Children</td>
<td>11.9</td>
<td>75/75</td>
<td>55.2</td>
<td>Dexamethasone (oral)</td>
<td>0.6 mg/kg, max 10 mg, single dose</td>
<td>47.1</td>
<td>63.0</td>
<td>35.1</td>
<td>41.2</td>
<td></td>
</tr>
<tr>
<td>Kiderman, 2005</td>
<td>Primary care</td>
<td>Adults</td>
<td>33.9</td>
<td>40/39</td>
<td>57.5</td>
<td>Prednisone (oral)</td>
<td>60 mg, single dose (100%) or for 2 days (50%)</td>
<td>51.4</td>
<td>63.2</td>
<td>NR</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>Bulloch, 2003</td>
<td>ED</td>
<td>Children</td>
<td>9.7</td>
<td>92/92</td>
<td>46.2</td>
<td>Dexamethasone (oral)</td>
<td>0.6 mg/kg, max 10 mg, single dose</td>
<td>48.9</td>
<td>43.5</td>
<td>NR</td>
<td>NR</td>
<td></td>
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<tr>
<td>Ahn, 2003</td>
<td>ED</td>
<td>Adults</td>
<td>35.3</td>
<td>36/36</td>
<td>45.0</td>
<td>Dexamethasone (oral)</td>
<td>5 mg, single dose</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Wei, 2002</td>
<td>ED</td>
<td>Adults</td>
<td>28.1</td>
<td>42/38</td>
<td>39.0</td>
<td>Dexamethasone (oral and IM)</td>
<td>10 mg, single dose</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Marvez-Valls, 1998</td>
<td>ED</td>
<td>Adults</td>
<td>29.2</td>
<td>46/46</td>
<td>53.2</td>
<td>Betamethasone (IM)</td>
<td>8 mg/2 mL injection‡, single dose</td>
<td>100</td>
<td>100</td>
<td>NR</td>
<td>NR</td>
<td></td>
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<tr>
<td>O'Brien, 1993</td>
<td>ED</td>
<td>Both</td>
<td>26.4</td>
<td>31/27</td>
<td>NR</td>
<td>Dexamethasone (IM)</td>
<td>10 mg, single dose</td>
<td>100</td>
<td>100</td>
<td>NR</td>
<td>NR</td>
<td></td>
</tr>
</tbody>
</table>

ED=emergency department; NR=not reported. *Positive result on culture or rapid test for group A β haemolytic streptococcus (GABHS). †Median (interquartile range 6-12). ‡Dose is best guess from US formularies.
found no evidence of subgroup effect for this outcome (table B in appendix 3).

To assess the possibility that there was selective reporting, we examined the magnitude of effect on the time to onset of pain relief, time to complete resolution of pain, and absolute pain reduction in studies that did and did not report resolution of pain at 24 and 48 hours. The magnitude of effect on the other pain outcomes was similar in both sets of studies, making selective reporting less likely (table C in appendix 3).

Other outcomes

The authors of one study reported a possible decrease in the likelihood of receipt of antibiotics in patients treated with corticosteroids (relative risk 0.83, 95% confidence interval 0.61 to 1.13; moderate quality). Three studies suggested a possible lower risk of recurrence/relapse of the symptoms (0.52, 0.16 to 1.73; I²=23%; moderate quality, table D in appendix 3, table 2).

Kiderman and colleagues reported that 22/40 (55%) patients treated with corticosteroids and 27/39 (69%) taking placebo took time off work because of sore throat (relative risk 0.8, 95% confidence interval 0.6 to 1.1). Marvez-Valls and colleagues reported that adult patients treated with corticosteroids missed an average of 0.4 (SD 1.4) days, whereas patients in the placebo arm missed an average of 0.7 (SD 1.4) days (mean...
In patients with acute sore throat, there is primarily moderate to high quality evidence that one or two low doses of corticosteroids reduces the intensity and duration of pain—pain scores at 24 hours, complete resolution of pain at 24 and at 48 hours, time to onset of pain relief, and time to complete pain relief. In this review, results were consistent across studies and across all pain outcomes (table 2). The reduction in pain achieved was modest—for example, mean time to complete resolution of pain was about 11 hours shorter, and about 18% more patients had complete pain relief at 48 hours. At 24 hours, the mean improvement in

Fig 2 | Relative risk for complete resolution of pain at 24 hours for corticosteroid v placebo groups in review of treatment of sore throat. Pooled relative risk calculated by DerSimonian-Laird random effects model

Table 3 provides details of adverse effects assessed and methods used for capturing them. Six studies reported no adverse effects, and three studies reported adverse events, in both steroids and comparator arms, which were mostly complications related to disease and occurred with similar frequency in the intervention and control groups (table 3). Hayward and colleagues reported two serious adverse events (admission to hospital for pharyngeal or peritonsillar abscess, tonsillitis, and pneumonia) in the corticosteroids group (0.7%) and three in the placebo group (1.1%).

Olympia and colleagues reported one out of the 57 (1.8%) children in the corticosteroids group and two out of the 68 (2.9%) children in the placebo group developed a peritonsillar abscess (moderate quality, table 2 and table 3).

Discussion

![Diagram of relative risk](image)

**Fig 3 | Relative risk for complete resolution of pain at 48 hours for corticosteroid v placebo groups in review of treatment of sore throat. Pooled relative risk calculated by DerSimonian-Laird random effects model**
pain scores was about 13 mm on a visual analogue scale from 0 to 100 mm (with the minimal important difference being about 10 mm). The relative effects were similar across severities, though patients with less severe sore throat had less absolute benefit from corticosteroids. The balance of benefits and harms therefore almost certainly depends on the severity of the patient’s sore throat.

Whether corticosteroids reduce recurrence/relapse of symptoms, number of days missed from school or work, duration of bad/intolerable symptoms, or antibiotic use remains uncertain. Regarding the safety of the short courses and low doses of corticosteroids, studies reported few adverse effects, with no apparent increase in events in patients treated with corticosteroid.

Strengths and limitations of study

Strengths of this review include explicit eligibility criteria; a comprehensive search developed with a research librarian; duplicate assessment of eligibility, risk of bias, and data abstraction; consideration of all outcomes important to patients; consideration of selective reporting bias; consideration of possible subgroup effects; and rigorous use of the GRADE approach to rate quality of evidence. The limitations of our review have to do with the underlying evidence. Only three trials explicitly reported adverse events, and they did so inconsistently. We observed substantial statistical heterogeneity in some of the outcomes. We explored the source(s) of heterogeneity by subgroup analysis and rated down for inconsistency in GRADE assessments for outcomes with unexplained heterogeneity.

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**Table:**

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No in group</td>
<td>Mean (SD) time</td>
</tr>
<tr>
<td>O'Brien 1994</td>
<td>26</td>
<td>15.0 (11.4)</td>
</tr>
<tr>
<td>Marvez-Valls 1998</td>
<td>46</td>
<td>42.0 (43.3)</td>
</tr>
<tr>
<td>Bulloch 2003</td>
<td>92</td>
<td>45.1 (36.9)</td>
</tr>
<tr>
<td>Olympia 2005</td>
<td>57</td>
<td>30.3 (27.8)</td>
</tr>
<tr>
<td>Tasar 2008</td>
<td>31</td>
<td>28.9 (12.0)</td>
</tr>
<tr>
<td>Hayward 2017</td>
<td>101</td>
<td>65.8 (48.1)</td>
</tr>
<tr>
<td>Overall (I²=85%, P=0.000)</td>
<td>353</td>
<td></td>
</tr>
</tbody>
</table>

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**Fig 4:** Weighted mean difference in mean time to onset of pain relief (hours) between corticosteroids and placebo groups in review of treatment of sore throat. Pooled mean difference was calculated by DerSimonian-Laird random effects model.

**Fig 5:** Weighted mean difference in mean time to complete resolution of pain (hours) between corticosteroids and placebo groups in review of treatment of sore throat. Pooled mean difference was calculated by DerSimonian-Laird random effects model.
In comparison with previous systematic reviews,\textsuperscript{11}\textsuperscript{12} we included two additional randomised controlled trials,\textsuperscript{16}\textsuperscript{26} which almost doubled the number of participants. Results from our meta-analysis are consistent with previous findings that corticosteroids reduce pain at 48 hours and probably reduce other pain outcomes. In addition to enhanced precision with the additional studies, our meta-analysis adds to the existing evidence that we considered absolute in addition to relative effect measures, providing a clear picture of the magnitude of effect.\textsuperscript{33} In part because of input from the guideline panel, we considered additional outcomes that participating patients considered important, including risk of recurrence of symptoms, duration of bad/non-tolerable symptoms, need for antibiotics, and days missed from school or work.
work. An important additional contribution of the new evidence is that it extends the applicability beyond patients with severe sore throat treated with antibiotics for group A β haemolytic streptococcus pharyngitis in the emergency department, to a broader range of patients not treated with antibiotics.

We explored and were able to dismiss subgroup effects, with one exception: the reduction in mean time to complete resolution of pain was greater with intramuscular than with oral corticosteroids. The subgroup effect and its direction was specified a priori, the difference between subgroups was relatively large (about 21 hours), and chance seems an unlikely explanation (P<0.001). Credibility of the effect, however, is undermined as the effect modification is suggested by comparison between rather than within studies, and we found no similar difference in any other outcome. In addition, the only randomised controlled trial that compared oral and intramuscular treatment with dexamethasone reported no significant difference in any outcome.15

The few serious adverse effects in the included trials occurred with similar frequency in the intervention and control groups, although some minor adverse effects reported by patients might not always have been noted. Potential adverse effects that appear later are more likely to occur after repeated use or are rare would not have been captured in the trials. Recent observational studies have raised the possibility of extremely rare but serious adverse effects after short courses of corticosteroids.15 The quality of this evidence is, for several reasons, low with respect to the current question. The studies used observational designs from large databases with suboptimal verification of diagnoses; serious confounding by indication raises the possibility that the association is a result of the underlying disease process (such as acute inflammation or exacerbation) rather than the corticosteroids themselves; and indirectness in that the doses used in the trials were lower and the duration of treatment was considerably shorter than the duration in the observational studies. Among children, a recent overview of reviews looked at evidence from 44 randomised controlled trials on conditions that appear to have influenced the submitted work. RACS, LL, DP, and RB-P acquired the data and judged risk of bias in the studies. BS performed the data analysis and is guarantor. All authors interpreted the data analysis and critically revised the manuscript.

Contributors: BS and RACS contributed equally to this work. TA, RACS, POV, and GHG conceived the study idea. BS, RACS, RB-P, TA coordinated the systematic review. BS, RACS, and TA wrote the first draft of the manuscript. BS and LL designed the search strategy. BS, RACS, LL, DP, and RB-P screened abstracts and full texts. BS, RACS, RB-P, and DP acquired the data and judged risk of bias in the studies. BS performed the data analysis and is guarantor. All authors interpreted the data analysis and critically revised the manuscript.

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Competing interests: All authors have completed the ICMJE uniform disclosure form and declare: no support from any organisation for any part of the submitted work. RACS, AM, and GHG are members of the GRADE working group. There are no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval: Not required.

Data sharing: All data are freely available within the appendices. No additional data available.

Transparency: The lead author affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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Corticosteroids for sore throat: a clinical practice guideline

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What is the role of a single dose of oral corticosteroids for those with acute sore throat? Using the GRADE framework according to the BMJ Rapid Recommendation process, an expert panel make a weak recommendation in favour of corticosteroid use. The panel produced these recommendations based on a linked systematic review triggered by a large randomised trial published in April 2017. This trial reported that corticosteroids increased the proportion of patients with complete resolution of pain at 48 hours. Box 1 shows all of the articles and evidence linked in this Rapid Recommendation package. The infographic provides the recommendation together with an overview of the absolute benefits and harms of corticosteroids in the standard GRADE format. Table 2 below shows any evidence that has emerged since the publication of this article. Clinicians and their patients can find consultation decision aids to facilitate shared decision making in MAGICapp, the online tool for local implementation of evidence based guidelines. The MAGICapp tool is available at www.magicapp.org. The full version including links to MAGICapp to link or extract its content or contact The BMJ for permission to reuse content in this publication Package is on the MAGICapp site, along with a summary here and a decision aid in MAGICapp.

Acute sore throat is defined as pain in the throat for less than 14 days. Acute sore throat could be caused by pharyngitis, nasopharyngitis, tonsillitis, peritonsillar abscess, or retropharyngeal abscess. Some patients with sore throat also experience headache, fever, muscle stiffness, cough, and general malaise.

Acute sore throat is common, but only a minority of patients will visit their general practitioner.1 A survey reported that the main reasons are to establish the cause of the symptoms, obtain pain relief, and to gain information on the course of the disease.2 Data from Dutch and Flemish primary care databases show that, for every 1000 consecutive patients consulting a general practitioner, 50 present with an acute sore throat.3 In the US, more than 92 million visits by adults to primary care practices and emergency departments between 1997 and 2010 were recorded.4 Sore throat presenting as acute tonsillitis is the commonest cause for emergency admission to otolaryngology services in the US.5

Acute sore throat is a self limiting disease and typically resolves after 7-10 days in adults and 2-7 days in children.6 Most infections are of viral origin; only a few are caused by a bacterial infection, of which group A β-haemolytic streptococcus, Haemophilus influenzae, and Moraxella catarrhalis are the most common pathogens. Evidence suggests that the time to resolution is not associated with the type of pathogen.7 About 2% of patients initially presenting with sore throat will have a mononucleosis infection caused by an Epstein-Barr virus, which could prolong the duration of symptoms.8

Some patients experience unacceptable morbidity and inconvenience, and miss school or work due to recurrent sore throat.9 Pain is a common reason for work or school absence. Complications of sore throat are rare: about 0.2% of patients with tonsillitis will develop a peritonsillar abscess.10

The diagnosis of an acute sore throat is based on signs and symptoms. The Center clinical prediction rules can be used to help predict whether the sore throat is caused by a bacterial pathogen, and thus guide the decision whether to prescribe an antibiotic.11 12
RAPID RECOMMENDATIONS

Population

This recommendation applies to almost all patients with sore throat:
- Children 5 years and older and all adults
- Severe and not severe sore throat
- Emergency and primary care settings
- Patients with a viral or bacterial sore throat
- Patients who receive immediate or deferred antibiotics

However the recommendation is not applicable to patients with:
- Infectious mononucleosis
- Immunocompromising conditions
- Sore throat following surgery or intubation
- Children under 5 years old

Comparison

People with sore throat

Short course of steroids
- 1–2 doses of oral Dexamethasone (or equivalent dose of alternative corticosteroid) + standard care

No steroids
- Standard clinical care, which typically includes analgesics, and may include antibiotics

Favours steroids
- Strong
- Weak

OR

Favours no steroids
- Strong
- Weak

We suggest short course of steroids. Discuss with patients in shared decision making.

Comparison of benefits and harms

<table>
<thead>
<tr>
<th></th>
<th>Events per 1000 people</th>
<th>Evidence quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete pain resolution (24 hrs)</td>
<td>224/124 more</td>
<td>Moderate</td>
</tr>
<tr>
<td>Complete pain resolution (48 hrs)</td>
<td>608/183 more</td>
<td>High</td>
</tr>
</tbody>
</table>

Mean time to resolution (hours)

<table>
<thead>
<tr>
<th></th>
<th>Events per 1000 people</th>
<th>Evidence quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete pain resolution</td>
<td>33.0/11.1 fewer</td>
<td>Low</td>
</tr>
</tbody>
</table>

Preferences and values

The panel believes that there is a great variability on how much reduction in pain severity or time to complete pain resolution each patient would consider important. Shared decision making may help establish what matters most to each patient.

Serious adverse events

One-dose administration of steroids is not likely to cause serious adverse events. Very low quality evidence exists for extremely rare but serious adverse effects following higher doses or longer courses of steroids (up to 30 days).

Multiple doses

Risks may outweigh benefits when cumulative doses of steroids are given for multiple episodes of sore throat. To mitigate this issue, clinicians could administer the medication in office if possible, or prescribe only one dose per visit.
**RAPID RECOMMENDATIONS**

**Box 1 | Linked articles in this BMJ Rapid Recommendations cluster**

  - Summary of the results from the Rapid Recommendation process
  - Review of all available randomised trials that assessed corticosteroids as adjunct treatment versus standard care for sore throat.
- MAGICapp (www.magicapp.org/goto/guideline/JjXYAL/section/j79pvn)
  - Expanded version of the results with multilayered recommendations, evidence summaries, and decision aids for use on all devices

Most guidelines recommend paracetamol or ibuprofen as the first choice treatment. The use of corticosteroids is mentioned in few, and is generally discouraged (table 1). Antibiotics are probably not helpful for pain relief in an episode of acute sore throat caused by viruses, but may help those with a bacterial infection. Recommended management of sore throat varies widely, and table 1 summarises current guidelines.

**The evidence**

The linked systematic review reports the effects of corticosteroids when added to standard care in patients with acute sore throat.

Figure 1 gives an overview of the number and types of patients included, the study funding, and patient involvement, as well as a summary of the benefits and harms of corticosteroids for treating acute sore throat.

The panel identified eight patient-important outcomes needed to inform the recommendation: complete resolution of pain, time to onset of pain relief, pain severity, need for antibiotics, days missed from school or work, recurrence of symptoms, duration of bad or non-tolerable symptoms, and adverse effects. The included studies reported on all patient-important outcomes, except for duration of bad or non-tolerable symptoms. Regarding pain, the panel appraised the likelihood of complete resolution of pain at 24 hours and 48 hours, as well as the mean time to complete resolution of pain and the mean time to onset of pain relief.

Although most of the studies (80%) were conducted in emergency departments, they accounted for 54% of all patients enrolled across studies. The remaining 46% were enrolled in the studies conducted in primary care settings, and the panel was therefore confident that the evidence was applicable to them as well. Most of the studies focused in adults only (60%). The studies that focused only on children (three studies, 2% of all the patients enrolled in the studies) did not include children younger than 5 years old, and thus the recommendation does not apply to younger ages.

Since the randomised controlled trials focused on patients who did not have recurrent episodes of sore throat, the panel was less confident of the applicability of the evidence to such patients, and the recommendation therefore does not apply to them. Similarly, the panel did not consider patients with sore throat after surgery or intubation, nor immunocompromised patients.

**HOW THE RECOMMENDATION WAS CREATED**

A large randomised controlled trial published in April 2017 found that corticosteroids increased the proportion of patients with complete resolution of symptoms at 48 hours. However, corticosteroids did not seem to decrease the duration of moderately bad symptoms, pain severity, healthcare attendance, days missed from school or work, or the consumption of delayed antibiotics. This study adds to the body of evidence that suggests that, although corticosteroids probably have benefits in patients with sore throat, these benefits may be modest.

Our international panel— including general practitioners, general internists, paediatricians, an otolaryngologist, epidemiologists, methodologists, statisticians, and people with lived experience of sore throat—decided what was the scope of the recommendation and the outcomes that are most important to patients. After a parallel team conducted a systematic review on the benefits and harms of corticosteroids, and a systematic search for evidence about patients’ values and preferences (appendix 1 on bmj.com), the panel met to discuss the evidence and formulate a recommendation. No person had financial conflicts of interest; intellectual and professional conflicts were minimised and managed (appendix 2 on bmj.com).

The panel followed the BMJ Rapid Recommendations procedures for creating a trustworthy recommendation, including using the GRADE approach to critically appraise the evidence and create recommendations (appendix 3 on bmj.com). The panel considered the balance of benefits, harms, and burdens of the drug, the quality of the evidence for each outcome, typical and expected variations in patient values and preferences, and acceptability. Recommendations can be strong or weak, for or against a course of action.

**Understanding the recommendation**

The recommendation for using corticosteroids made by the panel was weak because of the modest reduction of symptoms and the large variability in patient preferences.

The panel is confident that the recommendation applies to almost all patients with acute sore throat: children 5 years and older and adults, severe and not severe sore throat, patients who receive immediate antibiotics and those who receive deferred antibiotics, patients with a viral or bacterial sore throat, and patients who seek...
Rapid Recommendations

A single dose of corticosteroids is unlikely to cause serious adverse events
- The randomised trials did not report any major event attributable to single dose corticosteroids (GRADE moderate quality evidence)
- The panel also considered evidence from observational studies that used higher doses of steroids. A large retrospective US cohort study of private insurance claims assessed adverse events in 327,452 adults who received an outpatient prescription of corticosteroids. There was a small absolute increase in the rate of sepsis, venous thromboembolism, and fracture in the first 30 days (GRADE low quality evidence, due to suboptimal verification of diagnosis in large databases and confounding by indication). The panel agreed that such events seemed unlikely with single dose steroids
- Similarly, among paediatric populations, indirect evidence from a meta-analysis of 44 randomised trials did not report any major adverse events in patients with conditions requiring a short course of corticosteroids (such as asthma, bronchiolitis, croup, wheeze, and pharyngitis or tonsillitis).

There are no differences in the relative effects of corticosteroids (when compared with usual care) between primary care settings and emergency departments

It is unlikely that new information will change interpretation for outcomes that are high to moderate quality of evidence.

Data Sources

<table>
<thead>
<tr>
<th>Trial Characteristics</th>
<th>Patient Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of Trials</strong></td>
<td>10</td>
</tr>
<tr>
<td><strong>Number of Patients</strong></td>
<td>1,426</td>
</tr>
<tr>
<td><strong>Mean Number of Patients Enrolled</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Antibiotic Prescription</strong></td>
<td></td>
</tr>
</tbody>
</table>

Mean age at baseline:
- Male: 37
- Female: 34

Streptococcus positive:
- Male: 51
- Female: 57

Analgesic use:
- Male: 78
- Female: 83

The proportion of Streptococcus positive people across all trials was 37%.

Fig 1 | Characteristics of patients and trials included in systematic review of effects of corticosteroids on acute sore throat
**RAPID RECOMMENDATIONS**

**PRACTICAL ISSUES**

<table>
<thead>
<tr>
<th>Steroids</th>
<th>No steroids</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MEDICATION ROUTINE</strong></td>
<td></td>
</tr>
<tr>
<td>One (or two) doses of steroids, taken as pill(s) or intramuscular injection(s)</td>
<td>May require concomitant antibiotics, and/or over the counter pain relievers</td>
</tr>
<tr>
<td><strong>TESTS &amp; VISITS</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>May need additional visits if symptoms do not resolve or worsen</td>
</tr>
<tr>
<td><strong>ADVERSE EFFECTS</strong></td>
<td></td>
</tr>
<tr>
<td>Serious adverse events are unlikely with one-dose steroids. There may be risks with repeated doses across multiple episodes of sore throat, or through self-medication</td>
<td>May require concomitant antibiotics, and/or over the counter pain relievers</td>
</tr>
<tr>
<td><strong>EMOTIONAL WELL-BEING</strong></td>
<td></td>
</tr>
<tr>
<td>May cause transient sleep disturbance and excitability, although infrequently with one-dose steroids</td>
<td></td>
</tr>
<tr>
<td><strong>PREGNANCY &amp; NURSING</strong></td>
<td></td>
</tr>
<tr>
<td>Dexamethasone crosses the placenta, and is generally avoided during pregnancy. There is, however, probably no risk of malformation</td>
<td></td>
</tr>
<tr>
<td><strong>COSTS &amp; ACCESS</strong></td>
<td></td>
</tr>
<tr>
<td>Inexpensive, available by prescription</td>
<td></td>
</tr>
<tr>
<td><strong>FOOD &amp; DRINK</strong></td>
<td></td>
</tr>
<tr>
<td>May increase appetite, particularly in children</td>
<td></td>
</tr>
</tbody>
</table>

**EDUCATION IN PRACTICE**

- How do you currently approach giving advice for those with acute sore throat? Do you consider offering corticosteroids?
- The recommendation for corticosteroid use is weak, and patient’s preferences are likely to vary. What information could you share with your patient to help reach a decision together?
- Have you learnt one thing from this article that might alter how you consult with patients with sore throat? How might you share this information with colleagues to learn together?
- To what extent do you practice shared decision making for such preference-sensitive decisions?

**HOW PATIENTS WERE INVOLVED IN THE CREATION OF THIS ARTICLE**

Five people with lived experience of sore throat were full panel members. These panel members identified important outcomes, and led the discussion on values and preferences. These patient representatives agreed that while small reductions in pain severity and time to complete pain resolution (for example 12 compared to 24 hours) were important to them, these values may not be shared by all patients; they expected moderate to great variability in how much importance other patients would place in small reductions in pain. These panel members participated in the teleconferences and email discussions and met all authorship criteria.

The panel was less confident about whether:

- Corticosteroids reduced antibiotic use, due to a lack of improvement or worsening of symptoms in patients not prescribed antibiotics immediately when consulting the physician (GRADE low quality evidence)
- Corticosteroids reduced the average time to complete resolution of pain (GRADE low quality evidence).

**Values and preferences**

The weak recommendation for corticosteroids reflects a high value on a modest reduction of symptom severity and the time that it takes to achieve such improvement, and a substantial and important increase in the chance of complete resolution of pain at 48 hours.

The panel, including the patient representatives, felt that the values and preferences are likely to vary greatly across patients, which justifies a weak recommendation. For example, achieving complete pain resolution 12 hours earlier may be of little importance for patients who feel less busy in their daily life, have higher tolerance to pain, or whose symptoms are not so severe; whereas it may be very important to patients whose ability to go to school or to perform at work are compromised, caregivers wishing to reduce their children’s pain, or patients experiencing their pain as severe.

The panel believes that there is great variability in how much reduction in pain severity or time to complete pain resolution each patient would consider important. However, the greater the reduction in hours to achieve complete resolution of pain, the more likely it is that typical patients would place high value on those outcomes. Patients who place a high value in reducing the symptoms by any amount (such as patients with lower tolerance to pain or with severe symptoms) are more likely to accept receiving corticosteroids.

The weak recommendation for corticosteroids also reflects the concerns that the panel had with acceptability. Specifically, how acceptable is it to treat a condition that is usually not severe and is self-limiting with a drug that many patients, practitioners, and other stakeholders know is almost always used for more severe diseases.

The systematic search for empirical data on patients’ values and preferences related to sore throat identified 4149 references that were screened at the title and abstract level. From these, we screened 99 full text articles, from which only two provided relevant information on patients’ values and preferences (see appendix 1 on bmj.com). Neither of the studies provided additional data that had not been raised by the panel members: the panel had identified appropriate patient-important outcomes and considered the variability in patient values and preferences regarding sore throat management.
Table 2 | New evidence which has emerged after initial publication

<table>
<thead>
<tr>
<th>Date</th>
<th>New evidence</th>
<th>Citation</th>
<th>Findings</th>
<th>Implications for recommendation(s)</th>
</tr>
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</table>

Practical issues and other considerations

Figure 2 outlines the key practical issues for patients and clinicians discussing adjunct steroids for sore throat, which are also accessible along with the evidence as decision aids to support shared decision-making in MAGI-Capp. Steroids are typically given as 10 mg dexamethasone (or adapted to weight for children: 0.6 mg/kg, up to a maximum dose of 10 mg), typically taken as pill or intramuscular injection.

The risks may outweigh the benefits when larger cumulative doses of corticosteroids are given to patients who experience multiple episodes of sore throat, either through multiple visits or for patients who self-medicate if prescribed more than one pill for their previous episode. To mitigate this issue, clinicians should administer the medication in office if possible or prescribe only one dose per visit.

Costs and resources

The panel focused on the patient perspective rather than that of society when formulating the recommendation. Given the low cost of corticosteroids for treating sore throat, implementation of this recommendation is unlikely to have an important impact on the costs for health funders. The treatment is inexpensive and likely to be offered in the context of a consultation that would have taken place anyway. Nevertheless, it remains uncertain whether it may increase the proportion of patients visiting a doctor to get a prescription of corticosteroids.

Uncertainties for future research

Key research questions to inform decision makers and future guidelines include:

- Are there any severe adverse effects of using one-dose of steroids for treating sore throat?
- What are the effects of corticosteroids, in addition to standard care, in patients with recurrent episodes of acute sore throat?

Updates to this article

Table 2 shows evidence which has emerged since the publication of this article. As new evidence is published, a group will assess the new evidence and make a judgment on to what extent it is expected to alter the recommendation.

Competing interests: All authors have completed the BMJ Rapid Recommendations interests disclosure form and a detailed, contextualised description of all disclosures is reported in appendix 2 on bmj.com. As with all BMJ Rapid Recommendations, the executive team and The BMJ judged that no panel member had any financial conflict of interest. Professional and academic interests are minimised as much as possible, while maintaining necessary expertise on the panel to make fully informed decisions.

Funding: This guideline was not funded.

Transparency: Bargent affirms that the manuscript is an honest, accurate, and transparent account of the recommendation being reported; that no important aspects of the recommendation have been omitted; and that any discrepancies from the recommendation as planned (and, if relevant, registered) have been explained.

RAPID RECOMMENDATIONS


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Corticosteroids for sore throat: a clinical practice guideline

On publication of this Practice paper (BMJ 2017;358:j4090, doi:10.1136/bmj.j4090), the main graphical summary of the evidence for this recommendation contained an error. For the outcome “Complete pain resolution (48 hrs),” the value of 608 people per 1000 (183 more) was stated for those people taking steroids. The correct value should have been 629 per 1000 (204 more), as stated in the systematic review supporting the recommendation (www.bmj.com/content/358/bmj.j3887). This error has been corrected in the graphical summary.