

# A review of tonsillectomy for recurrent throat infection

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## SUMMARY

*Tonsillectomy is most frequently carried out for recurrent throat infection, but there is uncertainty about its effectiveness. This paper reviews the evidence of its effectiveness obtained from a search of the Cochrane database and MEDLINE for randomized controlled trials comparing tonsillectomy with non-surgical management of recurrent throat infection. The results show that the effectiveness of a procedure such as tonsillectomy, needs to be considered in the light of its adverse effects. Attempts should be made to inform patients about the uncertainty surrounding the procedure.*

**Keywords:** *tonsillectomy; tonsillitis; pharyngitis; randomized controlled trials.*

## Introduction

**T**ONSILLECTOMY is one of the UK's commonest surgical procedures — over 78 000 were carried out in England during 1994 and 1995.<sup>1</sup> The most frequent indication of tonsillectomy is recurrent throat infection: either tonsillitis or pharyngitis.<sup>2,3</sup> This paper reviews the evidence for tonsillectomy as an effective treatment for recurrent throat infection. This work was conducted as part of a larger review of tonsillectomy, and was constrained by time and the availability of a single researcher. Rather than being comprehensive, the search strategy was restricted, and conclusions should therefore be regarded as preliminary, pending the results of more comprehensive reviews.

## Method

The primary outcome of interest was the frequency and severity of throat symptoms. A secondary outcome was the change in the number of days of incapacity due to either throat infection or tonsillectomy.

## Inclusion criteria

Studies were included in the review if they met the following initial criteria: participants had suffered from recurrent throat infections (pharyngitis or tonsillitis); the experimental intervention was tonsillectomy or adeno-tonsillectomy; and study participants were assigned in a random or quasi-random way to intervention or control groups.

## Appraisal of trials

A number of issues were considered in assessing the validity of included trials. It had been observed that there was little consistency between clinicians in the use of the diagnoses of tonsillitis and pharyngitis. For example, in one two-doctor

practice, the tonsillitis-pharyngitis ratio was 51:0 for one partner, and 7:46 for the other.<sup>4</sup> Therefore, entry criteria should be defined in terms of repeatable observations rather than subjective assessments. Bias can also be introduced if patients are allocated non-randomly to tonsillectomy or control groups. Since patients and researchers cannot be blind as to whether subjects underwent tonsillectomy, there is a risk of bias in the assessment of outcomes. Follow-up should therefore be frequent (to minimize recall bias), outcome assessment should be based on defined criteria (to minimize observer bias), and observer reliability should be validated. Follow-up should also be reasonably complete and without systematic differences in losses to follow-up. Ideally, analysis should be on the basis of intention to treat. Patients allocated to the control group who subsequently underwent tonsillectomy should not be analyzed as cases.

## Identification of relevant trials

Issue 4, 1997, of the Cochrane Library was searched using the term 'tonsillectomy'. Citations were examined on screen to identify relevant studies, and the references of identified studies were examined to identify additional relevant studies. Trials from all the main databases are included in the Cochrane Controlled Trials Register. In addition, MEDLINE, 1966 to April 1997, was searched using the search strategy shown in Appendix 1. The search results were examined on screen to identify relevant randomized controlled trials (RCTs).

The principal author of the most recent RCT, Paradise,<sup>5</sup> and the Scottish Intercollegiate Guidelines Network Committee Register were contacted and asked to identify any further published or unpublished work. Other authors were not contacted. The remaining studies had been published between 1963 and 1970, and authors were unlikely to be contactable. Because of time constraints, no attempt was made to hand-search English language or non-English language journals.

## Results

A large number of RCTs were identified, however, the majority of these were investigations of analgesia or surgical techniques. A small number of trials investigated the effectiveness of tonsillectomy; of these, six included a control group. One was a non-randomized trial (conducted in parallel with one of the randomized trials) and was excluded.<sup>5</sup> Five trials met the initial inclusion criteria.<sup>5,6,7,8,9</sup> Four of these were published studies.<sup>5,6,8,9</sup> One was published only as an abstract but data was made available by the author.<sup>7</sup> The numbers of subjects, entry criteria, and criteria for outcome assessment for these trials are presented in Table 1. No trial included patients over the age of 15.

Two trials were carried out by the same researchers on subjects drawn from the same population of children.<sup>5,7</sup> Both were based on clearly defined entry criteria, which specified the number of episodes of prior throat infection, and clearly defined which episodes should be counted (Table 4 and Appendix 2). Follow-up was by bi-weekly interviews and six weekly examinations. Outcome data was collected using standardized methods, and inter-observer reliability was tested. Throat infection episodes were defined according to detailed criteria and rated as 'mild', 'moderate', or 'severe' according to a scoring system.

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**Table 1.** Numbers of subjects, entry criteria and outcome assessment in trials.

| Author                      | Numbers Intervention and control groups | Entry criteria Age and clinical entry criteria as stated by author(s).  | Frequency of follow-up                      | Outcome assessment   |
|-----------------------------|---|---|---|--|
| Paradise 1984 <sup>5</sup>  | 43                                      | Children aged 3 to 15 years. For clinical entry criteria see Table 4.   | Bi-weekly interviews and six weekly visits. | Standardized data collection. Detailed case definitions of mild, moderate and severe throat infections. Inter-observer reliability was tested. |
|                             | 48                                      |   |   |  |
| Paradise 1992 <sup>7</sup>  | 142                                     | Children aged 3 to 15 years. For clinical entry criteria see Table 4.   | Bi-weekly interviews and six weekly visits. | As for Paradise 1984.  |
| Mc Kee 1963 <sup>3</sup>    | 231                                     | Children aged 2 to 15 years. No clinical entry criteria are reported, it is simply stated that the study those with: 'a history of three or more isolated throat infections or acute respiratory infections with cervical adenitis within the past 12 months, in addition to a variety of other upsets.'* | Two-monthly visits for 2 years.             | No clinical criteria provided for case definition of outcome measures. Inter-observer reliability in assessing outcomes was not tested.        |
|                             | 182                                     |   |   |  |
| Roydhouse 1970 <sup>2</sup> | 251                                     | The author states that the age group and clinical entry criteria are the same as McKee 1963.  | Two-monthly visits for two years.           | Not decided. It is stated that the same outcomes were measured as in McKee 1963.   |
|                             | 175                                     |   |   |  |
| Mawson 1967 <sup>2</sup>    | 202                                     | Children ages 3 to 12 years. No clinical entry criteria are reported. It is stated that the study includes those in whom it was 'impossible to predict in any one case whether benefit would prove greater from operation or non-operation.'*   | Two-monthly visits for two years.           | No case definition of outcome measures was provided. Inter-observer reliability in assessing outcomes was not tested.                          |
|                             | 202                                     |   |   |  |

\* These are direct quotations from the original papers.

Data from three years of follow-up was presented in the Paradise 1984 paper.<sup>5</sup> However, by the end of the second year, 34% of the patients had been lost in follow-up, and by the end of the third year, 54%. Sixteen children, one-third of the control group, ultimately underwent surgery and were excluded from further analysis from the time of surgery. It was also noted that there was a significant tendency for children who underwent surgery and then experienced few throat infections to be lost to follow-up. Despite these limitations, this trial was judged likely to be free from serious bias. The Paradise 1992 trial followed the same methodology but reported data from two years of follow-up. Only 17% of children were lost in the follow-up by the end of the second year.<sup>7</sup> The risk of bias in this trial was also judged to be low.

The Mawson trial did not specify entry criteria: neither a case definition of a throat infection, nor a specified number of throat infections.<sup>6</sup> Follow-up was for two years by two monthly visits and, since patients and their parents were aware of the intervention they had received, there may have been some recall bias by patients or their parents. In addition, no attempt was made to provide case definitions of outcomes or to validate observers' assessments during follow-up. The risk of recall and observer bias was therefore judged to be high.

Entry criteria in the McKee trial were inadequately defined; a minimum number of throat infections was specified, but there was no case definition of a throat infection.<sup>8</sup> The intervention and control groups were of an unequal size, and it was indicated in the paper that some children allocated to the control group may have been selectively withdrawn. This potentially introduced bias into the process of allocation. Follow-up was for two

years with two monthly visits supplemented by parental records. This may have led to recall bias. Case definitions of outcomes were provided, but these were general and did not include clinical criteria. For example, sore throat was defined as: 'A respiratory illness with prominent sore throat, with or without associated fever, glandular enlargement or nasal catarrh.'<sup>8</sup> No attempt was made to validate observers' outcome assessments. Children in the control group who underwent tonsillectomy were excluded from further follow-up. In addition to allocation bias, the risk of observer and recall bias was high because of the lack of defined or validated outcome assessment in an unblinded study.

The Roydhouse trial provided few details of methodology and stated that it had been the same as the McKee trial.<sup>9</sup> The intervention and control groups were also of unequal size. It was judged to have the same potential for allocation, observer, and recall bias as the McKee trial.

#### *Reduction in episodes of throat infection*

In all the studies, the incidence of throat infection declined in both treatment and control groups over the period of follow-up (Table 2). In the first two years after surgery, and especially in the first year, children undergoing tonsillectomy experienced fewer throat infections than those in the control group (Table 3).

In the Paradise 1984 study, each child who had undergone tonsillectomy had suffered from 4.62 throat infections over the following three years, of which 0.51 were 'moderate or severe'. In the control group, children had suffered from 7.95 throat infections in the next three years, of which 2.65 were 'moderate or severe'. Most of this benefit was within the first two years

**Table 2.** Annual incidence of throat infection episodes during follow-up.

| Severity of throat infection |               | Year 1             |      | Year of follow-up<br>Year 2 |      | Year 3             |      |
|------------------------------|---------------|--------------------|------|-----------------------------|------|--------------------|------|
|                              |               | Moderate or severe | All  | Moderate or severe          | All  | Moderate or severe | All  |
| Paradise 1984 <sup>5</sup>   | Tonsillectomy | 0.08               | 1.24 | 0.16                        | 1.16 | 0.27               | 1.77 |
|                              | Control       | 1.17               | 3.09 | 1.03                        | 2.66 | 0.45               | 2.20 |
| Paradise 1992 <sup>7</sup>   | Tonsillectomy | 0.06               | 1.45 | 0.09                        | 1.67 | -                  | -    |
|                              | Control       | 0.26               | 3.01 | 0.34                        | 2.75 | -                  | -    |
| McKee 1963 <sup>8</sup>      | Tonsillectomy | -                  | 0.36 | -                           | 0.31 | -                  | -    |
|                              | Control       | -                  | 1.96 | -                           | 1.03 | -                  | -    |
| Roydhouse 1970 <sup>9</sup>  | Tonsillectomy | -                  | 0.56 | -                           | 0.25 | -                  | -    |
|                              | Control       | -                  | 2.25 | -                           | 1.86 | -                  | -    |
| Mawson* 1967 <sup>6</sup>    | Tonsillectomy | -                  | 0.64 | -                           | 0.64 | -                  | -    |
|                              | Control       | -                  | 2.15 | -                           | 1.40 | -                  | -    |

**Table 3.** The mean numbers of throat infections avoided as a result of tonsillectomy.

| Author of study             | Reduction in annual incidence of<br>'all throat infections' |        |        |               | Reduction in annual incidence of 'moderate' or<br>'severe' throat infection |        |        |               |
|-----------------------------|---|--------|--------|---------------|---|--------|--------|---------------|
|                             | Year 1  | Year 2 | Year 3 | Total avoided | Year 1  | Year 2 | Year 3 | Total avoided |
| Paradise 1984 <sup>5</sup>  | 1.9   | 1.1    | 0.7    | 3.6           | 1.1   | 0.9    | 0.18   | 2.1           |
| Paradise 1992 <sup>7</sup>  | 1.6   | 1.1    | -      | 2.6           | 0.2   | 0.3    | -      | 0.5           |
| McKee 1963 <sup>8</sup>     | 1.6   | 0.7    | -      | 2.3           | -   | -      | -      | -             |
| Roydhouse 1970 <sup>9</sup> | 1.7   | 1.6    | -      | 3.3           | -   | -      | -      | -             |
| Mawson 1967 <sup>6</sup>    | 1.5*  | 0.8*   | -      | 2.3*          | -   | -      | -      | -             |

\* The Mawson study did not record mean numbers of throat infections per year. These figures have been estimated, calculating the mean annual incidence from the numbers of children experiencing one episode, two to three episodes, four to six episodes, and seven or more episodes.

and, by the third year, the difference failed to reach statistical significance ( $P \leq 0.01$ ). No confidence interval was reported. By undergoing tonsillectomy, each child therefore avoided about three throat infections over the following two years. Two of these were 'moderate or severe' throat infections.

In the Paradise 1992 trial (where the entry criteria was slightly relaxed), each child who had undergone tonsillectomy had 3.12 throat infections over the next two years following surgery, of which 0.15 were 'moderate or severe'. Children who had not undergone tonsillectomy had 5.76 throat infections of which 0.60 were 'moderate or severe'. The results reached a statistical significance for each of the two years of follow-up ( $P \leq 0.01$ ). By undergoing tonsillectomy, each child had therefore avoided about two or three throat infections over the two years following surgery. However, only one in every two children avoided a 'moderate or severe' throat infection. Neither trial reported the confidence intervals for their results.

Results in the three other trials were similar in magnitude. Over the subsequent two years, children who underwent tonsillectomy had suffered 2.3 and 3.3 fewer throat infections than controls in the McKee and Roydhouse trials.<sup>8,9</sup> In the Mawson study, the average annual incidence of throat infections was not recorded.<sup>6</sup> For the purposes of comparison, an estimated effect size was calculated from the numbers of children experiencing one annual episode, two to three episodes, four to six episodes, or over seven episodes. By this calculation, in the two years of follow-up, children undergoing tonsillectomy avoided, on average, about 2.3 throat infections.

### Secondary outcome measures

The Paradise 1984 trial also reported on 'sore-throat days', 'sore-throat associated school absence', and the 'frequency with which

cervical lymphadenopathy was found at non-throat infection visits'.<sup>5</sup> Differences in these outcomes were small, and appeared to favour the intervention group, but none achieved statistical significance. Paradise 1984 reported five fewer days of 'sore-throat associated school absence'. Roydhouse and McKee reported six and four fewer days of school absence respectively. However, these excluded school absence resulting from surgery which, in the United Kingdom (the UK), is usually between one and two weeks.<sup>2</sup>

### Discussion

There was little evidence on the use of tonsillectomy for recurrent throat infection and conclusions were based on the findings of a single group of authors whose subjects were drawn from the same community-based population of children. Together, both studies included less than 350 patients. Both studies dealt with children seen as outpatients by a first-contact doctor, and may be broadly generalizable to children seen by GPs in the UK. There was no evidence to indicate whether tonsillectomy is either harmful or beneficial in adults.

Children under 15 years of age who meet the strict criteria listed in Table 4, have a reduced incidence of throat infection in the two years following tonsillectomy. Each child undergoing tonsillectomy, on average, avoids about two 'moderate' or 'severe' throat infections. However, this was a small study and one-third of the patients were lost to follow-up by the end of the second year. Conclusions must therefore be treated with a degree of caution. Parents should be informed of the limited nature and short-term duration of the procedure's effectiveness in order to weigh this against the morbidity of tonsillectomy itself.

There was no evidence that tonsillectomy reduced the number of lost schooldays. If we had included morbidity caused by the

**Table 4.** Entry criteria for tonsillectomy trial — Paradise 1984.

| Frequency of throat infections  | Defining features of a throat infection  |
|---|--|
| At least seven in the year prior to entry, or five in each of the two years prior to entry, or three in each of the three years prior to entry. | <ol style="list-style-type: none"> <li>1. Documentation of every episode.</li> <li>2. A painful throat with one of the following four features: oral temperature <math>\geq 38.3</math> °C tonsillar exudate tender anterior cervical lymph nodes or lymphadenopathy &gt; 2cm Streptococcus Group A on throat culture.</li> <li>3. Penicillin V prescribed if Streptococcus is isolated or suspected.</li> </ol> |

operation, the number of lost schooldays may have been increased.

Tonsillectomy is substantially less effective in children who meet the slightly less stringent entry criteria shown in Appendix 1. Only one in every two children undergoing tonsillectomy will avoid a 'moderate or severe' throat infection in the next two years after surgery. This suggests that tonsillectomy is not justified in children who do not meet strict clinical criteria. Because of their importance, the trial entry criteria listed in Table 1 need

to be examined in some detail. Patients should have experienced seven throat infections in the year prior to surgery, five in each of the two successive years, or three in each of three successive years. A key element is that all of these throat infections should be documented, as there is evidence that undocumented episodes do not predict future infection.<sup>1</sup>

Entry criteria for the Paradise 1992 trial was more complex. Broadly speaking, subjects failed to meet any one of the three criteria for throat infection episodes that were listed in the Paradise trial 1984. Throat infection episodes were either less frequent or less severe or less completely documented. The entry criteria are explained in detail in Appendix 2.

The effectiveness of a procedure needs to be considered in the light of its adverse effects. The principal side-effect of tonsillectomy is post-operative bleeding, but vomiting and fever are also recognized. The incidence of serious post-operative bleeding has been reported as less than 1% in the UK.<sup>11,12,13</sup> Bleeding can also occur a number of days after surgery.<sup>14</sup>

To improve the knowledge base for this common therapeutic procedure, a number of questions need to be addressed by future research. First, which outcomes are important to patients (and their parents). Clinical trials focus on the frequency of throat infection, but it may be that reductions in lost schooldays, the risks attached to surgery, or other outcomes are of more importance to patients. This might be investigated by qualitative research methods. Secondly, we need more evidence of the effects of tonsillectomy on these outcomes, on both adults and

#### Appendix 1. Medline search strategies for studies on tonsillectomy.

| Recurrent throat infection                     | Chronic tonsillitis                      |
|--|--|
| 001 exp tonsillectomy/all sub-headings         | 001 exp tonsillectomy/all sub-headings   |
| 002 tonsillectomy                              | 002 tonsillectomy                        |
| 003 adenotonsillectomy                         | 003 adenotonsillectomy                   |
| 004 exp clinical trials/all sub-headings       | 004 exp clinical trials/all sub-headings |
| 005 exp pharyngitis/all sub-headings           | 005 chronic tonsillitis                  |
| 006 pharyngitis                                | 006 (1 or 2 or 3) and 4 and 5            |
| 007 exp tonsillitis/all sub-headings           | No results                               |
| 008 tonsillitis                                | 007 (1 or 2 or 3) and 5                  |
| 009 (1 or 2 or 3) and 4 and (5 or 6 or 7 or 8) | 008 PT = review                          |

#### Appendix 2. Entry criteria for Paradise 1992 trial.

| Age           | Frequency   | Defining features   |
|---------------|---|---|
| 3 to 6 years  | More than 5 QEs of sore throat in one year.   | At least 2 but less than 7 episodes with the features in Table 1.   |
|               | More than 4 QEs of sore throat in each of two years.  | At least 2 but less than 5 episodes with the features in Table 1.<br>Documentation of at least 2 QEs.     |
| 7 to 15 years | More than 4 QEs of sore throat in one year.   | At least 1 but less than 7 episodes with the features in Table 1.   |
|               | More than 3 QEs of sore throat in each of two years.  | At least 1 but less than 5 episodes with the features in Table 1.<br>Documentation of at least 2 QEs.     |
| Or<br>3 to 15 | At least seven in the year prior to entry or; five in each of the two years prior to entry or; three in each of the three years prior to entry. | With all the features in Table 1, except complete documentation.<br>With at least one documented episode. |

Episodes of throat infection are grouped into three categories: type A episodes are those which meet the criteria in Table 4; type B episodes are those where there is a complaint of sore throat and a fever, with oral temperature of less than 38.3°C; type C episodes are those where there is a complaint of sore throat but no noticeable fever or other any of the other four features. A qualifying episode (QE) is defined as three type C episodes, two type B episodes, or one type A episode.

children. There is evidence that, in the elective management of non-life-threatening conditions, patients are positive about shared decision-making, and that their decisions are significantly influenced by education.<sup>15</sup> Attempts should be made to inform patients about the uncertainty surrounding the procedure.

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