

Tonsillectomy versus watchful waiting in recurrent streptococcal pharyngitis in adults: randomised controlled trial

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ABSTRACT

Objective To determine the short term efficacy and safety of tonsillectomy for recurrent streptococcal pharyngitis in adults.

Design Randomised controlled trial.

Setting Academic referral centre in Finland.

Participants 70 adults with documented recurrent episodes of streptococcal group A pharyngitis.

Intervention Instant tonsillectomy (n=36) or remaining on waiting list as control (n=34).

Main outcome measures Percentage change in the risk of an episode of streptococcal pharyngitis at 90 days. Rates of all episodes of pharyngitis and days with symptoms and adverse effects.

Results The mean (SD) follow-up was 164 (63) days in the control group and 170 (12) days in the tonsillectomy group. At 90 days, streptococcal pharyngitis had recurred in 24% (8/34) in the control group and 3% (1/36) in the tonsillectomy group (difference 21%; 95% confidence interval 6% to 36%). The number needed to undergo tonsillectomy to prevent one recurrence was 5 (3 to 16). During the whole follow-up, the rates of other episodes of pharyngitis and days with throat pain and fever were significantly lower in the tonsillectomy group than in the control group. The most common morbidity related to tonsillectomy was postoperative throat pain (mean length 13 days, SD 4).

Conclusions Adults with a history of documented recurrent episodes of streptococcal pharyngitis were less likely to have further streptococcal or other throat infections or days with throat pain if they had their tonsils removed.

Trial registration Clinical Trials NCT00136877.

INTRODUCTION

Group A streptococcal pharyngitis is an acute infection, mainly of the oropharynx, caused by *Streptococcus pyogenes*.^{1,2} Recommended treatment is antibiotics to prevent rheumatic fever and suppurative complications and to ameliorate symptoms and decrease contagion.¹⁻³ Some patients experience multiple episodes of acute pharyngitis with results of culture positive for group A streptococci. Traditionally, tonsillectomy has been used to prevent recurrent streptococcal throat infections. Yet according to a recent Cochrane review, there is no empirical evidence to show that it is effective in adults.⁴

We conducted a randomised controlled trial on adults with documented recurrent episodes of streptococcal pharyngitis to determine the effects of tonsillectomy.

METHODS

Participants—From October 2001 to May 2005, consecutive patients referred for tonsillectomy because of recurrent episodes of streptococcal pharyngitis were screened for enrolment at an ear, nose, and throat department of a university hospital. All patients provided written informed consent. The clinical criterion for study entry was three or more episodes of pharyngitis in six months or four episodes in 12 months. The symptoms and signs during the episodes had to be typical of streptococcal pharyngitis.¹ In addition, these episodes had to be severe enough for the patient to seek medical attention and at least one episode had to be group A streptococcal infection proved by culture or rapid antigen test.

Study design—We allocated patients to tonsillectomy or the waiting list (control). To avoid disparity between group sizes, we used replacement randomisation.

Outcomes—The primary end point was the proportion of patients with an acute episode of group A streptococcal pharyngitis during the 90 days' follow-up, as determined by signs and symptoms of acute pharyngitis with a positive result of throat culture. The secondary end points were the percentage change in the proportions of patients with all episodes of pharyngitis at 90 days, the times to episodes, and the difference in the mean rates of episodes and days with symptoms during the whole follow-up. Patients recorded episodes and days with symptoms in diaries. We considered an episode to be at least two consecutive days with a sore throat. We recorded data on adverse effects related to tonsillectomy from the diaries and the patients' charts.

Intervention—After baseline data collection and randomisation, the participants were operated on as soon as possible (tonsillectomy group) or placed on the waiting list for tonsillectomy (control group). In the tonsillectomy group, the median time between the randomisation and the tonsillectomy was 13 days (interquartile range 8-21) for practical reasons. The operation was performed under general anaesthesia

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Table 1 Primary outcomes at three months in adults with recurrent streptococcal A pharyngitis randomised to waiting list (control) or immediate tonsillectomy. Figures are numbers (percentages) of patients

Outcome	Control (n=34)	Tonsillectomy (n=36)	% difference (95% CI)
Experienced episode of group A streptococcal pharyngitis*	8 (24)	1 (3)	21 (6 to 36)
Experienced episode of pharyngitis with medical consultation	14 (41)	4 (11)	30 (11 to 49)
Experienced acute episode of pharyngitis of any kind	19 (56)	11 (31)	25 (3 to 48)

*Determined by signs and symptoms of acute pharyngitis with positive result of throat culture.

as day surgery. Four experienced ear, nose, and throat surgeons performed total extracapsular tonsillectomy using blunt or diathermy dissection. In the control group, the waiting times ranged from three to six months, during which time the patients did not receive any prophylactic treatment for their tonsillitis.

Protocol and analysis—Details of the surveillance protocol and statistical analysis are on bmj.com.

RESULTS

Patients—We screened 298 candidates, 226 of whom were excluded, and two declined to participate. Of the 70 remaining patients who we enrolled, 34 were randomly assigned to the control group and 36 to the tonsillectomy group. All patients were seen at follow-up visits and were followed up for at least the scheduled 90 days, the mean lengths of follow-up being 164 days (SD 63) in the control group and 170 days (SD 12) in the tonsillectomy group (see bmj.com). There were no clinically important differences between groups in the baseline characteristics (see bmj.com).

Primary outcome—At 90 days, according to the intention to treat in all randomised patients, eight patients (from 20 samples taken) in the control group and one (from five samples taken) in the tonsillectomy group had had an episode of group A streptococcal sore throat (difference 21%, 95% confidence interval 6% to 36%; number needed to treat 5, 3 to 16) (table 1). None of these patients were streptococcal carriers. This difference between the two groups was also evident in the time to the first episode (figure).

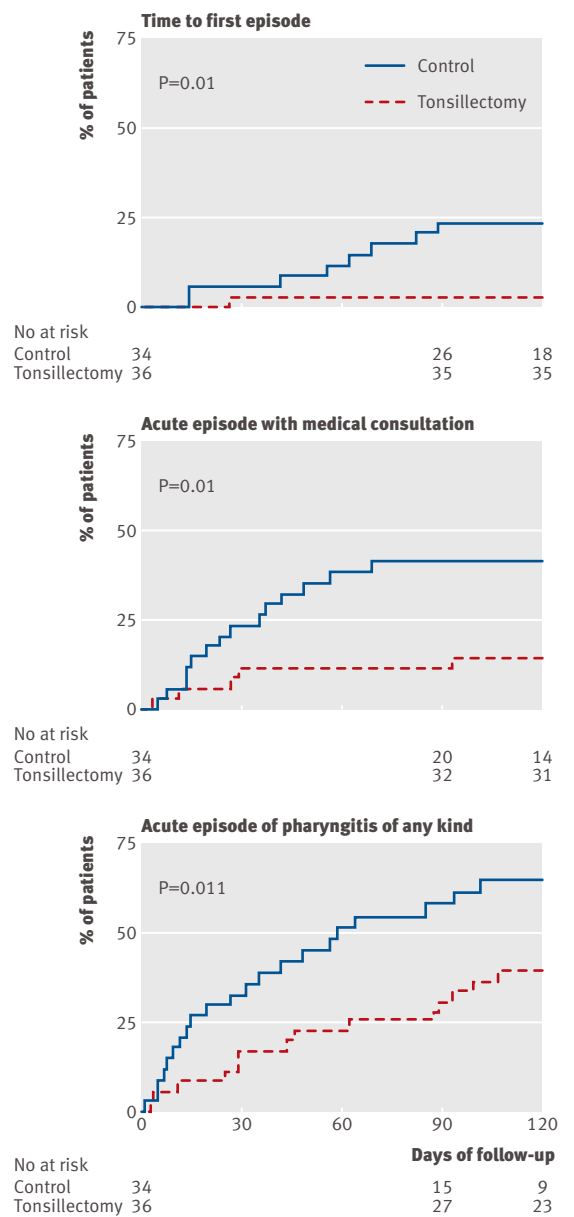
Secondary outcomes—At 90 days, compared with the tonsillectomy group, a significantly larger proportion of the control group had had acute episodes of pharyngitis, both with and without need for medical assessment (table 1). The times to these first episodes were significantly shorter in the control group than in the tonsillectomy group (figure). Similarly, the mean numbers of days with fever or throat pain, but not rhinitis or cough, during follow-up were significantly higher in the control group than in the tonsillectomy group (table 2).

Adverse effects of tonsillectomy—On average, the tonsillectomy operation required a one hour stay in the operating room, a one day stay in hospital, and a 13 days recovery period with postoperative throat pain (see bmj.com). There were no serious adverse effects related to tonsillectomy. Two patients (6%) had mild secondary bleeding 9 and 11 days after the operation.

DISCUSSION

Principal findings

Our trial supports the surgical removal of palatine tonsils to prevent immediate further episodes of group A streptococcal pharyngitis in adults with a documented history of recurrent episodes. We estimate that performing tonsillectomy on such adults would lead to one extra patient avoiding streptococcal infection during the following months for every five patients treated. Tonsillectomy also significantly reduced the short term risk of other episodes of pharyngitis with or without need for medical intervention and the mean number of days with fever or throat pain, but not with rhinitis or cough. The most important morbidity related to the operation was



Times to first episode of group A streptococcal pharyngitis proved by culture, acute pharyngitis episode with medical consultation, and acute pharyngitis episode of any kind (differences between groups tested with log rank test)

Table 2 | Secondary outcomes at end of whole follow-up* in adults with recurrent streptococcal A pharyngitis randomised to waiting list (control) or immediate tonsillectomy. Figures are means (SDs)

Outcome	Control (n=34)	Tonsillectomy (n=36)	P value†
Medical consultations for episodes of pharyngitis	0.9 (1.1)	0.1 (0.3)	0.002
All episodes of pharyngitis	2.1 (2.3)	0.6 (0.9)	0.001
Days with sore throat‡	12.1 (14.1)	3.2 (5.3)	0.002
Days with fever	2.8 (3.9)	0.6 (1.5)	0.01
Days with rhinitis	7.6 (11.9)	6.3 (7.1)	0.55
Days with cough	2.6 (5.5)	2.6 (3.3)	0.17

*Mean length of follow-up 164 days (SD 63) in control group and 170 days (SD 12) in tonsillectomy group.

†Mann-Whitney U test.

‡Not including postoperative throat pain in tonsillectomy group.

postoperative throat pain and a small risk of bleeding after the operation.

Comparison with other studies

A recent systematic review of randomised trials in children estimated that (adeno)tonsillectomy reduced the incidence of episodes of sore throat by 1.2 episodes a year and reduced school absence associated with sore throat by 2.8 days a year, differences regarded by the authors as clinically insignificant.⁵ The respective decreases we found after tonsillectomy in adults were significantly higher at 3.3 episodes and 20 days with sore throat. The reduction in days with sore throat would have been smaller if we had included the days with postoperative throat pain. The reasons for the smaller effect size found in children may be that parents of the most severely affected children refused to participate in the trial, a high number of children switched from the control group to the surgery group, and a large proportion were lost to follow-up, which may have resulted in an underestimation of the treatment effect.⁵ A recent Cochrane review found no similar trials in adults.⁴

Strengths and weaknesses

As we had waiting list controls we could not exceed our normal waiting time for tonsillectomy, which resulted in a relatively short follow-up period. However, we think that the immediate effect of tonsillectomy reflects its overall usefulness. Moreover, when we consider the objective outcomes in earlier trials, the effect of tonsillectomy has not depended markedly on the follow-up time.⁵ A substantial improvement over time in the rate of episodes of pharyngitis occurred in the control group during the follow-up, probably because of the natural course of the disease. This improvement, however,

makes it unlikely that the patients in the control group would have reported negatively biased data in their diaries, indicating that the difference between the groups was because tonsillectomy was beneficial rather than any detrimental effect of remaining on the waiting list. The use of waiting list controls had advantages as well. We wanted to enrol severely affected patients, to keep them in their assigned groups, and to follow them up. With this method, the patients in the control group knew they were going to be operated on, and 97% (70/72) agreed to participate, only 6% (2/34) switched from the control group, and none were lost to follow-up.

We chose the objective outcome of prevention of group A streptococcal throat infection as our main end point to minimise information bias. In view of the baseline characteristics and the fact that most eligible patients entered the trial, we consider that our results are generalisable to the population seen in otolaryngological outpatient clinics in Finland.⁶ Extracapsular complete tonsillectomy is a clear cut procedure, and the use of several surgeons and surgical techniques further increase the generalisability of our results.

Implications

According to our results, tonsillectomy is an effective alternative for adults with a documented history of recurrent episodes of pharyngitis. Naturally, the morbidity and complications related to the operation must be considered. The most common postoperative complications were sore throat and mild bleeding. Several other factors, such as risks of anaesthesia, otalgia, fever, dehydration, dental injuries, burns, and soft tissue injuries, have been described.⁷ These complaints are usually mild, but a small risk of even life threatening complications exists (recent reported mortality ranging from 1 in 16 000 to 1 in 35 000).⁷ Physicians and patients must decide whether these clinical benefits outweigh the risk of further morbidity and the risks involved in the operation.

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WHAT IS ALREADY KNOWN ON THIS TOPIC

Observational studies have suggested that tonsillectomy may be effective in preventing recurrent streptococcal throat infections in adults

Evidence from randomised controlled trials has been lacking

WHAT THIS STUDY ADDS

Adults who have documented recurrent episodes of streptococcal pharyngitis are less likely to have further streptococcal or other throat infections or days with throat pain during the months after tonsillectomy

The most important morbidity related to tonsillectomy was postoperative throat pain and a small risk of bleeding after the operation