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Papers

Effectiveness of adenotonsillectomy in children with mild symptoms of throat infections or adenotonsillar hypertrophy: open, randomised controlled trial

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Abstract

Objective To assess the effectiveness of adenotonsillectomy in children with mild symptoms of throat infections or adenotonsillar hypertrophy.
Design Open, randomised controlled trial.
Setting 21 general hospitals and three academic centres in the Netherlands.
Participants 300 children aged 2-8 years requiring adenotonsillectomy.
Intervention Adenotonsillectomy compared with watchful waiting.
Main outcome measures Episodes of fever, throat infections, upper respiratory tract infections, and health related quality of life.
Results During the median follow up period of 22 months, children in the adenotonsillectomy group had 2.97 episodes of fever per person year compared with 3.18 in the watchful waiting group (difference −0.21, 95% confidence interval −0.54 to 0.12), 0.56 throat infections per person year compared with 0.77 (−0.21, −0.36 to −0.06), and 5.47 upper respiratory tract infections per person year compared with 6.00 (−0.53, −0.97 to −0.08). No clinically relevant differences were found for health related quality of life. Adenotonsillectomy was more effective in children with a history of three to six throat infections than in those with none to two. 12 children had complications related to surgery.
Conclusion Adenotonsillectomy has no major clinical benefits over watchful waiting in children with mild symptoms of throat infections or adenotonsillar hypertrophy.

Introduction

Tonsillectomy, with or without adenoidectomy, is a common procedure in children in western countries, yet the indications for surgery remain uncertain, as reflected by the large variation in surgical rates across countries. In 1998, for example, 115 per 10 000 children underwent adenotonsillectomy in the Netherlands, 65 per 10 000 in England, and 50 per 10 000 in the United States.[1]

We previously reported that in the Netherlands 35% of children underwent adenotonsillectomy for frequent throat infections (seven or more a year) or obstructive sleep apnoea, and the remainder for less frequent throat infections, mild adenotonsillar hypertrophy, or indications such as upper respiratory tract infections.[2] Although frequent throat infections and obstructive sleep apnoea are considered adequate indications for adenotonsillectomy in children,[3–8] evidence for the benefits of surgery in children with milder symptoms is lacking.[2 9–12] We carried out a randomised controlled trial to assess the effectiveness of adenotonsillectomy in children with mild symptoms of throat infections or adenotonsillar hypertrophy.

Participants and methods

We carried out an open, multicentre, randomised controlled trial between March 2000 and February 2003. Otorhinolaryngologists from 21 general hospitals and three academic centres in the Netherlands were asked to complete a questionnaire on all their patients aged 2 to 8 years with indications for adenotonsillectomy according to current medical practice. They were asked to give the indication they considered most important for surgery: recurrent throat infections (three or more a year) or other indications such as obstructive problems or recurrent upper respiratory tract infections.

We excluded children with a history of seven or more throat infections in the preceding year, with five or more in each of the previous two years, or with three or more in each of the previous three years (Paradise criteria),[3] and children with suspected obstructive sleep apnoea—that is, Brouillette's obstructive sleep apnoea score of more than 3.5.[13] Other exclusion criteria were Down's syndrome, craniofacial malformations such as cleft palate, and immunodeficiency, other than deficiencies of IgA or IgG_2.

Randomisation

Children whose parents gave informed consent were randomly assigned to either adenotonsillectomy within six weeks or watchful waiting. Randomisation was by a computer generated list of four numbers in each block and fixed blocks within each hospital.

When children were entered in the study, the study doctors completed a disease specific questionnaire on the basis of information provided by the parents. This elicited information on the number of throat infections and upper respiratory tract infections experienced by the children in the previous year; obstructive symptoms during sleep[13]; eating patterns; previous ear, nose, and throat operations; and risk factors for upper respiratory tract infections.

The participating hospitals and members of the executive steering committee are on bmj.com

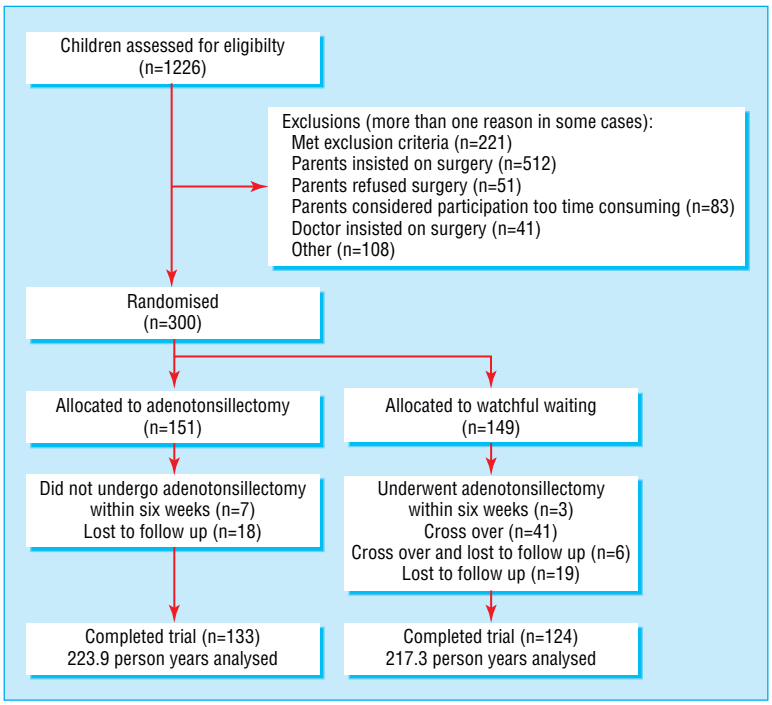

Fig 1 Flow of participants through trial

The parents completed two generic health related quality of life instruments: the TNO-AZL preschool children quality of life questionnaire (TAPQoL for children aged 2 to 5 years and TACQoL for children aged 5 years or older) and the child health questionnaire parental form (CHQpf50).[14 15] The children underwent an ear, nose, and throat examination and had their height and weight measured.

Follow up

The parents kept a diary of upper respiratory tract infections in their child, which included sore throat, pain or difficulty in swallowing, cough, rhinorrhoea, earache, and otorrhoea. They also noted absences from day care or school due to upper respiratory tract infections, and they measured the child's temperature daily with a validated tympanic membrane thermometer.[16] To avoid information bias, we had an electronic device built into the thermometer, which stored the date and first measurement of each day. The study doctors collected the diary and thermometer data during follow up visits at 3, 6, 12, 18, and 24 months. At these visits, the disease specific and health related quality of life questionnaires were again completed. An ear, nose, and throat examination was carried out, and the child's height and weight were measured. The parents, general practitioners, and otorhinolaryngologists were encouraged to manage sore throats and upper respiratory tract infections during follow up according to regular practice.

Primary and secondary outcomes

Our primary outcome was the incidence of fever (a temperature of 38.0°C or higher) for at least one day, measured in number of episodes and days. An episode was considered finished when at least one day was without fever. New episodes were those occurring after a fever-free interval of at least seven days.

Secondary outcomes were throat infections, sore throat, upper respiratory tract infections, absence from day care or school due to upper respiratory tract infections, health related quality of life, patterns of sleep and eating, height, and weight. A throat infection was defined as sore throat or pain or difficulty in swallowing combined with fever. A sore throat was defined as sore throat or pain or difficulty in swallowing with or without fever. Upper respiratory tract infections were defined as one or more symptoms of sore throat, pain or difficulty in swallowing, cough, rhinorrhoea, earache, and otorrhoea with or without fever. Throat infections, sore throats, and upper respiratory tract infections were measured in episodes and days. We also included sore throats and upper respiratory tract infections immediately after adenotonsillectomy.

We calculated absence from day care or school due to upper respiratory tract infections on the basis of data from the diaries. We used the generic questionnaires to assess health related quality of life.[14 15] Sleeping patterns were evaluated by Brouillette's obstructive sleep apnoea score and by the percentage of children experiencing snoring, difficulties breathing at night, or apnoea.[13] Eating patterns were assessed by difficulties in eating solids.

Statistical analysis

Our sample size calculation was based on a clinically relevant reduction of fever episodes and throat infections after adenotonsillectomy of 25%. Assuming a mean baseline (standard deviation) incidence of 4 (2) fever episodes and throat infections each year, and taking $\alpha = 0.05$ and a power of 0.80, we determined that we would need 104 children in each group. To allow for subgroup analyses, we aimed at including 300 children.

We calculated the effects of adenotonsillectomy on fever, sore throat, and upper respiratory tract infections as differences in incidence and incidence rate ratios per person year, with 95% confidence intervals. Scores on health related quality of life instruments were linearly transformed into scales of 0-100. For the mean number of fever episodes we calculated a short term (0-6 months) and long term (6-24 months) effect. We also evaluated health related quality of life, sleep and eating patterns, height, weight, and short and long term effects at six and 24 months. We used χ^2 tests and Student's t tests to evaluate differences in percentages and mean values between the groups. We used the Bonferroni correction to adjust for multiple testing and the Mantel-Haenzel test to adjust for potential confounders.

Table 1 Personal and clinical characteristics of 300 participants at baseline according to treatment allocation. Values are numbers (percentages) unless stated otherwise

Characteristics	Adenotonsillectomy group (n=151)	Watchful waiting group (n=149)
Boys	81 (54)	66 (44)
Mean (SD) age (months)	54 (17.0)	54 (16.2)
Indication for surgery:		
Recurrent throat infections	76 (50.3)	67 (45.0)
Other	73 (48.3)	82 (55.0)
Median No (range) of throat infections in previous year*	3 (0 to 6)	3 (0 to 6)
Median duration (months) of throat infections (range)*	13 (0 to 50)	12 (0 to 60)
Median No (range) of episodes with rhinorrhoea or cough in previous year	12 (0 to 24)	10 (0 to 24)
Median No (range) of episodes of otitis media in previous year	0 (0 to 12)	0 (1to 6)
Median obstructive sleep apnoea score (range)†	−1.7 (−3.83 to 2.55)	−1.7 (−3.83 to 2.56)
Previous ear, nose, and throat surgery:		
Adenoidectomy	35 (23.2)	33 (22.1)
Tympanostomy tubes	19 (12.7)	17 (11.4)
Enlarged tonsils‡:		
Yes	114 (78.1)	114 (77.6)
No	32 (21.9)	33 (22.4)
Mean (SD) weight (kg)	18.6 (4.0)	19.0 (4.4)
Mean (SD) height (cm)	108 (10.8)	109 (9.9)
Atopy§	78 (51.7)	70 (47.0)
Breastfed for >1 month	85 (57.4)	92 (61.7)
Exposure to tobacco smoke at home	48 (32.0)	52 (35.1)
Day care attendance¶:	49 (89.1)	49 (89.1)
No of siblings:		
0	32 (21.2)	27 (18.1)
1	71 (47.0)	77 (51.7)
≥2	48 (31.8)	45 (30.2)
Father's level of education:		
Low	34 (22.5)	32 (22.5)
Average	73 (48.3)	71 (50.0)
High	44 (29.1)	39 (27.5)
Mother's level of education:		
Low	22 (14.8)	27 (18.6)
Average	95 (63.8)	81 (55.9)
High	32 (21.5)	37 (25.5)

*Children with recurrent throat infections (n=143).
†Brouilette's obstructive sleep apnoea score: ≤1 (none), −1.0 to 3.5 (possible), >3.5 (highly predictive).
‡Protruding beyond pillars but not meeting uvula, or meeting uvula.
§History of eczema, hay fever, recurrent wheeze, or asthma.
¶Aged <4 years (n=110).

As the estimates of effect were not influenced by these adjustments, we present the estimates of crude effect.

To detect possible modification from effects, we carried out subgroup analyses according to the burden of upper respiratory tract symptoms in the year before entry to the trial and age. We analysed interactions with Poisson regression. All analyses were performed on an intention to treat basis.

Results

Between March 2000 and August 2002 we enrolled 300 children in our study; 151 were allocated to adenotonsillectomy and 149 to watchful waiting (fig 1). Characteristics at baseline were similar between the two groups (table 1). Overall, 43 children (18 from the adenotonsillectomy group) were lost to follow up. Reasons were non-medical (n=36), serious comorbidity (n=1), or unknown (n=6). Fifty children allocated to watchful waiting underwent adenotonsillectomy and seven allocated to adenotonsillectomy did not undergo surgery. Median follow up was 22.0 months in the adenotonsillectomy group and 22.4 months in the watchful waiting group.

Table 2 Incidence of fever, throat infections, sore throats, and upper respiratory tract infections per person year for children with mild symptoms of throat infections or adenotonsillar hypertrophy after adenotonsillectomy or watchful waiting

Variable	Adenotonsillectomy group	Watchful waiting group	Incidence rate ratio (95% CI)	Difference (95% CI)
Fever:				
No of episodes	2.97	3.18	0.94 (0.84 to 1.04)	−0.21 (−0.54 to 0.12)
No of days	5.31	5.93	0.90 (0.83 to 0.97)	−0.62 (−1.06 to −0.18)
Throat infections:				
No of episodes	0.56	0.77	0.73 (0.58 to 0.92)	−0.21 (−0.36 to −0.06)
No of days	0.83	1.36	0.61 (0.51 to 0.73)	−0.53 (−0.73 to −0.34)
Sore throat:				
No of episodes	2.25	2.85	0.79 (0.70 to 0.89)	−0.60 (−0.90 to −0.30)
No of days	9.81	15.71	0.62 (0.59 to 0.66)	−5.91 (−6.57 to −5.24)
Upper respiratory tract infections and fever:				
No of episodes	1.59	1.88	0.85 (0.73 to 0.98)	−0.29 (−0.53 to −0.04)
No of days	2.81	3.63	0.77 (0.70 to 0.86)	−0.82 (−1.16 to −0.49)
Upper respiratory tract infections:				
No of episodes	5.47	6.00	0.91 (0.84 to 0.99)	−0.53 (−0.97 to −0.08)
No of days	78.16	89.92	0.87 (0.85 to 0.89)	−11.76 (−13.47 to −10.05)

Outcomes

Children in the adenotonsillectomy group had 0.21 fewer episodes of fever (95% confidence interval −0.12 to 0.54) per person year (table 2). During the first six months of follow up, the number of episodes was lower in children in the adenotonsillectomy group. From six to 24 months there was no difference between the groups.

Compared with the watchful waiting group, children in the adenotonsillectomy group had, per person year, fewer throat infections (0.21, 95% confidence interval 0.06 to 0.36), fewer sore throats (0.60, 0.30 to 0.90), fewer days with sore throat (5.91, 5.24 to 6.57), and fewer upper respiratory tract infections (0.53, 0.08 to 0.97; see table 2).

Absence from day care or school due to upper tract respiratory infections was comparable between the groups (difference 0.09, −0.27 to 0.44).

At six months, small significant differences were found for some domains of the health related quality of life questionnaires, but these were not clinically relevant. We found no differences in other domains and at 24 months (figs 2 and 3).

At six months, Brouillette's scores were lower for children in the adenotonsillectomy group (fig 4). At 24 months there was no

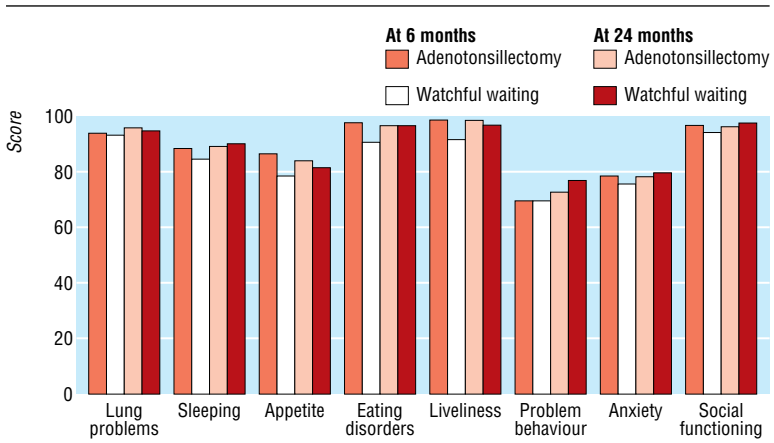

Fig 2 Health related quality of life (preschool children quality of life questionnaire; TAPQoL) six and 24 months after adenotonsillectomy or watchful waiting for children aged 2-5 years

difference between the groups. Fewer children in the adenotonsillectomy group experienced snoring and difficulties in eating at six months, whereas there were no differences at 24 months (data not shown). Height and weight of children in both groups remained similar during follow up (data not shown).

Subgroup analysis

The effects of adenotonsillectomy were more pronounced in children who had had three to six throat infections in the year before entry to the trial than in those with none to two throat infections: fever episodes (difference −1.07 (95% confidence interval −1.59 to −0.56) *v* 0.34 (−0.08 to 0.77), P=0.01; table 3) and days with sore throat per person year (difference −11.33 (−12.48 to −10.17) *v* −2.38 (−3.19 to −1.60), P=0.01). Age did not influence the effectiveness of adenotonsillectomy.

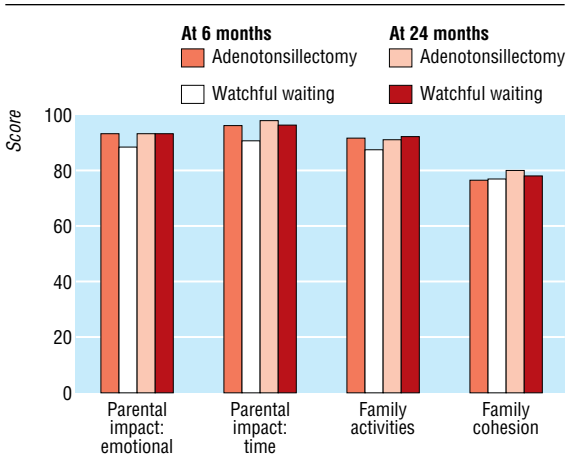

Fig 3 Health related quality of life (child health questionnaire parental form) six and 24 months after adenotonsillectomy or watchful waiting

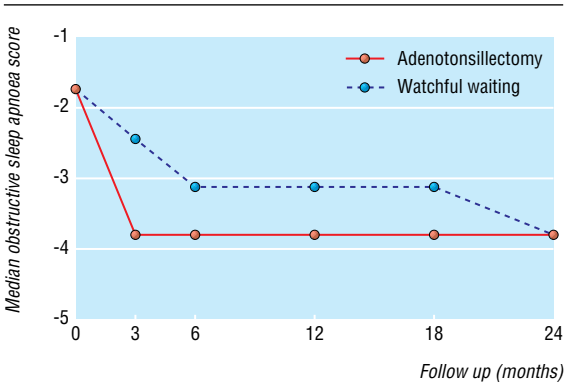

Fig 4 Median Brouillette's obstructive sleep apnoea scores for children after adenotonsillectomy or watchful waiting

Complications of surgery

Of the 195 children who underwent adenotonsillectomy (145 in the adenotonsillectomy group and 50 in the watchful waiting group), 12 (6%) had complications related to surgery. Seven children (4%) had primary haemorrhage: two (1%) were managed surgically, five (3%) were managed non-surgically; and three (2%) were admitted for overnight observation. None of these children needed a blood transfusion. Five children (3%) had postoperative nausea, which was managed by antiemetics and intravenous hydration.

Discussion

Adenotonsillectomy for mild symptoms of throat infections or adenotonsillar hypertrophy in children has little clinical benefit over watchful waiting. Surgery marginally reduced the number of episodes of fever, throat infections, and upper respiratory tract infections per person year. The effects of surgery were more pronounced in children who had had three to six throat infections in the year before entry to the trial than in those with none to two throat infections. No clinically relevant differences were found for health related quality of life.

Short term effect

During the first six months of follow up the incidence of fever was significantly lower in the adenotonsillectomy group than in the watchful waiting group, but was the same from six to 24 months. Sleep and eating patterns initially improved more in children in the adenotonsillectomy group, but by 24 months the differences had disappeared. The reduction of problems in the first six months might explain why parents and doctors are usually satisfied with adenotonsillectomy.[12 17 18]

Possible limitations

Our trial has several limitations. Firstly, we excluded children with frequent throat infections or obstructive sleep apnoea, which are generally considered adequate indications for surgery. Our results are therefore generalisable only to children with milder symptoms of throat infections or adenotonsillar hypertrophy.

Secondly, 50 children (34%) changed from watchful waiting to surgery. Similar rates have been reported.[3 19–22] In surgical tri-

Table 3 Differences in incidence of fever, throat infections, upper respiratory tract infections, and days with sore throat in subgroups of children after adenotonsillectomy or watchful waiting for mild symptoms of throat infections or adenotonsillar hypertrophy

Variable	Fever (95% CI)	P value*	Throat infections (95% CI)	P value*	Days with sore throat (95% CI)	P value*	Upper respiratory tract infections (95% CI)	P value*
Overall	−0.21 (−0.54 to 0.12)		−0.21 (−0.36 to −0.06)		−5.91 (−6 57 to −5.24)		−0.53 (−0.97 to −0.08)	
Indication:								
Recurrent throat infections	−0.84 (−1.33 to −0.35)	0.10	−0.38 (−0.62 to −0.13)	0.12	−9.70 (−10.79 to −8.61)	0.06	−0.33 (−0.99 to 0.34)	0.79
Other	0.27 (−0.18 to 0.72)		−0.08 (−0.28 to 0.11)		−3.19 (−4.04 to −2.35)		−0.63 (−1.24 to −0.02)	
No of throat infections†:								
0-2	0.34 (−0.08 to 0.77)	0.01	−0.03 (−0.21 to 0.15)	0.05	−2.38 (−3.19 to −1.60)	0.01	−0.27 (−0.86 to 0.32)	0.18
3-6	−1.07 (−1.59 to −0.56)		−0.49 (−0.75 to −0.22)		−11.33 (−12.48 to −10.17)		−0.92 (−1.61 to −0.23)	

*Values of interaction term in Poisson regression analysis.
†In year before entry to trial.

als, only the children in the watchful waiting group are allowed to change treatment group because of persisting problems. Per protocol analyses that exclude children who change groups will therefore underestimate the effect of treatment. Conversely, analysing children on the basis of time spent in a treatment arm might overestimate or underestimate this effect. For these reasons we chose an intention to treat analysis.

Thirdly, we measured health related quality of life with generic questionnaires because disease specific instruments for children with tonsil and adenoid disease were not available when we started our study.[23] We chose the TAPQoL and TACQoL preschool children quality of life questionnaires because they include domains relevant for children with tonsil and adenoid disease.[14] We did not expect large improvements during follow up, because the scores of our study population at baseline were similar to those of healthy children.

Finally, not all eligible children entered the trial, which might have influenced the generalisability of our results. In an earlier study, however, we found no major differences between included children and those who were eligible but not included.[24]

Strengths of the study

Previous trials are potentially limited by information bias. This is due to the absence of an objective outcome measure and because the parents of children in the watchful waiting group are more likely to report sore throat or upper respiratory tract infections than parents of children in the intervention group.[3 19–22 25] These lead to an overestimation of the intervention effect.[26 27] The major strength of our study is the inclusion of the objective primary outcome of fever measured daily by a validated thermometer that automatically stored data.[16] Fever is an important physical sign in many diseases of children, and most episodes of fever in children under 8 years of age are caused by upper respiratory tract infections.[28 29] We found that adenotonsillectomy did not significantly reduce the number of fever episodes but did have a small but statistically significant effect on the number of throat infections.

The power of our study was large enough to allow for subgroup analyses, providing a tool for clinicians to identify children who are likely to benefit from adenotonsillectomy.

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Contributors: BKvS and EhvdA planned the study; collected, analysed, and interpreted the data; and wrote the paper equally. MMR analysed and interpreted the data. GJH contributed to the initial concept and design of the study and interpreted the data. AGMS and AWH designed, planned, and supervised the study and interpreted the data. The manuscript was prepared by BKvS and EHvdA and commented on by all authors. AGMS is guarantor.

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Competing interests: None declared.

Ethical approval: This study was approved by the medical ethics committees of all participating hospitals.

What is already known on this topic

Frequent throat infections and obstructive sleep apnoea are adequate indications for adenotonsillectomy

Evidence of the benefits of adenotonsillectomy in children with milder symptoms is lacking

What this study adds

Adenotonsillectomy has no major clinical benefits over watchful waiting in children with mild symptoms of throat infections or adenotonsillar hypertrophy

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