North of England and Scotland Study of Tonsillectomy and Adeno-tonsillectomy in Children

North of England and Scotland Study of Tonsillectomy and Adeno-tonsillectomy in Children (NESSTAC): a pragmatic randomised controlled trial with a parallel non-randomised preference study

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Executive summary

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Executive summary

Background

Tonsillectomy and adeno-tonsillectomy have been widely used surgical procedures for the treatment of children with recurrent sore throat in the UK. The incidence of tonsillectomy has declined in recent years to some 50,000 tonsillectomy procedures carried out on children per year. There remains little clear evidence of clinical effectiveness and cost-effectiveness of surgical or medical management (Burton *et al.*, 2008) that would guide clinicians in treatment decisions or commissioners in commissioning decisions.

Objectives

To examine the cost-effectiveness of tonsillectomy/adeno-tonsillectomy in children aged 4–15 years with recurrent sore throats in comparison with standard non-surgical management.

Design

A pragmatic randomised controlled trial with economic analysis comparing surgical intervention with conventional medical treatment in children with recurrent sore throats (trial) and a parallel non-randomised cohort study (cohort study).

Setting

Five secondary care otolaryngology departments located in the north of England or west of Scotland.

Participants

Two hundred and sixty-eight (trial) and 461 (cohort study) children aged between 4 and 15 years on their last birthday with recurrent sore throats.

Interventions

The treatment arm consisted of tonsillectomy and adeno-tonsillectomy with adenoid curettage and tonsillectomy by dissection or bipolar diathermy according to surgical preference within 12 weeks of randomisation. The control arm consisted of non-surgical conventional medical treatment only.

Main outcome measures

The primary clinical outcome was the reported number of episodes of sore throat in the 2 years after entry into the study. Secondary clinical outcomes included: the reported number of episodes of sore throat; number of sore throat-related GP consultations; reported number of symptom-free days; reported severity of sore throats; and surgical and anaesthetic morbidity. In addition to the measurement of these clinical outcomes, the impact of the treatment on costs and quality of life was assessed.

Analysis

An intention-to-treat analysis was performed according to the original protocol.

Economic evaluation

An intention-to-treat cost-effectiveness analysis, willingness-to-pay survey and cost–utility analysis were undertaken to estimate the incremental cost-effectiveness ratio, how much parents would be willing to pay and the incremental quality-adjusted life-years (QALYs) gained.

Results

Of the 1546 children assessed for eligibility, 817 were excluded (531 not meeting inclusion criteria, 286 refused) and 729 enrolled to the trial (268) or cohort (461).

Patient preferences

Sixty-three per cent (461/729) of children and parents participating in the study stated a preference for medical or surgical management: 16% (74/461) of these who were recruited to

the cohort study opted for continuing medical management and 84% (387/461) for surgical management. Prior to recruitment to the cohort study, participants opting for surgical management reported more sore throat episodes and that progress at school was impeded compared with cohort participants opting for medical management and trial participants.

Response rates at baseline and outcome

Eighty-eight per cent (642/729) of all study participants completed and returned baseline questionnaires. The response rate to self-completed outcome questionnaires was 56% at 3 months, 38% at 12 months and 33% at 24 months. At 12 months, the response was 48% for the trial and 33% for the cohort; at 24 months, trial response was 44% and cohort 27%. Each participant was sent 24 4-weekly diaries; there was a poor diary response rate: trial 41% and cohort 29%. The mean number of diaries returned per child was 9.9 for the trial and 6.8 for the cohort. The percentage of GP records accessed was 69 for the trial and 31 for the cohort.

Primary outcome

The primary outcome was the number of episodes of sore throat experienced during 2 years of follow-up by each participating child recorded each day in health diaries. The mean (standard deviation) episode of sore throats per month differed between years and treatment groups, and was in year 1: cohort medical 0.59 (0.44); cohort surgical 0.71 (0.50); trial medical 0.64 (0.49); and trial surgical 0.50 (0.43). Year 2: cohort medical 0.38 (0.34); cohort surgical 0.19 (0.36); trial medical 0.33 (0.43); and trial surgical 0.13 (0.21). During both years of follow-up, children randomised to surgical management were less likely to record episodes of sore throat than those randomised to medical management; the incidence rate ratios in year 1 and year 2 were 0.70 [95% confidence interval (CI) 0.61 to 0.80] and 0.54 (95% CI 0.42 to 0.70) respectively.

Secondary outcomes

The mean (standard deviation) number of sore throats differed between years and treatment groups, and was: year 1: cohort medical 30.6 (28.7); cohort surgical 42.8 (7.5); trial medical 49.1 (7.3); and trial surgical 31.0 (5.0). Year 2: cohort medical 20.4 (2.5); cohort surgical 10.5 (1.5); trial medical 20.2 (3.2); and trial surgical 8.0 (0.9). During both years of follow-up, children randomised to surgical management recorded less sore throats than children randomised to medical management; the incidence rate ratios were: year 1: 0.67 (95% CI 0.52 to 0.85) and year 2: 0.27 (95% CI 0.16 to 0.46).

The mean (standard deviation) number of recorded GP consultations for sore throats differed between years and treatment groups. Year 1: cohort medical 1.6 (2.0); cohort surgical 1.9 (2.2); trial medical 2.4 (2.4); and trial surgical 1.9 (2.8). Year 2: cohort medical 1.5 (2.1); cohort surgical 0.8 (1.3); trial medical 1.3 (1.6); and trial surgical 0.9 (1.4). During both years of follow-up, children randomised to surgical management recorded less sore throat-related consultations than children randomised to medical management; the incidence rate ratios were: year 1: 0.81 (95% CI 0.59 to 1.10) and year 2: 0.67 (95% CI 0.46 to 0.97).

The incremental cost-effectiveness ratio was estimated as £261 per sore throat avoided (95% CI £161 to £586). Parents were willing to pay for the successful treatment of their child's recurrent sore throat (mean £8059). The estimated incremental cost per QALY ranged from £3129 to £6904 per QALY gained.

Conclusions

Children and parents exhibited strong preferences for the surgical management of recurrent sore throats. The health of all children with recurrent sore throat improves over time, but trial participants randomised to surgical management tended to experience better outcomes than those randomised to medical management. The limitations of the study due to poor response at follow-up support the continuing careful use of 'watchful waiting' and medical management in both primary and secondary care in line with current clinical guidelines until clear-cut evidence of clinical effectiveness and cost-effectiveness is available.

Implications for practice

- There are clinical benefits of tonsillectomy that persist for at least 2 years.
- Participants were more likely to express a preference for tonsillectomy if they had experienced more severe symptoms of sore throat.

- There is a strong parental preference for tonsillectomy.
- The findings support careful use of 'watchful waiting' and medical management in both primary and secondary care until clear-cut evidence of effectiveness is available.

Recommendations for research

- Exploratory secondary analysis to estimate the impact at surgical management on study participants whose tonsils were surgically removed.
- Methodological research of alternative methods of data collection.
- Larger utility elicitation/willingness-to-pay studies.

Trial registration

This trial is registered as ISRCTN47891548.

Publication

Lock C, Wilson J, Steen N, Eccles M, Mason H, Carrie S, *et al.* North of England and Scotland Study of Tonsillectomy and Adeno-tonsillectomy in Children (NESSTAC): a pragmatic randomised controlled trial with a parallel non-randomised preference study. *Health Technol Assess* 2010;**14**(13).

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The research reported in this issue of the journal was commissioned by the HTA programme as project number 99/20/03. The contractual start date was in September 2001. The draft report began editorial review in February 2009 and was accepted for publication in July 2009. As the funder, by devising a commissioning brief, the HTA programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

The views expressed in this publication are those of the authors and not necessarily those of the HTA programme or the Department of Health.

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