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Parent satisfaction and symptom relief in children with otitis media undergoing tympanostomy tube insertion

Lene Dahl Siggaard[1], Thomas Qvist Barrett[2], Michael Lüscher[3], Peter Koefoed Tingsgaard[4] & Preben Homøe[5]

ABSTRACT

INTRODUCTION: The objective of this study was to investigate parent satisfaction and symptom relief in children younger than 12 years undergoing tympanostomy tube (TT) insertion for otitis media (OM) using electronic patient-reported outcome (ePRO) data in private ear-nose & throat (ENT) practice settings.

METHODS: A total of 3,553 children aged 0-11 years and registered in the Danish ENT Specialists Organisation (DØNHO) database were included. Following parental consent to participate, we e-mailed a pre-surgical questionnaire two days prior to surgery. Follow-up questionnaires were sent one, three, six, nine and 12 months after surgery. The pre-operative questionnaire collected information on symptom duration, number of acute OM (AOM) episodes within one year before TT insertion and ear-related symptoms. The post-operative questionnaires collected information on symptom relief, number of AOM episodes and parental satisfaction.

RESULTS : Pre- and post-operative questionnaires from 2,462 children were eligible for complete analysis. Before surgery, 89.8% of parents reported a symptom duration of three months or longer and/or recurrent AOM (RAOM). Complete symptom regression was reported in more than half of the children post-operatively. For the rest, significant symptom relief was reported 1-12 months following TT insertion. Parent satisfaction rose from 94.8% to 97.2% in the course of the observation period.

CONCLUSIONS: We report a consistent, high rate of symptom relief 1-12 months following TT insertion in children < 12 years of age. Furthermore, parental satisfaction throughout the 12-month observation period was compelling.

FUNDING: none.

TRIAL REGISTRATION: The database was approved by the Danish Data Protection Agency as a private, clinical database (no. 2016-42-3152). According to Danish law, approval by the Danish Research Ethics Committee system was not necessary.

Otitis media (OM) is common in children. A previous study shows that approximately 60% of Danish preschool children experience at least one episode of OM [1]. The self-limiting nature of OM often makes treatment superfluous. However, in some children, recurrent acute OM (RAOM) and/or chronic OM with effusion (COME) causes prolonged symptoms, e.g. hearing problems, disrupted sleep, recurrent fever periods, earache, ear secretion and delayed speech development [2, 3].

Tympanostomy tube (TT) insertion is a well-established treatment for RAOM and/or COME. Earlier studies have explored both the short-term and long-term effectiveness of TT insertion without providing exact, strong evidence for the current treatment regime for children with OM [4-8]. A study from 2007 investigating long-term effects of TT insertion in children with COME below three years of age showed no developmental improvement or long-term benefits at 9-11 years of age [4]. Other studies show that TT insertion improves hearing and quality of life (QOL) the first months post-operatively in children with COME, suggesting short-term symptom relief after TT insertion [5, 6]. Although several QOL analyses of patients treated with TT insertion for COME, RAOM or both have been presented, [7, 8] controversy about correct surgical management of OM remains.

Electronic patient-reported outcome (ePRO) data have gained considerable scientific attention as an effective, time-efficient and accurate tool for assessing treatment outcomes [9]. To our knowledge, ePRO data have not yet been applied in children undergoing TT insertion for OM.

We here aimed to investigate the parent-perceived treatment effect of and satisfaction with TT insertion in children with OM by using ePRO data in private ENT practice settings.

METHODS

This study was a prospective, observational, multicentre study based on ePRO data from the Danish ENT Specialists Organisation (DØNHO) database, which was established in early 2017. A total of 17 Danish private ENT clinics, comprising 26 ENT specialists, have joined the database, registering patients offered TT insertion. The participating ENT clinics are geographi-

ORIGINAL ARTICLE

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Otomicroscopy of an 8-month-old child performed by an ear- nose & throat specialist.

cally located in all five Danish regions. Inclusion of patients into the database is on-going, and the project can, if needed, prospectively be expanded to all 160 private ear-nose and throat (ENT) specialists in Denmark. The present study reports on the results from the first 3,553 patients enrolled from March 2017 to August 2018.

Inclusion and exclusion criteria

The caregiver of every child below 12 years of age scheduled for TT insertion in general anaesthesia was offered study inclusion. If one or more of the six exclusion criteria were met (children aged ≥ 12 years, parents with no e-mail address, insufficient language or cognitive capabilities, no wish to participate, or illiterate parents), the child was registered anonymously and excluded immediately. Data were encrypted and anonymously stored electronically in the database.

Participation

At the pre-operative examination, parents were given information about the study. Following parental consent to participate, we e-mailed a pre-operative questionnaire to the parent two days before surgery. Post-operative questionnaires were sent one month after surgery and then every three months until completion of the two-year follow-up period. The parents completed the questionnaires at home without interference from the doctor or the clinic staff. Routines regarding surgical procedure and post-operative follow-up and treatment remained unchanged. In this initial report of results, we include data covering the first 12 months after TT insertion.

Contents of the Danish National Tympanostomy Tube Insertion Questionnaires

Prior to surgery, the parents were asked for information on caregiver's labour market absence, occurrence of ear-related problems, symptom duration and number of AOM episodes within one year prior to TT insertion. The post-operative follow-up questionnaires obtained information on relief from and remaining pre-operative symptoms, number of AOM episodes, AOM treatment, parental satisfaction and caregiver's labour market absence. In this study, we focussed on pre- and post-operative symptoms and parental satisfaction following TT insertion.

The Danish National Tympanostomy Tube Insertion Questionnaires (DANTIQ) were developed by a group of ENT specialists and has undergone validation as reported elsewhere [10].

Completeness of inclusion

To investigate study inclusion completeness, three clinics manually and retrospectively examined a total of 162 consecutive children younger than 12 years scheduled for TT insertion in general anaesthesia (GA) in the survey period. Among these, 149 children (92%) were included in the database. Non-participation was due to unregistered exclusion or incomplete registration by clinic staff.

Non-responders

Age and gender composition were analysed in the group of children whose parents did not answer the pre-operative questionnaire and compared with the responder group.

Statistical analysis

The Biostatistical Advisory Service at the University Hospital in Aarhus (BIAS) checked and validated all data calculations and performed all statistical analyses. Confidence intervals (CI) for proportions were calculated, and the chi-squared test was used for inter-group comparison. The change in symptom severity was calculated for those with paired observations pre- and post-operatively and the reduction in probability of each symptom was tested with McNemar's test. A two-sided p value <0.05 was considered statistically significant.

Trial registration: The database was approved by the Danish Data Protection Agency as a private, clinical database (no. 2016-42-3152). According to Danish law, approval by the Danish Research Ethics Committee system was not necessary.

RESULTS

A total of 3,553 children younger than 12 years were registered in the database between March 2017 and

August 2018. Baseline characteristics are shown in **Table 1**. For 808 children, pre-operative questionnaires were unanswered. A total of 283 children needed TT re-insertion and were re-registered in the database during the observation period. The need for TT re-insertion was considered due to symptom relapse of a pre-operatively registered symptom history. Hence, a full pre-operative symptom profile was not re-registered, and re-entries were therefore excluded. The remaining 2,462 pre-operative questionnaires were adequately answered and eligible for analysis for the observation period. The pre-operative response rate was 75.3% (95% confidence interval (CI): 73.8; 76.8). Post-operative response rates are shown in **Table 2**. Non-responder analysis showed no significant gender difference between participants and non-participants. The age of non-participants was significantly higher (1.06 times (95% CI: 1.007; 1.109)) than that of participants.

Parents spent a mean two minutes and 22 seconds completing the pre-operative questionnaire and less than one minute completing each questionnaire post-operatively. The private clinics spent an average of 16 seconds on manual registration and inclusion of a patient in the database, and after registration was completed, only three seconds extra on potential exclusion. This did not cover time spent by the clinic staff to inform parents about database inclusion, nor the time spent by ENT specialists on feedback or analyses of their own clinic-specific data.

TABLE 1

Baseline characteristics and pre-operative results in children aged 0-11 years with otitis media receiving tympanostomy tube insertion in Danish private ear, nose & throat clinics based on electronic patient-reported outcome data.

Baseline characteristics and pre-operative results	n	%	CI
Total number of participants	3,270		
Responses			
Responders	2,462	75.3	73.8-76.8
Non-responders	808	24.7	23.2-26.2
Age, median (range), months	22 (4-142)		
IQR, months	28		
Gender			
Male	1,416	57.5	55.5-59.5
Female	1,046	42.5	40.5-44.5
Previous TT insertion			
Yes	912	37.0	35.1-39.0
No	1,538	62.5	60.5-64.4
Unknown	12	0.5	0.3-0.8
Symptom duration (with or without concurrent RAOM)			
≥ 3 months and/or RAOM	2,211	89.8	88.5-91.0
⟨ 3 months and no RAOM	112	4.5	3.8-5.4
Unknown with respect to symptom duration and/or RAOM	139	5.6	4.8;.6

CI = confidence interval; IQR = interquartile range; RAOM = recurrent acute otitis media; TT = tympanostomy tube

TABLE 2

Post-operative response rates, degree of symptom regression and parent satisfaction 1-12 months after tympanostomy tube insertion in children aged 0-11 years with otitis media, based on electronic patient-reported outcome data

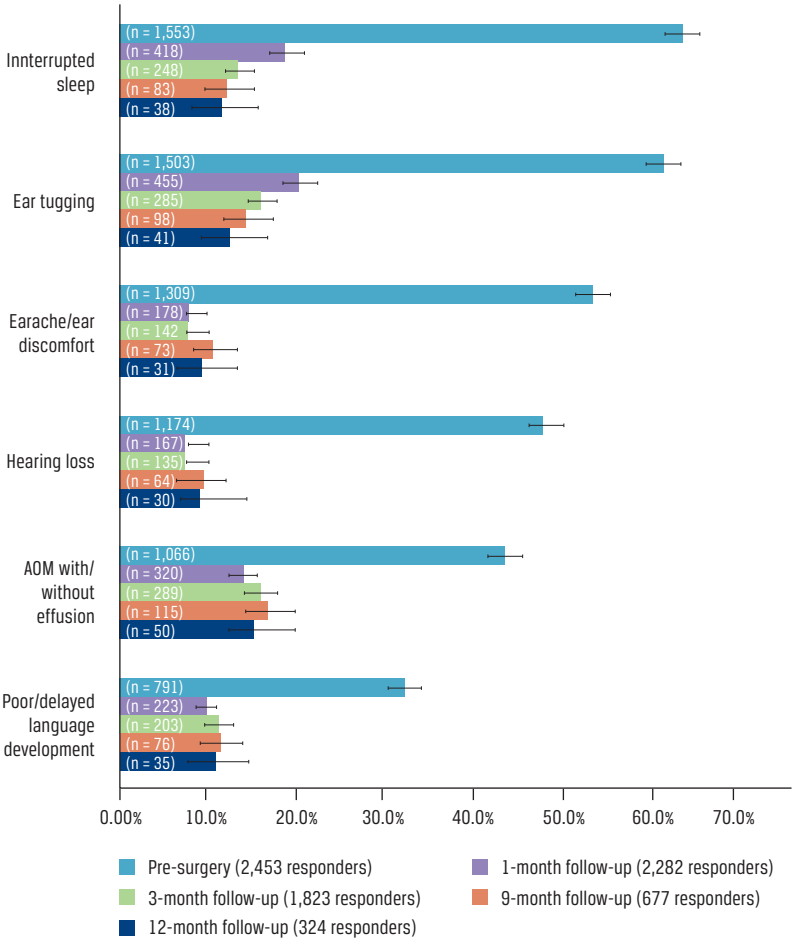
Post-operative results												
Follow-up after TT insertion	**1-month follow-up**			**3-month follow-up**			**9-month follow-up**			**12-month follow-up**		
	n	**%**	**95% CI**	**n**	**%**	**95% CI**	**n**	**%**	**95% CI**	**n**	**%**	**95% CI**
Responders	2,248 (1,861[a])	70.4	68.8-72.0	1,823 (1,592[a])	62.1	60.3-63.9	677	57.2	54.4-60.1	324	49.0	45.1-52.9
"Has the surgery improved your child's ear-related problems?"												
Yes, completely	1,210	53.8	51.7-55.9	1,110	60.9	58.6-63.1	393	58.1	54.2-61.8	200	61.7	56.2-67.0
Yes, partly	689	30.6	28.7-32.6	541	29.7	27.6-31.8	208	30.7	27.3-34.4	88	27.2	22.4-32.4
Undecided	301	13.4	12.0-14.9	108	5.9	4.9-7.1	47	6.9	5.1-9.1	17	5.2	3.1-8.3
No	46	2.0	1.5-2.7	64	3.5	2.7-4.5	29	4.3	2.9-6.1	19	5.9	3.6-9.0
Unanswered	2	0.1	0.0-0.3	-	-	-	-	-	-	-	-	-
"Are you satisfied with having the surgery performed?"												
Yes	1,765	94.8	93.7-95.8	1,523	95.7	94.5-96.6	655	96.8	95.1-98.0	315	97.2	94.8-98.7
No	11	0.6	0.3-1.1	16	1.0	0.6-1.6	3	0.4	0.1-1.3	4	1.2	0.3-3.1
Undecided	85	4.6	3.7-5.6	53	3.3	2.5-4.3	19	2.8	1.7-4.3	5	1.5	0.5-3.6

CI = Confidence interval

a) The question regarding post-operative parent satisfaction, "Are you satisfied with having the surgery performed?", was belatedly implemented in the database in September 2017, why the total number of responders for this question alone was lower at the 1-month (n = 1,860) and the 3-month follow-up (n = 1,592).

FIGURE 1

Pre -and post-operative symptom severity in children aged 0-11 years with otitis media undergoing typpanostomy tube insertion in general anaesthesia based on electronic patient-reported outcome data



Pre-surgical results

Table 1 shows symptom duration before TT insertion. In all, 89.8% of TT insertions were in accordance with the Danish National Clinical Guideline (NCG) definition of COME and RAOM. The median symptom duration interval was 6-12 months. Symptom profiles of the group of children deviating from guideline recommendation before TT insertion were not analysed separately. The most frequent pre-operative parent-reported symptoms were disrupted sleep and ear tugging, both of which were present in two thirds of the children (see **Figure 1**).

Post-surgical results

The pre- and post-operative symptom severity is illustrated in Figure 1. More than half of the children experienced complete symptom regression post-operatively. For the rest, either partial, no or unknown symptom regression was reported, and the severity of remaining symptoms was re-registered (see Table 2). Immediate, significant symptom relief was reported for earache/ear discomfort, hearing loss, interrupted sleep, delayed language development, AOM with or without effusion and ear tugging already at the one-month follow-up after TT insertion ($p < 0.001$). Results are specified in **Figure 2**. Data at the six-month follow-up are not presented here, but showed the same significance in symptom relief for all symptoms presented. Post-operative parent satisfaction is presented in Table 2.

DISCUSSION

This study is among the largest yet to report the outcome of TT insertion in patients with OM using ePRO data. We present the first results of 3,553 children. Our main results show significant short-term symptom relief up to 12 months after TT insertion in children with OM below 12 years of age. Most parents reported a symptom duration of three months or longer and/or RAOM for up to one year before TT insertion. This is in accordance with the Danish NCG. Symptoms of COME and RAOM may differ according to age. However, the results are calculated as individual symptom relief and the median age is 22 months (range 4-142 months). Therefore, age differences in symptoms in this study are of minor concern.

In all, 94.8% of the parents were satisfied with the TT insertion in their child one month post-operatively. Parent satisfaction remained compellingly high throughout the entire 12-month observation period. Based on these data, TT insertion seems to have a substantial short-term effect in children with OM.

ePRO data have shown significant strength for monitoring treatment effects [11, 12]. In the present study, questionnaires were sent electronically at specific predefined intervals via an automated software platform to facilitate parental participation. A minimum of time was spent on patient registration in the database by the ENT clinic staff, and no extra clinical examinations were needed, making data collection both swift, easily accessible, time efficient and cost beneficial. This has allowed the database to grow at a tremendous speed, providing us with a large body of data.

However, the database does not report on clinical ENT specialists' assessments and exams, tympanometry findings and hearing threshold measurements. Although parent-provided information is essential to the overall assessment, private ENT specialists rely heavily on their objective findings as well when assessing the treatment effect of TT insertion. Furthermore, our study is susceptible to response-biased parents who prefer to have the procedure performed on their child. Even so, we believe that the quantity of ePRO data in this study carries considerable strength, making it a

promising and sustainable tool for outcome monitoring in patients with OM undergoing TT insertion.

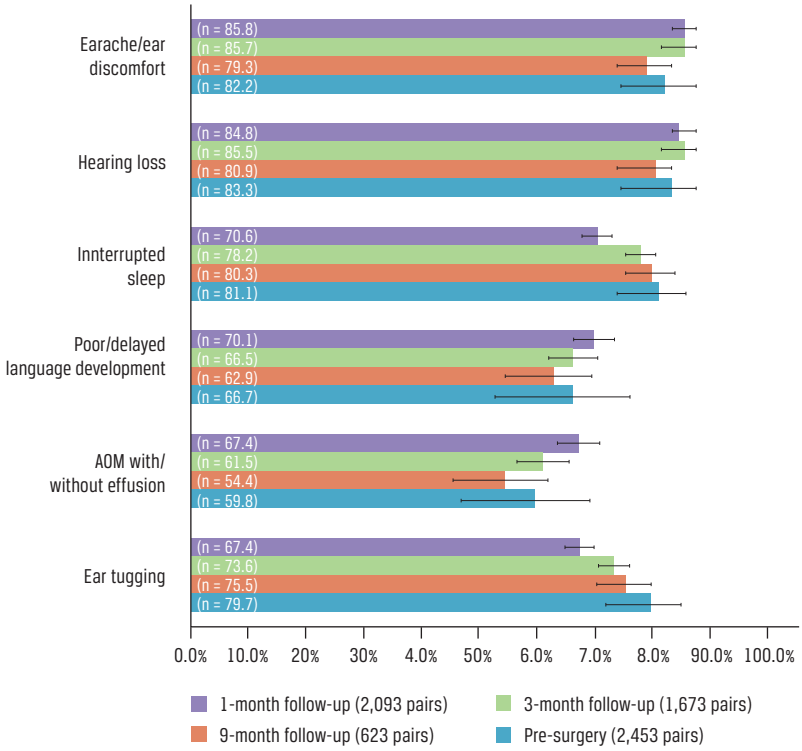
Earlier studies have investigated parent-perceived treatment effect after TT insertion in Danish children with COME and/or RAOM. A study among 24 private ENT specialists from 2010 investigated guideline adherence and parental satisfaction following TT insertion. A total of 426 children aged 0-6 years with OM offered first-time TT insertion were included. Parents and participating ENT specialists answered pre- and three-month post-operative questionnaires. Interrupted sleep and earache before TT insertion were reported in 60% of the children and hearing loss in 33%. Significant post-operative symptom regression was found, and 96% of the parents were satisfied with their child's TT insertion [13]. Another study from 2015 investigating QOL differences among diagnostic subgroups of Danish children receiving TT for OM using the Otitis Media-6 questionnaire found significant QOL improvements in 491 children with RAOM, COME or both at 1-18 month follow-up after TT insertion [14]. As our study population was comparable in regard to age, gender composition and symptom burden prior to TT insertion, we believe that our data support these previous findings and vice versa.

Danish and international clinical guidelines mainly focus on child hearing when outlining proper use of TT insertion [15-17]. Likewise, changes in hearing thresholds have been used in various studies to evaluate the treatment effect of TT insertion in children with COME [18, 19]. An international consensus guideline from 2017 confirms that COME-attributed hearing loss is the main reason for surgical intervention in children with COME [20]. However, our study shows that other ear-related symptoms like disrupted sleep and earache also affect children suffering from OM. According to our data, TT insertion has a significant effect on these and other ear-related symptoms. Most children experienced symptom relief already one month after TT insertion; a prompt change pointing towards a real effect of TT insertion rather than spontaneous symptom relief associated with the self-limiting nature of OM. Although these specific QOL variables are not current indications for TT insertion in children with OM, they could very well be the main reason why the Danish TT insertion frequency ranks highest in the world. We therefore suggest that symptoms like sleep disruption and earache are important variables when reporting the results of TT insertion in future investigations.

Our study did not include a control group, and our observations need to be confirmed in a randomised trial. However, as TT insertion has been well established in Denmark for decades, a randomised trial will be difficult to conduct in a Danish private ENT specialist setting.

FIGURE 2

Reduction in probability of symptoms following tympanostomy tube insertion in children aged 0-11 years with otitis media based on electronic patient-reported outcome data.



AOM = Acute otitis media.

CONCLUSIONS

Our main findings underpin a high degree of short-term symptom relief following TT insertion in children with OM under the age of 12 years. We also found a persistently high percentage of parents who were satisfied with TT insertion in their child throughout the 12-month observation period. Finally, in this setting, ePRO data proved to be a promising tool for the assessment of treatment outcome in children undergoing TT insertion.

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