DANISH MEDICAL JOURNAL

Original Article

Dan Med J 2023;70(8):A10220608

Ear tubes in children with otitis media reduce parental sick leave from work and socioeconomic costs

Louise Jürgens[1], Michael Lyscher[2], Thomas Qvist Barrett[3], Peter Koefoed Tingsgaard[4] & Lene Dahl Siggard[5]

1) Health, Aarhus University, 2) ENT Private Clinic, Aarhus, 3) ENT Private Clinic, Randers, 4) ENT Private Clinic, Slagelse, 5) Department of Otorhinolaryngology, Head & Neck Surgery and Audiology, Aalborg University Hospital, Denmark

Dan Med J 2023;70(8):A10220608

ABSTRACT

INTRODUCTION. This study aimed to investigate changes in parental sick leave after tympanostomy tube (TT) insertion in children with otitis media (OM) and to estimate the overall cost reduction in case of decreased caregiver sick leave from work during a 12-month period after TT insertion.

METHODS. A total of 4,708 children < 12 years from the database of the Danish ENT Specialists Organisation were included. Questionnaires were sent two days prior to TT insertion and subsequently 1, 3, 6, 9, 12, 15, 18, 21 and 24 months after TT insertion. The questions included symptom duration, patient satisfaction and symptom relief. Furthermore, parental sick leave occurrence was registered before and after TT insertion. The overall cost reduction estimate was based on comparison of the direct and indirect costs of two treatment regimes. Treatment A was non-surgical and antibiotics only. Treatment B comprised TT insertion and antibiotics as needed.

RESULTS. The main results were that the risk of parental sick leave decreased significantly ($p < 0.005$) one month after TT insertion compared with baseline; odds ratio = 0.21 (95% confidence interval: 0.19-0.24). The decrease remained stable during the entire follow-up period. The estimate of the total cost reduction between Treatment A (non-TT insertion) and Treatment B (TT insertion) was 3,118.34 DKK/child/year.

CONCLUSION. TT insertion is associated with a significant decrease in parental sick leave and may possibly contribute to substantial socioeconomic savings.

FUNDING. None.

TRIAL REGISTRATION. Not relevant.

Otitis media (OM) is common in small children [1]. OM is roughly divided into OM with effusion (OME) and acute OM (AOM). OME is defined as the presence of liquid in the middle ear without associated signs of ear infection. In AOM, infected middle ear fluid often results in fever, irritability and ear secretion [2]. Among Danish children, 60% have suffered from OM before reaching school age [1].

OM is often self-limiting, but in some cases recurrent AOM (RAOM) (≥ 3 episodes in six months or ≥ 4 episodes in 12 months) [2] or persistent OME (symptom duration ≥ 3 months) may cause disrupted sleep, recurring fever episodes, ear secretion, hearing loss and delayed speech development. These symptoms negatively affect children's and caregivers' quality of life (QoL) and increase parental sick leave (PSL) [3, 4].

In Denmark, 16% of all registered PSL was caused by child illness, most commonly infectious diseases [5]. One

AOM episode is associated with a mean increase of 1.35 sick leave days for mothers and 0.5 for fathers ($p < 0.01$) compared with controls. This indicates that OM has socio-economic consequences [6].

Non-surgical management of OM mainly consists of analgesics and antibiotics [7]. However, the 2015 Danish National Clinical Guideline recommends tympanostomy tube (TT) insertion for children aged 0-5 years with persistent bilateral OME and hearing loss with or without delayed speech development and/or RAOM [2]. TT insertion is the most frequent surgical intervention in the Western world [8]. In 2019 (before the COVID-19 pandemic), 28,393 TT insertions were performed in Danish children aged 0-12 years [9]. The majority of these TT insertions were performed in private ear, nose and throat (ENT) specialist clinics.

TT insertion in children with OM is associated with significant parent-observed symptom regression [3] and improved caregiver QoL measured by number of interrupted nights, absenteeism, cancelled social activities and doctor visits [4].

However, PSL has not previously been used as an outcome to measure the effect of TT insertion in children with OM, nor has the financial impact of TT insertion been explored. Thus, the aim of this study was to 1) investigate changes in PSL after TT insertion in children with OM under the age of 12 years; and 2) estimate the overall cost reduction in case of reduced caregiver sick leave (if any) one year following TT insertion.

METHODS

This prospective, observational, multicentre study based on electronic patient-reported outcome (ePRO) data retrieved from the Danish ENT Specialist Organisation database on ear-related symptoms, symptom duration, number of AOM episodes, treatment effect and PSL before and after TT insertion using the Danish National Tympanostomy Tube Insertions Questionnaires (DANTIQ) [10]. A total of 17 Danish private ENT clinics, comprising 26 ENT specialists, assisted with patient recruitment and data collection.

Parents of children < 12 years who were scheduled for TT insertion were offered inclusion. The exclusion criteria were children ≥ 12 years; for parents, the exclusion criteria were no email address, insufficient language abilities, reduced cognitive capabilities or illiteracy and unwillingness to participate.

Data were collected: two days prior to TT insertion (baseline) and 1, 3, 6, 9, 12, 15, 18, 21 and 24 months after TT insertion. Questionnaires were emailed to parents who completed them at home without interference from physicians or clinic staff.

The pre- and post-operative DANTIQ question in focus for this study was: “Did you have any sick leave days because of your child’s ear problems in the past four weeks?”. Possible answers were “Yes”, “No” and “Do not recall”. Multiple answers were not allowed.

Cost estimates

Cost of illness was defined as resource use including both direct costs, e.g., health sector costs, and indirect costs, e.g., decreased or lost productivity [11].

Direct costs

In this study, direct costs comprised general practitioner (GP), private anaesthesiologist (PA) and ENT specialist consultation costs along with treatment and follow-up expenses. GP and ENT specialist consultation frequency was determined by a “minimum necessary” principle, and the costs were calculated based on the Danish official GP, PA and ENT specialist performance price lists from 2021 [12-14]. Estimated costs of antibiotics were based on the daily dosage price of a frequently administered oral antibiotic (amoxicillin), the average weight of a 22-month-old Danish child [15] and assuming a seven-day treatment period.

Indirect costs

The Danish Medicines Council's Unit Cost Valuation Catalogue was used for estimating the indirect costs of PSL [16]. The average hourly wage for a Danish employee in 2020 was 179 DKK/hour after tax, and a full-time workday was 7.4 hours [13]. Thus, the indirect cost of one sick leave day was estimated to 1,324.6 DKK. To estimate the overall cost reduction achieved by the decrease in PSL from work following TT insertion in a symptomatic child with OM, direct and indirect costs of two potential treatment regimes, A and B, were compared for a 12-month period. A was non-surgical and antibiotics only. This treatment regime is hypothetical, as caregivers and healthcare professionals find it unethical to adopt this regime. B comprised TT insertion and possibly antibiotics, which represents the standard procedure applied today.

Statistics

The Biostatistical Advisory Service at Aarhus University Hospital validated all data calculations and conducted all statistical analyses.

95% confidence intervals (CI) were calculated and a two-sided $p < 0.05$ was considered statistically significant. The pre- and postoperative odds ratio (OR) for PSL was calculated and adjusted for patient re-entries in the dataset.

Trial registration: not relevant.

RESULTS

Between March 2017 and September 2020, 4,708 children < 12 years were registered in the database. During the study period, 309 children (5.6%) needed TT re-insertion. Parents of 3,918 children (70.5%) completed the pre-operative questionnaire. Post-operative response rates decreased to 19.1% during the 24-month follow-up period [5]. A non-responder analysis showed no significant difference in gender composition. The age of non-participants was significantly higher (× 1.06 (95% CI: 1.007-1.109)) than that of participants [3]. Baseline characteristics are shown in Table 1.

TABLE 1 Baseline characteristics and pre-operative results.

	n (%)	Median (range), mos.	IQR, mos.
Participants, total	4,708 (100)		
Age		22 (4-143)	28
Gender			
Boys	2,317 (58.4)		
Girls	1,648 (41.6)		
Questionnaire response			
Responders	3,965 (84.2)		
Non-responders	743 (15.8)		
Who answered the questionnaire?			
Both parents	607 (15.3)		
Mother	2,886 (72.8)		
Father	463 (11.7)		
Others: grandparents, family member, other	9 (0.2)		

IQR = interquartile range.

Responses to the pre- and post-operative DANTIQ question regarding PSL are shown in Table 2. OR of PSL after TT insertion was calculated and compared to baseline. PSL risk decreased significantly ($p < 0.005$) one month after TT insertion compared with baseline; OR = 0.21 (95% CI: 0.19-0.24). PSL risk decreased further during the 24-month follow-up period.

TABLE 2 Responses to the DANTIQ question: "Did you have any sick leave days because of your child's ear problems in the past four weeks?".

	Answers, n			
	"no"	"yes"	Responses in total, n	OR (95% CI)[a], *
Pre-operatively	2,041	1,877	3,918	-
1 mo. post-operatively	2,998	778	3,776	0.21 (0.19-0.24)
3 mos. post-operatively	2,909	418	3,327	0.11 (0.1-0.13)
6 mos. post-operatively	2,815	331	3,146	0.09 (0.08-0.1)
9 mos. post-operatively	2,507	355	2,862	0.11 (0.1-0.13)
12 mos. post-operatively	2,178	262	2,440	0.09 (0.08-0.11)
15 mos. post-operatively	1,769	170	1,939	0.07 (0.06-0.09)
18 mos. post-operatively	1,374	125	1,499	0.07 (0.06-0.09)
21 mos. post-operatively	1,180	121	1,301	0.08 (0.07-0.1)
24 mos. post-operatively	974	87	1,061	0.07 (0.06-0.09)

CI = confidence interval; DANTIQ = Danish National Tympanostomy Tube Insertions Questionnaires; OR = odds ratio for parental sick leave after TT insertion; TT = tympanostomy tube.
*) $p < 0.05$.
a) "Do not recall-answers" were not included in the OR calculations.

Table 3 compares direct and indirect costs (DKK) for a child with symptomatic RAOM and/or persistent OME undergoing two different treatment regimens: Treatment A (antibiotics only) and Treatment B (TT insertions and possibly antibiotics) within a 12-month period.

TABLE 3 Twelve-month treatment costs in DKK of two treatment regimes: antibiotics only and tympanostomy tube insertion and antibiotics for a child with symptomatic recurrent acute otitis media and/or persistent otitis media with effusion.

	Treatment regime A: antibiotics only			Treatment regime B: TT insertion and antibiotics		
	price/unit	unit amount	price in total	price/unit	unit amount	price in total
Direct costs						
Consultation GP:						
Consultation	143.44	4.0	573.76	143.44	1.0	143.44
Tympanometry	109.67	4.0	438.68	109.67	1.0	109.67
Consultation ENT:						
1st consultation				240.49	1.00	240.49
Tympanometry				109.46	1.0	109.46
Hearing screening: OAE				219.01	1.0	219.01
Treatment:						
Antibiotics, systemic[a]	14.29	4.0	57.16	14.29	1.0	14.29
TT insertion, 1st ear[b]				831.88	1.06	878.47
TT insertion, 2nd ear[b]				415.95	1.06	440.91
Anaestheasia, brief GA with mask				833.38	1.06	883.38
1st follow-up after 1 mo.:						
Follow-up consultation				101.81	1.0	101.81
Hearing screening: OAE				219.01	1.0	219.01
Follow-up every 6 mos.:						
1st consultation				240.49	2.0	480.98
Tympanometry at every 2nd follow-up				109.46	1.0	109.46
Antibiotics, ear drops[c]				7.84	12.0	94.05
Total direct costs			1,069.60			4,044.42
Indirect costs						
Cost of 1 parental sick leave day	1,324.60			1,324.60		
Sick leave days/yr		6.2			1.6	
Total indirect costs			8,212.52[d]			2,119.36[e]
Total direct + indirect costs			9,282.12			6,163.78

ENT = ear, nose, throat; GA = general anaesthesia; GP = general practitioner; OAE = otoacustic emissions; TT = tympanostomy tube.
a) The unit amount of systemic antibiotics was set to 4 in Treatment A to account for re-occuring AOM episodes once/3 mos. in the entire 12-mo. observation period, thus the unit amount of GP consultations were likewise set to 4 during the 12-mo. observation period in Treatment A. The unit amount of systemic antibiotics was set to 1 in Treatment B to account for 1 preoperative AOM episode prior to TT insertion.
b) As 5.6% of the study population had TT re-inserted the unit amount for TT insertion for the 1st and 2nd ear was roughly set to 1.06 to account for TT re-insertion costs.
c) The unit amount of local antibiotics (ear drops) was set to 12 in Treatment B to account for 1 glue episode/mo. in the entire 12-mo. observation period.
d) 1,324.60 DKK × 6.2 sick leave days/yr.
e) 1,324.60 DKK × 1.6 sick leave days/yr.

Systemic antibiotics were given at least once to 35.2% of the children in the three-month period leading up to TT insertion and 10.9% had antibiotics administered at least once in the month after their TT insertion.

In Treatment A, Amoxicillin was used to calculate the "price per unit": 40.61 DKK × 0.352 = 14.29 DKK/child/three-month period.

Local antibiotic treatments (such as ciprofloxacin and dexamethasone combination ear drops) are recommended for children after TT insertion. Thus, post-operative antibiotic treatment costs were calculated as follows: 71.9 DKK × 0.109 = 7.83 DKK/child/one month.

As the response option for the DANTIQ question regarding PSL in a four-week period was trichotomic (Yes/No/Do not recall), exact numbers of PSL days were not reported. Therefore, estimates of total pre- and post-operative PSL days were calculated based on the conservative assumption that a "Yes" response was equivalent to one PSL day/child/four weeks.

The preoperative PSL probability was 47.8% (95% CI: 46.2-49.3%). The preoperative PSL probability was assumed

to be independent from month to month prior to TT insertion. To estimate the number of preoperative PSL days/child/year, the preoperative PSL probability per four weeks was multiplied by 13 (13 four-week cycles in a year) equal to 6.2 PSL days/child/year.

The post-operative PSL probabilities at 1, 3, 6, 9 and 12 months were 20.5% (19.2-21.8%), 12.7% (11.6-13.9%), 10.7% (9.7-11.8%), 12.8% (11.5-14.0%) and 11.2% (10.0-12.5%), respectively. To calculate an estimate of the number of post-operative PSL days/child/year, the post-operative PSL probabilities per four weeks were calculated for each follow-up period 12 months after TT insertion and thereafter added together: $0.205 + 2 \times 0.127 + 3 \times 0.107 + 3 \times 0.128 + 3 \times 0.112 = 1.5$ PSL days/child/year.

The total cost estimates for a 12-month period were 9,282.12 DKK for Treatment A (antibiotics only) and 6,163.78 DKK for Treatment B (TT insertion and antibiotics if needed). This corresponded to a difference in costs between Treatment A and B of 3,118.34 DKK/child/year.

DISCUSSION

The primary aim of this study was to investigate the effect of TT insertion in children with OM < 12 years on PSL. The data revealed a significant PSL reduction already one month after TT insertion.

No previous studies have applied change in post-operative PSL as an outcome to measure the effect of TT insertion in symptomatic children with OM. However, an association between OM in children and increased PSL from work was described in previous studies [17, 18]. Barber et al. [18] found that 50% of 2,867 parents experienced more than one medically diagnosed AOM episode in their child during a six-month period. Among those, 73% had been absent from work or had rearranged their working hours. Thus, PSL appears to be a relevant outcome with which to measure the effect of TT insertion in children with OM.

PSL within four-week periods was reported in this study. However, the exact number of PSL days before and after TT insertion was not registered. Therefore, a PSL reduction estimate was calculated based on the decline in the number of "Yes" answers after TT insertion (Table 2). A "Yes" answer was interpreted as being equivalent to only one PSL day every four weeks even though the real number of sick leave days was probably higher. Rare cases of re-tubulation were not included as an expense in Treatment B. However, we believe that this possible expense is counterbalanced by the conservative assumption that a "Yes" answer was equivalent to only one PSL day every four weeks.

Although the significant reduction in PSL one month after surgery compared with baseline suggests a real effect of TT insertion, children with remaining ear problems may be overrepresented in the group of responding parents. Also, post-operative reduction in PSL after TT insertion may be a result of the self-limiting nature of OM. Furthermore, as parents were predisposed to the idea of surgical intervention, referral bias must be considered.

To provide an overall cost-reduction estimate of the decrease in PSL after TT insertion, we compared two hypothetical scenarios. The total cost reduction between the non-TT insertion treatment regime and the TT insertion treatment regime was 3,118.34 DKK in a 12-month period. Decrease in PSL was the main contributor to this reduction. As 28,393 children had TT inserted in Denmark in 2019 [9], TT insertions may have prevented a substantial productivity loss in society (indirect costs) in 2019 alone.

In a previous study, parents to AOM children reported that the condition resulted in substantial use of medical services and loss of workdays [17]. The total costs of one episode of AOM in children from seven European countries was estimated [19]. The direct costs included number of physician and emergency room visits, telephone consultations, hospitalisations and prescription and over-the-counter drug use. Diagnostic tests and

surgical interventions were not included. The indirect costs included workdays lost and travel costs. The total costs per AOM episode ranged from 332.00 € (2,470.77 DKK) in the Netherlands to 752.49 € (5,600.23 DKK) in the UK during a 12-month period with indirect costs representing 61-83% of the total episode. Interestingly, the Netherlands, where the lowest costs were recorded, are also known to have one of the highest rates of TT insertions compared with other Western countries [20].

The total cost estimates in this study are rough estimates. Although the post-operative treatment course after TT insertion is well known and understood, the non-TT insertion scenario is hypothetical as most Danish symptomatic children with OM receive TTs if assessed by an ENT specialist. Also, TTs may take longer than 12 months to fall out or may need to be re-inserted, and some children may develop complications to the procedure that require additional and more expensive treatments. These situations will increase the cost of the post-operative treatment course. Consequently, the direct cost calculations are approximations based on a mix of parent-provided ePRO data, ENT specialist knowledge, experience and guesswork. Also, the indirect cost calculation is based on an average hourly wage for a Danish employee.

However, the significant PSL reduction shortly after TT insertion underpins the results of our analysis. The study methodology was thoroughly revised by a group of four experienced private ENT specialists to ensure alignment between reality and the two treatment regimens (Table 3). Furthermore, revision by a professional health economist ensured that proper indirect cost measurements were applied.

CONCLUSION

TT insertion is associated with a significant decrease in PSL 1-24 months after surgery. Overall cost estimates show that the socioeconomic burden of children with OM who receive TTs is smaller than that of children with OM who hypothetically do not. This indicates that TT insertion improves the clinical symptoms of OM in children while contributing to substantial socioeconomic savings.

Correspondence *Louise Jürgens*. E-mail: louise.jurgens@gmail.com

Accepted 3 May 2023

Conflicts of interest none. Disclosure forms provided by the authors are available with the article at Ugeskriftet.dk/dmj

Aknowledgements The authors express their gratitude to the people who participated in patient registration in the database used, including *Peter Bonvin, Mikkel Bruun, Janus Jespersen, Peder Frandsen, Christian Bak, Jakob Korsholm Nielsen, Jonas Peter Holm, Malene Sine Rokkjær, Jette Berg, Bo Karlsmose, Andreas Agger, Torben Lilholt, Rikke Haahr, Pia Juul, Lotte Jung, Liviu Guldfred, Kim Werther, Thomaas Ravn, Ann-Louise Reventlow-Mourier, Anders Schermacher, Christian Prætorius, Roland Welinder* and *Mikkel Holmelund*.

References can be found with the article at Ugeskriftet.dk/dmj

Cite this as Dan Med J 2023;70(8):A10220608

REFERENCES

1. Todberg T, Koch A, Andersson M et al. Incidence of Otitis media in a contemporary Danish national birth cohort. PLoS One. 2014;9(12):e111732.
2. Danish Health Authority. [National clinical guideline tympanostomy tube treatment. Danish]. Danish Health Authority, 2015. www.sst.dk/da/udgivelser/2015/~/media/B23EC346DEC1408C8419725D96A76C0A.ashx (4 Oct 2021).
3. Siggaard LD, Barrett TQ, Lüscher M et al. Parent satisfaction and symptom relief in children with otitis media undergoing

tympanostomy tube insertion. Dan Med J. 2019;66(9):A5567.
4. Heidemann CH, Lauridsen HH, Kjeldsen AD et al. Caregiver quality of life and daily functioning in relation to ventilating tube treatment. Otolaryngol Head Neck Surg. 2014;151(2):341-7.
5. [Sick leave in Denmark. Danish]. MedHelp, 2011. www.danskhr.dk/media/1123/nationens_tilstand_2_kvt.pdf (4 Oct 2021).
6. Niemelä M, Uhari M, Möttönen M et al. Costs arising from otitis media. Acta Paediatr. 1999;88(5):553-6.
7. Harmes KM, Blackwood AR, Burrows HL et al. Otitis media: diagnosis and treatment. Am Fam Physician. 2013;88(7):435-40.
8. Djurhuus BD, Skytthe A, Christensen K et al. Increasing rate of middle ear ventilation tube insertion in children in Denmark. Int J Pediatr Otorhinolaryngol. 2014;78(9):1541-4.
9. [Danish Regions and The Union of Private Practice Medical Specialists. Danish]. Copenhagen: FAPS, 2021.
10. Tingsgaard JK, Tingsgaard PK, Siggard LD et al. Validation of the Danish National Tympanostomy Tube Insertion Questionnaires. Dan Med J. 2019;66(9):A5568.
11. Jo C. Cost-of-illness studies: concepts, scopes, and methods. Clin Mol Hepatol. 2014;20(4):327-37.
12. [Performance price list for Danish General Practitioners. Danish]. www.laeger.dk/sites/default/files/honorartabel_01.04.2021.pdf (5 Oct 2021).
13. [Performance price list for Danish private practice Anaesthesiologists. Danish]. www.laeger.dk/sites/default/files/anaestesiologi_takstkort_pr_011021_1.pdf (5 Oct 2021).
14. [Performance price list for private practicing ENT specialists. Danish]. www.laeger.dk/sites/default/files/oenh_takstkort_pr_011021.pdf (5 Oct 2021).
15. [Danish average growth curve, boys 0-20 years. Danish]. 2020. www.sundhed.dk/borger/patienthaandbogen/boern/illustrationer/tegning/vaekstkurve-drenge-0-20/ (5 Oct 2021).
16. [Unit cost valuation. Danish]. The Danish Medicines Council, 2020. https://medicinraadet.dk/media/weslftgk/vaerdisaetning-af-enhedsomkostninger-vers-13_adlegacy.pdf (4 Oct 2021).
17. Greenberg D, Bilenko N, Liss Z et al. The burden of acute otitis media on the patient and the family. Eur J Pediatr. 2003;162(9):576-81.
18. Barber C, Ille S, Vergison A et al. Acute otitis media in young children – what do parents say? Int J Pediatr Otorhinolaryngol. 2014;78(2):300-6.
19. Wolleswinkel-van den Bosch JH, Stolk EA, Francois M et al. The health care burden and societal impact of acute otitis media in seven European countries: results of an Internet survey. Vaccine. 2010;28(suppl 6):G39-G52.
20. Schilder AGM, Lok W and Rovers MM. International perspectives on management of acute otitis media: a qualitative review. Int J Pediatr Otorhinolaryngol. 2004;68(1):29-36.