

Office Insertion of Tympanostomy Tubes without Anesthesia in Young Children

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Tympanostomy tube insertion is one of the most common surgical procedures under anesthesia in children.¹ General anesthesia for tube insertion, however, has a 9% incidence of minor complications and 2% incidence of major adverse events.² Moreover, exposing young children to general anesthesia may predispose to adverse behavioral or developmental outcomes,³ leading some groups to recommend postponing elective surgery because of risk to the developing brain.⁴

In response to parental concerns over general anesthesia, the senior author (R.M.R.) began offering office insertion of tubes in 2006. We report outcomes of office insertion of tympanostomy tubes, without general anesthesia, in children aged ≤ 18 months and compare these with those from a similar cohort of children who had tubes in the operating room (OR) under general anesthesia.

Methods

This study was conducted at a hospital-based pediatric otolaryngology practice. A concurrent historical cohort of all eligible children was identified by chart review of children aged 3 to 18 months who had bilateral tubes inserted as a sole procedure, in the office or in the OR, by the principal investigator (R.M.R.) between January 2006 and March 2009. Children were excluded if they had concurrent surgery, if tubes were inserted for an indication other than otitis media, if the child had a syndrome or craniofacial anomaly, or if the caregiver could not speak English. The study was approved by the Institutional Review Board at Long Island College Hospital.

All procedures were performed with Armstrong beveled fluoroplastic tympanostomy tubes and a binocular microscope. The choice of office vs OR was based on parental preference, except for children with stenotic ear canals, who were done

only in the OR. Office insertion was accomplished without local anesthesia with a papoose board for restraint and an assistant to steady the child's head. Parents were in the room and were counseled that the child might cry upon being restrained but would experience discomfort only during the myringotomy and actual tube insertion. Tube insertion in the OR was performed with midazolam premedication, followed by mask anesthesia with nitrous oxide and sevoflurane. Parents were not present in the OR during anesthesia induction.

The office charts were reviewed for clinical and demographic data. The primary outcome was caregiver responses about changes observed at a minimum of 6 months after ear tube insertion (data collected in November 2010) based on a 5-point Likert scale (*agree strongly, agree, neither agree nor disagree, disagree, disagree strongly, don't know*). An impartial research assistant (K.S.) recited the following items by telephone interview:

- Getting the ear tubes inserted was pleasant for my child.
- Having my child get ear tubes was pleasant for me as a parent.
- My child recovered quickly after the tubes were placed.
- My child had nightmares or bad memories after the procedure.
- I am satisfied with the overall experience of getting the ear tubes.

Secondary outcomes included time to obstruction of first tube, time to extrusion of first tube, time to malfunction (obstruction or extrusion) of first tube, and time to extrusion of both tubes. All statistical analyses were performed with

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Table 1. Characteristics of 94 Children Aged <19 Months Receiving Tympanostomy Tubes.

Characteristic	Inserted in Office	Inserted in OR	Total	P Value
Total subjects, n (%)	46 (49)	48 (51)	94 (100)	—
Child age, mo, mean \pm SD	11.3 \pm 3.2	13.4 \pm 3.6	12.5 \pm 3.6	.021 ^a
Male sex, n (%)	19 (40)	29 (60)	48 (51)	.098 ^b
Developmental delay or in therapy, n (%)	9 (20)	21 (44)	30 (32)	.012 ^b
Otitis media duration, mo, median (IQR)	6 (5)	6 (5)	6 (5)	.811 ^a
Prior AOM episodes, median (IQR)	5 (6)	5 (5)	5 (5)	.730 ^a
Indication for tubes, n (%)				
AOM or recurrent AOM only	19 (41)	4 (8)	23 (25)	<.001 ^b
OME only	10 (22)	9 (19)	19 (20)	
Both AOM and OME	17 (37)	35 (73)	52 (55)	
Middle ear effusion, n (%)				
None	2 (4)	4 (8)	6 (6)	.695 ^b
Unilateral	5 (11)	6 (13)	11 (12)	
Bilateral	39 (85)	38 (79)	77 (82)	
Bilateral flat (B) tympanogram, n (%)	23 (72)	24 (63)	47 (67)	.737 ^b
Valid audiogram, n (%)	38 (83)	44 (92)	82 (87)	.227 ^c
Hearing level in decibels, mean \pm SD				
Pure tone average (0.5, 1, 2 kHz)	37 \pm 15	36 \pm 10	35 \pm 18	.782 ^a
Speech reception threshold	30 \pm 23	33 \pm 14	30 \pm 15	.863 ^a
Years until survey, median (IQR)	1.1 (1.7)	1.6 (1.7)	1.6 (1.7)	.022 ^a

Abbreviations: AOM, acute otitis media; IQR, interquartile range; OME, otitis media with effusion; OR, operating room.

^aMann-Whitney *U* test.

^bPearson chi-square.

^cFisher's exact test.

Table 2. Mean Caregiver Responses Regarding the Tube Insertion Experience.

Survey Item	Response, Mean \pm SD ^a		P Value ^b
	Inserted in Office	Inserted in OR	
Getting the ear tubes inserted was pleasant for my child.	3.2 \pm 1.5	2.6 \pm 1.2	.060
Having my child get ear tubes was pleasant for me as a parent.	2.6 \pm 1.5	2.6 \pm 1.4	.848
My child recovered quickly after the tubes were placed.	1.5 \pm 0.8	1.6 \pm 0.7	.386
My child had nightmares or bad memories after the procedure.	4.2 \pm 1.0	4.5 \pm 0.6	.113
I am satisfied with the overall experience of getting the ear tubes.	1.4 \pm 0.7	1.3 \pm 0.6	.676

Abbreviation: OR, operating room.

^aRange from 1 (agree strongly) to 5 (disagree strongly).

^bMann-Whitney *U* test.

SPSS software,⁵ with a 2-sided alpha level of 0.05 for statistical significance.

Results

The sample included 46 children with tubes inserted in the office and 48 children with tubes inserted in the OR. The 2 cohorts were comparable (**Table 1**) with the exception of a slightly younger age and greater prevalence of acute otitis media in the office group. Tubes were inserted for recurrent acute otitis media (25%), otitis media with effusion (20%), or both (55%). Most children had bilateral effusions (82%) and mild hearing loss (median pure-tone average, 35 dB HL).

No differences were found (**Tables 2** and **3**) for tube insertion in the office vs OR for parent perceptions of child recovery ($P = .386$), overall satisfaction ($P = .676$), postprocedure nightmares or bad memories ($P = .113$), pleasantness of procedure for the parents ($P = .848$), or pleasantness of procedure for the child ($P = .060$). Similarly, no differences were found (**Table 4**) for median time to failure (extrusion or obstruction) of 1 tube ($P = .252$) or both ($P = .445$). No adverse events occurred during tube placement.

An additional 156 children (mean age, 12.6 months) had office insertion through June 2015, with a mean procedure time of 6 minutes (range, 4-10 minutes) and no complications.

Table 3. Caregiver Agreement with Survey Items Regarding Tube Insertion Experience.

Survey Item	Agreement, n (%) ^a		Odds Ratio (95% CI)	P Value
	Inserted in Office	Inserted in OR		
Getting the ear tubes inserted was pleasant for my child.	21 of 46 (46)	28 of 45 (62)	0.51 (0.22-1.18)	.113
Having my child get ear tubes was pleasant for me as a parent.	25 of 44 (57)	31 of 48 (65)	0.72 (0.31-1.67)	.446
My child recovered quickly after the tubes were placed.	43 of 46 (94)	46 of 48 (96)	0.62 (0.10-3.91)	.611
My child had nightmares or bad memories after the procedure.	4 of 44 (9)	0 of 42 (0)	—	.117
I am satisfied with the overall experience of getting the ear tubes.	44 of 46 (96)	47 of 48 (98)	0.47 (0.04-5.35)	.613

Abbreviation: CI, confidence interval.

^aIncludes *agree* and *strongly agree* responses.

Table 4. Outcomes of Tympanostomy Tube Insertion.

Outcome	Months to Outcome, Median (95% CI) ^a		P Value
	Inserted in Office	Inserted in OR	
One tube nonfunctional ^b	12.9 (8.3-17.0)	15.6 (12.3-18.8)	.252
Both tubes nonfunctional ^b	28.2 (17.2-39.2)	24.8 (20.4-29.1)	.445
Repeat tube insertion, if occurred	30.0 (27.9-33.6)	25.3 (22.9-27.7)	.138

Abbreviations: CI, confidence interval; OR, operating room.

^aKaplan-Meier survival analysis with log rank comparison.

^bNonfunctional defined as obstructed or extruded.

One case was aborted because of ear canal stenosis, and 1 child had early extrusion of 1 tube at 3 weeks that required replacement in the office.

Discussion

Our study found no differences between insertion of tubes in the office vs OR for caregiver reports of satisfaction with the tube insertion, the child's recovery, or the duration of tube patency. Office insertion of tubes may appeal to parents because it is rapid, avoids general anesthesia, does not require the child to fast, and allows the parent to immediately console and feed the child after the procedure.

Limitations of this study include nonrandomized allocation, recall bias by caregivers, the significant difference in median survey times between groups (1.1 years for office vs 1.6 years for OR; **Table 1**), and allocation bias caused by self-assignment to procedure setting by the caregivers. The generalizability of results is also unknown, since successful office insertion depends on the clinician's experience, technical skill, and judgment in identifying which children (and families) are best suited for in-office management. None of the procedures in this study were done by residents in training, so the feasibility and advisability of allowing trainees to do office tube insertion are unknown. Last, we did not analyze the financial impact of service site on caregiver perceptions, but nearly all procedures were performed as in-network insurance status.

The lack of differences between groups could be attributable to low statistical power. For example, parents of children who had tubes inserted in the OR reported that it was

“pleasant for their child” (**Table 3**) 62% of the time, compared with 46% in the office setting. Although the difference of 16% is not statistically significant, the sample size had only 36% power, with a 2-tailed alpha level of 0.05, to detect a difference of this magnitude.⁶ The impact of low statistical power on the precision of the results is also apparent in the wide 95% confidence intervals for all comparisons in **Table 3**.

We conclude that office insertion of tubes in young children is a feasible alternative to general anesthesia for caregivers and clinicians who are comfortable with this choice. The appeal of office insertion is enhanced by growing concerns over the potential adverse effects of general anesthesia on child development.

Author Contributions

Richard M. Rosenfeld, conception, analysis, interpretation, drafting, final approval; **Krishna Sury**, data acquisition, revision, final approval; **Christopher Mascarinas**, data acquisition, revision, final approval.

Disclosures

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