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Infectious Complications and Ventilation Tubes in Pediatric Cochlear Implant Recipients

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Objectives/Hypothesis: At many centers, ventilating tubes (VTs) are placed routinely in otitis-prone pediatric cochlear implant recipients. However, this practice is controversial, as many otologists believe VTs represent a possible route for contamination of the device. Toward better understanding of the safety of VTs, we reviewed our center's infectious complications and their relationship to the presence of tubes.

Study Design: Retrospective cohort study.

Methods: All patients undergoing cochlear implantation at our institution between 1990 and 2012 were reviewed for complications and their association with the presence of VTs.

Results: A total of 478 patients (557 ears) were reviewed, representing over 2,978 patient-years of follow-up. In 135 ears (24.2%), a VT was present at time of, or placed at some point after, implantation. The remainder either never had a VT or it had extruded prior to implantation. Overall, 63 complications occurred, of which 17 were infectious. The most common were cellulitis (four), device infection (five), and meningitis (four). Only one occurred while a tube was present, and was a device infection in an ear having a retained VT in place for almost 4 years. No difference was observed in overall rates of infectious complications between the group with VTs and those who never had VTs.

Conclusions: This series, the largest to date, indicates that infectious complications after cochlear implantation are rarely associated with the presence of VTs, supporting the concept that, overall, VTs are safe in cochlear implant recipients. Close monitoring is essential, including prompt removal of tubes when they are no longer needed.

Key Words: Cochlear implant, tympanostomy tubes, complications.

Level of Evidence: 4.

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INTRODUCTION

Cochlear implantation (CI) in children is being performed at an increasingly young age. In 2000, the US Food and Drug Administration lowered the age of eligibility from 24 to 12 months, and many centers are performing implantation even earlier.[1–3] As a result, the majority of children are now implanted before age 2 years, when they are also most prone to ear infections.[4,5] Hence, the pediatric CI surgeon is increasingly faced with the decision of whether to perform ventilating tympanostomy tube (VT) insertion in young cochlear implant recipients or candidates.

Insertion of VTs in the setting of CI is controversial. Proponents reason that ventilation reduces frequency of acute otitis media (AOM), which should reduce infectious complications such as otogenic meningitis.[6,7] Reduced surgical difficulty, due to decreased middle ear inflammation and bleeding, has also been reported after VTs.[8] On the other hand, critics argue that intubation of the tympanic membrane (TM) provides a route for external contamination of the middle ear and hardware by organisms residing in the ear canal. Also, some postulate that the mastoidectomy/posterior tympanotomy inherent in CI surgery may improve eustachian tube function, obviating the need for tubes. As a result, many pediatric CI surgeons avoid placing VTs in CI patients, and even remove existing tubes before implantation.[9,10]

The existing literature provides little guidance to the clinician faced with this dilemma. Several studies report CI to be generally safe in the presence of VTs,[8,11–14] though these were small studies. To help better understand the relative safety of VTs in cochlear implant recipients, we reviewed our center's experience with infectious complications, specifically in the context of whether VTs were present or absent. Our hypotheses were 1) that children who had tubes would not be more likely to experience infectious complications than those

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who did not; and 2) that infectious complications would rarely occur while tubes were in place, in accord with our clinical observations. At our center, VTs are placed routinely in pediatric CI candidates and recipients who have chronic otitis media (OM) with effusion or recurrent AOM, and are not routinely removed prior to implantation.

MATERIALS AND METHODS

Study Design and Setting

This retrospective cohort study was performed at The Children's Hospital of Philadelphia (Philadelphia, PA), an urban, tertiary care children's hospital. The Committees for the Protection of Human Subjects at our institution approved this study with a waiver of informed consent.

Participants

A total of 506 consecutive children who received CIs between 1990 and 2012 were reviewed. Of these, 478 met the following inclusion criteria: 1) underwent the surgery at our institution and 2) had postoperative follow-up data for at least 6 months that allowed assessment of middle ear and VT status.

Data Collection and Study Protocol

Data collection. Inpatient and outpatient charts, audiologic results, and surgical records were reviewed by the first six authors, and the following data were collected: age at cochlear implantation, model of cochlear implant, surgical details, and VT presence/patency on physical exam. A precise timeline was constructed to reflect the period of TM intubation (defined as the period between insertion date and the date of either extrusion or removal). Patency of VT was established by recording physical examination findings, volume on tympanometry, or both. The end date of VT intubation was defined as the first physical exam findings or tympanometry findings of an intact TM.

Each ear was considered individually and the ears were divided into two groups for the final analysis. The "tube" group was defined as any ear that had a VT present at the time of CI surgery, or received one at any time following implantation. The "control" group was defined as ears with no VT present at time of implantation and none placed subsequently. Ears in which VTs had once been present prior to CI surgery, but which had extruded and healed prior to implantation, were included in the control group. A small subset (six ears) of controls never previously had VTs, but received them only as part of urgent treatment for a complication (e.g., to drain acute mastoiditis). Because the objective of this study was to investigate whether VTs actually cause complications, not their role in treating them, these six ears were kept in the control group.

Any complication occurring after implantation was recorded. Infectious complications were defined as meningitis, mastoiditis, labyrinthitis, refractory AOM requiring intravenous antibiotics, wound infection, device infection, or exposure. Noninfectious complications included fluid leaks, device failures, or migration. TM perforations were recorded separately, but were not considered infectious complications. Dates of each complication were correlated to periods in which the respective ear had a VT present.

Statistical Analysis

The rates of infectious complications, both overall rate and rates of each infection subtype, in the tube and control groups were compared using Fisher Exact test. In ears having more than one infectious complication, each was considered a separate event.

TABLE I.
Demographic Information.

	No.	%
Gender		
Male	233	49
Female	245	51
Age at implantation		
Median	30 months	
Range	8 months–18 years	
Type of implantation		
Unilateral	399	83
Bilateral	79	17
Manufacturer		
Cochlear Corp.	405	73
Advanced Bionics	136	24
MED-EL	16	1

RESULTS

A total 557 ears were implanted at our institution between September 1991 and July 2012. Demographics and implant information are summarized in Table I. All procedures used a standard transmastoid, posterior tympanotomy/facial recess approach. Median follow-up duration was 5.6 years (range, 0.5–18.4 years). A total 135 ears (24.2%) had VTs either present at the time of implantation or placed at some point afterward. There were 252 VT insertions performed in this group, for an average of 1.9 insertions per ear. The control group consisted of 422 ears.

Sixty-three ears (11.3%) experienced complications in 53 children. These were hardware problems (39), infectious complications (17), perilymph/cerebrospinal fluid (CSF) leaks (three), and other (four). Hardware problems were the most common type (62%), with device failure the most common complication. Three patients had clear fluid leaks associated with inner ear malformations. No instances of facial nerve paralysis or paresis were observed. Eleven ears experienced episodes of transient skin inflammation at the magnet site, but these all resolved and were not counted as complications.

There were 17 infectious complications in 14 ears, detailed in Tables II and III. Eleven occurred in the control group (infectious complication rate, 2.6% per ear), and six occurred in the tube group (4.4% per ear) (Table III). This difference was not significant ($P = .39$, Fisher Exact test). The most common infectious complications were device infection, wound cellulitis, and meningitis. Of these, only meningitis was statistically different between tube and control groups and is discussed below. Of the 135 ears in the tube group, 131 (97.0%) never developed any infectious complication; the same was true for 412 of the 422 ears in the control group (97.6%).

TABLE II.
Infectious Complications in Control and Tube Groups.

	Case	Sex	Device	Complication	Age at Complication (Years)	Time Since Implantation	VT in Place at Time of Complication?	Time Since VT Extrusion	Cultures	Treatment	Outcome
Control Group: No VT/CI Overlap	1	M	Nucleus 24RECA	Wound cellulitis	4.0	7 days	N	—	—	Antibiotics	Resolved
	2	F	Nucleus 24RECA	Would cellulitis	4.5	40 days	N	—	—	Antibiotics	Resolved
	3	F	Clarion 1.2 with positioner	Wound cellulitis	3.0	4 months	N	—	—	Antibiotics	Resolved
	4	F	Nucleus 24RECA	Labyrinthitis	1.1	3 days	N	—	Negative (CSF)	Antibiotics	Resolved
	5	F	Clarion CII	Device infection, mastoid and cochlear portions	9.8	7 years	N	—	*Pseudomonas aeruginosa*	Antibiotics, steroids, explantation	Explantation, contralateral implantation
	6	M	Nucleus 24RECA	Device infection	3.0	14 months	N	—	*Haemophilus influenzae*	Antibiotics, explantation	Explantation, delayed reimplantation
	7	F	Clarion CII	Meningitis	4.0	28 months	N	—	Negative (CSF)	Antibiotics	Temporary hemiparesis that resolved
	8	F	Clarion 1.2 with positioner	Labyrinthitis, causing facial palsy and loss of stimulation	10.1	6 years	N	—	*Streptococcus pyogenes*	Explantation/ reimplantation, VT placement, antibiotics	Facial palsy resolved; no auditory recovery; contralateral implantation
	9	M	Clarion CII	Mastoiditis	4.5	10 months	N	—	Negative	VT placement, antibiotics	Resolved
	10	F	Clarion CII	Refractory AOM	6.9	5 years	N	—	*Streptococcus pneumoniae*	VT placement, antibiotics	Resolved
	11	F	Clarion CII	Device infection (abscess) with AOM	11.0	10 years	N	—	*Streptococcus pyogenes*	VT placement, I&D abscess, antibiotics	Resolved
Tube Group: VT Present at or After CI	12	F	Clarion CII	Wound cellulitis	3.4	18 months	N	22 months	Skin flora	Antibiotics	Resolved
	13	M	Clarion HiFocus	Meningitis (intraoperative CSF leak)	1.3	4 days	N	4 days	*Acinetobacter baumannii*	Antibiotics, lumbar drain, VT removal	Resolved
	14	M	AB HiRes 90K	Meningitis	2.0	10 months	N	3 months	*Streptococcus pneumoniae*	Tympanocentesis, antibiotics	Resolved
	15	M	AB HiRes 90K	Meningitis	3.8	32 months	N	25 months	Negative (CSF)	Antibiotics	Resolved
	16	M	Clarion HiFocus	Device infection, with spread to IAC	9.3	8 years	N	14 months	*Pseudomonas aeruginosa*	Ventricular drain, antibiotics, explantation	Explantation
	17	M	Clarion CII with positioner	Device infection (*Pseudomonas*) with abscess	4.6	3 years	Y	—	*Pseudomonas aeruginosa*	Antibiotics, debridement, explantation	Explantation, delayed reimplantation

AOM = acute otitis media; CI = cochlear implant; CSF = cerebrospinal fluid; I&D = incision and drainage; IAC = internal auditory canal; VT = ventilation tube.

TABLE III.
Comparison of Infectious Complications by Groups.

Complication	All Ears (N = 557)	Rate	Control Ears (N = 422)	Rate	Tube Ears (N = 135)	Rate	*P* (Control vs. Tube Groups)
Device infection	5	0.90%	3	0.71%	2	1.48%	.600
Cellulitis	4	0.72%	3	0.71%	1	0.74%	.999
Meningitis	4	0.72%	1	0.24%	3	2.22%	.047
Labyrinthitis	2	0.36%	2	0.47%	0	0%	.999
Refractory AOM	1	0.18%	1	0.24%	0	0%	*
Mastoiditis	1	0.18%	1	0.24%	0	0%	*
All infectious complications	17	3.05%	11	2.61%	6	4.44%	.388

Infection rates were compared using Fisher Exact test.
*Insufficient data.
AOM = acute otitis media.

Meningitis was uncommon (rate, 0.7% per ear overall). It was observed in both groups, but was more common in the tube group (2.2% vs. 0.24%, $P = .047$). A total of four episodes occurred in three patients, all of whom had severe inner ear dysplasias (all common cavity). None had a positioner in place. Two episodes (cases 14 and 15) occurred in one patient, who also had a previously repaired perilymph fistula. Her first episode was due to pneumococcus and occurred during AOM. She had VTs previously, but they had extruded 3 months earlier. Her second episode occurred 3 days after reimplantation surgery for device failure; no VTs were in place. Case 13 was a child whose initial implantation was complicated by a CSF leak from his cochleostomy; to control fluid flow, his existing VTs were removed and a lumbar drain was placed. Four days later fever prompted culture of the CSF from the lumbar drain; this revealed *Acinetobacter baumannii*. The lumbar drain was removed on suspicion of nosocomial infection. The third patient (case 7) had never undergone VT; she developed meningitis during a bout of AOM 2 years after implantation. All three patients recovered without sequelae.

Notably, of the six infectious complications that occurred in the tube group, all but one occurred after their VTs had already extruded (median 1.2 years after the TMs were noted to be healed). In only one case did an infectious complication occur while a tube was present. This single case (case 17) had VTs in place at the time of implantation, but was lost to follow up after 18 months. He returned 2 years later (42 months after VT placement) with an abscess over the receiver/stimulator. His ipsilateral tube was still in place, with chronic otorrhea. Cultures revealed *Pseudomonas aeruginosa*. The infection did not respond to aggressive debridement and intravenous antibiotics, and he ultimately required partial explantation (removing all except the electrode array to maintain cochlear patency). This was followed by reimplantation several weeks later, once the infection had cleared. This case was previously reported.[15]

Although not considered an infectious complication, TM perforations were recorded. Twelve tube-related perforations were observed, all in the tube group. Five of these healed spontaneously, leaving seven chronic perforations (or a 5.1% tube perforation rate). Of these, three were repaired surgically, two remain as stable perforations, and two were lost to follow-up. Not counted in those totals were three ears in the tube group that developed perforations associated with TM atrophy, atelectasis, or retraction pocket cholesteatomas; their VTs did not cause the perforations, rather, they were placed as part of their surgical treatment for that primary disease.

DISCUSSION

VTs are effective in reducing frequency of AOM and in clearing chronic middle ear effusions in children. Many pediatric implant surgeons routinely employ VTs in implant recipients in the same manner as for nonimplanted children, but this practice is the subject of debate. Several studies support their use, finding that otitis-prone implantees had no complications attributable to their VTs.[8,11–14,16] Additionally, a recent review of the literature by Preciado and Choi favors the use of tubes in patients prone to OM; however, the authors acknowledge that there is a lack of large, comprehensive studies of this topic.[17] On the contrary, many otologists steadfastly oppose the use of VTs in an implanted ear, citing a risk for contamination of the cochlear implant by organisms from the ear canal. A survey of the American Neurotology Society members found that 61% of respondents would remove an existing dry ventilation tube before or at the time of cochlear implantation.[10] Only 38% would proceed with CI surgery with the VT patent. Nevertheless, the same study reported that for a child who has serous OM preoperatively, the majority of otologists (59%) would place a tube at the time of CI or beforehand. Moreover, faced with an implanted child who develops recurrent OM, 67% reported they were at least as likely to place VTs as for a child without a cochlear implant. Combining these results with a low rate of reported complications due to VTs, this study concluded that children with serous OM or recurrent OM should have a VT placed and that a dry VT at the time of CI should be left in place.

One argument against VT placement is that ears undergoing CI may be protected from future infections due to the mastoidectomy intrinsic to the procedure, on the theory that the latter provides an "air reservoir" to buffer against middle ear pressure changes. This concept arose after several older studies showed improved outcomes in chronic TM perforations and chronic refractory OM after mastoidectomy.[18–20] By contrast, several more recent studies have failed to find benefit from mastoidectomy for either chronic OM,[21,22] or for OM in cochlear implant children.[23,24]

Toward the goal of understanding the safety of VTs in cochlear implant recipients, we designed the present study to directly investigate infectious complications and their specific relationship to the presence of a VT. This was done across a 22-year period in a large number of pediatric cochlear implant ears (557), a large percentage of which (24%) had undergone VT placement. Patients were divided into two groups based on whether tubes were ever present in the implanted ear after the date of implantation. In 557 ears, with a cumulative follow-up of 3,194 ear-years, we identified 63 complications, of which 17 were infectious. This overall rate of infectious complications (3%) was similar to that found in other recent series (1%–4%).[25,26] Importantly, we did not detect a significant difference in the overall rate of infectious complications between the group that had tubes and the control group (Table III). It is possible that a difference exists, but that our sample size provided insufficient power to detect a difference in such rare events. Nevertheless, it is noteworthy that we did not observe markedly higher infection rates in the tube group, because this group of ears is otitis prone by definition. It is conceivable that the VT protected these ears against at least a few serious infectious events. This idea is further supported by the fact that none of our patients with tubes suffered an infectious complication due to a middle ear pathogen during the period they had tubes in place, a time when presumably they were most prone to AOM.

Others have also found that VTs are likely protective against complications resulting from AOM. A study by Fayad et al.[13] and others (reviewed in Preciado and Choi[17]) found that VTs reduce the occurrence of AOM in cochlear implant recipients. These have led to a recent policy statement from the American Academy of Pediatrics, which includes the use of VT placement in the management of otitis-prone children, before or at the time of implantation.[27] Our results further support these recommendations.

Whether or not VTs protect against infectious complications, our series indicates that they rarely cause them. This is because 16 of our 17 infectious complications occurred when there was no VT in place: 11 in ears that never had VT, and five in ears well after their tubes had extruded. This suggests that VTs are safe in cochlear implant recipients, and agrees with prior, smaller series, which also failed to find infectious complications attributable to VTs.[17] Only one infectious complication occurred while a VT was present (case 17). His course was reported previously.[15] This child had a device infection that ultimately required explantation. Notably, the causative organism was *P aeruginosa,* a common bacteria in the ear canal. This suggests that external contamination of the middle ear via the VT was the likely etiology. It is noteworthy that this patient had prolonged retention of his VT (42 months), which is far longer than our usual practice. At our institution, VTs are routinely removed if they are retained in the TM longer than 2 to 3 years, with 2 years being preferred for implant recipients if they are no longer prone to infection. Prolonged intubation of case 17's TM may have created a surface for biofilm formation as well as a prolonged conduit for pathogens. It is possible that earlier removal of his VT may have prevented this complication in our patient. Certainly, if VTs are employed in patients with cochlear implants, they require close monitoring and expedient removal when they are no longer needed.[15]

Bacterial meningitis is a feared complication of CI and deserves special mention. It can originate from OM, with the cochlear implant serving to facilitate the ascending spread of bacteria, especially pneumococcus. Increased awareness has renewed interest in reducing OM risk after implantation, even changing the attitudes of some CI surgeons who previously opposed VT placement.[10] Meningitis risk is further increased by the presence of inner ear malformations and the use of intracochlear electrode positioners.[28,29] In the present series, all cases occurred in ears with severe inner ear anomalies. An otogenic source (particularly pneumococcus) was suspected or confirmed in three of the four episodes, two of which followed ear infections and one shortly after reimplantation surgery. Though the number of infections was very small, the rate of meningitis was statistically higher in the group that had VTs than in those who never had one. The most logical reason is that children needing tubes, as a group, are more otitis prone, hence already at higher risk. We suspect that, were it not for their tubes, this group would have had even more of these infections, though no definitive conclusions can be drawn given the low rate of meningitis in our series. Tubes or not, pneumococcal vaccination should be emphasized for all patients with cochlear implants, especially those with inner ear anomalies.[29]

This study has several limitations. It was a retrospective review and was not designed to systematically test the safety of ventilation tubes in the implant population. Because of the low incidence of infectious complications, such a study would require randomization of thousands of patients from multiple centers to be able to detect a meaningful difference in such a rare complication as device infection. It is possible our retrospective design missed patients who sought treatment at another institution without reporting it to us. However, this number is likely small, as we found detailed follow-up data on almost all of our program's cochlear implant recipients, especially for VT recipients, who follow up more often for tube checks (every 4–6 months).

CONCLUSION

The appropriateness of VTs in patients with cochlear implants remains a controversial topic. Practices

and opinions vary widely among otologists, in part due to the lack of prior studies and the rarity of these complications. Our retrospective review of 557 consecutive implant ears over 22 years, the largest to date, demonstrates that VTs are generally safe in the setting of cochlear implant. Ears with VTs in place at any time since implantation did not show a higher rate of infectious complications compared to ears that were never intubated. Only one infectious complication occurred while a VT was in place. This serious complication, a device infection requiring explantation, occurred in the setting of a retained tube present nearly 4 years. Tympanostomy tubes in implanted ears should be closely monitored and removed expediently when they are no longer needed.

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