**Objective:** To determine the long-term effects of ventilation tube insertion on hearing thresholds and tympanic membrane pathologic abnormalities in children with otitis media with effusion.

**Design:** Prospective cohort study.

**Setting:** Tertiary care children’s hospital, otorhinolaryngology and audiology service.

**Participants:** Patients aged 8 to 16 years who participated in a randomized controlled trial of medical vs surgical (ventilation tube [VT]) treatment for recurrent otitis media with effusion at ages 2.5 to 7 years.

**Main Outcome Measures:** Hearing thresholds and tympanic membrane sequelae.

**Methods:** One hundred thirteen of 125 children who had participated in the trial underwent blinded audiometric, tympanometric, otomicroscopic, and parental questionnaire evaluation 6 to 10 years following the trial. Thirty of 56 medical subjects received ventilation tubes and 18 of 57 VT subjects received more than 1 set of tubes. To evaluate sequelae risk associated with ventilation tubes independent of disease severity, we compared 27 medical subjects who never received ventilation tubes and 38 subjects randomized to VT who only received 1 set of tubes.

**Results:** Tympanic membrane pathologic abnormalities were present in 81% of VT subjects and 19% of medical subjects (relative risk, 4.4; 95% confidence interval, 2.2-9.9). Hearing thresholds were 2.1 to 8.1 dB higher in subjects treated with tubes (P=.005).

**Conclusions:** In children who were candidates for ventilation tube insertion randomly assigned to receive medical or VT treatment for otitis media with effusion, elevated hearing thresholds and tympanic membrane pathologic abnormalities were more common in VT subjects 6 to 10 years after insertion.

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UPTO 30% OF CHILDREN EXPERIENCE 3 OR MORE EPISODES OF OTITIS MEDIA BY AGE 6 YEARS; AS MANY AS 700,000 CHILDREN UNDERGO MYRINGOTOMY AND INSERTION OF VENTILATION TUBES (VTs) FOR THE TREATMENT OF CHRONIC AND RECURRENT OTITIS MEDIA WITH EFFUSION (OME) ANNUALLY IN THE UNITED STATES. Controversy surrounds VT utility for treatment of recurrent and chronic OME with regard to effectiveness and long-term sequelae. Studies have reported a several-fold increase in long-term risk of tympanic membrane (TM) pathologic abnormalities (scarring, perforation, and atelectasis) in children treated with VTs compared with medical management for OME. Other research has documented increased occurrence of TM pathologic abnormalities with number of VT insertions. A meta-analysis reported a 3.5-fold increased risk of TM pathologic abnormalities in ears receiving VTs vs ears without.

Long-term elevation of hearing thresholds have also been attributed to VT insertion. Hearing deficits of 1 to 7 dB have been observed in children with OME 3 to 7 years after VT placement compared with children not receiving VTs.

**For editorial comment see page 1183**

Methodological criticisms have been leveled against these studies. Some studies were not randomized raising the possibility that differences in TM pathologic abnormalities and hearing thresholds could be explained by more severe disease in children who received VTs (confounding by indication). In 1 study, follow-up was just over 50%, introducing possible selection bias. Also, outcome assessment was not blind. Finally, hearing threshold deficits of 1 to 7 dB, although statistically significant, may not be clinically relevant.
The lack of clarity surrounding the long-term sequelae of VT insertion prompted the present study. We followed up 113 children with chronic OME (all of whom were candidates for VT insertion) who participated in a randomized controlled trial (RCT)10 of VT insertion or medical treatment for 6 to 10 years following randomization to assess TM pathologic abnormalities and hearing thresholds.

### METHODS

#### SETTING, PATIENTS, AND SAMPLE SIZE

Patients were from a tertiary care pediatric hospital and were referred for otolaryngologist assessment of persistent OME episodes with hearing loss. Subjects were derived from 125 children who participated in an RCT (1985 and 1989) of VT or medical (M) treatment (low-dose sulfisoxazole for 6 months) for longstanding OME.10

All participants in this initial trial were candidates for VT insertion based on accepted conservative criteria (aged 2.5-7 years; long-standing middle ear effusion (>3 months); more than 2 physician-documented trials of short-term [10-day] antimicrobials; documented or parental reports of hearing loss of more than 3 months; greater than 25 dB hearing loss in 1 or both ears at 0.5, 1, 2, and 4 kHz at the time of entry into the trial; bone-conducted hearing thresholds of less than 10 dB; middle ear effusion at time of entry into trial). Patients were excluded if they had medically compelling reasons to have VTs placed (documented speech or language delay, poor school performance, Down syndrome, or cleft palate). These criteria and other details of this trial have been published previously.10

Fifty (83%) of 60 patients randomized to the VT group received T-type VTs. Thirty of the 38 VT subjects in the current study had T-type VTs placed. In the initial RCT, T-type VTs were routinely removed 12 to 14 months after insertion.

Subjects available for this follow-up were the 125 who participated in the initial study.10 Power calculations were conducted to establish the feasibility of obtaining adequate power for this study, based on mean hearing threshold difference between medical and surgical subjects using these assumptions: a 2-tailed α error rate of .05, a minimum difference to be detected in hearing thresholds of 5 dB hearing level (HL) (based on the American National Standards Institute standard 53.6, 1969), and a standard deviation of hearing thresholds of 6 dB HL (based on the initial trial). Using these estimates, statistical power was greater than 80% for sample sizes of more than 25 subjects per group.

Caregivers of children in the initial trial10 were contacted by phone and asked to attend 1 appointment for hearing testing and otomicroscopic examination. A tracking agency was used to locate subjects whose phone numbers were no longer current. A total of 122 of 125 subjects were contacted using these methods. Seven had moved out of town and 2 refused to return for the assessment, leaving 113 subjects (57 M and 56 VT) or 90.4%.

#### STATISTICAL ANALYSES

Based on an a priori decision (justified in the “Comment” section), the primary analyses were conducted on the 27 M subjects who never received VTs and 38 VT subjects who had only 1 set of VTs placed. For completeness, hearing threshold data and TM pathologic abnormalities data are also analyzed by intent to treat and by exposure to VTs (any subject who received VTs is counted in the VT group).

Using SAS software (SAS Institute Inc, Cary, NC), we analyzed the presence of TM pathologic abnormalities by comparing the proportion of subjects affected (either ear) in each group. Relative risks (RRs) and 95% confidence intervals (CIs) are reported.

To assess factors associated with any TM pathologic abnormalities and to adjust for potential confounders, multivariable logistic regression modeling was used. In addition to treatment group, we chose the following independent variables a priori on the basis of biologic relevance or because they have been identified as risk factors for recurrent otitis media in other studies: sex, number of physician-documented episodes of acute otitis media (lifetime), exposure to environmental tobacco smoke, and number of upper respiratory infections in preceding 12 months (parental report). Parental reports of school performance, ear complaints, and satisfaction with treatment were assessed using the Fisher exact test.

Air-conducted hearing thresholds (in decibels of hearing loss [dB HL]) were analyzed in 2 ways:

1. Continuously, using a random-effects, 2-way repeated-measures analysis of variance (ANOVA) with treatment as the between-subjects factor and frequency as the within-subjects factor. Interaction between the 2 factors was assessed first. Absence of interaction allowed for assessment of main effects of treatment and frequency. The mean hearing threshold for each frequency averaged across both ears was used. Post hoc comparisons were done with a modified Tukey procedure.

2. Dichotomously, by obtaining a mean of all 6 frequencies in the ear having higher hearing thresholds and designating subjects as having normal (≤15 dB HL) or elevated (>15 dB HL) hearing levels. Relative risk of elevated hearing thresholds and the 95% CI were calculated.

The usual assumptions underlying the use of ANOVA (homogeneity of variances and normality of the distribution of hearing thresholds at each level of independent variable) were assessed and considered valid for these data. Model fit and

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regression diagnostics were also assessed for the logistic regression analyses.

ETHICS

This study was reviewed and received approval from the institutional ethics review committee where the research was conducted (Children’s Hospital of Eastern Ontario, Ottawa).

RESULTS

SUBJECTS FOR ANALYSIS

The derivation of the subjects for the primary analysis is presented in Figure 1. Secondary analyses of hearing threshold data and TM pathologic abnormality data were based on initial randomization (intent to treat) and exposure to VTs (30 subjects who were randomized to the M group but ultimately received VTs are combined with all of the subjects randomized to VT treatment [n=86] and compared with the 27 subjects randomized to M treatment who never received VTs).

Table 1 displays descriptive statistics for medically and surgically treated subjects.

TM PATHOLOGIC ABNORMALITIES

Table 2 demonstrates a strong univariable relationship between surgical treatment and risk of myringosclerosis (RR, 4.5; 95% CI, 1.8-11.3); other TM pathologic abnormalities, such as perforation, retraction, or atelectasis (RR, 9.9; 95% CI, 1.4-71.2); and all TM pathologic abnormalities combined (RR, 4.4; 95% CI, 2.0-9.9).

When analyzed by intent to treat, the RR of any TM pathologic abnormality was 1.5-fold higher in subjects randomized to surgical treatment (95% CI, 1.2-1.9). Comparing all subjects who were exposed to VTs at any time (n=86) to the 27 subjects randomized to the M group but who never received VTs, the RR for any TM pathologic abnormality was 4.8 (95% CI, 2.2-10.6).

Risk factors for any TM pathologic abnormality were assessed using both univariable \( \chi^2 \) analysis and multivariable logistic regression. Both approaches indicated that the only statistically significant predictor of TM pathologic abnormality was treatment group (Table 3).

In the fully adjusted model, the odds ratio for surgical treatment increased to 26.1 compared with 19.5 in the univariable model. No other independent variable demonstrated a statistically significant association with risk of any TM pathologic abnormality.

The Hosmer-Lemeshow goodness-of-fit \( \chi^2 \) value was 5.0 (df = 7; \( P = .79 \)), indicating adequate fit of the model to these data.

Because the outcome of interest in this study (TM pathologic abnormalities) was common, the odds ratio does not approximate the true RR. The RR for surgical vs medical treatment (based on the adjusted odds ratio from the multivariable logistic regression model) was 4.5 (95% CI, 3.2-5.7) when a correction factor was applied.

None of the 2-way interactions between treatment and the other 4 independent variables significantly improved the fit of the model.
PARENTAL REPORTS OF SATISFACTION WITH TREATMENT, SCHOOL PERFORMANCE, AND EAR COMPLAINTS

During the parental interview, parents and caregivers were queried as to their children’s school performance in the past year, ear complaints (pain, decreased hearing, etc), and satisfaction with initial treatment provided (surgery or low-dose sulfisoxazole). Based on dichotomous responses, there were no statistically significant differences between treatment groups, based on the Fisher exact test (P>.10). These results are shown in Table 4.

HEARING THRESHOLDS

Examined continuously, a 2-way random-effects repeated-measures ANOVA demonstrated no statistically significant interaction between treatment and frequency in Hz (F$_{5,314}$=1.56, P=.17), thus permitting an interpretation of main effects. A significant main effect of treatment (F$_{1,63}$=8.8, P=.005) and a significant main effect of threshold (F$_{5,314}$=32.3, P<.001) were observed. Mean hearing thresholds were between 2.1 and 8.1 dB HL higher in surgical subjects at all frequencies. Using a modified Tukey procedure, we compared mean hearing thresholds between M and VT subjects at each frequency (250, 500, 1000, 2000, 4000, and 6000 Hz) and found statistically significant (P<.05) differences at 250, 500, 1000, and 6000 Hz. These results are displayed visually in Figure 2.

When hearing thresholds were dichotomized at less than 15 dB HL and at 15 dB HL or more, 3 M and 14 VT subjects had elevated thresholds. The RR of elevated hearing thresholds was 3.3 in surgical compared with medical subjects (95% CI, 1.1-10.4).

When analyzed by intent to treat, differences in hearing thresholds were 2.1 to 4.7 dB HL poorer in surgical subjects, but these differences were not statistically significant (2-way repeated-measures ANOVA, F$_{1,111}$=2.04, P=.15). The RR of pure-tone average hearing thresholds of 15 dB HL or more was 1.8 times higher in subjects randomized to surgical treatment vs those randomized to medical treatment (95% CI, 1.1-3.1). Analyzed by exposure to VTs, hearing threshold differences between those subjects with VTs and those without ranged from 5.1 to 10.8 dB HL worse in the former group (2-way repeated-measures ANOVA, F$_{1,111}$=12.2, P<.001). Statistically significant differences were observed at all frequencies (P<.05). The RR of pure-tone average hearing thresholds of 15 dB HL or more was 3.8 (95% CI, 1.3-11.3).

TM PATHOLOGIC ABNORMALITIES AND ASSOCIATED HEARING THRESHOLDS

To characterize the association of TM pathologic abnormalities and hearing thresholds, we compared mean hearing thresholds (pure-tone average over all frequencies) in those with or without specific otomicroscopic findings. In 46 (40.7%) of 113 children, otomicroscopic evidence of myringosclerosis was present. Mean hearing thresholds were not significantly different (9.2 dB HL in children with myringosclerosis vs 7.6 dB HL in those without) (t$_{112}$=0.79, P=.43). Forty-three (38.1%) of 113 subjects had “other” TM pathologic abnormalities (perforation, retraction pocket, or focal TM atelectasis). Mean hearing thresholds were significantly poorer in children

| Table 3. Tympanic Membrane Pathologic Abnormalities in Relation to Predictors Based on Multivariable Logistic Regression |
|--------------------|----------------|----------------|----------------|----------------|
| Predictor (Referent) | Affected by Group, No. | Crude Odds Ratio (95% Confidence Interval) | Adjusted Odds Ratio (95% Confidence Interval) |
| Surgical treatment (med) | 38 (27) | 19.5 (5.5-69.5) | 26.1 (5.9-114.4) |
| Boys (girls) | 37 (28) | 1.3 (0.5-3.4) | 1.8 (0.4-7.8) |
| AOM episodes, ≥5 (<5) | 29 (36) | 2.1 (0.8-5.9) | 2.5 (0.6-8.1) |
| Exposed to ETS (no exposure) | 30 (35) | 0.8 (0.3-2.1) | 2.2 (0.6-8.1) |
| URIs in prior year, >3 (≤3) | 36 (29) | 1.5 (0.6-4.0) | 1.2 (0.3-4.4) |

Abbreviations: AOM, acute otitis media; ETS, environmental tobacco smoke; URIs, upper respiratory infections.

*The crude odds ratio is a cross products ratio.
†The odds ratios in the multivariable model were adjusted for all other variables in model.

| Table 4. Parental Reports of Satisfaction With Treatment, School Performance, and Ear Complaints (Ear Pain or Difficulty Hearing) by Treatment Group |
|----------------|----------------|----------------|----------------|
| Variable | Outcome | Affected by Group, No. | P Value* |
| School performance | Not adequate | Surgical, 5/38 | .68 |
| Ear complaints | Yes | Surgical, 11/38 | .13 |
| Parental satisfaction | Yes | Surgical, 35/38 | .26 |

*The P values are based on the Fisher exact test, 2-tailed.
with 1 or more of these findings (18.1 dB HL in subjects with other TM pathologic abnormalities vs 8.4 dB HL in subjects without \( t_{112} = 5.1; P < .001 \)).

**STUDY FINDINGS**

Six to 10 years following randomization, VT insertion was associated with 4.5-fold and 9.9-fold increases in risk of myringosclerosis and other TM pathologic abnormalities, respectively. These findings are consistent with other published studies on this topic.3-9,13 We did not identify any other risk factors for the development of TM pathologic abnormalities other than treatment with VTs. Myringosclerosis itself was associated with only a small, statistically nonsignificant hearing loss (1.4 dB HL), whereas ears with other TM pathologic abnormalities (retraction, perforation, or atelectasis) had hearing thresholds 10 dB HL poorer than those without.

Hearing levels at follow-up were significantly worse in children who were initially randomized to VT treatment for OME. When hearing was analyzed continuously, these children had thresholds that were 2.1 to 8.1 dB HL worse than those of medically treated subjects. Examined dichotomously (using a 15 dB HL cutoff), the risk of elevated hearing thresholds was 3.3 times higher in subjects randomized to surgical treatment. Other published research has demonstrated similar results. One study reported a 5 to 7 dB HL hearing deficit in ears treated with VTs,21 while another found a 1.9- to 2.8-fold increase in RR (depending on frequency) of hearing loss of more than 20 dB HL in children receiving VTs.22

Based on our findings, the increase in mean thresholds between M and VT subjects of 2.1 to 8.1 dB HL is additive to the effect of recurrent OME. Some authorities would consider differences of this magnitude (2-8 dB HL) to be trivial, but our study also demonstrated a 3.3-fold increase in the risk of mean hearing thresholds greater than 15 dB HL. Although this represents only a mild degree of hearing loss, 2 points need to be considered. First, it appears (based on this study and others5,7,14) that elevated hearing thresholds associated with VT insertion are permanent. Second, conductive hearing deficits associated with VT insertion are probably additive to inevitable age-related sensorineural hearing loss (presbycusis) and noise-induced hearing loss.

Several possible mechanisms of VT-induced TM pathologic abnormalities and hearing loss have been postulated. Foreign body reaction and shear-stress forces have been put forth as possible mechanisms,15 as well as increased oxygen concentrations in the middle ear following VT insertion.16 One study identified aspiration of middle ear effusion at the time of VT placement as an etiologic factor for myringosclerosis,17 although a similarly designed study did not reach this conclusion.18

**SUBJECTS FOR COMPARISON**

Because subjects for this study were initially recruited into an RCT,10 it could be argued that these results should be analyzed by intent to treat and that to do otherwise introduces the possibility of postrandomization selection bias.19 Alternatively, these data could have been reported by exposure to VTs (all subjects who received VTs in both groups are counted as “exposed”). This approach clearly introduces confounding by indication (patients with more severe disease being more likely to receive a specific treatment)20—a criticism leveled against some previous studies of hearing loss associated with VT placement.21,22

Despite sacrificing statistical power, we determined a priori that the primary analyses for this study should be based only on those who were managed medically and never received VTs or who were managed surgically but received only 1 set of VTs. The present study is, in fact, a nonrandomized cohort study based on the initial randomization employed in the initial RCT. This randomization process ensured comparability of OME severity prior to enrollment into the RCT. During or after the RCT, 30 (52.6%) of 57 M subjects had VTs inserted and 18 (32.1%) of 56 VT subjects had more than 1 set of VTs placed for recurrent OME and associated hearing loss. Excluding these subjects from the analyses allowed us to assess a relatively homogeneous group of children (with respect to the severity of OME) and to obtain an accurate estimate of the effect of VT insertion. This approach permits the fairest estimate of the effect of VT insertion as a putative cause of TM pathologic abnormalities and associated hearing loss, independent of OME severity.

When data for all subjects were analyzed by intent to treat, we observed a RR of 1.5 for any TM pathologic abnormality (95% CI, 1.2-1.9) in surgical vs medical subjects. We did not detect statistically significant differences in mean hearing thresholds, but subjects randomized to surgical treatment were still 1.8 times more likely to have mean hearing thresholds of 15 dB HL or greater (95% CI, 1.1-3.1). When all subjects who were exposed to VTs were compared with subjects who never received VTs, markedly elevated risks of TM pathologic abnormalities and hearing thresholds of 15 dB HL or greater were observed (RR, 4.8; 95% CI, 2.2-10.6; and RR, 3.8; 95% CI, 1.3-11.3, respectively). Significantly poorer hearing (5-11 dB HL) was evident at all frequencies tested in subjects who had VTs placed (P<.05).

**LIMITATIONS**

This study is limited by the number of subjects included in the analyses. Although the sample size was adequate in terms of statistical power, the generalizability of the findings may be an issue.

Eighty-three percent of the subjects in this study had T tubes placed initially. Current practice is to reserve this tube type for children who fail an initial trial of bobbins. In the RCT,10 T tubes were removed 10 to 14 months after insertion. Usual practice is to leave them in situ for up to 24 months, so subjects in this study had T tubes in the TM for a shorter period of time than under normal circumstances. However, the number of subjects in this study who received bobbin-type VTs is sufficiently small that we avoid extrapolating these results to this more commonly used VT type.
Follow-up for this study was in excess of 90%, but, again because of small numbers, it is possible that data from the 12 subjects lost to follow-up would have altered the findings. A sensitivity analysis was not conducted because we could not ascertain which M subjects had VT insertions or which VT subjects had multiple insertions and would have therefore been excluded from the analyses.

Finally, the reliability and validity of parental reports of school performance were not assessed. However, these analyses were not central to the main objective of this study.

### CONCLUSIONS

In children who were candidates for VT insertion randomly assigned to receive medical or surgical treatment for chronic OME, poorer hearing thresholds and TM pathologic abnormalities were more common in VT subjects followed up for a mean average of 7 years. These findings are not explainable by differences in otitis media severity. More rigorous criteria for the selection of children receiving VTs for the treatment of chronic OME should be adopted.

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### REFERENCES


Someday, perhaps it will be possible to discover ways to change the arrangements of maternity hospitals so that they will still be safe and restful, and yet give fathers and mothers a little more chance, right from the beginning, to feel close and useful to their babies.

—From Dr Spock’s Pocket Book of Baby and Child Care, 1947
dren is less likely to involve vaginal intercourse because of the relatively small size of the hymen and vagina. The likelihood of identification of seminal fluids in the vagina is, thus, diminished. The collection technique for prepubertal children is also different from that of adolescents and adults. For vaginal swabs in young children, a blind swab is the preferred collection method, and there is no anticipation of collecting cervical fluids. In the adolescent and adult collections, a vaginal speculum is used, thus ensuring that deep vaginal, cervical, and other noticeable fluids can be obtained, which would likely increase the positive yield. One study reports that it is possible that sperm can be found in the adult endocervix up to 6 days after intercourse. In vaginal samples, mobile sperm commonly are not found after a few hours. In a study that looked at 1007 adult rape survivors, 919 vaginal specimens were collected and 344 (37.4%) were positive for sperm; 37% of the total number of cases were examined within 20 hours of the assault.

This study had limitations. It was a retrospective review, and many patient medical records had incomplete data. In addition, the number of semen-positive subjects was small.

In conclusion, our findings support those of the study by Christian et al that forensic evidence collections from child or adolescent patients are unlikely to yield positive results more than 24 hours after the event. No child younger than 12 years in our study was positive for semen from body sites; if semen is present in children younger than 12 years, it is likely to be on linens and clothing. Evaluation of these findings by experts in the field is recommended so that guidelines can be amended to reflect the latest medical evidence.

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REFERENCES


Correction

Error in Abstract. The article “Hearing Thresholds and Tympanic Membrane Sequelae in Children Managed Medically or Surgically for Otitis Media With Effusion,” by Stenstrom et al in the December issue of the ARCHIVES (2005;159:1151-1156), contained 2 incorrect numbers in the abstract. The sentence in the methods paragraph of the abstract on page 1151 should read as follows: “Thirty of 57 medical subjects received ventilation tubes and 18 of 56 VT subjects received more than 1 set of tubes.”