Incidence of and Risk Factors for Additional Tympanostomy Tube Insertion in Children

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Objective: To determine the incidence and risk factors that account for additional tympanostomy tube placement among children who have undergone an initial placement of ventilation tubes.

Design: Retrospective case review of consecutive patients.

Setting: A tertiary care pediatric hospital.

Patients: Five-year consecutive series of 2121 children cared for in a hospital-based, tertiary care pediatric otolaryngology practice.

Intervention: Subsequent need for additional ventilation tube surgery.

Results: Four hundred twenty-three (19.9%) of the 2121 children who underwent initial placement of bilateral myringotomy tubes (BMTs) between April 20, 1995, and May 25, 1998, subsequently had a second set of tubes placed by May 25, 2000. Children 18 months or younger at the time of initial BMT placement were nearly twice as likely (26.3% vs 15.9%) to undergo a second BMT procedure when compared with children who were older than 18 months at initial surgery (P < .005). The probability of having a second BMT procedure was reduced if adenoidectomy was performed at the first BMT procedure (0.08 vs 0.24, P < .001). Adenoidectomy status, craniofacial deformities, and a family history of adenoidectomy or tonsillectomy with or without BMTs were independent risk factors for multiple BMTs.

Conclusions: Epidemiologic analysis of this consecutive series of patients who underwent BMT placement in a tertiary care pediatric otolaryngology practice suggests that 1 in 5 patients will subsequently require a second set of ventilation tubes. Age younger than 18 months at the time of the initial BMT procedure is associated with an increased risk for additional surgery but is not an independent risk factor. Adenoidectomy reduces the incidence of subsequent BMTs following initial surgery.


Acute otitis media (AOM) and otitis media with effusion (OME) are the most common diseases that result in visits to the primary care physician by young children.1 Otitis is also the most common disease for which antibiotics are prescribed in childhood.2 Approximately 9 of every 10 children treated with antibiotics for recurrent AOM and OME will respond to the therapy.3 However, this still leaves about 1 million children a year in the United States in whom medical management fails. Thus, placement of bilateral myringotomy tubes (BMTs) is currently the most frequently performed surgical procedure on US children in whom antibiotic therapy for otitis has failed.4

There is a paucity of research that quantifies how often children who have undergone placement of an initial set of BMTs will subsequently require additional tympanostomy tube surgery.2 Recurrent AOM and chronic OME have been correlated with the maturation of the anatomic and physiologic structures of the eustachian tube and the immune system. In most published studies, the peak incidence for otitis appears to be in the 6- to 36-month age group, whereas the median age for placement of ventilation tubes is about 18 months.5 Since grommet-style ventilation tubes typically remain functional for 6 to 24 months (median, 12 months), it seems likely that children who undergo BMT placement at a younger age (<18 months) might experience a higher rate of additional tube placement and other related procedures (adenoidectomy, tonsillectomy) than children who undergo initial BMT placement at an older age (>18 months).

Published studies have indicated that the most significant risk factors for the de-
Description of 686 Pediatric Patients Undergoing BMT Procedures

<table>
<thead>
<tr>
<th>Variable</th>
<th>Single BMT Procedure (n = 263)</th>
<th>Multiple BMT Procedures (n = 423)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>196 (74.5)</td>
<td>353 (83.5)</td>
</tr>
<tr>
<td>Black</td>
<td>62 (23.6)</td>
<td>64 (15.1)</td>
</tr>
<tr>
<td>Asian</td>
<td>0 (0.0)</td>
<td>2 (0.5)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>4 (1.5)</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (0.4)</td>
<td>3 (0.7)</td>
</tr>
<tr>
<td><strong>Age at first BMT procedure</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>21.3 mo</td>
<td>17.8 mo</td>
</tr>
<tr>
<td>25th-75th percentile</td>
<td>13.6 to 38.1 mo</td>
<td>11.7 to 32.0 mo</td>
</tr>
<tr>
<td>Range</td>
<td>5.8 mo to 9.3 y</td>
<td>1.8 mo to 12.8 y</td>
</tr>
<tr>
<td><strong>Comorbidities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crianiotonal abnormalities</td>
<td>13/259 (5.0)</td>
<td>68/422 (16.1)</td>
</tr>
<tr>
<td>Presence of asthma, GERD, or seizures</td>
<td>54/244 (22.1)</td>
<td>90/367 (24.5)</td>
</tr>
<tr>
<td><strong>Premature birth</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>22 weeks' gestation</td>
<td>2/233 (0.9)</td>
<td>16/324 (4.9)</td>
</tr>
<tr>
<td>30-36 weeks' gestation</td>
<td>18/233 (7.7)</td>
<td>32/324 (9.9)</td>
</tr>
<tr>
<td>Total 36 weeks' gestation</td>
<td>20/233 (8.6)</td>
<td>48/324 (14.8)</td>
</tr>
<tr>
<td><strong>Day care (≥1 day per week with ≤3 children)</strong></td>
<td>116/249 (46.6)</td>
<td>131/371 (35.3)</td>
</tr>
</tbody>
</table>

Abbreviations: BMT, bilateral myringotomy tube; ENT, ear, nose, and throat; GERD, gastroesophageal reflux disease.
*All data are presented as number (percentage) of patients unless otherwise indicated.
† Significant unadjusted risk factor of multiple BMT procedures.

Development of recurrent AOM and chronic OME are attendance at large day care centers (>5 children), exposure to secondary tobacco smoke, a family history of ear disease, and craniofacial abnormalities. In addition, adenoid hypertrophy and chronic or recurrent adenoiditis have been postulated as contributing factors for the development of recurrent AOM and chronic OME. Several authors have recommended that adenoidectomy be performed at the time of second BMT placement to lessen the risk of subsequent otitis, although recently this recommendation has come under reconsideration. The aims of this study are (1) to determine the incidence of additional tympanostomy tube surgery and (2) to determine risk factors that account for additional surgery in children who have undergone initial placement of ventilation tubes.

**METHODS**

With the approval of our institutional review board, we performed a retrospective, cross-sectional analysis of all patients undergoing BMT placement by members of the Pediatric Otolaryngology Department at the Children’s Hospital of the King’s Daughters from April 20, 1995, to May 25, 2000. A list of all medical records to be reviewed was determined electronically through the billing service database using Current Procedural Terminology codes. Patients whose first BMT was placed before April 20, 1995, were excluded unless subsequent adenoidectomy was performed on April 20, 1995, or later. Patients were also excluded if the first BMT procedure or adenoidectomy was performed after May 25, 1998. This yielded 2121 records for review. Of these, 423 records were identified as having 2 or more BMTs. In addition, we randomly selected 263 medical records of patients undergoing only 1 BMT procedure for further analysis of information not kept in the billing database. Information collected included patient age, sex, race, comorbid conditions, number of otitis-related surgical procedures and dates, and risk factors and indications for these procedures. The following risk factors were tabulated: day care attendance, tobacco smoke exposure, family history (first-degree relative) of BMTs, adenoidectomy or tonsillectomy, presence of craniofacial abnormalities, and comorbid disease (asthma, environmental allergies, gastroesophageal reflux, seizure). Patients whose procedures were performed outside the Children’s Hospital of the King’s Daughters and for whom detailed information was unavailable were excluded from review. Data were entered into a Microsoft Access (Microsoft Corp, Redmond, Wash) database created specifically for this study. Data were analyzed using Stata 6.0 statistical software (Stata Corp, College Station, Tex). A χ² test was used to analyze the difference in the probability of having 1 vs multiple BMTs with regard to age and adenoidectomy status. A Wilcoxon rank sum test was used to examine the difference between median ages of the single- and multiple-BMT groups. Adjusted logistic regression analysis was used to determine independent risk factors for subsequent BMT procedures.

We identified 2121 patients presenting to the Department of Pediatric Otolaryngology at the Children’s Hospital of the King’s Daughters from April 20, 1995, to May 25, 2000, for BMT placement. A total of 1698 (80.1%) underwent a single BMT procedure, whereas 423 (19.9%) underwent 2 or more BMT procedures. Of the patients who required additional BMTs, 334 (15.7%) had only 2 procedures, whereas 94 (4.5%) had 3 or more procedures. No patient had more than 5 BMT procedures. After initial BMT placement, 957 patients (45.1%) had to undergo a third BMT procedure. The probability of needing a second BMT procedure was significantly reduced in this group compared with the single-BMT group and 57.9% of the multiple-BMT group. Whites had a 1.8 times greater risk of subsequent BMTs than did blacks, but race was not found to be an independent risk factor for multiple BMT procedures. A total of 527 patients (24.5%) in our study had adenoidectomy performed at the time of their first BMT procedure. The probability of needing a second BMT procedure was significantly reduced in this group compared with patients who had only a BMT procedure as their first procedure (0.08 vs 0.24, P < .001). In addition, the probability of undergoing a third BMT procedure was re-
duced when adenoidectomy was performed at or before the second BMT procedure (0.15 vs 0.40, P<.001). The median age of patients who underwent BMT placement plus adenoidectomy at the first procedure was 3.67 years vs those patients who had only a BMT placement at 1.54 years (P<.001). The median age of patients undergoing a second BMT procedure plus adenoidectomy was 3.49 years vs those who underwent a second BMT procedure without adenoidectomy at 3.09 years (P=.08).

Risk factors were analyzed using logistic regression analysis. Craniofacial abnormalities, family history of BMT procedures and/or adenoidectomy or tonsillectomy, and a family history of otitis, as evidenced by BMTs, were associated with an increased risk for additional BMT surgery. The presence of a craniofacial abnormality increased the odds of subsequent BMT procedures 3.91 (95% confidence interval [CI], 2.08-7.38; P<.001) times the odds of subsequent BMT procedures for patients without a craniofacial abnormality. A family history of adenoidectomy, tonsillectomy, or BMT placement increased the odds of subsequent BMT surgery 1.73 (95% CI, 1.24-2.41; P<.001) times the odds of patients without a family history of these procedures. A family history of only BMT placement marginally increased the odds of subsequent BMT procedures 1.44 (95% CI, 1.00-2.06; P=.048) times the odds of subsequent BMT procedures for patients without a family history of BMTs.

Potential risk factors not associated with increased odds of subsequent BMT procedures include exposure to tobacco smoke (0.81, P=.23) and the presence of asthma, seizures, reflux, or allergies (1.11, P=.58). The odds of subsequent BMT procedures in a child attending day care were 0.61 (95% CI, 0.44-0.85; P=.004) times the odds of subsequent BMT procedures for children not in day care.

Adjusted odds ratios using multiple logistic regression revealed that only the presence of craniofacial abnormalities, adenoidectomy status, and family history of adenoidectomy and/or tonsillectomy with or without BMT placement were independent risk factors for additional BMT procedures in our patient population.

### COMMENT

Bilateral myringotomy tube placement is the second most frequently performed pediatric surgical procedure, next to circumcision. Although there is much information available concerning the indications for and complications of BMT procedures, few data are available regarding the need for subsequent tympanostomy tube surgery following initial BMT placement in the pediatric population. In our study, 1 in 5 children undergoing BMT procedures required additional BMT surgery within a minimum follow-up of 2 years since their first procedure. As has been previously shown, male patients were more likely to undergo BMT procedures than female patients (61% vs 39%, respectively). Sex, however, was not a risk factor for additional BMT procedures in our study.

The highest prevalence of otitis media occurs in the 6- to 36-month age range and decreases thereafter. Given that the typical tympanostomy tube will remain functional for approximately 1 year, it should be expected that children undergoing their first BMT procedure at a younger age would be at increased risk for subsequent tube placement. In our analysis, children younger than 18 months at the time of first BMT procedure are 65% more likely to require subsequent BMT procedures than children older than 18 months. The median age at first BMT procedure for children who required only 1 BMT was nearly 24 months; therefore, tubes that function properly for 12 months in this subpopulation would span the time of greatest otitis media risk. However, age at first BMT procedure, although related to the need for further BMT surgery, is not an independent risk factor for additional BMT in our study. Other factors in our study, particularly craniofacial deformities and adenoidectomy status, may help to explain some of the difference seen with age. In addition, we chose 18 months as the cutoff for age comparison, and it may be that an older or younger age provides a significant result.

The rationale for adenoidectomy in the treatment of otitis media includes the reduction of nasal obstruction, improved eustachian tube function, and removal of a chronic nidus of infection from the nasopharynx. Clinical trials have demonstrated the efficacy of adenoidectomy in reducing the morbidity of chronic OME in older children. Neither of these studies specifically addressed the need for subsequent BMTs. Adenoidectomy, whether performed at the first or second BMT procedure, reduced the subsequent need for additional tube surgery in the present study. Patients undergoing BMT procedures alone were 2.5 times more likely to require another BMT compared with patients who had an adenoidectomy with their first BMT. In addition, adenoidectomy at the time of the second BMT placement resulted in a 3-fold decrease in the risk of needing subsequent BMTs.

Patients undergoing adenoidectomy in conjunction with their first BMT procedure were significantly older than those patients who underwent a BMT procedure alone (3.67 vs 1.54 years, P<.001). This finding is expected and is in agreement with our clinical practice of performing adenoidectomy in older children with chronic otitis in conjunction with the initial BMT procedure. There is not a significant age difference, however, between children undergoing a second BMT procedure plus adenoidectomy vs those undergoing a BMT procedure alone (3.49 vs 3.09 years, P=.08). In addition, age is not an independent risk factor for additional BMTs in our analysis.

It would appear from the data presented, therefore, that adenoidectomy status is an independent predictor of the need for subsequent BMT procedures and is independent of patient age. The adenoidectomy data presented herein are not controlled for indication (AOM vs OME), however, and these variables may change our results.

A recent retrospective review of 37,316 children in Canada found that adjuvant adenoidectomy reduced the need for subsequent tympanostomy tube insertion and readmission for otitis media–related conditions by half. The study also found that adenotonsillectomy provided an additional benefit beyond adenoidectomy. The percentage of children receiving adjuvant adenoidectomy or adenotonsillectomy at the time of the initial BMT procedure is similar between the Canadian study and ours.
(28% vs 24%), as is the reduction in need for subsequent BMTs. Although our study was smaller and did not specifically address adenotonsillectomy as a variable, the authors of the Canadian study were unable to address risk factors such as smoking, day care attendance, or comorbid medical conditions.

Previous studies have shown that attendance at day care centers, secondary exposure to tobacco smoke, family history of ear disease, allergies, and craniofacial abnormalities are risk factors for otitis media. In the present study, only craniofacial abnormalities and family history of adenoidectomy and/or tonsillectomy with or without BMT procedures were significant risk factors for subsequent BMT procedures. Attendance at day care conveyed a protective effect in our study. This may be due to a sampling error given the smaller size of the single-BMT group we analyzed. In addition, the data are not controlled for indication for BMT or for socioeconomic status, both of which may confound the day care results.

Craniofacial abnormalities were the most significant risk factor for subsequent BMT procedures in our study. A large number of children with craniofacial abnormalities are cared for at our tertiary care pediatric hospital, and this may not be reflective of the general pediatric population. The most frequently encountered craniofacial abnormalities in our population include cleft palate and Down syndrome. These special patient populations are known to have chronic ear disease and poor eustachian tube function, possibly as well as other developmental and sensory abnormalities. The presence of significant ear disease, hearing loss, and/or other developmental abnormalities in these children may lower both the surgeon’s and the families’ thresholds to perform BMT procedures. In addition, because of the small population of children with craniofacial deformities in our study, we could not determine if adenoidectomy at the time of initial BMT placement reduced the need for subsequent BMTs in this subgroup. This is an intriguing question that should be applied to other risk factor subgroups in future studies.

A family history of BMT procedures alone was not an independent risk factor for subsequent tube surgery; however, a family history of adenoidectomy and/or tonsillectomy and/or BMT procedure was an independent risk factor for additional BMTs. This finding may indicate a genetic predisposition for upper airway obstruction or chronic infection that may predispose the patient to middle ear disease. On the other hand, it may be that families who have experience with multiple surgical procedures are more likely to seek and agree to additional surgery.

The results of this study show that 20% of all children in our tertiary care pediatric otolaryngology practice undergoing a BMT procedure will require an additional set of ventilation tubes. Only the presence of a craniofacial abnormality, a family history of adenoidectomy and/or tonsillectomy with or without BMT placement, and not having an adenoidectomy with the initial BMT procedure were independent risk factors for additional tympanostomy tube placement. In agreement with previous studies, we found that adenoidectomy, performed at the time of initial or subsequent BMT, reduced the need for additional BMT surgery. Not all children undergoing ventilation tube insertion for the first time will require an adenoidectomy or adenotonsillectomy, however. Further study is needed to determine which subgroups of children will benefit most from adenoidectomy at the time of initial tube placement.

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REFERENCES