Anesthetic Complications of Tympanostomy Tube Placement in Children

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**Objective:** To determine the incidence of perioperative anesthesia complications during bilateral myringotomy with tympanostomy tube placement (BMTT).

**Setting:** Tertiary care children’s hospital where otolaryngology attending physicians and residents performed surgical procedures. Anesthesia providers included pediatric anesthesiologists, residents, nurse anesthetists, and students.

**Methods:** Medical record review was performed for a consecutive series of 3198 children undergoing BMTT (1000 prospectively, 2198 retrospectively). For the prospectively studied patients, major adverse events, which included laryngospasm and stridor, and minor adverse events, including upper airway obstruction, prolonged recovery, emesis, and persistent postprocedural agitation, were noted. Also recorded were the patient’s American Society of Anesthesiologists (ASA) physical class status, age, concurrent medical conditions, and type of anesthesia provider.

**Results:** Fewer than 9% of prospectively studied pediatric patients experienced a minor adverse event, whereas a major event occurred in 1.9%. Eighty-one percent of the events experienced were attributable to agitation or prolonged recovery. Neither ASA status ($P = .38$), age ($P = .15$), nor type of anesthesia provider ($P = .06$) were significantly related to the occurrence of an adverse event. However, a child with an acute or chronic illness has 2.78 times the odds of experiencing an adverse event compared with a child with no illness ($P < .001$).

**Conclusions:** Anesthesia administered for placement of tympanostomy tubes by physicians who specialize in the care of children in a tertiary care children's hospital is safe. The most significant predictor of a minor anesthetic event during BMTT is the presence of a preexisting medical condition or concurrent acute illness.

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The study was conducted at the Children's Hospital of the King's Daughters, Norfolk, Va, a tertiary care children's hospital. A total of 3198 patients underwent BMTT for indications of recurrent acute otitis media and chronic otitis media during the study period. The surgical procedures were performed by otolaryngology attending physicians and residents. Anesthesia providers included pediatric anesthesiologists, residents, nurse anesthetists, and students. Fellowship-trained pediatric anesthesiologists supervised all anesthesia providers. Induction was accomplished with mask anesthesia using halothane, oxygen, and nitrous oxide. All patients were given ibuprofen at standard doses (10 mg/kg) orally 30 to 60 minutes before induction of anesthesia.

A consecutive series of 1000 children was studied prospectively between November 1, 1998, and March 31, 2000. A data sheet was placed in the medical record of each child undergoing BMTT, and the anesthesia provider collected the information. The ASA status was used in an attempt to categorize the severity of illness (not including middle ear disease) for each patient (Table 1) before surgery. Data collected also included the age of the patient, concurrent or chronic medical conditions, level of anesthesia staff, anesthesia technique if different from the standard (halothane, oxygen, nitrous oxide), intraoperative and postoperative adverse events, treatment initiated in case of an adverse event, and outcome.

Major adverse events included laryngospasm, bradycardia, stridor, decreased oxygen saturation greater than 10% of baseline, and dysrhythmia. Minor adverse events included upper airway obstruction (transient loss of glossal and pharyngeal muscle tone), prolonged recovery longer than 30 minutes, emesis, and persistent agitation. Agitation was a subjective measure that was determined by recovery room nursing staff experienced in the care and recovery of pediatric surgical patients.

Complications documented as part of a hospital quality improvement program in a series of 2198 consecutive patients during a 3-year period were evaluated retrospectively. Under this passive surveillance system, the anesthesia provider recorded complications that occurred during a surgical procedure on a data sheet, and the information was entered into the computer system by the anesthesia administrative staff.

Concurrent medical conditions included upper respiratory tract infection (URI) the day of surgery, reactive airway disease (RAD), chronic pulmonary disease, gastroesophageal reflux disease (GERD), and other (congenital heart disease, chromosomal anomalies including trisomy 21, cerebral palsy, hydrocephalus, attention-deficit/hyperactivity disorder, and seizure disorder). These conditions were grouped according to type and frequency and related to the occurrence of specific adverse events.

The χ² test and logistic regression analysis were used to evaluate the association and the strength of the association between the occurrence of any adverse event and the proposed predictors. A large sample test of proportions was conducted to test a difference in incidence of any adverse event. A generalized logit model was fit to determine the predicted probability of a specific adverse event given a child’s medical condition. Significance was declared at P<.05. Analysis was conducted using STATA 6.0 software (Stata Corp, College Station, Tex).

### PATIENTS, MATERIALS, AND METHODS

The study was conducted at the Children's Hospital of the King's Daughters, Norfolk, Va, a tertiary care children's hospital. A total of 3198 patients underwent BMTT for indications of recurrent acute otitis media and chronic otitis media during the study period. The surgical procedures were performed by otolaryngology attending physicians and residents. Anesthesia providers included pediatric anesthesiologists, residents, nurse anesthetists, and students. Fellowship-trained pediatric anesthesiologists supervised all anesthesia providers. Induction was accomplished with mask anesthesia using halothane, oxygen, and nitrous oxide. All patients were given ibuprofen at standard doses (10 mg/kg) orally 30 to 60 minutes before induction of anesthesia.

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### RESULTS

Active monitoring recorded adverse events in 8.8% of children undergoing BMTT who were studied prospectively, whereas major events occurred among 1.9%. All patients were discharged home the same day as the procedure; there were no admissions, no consultations required from other services, and no deaths during this study period. Table 2 lists the classification and frequency of adverse events recorded. Note that 11 patients (1.1%) experienced more than one adverse event.

Of the 2198 operative cases studied retrospectively, 3 adverse events (0.1%) were documented using passive surveillance. All recorded events involved laryngospasm, with 1 patient requiring intubation and 2 cases of spontaneous resolution with supportive care. A significantly greater number of events, 104 (incidence, 10.4%), was reported in the 1000 cases using prospective, active monitoring (P<.001). Subsequent results reflect only the 1000 patients studied under the active monitoring system.

Table 1 demonstrates the distribution of ASA status with the observed incidence of any adverse event. There was a higher incidence of adverse events in patients classified as having a physical class status of ASA 2 when compared with patients classified as having a status of ASA 1, 3, or 4. Although there was no statistically significant relationship between ASA status and the occurrence of an adverse event overall, the number of patients with an ASA 3 or 4 status was very small, creating a low statistical power and an inability to detect a relationship. The incidences of adverse events for patients grouped by age were as follows: 0- to 1-year-old patients, 9.5% (17/178); 1- to 3-year-old patients, 10.9% (49/450); 3- to 6-year-old patients, 7.5% (18/239); and patients 6 years and older, 15.0% (20/133).
Table 3. Predicted Probability of an Adverse Event for a Given Medical Condition*

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Pulmonary Disease</th>
<th>URI</th>
<th>GERD</th>
<th>Other</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agitation</td>
<td>.14</td>
<td>.01</td>
<td>.03</td>
<td>.01</td>
<td>.047</td>
</tr>
<tr>
<td>Airway obstruction</td>
<td>.03</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
<td>.02</td>
<td>.005</td>
</tr>
<tr>
<td>Emesis</td>
<td>&lt;.001</td>
<td>.05</td>
<td>.03</td>
<td>.01</td>
<td>.006</td>
</tr>
<tr>
<td>Laryngospasm</td>
<td>.02</td>
<td>.045</td>
<td>.03</td>
<td>.02</td>
<td>.001</td>
</tr>
<tr>
<td>Prolonged recovery</td>
<td>.06</td>
<td>.07</td>
<td>.03</td>
<td>.04</td>
<td>.02</td>
</tr>
<tr>
<td>Other</td>
<td>.01</td>
<td>.01</td>
<td>.05</td>
<td>.01</td>
<td>.005</td>
</tr>
<tr>
<td>None</td>
<td>.73</td>
<td>.75</td>
<td>.82</td>
<td>.87</td>
<td>.91</td>
</tr>
</tbody>
</table>

* URI indicates upper respiratory tract infection; GERD, gastroesophageal reflux disease.

No association between age and the occurrence of an adverse event was found (P = .14).

The most commonly noted concurrent medical conditions in this patient population with middle ear disease were URI (25.3%), RAD (31.6%), chronic pulmonary disease (33.3%), and GERD (19.4%). In addition, there is a significantly higher prevalence of adverse events in patients with other medical conditions (13.0%) compared with children with no concurrent medical conditions (7.7%). Additionally, the probability of experiencing an adverse event is greater for a patient with a medical condition vs one with no medical condition (Table 3). Of the 104 patients experiencing an adverse event, only 4 patients (3.8%) had congenital heart disease, chromosomal anomalies, cerebral palsy, hydrocephalus, or seizure disorder. None of these patients experienced multiple adverse events.

Overall, the type of anesthesia provider was not a significant predictor of the occurrence of an adverse event (P = .06). All anesthesia providers were supervised by attending pediatric anesthesiologists, and no differences in the occurrence of adverse events were found when comparing attending anesthesiologists to nurse anesthetists or students. Twelve occurrences of persistent agitation or prolonged recovery were recorded when a resident was an anesthesiology provider (n = 60), for a relative risk of an event of 2.3 (95% confidence interval, 1.28-4.12; P = .006), when compared with anesthesia administration by a staff anesthesiologist. However, there was not a higher incidence of major adverse events when the resident was the anesthesia provider.

The ability of the hospital quality improvement program to provide useful information for changing medical practice was evaluated by comparing the data obtained from retrospective analysis of 2198 patients who underwent BMTT to the data obtained from 1000 patients studied prospectively. Three episodes of laryngospasm were recorded with the passive monitoring system (incidence, 0.1%), whereas 104 events (incidence, 10.4%) were recorded with the active monitoring system. Of the events recorded prospectively, 86.5% were classified as minor events, and 13.5% were classified as major events. It is likely that only major events would be recorded through a voluntary reporting system such as the quality improvement program. Even when comparing only the number of major events documented in the 2 systems, more events were reported with the active monitoring system. A possible reason for this is that there was no stated penalty for noncompliance with the passive monitoring system and little incentive for individuals to participate. Such a program would be less likely to change practice patterns or improve patient outcomes.

There are few perioperative anesthetic complications associated with BMTT. Indeed, only 8.8% of children experienced a minor event, 1.9% experienced a major event, and no patient required admission to the hospital. All events were successfully treated without significant or long-term morbidity. Most adverse events (81%) recorded were attributable to agitation (57/104) and prolonged recovery of more than 30 minutes (27/104). This study attempted to calculate the frequency of events related to the administration of general anesthesia for the placement of tympanostomy tubes. Although persistent agitation and prolonged recovery are not truly complications of the administration of general anesthesia, the authors believed that these were common occurrences that should be documented. Both persistent agitation and prolonged recovery are subjective measures of the degree of impairment of the patient postoperatively, as determined by the experienced nursing staff and supervising fellowship-trained pediatric anesthesiologists, respectively. No attempt was made to quantify the degree of agitation apart from allowing descriptions by the nursing staff; everything from “fussy” to “totally inconsolable” was included under this heading. Prolonged recovery was a measure of the sleepiness of the patient after the procedure. The benefit of including these subjective events in the study is to relay to parents that both agitation and sleepiness are common and expected occurrences after general anesthesia and that they resolve without sequelae. If agitation and prolonged recovery are not included as adverse events, then the number of minor adverse events decreases significantly to 25 (incidence, 2.5%).

The most commonly occurring events requiring some form of intervention in this study were upper airway obstruction (n = 9), laryngospasm (n = 9), and cardiac dysrhythmia (n = 1). Airway events were treated successfully with jaw thrust, placement of an oral airway, or positive pressure ventilation in all cases. One patient with laryngospasm required the placement of a peripheral intravenous tube for intravenous medication, but no patients in the prospectively studied group required intubation. One patient developed premature ventricular complexes that
resolved with discontinuation of halothane use. Halothane has been reported to cause cardiac dysrhythmias in up to 34% of children younger than 14 years, but there were no cases of malignant arrhythmias or cardiac events documented during the study period.

This study found no statistically significant association between the ASA status and the occurrence of an adverse event, which contrasts with the finding that the existence of a concurrent medical condition was associated with occurrence of an adverse event. Although the ASA status does not directly measure the patient’s anesthetic risk, it should relate closely to an associated illness. The assignment of the ASA physical status is contingent on individual subjectivity by the anesthesia provider as used in practice without external intervention. Although the authors corrected grossly obvious errors in classification, the subjective nature of the classification system still leaves room for a lack of statistical correlation between the ASA status and the occurrence of an adverse event. The discrepancy is most likely due to failure of the system to classify correctly and consistently an illness to the proper ASA status. The most significant predictor of an adverse event during BMTT was the presence of a preexisting medical illness or concurrent acute illness. Otherwise healthy children with a history of recurrent acute otitis media or chronic otitis media have only a 9% probability of experiencing any adverse event. The results of the study support the intuition that a patient with pulmonary disease has a higher probability of experiencing airway obstruction, a patient with GERD would be more likely to have emesis, and a patient with a URI is more likely to experience laryngospasm than a patient with no comorbid factors. Tait and Knight found that the prevalence of perioperative complications in children with URIs was similar to that in children without URIs. Markowitz-Spence et al noted that 4 of 7 patients with severe airway obstruction requiring medication intravenously and/or intubation had a URI at the time of surgery. They concluded that when a URI is present with other chronic medical problems, the anesthesia risk might be higher. This study similarly demonstrates a higher probability of an adverse event occurring in a patient with a URI ($P=.25$) compared with a healthy patient with no comorbid factors ($P=.09$). However, there were no serious complications that resulted in significant morbidity, and such adverse events that do occur can be managed expectantly with good success. We concur that in an otherwise healthy child the presence of a URI is not a reason to abandon BMTT.

At the time that the study was conducted, sevoflurane was not available for use in this tertiary care children’s hospital because of its high cost. Halothane, with its well-known effects, was the anesthetic of choice. Halothane has been in widespread use for the past 40 years, has a proven clinical track record, remains the least costly of the inhalation agents, and possesses the highest potency. Disadvantages of halothane include its pungent odor, tendency for a prolonged emergence, and potential for induction of bradycardia, hypotension, and ventricular ectopy. The adverse events directly attributable to halothane, prolonged recovery in particular, could be better defined with a comparable study using sevoflurane as the anesthetic agent.

Sevoflurane, on the other hand, is not without its disadvantages. There is increasing concern about sevoflurane’s relationship to postoperative agitation and behavioral changes that may last for days. There is an increase in the incidence of agitation and excitement during emergence from sevoflurane, almost 3-fold greater than the incidence after halothane anesthesia, which is noted in 67% of children.

Given the well-established efficacy of ibuprofen in treating mild pain, we thought that the use of this medication in the study was warranted to provide analgesia for postoperative pain. Ibuprofen was chosen as the medication most likely to be efficacious with the fewest adverse effects, including lack of behavioral changes. Although anxiolytics such as midazolam are routinely used in some centers to decrease perioperative anxiety, we prefer to avoid the routine administration of these medications in all patients. Midazolam is well known to increase the incidence of dysphoria in the recovery room, which may increase the incidence of recorded events that could be directly attributable to the medication and mask the true results of the study. Additionally, patients receiving oral midazolam premedication (prior to returning to the operating room) have significantly longer recovery times.

We acknowledge that the use of preoperative ibuprofen may falsely lower the recorded incidence of postoperative agitation that could be attributable to pain.

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REFERENCES


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