Tubes, Antibiotic Prophylaxis, or Watchful Waiting: A Decision Analysis for Managing Recurrent Acute Otitis Media

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BACKGROUND. The two most frequently used options to reduce the occurrence of acute otitis media (AOM) are tympanostomy tubes and prophylactic antibiotics. The goal of this study was to create a decision model to identify which intervention, if any, is preferred from the perspective of parents with young children.

METHODS. We developed a decision analysis model based on probabilities obtained from the literature and outcome disutilities obtained by interviewing parents. These parameters were placed into the model along with the anticipated number of episodes of AOM a child was expected to have in the coming year without intervention. Sensitivity analyses were performed on the effectiveness of the interventions, the disutilities (burdens associated with specific outcomes or interventions) associated with the interventions, and the characteristics of AOM episodes that the child would experience without any intervention.

RESULTS. Thirty-seven parents with young children were interviewed for this project. The preferred intervention for a child was sensitive to the number of episodes of AOM the child was anticipated to have in the coming year, the percentage of these episodes predicted to be severe, and how parents rated tympanostomy tubes compared with prophylactic antibiotics. In our base case of four episodes of AOM in the coming year (two mild episodes and two severe episodes), we found that tympanostomy tubes resulted in the best average outcome. Under different patient conditions, however, the preferred strategy could be either the use of prophylactic antibiotics or watchful waiting.

CONCLUSIONS. In our base case, the model suggested that typanostomy tubes were preferable to prophylactic antibiotics. However, there is no single preferred preventive intervention for all children with recurrent AOM because of variation in the character of infections and the values parents give to the potential outcomes.

KEY WORDS. Otitis media; decision analysis; tympanostomy tubes insertion; prophylaxis; physician, family.
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Few people escape childhood without an episode of acute otitis media (AOM) and some experience a recurrent string of episodes.[1] There are multiple reasons to modify a child's recurrent pattern of acute otitis media. From the child's perspective, possibly the biggest benefit of intervention is the reduction of days with illness, pain, and fever. The prevention of recurrent AOM can also be beneficial to families. A recurrently ill child can be a source of stress and frustration for parents, can disrupt their daily routine, and give rise to difficult and competing time demands. Additionally, the expense of treating recurrent AOM is not trivial. The average total cost for a single episode has been estimated to be more than $100, mainly because of indirect costs resulting from a parent's time away from work and lost wages.[2] Permanent hearing loss and delayed language development are also reasons cited to support intervention.

Two interventions widely used to reduce the occurrence of AOM are tympanostomy tubes and daily prophylactic antibiotics.[3] The relative advantages and disadvantages of these two interventions are debated, making it difficult for parents and physicians to select which intervention, if any, to use. To help with this task, we built a decision model based on measures of parental preferences.

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METHODS

Decision analysis can be used to determine the preferred intervention under different conditions. This approach is able to incorporate estimates of the probability of future events with the utilities of these outcomes into a single metric. By calculating the expected utility of competing therapies, a physician can recommend the therapy that offers the best average outcome for a patient.

MODEL

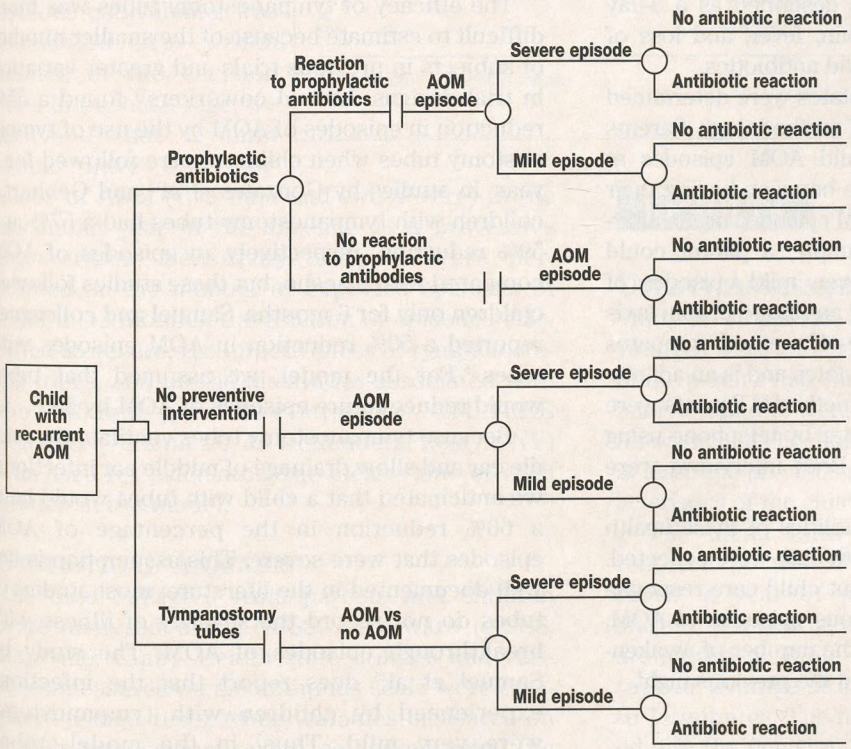
A decision model was developed in which children were followed for a 1-year period using one of three strategies: tympanostomy tubes, antibiotic prophylaxis, or no intervention (Figure 1). The different strategies can impact the health status of a child because the interventions differ in their effectiveness of reducing illness and differ in their adverse effects. We assumed that the number of episodes of AOM and the severity of these episodes in the coming year could be predicted from a child's past experience. Future episodes of AOM were dichotomized as being either mild or severe. The model incorporated disutilities for each episode of AOM on the basis of severity of illness.

Disutilities associated with tympanostomy tubes and antibiotic prophylaxis were included in the treatment branches. The disutility for an antibiotic reaction is incorporated into each branch of the model whenever a child was exposed to antibiotics. Therefore, the net health effect for each branch of the model was the sum of the disutilities from the infections, the disutilities of antibiotic reactions, and the disutility from the preventive intervention.

We used a 1-year time horizon because the long-term outcomes of middle ear infections and of the preventive interventions are poorly understood. Acute otitis media may cause permanent injury from scarring and sclerosis of the tympanic membrane, fixation of the ossicular chain, and sensorineural injury, but the relationship between these complications and recurrent AOM is not defined.[4] The medical literature also contains reports about tympanic membrane sclerosis, scarring, and perforation associated with tympanostomy tubes, although the true long-term impact of tubes remains unknown.[5,6] Finally, there is concern about the problem of bacterial resistance associated with long-term antibiotics, but the impact of this on an individual child has not been well defined.[7]

FIGURE 1

Decision model used for the analysis of the management of recurrent acute otitis media



AOM denotes acute otitis media.

DISUTILITIES

Disutilities, ie, burdens associated with specific

outcomes or interventions, for the model were obtained by interviewing parents. Over a 10-week period, parents of children between the ages of 6 months and 6 years seen at the Department of Family Medicine for AOM were eligible for interview. Parents of children in this age group who were seeing a physician for a well-child checkup during the study period were also interviewed.

TABLE 1

Demographic and Clinical Descriptors of the 37 Children in the Study

Descriptor	Children with AOM (n=19)	Children without AOM (n=18)	P
Mean age, in months	21.8	23.3	.82*
Mean previous episodes of AOM	5.7	4.7	.35*
Mean temperature of child, in °F	99.4	98.5	.04*
No. with normal activity in past 24 hours (%)	8 (42)	18 (100)	<.01†
Mean awakenings during night before visit	2.0	0.5	<.01*
No. in daycare (%)	3 (16)	6 (33)	.21†
No. with health insurance (%)	17 (89)	18 (100)	.16†
Current physician visit self-paid (%)	4 (21)	2 (11)	.41†
No. with single parent (%)	2 (11)	2 (11)	.96†
Mean no. of children in family	2.0	1.5	.01*

*P value determined by *t* test.
†P value determined by chi-squared test.

Participating parents were asked to read descriptions of mild AOM, severe AOM, antibiotic reaction, antibiotic prophylaxis, and tympanostomy tube placement and maintenance. A mild episode of AOM was described as ear pain but no fever, and full recovery within 24 hours of starting antibiotics. A severe episode of AOM was described as a 3-day course of illness with ear pain, fever, and loss of appetite treated by bed rest and antibiotics.

Disutilities for the health states were determined by using an episode trade-off methodology. Parents identified the number of mild AOM episodes at which they felt no preference between having their child experience the mild AOM episodes or the alternative health state. For example, a parent could decide that experiencing seven mild episodes of AOM was equivalent to using antibiotic prophylaxis for 1 year. The episode trade-off method compares competing temporary health states and is an adaptation of the sick-day trade-off method.[8,9] Parents were reinterviewed 7 to 10 days later by telephone using the same trade-off method. Both interviews were timed.

After determining the disutilities of these health states, demographic and health data were collected. Parents were questioned about child care responsibilities, the number of previous episodes of AOM, health insurance status, and the number of awakenings the child had experienced the previous night.

PROBABILITIES

Prophylactic antibiotics were estimated to reduce the number of episodes of AOM by 58% on the basis of a previous meta-analysis.[10] We estimated the probability of a drug reaction from a single course of antibiotics to be 5%, and the probability of a drug reaction from a course of prophylactic therapy to be 7%.[11]

The efficacy of tympanostomy tubes was more difficult to estimate because of the smaller number of subjects in previous trials and greater variation in trial designs. Le and coworkers[12] found a 55% reduction in episodes of AOM by the use of tympanostomy tubes when children were followed for 1 year. In studies by Gonzales et al[13] and Gebhart,[14] children with tympanostomy tubes had a 57% and 59% reduction, respectively, in episodes of AOM compared with placebo, but these studies followed children only for 6 months. Samuel and colleagues reported a 50% reduction in AOM episodes with tubes.[15] For the model, we assumed that tubes would reduce future episodes of AOM by 55%.

Because tympanostomy tubes ventilate the middle ear and allow drainage of middle ear infections, we anticipated that a child with tubes would have a 66% reduction in the percentage of AOM episodes that were severe. This assumption is not well documented in the literature; most studies of tubes do not record the severity of illness with breakthrough episodes of AOM. The study by Samuel et al[15] does report that the infections experienced by children with tympanostomy were very mild. Thus, in the model, tubes reduced both the total number of episodes of AOM and the percentage of these episodes that

TABLE 2

Mean Disutilities of Health States as Measured in the Number of Episodes of Mild AOM

Health State	All Children (n=37)	Children with AOM (n=18)	Children without AOM (n=19)	P*
Severe AOM, mean (SD)	8.9 (7.7)	7.3 (6.3)	10.4 (8.7)	.23
Antibiotic reaction, mean (SD)	8.4 (7.0)	5.8 (4.0)	10.8 (8.4)	.03
Prophylactic antibiotics, mean (SD)	7.2 (6.5)	7.2 (6.2)	7.4 (7.0)	.94
Tympanostomy tubes, mean (SD)	10.0 (6.3)	10.3 (6.6)	9.8 (6.1)	.80

Note: Data are from the initial measurement of utilities.
* *t* test comparing the disutilities reported by parents of children with AOM compared with those reported by parents of children being seen for well-child checkups.
AOM denotes acute otitis media; SD, standard deviation.

were severe, and prophylaxis reduced the total number of episodes of AOM but had no impact on the fraction of AOM episodes that were severe.

The net health effect, measured in mild AOM episode equivalents, was calculated for each branch of the decision tree. In the base case, we assumed that a child would have four episodes of AOM (two mild and two severe) in the upcoming year in the absence of a preventive intervention. Sensitivity analyses were performed on the number of expected episodes of AOM in 12 months, the fraction of episodes classified as severe, the effectiveness of tympanostomy tubes, and on the disutilities associated with the different preventive strategies. SMLTREE software (version 2.9, JP Hollenberg, Roslyn, NY) was used for calculating the mean value of each branch in the model.

TABLE 3

Preferred Intervention to Prevent AOM as Determined by the Decision Model

Anticipated Total No. of AOM Episodes in Next 12 Months	No. of Severe Episodes of AOM in Next 12 Months: None	One	Two or more
Three	Nothing	Nothing	Tubes
Four	Nothing	Prophylaxis	Tubes
Five	Nothing	Prophylaxis	Tubes
Six	Nothing	Prophylaxis	Tubes

AOM denotes acute otitis media.

Statistical Analysis

The data collected from parents and children were analyzed using NCSS97 software (NCSS, Kaysville, Utah). Health state utilities and variables measured on a continuous scale were compared using *t* tests, while variables measured on a dichotomous scale were compared using the chi-square test. An alpha of .05 was deemed significant.

RESULTS

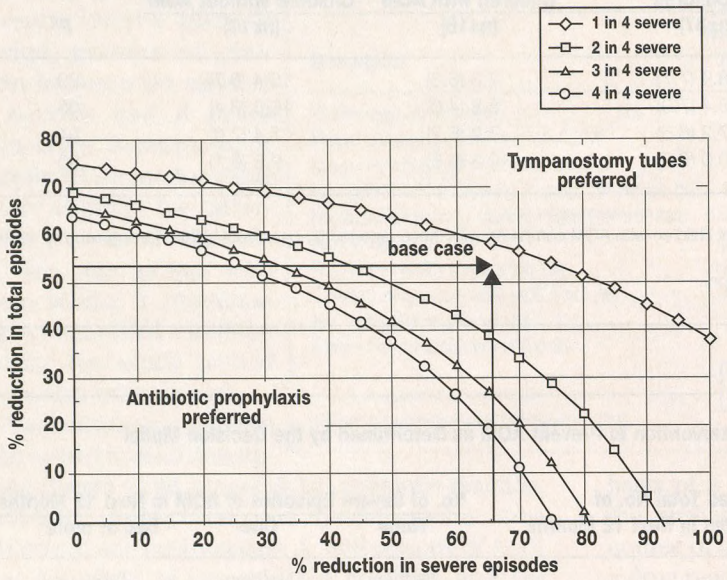
Utility Assessment

Thirty-seven parents, all with a child aged 6 years or younger, were interviewed for this project. Eighteen of the parents had children with AOM at the time of interview and 19 were parents of children being seen for well-child checkups. All children had a history of at least one previous middle ear infection. The characteristics of the children can be found in Table 1.

The mean mild AOM episode equivalents reported by the 37 parents for tympanostomy tubes, a year of prophylactic antibiotics, an antibiotic reaction, and a severe episode of AOM are shown in Table 2. These utility assessments took an average of 5.8 minutes, with a range of 2 to 11 minutes. The mean values were incorporated into the decision model. A total of 31 subjects were successfully interviewed a second time and showed no significant change in mean mild AOM

FIGURE 2

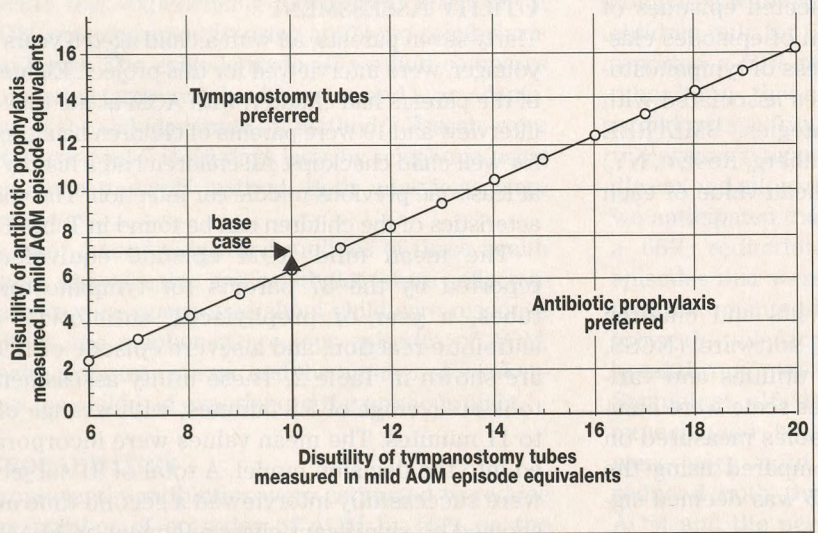
Three-way sensitivity analysis in which the efficacy of tympanostomy tubes is varied



NOTE: In this analysis a child is anticipated to have 4 episodes of AOM in the next 12 months, but the number of severe episodes ranges between 1 and 4. The watchful waiting strategy is never preferred within this range of assumptions. Tubes are preferred when the intersection of the reduction in total episodes and severe episodes lies above the curve that describes the expected infection pattern of a child.

FIGURE 3

A two-way sensitivity analysis showing the relationship between the disutilities of tympanostomy tubes and antibiotic prophylaxis and the preferred intervention



episode equivalents reported for the four health states. The repeat utility assessments took significantly less time with a mean of 2.6 minutes ($P < .01$). The group of subjects who could not be interviewed a second time (n=6), despite many attempts on our part, gave valuations similar to the reinterviewed group, with the exception of the value assigned to daily antibiotic prophylaxis (12.9 mild AOM episodes vs 6.2 episodes, $P = .02$). These individuals who could not be contacted a second time felt that having to give a daily dose of prophylactic antibiotics for one year was the least desirable of the health states.

DECISION ANALYSIS

In the base case a child was expected to have two mild and two severe AOM episodes over the next 12 months without any preventive intervention. Given these assumptions, the model indicated that the child would have the least burden from illness (14.9 mild AOM episode equivalents) if tympanostomy tubes were used, compared with using antibiotic prophylaxis (16.8 mild AOM episode equivalents) or doing nothing (21.5 mild AOM episode equivalents).

Table 3 shows the preferred preventive strategy over a range of assumptions about the total number of expected episodes and number of severe episodes. In this sensitivity analysis, when a child was expected to have a total of three episodes of AOM in the next 12 months with only

one severe episode, then no prevention was warranted. If a total of four episodes were anticipated with one being severe, then the use of antibiotic prophylaxis was the preferred strategy.

As our estimates of the effectiveness of tympanostomy tubes in reducing the total number of AOM episodes and the percentage of episodes classified as severe have limited support in the literature, we performed a three-way sensitivity analysis on these estimates and the number of severe infections. Figure 2 shows the preferred intervention for a child who was anticipated to have four episodes of AOM. Prophylactic antibiotics were preferred over tympanostomy tubes as the overall effectiveness of tubes declined or as the ability of tubes to prevent severe infections declined.

Tympanostomy tubes were the preferred intervention in our base case but this preference was sensitive to how patients felt about the preventive strategies. Antibiotic prophylaxis became preferred when a parent felt that the disutility associated with prophylactic antibiotics was less than 6.3 mild AOM episode equivalents. A graph of the relationship between the ratings of the interventions and the preferred intervention is shown in Figure 3.

Because the two groups of parents interviewed for this project differed on the mean disutility associated with an antibiotic reaction, we performed a sensitivity analysis using the mean values of both groups. Reanalyzing the decision model using the mean disutility reported by each group of subjects did not change the conclusions over the range of 1 to 6 future episodes of AOM.

DISCUSSION

We integrated estimates of the burden associated with tympanostomy tubes, prophylactic antibiotics, and episodes of AOM into a decision model to identify the preferred management of a child with recurrent middle ear infections. Other parameters included in the model were the number of middle ear infections that were anticipated to occur over the coming 12 months and the percentage of these infections that were anticipated to be severe.

From the parents' perspective, the use of tympanostomy tubes was preferred for a child expected to have only three episodes of AOM, if at least two of these episodes included fever with a 3-day course of illness. However, if a child was expected to have five episodes of AOM in the coming year, all predicted to be mild, then a preventive intervention was not warranted.

Our model identified the preferred intervention as the one that minimized the mild AOM episode equivalents experienced by the patient. There are alternate metrics to use in a decision analysis, such as selecting a treatment based on clinical effectiveness, cost, or marginal cost-effectiveness. We did not select these alternate metrics because we were interested in the best decision from the patients' perspective. Our conclusion differs from that of a previous cost-utility analysis on recurrent otitis media that concluded that prophylactic antibiotics should always be utilized before tympanostomy tubes, largely because of lower costs.[16] Using similar reasoning, physicians have been encouraged to use prophylaxis before going on to use tubes.[17-20] However, surveys have found that tubes are frequently employed as the first preventive strategy, a practice that has been criticized as "inappropriate."[21,22] Our model found that tubes may be, from a parent's perspective, the preferred first intervention for many children and this finding may help explain current practice patterns.

Our conclusions should be interpreted with a degree of caution. The efficacy of the preventive strategies reported in the literature may not be the same as those actually observed in a clinical setting. Our estimate of the effectiveness of tympanostomy tubes was based on small numbers, and our estimate of the effectiveness of antibiotic prophylaxis was from research studies and may be higher than observed in a community setting.[23] Additionally, we analyzed only two preventive strategies, although additional ones can be found in the literature.[24-26] It is our perception that the management debate is usually between tympanostomy tubes, prophylactic antibiotics, and continued observation.

Our model also required a prediction of future episodes of AOM, and recent work indicates that these predictions may generally be too high.[27] Finally, our model views prevention only as a way to limit the short-term morbidity for children and their parents. The long-term perspective was left out of the model because there are insufficient data to define it. The clinical impact of recurrent AOM on future hearing and language development remains unclear.[28,29]

In using decision analysis to evaluate medical interventions, the best strategy is determined by the probabilities and the utilities associated with outcomes. The mild AOM episode equivalents we used in the model are means and therefore our model identifies the preferred intervention for the average child with recurrent otitis media. Variations in personal utilities can result in differences in what is the preferred therapy for an individual.[30] We had hoped to identify sociodemographic factors that predicted the disutilities held by patients but we were unable to find any significant predictors (analysis not shown). This suggests that the physician needs to directly discuss these issues with patients to determine their values. Once these values are collected, the decision model can be personalized. To facilitate this process, patient-derived disutilites can be placed into a spreadsheet containing the model used for this research, and the spreadsheet will calculate the expected number of mild AOM episode equivalents associated with the three strategies. (An Excel or Lotus 1-2-3 spreadsheet containing an equivalent model can be obtained by sending an e-mail request to: george-bergus@uiowa.edu. The spreadsheet will be delivered as an e-mail attachment.)

Our work grew out of an effort to define the preferred strategy for a child with recurrent AOM and could be used as a starting point for discussions with parents. While our analysis may not maximize clinical outcome or minimize cost, it does maximize the well-being of children from the perspective of their parents.

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