EDITORIAL

Management of Recurrent Acute Otitis Media

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Acute otitis media is one of the most common indications for both seeking medical care and prescribing antibiotics for children.[1] The disorder is attributable to eustachian-tube dysfunction, which is most often caused by viral upper respiratory infections, and its prevalence is highest in children between 6 and 12 months of age.[2] Young children who have a first episode of acute otitis media early in life (<12 months) are susceptible to the development of recurrent acute otitis media — defined as the occurrence of at least three episodes of acute otitis media within 6 months or four episodes within 12 months, with at least one of those episodes occurring in the immediately preceding 6 months.

Episodes of recurrent acute otitis media are characterized by the symptoms of the acute illness, as well as the persistence of middle-ear fluid accompanied by decreases in hearing and the possible development of antimicrobial resistance from repeated prescription of antimicrobial agents. Recommendations regarding the management of recurrent acute otitis media have included antimicrobial prophylaxis (no longer favored), tympanostomy-tube placement, and individual management of separate episodes of acute otitis media.[3,4] Concerns regarding tympanostomy-tube placement include the risk of anesthesia during placement, recurrent or persistent otorrhea, and possible scarring or perforation of the tympanic membrane. However, these concerns are potentially offset by a decrease in the number and severity of episodes of acute otitis media, an associated decrease in the use of systemic antibiotics, and improved hearing because of a reduction in middle-ear fluid during a time of rapid acquisition of spoken language. The current paucity of data bearing on the best option for management of recurrent acute otitis media led the Agency for Healthcare Research and Quality to call for appropriate pragmatic trials.[5]

A group of researchers in Pittsburgh has a long and distinguished record of conducting elegant studies of acute otitis media and related disorders. Accordingly, the stringency of entry requirements, documentation of previous episodes of acute otitis media, and serial assessments of children were performed as meticulously as possible in the researchers' prospective, randomized clinical trial to determine the relative benefits of tympanostomy-tube placement as compared with medical management in the prevention of subsequent episodes of acute otitis media.[6]

In estimating the sample size of 240 children to detect a relative difference of at least 33% in the frequency of episodes of acute otitis media between the two trial groups, the authors appropriately considered likely rates of acute otitis media according to the year of the trial and participant retention. However, they may not have anticipated the parental decision to opt for tympanostomy-tube placement after randomization to medical management; this led to "treatment failure" by definition without meeting specified criteria for failure. The 19 children in the medical-management group whose parents opted for tympanostomy-tube placement plus the 35 who met the specified criteria for treatment failure constitute nearly 45% of the 121 children originally assigned to receive medical management. Therefore, when outcomes are compared between the two groups with the use of intention-to-treat analysis, only 55% of the

children in the medical-management group were actually treated medically throughout the trial. Accordingly, for every outcome measure reported in the intention-to-treat analysis, nearly half the children in the medical-management group were treated with the comparator strategy. The per-protocol analysis, shown only for the primary outcome measure, falls far short of the desired sample size.

Although the frequency of episodes of acute otitis media was similar in the two groups and the reported likelihood of severity did not differ significantly in an intention-to-treat analysis, a significant difference was observed in a per-protocol analysis, and it might be expected that qualitatively the episodes of acute otitis media were substantially different between the two groups. Criteria for an episode of acute otitis media in the tympanostomy-tube group required otorrhea and only one symptom from the Acute Otitis Media–Severity of Symptoms scale (unlikely to be otalgia given a nonintact tympanic membrane), which usually results in mild episodes save for the annoyance of persistent otorrhea in approximately 10% of children. This is reflected by between-group differences in secondary outcome measures: children in the tympanostomy-tube group had fewer "other symptoms of acute otitis media" and a lower mean number of days of antimicrobial treatment than those in the medical-management group. In addition, a smaller percentage of children with tubes met criteria for treatment failure.

Still, results of this trial are very useful for shared decision making with caregivers. When a child meets criteria for recurrent acute otitis media and parents ask, "what can we do?," they can be informed that the present course of medical management may be continued with no greater likelihood of antimicrobial resistance than if we choose a surgical option. In a child older than 2 years of age, we can forecast that infections will be fewer in the coming year and that medical treatment should be continued. In the younger child, there is a nearly 50% likelihood that the frequency of infections will continue; the child is likely to have fewer and less severe episodes of acute otitis media with less exposure to antibiotics if tympanostomy-tube placement is undertaken, with only occasional development of persistent otorrhea. Thus, management decisions can be made jointly with a high degree of parental satisfaction.

Disclosure forms provided by the author are available with the full text of this editorial at NEJM.org.

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