PEDIATRICS®
OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

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Pediatrics 2003;112;527-531
DOI: 10.1542/peds.112.3.527

Treatment of Otitis Media With Observation and a Safety-Net Antibiotic Prescription

Robert M. Siegel, MD*; Michele Kiely, DrPH‡; James P. Bien, MD*; Evelyn C. Joseph, MD*; James B. Davis, MD*; Sandra G. Mendel, MD*; John P. Pestian, PhD§; and Thomas G. DeWitt, MD*

ABSTRACT. *Objective.* **Several studies have demonstrated that acute otitis media (AOM) in children can be managed without antibiotics. Because children with AOM have traditionally been treated with antibiotics in the United States, there are concerns that parents may not be comfortable with their children being treated with pain control alone. Recently, Cates in England showed that antibiotic usage for AOM could be decreased by prescribing a safety-net antibiotic prescription (SNAP) to be filled if symptoms do not resolve with observation after 48 hours. It is not clear whether a SNAP will be acceptable to parents in other settings such as the United States. The objective of our study was to determine whether parents in the United States find a SNAP for AOM acceptable and whether antibiotic usage could be decreased by its use.**

Methods. **A pediatric practice-based research network in a midwestern community of 1.8 million was the setting for this study. The Cincinnati Pediatric Research Group (CPRG) includes practices in Ohio, Kentucky, and Indiana. Children who were between 1 and 12 years of age and presented to the offices of the CPRG with uncomplicated AOM were eligible for the study. Children were excluded when they had temperature >101.5°F, had an ear infection in the past 3 months, showed signs of another bacterial infection, or were toxic appearing. Families were given acetaminophen, ibuprofen, or topical otic anesthetic drops for pain control. They were also given a prescription for an antibiotic and instructed not to fill it unless symptoms either increased or did not resolve after 48 hours. The data were entered directly by investigators via an Internet site.**

Results. **A total of 194 children were enrolled in 11 offices over 12 months; 175 (90%) completed the follow-up interview. The average child's age was 5.0 years. Only 55 (31%) of the 175 who were contacted for follow-up had filled their antibiotic prescription. Compared with their previous experience, parents were overwhelmingly willing to treat AOM with pain medication alone (χ^2 = 111). Seventy-eight percent (95% confidence interval: 71%–84%) of parents reported that the pain medication was effective. Sixty-three percent (95% confidence interval: 55%–70%) of parents reported that they would be willing to treat future AOM episodes without antibiotics and with pain medication alone.**

Conclusions. **A subset of parents find a safety-net prescription and pain control acceptable in the treatment of AOM, and antibiotic usage can be lowered with this strategy.** *Pediatrics* **2003;112:527–531;** ***acute otitis media, safety-net antibiotic prescription, practice-based research network, observation.***

ABBREVIATIONS. AOM, acute otitis media; SNAP, safety-net antibiotic prescription; CPRG, Cincinnati Pediatric Research Group; PBRN, practice-based research network; CI, confidence interval.

Acute otitis media (AOM) is the most commonly treated bacterial infection in children.[1] Treatment of this infection accounts for >50% of pediatric antibiotic prescriptions and as much as $5 billion annually in cost.[2–4] Several investigators have shown that there is little benefit to using antibiotics in most children with otitis media.[5,6] Because the spontaneous resolution of AOM is between 70% and 90%, theoretically only 1 in 7 to 14 children with AOM benefits from treatment with antibiotics.[7–9]

Recently, there has been growing concern over prescription of antibiotics and resistance of common bacteria to antibiotics.[10,11] These concerns, along with potential side effects from antibiotics, make initial observation without antibiotics an attractive strategy for reducing antibiotic use in children.[12] Most parents in the United States, however, believe that antibiotics are necessary to treat AOM.[13] In addition, many physicians believe that parents want antibiotics for their sick children, and this is reflected in their antibiotic prescribing habits.[14,15] Although a strategy of watchful waiting with initiation of antibiotics for children who do not recover quickly has been the norm in parts of Europe such as the Netherlands, it is not clear whether such a strategy will be accepted in the United States.[1,16]

Recognizing the potential for both parent and practitioner discomfort in not having antibiotics available for a diagnosed AOM, Cates[17] in England introduced the concept of a safety-net antibiotic prescription (SNAP). It was the policy in his practice to ask patients to wait a day or 2 to fill the antibiotic

From the *Cincinnati Pediatric Research Group, Division of General and Community Pediatrics, Children's Hospital Medical Center, Cincinnati, Ohio; ‡Division of Epidemiology, Statistics and Prevention Research, National Institute of Child Health and Human Development, National Institutes of Health, Department of Health and Human Services, Bethesda, Maryland; and §Division of Information Services, Children's Hospital Medical Center, Cincinnati, Ohio.

This work was presented in part at the Pediatric Academic Societies Meeting; Ambulatory Pediatric Association Presidential Plenary Session; May 7, 2002; Baltimore, MD.

Received for publication Dec 16, 2002; accepted Feb 21, 2003.

Address correspondence to Robert M. Siegel, MD, Cincinnati Pediatric Research Group, Division of General and Community Pediatrics, Children's Hospital Medical Center, Cincinnati, OH 45229. E-mail: robertsiegel56@pol.net

prescription in relatively well children with diagnosed AOM. Using this strategy, Cates was able to lower the total antibiotics prescribed in his family practice by 20%. The objective of our study was to determine whether a population of parents in the United States find a SNAP for AOM acceptable and whether antibiotic usage could be decreased by its use.

METHODS

Participants and Procedures

Eleven of the 25 offices of the Cincinnati Pediatric Research Group (CPRG) elected to participate in the study. The CPRG is a local pediatric practice-based research network (PBRN) of 30 practitioners at 25 practice sites in a metropolitan area of 1.8 million people. The study was approved by the institutional review boards of Children's Hospital Medical Center of Cincinnati, Ohio, and the St. Luke Hospitals of Northern Kentucky.

Children ages 1 to 12 years of age with diagnosed AOM were eligible for the study. The children were determined to have otitis by a CPRG practitioner using the following minimal criteria: 1) bulging or pustular tympanic membrane on otoscopy or 2) red tympanic membrane with decreased mobility by pneumatic otoscopy or tympanogram. These criteria were selected as they conformed to the minimum used by the study practitioners and were thought to be consistent with those previously described for the acute care setting by McCracken.[18]

Children were ineligible for the study for any of the reasons listed in Table 1. When a child met these entry criteria, the practitioner described the study to the child's parent or guardian and obtained written informed consent. At the time of enrollment, the practitioner used the CPRG Internet web site to complete a study form that included demographic data, physical examination findings, and treatment regimen.

Once the child was entered into the study, the parent or guardian was given a prescription for an appropriate antibiotic as determined by the practitioner. The SNAP was written to be filled only within 5 days of study enrollment. The parent or guardian of the child was instructed not to fill the SNAP unless symptoms worsened or did not improve after 48 hours. The parents were told to call the office anytime the child's condition worsened with increased pain, with fever, or in any other manner. The treating practitioner also recommended appropriate pain control medication. At the time of enrollment, samples of ibuprofen, acetaminophen, and otic drops containing antipyrine/benzocaine were provided at no expense in the offices as deemed appropriate by the practitioners. A handout about AOM that explained the treatment plan was given to the parent or guardian.

Five to 10 days after study enrollment, the study nurse conducted a structured telephone interview with the parent or guardian. The responses to the interview were recorded directly by the study nurse into the Internet-based study-specific web site. The interview questions are provided in Table 2.

TABLE 1. Exclusion Criteria for Study Children

1. Temperature on examination or by history of >101.5 by any method within the past 48 h
2. Symptoms suggestive of AOM for >48 h
3. The child was toxic appearing
4. The tympanic membrane of the infected ear was not intact
5. The child had any chronic condition that may impede the child's immunity or ability to clear the infection as judged by the examining practitioner
6. Another episode of AOM within the past 3 mo
7. The infected ear had signs of impending perforation as judged by the examining clinician
8. A coexisting bacterial infection
9. The practitioner believed that the family would be unable to seek medical care if the child's clinical status were to worsen
10. The child's parent/guardian or the practitioner believed that the parent or guardian could not gain an acceptable understanding of the protocol

TABLE 2. Structured-Interview Questions

1. How is your child doing? __
2. Did you fill the antibiotic prescription and when? __
3. For how many days did your child have fever? __
4. How long after the office visit for ear infection did your child have pain? __
5. Which pain medicine did you use? __
6. Was the pain medicine effective? __
7. How many ear infections has your child had before this episode? __
8. Has your child ever had ear tubes? __
9. How many children in the household? __
10. How many smokers in the household? __
11. Is your child who is enrolled in the study in daycare? __
12. If you filled the antibiotic prescription, which of the following were reasons:
    Continued pain __
    Continued fever __
    Missed work days __
    Need to keep child out of daycare __
    Disruption of sleep for family __
13. If you did not fill the antibiotic prescription:
    Were you pleased with using pain medicines alone? __
    Would you be willing to treat your child for AOM again without antibiotics and just pain medicines? __
14. Think back to your child's last ear infection before this episode
    Were you given a prescription for antibiotics? __
    Did you fill the prescription? __
    How long did you give the medicine? __
15. How strongly do you agree with this statement?
    "In general antibiotics are needed to treat ear infections"
    Strongly disagree __
    Disagree somewhat __
    Not sure __
    Agree somewhat __
    Strongly agree __
16. Has being in the study changed your opinion about the need for antibiotics in treating ear infections? Yes __ No __ Not sure __
17. How many adults share in the daily care of your child? __
18. Do you live at home with your child in the study? __
19. How many adults work outside the home? __
20. Your estimated total family income for a year: <$10 000__ $10 000–$20 000__ $20 000–$40 000__ >$40 000__
21. Type of insurance: private__ Medicaid__ self-pay__
22. Your level of education: Less than 12th grade__ HS grad__ some college__ college grad__ advanced degree__ trade school__

Sample Size and Statistical Analysis

Sample size calculations were conducted under the assumption that we wanted a statistical power of 80% to detect a 5% reduction in antibiotic use. With a projected baseline of >95% of children receiving antibiotics for a previous episode of AOM, a sample size of 185 was determined to be sufficient to demonstrate a statistically significant difference ($P < .05$).

The outcome of greatest interest was whether parents were willing to treat diagnosed AOM with pain medication alone without antibiotics. Other outcomes were whether parents filled the prescription at the time of the study AOM episode compared with whether they filled an antibiotic prescription at their child's last episode of AOM and whether they planned to treat their child's next episode of AOM with antibiotics. Statistical analyses were performed with SAS. PROC FREQ was used to examine the bivariate relationships. Proportions of people who filled the SNAP and of parents willing to use pain medication again were calculated, and 95% confidence intervals (CIs) were computed. PROC FREQ was also used to analyze the relationship of child's age, parental income, parental education, insurance status, and number of previous episodes of AOM to outcomes. McNemar's test for matched pairs was used to test for reduction in antibiotic usage in the study compared with the baseline as recalled by the parent in the telephone survey.

RESULTS

A total of 194 patients were enrolled at 11 practice sites. A total of 100% of those eligible were approached, and only 5 patients declined to participate. Ninety percent ($n = 175$) completed the follow-up interview. Five (33%) of 15 nonwhite children were lost to follow-up, compared with 14 (7.9%) of 178 white children ($\chi^2 = 11.45$; $P < .001$; race was missing for 1 child). The proportion of children followed up did not differ by gender. The age distribution of children lost to follow-up was slightly younger than those not lost, but the difference was not statistically significant. Among the 175 who completed the study, the average age of the children was 5.0 years (range: 1–12 years). Forty-four percent were girls, and 56% were boys. Ninety-four percent of parents described their children as white, 3% as black, and 3% as other. Seventy-one percent of families had private insurance, 27% had Medicaid, and 2% were self-pay. Table 3 shows the pain medications and antibiotics prescribed as a SNAP.

A total of 120 (69%) of 175 families did not fill the antibiotic prescription (95% CI: 61.7%–75.5%). Of these 120 parents, 117 (97.4%) said that they were willing to use pain medication without antibiotics in the future (95% CI: 94.4%–100%). Of the 55 families who did fill the prescription, 33 filled the prescription within 48 hours of diagnosis. Parents' reasons for filling the prescriptions, based on the structured interview, are described in Table 4. (Note that the responses are not mutually exclusive.)

Of the 175 children who completed the study, 161 had had at least 1 previous episode of AOM. For 2 of the subjects, data on previous episodes were missing. For the 159 remaining, all of the parents of these children reported being given antibiotics in the past. Of these 159 children, 155 (97%) had used antibiotics during their last AOM episode, whereas only 52 (33%) used antibiotics during this episode (McNemar $\chi^2 = 101.00$; $P < .0001$).

In trying to understand further which factors predicted the parents' behavior, we examined a number of demographic variables. Child's age, income, insurance status, parental education, and diagnostic criterion did not predict whether parents did not fill the prescription (Table 5). In addition, practitioner site did not predict parent behavior (data not shown). Previous episodes of AOM was the only variable that we analyzed that seemed to explain parents' behavior. When the child had had 2 or more previous episodes of AOM, parents were significantly more likely to fill the prescription than parents of a child who had 1 or no previous episodes (83.9% vs 65.3%; $\chi^2 = 4.09$; $P = .04$).

TABLE 3. SNAP Antibiotics and Pain Medications Used

Medication	No. of Patients
SNAP	
Amoxicillin	167
Amoxicillin/clavulanate	8
Azithromycin	5
Cefprozil	4
Others	10
Pain medicine	
Ibuprofen	160
Acetaminophen	141
Antipyrine/benzocaine drops	139
Other	22
None	4

TABLE 4. Reasons for Filling the SNAP

Reason for Filling SNAP	No. of Patients	% of Those With Follow-up
Continued pain	42	24%
Continued fever	19	11%
Sleep disruption	11	6%
No reason	8	5%
Missed days of work	6	3%
Missed days of child care	5	3%

There were no complications reported as a result of the study. The course of 1 patient, however, is worth noting. A 16-month-old boy was diagnosed as having AOM and given the SNAP. The amoxicillin prescription was filled at 48 hours when his symptoms did not resolve, but he did improve after 48 hours of antibiotic therapy. He was seen 6 weeks later with AOM in the opposite ear, treated with antibiotics, and had postauricular swelling suggestive of early mastoiditis. He received a diagnosis of postauricular cellulites by our hospital otolaryngology team, responded to intravenous antibiotics, and had no additional difficulties.

DISCUSSION

Antibiotic resistance has become an increasing clinical problem over the past decade. Duchin et al[10] described that more than half of *Streptococcus pneumoniae* cultured from nasopharyngeal swabs of children who attended child care in 1 community were penicillin-resistant. Looking specifically at AOM, Block et al[19] demonstrated that the pneumococcal isolates from middle-ear fluids were 16% relatively resistant and 15% highly resistant to penicillin. With growing resistance in mind, several authorities have suggested guidelines for more judicious use of antibiotics.[1,20]

Although studies have shown that there is little if any benefit in treating AOM, it is not clear whether a strategy of watchful waiting is practical in the United States, where antibiotics traditionally have been used for this infection. Watson et al,[15] in a survey of 366 physicians, showed that 97% recognized that overuse of antibiotics contributed to resistance. Still, 46% of these physicians were prescribing antibiotics for the common cold. Parents also have conflicting concerns over the use of antibiotics. Palmer and Bauchner[13] showed that the vast majority of parents (85%) believed that there were problems with antibiotic overuse, but 93% thought that antibiotics were necessary for the treatment of AOM. Adding to the pressure on practitioners to prescribe antibiotics is the concern that the child may legitimately need antibiotics if the infection does not respond to 48 hours of watchful waiting. This may lead to an additional office visit and add to the expense and inconvenience of the infection.

Any successful treatment strategy for AOM must

TABLE 5. Variables and Likelihood of Not Filling SNAP

Variable	*N*	% Who Did Not Fill Prescription	χ^2 and Degrees of Freedom	*P* Value
Total	175	68.6		
Insurance status*	171		0.28 (df = 1)	NS
Medicaid	47	66.0		
Private	124	70.2		
Income	175		0.63 (df = 3)	NS
<$10 000	16	62.5		
$10 000–$20 000	15	73.3		
$20 000–$40 000	31	67.7		
>$40 000	90	71.1		
Child's age, y	175		4.11 (df = 2)	NS
<2	28	53.6		
2–5	102	70.6		
>5	45	73.3		
Diagnostic criteria	175		0.55 (df = 1)	NS
Bulging or pustular tympanic membrane	74	64.9		
Red tympanic membrane with decreased mobility	101	71.3		
No. of previous episodes of AOM	175		4.09 (df = 1)	.04
0–1	31	83.9		
≥2	144	65.3		
Parental education†	174		.067 (df = 4)	
<12th grade	17	70.6		
High school graduate	36	69.4		
Some college	44	68.2		
College graduate	55	67.3		
Advanced degree	22	68.2		
Practice site‡	157		7.93 (df = 6)	NS

NS indicates not significant
* Self-pay (n = 4) was dropped from insurance analysis.
† Trade school (n = 1) was dropped from education analysis.
‡ Analysis of practice site was limited to the 7 practice sites that enrolled 90% of followed patients.

take into account that there is a hesitancy of both physicians and parents not to have antibiotics available for this infection. The SNAP pioneered by Cates is an attractive method in AOM treatment, as it gives both practitioners and parents the security of having antibiotics available if the child's infection does not respond to watchful waiting. In our study, the majority of parents did not fill the SNAP and reported that they would be willing to treat AOM without antibiotics in the future. The majority of parents also believed that their children had adequate pain control, and there was a significant lowering of antibiotic use compared with previous episodes as reported by parents. Also, no significant complications were reported in those who were treated by observation alone or those who went on to fill their SNAP.

The most common major complication of AOM is progression to mastoiditis.[21] Although none of the episodes of AOM in the study progressed to mastoiditis, 1 child who was enrolled in the study developed what may have been mastoiditis 6 weeks after treatment in the opposite ear. Whether children who are treated initially for AOM are at lower risk for mastoiditis is not clear.[22] Historically, approximately half of children who develop mastoiditis do so on antibiotics. Although uncommon, the incidence of mastoiditis is approximately twice as high in countries where practitioners treat AOM with observation compared with countries in which antibiotics are used initially, such as the United States.[23] The incidence of mastoiditis, however, is increasing in the United States and may be related to the increasing frequency in antibiotic resistance in common AOM pathogens.[24–26] Use of the SNAP could potentially reduce the risk of the development of mastoiditis compared with watchful waiting alone, as antibiotics are readily available if a child's condition worsens or does not improve after an adequate observation period. A larger study with a longer follow-up is needed to determine this potential added benefit.

Potential concerns with our study are that the diagnosis of AOM was a clinical one and that AOM may have been overdiagnosed. Children who did not actually have AOM would presumably respond to watchful waiting. If more selective criteria were used, such as a bacteriologic diagnosis by tympanocentesis, then the acceptance of the SNAP and antibiotic usage may have been altered. In our study, we chose a clinical definition of AOM to reflect how clinicians make the diagnosis in real practice settings. All children who received the SNAP in our study would have received antibiotics based on the practitioners' past performance. We believe that the acceptance of the SNAP and decreased antibiotic use in a real-practice setting demonstrate the effectiveness of the SNAP approach.

There are several other limitations to our study. Our sample size, as in most AOM studies, was small. The population, although having a broad socioeconomic spread, was lacking in minority enrollment. It certainly is not clear whether these results can be generalized to other settings. It is also unclear how this select group of patients compares with all children with AOM and whether the results can be extended to children with more severe disease. Another concern is that the criteria that we used for the diagnosis of AOM differ from other proposed criteria. Finally, the follow-up period was relatively brief,

and it is uncertain how many children ultimately will go on to receive antibiotics shortly after the acute episode. We are planning a larger study with a broader range of disease and a longer follow-up period to settle some of these issues.

CONCLUSIONS

Our results suggest that the use of a SNAP can safely reduce the use of antibiotics in children with uncomplicated AOM and that a population of parents in the United States find this strategy acceptable. Antibiotic prescribing strategies, such as the SNAP, may help alter the trend of antibiotic overprescribing and development of resistant organisms occurring in the United States.

ACKNOWLEDGMENTS

We gratefully acknowledge the financial support of Whitehall-Robins Healthcare with this project.

We also thank the following physicians for help and participation with this project: Kimberly Daly, MD; Catherine Hughes MD; Amy Heisel, MD; Catherine DeFoor, MD; Philip Walson, MD; Radhika Ramesh, MD; Christopher Peltier, MD; Gail Chang, MD; Michael Hunter, MD; Cynthia Spicker, MD; Kevin Reidy, MD; and Jeralyn Bernier, MD. Finally, we thank John L. Kiely, PhD, for editorial comments and Ann C. Trumble, PhD, for computer programming.

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A MODERN DILEMMA

"The real challenge here from an ethical perspective is the realization that you're taking a perfectly good heart and taking a chance now in a very, very high-risk recipient. I understand why you're doing it, and I would probably do the same, but you are gambling with a very scarce resource."

Dr Mehmet Oz on giving a 17-year-old girl a second heart-lung transplant. *New York Times.* February 21, 2003

Submitted by Student

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