The Libyan International Medical University

Faculty of Basic Medical Science

Otitis Media: Treatment with Observation &

A Safety-Net Antibiotic Prescription

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Abstract

Widespread use of antibiotics in the treatment of acute otitis media (AOM) has contributed to the prevalence of multidrug-resistant pathogens that are difficult to treat. It has been shown, however, that non-severe AOM in most children can be managed without antibiotics. This report describes a study where the parents of 194 children with AOM were given safety-net antibiotic prescriptions, only to be filled in case symptoms of AOM didn't resolve within 48 hours by the use of analgesics and otic drops alone. The aim of this study was to evaluate and determine the safety, efficacy and suitability of non-antibiotic intervention for children with non-severe AOM. A subset of parents found that using safety-net prescriptions and pain control was acceptable in the treatment of AOM, and that antibiotic usage can be lowered with this strategy.

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

Introduction

Otitis media (OM) is an inflammation of the middle ear characterized by the accumulation of infected fluid in the middle ear, bulging of the eardrum, pain in the ear (otalgia), drainage of pus into the ear canal (otorrhea), fever and irritability [1].

Very little was known about ear disease until the 17th century. Otitis and draining ears were so common then, especially among the poverty of people, that they were considered a normal condition. Prior to the existence of antibiotics, ear infections and complications were primarily treated by surgical drainage [1].

Acute otitis media (AOM), one of the types of otitis media, is the most commonly treated bacterial infection in children and its treatment accounts for around 60% of pediatric antibiotic prescriptions [2-4]. Several studies have shown that there is little benefit to using antibiotics in most children with otitis media. Being that spontaneous resolution of AOM is between 70%-90%, theoretically only 1 in 7 to 14 children with AOM benefits from treatment with antibiotics [5-8].

In recent years, antibiotic use has been a growing concern as it has contributed to the emergence of multidrug-resistant pathogens. These concerns, in addition to potential side effects from antibiotics, make initial observation or "watchful waiting" a promising new strategy for reducing antibiotic use in children. However, in the United States, most parents believe that antibiotic use is necessary for the treatment of AOM. Additionally, many physicians believe that parents want antibiotics for their sick children, and this is reflected in their antibiotic prescribing habits. Although, the principle of watchful waiting with initiation of antibiotics only for children who do not recover quickly has proved to be successful in parts of Europe, such as the Netherlands, it is not yet clear whether this approach can be applied in the United States. This strategy, however, has given rise to the potential for both parent and practitioner discomfort in not having antibiotics available for a diagnosed AOM [2-3, 5].

Recent studies by Cates in England introduced the concept of a safety-net antibiotic prescription (SNAP). The principle of SNAP is to ask patients to wait a day or two to fill the antibiotic prescription in children with diagnosed, non-severe AOM. By using this

strategy, Cates was able to minimize total antibiotic prescriptions in his practice by around 20% [9].

The objective of this 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 [1].

Materials & Methods

The Cincinnati Pediatric Research Group (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. Eleven of the 25 offices of the CPRG were elected to participate in the study. It was approved by the institutional review boards of Children's Hospital Medical Center of Cincinnati, Ohio, and the St. Luke Hospitals of Northern Kentucky [1].

A total of 194 children aged between 1 to 12 years, diagnosed with AOM were selected for the study. The children were diagnosed 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 used as they conformed to the minimum used by the study practitioners and were consistent with criteria previously described by McCracken for the acute care setting [1, 10].

Once the children were confirmed for the study, the procedure was described to the child's parent or guardian by the practitioner and a written informed consent was requested. At the time of the enrollment, the practitioner completed a study form that included demographic data, physical examination findings, and treatment regimen. The parent or guardian was given a prescription for an appropriate antibiotic once the child was entered into the study. The SNAP was written to be filled only within 5 days of study enrollment. The parent or guardian of the child was informed not to fill the SNAP unless the condition of the child worsened or did not improve after 48 hours. The practitioner recommended appropriate pain control medication, and they also instructed the parents to

call the office anytime the child's condition worsened with increased pain or fever. Samples of ibuprofen, acetaminophen, and otic drops containing antipyrine/benzocaine were provided in the offices by the practitioners. In addition, a handout about AOM was given to the parent or guardian explaining the treatment plan [1].

Five to 10 days after study enrollment, the study nurse conducted a structured telephone interview with the parent or guardian. The results of the interview were recorded by the study nurse [1].

Results

A total of 194 patients were enrolled at 11 practice sites and 100% of those eligible were approached, with only 5 patients declining to participate. 90% (n 175) completed the follow-up interview. Amongst the 175 who completed the study, the average age of the children was 5 years (range: 1–12 years). 44% were girls, and 56% were boys. Table 1 shows the pain medications and antibiotics prescribed as a SNAP [1].

A total of 120 (69%) of 175 families did not fill the antibiotic prescription (see Chart 1). Of these 120 parents, 117 (97.4%) said that they were willing to use pain medication without antibiotics in the future. 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 2. (Note: the responses are not mutually exclusive) [1].

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 remaining 159, 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. Previous episodes of AOM was the only variable that was analyzed that seemed to explain parents' behavior. In cases where 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 [1].

There were no complications reported as a result of the study. However, there was a case involving 1 that is worth noting. A 16-month-old boy was diagnosed with AOM and given the SNAP. The amoxicillin prescription was filled within 48 hours when his symptoms did not improve, but he did improve after 48 hours of antibiotic therapy. After 6 weeks, he was seen with AOM in the opposite ear, treated, and had postauricular swelling indicative of early mastoiditis. He was diagnosed with postauricular cellulites by the CPRG hospital otolaryngology team, responded to intravenous antibiotics, and had no additional complications [1].

Chart 1: Parents' use of the SNAP

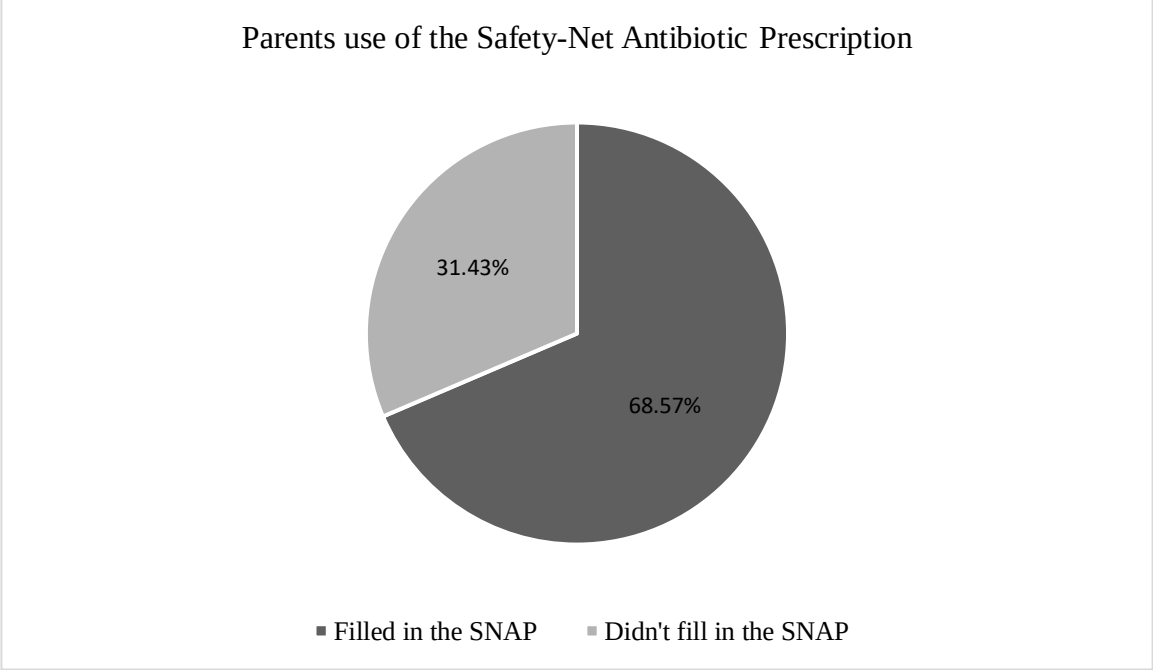

Table 1: SNAP Antibiotics and Pain Medications Used

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 2: 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%

Discussion

Over the past decade, antibiotic resistance became an increasing clinical problem. Duchin et al [5] demonstrated that more than half of Streptococcus pneumoniae cultured from nasopharyngeal swabs of children who attended child care in one community were penicillin-resistant. With focus on AOM, Block et al [11] showed that the pneumococcal isolates from middle-ear fluids were 16% moderately resistant and 15% highly resistant to penicillin. With the prevalence of antibiotic resistance, several authorities have suggested guidelines for more strict use of antibiotics [1-2, 12].

Although numerous studies have shown that there is little to no benefit in treating AOM with antibiotics, it is not yet clear whether an approach of watchful waiting is convenient in the United States, where antibiotics have been used for this infection for a long period of time. In another survey of 366 physicians, Watson et al [12], demonstrated that 97% recognized that overuse of antibiotics leads to resistance. However, 46% of these physicians were still prescribing antibiotics for the common cold. Moreover, parents also have conflicting concerns over the use of antibiotics. Palmer and Bauchner [8, 13] showed that the majority of parents (85%) believed that there were complications with antibiotic overuse. Still, 93% thought that antibiotics were necessary for the treatment of AOM, adding pressure on practitioners to prescribe antibiotics. This is mainly due to the concern that the child may legitimately need antibiotics if the infection does not resolve within 48 hours of watchful waiting, which may lead to an additional office visit and add to the expense and inconvenience of the infection [1].

In finding any new treatment for AOM, the hesitancy of both physicians and parents not to use antibiotics must be accounted for. The SNAP approach, pioneered by Cates, is a promising method in AOM treatment as it gives both practitioners and parents the security of having antibiotics available if the child's infection does not improve with watchful waiting. In this 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. Additionally, most parents also believed that their children had adequate pain control, and there was a significant lowering of antibiotic use compared with previous infections as reported by parents. No notable complications were reported in those who were treated by observation alone or those who went on to fill their SNAP [1].

Mastoiditis is the most common major complication of AOM [14]. Although none of the cases of AOM in the study progressed to mastoiditis, one child who participated in the study developed what may have potentially been mastoiditis in the opposite ear, 6 weeks after treatment [1]. It is not yet clear whether children who are treated for AOM initially with antibiotics are at lower risk for mastoiditis. Statistically, approximately half of children who develop mastoiditis, do so while on antibiotic therapy. The incidence of mastoiditis is almost twice as high in countries where practitioners treat AOM with

watchful waiting compared with countries where antibiotics are used initially, such as the United States. However, even in the United States, the incidence of mastoiditis is increasing due to the increasing emergence in antibiotic resistance in common AOM pathogens [1, 14].

Using the SNAP approach could potentially reduce the risk of development of mastoiditis compared with watchful waiting alone, as it ensures that antibiotics are readily available in case a child's condition worsens or does not resolve after an adequate observation period [1].

A concern with this study was that the diagnosis of AOM was a clinical one and that it could have potentially been over-diagnosed, meaning that children who did not actually have AOM would presumably respond to watchful waiting. However, if more selective criteria were used (i.e. bacteriologic diagnosis by tympanocentesis), then antibiotic usage, as well as the acceptance of the SNAP may have been significantly altered. Another concern in this study was the brief follow-up period. It is therefore important to study the acceptance of the SNAP and decreased antibiotic use in a real-practice setting to demonstrate the effectiveness of the approach. A larger study with a longer follow-up is needed to settle some of these issues [1].

Conclusion

The results of this study suggest that the use of a safety-net antibiotic prescription (SNAP) can safely minimize antibiotic use in children with non-severe acute otitis media (AOM), showing that a population of parents in the United States find this approach beneficial. Along with SNAP, other antibiotic prescribing approaches may help to drastically alter the emergence of antibiotic overprescribing and the development of resistant organisms [1].

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