Evidence Based Critically Appraised Topic

Otitis Media and using Augmentin versus watchful waiting

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**Clinical Scenario:**
A 7 year old male presents to the clinic complaining of right ear pain for the past day. Inspection of the right ear indicates erythematous and bulging tympanic membrane, no loss of tympanic membrane light reflex. Left ear was unremarkable. Patient currently has a low grade fever of 99.5-degrees Fahrenheit. He recently completed a full course of antibiotics for an upper respiratory infection. Diagnosis of patient is acute otitis media (AOM), for which Augmentin was prescribed. Patient should increase fluid intake and take the full course of antibiotics.

**Clinical Question:**
In children with acute otitis media, are antibiotics such as Augmentin more effective compared to watchful waiting for the reduction of symptoms of ear pain and fever?

**Articles Reviewed:**


**Summary and Appraisal of Key Evidence:**
**Study 1:** A randomized, double-blind, placebo-controlled study, free of commercial entities consisting of children age 6 months to 35 months of age and a diagnosis of acute otitis media was used to evaluate and assess the effectiveness of antibiotic therapy versus watchful waiting (Tahtinen, Laine, Huovinen, Jalava, Ruuskanen, & Ruohola, 2011). Included in the study were 319 children with a diagnosis of acute otitis media. Of the 319 children enrolled in the study, 161 randomly selected children of the study received amoxicillin-clavulanate (Augmentin) while 158 random children received a placebo for treatment. Children’s symptoms were evaluated and a nasopharyngeal sample was taken from all participants on day one of the study, or enrollment day. Parents were given a diary and asked to keep a record of symptoms and doses of study medication along with other medications the child was taking. Follow up visits were scheduled during the treatment course to check on the child’s symptoms and progress toward recovery. The course of treatment for both groups was seven days. This trial is considered Level 1, Grade A level of evidence (Ebell, Siwek, Weiss, Woolf, Susman, Ewigman & Bowman, 2004). It is identified as clinical trial number NCT00299455.

**Study 2:** A Cochrane review (2013) of randomized controlled trials comparing antimicrobial medication to a placebo control, or watchful waiting, group for children with acute otitis media.
was studied. This Cochrane review was performed to update the original 1997 review, and updated 2009 review, with trials between June 2008 and October 2012. An additional two studies, which included children less than 35 months of age, were now incorporated to be included in this study. The overall study consists of a total of 12 trials, or 3317 children, with acute otitis media age 12 years of age and younger. Therapy varied from seven to 14 days and consisted of children taking antibiotics and children in a control group or watchful waiting group. This study is considered a Level 1, Grade A level of evidence (Ebell et al., 2004).

**Results:**

**Study 1:** The Kaplan-Meier method was used to analyze children with acute otitis media with the time-to-event data using the log-rank test and confidence interval was calculated using the Cox regression model. Categorical outcomes were compared using the chi-square test. The results of this trial found children with acute otitis media benefited from antimicrobial therapy compared to those children in the placebo group. While 30 children, or 18.6%, in the antimicrobial group did experience treatment failure, this was significantly less than the placebo group, where 71 of the 158 children experienced treatment failure, or 44.9%. By treating acute otitis media with Augmentin, a 62% reduction of risk of treatment failure was found. This includes a hazard ratio of 0.38, a 95% confidence interval (CI), and a p value of p<0.001. An evaluation of otoscopic signs and overall condition of the internal ear was conducted at the end of the 7 day treatment and again, the antimicrobial group was also found to have a better end-of-treatment result. With otoscopic examination 119 of the 161 children, or 73.9%, were found to have “better” otoscopic signs and 34 of the 161, or 21.1%, were found to have completely resolved their signs of acute otitis media upon otoscopic exam. In comparison, 79 of the 158, or 50%, of the children in the placebo group were found to have “better” otoscopic signs and 19 children, or 12%, to have completely resolved their acute otitis media signs upon otoscopic exam. Parents of the children in both groups were asked to rate the overall condition of their children compared to their initial visit. Approximately 34% of parents with children in the antibiotic group felt their children were “healthy” compared to 12.6% of parents with children in the placebo group. While antibiotics may pose a chance of antimicrobial resistance in the future, this study found antibiotics did have a significant time benefit to recovery in children age 6 to 35 months of age with acute otitis media. A SWOT analysis of this study does indicate a weakness based upon the limited number of participants.

**Study 2:** Two review authors independently evaluated trial quality and reviewed that data collected. It was found antibiotics produced a small reduction of pain for children with acute otitis media at approximately day two or three. Antibiotics did significantly reduce the number of tympanic membrane perforations and did reduce the likelihood of developing contralateral otitis in children compared to the placebo group. In the Cochrane review, it was found that one
out of every 14 children treated with antibiotics experienced an adverse event or side effect to antibiotics. Side effects included vomiting, diarrhea, or rash. A statistical analysis was looked at for varying outcomes in comparison between the two groups, including pain at varying days of treatment, abnormalities of tympanometry, and side effects including vomiting, diarrhea, or rash. When reviewing the statistical data, a 95% confidence interval was found in all results and the methodological quality of outcomes was ranked high in quality of evidence in all comparison results.

**Clinical Bottom Line/Relevance:**
Acute otitis media is one of the most common childhood infections. It can cause severe pain, mastoiditis, or possibly deafness. While both studies showed faster recovery of AOM in children who took antibiotics, this does not mean this is the best option. In both studies, the group without antimicrobial therapy had very few children that developed complications from AOM. Even though their recovery may have taken a few more days, these children did not experience any side effects to antibiotics, nor did they possibly become susceptible to antimicrobial resistance. Providers need to weigh the benefits for each child presenting with acute otitis media against the potential risks. While these studies included strict criteria for a diagnosis of acute otitis media, not all providers diagnose AOM accurately therefore antibiotics may be more harmful (Darby-Stewart, Graber, Dachs, 2011).

**Implications for Practice:**
Given the results of these studies and because the majority of children experience a mild case of acute otitis media, I would recommend watchful waiting in the majority of AOM cases to prevent side effects or future problems with antimicrobial resistance. Watchful waiting appears to be a better option instead of exposing children to antibiotics and potentially causing an adverse effect or antimicrobial resistance. The exception would be in cases of children less than two years of age, experiencing bilateral acute otitis media, antimicrobial treatment was found to be beneficial due to the higher chance of complication. While these research studies did not address which children are more likely to suffer from complications of acute otitis media, this would be an interesting addition to incorporate.
References


