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Abstract

Aim

Unnecessary antibiotic prescriptions to treat otitis media contribute to adverse drug reactions, increased cost, and antibiotic resistance. Clinical care guidelines can help promote consistent treatment of conditions such as otitis media. This study evaluates adherence before and after implementation of an institutional guideline for diagnosis and treatment of paediatric otitis media.

Methods

A retrospective chart review was performed to collect encounter information for paediatric patients seen within a primary care clinic network and diagnosed with otitis media before and after full implementation of a clinical care guideline. Patient cohorts from 2013 and 2016 were compared to determine which factors, including age, symptoms, and diagnosis, were associated with treatment guideline adherence.

Results

Comparison of encounters from 2013 (n = 418) to 2016 (n = 635) revealed a significant difference in adherence to the 2013 Michigan Medicine Otitis Media Guideline. Overall adherence increased from 61.2% in 2013 to 70.6% in 2016 (χ^2 = 9.85, p < .0017). Antibiotic use for acute otitis media decreased from 99.7% in 2013 to 96.7% in 2016 (χ^2 = 10.04, p = .0015). Antibiotic prescriptions for otitis media with effusion decreased significantly from 42.9% in 2013 to 17.4% in 2016 (χ^2 = 11.93, p < .0006).

Conclusion

Implementation of an institutional OM clinical practice guideline contributed to a significant increase in overall treatment adherence of OM for paediatric patients between the 2013 and 2016 cohorts. The number of antibiotic prescriptions for paediatric patients diagnosed with AOM or OME significantly decreased from 2013 to 2016.

Keywords: otitis media; adherence; clinical care guidelines

Introduction

Otitis media (OM) is a common diagnosis in paediatric patients, with over 5 million annual cases of acute otitis media (AOM) and 2.2 million annual cases of otitis media with effusion (OME) in the United States[1,2]. The estimated cost of paediatric AOM in the United States is approximately $4.4 billion per year[1]. AOM is characterised by the bulging of the tympanic membrane, and/or the presence of sudden onset otorrhea, otalgia, or erythema. OME is characterised as a middle ear effusion without acute symptoms, often involving the persistence of fluid[2,4]. OM is one of the primary diagnosis resulting in antibiotic over-prescription, contributing to antibiotic resistance[5]. Antibiotic over-use contributes to adverse drug events, including diarrhea and rash[6,7].

Due to variation in presentation and provider thresholds, consistent diagnosis and management of OM across healthcare systems is challenging. To promote uniform management, clinical practise guidelines have been established at varying levels. Past studies have shown that implementation of clinical practise guidelines contributes to improved patient outcomes[8,9,10]. Using clinical decision support for OM has been associated with increased adherence[11,12].

Michigan Medicine is a large tertiary health system based in southeast Michigan with a network of 9 paediatric primary care clinics with over 60 faculty and 70 paediatric residents caring for patients ages 0-21. In 2013, Michigan Medicine initiated the development of an institutional clinical practise guideline for the diagnosis and treatment of paediatric OM (patients 0-18 years). The guideline was reviewed by stakeholders and fully implemented in March of 2014. The guideline disseminated to all faculty and physicians who see primary care patients at faculty meetings, via emails, and published on the network's internal website. This guideline is directly based on recommendations from the American Academy of Pediatrics (AAP)[13]. A published summary of AOM guidelines highlights the similarities of the two guidelines[14]. Table 1 lists the congruent recommendations of both guidelines[3,13].

The criteria for treatment of AOM per the Michigan Medicine guideline is outlined in Table 2 based on age, symptom severity, and laterality[3]. Watchful waiting (WW) is an alternative to providing immediate antibiotic therapy that encourages families to observe for 48-72 hours before initiating antibiotics. This can be achieved by providing a prescription that is only to be filled if symptoms persist[4,13,15]. This form of judicious antibiotic use attempts to combat resistance by decreasing unnecessary antibiotic use. Observation is recommended for children ages ≥2 years with AOM without severe symptoms when possible[3,13,16].

Antibiotics are not recommended for OME because they do not hasten the clearance of middle ear fluid[2,3,4]. Instead, clinical evaluation is recommended at three months[13]. In this study, OME cases were evaluated in order to understand how often antibiotics were prescribed unnecessarily and against guideline recommendations.

This study compared encounters from before and after implementation of the 2013 Michigan Medicine OM guideline to assess whether promulgation of guidelines was followed by more accurate diagnosis and treatment of paediatric OM.

Methods

Participants

Data were extracted using retrospective chart review. Since the data were part of standard medical care, this study was determined to be Not-Regulated by the IRB. Charts were identified from 5 months during 2016 ("after implementation") (January-February, October-December, *N* = 686). Criteria for inclusion required that patients were ≤18 years of age at the time of encounter, seen in-person at a primary care clinic in the system, and diagnosed with OM. Encounters which did not meet inclusion criteria and cases of OM with ruptured tympanic membrane or otitis externa were excluded, resulting in 635 encounters for analysis. A comparative sample (*N* = 485) was generated from encounters between October 2013 and February 2014 ("before implementation"), of which 418 charts fit inclusion criteria. Charts from the 2013 cohort were selected beginning in October as the medical system switched to a new electronic medical records (EMR) system and prior records were inaccessible.

Demographics

Demographic factors including age, gender, and race/ethnicity were recorded. Age was split into three groups consistent with the guideline (<6 months, 6-23 months, ≥24 months). Gender was also coded (female = 1, male = 0). An underrepresented minority (URM) variable was created for race/ethnicity (URM (Hispanic, black, other) = 1, non-URM (white, Asian) = 0).

Illness

Information collected included symptom duration, presence and severity of otalgia, presence of fever at visit, ear exam findings (erythema, bulging, fluid, lack of movement), laterality, diagnosis, medication prescribed, medication allergies, OM risk factors (undervaccination, tobacco exposure, craniofacial abnormalities), and prior OM. Being undervaccinated was defined as being past due on vaccines at the time of the visit as denoted in the chart or a specific physician note stating the patient was undervaccinated. Day-care attendance was not included as a risk factor as it was not consistently documented in the medical records. A label of “not recorded” was used to denote missing information.

Duration of symptoms was coded based on days with OM related symptoms (1 day = 0, 2 days = 1, >2 days = 2). Otalgia and fever were similarly coded (none = 0, mild = 1, severe = 2). Severe symptoms included instances of moderate or severe otalgia, >48 hours of pain, and/or a fever of ≥ 39°C, whereas mild symptoms included fevers below 39°C and low to medium pain[3,13]. Ear pain was considered severe when words such as “severe, searing” were used and if young children were grabbing ears and/or crying due to pain. Charts that listed pain without specifying severity were considered mild. If applicable, physician documentation pertinent to the antibiotic treatment was recorded. These notes included information about coexisting illnesses or other factors affecting treatment decisions (e.g., amoxicillin/clavulanate for concurrent conjunctivitis or ceftriaxone due to oral intolerance).

Adherence

Adherence was coded in a systematic way to look at major aspects of guideline adherence, with an emphasis on age, symptoms, diagnosis, and treatment (adhered = 1, did not adhere = 0). The guideline states that AOM should not be diagnosed without a middle ear effusion[3,13]. If a physician listed a diagnosis of OM, we did not second guess that diagnosis and used that as the basis for the analysis. AOM encounters in which antibiotics other than amoxicillin were prescribed were classified as non-adherent unless there was a documented reason for which the physician prescribed a different antibiotic. Reasons for which different antibiotics were prescribed included amoxicillin/penicillin allergies, past negative reactions, and coexisting infections requiring alternate treatment. Encounters with documented reasons for different antibiotic prescription were classified as adherent.

Encounters that adhered to antibiotic treatment and selection recommendations were analysed based on symptoms and age. If the patient was <6 months and correctly prescribed antibiotics, the encounter was determined to be adherent, regardless of symptom severity. For patients 6-23 months with bilateral AOM, encounters were deemed adherent if they were prescribed an appropriate antibiotic, regardless of symptom severity. For patients 6-23 months with unilateral AOM with mild symptoms and patients ≥24 months with unilateral or bilateral AOM, observation or deferred antibiotic treatment were recommended[3]. Cases in this category that received a “watchful waiting” prescription of the appropriate antibiotic were deemed adherent. Cases were also labelled adherent if physicians discussed watchful waiting and parents elected antibiotic treatment[15]. Common reasons for nonadherence included insufficient documentation of symptoms and antibiotic selection deviation.

OME encounters were determined to be non-adherent if antibiotics were provided since the guideline stipulates that antibiotics are not recommended[3]. If the patient presented with coexisting infections requiring antibiotics, the OME encounter was considered adherent if the rest of the encounter was compliant.

Since the guideline stipulates that the presence of ear pain and/or fever are necessary to make a diagnosis, charts that did not address these criteria were classified as non-adherent due to insufficient diagnostic information.

Analysis

Data were analysed in Statistical Package for the Social Sciences (SPSS 24.0)[17]. Bivariate logistic regressions were completed for 2013 and 2016 to identify associations. A variable, “cohort,” was designed to represent the difference in years. A 5-block multivariate logistic regression of predictors was run to discern whether the guideline impacted adherence between 2013 and 2016. A significance level of 0.05 was used for all analyses.

Results

A comparison of the encounters reviewed in 2013 (n = 418) and 2016 (n = 635) revealed a significant difference in the overall adherence rate to the 2013 Michigan Medicine OM guideline. Treatment adherence significantly increased from 61.2% in 2013 to 70.6% in 2016 (χ^2 = 9.85, $p < .0017$).

Demographics

Table 3 breaks down the demographics of each cohort. The 2013 cohort had a significantly larger proportion of children >6 months than the 2016 cohort (χ^2 = 4.07, p = .044). There were significantly more patients who identified as Non-Hispanic Asian in 2013 compared to 2016 (χ^2 = 4.07, p = .044). There were significantly more patients who identified as "other" in 2016 (χ^2 = 9.40, p = .002) No other significant demographic differences between cohorts were found.

Primary Analysis

When analysed together, OM risk factors were more prevalent in 2016 (23.3%, n = 148) than 2013 (18.9%, n = 79), but this difference did not reach statistical significance (χ^2 = 2.89, p = .089). Patients were more likely to be undervaccinated in 2016 (7.9%, n = 50) compared to 2013 (2.2%, n = 9) (χ^2 = 15.59, p < .0001).

Table 4 shows bivariate within-groups comparisons for the adherence rate for each type of OM and age group in 2013 and 2016. Overall, adherence for all cases of AOM increased from 2013 to 2016 (χ^2 = 6.25, p = .012). Adherence for unilateral AOM significantly increased from 2013 to 2016 (χ^2 = 16.35, p < .0001). Adherence for bilateral AOM significantly decreased from 2013 to 2016 (χ^2 = 4.21, p = .040). In both cohorts, adherence for bilateral OME was the highest, but there was no statistical difference in adherence rates for OME between 2013 and 2016. Adherence for children ≥24 months significantly increased from 2013 to 2016 (χ^2 = 13.84, p < .0002). There were no other differences in adherence related to age.

A bivariate cross-tabulation was conducted to assess if the quantity of missing diagnostic data changed between 2013 and 2016. In 2013, 37.3% of charts (n = 156) contained at least one missing piece of diagnostic information, defined as not recording fever, otalgia, and/or duration of symptoms. In 2016, 31.5% of charts (n = 200) contained at least one missing piece of diagnostic information (χ^2 = 3.82, p = .051).

Logistic Regression

Table 5 shows the multivariate logistic regression that was conducted to identify significant predictors of adherence. For this chart, p values ≤.05 indicate that the factor led to increased (odds ratio >1) or decreased (odds ratio <1) adherence. Demographics were added in Block 1

(URM, older, younger, gender). Age was found to be a significant predictor of decreased adherence for patients ≥24 months (OR = 0.50, p = .001). No other demographics were found to be significant predictors. The cohort variable (Block 2) did not indicate a statistically significant difference in adherence between 2013 and 2016 due to difference in years (OR = 1.11 p = .085). OM risk factors (Block 3) were not found to be significant. Fever, pain, and symptom duration (Block 4) were all found to be predictors of increased adherence (OR_{fever} = 2.29, OR_{pain} = 3.56, OR_{longer} = 1.73; p < .0001). In the final model, a bilateral diagnosis was not found to be significant, but an acute diagnosis was a predictor of decreased adherence (OR = 0.55, p = .026). The final model indicated that having fever, pain, and a longer duration of symptoms were significant predictors of increased adherence (OR_{fever} = 2.42, OR_{pain} = 3.70, OR_{longer} = 1.73; p < .0001) and being older (≥24 months) was a significant predictor of decreased adherence (OR = 0.53, p = .005).

Antibiotic Analysis

Antibiotic prescription for AOM significantly decreased from 2013 to 2016. 99.7% of AOM encounters in 2013 (n = 375) and 96.7% of AOM encounters in 2016 (n = 470) resulted in antibiotic treatment (χ^2 = 10.04, p = .0015). In 2013, 70.9% (n = 266) of all AOM related prescriptions were amoxicillin compared to 74.0% (n = 348) in 2016 (χ^2 = 1.02, p = .314). Of AOM encounters that resulted in an antibiotic prescription, 60.0% (n = 225) adhered to treatment guidelines in 2013 compared to 67.7% (n = 318) in 2016 (χ^2 = 5.33, p =.021). Antibiotic prescription for cases of OME decreased significantly between 2013 (42.9%, n = 18) and 2016 (17.4%, n = 26) (χ^2 = 11.93, p < .0006).

Discussion

This cohort study suggests that presence of fever, otalgia, and longer symptom duration are the strongest predictors of paediatric OM diagnosis and treatment.

For the treatment of children ≥24 months without severe symptoms, there is some ambiguity in the guideline since there is an option between observation and antibiotics. In these cases, physician perception and judgment play a role in determining the proper course of treatment. This decision could vary based on physician level of training, clinical experience, and parental preferences. Future guideline recommendations could increase emphasis on “watchful waiting” as an option to promote judicious antibiotic use.

The overall antibiotic prescription rate for AOM decreased between 2013 and 2016 cohorts, which could indicate more judicious use of antibiotics. Lower antibiotic use could indicate a higher incidence of observation, which was addressed in the 2013 guideline. Additionally, AOM cases that resulted in prescriptions adhered significantly more frequently in 2016, further indicating a change in prescribing patterns. Antibiotics were prescribed significantly less often for OME after guideline implementation. This decrease could suggest that physicians were more closely adhering to the guideline by withholding antibiotics for OME.

In this study, missing data was associated with non-adherence. The percentage of encounters with missing diagnostic data decreased from 37.3% to 31.5% between 2013 and 2016, indicating that the guideline may have encouraged more thorough documentation, but only at trend level. Additional factors could explain this improvement, such as increased use of EMR documentation templates.

Our study had limitations relating to sample composition and methodology. The sample sizes for the young age group (<6 months) were small, resulting in difficulty conducting powerful between- groups analyses. Future studies should gather a larger cohort of younger patients to further explore treatment differences. The retrospective chart review methodology makes it difficult to fully operationalize variables and only shows association[18]. Additional factors, including the AAP guidelines, that may have contributed to changes in treatment of paediatric OM.

Conclusion

In this study, implementation of an institutional OM clinical practice guideline contributed to a significant increase in overall treatment adherence of OM for paediatric patients between the 2013 and 2016 cohorts. The number of antibiotic prescriptions for both paediatric AOM and OME significantly decreased between 2013 and 2016. The decrease for OME was especially notable since antibiotic treatment is not recommended. Future research could consider utilizing prospective study design or assessing physicians’ awareness of the guideline and Additional studies could evaluate differences in guideline compliance based on physician characteristics such as level of training or years of experience.

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Adopting Otitis Media Practice Guidelines Increases Adherence within a Large Primary Care Network

Type of Manuscript: Original Article

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Conflicts of interest: None.