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Comparison of first year of life acute otitis media admissions before and after the 13-valent pneumococcal conjugate vaccine

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ABSTRACT

BACKGROUND: Acute otitis media (AOM) is a common childhood infection, which is usually managed in the outpatient setting. Yet, the more severe cases are referred for inpatient treatment. We hypothesized that pneumococcal conjugate vaccines (PCVs), administered during the first year of life, would decrease AOM admissions rate in this age group. We studied the characteristics of infants admitted with AOM and acute mastoiditis (AM) in the PCV13 era, routinely given from November 2010 to all infants.
METHODS: Charts of infants ≤1 year that were hospitalized during 1/1/2010–31/12/2015 with AOM, with or without AM, were retrieved using hospitalization codes. We compared 2010–11 (transition years, from PCV7 to PCV13) to 2012–15 (post-PCV13 marketing years).
RESULTS: AOM was the primary/secondary discharge diagnosis in ~4% of all admitted infants ≤1 year. Boys had more admissions than girls (62% vs 38%). Accuracy of AOM diagnoses substantially increased in the post-marketing years. The average hospitalization duration slightly shortened, from 3.21 (2010–11) to 2.99 days (2012–15) ($p = 0.52$). Despite considerably modest pre-admission antibiotic treatment rate (<30%), AM was infrequent (~3.4% of AOM admissions). Amoxicillin was the most common antibiotic therapy given before admission and during hospitalization. The number of myringotomies, usually reserved for treatment failure cases, significantly declined, and there were almost no cases of resistant bacteria. Respiratory syncytial virus was detected in ~20% of collected respiratory samples, and influenza A/B viruses in ~8%.
CONCLUSIONS: AOM is still a major cause for hospitalization of infants in the PCV13 era. Yet, complications are infrequent, and AM rate is low.

1. Introduction

Acute otitis media (AOM) is a leading cause for medical consultation, antibiotic prescription, and surgery in children [1–4]. The incidence of AOM peaks between 6 and 24 months of age; of them, infants aged 6–12 months are at the highest risk for AOM [5,6]. Several recent reports described the burden of AOM in the first year of life. For example, the first year of life incidence rate of Dutch parent-reported AOM was 569 per 1000 child-years (95% confidence interval (CI) 523–618), and infants who attended day-care had higher odds of developing symptomatic AOM episodes, compared to those not attending (OR: 5.0; 95%CI 2.6–9.6) [7]. According to the Danish National Birth Cohort, 5.3% of infants aged 6 months had already experienced one or more AOM episodes (95% CI 5.1–5.5%) [8]. The cumulative AOM incidence by ages 3, 6, and 12 months was 6%, 23% and 46% in infants who were prospectively followed in Galveston, TX, USA [9].

AOM in the first year of life has some distinctive features:(1) diagnosis is influenced by the varying sensitivity and specificity of the description of signs and symptoms of a non-verbal patient [10–12], (2) presence of cerumen, small diameter of the external ear canal, different anatomic position of the tympanic membrane (TM), and lack of cooperation during examination-all make otoscopy harder to perform, (3) many AOM diagnosis and treatment guidelines refer only to children >6 months, but not to younger patients [13], (4) upper respiratory tract infections are common in this age group, including infections caused by ototropic viruses,

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which can cause AOM without bacterial superinfection, such as respiratory syncytial virus (RSV), adenovirus and influenza (INF) viruses [14,15], and (5) 3 doses of pneumococcal conjugate vaccines (PCVs) are given during the first year of life, usually at 2, 4 and 12 months of age.

Most AOM patients are diagnosed and treated as outpatients. However, minority of them are referred for in-house examination and treatment. AOM itself is not a common cause for hospitalization. The more severe AOM cases that had failed treatment, had an intercurrent disease (mostly respiratory infections), or developed complications, such as acute mastoiditis (AM), are admitted [16–18].

In the last decade, several means were implemented in order to reduce AOM burden in Israel: publication of designated guidelines by the Israeli AOM Task Force (2010, 2013), introduction of the PCVs and the influenza vaccines into the National Immunization Program (NIP), and continuous surveillance of circulating pathogens causing AOM.

We hypothesized that: (1) there will be fewer AOM-related admissions during the PCV13 post-marketing years; (2) the clinical presentation would change, as the pathogen distribution would have altered, and the pre-admission antibiotic treatment was heavily restrained, and (3) accuracy of diagnosis will increase, since diagnostic criteria are clearer nowadays. We sought to assess the burden of admitted infants ≤1 year with AOM in the PCV13 era, to characterize their clinical presentation, and to assess the accuracy rate of their diagnosis.

2. Patients and METHODS

The study was approved by the Institutional Review Board (protocol number: 0004-16-ASF).

2.1. Study design and population

We retrospectively identified and reviewed charts of infants ≤1 year who were admitted with AOM, with or without AM, in the General Pediatrics ward in a secondary medical center in central Israel (which serves some 250,000 children) during 1/1/2010–12/31/2015. Due to the retrospective nature of this study, and since we could not identify only complicated AOM cases beforehand, we decided to include both suppurative and not suppurative AOM admissions, by using primary or secondary International Code of Disease-9 discharge codes included 381.0X, acute non-suppurative otitis media (OM); 381.4, non-suppurative OM, not specified as acute or chronic; 382.4, unspecified suppurative OM and 382.9, unspecified OM. In addition, charts of children with the preceding AOM diagnosis codes were reviewed for concurrent AM, if they had relevant codes: 383.0, acute mastoiditis or 383.9, unspecified mastoiditis. For each calendrical year, we retrieved the number of admitted children to the Pediatrics wards (aged ≤1 year and 0–18 years), and then identified AOM admissions. At first, we retrieved 409 infants who contributed 418 AOM admissions; 9 infants were admitted twice. In their case, we included their first admission only. Consequently, we analyzed 409 AOM admissions.

2.2. AOM and AM episodes

Since myringotomy is not required anymore for AOM diagnosis, and due to the retrospective nature of this study, we categorized each AOM admission as following:

1 ***Suspected episode***: when an infant had the following signs/symptoms as reported by caregivers: ear-related symptoms, such as ear pain, ear rubbing/tugging, otorrhea and constitutional signs, such as fever (defined as oral temperature >37.8 °C or rectal temperature >38 °C), runny nose, cough, dyspnea, conjunctivitis, decreased appetite, irritability, lethargy, vomiting or diarrhea.
2 ***Probable episode***: when findings on otoscopy were compatible with AOM, regardless of the symptoms/signs. In these cases, middle ear fluid (MEF) showed at least two of the following TM findings: bulging, decreased or absent mobility (if pneumatic otoscopy was performed), abnormal color or opacity not due to scarring, or air-fluid interfaces.
3 ***Confirmed episode***: when the otoscopy findings were compatible with AOM and were accompanied with AOM-related symptoms and constitutional signs.

AM episode was considered when there was a preceding AOM history in an infant with suggestive typical clinical findings (postauricular tenderness, erythema or swelling, protruding auricle, palpable/fluctuating subperiosteal mass) and systemic signs (fever, lethargy, irritability, poor feeding, diarrhea).

2.3. Parameters

For each eligible AOM admission, with or without AM, we recorded the patient's age and gender; AOM risk factors (past or current breastfeeding, second-hand smoking exposure, day care attendance, older siblings, lack of breastfeeding), childhood vaccination status; history of current disease: maximal temperature recorded and clinical presentation, with an emphasis on ear-related symptoms/signs, such as ear tugging or rubbing, otorrhea or protrusion of the auricle) and respiratory-related symptoms/signs, such as wheezing, cough, runny nose or dyspnea; duration of admission; antibiotic treatment prior, during and after hospitalization; laboratory tests: (1) highest white blood cell (WBC) count, (2) C-reactive protein (CRP) levels, (3) hemoglobin level (anemia was considered as 2 standard deviations below the mean hemoglobin levels, which changed according to age) (4) culture type and results, if obtained, and (5) results of the respiratory panel from swab from nasal secretions (RSV and INF A/B), when obtained (usually during the winter months, if constitutional respiratory symptoms also occurred); the need for imaging studies or surgery; and other AOM complications (otorrhea, facial nerve paresis, etc). We could not collect data on history of previous/recurrent AOM episodes which were diagnosed and treated elsewhere in a credible manner.

2.4. Childhood vaccinations in Israel

In Israel, vaccines are routinely administered free-of-charge to all children at state-run Mother and Child Health Clinics. Of them, 3 vaccines potentially reduce AOM, and are given during the first year of life: (1) pneumococcal conjugate vaccine (PCV, previously PCV7, currently PCV13), at 2, 4 and 12 months, (2) *Haemophilus influenzae* type b *(Hib)* conjugate vaccine, at 2, 4, 6 and 12 months, which was introduced in the Israeli NIP already in 1991, and (3) influenza vaccine, with an efficacy that varies on the seasonal activity of circulating strains. Unlike the first 2 vaccines, the influenza vaccine is administered in community-based health maintenance organization clinics from 2006. The licensed inactivated vaccine is approved for infants >6 months, and should be given in 2 doses, with at least 4 weeks interval apart. According to the Israeli Public Health Services in the Ministry of Health, the influenza vaccination rates were relatively low, among children aged 6–59 months in the influenza seasons 2013/4, 2014/5 and 2015/6 were 19%, 25.5% and 24%, respectively (http://www.health.gov.il/English/MinistryUnits/HealthDivision/PublicHealth/Pages/Default.aspx). Nevertheless,