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Brief communication

A prospective observational cohort study to assess the incidence of acute otitis media among children 0–5 years of age in Southern Brazil

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ABSTRACT

Objectives: To estimate acute otitis media incidence among young children and impact on quality of life of parents/caregivers in a southern Brazilian city.
Methods: Prospective cohort study including children 0–5 years of age registered at a private pediatric practice. Acute otitis media episodes diagnosed by a pediatrician and impact on quality of life of parents/caregivers were assessed during a 12-month follow-up.
Results: During September 2008–March 2010, of 1,136 children enrolled in the study, 1074 (95%) were followed: 55.0% were ≤2 years of age, 52.3% males, 94.7% white, and 69.2% had previously received pneumococcal vaccine in private clinics. Acute otitis media incidence per 1000 person-years was 95.7 (95% confidence interval: 77.2–117.4) overall, 105.5 (95% confidence interval: 78.3–139.0) in children ≤2 years of age and 63.6 (95% confidence interval: 43.2–90.3) in children 3–5 years of age. Acute otitis media incidence per 1000 person-years was 86.3 (95% confidence interval: 65.5–111.5) and 117.1 (95% confidence interval: 80.1–165.3) among vaccinated and unvaccinated children, respectively. Nearly 68.9% of parents reported worsening of their overall quality of life.
Conclusion: Acute otitis media incidence among unvaccinated children in our study may be useful as baseline data to assess impact of pneumococcal vaccine introduction in the Brazilian National Immunization Program in April 2010.

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Acute otitis media (AOM) is a common bacterial infection affecting children at least once before their second birthday, and is a leading cause of health care visits and antibiotic prescription worldwide.[1,2] Globally, 709 million AOM cases are estimated to occur every year, of which 51% are seen in children ≤5 years of age.[3] In Latin America and the Caribbean, 11.7–360 AOM episodes per 1000 children <5 years of age are estimated to occur annually.[4] We report the incidence of AOM among children ≤5 years of age and impact on quality of life (QoL) of parents/caregivers in a southern Brazilian city before introduction of the pneumococcal vaccine in the National Immunization Program.

The study was conducted among privately insured children 0–5 years of age registered in a single private medical center in Paraná, Brazil, during September 2008–March 2010. Children who had no signs or symptoms of AOM or upper respiratory tract infection at the time of enrollment and whose parents/guardians provided written informed consent were followed for 12 months. The study was approved by a local independent ethics committee (Comitê de Ética em Pesquisa em Seres Humanos do Hospital de Clínicas da Universidade Federal do Paraná) and conducted according to the International Conference on Harmonization Guidelines for Good Clinical Practice, principles of Declaration of Helsinki.

Demographic data, medical history and pneumococcal vaccination history were collected from children's records. During the time of this study, *Prevnar* (7-valent PCV [PCV-7], Pfizer/Wyeth, USA) was available in private vaccination clinics.[5] We classified children as vaccinated if, either they received at least two doses of pneumococcal conjugate vaccine (PCV) or received only one dose after one year of age at any time prior to onset of AOM episode, and unvaccinated if they received only one dose of a conjugate pneumococcal vaccine during the first year of life or unvaccinated (no dose received) at any time prior to onset of AOM episode.

AOM episodes diagnosed by a pediatrician and AOM-related procedures, such as tympanocentesis, adenectomy, transtympanic aerator tube insertion were recorded during a 12-month follow-up period. Parents/guardians were contacted every two months to solicit information on any respiratory or AOM related symptom lasting >48 h, and visits to emergency rooms or other health care providers. A suspected AOM episode was defined as any AOM-related symptom reported only by parents, such as ear pain, discharge or tugging with one of the following symptoms: increased temperature, runny nose, sore-throat, cold-like symptoms, conjunctivitis, decrease in appetite, vomiting, diarrhea, trouble sleeping, irritability, or apathy. A probable episode was defined as an AOM episode diagnosed by a physician and documented in the medical chart, regardless of any documentation of symptoms. A probable AOM episode was confirmed when the visual appearance of the tympanic membrane was recorded (i.e. redness, bulging, loss of light reflex, presence of acute middle-ear effusion, as shown by otoscopy or tympanometry) and at least two of the following signs or symptoms were present: ear pain (otalgia), ear discharge, hearing loss, lethargy, irritability, anorexia, vomiting, diarrhea, fever (axillary temperature ≥38.0 °C, rectal temperature ≥38.5 °C) or analgesic/antipyretic therapy preceding fever. A new AOM episode was defined as an AOM episode after a 30-day symptom-free interval since the resolution of the previous AOM episode. AOM treatment failure was considered as persistence of AOM symptoms after 48–72 h of treatment with appropriate antibiotics.

To assess the impact of AOM episodes on the QoL of parents/caregiver, parents were asked to complete a questionnaire within 14 days after the child was diagnosed with AOM. The questionnaire was based on the parental QoL questionnaire for recurrent ears, nose and throat (ENT) infections in their children (PAR-ENT-QoL),[6] which was first adapted to be specific for AOM by a review panel from another study[7] and then translated to Portuguese.

To estimated AOM incidence and 95% confidence interval (CI), overall, by age group, and pneumococcal vaccination status, we used the following formula:

$$\text{Incidence of AOM} = \frac{\sum_{i=1}^{n} \varepsilon_i}{\sum_{i=1}^{n} \delta_i} \times 1000$$

where n is the total number subjects in the study cohort or subgroup; ε_i is the number of AOM episodes for subject i; δ_i is the number of days of the surveillance period for subject i.

Among 2083 children assessed for participation, 1136 (55%) were enrolled in the study. Among 1074 (95%) children who completed the 12-month follow-up, the median age was 32 months (range: 0–71), 52.3% were males, 94.7% were white, 72.6% attended school or childcare center, 97.5% had history of being breastfed, and 32.2% had at least one more child ≤5 years in the household. For pneumococcal vaccination status, 69.2% (743/1074) were classified as vaccinated, 28.6% (307/1074) remained unvaccinated, the vaccination status was unknown for 2% (22/1074), and the date of onset of AOM was missing for two children who went on to become vaccinated during the follow-up.

A total of 90 children experienced 99 AOM episodes, resulting in 133 health care center visits. Of the 99 AOM episodes recorded, seven (7%) were suspected and 92 (93%) were classified as probable, among which 45 (49%) were confirmed. Only one child had recurrent AOM episodes (i.e. at least three AOM episodes within six months). The most common clinical symptoms and signs of probable and confirmed AOM episodes were fever (67.4% and 86.7%, respectively), ear pain/otalgia (39.1% and 48.9%), redness of tympanic membrane (87.0% and 91.1%), bulging of tympanic membrane (50.0% and 55.6%), presence of acute middle-ear effusion (47.8% and 46.7%) and loss of light reflex (32.6% and 44.4%). Antibiotics were prescribed in 78.3% of probable AOM episodes and treatment failure was reported in 4.0%. Complications were reported for 4.3% AOM epsiodes, including persistent AOM, suppurative AOM, local abscess, and dysfunction of eustachian tube. Children were referred to consultation with otorhinolaryngologist in 7.6% of probable AOM episodes, and 2.2% had undergone any AOM-related procedure. None of the AOM episodes resulted in hospitalizations. The distribution of the QoL scores for emotional, daily disturbance and overall impact is described in Fig. 1. The highest scores, ≥3 on a scale of 1–5, were observed for worry (95.5%), impact on outdoor activities (84.5%), and sleep (84.4%). Overall, 68.9% of parents reported worsening (score 2–5) of their overall QoL, with 31.1% reporting somewhat considerable worsening (score 3–5).