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Incidence and economic burden of acute otitis media in children aged up to 5 years in three Middle Eastern countries and Pakistan: A multinational, retrospective, observational study

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ABSTRACT

Epidemiological data on acute otitis media (AOM), an infectious disease frequently affecting children, are lacking in some countries. This study was undertaken to assess the incidence of AOM in children ≤ 5 years in Saudi Arabia, Oman, Pakistan, and Turkey, as well as the economic burden from a parent/caregiver perspective. Medical records of 4043 children (Saudi Arabia = 1023, Oman = 998, Pakistan = 1022, Turkey = 1000) were retrospectively reviewed and the incidence of AOM episodes calculated from suspected and confirmed cases. Using a standardized Health Economics Questionnaire, parents recorded resource use and expenses incurred per AOM episode [in local currency and converted to US dollars (USD)]. The overall incidence of AOM episodes per 1000 person-years was: Saudi Arabia, 207 [95% confidence interval (CI): 178–238]; Oman, 105 (95% CI: 85–127); Pakistan, 138 (95% CI: 116–163); and Turkey, 99 (95% CI: 79–123). The mean total out-of-pocket healthcare expense incurred by parents/caregivers per episode was: Saudi Arabia USD67.1 [standard deviation (SD) = 93.0], Oman USD16.1 (SD = 16.4), Pakistan USD22.1 (SD = 20.5), and Turkey USD33.6 (SD = 44.9). The incidence of AOM episodes varied across all four countries, probably due to different diagnostic and management practices. Nevertheless, our results confirm that AOM causes a substantial burden to public health, reinforcing the need for cost-effective prevention strategies.

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1. Introduction

Acute otitis media (AOM), one of the most common infections in children aged < 5 years [1,2], is characterised by the presence of middle-ear effusion together with symptoms including ear discharge (otorrhoea), fever, irritability, and earache (otalgia) [2].

Approximately 80% of children are affected by AOM during their first 5 years of life [3]. The cumulative worldwide AOM incidence rate is 10.85%, that is, 709 million cases per year; out of which, 51% occur in children aged < 5 years [1]. Estimates from 2005 suggest that the incidence rates of AOM in South Asia and North Africa (Middle East regions) were 14.52% and 8.67%, respectively [1]. The disease burden is greatest between 6 months and 18 months of age and, if left untreated, may lead to permanent hearing loss [4]. Furthermore, recurrent AOM episodes may lead to chronic forms, such as chronic suppurative otitis media, potentially resulting in severe complications, such as intracranial infection, hearing impairment/loss, and facial paralysis [2,5].

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Bacteria and viruses are responsible for 35–55% and 20–30% of AOM cases, respectively [6], and the infection is one of the main reasons for primary care physician (PCP) consultations and antibiotic prescriptions [7]. Indeed, extensive antibiotic use has led to a significant increase in the prevalence of resistant AOM-causing pathogens [8].

AOM has a high economic burden in terms of direct and indirect cost [9,10], but pneumococcal vaccination of children can potentially reduce both the burden of AOM and its associated cost [11,12]. In 2007, the World Health Organization recommended the inclusion of pneumococcal vaccination in national immunization programmes (NIPs) [13]. Pneumococcal conjugate vaccines (PCVs) were subsequently introduced into the NIP of Oman (PCV-7; 2008) [14], Saudi Arabia (PCV-7; 2009) [15], Turkey (PCV-7; 2008) [16], and Pakistan (PHiD-CV; 2012) [17]. At the time of this study, PHiD-CV and PCV-13 were available in Pakistan [18]; PCV-13 was used in Oman [19], Saudi Arabia [20], and Turkey [21]. The vaccination coverage rates during the study period ranged from 99% in Oman, 98% in Saudi Arabia, 97% in Turkey, to 66% in Pakistan [22].

Epidemiological data on the incidence and cost of illness of AOM episodes are important for policy makers to understand both the public health burden and the potential economic impact of the disease. This study was undertaken to estimate the incidence of AOM episodes per person-years (PY) in Children aged ≤ 5 years in these three Middle Eastern countries and Pakistan, as well as the economic burden from a parent/caregiver perspective.

2. Materials and methods

2.1. Study design and participants

A large multinational, retrospective, observational study (Clinical Study Identifier: BEP115672) was conducted at two centres in Saudi Arabia (December 2012–July 2013), six centres in Oman (October 2012–December 2013), three centres in Pakistan (December 2012–December 2013), and two centres in Turkey (March–August 2013). The participating centres were primary care centres with physicians specialised in paediatrics. They were selected because they had an available ear-nose-throat (ENT) specialist, to identify how diagnosis is made by country and to assess differences between cases diagnosed by a PCP or ENT specialist. Target enrolment was 1000 children per country. In Saudi Arabia a simple randomisation scheme was followed to recruit patients [i.e., all eligible patients' files were allotted a serial number and stratified by age group (0–2 years and 3–5 years), and those with an odd number file were invited to participate]. In Pakistan, after screening the files, parents/guardians of eligible children were randomly called, although no randomisation scheme was used, and those who met the inclusion criteria and agreed to participate were enrolled. In Turkey and Oman, recruitment was based on convenience sampling, that is, all age-eligible children were included until the target number was reached.

The inclusion of potentially eligible participants was based on their age and the availability of their medical records for the 12 months before enrolment. Male or female children aged 0–5 years at the time of enrolment, registered in medical practices become ineligible at their sixth birthday. Children under the protection of an organisation or foster parents, or living in a care home, were excluded from the study.

2.2. Data collection

Parents/caregivers were invited to participate either during a medical consultation or by telephone.

Data were collected from medical records for the 12-month period prior to enrolment, thus ensuring coverage of all seasons. For patients aged < 12 months, data were collected from their first month onwards.

The medical histories of the children were retrospectively collected from their medical records. Demographic (e.g., birth date, height, weight, gender, and birth weight) and AOM visit information [medical history, diagnostic procedures (e.g., tympanocentesis, adenoidectomy, and transtympanic aerator tube insertion), AOM treatment (e.g., antibiotics, anti-inflammatories, antihistamines, corticosteroids, and cough medications), treatment failures, recurrent AOM, associated signs and symptoms, vaccination status, and hospitalisation] were recorded. In addition, parents/caregivers were asked to complete a Health Economics Questionnaire (HEQ) with information relating to the direct and indirect cost associated with an AOM episode and the assessed cost was converted from the local currency to US dollars (USD). The variables included out-of-pocket expenses: direct medical cost components (e.g., copayment related to treatment, procedures); direct nonmedical cost components (e.g., transportation fees or extraordinary babysitting fees); and indirect cost components (e.g., productivity loss of caregiver due to missing work). The cost of private transport was not captured due to a lack of unit cost data. Details on other visits, procedures, and medications for previous episodes in the 12 months before enrolment were also collected. The medical insurance status of the parent/caregiver and the child's missed attendance of school/day care were confirmed.

2.3. Case definitions

The level of certainty regarding the diagnosis was differentiated; according to whether a PCP or ENT specialist made the diagnosis and how it was made. A clinically suspected AOM (S-AOM) episode was defined as a PCP-diagnosed episode, with or without the visual appearance of the tympanic membrane [i.e. redness, bulging, loss of light reflex, the presence of acute middle-ear effusion (as shown by otoscopy or tympanometry)], and the presence of ≥ 2 of the following: ear pain, ear discharge, hearing loss, lethargy, irritability, anorexia, vomiting, diarrhoea, fever [temperature ≥ 38.0 °C (axillary); ≥ 38.5 °C (rectal)] or analgesic/antipyretic therapy preceding fever.

A clinically confirmed AOM (C-AOM) episode was defined as an ENT specialist-diagnosed episode.

A recurrent AOM (R-AOM) episode was defined as the occurrence of ≥ 3 new AOM episodes within 6 months, or ≥ 4 new AOM episodes within 1 year, as confirmed by an ENT specialist, regardless of the aetiology. AOM treatment failure was defined as no improvement in symptoms after 48–72 h of antibiotic therapy.

2.4. Statistical analysis

Analyses were performed on all recruited children who complied with the protocol-defined procedures. Descriptive statistics were used to summarise demographic characteristics by country and centre. The data sets from each country were analysed independently and missing data were excluded from the descriptive analysis.

The sample size estimation was based on a multinational European study that reported an overall incidence of 268 AOM episodes per 1000 PY and incidence rates of 299 per 1000 PY and 212 per 1000 PY in children aged 0–2 years and 3–5 years, respectively [23]. The sample size was estimated for a range of precision levels. For a proportion of $\sim 28\%$, with a precision of 4.5%, ~ 400 enrollees were required for the 0–2-year age group per country. For a proportion of $\sim 26\%$, with a precision of 3.5%, ~ 600 enrollees were required for the 3–5-year age group per country. Overall, 1000

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