



Contents lists available at ScienceDirect

International Journal of Pediatric Otorhinolaryngology

journal homepage: www.elsevier.com/locate/ijporl

Tracking tympanostomy tube outcomes in pediatric patients with otitis media using an electronic database



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ARTICLE INFO

Article history:

Received 5 February 2015

Received in revised form 27 April 2015

Accepted 20 May 2015

Available online 11 June 2015

Keywords:

Otitis media

Tympanostomy tubes

Complication rate

ABSTRACT

Objective: To implement and review a database for children with a diagnosis of otitis media (OM) to facilitate comparative outcomes and long-term prospective follow up of surgical outcomes. Specific aim is to review presenting symptoms, risk factors, tympanostomy tube outcomes and complications, and need for further procedures.

Methods: A web-based customized database was constructed to universally enroll all patients seen in consultation with a diagnosis of OM. Unique database fields include demographics, physical exam findings, risk factors, intervention, and long-term outcomes. Major surgical complications measured include: tympanic membrane perforation, retained tubes, chronic otorrhea, and cholesteatoma formation.

Results: Six hundred and thirty four unique patients have been prospectively enrolled. Five hundred and forty four tubes have been followed to extrusion. Outcomes demonstrate high prevalence of OM risk factors associated with surgical patients including: 63% in day care and 26% with a sibling requiring tympanostomy tubes. Complication rates; 1% developed perforations requiring surgical intervention, 2.6% required removal of retained tubes, 1% extruded early (<60 days), and 0.7% were surgically removed for other complications. Cholesteatoma was identified in 0.56%, all had ongoing chronic ear disease.

Conclusions: Long-term, outcome driven investigations assessing the surgical management of OM are needed given the prevalence of this disease and the frequency of surgical intervention required. The current database represents the largest prospective cohort of patients enrolled and followed in this fashion and has generated data demonstrating a procedure associated with significant improvement in patient quality of life in the short-term with low complication rates in the long-term. This ongoing prospective investigation is providing data that have the potential to be important in treatment algorithms, procedure justification, and risk factor modification.

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1. Introduction

Otitis media (OM) is the most common diagnosis in pediatric patients who visit physicians for illness in the United States, causing an estimated 5 million annual episodes at a national cost of almost \$6 billion [1]. Although OM can generally be managed with medical therapy for most children, increasing antibiotic resistance, concerns associated with hearing loss, and the potential for associated developmental delay result in the need for surgical intervention in some children. Several surgical interventions are

employed in the management of OM, including adenoidectomy and myringocentesis. However, the most common intervention is the placement of tympanostomy tubes (TT); with approximately 1 million TT placed in the US annually. The prevalence of OM and this requirement for surgical intervention has resulted in TT placement becoming the most frequently performed surgical procedure on children in the US [2,3]. Chronic otitis media with effusion (OME) is also the leading cause of hearing loss in children and may lead to speech, language, and developmental delays. When OME is prolonged, bilateral and associated with hearing loss, TT are the most effective means of middle ear effusion removal, improving hearing and quality of life in affected children [4]. Published studies have indicated that the most significant risk factors for the development of recurrent acute OM and chronic OME are attendance at large day care centers (>5 children), a family

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history of OM, exposure to secondary tobacco smoke, disadvantaged socioeconomic status, and craniofacial abnormalities [5,6].

Few studies to date have published prospective data examining the outcomes of patients undergoing this most common surgical procedure for children. No prospective studies exist to examine long-term surgical outcomes of these patients allowing for stratification by risk factors, type of TT employed, or eventual complications associated with surgical patients. The frequency of this procedure in children, questions regarding long-term outcomes, and potential complications demands a large-scale, long-term, prospective database to provide accurate longitudinal data describing this disease and its surgical treatment. This paper describes the first descriptive analysis of a prospective web-based database designed specifically to track OM patients and provide data to allow answers to a number of important clinical questions related to the care of OM patients.

2. Materials and methods

The Clinical Outcomes Registry (COR) is a secure, Health Insurance Portability and Accountability Act (HIPAA) compliant web-based system for prospective data collection. In collaboration with the Clinical Outcomes Team at Children's Hospital of Wisconsin (CHW), the Division of Pediatric Otolaryngology at the Medical College of Wisconsin developed a specific module designed to prospectively track all patients referred to the Pediatric Otolaryngology Clinic at CHW with a diagnosis of OM [7].

The methodology described by the Agency for Healthcare Research and Quality (AHRQ) was used to create standardized patient outcomes registries and the infrastructure. The AHRQ definition of a patient outcomes registry is "an organized system for the collection, storage, retrieval, analysis, and dissemination of information on individual persons who have either a particular disease, a condition (e.g., risk factor) that predisposes them to the occurrence of a health related event, or prior exposure to substances (or circumstances) known or suspected to cause adverse health effects [8]."

The COR is designed to allow for comprehensive data collection which begins when a patient is diagnosed or first seen in the clinic. Data are collected at multiple points during the continuum of care. All patients who presented with a diagnosis of otitis media were enrolled in the database. Surgical interventions, including tympanostomy tubes, were offered based on accepted clinical practice guidelines. All follow up visits were entered into the database as well as surgical information following standard clinical practice norms for the group. Patients were followed at least every 6 months through 1 year post tympanostomy tube extrusion with documentation of healthy ears.

Visits were documented in the database as either consultations, follow up, or post-surgical. Key fields entered for consultation visits include demographic information, chief complaint, comorbidities, physical exam, and diagnosis. Patient's initial consult visit also includes a questionnaire to evaluate common risk factors of otitis media including age at first episode, number of episodes before 1 year of age, number of episodes in the last year, sibling and parent history of OM, exposure to smoke or day care, history of previous ear tubes, and history of breast feeding. At follow up visits, chief complaint, exam findings, and diagnosis are recorded. Dates are entered when a patient is found to have an extruded tube. Post-surgical visits include information regarding surgical interventions, exam, and diagnosis. This provides data that can be evaluated longitudinally while also being coordinated with the patient care events (pre-surgical, surgical, and post-surgical). The specific description of these data for this manuscript was approved by the CHW Institutional Review Board (IRB).

The design for the OM module within the database is specifically constructed to allow for assessment of outcomes of patients referred to a tertiary pediatric otolaryngology practice with a diagnosis of OM. Patient queries are designed to allow for long-term follow-up of, primarily, surgical patients to assess outcomes and associated surgical complications. The OM subset of the COR was queried to assess the current prospectively collected data from a 3-year period (2009–2012). This time frame was chosen as the database was first incorporated into the routine clinical care for patients in the Pediatric ENT Clinic at Children's Hospital of Wisconsin in 2009. Information sought included demographics, chief complaint, questionnaire answers, exam findings, diagnosis, and surgical interventions. Database query identified patients with tympanostomy tubes placed and these patients were further studied to identify type of tube placed, time of tube extrusion, need for further surgical interventions (tube replacement, tube removal, tympanoplasty, and tympanomastoidectomy), and diagnosis. Analysis was performed using the data obtained from the database and retrospective analysis was used to fill in any missing data.

3. Results

3.1. Consultations

Visits from 634 unique patients have been collected since the database inception in 2009. Patient ages range from 1 month to 17 years (mean: 3 years, SD: 2.8) at consultation. There is a slight male predominance, with 57.6% male and 42.4% female.

The most common diagnosis is recurrent otitis media in 60% of patients. Second most common is chronic mucoid effusions, present in 38% of patients. 18.6% of patients have a history of speech delay. On exam at consultation, the most common findings are serous and mucoid effusions totaling 46.5% of ears together.

3.2. Risk factors

Risk factors for OM were gathered through a questionnaire completed at the time of consultation (Table 1). Early OM was associated with the patients referred to the pediatric otolaryngology clinic. A total of 52.6% of patients report high frequency of OM (4+ episodes) in the first year of life. Only 3.7% report no episodes in the first year of life.

A large proportion of patients report recurrent otitis media, with 68.8% of patients reporting 4 episodes or greater of OM in the previous 12 months. Given that 75% of patients were referred with a diagnosis of recurrent OM, this incidence of OM demonstrates the overlap of recurrent OM in patients with OME.

Family history is prevalent in patients referred with 45.8% of parents reporting a problem with ear infections as a child and 21.5% requiring tubes. 39.0% of siblings report a history of ear infection and 26.1% required tubes.

A large percentage of the OM patients report attending day care (63.4%). Most of these patients (87.0%) report attending a large day

Table 1

Risk factors	Yes (%)	No (%)	N/A (%)
Parent OM	46	54	
Parent tubes	22	78	
Sibling OM	39	54	7
Sibling tubes	26	67	7
Smoking	13	87	
Day care	63	37	
Breast fed	64	36	

OM: Otitis media.

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