International Journal of Pediatric Otorhinolaryngology (2008) 72, 1215–1223

ELSEVIER

International Journal of Pediatric Otorhinolaryngology

www.elsevier.com/locate/ijporl

Efficacy of allergy immunotherapy as a treatment for patients with chronic otitis media with effusion☆

David S. Hurst*

Tufts University, Boston, MA, United States

Received 20 February 2008; received in revised form 23 April 2008; accepted 26 April 2008
Available online 9 June 2008

KEYWORDS
Allergy;
Otitis media;
Effusion;
Intradermal testing;
Immunotherapy

Summary

Objective: Controversy persists over the significance of allergy as it might relate to chronic middle-ear disease as no controlled study of the efficacy of allergy immunotherapy has been published. The aim of this study was (1) to evaluate the atopic status of patients with intractable chronic otitis media with effusion or drainage from their middle ear and (2) to determine in this select population the efficacy of specific allergy immunotherapy in preventing or limiting the duration of their chronic middle-ear disease.
Methods: This was a prospective, cohort study of patients cared for in a private community practice. History, examination, audiogram, tympanometry and recurrence of effusion/infection were recorded on 89 patients (52 children <15 years old, 37 adults) referred with (1) effusion found to warrant myringotomy and ventilation tubes, or (2) chronic drainage from a perforation or tube. All were evaluated for allergy by intradermal skin testing according to criteria of the American Academy of Otolaryngic Allergy. A control cohort of 21 patients who refused therapy was included. Intervention consisted of immunotherapy for dust, pollen, and molds. Recurrence or persistence of fluid or drainage following 2–8 years of therapy was compared to the patient's pretreatment status.
Results: All 89 OME patients proved to be atopic. Most were allergic to dust (94%), animals (44%) and molds (88%) while 9% were allergic only to seasonal pollens. Associated allergic diseases included asthma (21%) and allergic rhinitis/sinusitis (63%). Otitis was the sole symptom among 37%. Immunotherapy provided complete resolution of effusion or drainage in 85% of 127 ears.
Conclusion: Intradermal testing proved all 89 patients with intractable middle-ear disease in this study who presented with chronic effusion or chronic draining perforations or tubes to be atopic. Specific allergy immunotherapy significantly improved

☆ Presented at European Society of Pediatric Otolaryngology, Paris, France, 21 June 2006.

* Correspondence address: 43 Carson Drive, Gorham, ME 04038, United States. Tel.: +1 207 839 6779; fax: +1 207 883 6556.
E-mail address: meear43@gmail.com.

0165-5876/$ – see front matter
doi:10.1016/j.ijporl.2008.04.013

5.5% and completely resolved 85% of chronic otitis media with effusion in these ears. None of the controls resolved spontaneously ($p < 0.001$). This supports the hypothesis that in many, otitis media with effusion is an immune mediated allergic disease and suggests that these patients deserve consideration for aggressive evaluation and allergy treatment, as most respond to immunotherapy.

1. Introduction

Otitis media with effusion (OME) describes an inflammatory process within the middle-ear space that is generally associated with accumulation of fluid. OME is associated clinically with hearing loss, subsequent delayed speech development and permanent middle-ear damage with mucosal changes. The cause of OME has been the source of much controversy, generating numerous studies in an effort to clarify the issue. Chronic middle-ear disease likely represents an entity with multiple etiologic factors such as genetic predisposition, endogenous and exogenous factors. It is heterogeneous in its presentation. Its categorization depends on the length of time effusion persists, presence of purulence and whether the tympanic membrane is intact, perforated, or draining.

Atopy has been defined as the sensitization or predisposition to hyperreactivity to a normally nonreactive antigen. Allergic patients are considered to be those who express symptoms related to exposure and are not merely sensitized [1].

Despite studies in China, Japan, USA, Canada, and Sweden demonstrating that all the mediators required for a Th-2 inflammatory response, including eosinophil cationic protein, tryptase, and/or IL-5 mRNA cells, CD3+ T cells [2], eosinophils [3], mast cells [4], Rantes [5], prostaglandins [6] and IgE [7] are present in the majority of ears with chronic effusion, a role of allergy with clinical applicability to chronic middle-ear disease is not embraced by most otologists. A recent clinical practice discussion and literature review states that ''the relation between allergy and OME will remain controversial until well-controlled clinical studies are conducted documenting that in select populations anti-allergy therapy is efficacious in preventing or limiting the duration of OME'' [8]. The aim of this study was to examine that premise.

It has been shown that ''there are no substantial differences in Eustachian Tube (ET) function between ears that develop OME recurrence and ears that do not'' [9]. It is also a commonly held myth that the eustachian tube will grow to normal size as children mature despite evidence that there is no difference in the size of either the isthmus or pharyngeal portion of the ET in children with OME vs. normals [10]. This suggests that our understanding of ET dysfunction as a reflection of a pathophysiologic manifestation of significant mucosal disease may be incomplete. A direct effect of allergy on ET dysfunction is conjecture, though supported by some mice studies [11]. This clinical study is an attempt to establish indirect evidence of such a relationship. The question being asked is: if a patient has documented allergies, will conventional immunotherapy directed at those specific allergens alter the course of their disease?

2. Methods

Lacking the milieu to conduct an ideal randomized, double blind placebo-controlled (DBPC) study, we designed a prospective, cohort study to assess both the atopic status of patients with intractable chronic OME or drainage from the middle-ear using intradermal skin testing (IDT) as well as the efficacy of allergy immunotherapy (IT) as a treatment intervention. All patients over 4 years of age presenting to a solo-practitioner, community-based otolaryngologist from 9/95 to 12/05 with any of the variations of intractable chronic middle-ear disease were enrolled prospectively; follow up continued to 12/07. All were assessed in an identical manner by history, otologic exam, pneumatic otoscopy, audiometry and tympanometry and offered the same treatment options. Any patient with (A) chronic OME >6 months during a 1-year period and no previous myringotomy and tubes (M&T) or OME >3 months warranting a second M&T, and/or (B) chronic supurative otitis media (CSOM) with persistent drainage from a perforation or tympanostomy tube which had been otherwise unresponsive to oral and/or topical antibiotics was included. Patients with cranial facial abnormalities, muscular dystrophy, or a history of previous cholesteotoma, mastoidectomy or autoimmune disorders were excluded. Selection for myringotomy with placement of pressure equalization tubes was based on standard criteria including persistent middle-ear effusion (MEE), abnormal tympanogram and a conductive hearing loss greater than 15-dB. IDT for specific allergens was performed on all patients following approval of the Franklin Memorial Hospital (Farmington, Me) Committee on Ethics and Human Experi-