



A new device for treatment of persistent otitis media with effusion



Armin Bidarian-Moniri^{a,b,*}, Maria-João Ramos^b, Ilídio Gonçalves^b, Hasse Ejnell^a

^a Department of Otorhinolaryngology, Sahlgrenska University Hospital Gothenburg, Sweden

^b Department of Otorhinolaryngology, Centro Hospitalar Barlavento Algarvio Portimão, Portugal

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ABSTRACT

Objectives: Most children suffer from otitis media with effusion (OME) before starting school. Insertion of grommets into the eardrum for treatment of OME is one of the most common operations performed in childhood. The efficiency and compliance of treatment with a new non-invasive device was evaluated in children with bilateral OME with disease duration of at least 3 months.

Methods: A device for autoinflation was developed to enable a combined modified Valsalva and Politzer maneuver. Ten children, aged 3–8 years (mean: 5 years and 2 months) with OME tested the device for estimation of its ability to ventilate the middle ear. Another thirty-one children, with persistent bilateral OME for at least three months, were divided into a treatment and a control group. Twenty-one children (42 ears), aged 2–7 year (mean: 4 years and 6 months), participated as the treatment group and ten patients (20 ears), aged 3–7 years (mean: 4 years and 5 months), were included as controls. Tympanometry and otomicroscopy were performed at inclusion and at the end of the study.

Results: In the treatment group the middle ear pressure was normalized in 52% and improved in 31% of the ears with 7 children (33%) achieving bilateral and 8 (38%) unilateral normalization. In the control group the middle ear pressure was normalized in 15%, improved in 15% and deteriorated in 10% of the ears with one child (10%) achieving bilateral and one child (10%) unilateral normalization. Statistically significant differences ($p < 0.001$) were observed in the pressure difference and the tympanometry type changes between the treatment and the control group. Otomicroscopic examination revealed that the number of ears judged as OME was reduced by 62% in the treatment group in comparison with 20% in the control group. All children managed to perform the maneuver and no side effects were neither reported nor detected.

Conclusions: The device was efficient in ventilation of the middle ear with normalization or improvement of the negative middle ear pressure and otomicroscopic findings in young children with persistent OME.

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1. Introduction

Otitis media with effusion (OME) is an inflammation with fluid in the middle ear often combined with impaired hearing [1]. The lack of acute symptoms in children with OME makes it difficult to estimate the accurate incidence, but most children have at least one episode of OME before starting school [2].

The recommended technique for diagnosing OME is impedance audiometry (tympanometry) in combination with otomicroscopy or pneumatic otoscopy [1,3–7].

The Eustachian tube plays an important role in maintaining the middle ear healthy [8,9]. The tube plays a ventilatory function

equilibrating the pressure between the middle ear and the ambient air [9,10]. The Eustachian tube in young children is short, floppy, more horizontal and therefore functions poorly [9]. These anatomical considerations are believed to cause the high prevalence of OME in young individuals [9]. Maturation of the tube is a gradual process, which explains the infrequency of OME after the age of 7 years [11,12].

The active opening ability of the Eustachian tube for equilibration of the middle ear pressure is reduced in children with middle ear disease [13,14]. Earlier studies have emphasized great variability of the Eustachian tube function in children with OME with a mean forced opening pressure of approximately 30 ± 15 cm H₂O [15,16].

The insertion of grommets into the eardrum is one of the most common operations performed under general anesthesia in childhood. The primary indication for the operation is restoration of normal hearing in children with long-standing bilateral OME [1,7,17]. The rationale for the procedure is to improve ventilation

* Corresponding author at: Department of Otorhinolaryngology, Sahlgrenska University Hospital Gothenburg, Sweden. Tel.: +46 760 747 970/+351 916 468 983.

E-mail addresses: armin.bidarian@vgregion.se, armin.bidarian@yahoo.com (A. Bidarian-Moniri).

