International Journal of Pediatric Otorhinolaryngology 78 (2014) 1298–1305

Contents lists available at ScienceDirect

International Journal of Pediatric Otorhinolaryngology

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

Autoinflation for treatment of persistent otitis media with effusion in children: A cross-over study with a 12-month follow-up

Armin Bidarian-Moniri [a,b,*], Maria-João Ramos [b], Hasse Ejnell [a]

[a] Department of Otorhinolaryngology, Institute of Clinical Sciences, Sahlgrenska Academy at the University Of Gothenburg, Sahlgrenska University Hospital, Gothenburg, Sweden
[b] Department of Otorhinolaryngology, Centro Hospitalar do Algarve, Department of Biomedical Sciences and Medicine, University of Algarve, Algarve, Portugal

ARTICLE INFO

Article history:
Received 30 November 2013
Received in revised form 17 March 2014
Accepted 10 May 2014
Available online 23 May 2014

Keywords:
Otitis media with effusion
Autoinflation
Non-invasive conservative treatment
Politzer
Valsalva

ABSTRACT

Objectives: The aims of the present study were to evaluate the efficacy of and compliance with a new device for autoinflation in the treatment of persistent otitis media with effusion (OME) in young children.
Methods: Forty-five children with persistent OME with a bilateral type B or C2 tympanogram for at least three months and history of subjective hearing loss, waiting for grommet surgery, were randomised to a treatment and a control group. Twenty-three children aged between three and eight years started as the treatment group with the new device for autoinflation. Another 22 children, aged between two and eight years were included as controls. After a period of four weeks, a cross-over was performed. Both groups underwent otomicroscopy, tympanometry and audiometry at inclusion and after one and two months for the evaluation of treatment efficiency. The primary outcome measurements were improvement in middle-ear pressure and hearing thresholds at eight weeks. Both groups were then followed up for another 10 months.
Results: In the treatment group, the mean middle-ear pressure for both ears and the mean hearing thresholds for the best ear improved by 166 daPa ($p < 0.0001$) and 6 dB ($p < 0.0001$), respectively after four weeks, while in the control group, non-significant alterations were observed. After the cross-over of the control group to treatment, equivalent improvements in the mean middle-ear pressure and the mean hearing thresholds of 187 daPa ($p < 0.0001$) and 7 dB ($p < 0.01$), respectively were achieved also in this group. After treatment in both groups at eight weeks, four of 45 children were submitted to grommet surgery. During the long-term follow-up another five children were submitted to surgery due to recurrence of disease. All the children managed to perform the manoeuvre and no side-effects were detected.
Conclusion: The device demonstrated efficiency in improving both middle-ear pressure and hearing thresholds in most children after four weeks of treatment. It might therefore be possible to consider this method of autoinflation in children with persistent OME during the watchful waiting period.

1. Introduction

Otitis media with effusion (OME) is an inflammation with fluid in the middle ear often combined with impaired hearing [1]. The insertion of grommets into the eardrum is one of the most common operations performed under general anaesthesia in childhood [2]. The primary indication for the operation is the restoration of normal hearing in children with long-standing bilateral OME by improving the ventilation and pressure regulation in the middle ear [1,3–5]. However, previous studies indicate that the benefits of grommets in children with OME are limited and that the effect on hearing diminishes during the first year [4,6,7]. Considering the potentially adverse effects on the tympanic membrane after grommet insertion, a period of watchful waiting is recommended for most children with OME [4].

Several non-invasive methods, i.e. autoinflation, have been developed to improve the negative middle-ear pressure in children with OME [8–12]. Autoinflation is a technique whereby the Eustachian tube is opened by increasing the intranasal pressure [2]. This can be achieved by forced exhalation with a closed mouth and nose or by blowing up a balloon through each nostril by active inflation [2]. A Cochrane review concluded that evidence for the

Abbreviations: OME, Otitis media with effusion; daPa, Decapascal; dB, Decibel hearing level.

* Corresponding author at: Department of Otorhinolaryngology, Institute of Clinical Sciences, Sahlgrenska Academy at the University of Gothenburg, Sahlgrenska University Hospital, Gröna stråket 5-9, 41345 Gothenburg, Västra Götaland, Sweden. Tel.: +46 760 747 970; fax: +351 91 646 89 83.
E-mail address: armin.bidarian@vgregion.se (A. Bidarian-Moniri).

http://dx.doi.org/10.1016/j.ijporl.2014.05.015
0165-5876/

use of autoinflation in the short term is favourable, but, given the small number of studies and the lack of follow-up, the long-term effects cannot be determined [2].

The authors of the present study tested a new device for autoinflation, enabling a combined, modified Valsalva–Politzer manoeuvre. In a previous pilot study, 21 children, aged two to seven years, were able to perform the procedure and >80% of the children achieved improved middle-ear pressure [13]. However, due to the small number of subjects, lack of hearing evaluation and the short follow-up time, the long-term effects of this treatment could not be determined.

The aims of the present study were to: (I) evaluate the efficiency of and compliance with the new device in young children with persistent OME in a cross-over study with a follow-up period of eight weeks and (II) assess the long-term effects of the device with a follow-up period of one year.

2. Methods

2.1. Device for autoinflation

A new autoinflation device (Fig. 1) for home treatment of children with persistent OME was used in the present study. The device consisted of (1) an inflatable facemask, (2) a T-shaped junction tube connecting at one end to the facemask, another end to (3) a balloon and the third end to (4) a handheld pump. The pump was covered by (5) a teddy bear in order to improve compliance in young children.

The inflatable facemask was used to cover the nose and mouth of the child, with individual adaptations in size. The parent helped the child to adapt the facemask in order to avoid air leakage during the manoeuvre.

The balloon was provided for pressure regulation and visual feedback on a correct manoeuvre to the child and the parent. The balloon also functioned as an air reservoir producing a counter-pressure for a few seconds. Three different balloons with the respective opening pressures of 20 ± 3, 40 ± 2 and 60 ± 5 cm H_2O were used. The balloon opening pressures were verified by an anaesthetic machine (Datex Ohmeda S5 ADU), with a pressure-monitoring and ventilation function, used at operating theatres. To eliminate the initial high opening pressure of the balloon, five inflations were performed before measuring the opening pressure of each balloon. The quality of the balloons chosen for the purpose of the study provided a mean opening pressure that was substantially preserved during approximately 50 inflations.

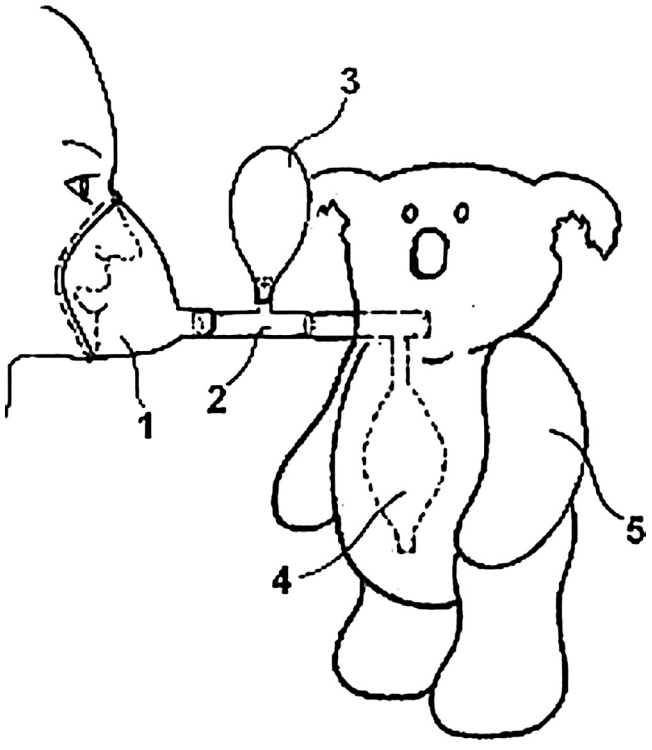

Fig. 1. The device for autoinflation consisting of (1) a facemask, (2) a T-shaped junction tube, (3) a balloon, (4) a handheld pump and (5) a teddy bear.

The handheld pump with a total volume of 250 ml was incorporated into the device. The pump, covered by a teddy bear, was used to produce a modified, controlled Politzer effect in order to facilitate the inflation of the balloon whenever necessary. To control the pressure produced by the handheld pump, a safety valve of 40 cm H_2O was installed in the system. The child would be able to blow up balloons with different opening pressures ($\leq 60 \pm 5$ cm H_2O) via the facemask, but any pressure exceeding 40 cm H_2O produced by the pump would activate the safety valve.

The parents performed five inflations before starting treatment on the child in order to eliminate the initial high opening pressure of each new balloon. The balloon with the lowest pressure was initially used to help the child become familiar with the device. Within the first day of treatment, the balloon type was changed to another one with opening pressure of $\geq$40 cm H_2O. The parents were advised to replace the balloons each day in order to maintain the desired pressure during the treatment. Middle-ear ventilation was considered to have taken place if the child mentioned symptoms such as mild transient discomfort, sensation of air, water, alteration in hearing or a crackling sound in one or both ears. The final balloon type chosen for treatment was determined when the child mentioned one or several of the above-mentioned symptoms. A doctor or a nurse followed up the children every week.

Audiometry, tympanometry and clinical ear, nose and throat examinations including otomicroscopy were performed at inclusion and after one, two, six and 12 months. During the 10 months follow-up period, when a new episode of OME was detected, a control was scheduled within eight weeks and, if the OME was persistent, a new four-week period of treatment was initiated.

2.2. Otomicroscopy

A clinical ear, nose and throat examination including otomicroscopy was carried out by one examiner (ABM). By otomicroscopy, the position and morphology of the tympanic membrane and the presence of liquid or gas bubbles in the middle ear were compared before and after the treatment. A neutrally positioned eardrum, with gas in the middle ear and no signs of effusion, gas bubbles or retractions, was regarded as normal. A retracted or neutrally positioned eardrum with middle-ear effusion with or without gas bubbles was judged as pathological. The otomicroscopy findings were primarily used to evaluate the correct performance of the manoeuvre by the child and to help the parents choose the right balloon pressure at the follow-ups. These results were not used in the statistical analyses due to possible subjective bias.

2.3. Tympanometry

The tympanometric equipment used in the study was a Grason–Stadler GSI 33, Version 2 Middle-Ear Analyser, with a probe frequency of 226 Hz. The tympanometry results produced by this equipment were regarded as pathological, i.e. representing OME, in type B tympanograms with a flat curve with a relative gradient of less than 0.1 or with middle-ear pressure of ≤ -400 daPa. In the present study, type B tympanograms were systematically