

Randomised controlled trial

# Autoinflation reduces middle ear effusion in children with otitis media with effusion

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**Commentary on:** Williamson I, Vennik J, Harnden A, *et al.* Effect of nasal balloon autoinflation in children with otitis media with effusion in primary care: an open randomized controlled trial. *CMAJ* 2015;187:961–9.

## Context

Otitis media with effusion (OME) is defined as accumulation of fluid in the middle ear in absence of signs or symptoms of an acute ear infection.<sup>1</sup> OME is usually associated with a conductive hearing loss that may affect the quality of life.<sup>1</sup> Surgical treatment of OME with grommets is associated with substantial healthcare costs and is usually considered after a period of watchful waiting, leaving most children with OME untreated during this period.<sup>1</sup> This raises the need for an efficient, non-invasive treatment option that can be offered to children with OME at an early stage.

In 1968, Hunt-Williams presented a new method for autoinflation involving a plastic end-piece connected to a balloon, later developed into the Otovent device.<sup>2</sup> The present study evaluates the effect of autoinflation with this method on children with OME.

## Methods

This was a randomised controlled trial (RCT) set in 43 family practices in the UK including 320 children aged 4–11 years with otitis media with effusion in one or both ears, confirmed by tympanometry.

The plastic end-piece in the Otovent device was adapted to a nostril and, while the other nostril was occluded, the children were instructed to inflate the balloon. The children were allocated to either autoinflation three times daily for 1–3 months in addition to usual care (intervention) or usual care alone (control). Clearance of middle-ear fluid at 1 and 3 months was evaluated by tympanometry. Ear-related quality of life was assessed at 3 months using the OMQ-14 (an ear-related measure of quality of life). The results are reported as relative risk (RR) or OR estimates and CIs. The methodology is adhered to recognised international protocols for RCTs.

## Findings

Children performing autoinflation were more likely to achieve a normal tympanogram at 1 month compared to controls (47.3% (62/131) vs 35.6% (47/132); adjusted relative risk (RR) 1.36, 95% CI 0.99 to 1.88) and at 3 months (49.6% (62/125) vs 38.3% (46/120); adjusted RR 1.37, 95% CI 1.03 to 1.83). The improvement in ear-related quality of life, as judged

by OMQ-14, was superior in the autoinflation group compared to the control group (score  $-0.42$ , 95% CI  $-0.63$  to  $-0.22$ ). Compliance was 89% at 1 month and 80% at 3 months. There was no significant difference in adverse events between the groups.

## Commentary

This RTC evaluated the effect of autoinflation with the Otovent device on children with OME, and achieved some positive results. However, only children aged 4–11 years were included, while OME culminates between the ages of 1–4 years with decreasing prevalence thereafter.<sup>3</sup> Additionally, the primary indication for treatment of OME is the restoration of normal hearing,<sup>1</sup> yet hearing testing was not performed in this study. The follow-up period was also limited to 3 months, making it impossible to evaluate the long-term outcome of this treatment.

The most recent Cochrane review gave a relatively weak recommendation regarding autoinflation in treatment for children with OME based on the short follow-up time and the lack of adequate hearing evaluation in previous studies.<sup>4</sup> An efficient treatment for OME should be appropriate for children younger than 4 years of age and the study protocol should include hearing testing and a long-term follow-up.<sup>5</sup>

This study shows that autoinflation reduces middle ear effusion and improves the quality of life in children with OME.

The large sample size from family practices may permit generalisation of the results to a normal population. The simplicity of the Otovent device allows for early intervention during the watchful waiting period. Future studies should assess the effect on hearing and the long-term outcome.

## Implications for practice

This study provides evidence that autoinflation may reduce middle ear effusion and the related symptoms in some children with OME. Given its low cost and non-invasive character, it may be reasonable to apply this method to improve symptoms and hopefully avoid surgery in children with OME.

**Competing interests** None declared.

**Provenance and peer review** Commissioned; internally peer reviewed.



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