

Autoinflation device (Otovent®)

Device name and manufacturer

Otovent®, Kestrel Medical Ltd.

What is the Technology and what is it designed to treat?

The device is promoted to treat 'glue ear' or otitis media with effusion (OME).¹ In OME, the middle ear becomes filled with serous or mucoid (but not purulent) fluid, causing deafness. This occurs typically in pre-school children who present with hearing impairment and speech problems.² OME is generally painless and contrasts with the acute otitis media, where children present with symptoms of acute ear pain, fever or malaise.

A high proportion of cases of OME (around 50%) remit spontaneously within 3 months and over 95% within a year, and it is much less common after the age of 6.² A variety of therapeutic treatments have been tried (antibiotics, antihistamines, oral decongestants, mucolytics) but none found to be effective in OME, though the evidence from trials is generally poor.²

The Otovent® device consists of a shaped nasal tube and 5 latex balloons.¹ The nasal tube fits into the neck of a balloon at one end and then the other end is pressed to one nostril while the other nostril is closed. The user then blows into the device, increasing pressure in the nasopharynx. This is intended to temporarily open the Eustachian tube and introduce air into the middle ear, thereby encouraging clearance of the effusion.

The manufacturer recommends the device be used on a regular basis two or three times a day, until fluid has drained and hearing restored. The normal duration of treatment is two weeks according to the manufacturer; each balloon can be used for 3-4 days. They recommend review by the GP before treatment is repeated.¹

What is the evidence for effectiveness of the device?

A Cochrane systematic review published in 2013 reviewed trials that used standard treatment with and without autoinflation in children with OME.³ Studies were small, with a total of 702 patients in 8 trials that lasted between 10 days and seven weeks. Three of these trials used the Otovent device, two used a carnival blower with balloon and three involved other devices. Most of the trials involved using the device three times a day. As the trials were of variable duration, the reviewers used two pooled estimates of effect – either up to one month's duration, or over one month's duration of use. They found no significant effect on tympanometry results, nor those for audiometry, which used either pure tone or a non-discrete sound. Pooled estimates favoured use of autoinflation for the composite measure of change in tympanometry and/or audiometry, but this was only statistically significant for use longer than one month (relative risk of improvement, RRI, 1.74, 95% CI 1.22 to 2.50).

Subgroup analysis of the five trials involving either Otovent or carnival blowers found there was a modest improvement in tympanogram or composite tympanogram plus audiometry results, though this was only statistically significant for use over one month (RRI 1.22, 95% CI 1.00 to 1.49).

The review authors concluded that in the absence of adverse effects it is reasonable to consider autoinflation whilst awaiting natural resolution of otitis media with effusion. They advocated further research in primary care including long term outcomes.³ NICE guidance also concluded that autoinflation may be considered during the active observation period in children with OME who are likely to co-operate with the procedure.⁴

An open randomised trial involving the addition of autoinflation to standard care in 4 to 11 year old schoolchildren recently completed in August 2014, results are not yet available.⁵

Costs

Cost per pack of tube with 5 balloons (sufficient for 2-3 weeks' treatment): £4.90 (Drug Tariff, November 2014)

Considerations

There are no data on long term outcomes with the device.

A reasonable amount of dexterity and co-ordination is necessary to blow the balloons up using one nostril while keeping the other occluded; not all small children are likely to be able to do this. Compliance with instructions to use the device several times a day may be a problem for some. Using carnival blowers as an alternative may be more attractive to some younger children.

References

1. Otovent manufacturers website at www.otovent.co.uk
2. Williamson. Otitis media effusion in children. Clinical Evidence 2007; 502, accessed via http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2943809/#BMJ_0502_REF30, October 2014
3. Glasziou P et al. Cochrane review: Autoinflation for hearing loss associated with otitis media with effusion ('glue ear'), accessed via <http://summaries.cochrane.org/CD006285/autoinflation-for-hearing-loss-associated-with-otitis-media-with-effusion-glue-ear>, October 2014.
4. CG60: Surgical management of otitis media with effusion in children. Accessed via <http://www.nice.org.uk/guidance/cg60/resources/guidance-surgical-management-of-otitis-media-with-effusion-in-children-pdf>, October 2014
5. Williamson I. Study of autoinflation in 4-11 year old schoolchildren with glue ear, accessed via <http://www.controlled-trials.com/ISRCTN55208702>, Nov 14