

Otovent nasal balloon for otitis media with effusion

Medtech innovation briefing

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Summary

Otovent is a balloon device designed to relieve the symptoms of otitis media with effusion, commonly known as glue ear. An Otovent kit consists of a nose piece and 5 latex balloons that are inflated by blowing through the nose. Four randomised controlled trials, all in children, have shown that using the device causes significant improvements, compared with standard care, in middle ear function; 1 of the trials also reported a significant reduction in the need for ventilation tube (grommet) insertion surgery. Outcomes varied by compliance with (that is, adherence to) treatment, and standard care was not consistently described. The Otovent kit is available to buy or can be provided on a NHS prescription. The recommended retail price is £7.84 including VAT and the current Drug Tariff price is £4.90 excluding VAT. No additional consumables are needed.

Product summary and likely place in therapy	Effectiveness and safety
<ul style="list-style-type: none"> • Otovent is designed to help open the Eustachian tubes and equalise the air pressure in the middle ear. • The device can be used in people with Eustachian tube dysfunction associated with glue ear (otitis media with effusion), or after flying, diving or pressure chamber treatment. • It would most likely be used in children with glue ear during or after an active observation period following diagnosis, to help avoid the need for surgery. 	<ul style="list-style-type: none"> • No relevant evidence was found for the use of Otovent in adults. • Four randomised controlled trials involving a total of 565 children showed statistically significant improvements in middle ear function with Otovent compared with standard care, as determined by tympanometry and pneumatic otometry. The comparator was not always fully described. • One study (n=320) reported that children having auto-inflation were more likely to have normal tympanograms at 1 month (47.3% compared with 35.6%; relative risk 1.36) and 3 months (49.6% compared with 38.3%; relative risk 1.37) than those having standard care alone. Auto-inflation also produced greater improvements in ear-related quality of life assessed using a validated tool (the OMQ-14). • One study (n=85) reported significant improvement in middle ear function, as assessed by tympanometry and pneumatic otoscopy, at 1, 2 and 3 months in those using Otovent with a compliance of more than 70% when compared with the control group. • One study (n=60) reported a significant reduction in the need for ventilation tube (grommets) surgery in the children having both Otovent and nasal saline irrigation compared with children having irrigation alone.

	<ul style="list-style-type: none">• One study (n=100) reported that 65% of ears improved, 33% remained unchanged and 2% deteriorated after 2 weeks of auto-inflation, compared with 15% of ears improving, 71% remaining unchanged, and 14% deteriorating in the control group.• No serious adverse effects associated with using the balloon were reported.
Technical and patient factors <ul style="list-style-type: none">• Otovent can be used at home by children aged 3 years and over and by adults. Young children should be supervised by an adult during use.	Cost and resource use <ul style="list-style-type: none">• The Otovent kit, comprising a nose piece and 5 latex balloons, has a Drug Tariff cost for the NHS of £4.90 (excluding VAT). The retail price is £7.84 (including VAT).• Initial treatment is 3 inflations per day for each affected nostril, and each balloon may be inflated 20 times before it needs replacing. Treatment normally lasts 2 to 3 weeks.

Introduction

Otitis media with effusion, also known as glue ear, is a common childhood condition in which fluid builds up in the middle ear space causing discomfort and hearing loss. The condition may affect 1 (unilateral) or both (bilateral) ears. The cause of glue ear is unclear, but it may be related to narrow or blocked Eustachian tubes that connect the middle ear to the back of the throat. The Eustachian tubes equalise the air pressure in the middle ear, and drain fluid and mucus produced as a result of inflammation, infection or an allergic reaction from it. Previous infection, swollen adenoid glands, allergy or smoke irritation may all affect Eustachian tube function. When the drainage process does not work properly, the middle ear air pressure can become negative, causing fluid to build up, affecting the movement of the eardrum and the transduction of sound (conversion of a sound wave into an electrical signal), resulting in conductive hearing loss (NHS Choices 2015).

Children are more susceptible to problems with the middle ear because the Eustachian tube is narrower and more horizontal during childhood, so it does not drain as effectively as in adulthood. As the Eustachian tube develops with age, glue ear becomes much less common. It is estimated that 1 in 5 children around the age of 2 years will be affected by glue ear, and about 8 in every 10 children will have had glue ear at least once by the time they are 10 years old (NHS Choices 2015). The most common sign of glue ear is conductive hearing impairment with associated speech and language problems; less common symptoms include ear pain, sleeping problems, balance problems, and tinnitus. If glue ear is unilateral, these are normally minor problems, but prolonged bilateral glue ear with significant hearing loss can delay speech development, affect educational progress and, in rare cases, cause permanent damage to hearing. Glue ear does not normally need treatment because the condition improves by itself, usually within 3 months. For persistent cases, surgery may be indicated. This usually means surgical drainage of fluid from the middle ear (myringotomy), insertion of grommets, adenoidectomy and tonsillectomy, or a combination of these. Normalising the pressure in the ear may reduce the symptoms associated with glue ear and may reduce the need for surgery.

Technology overview

This briefing describes the regulated use of the technology for the indication specified, in the setting described, and with any other specific equipment referred to. It is the responsibility of healthcare professionals to check the regulatory status of any intended use of the technology in other indications and settings.

About the technology

CE marking

Otovent is a Class 1 medical device. Abigo Medical AB received a CE mark for the device in 1998; the most recent renewal was in October 2015.

Description

The Otovent kit consists of a nose piece and 5 latex balloons. Before use, a balloon is connected to the nose piece. The nose piece is placed against 1 nostril while the other nostril is held closed; nothing is inserted into the nasal cavity. The user inflates the balloon

until it is the size of a grapefruit by blowing through their nose into the nose piece. The procedure, known as the Valsalva manoeuvre, is then repeated with the other nostril. The forced expiration against the closed airway leads to auto-inflation of the middle ear, increasing the pressure in the nasopharynx. This helps to open the Eustachian tube to equalise the air pressure and allow the fluid in the middle ear to drain naturally down the back of the throat. The user may feel increased pressure in the ear or hear a 'click' during the procedure. Symptoms of glue ear usually resolve with this treatment.

Setting and intended use

Otovent may be used in situations for people who cannot equalise air pressure in the middle ear, including those with glue ear. The technology can also be used for Eustachian tube dysfunction, which may follow an upper respiratory tract infection, an episode of acute otitis media, or air pressure changes associated with flying, diving or pressure chamber treatment.

Otovent may be used by children aged 3 years and over and by adults. It would be used on the advice of a clinician in either primary or secondary care; children would normally be taught how to use the device by a clinician, after which they can be treated at home under parental supervision.

Current NHS options

The first 3 months after diagnosis of glue ear is a period of active observation, because the condition usually resolves within this time. There is no medication available to shorten the length of time that the symptoms last. The NICE guideline on otitis media with effusion in under 12s recommends that advice on educational and behavioural strategies is offered during this period to reduce the effects of hearing loss. Auto-inflation may also be considered during this period for children who are likely to be able to carry out the procedure. After 3 months, children with persistent symptoms and significant hearing loss should be considered for surgery. Children with less severe hearing loss may also be considered for surgery if the effect of hearing loss on the child's developmental, social or educational status is significant. Surgery involves inserting a small ventilation tube (grommet) into the eardrum to maintain normal air pressure in the middle ear. The surgery is carried out under general anaesthetic and takes about 15 minutes. The grommet usually falls out about 6 to 12 months after surgery as the eardrum starts to heal. If a child's adenoids are swollen, they can block the Eustachian tubes and may also be removed during grommet insertion surgery. Adenoidectomy is not recommended if upper

respiratory tract symptoms are not persistent or frequent. Hearing aids should usually be offered as an option, or if surgery is contraindicated or not acceptable to parents or carers.

NICE is not aware of any other CE-marked devices that have a similar function to Otovent.

Costs and use of the technology

The Otovent kit consists of a nose piece and 5 balloons, and costs the NHS £4.90 (Drug Tariff cost excluding VAT) when prescribed by a GP. It can also be bought at pharmacies and online at a recommended retail price of £7.84 (including VAT). The kit is supplied as a self-contained treatment and does not need any further consumables, maintenance or calibration.

The manufacturer recommends that people starting treatment with Otovent should use it at least 3 times a day with 1 inflation through each nostril on each occasion. After 1 week, it should be used at least twice a day. The normal duration of treatment is 2 to 3 weeks, after which a physician should decide whether or not to continue the treatment. After each use, the nose piece should be cleaned with a mild detergent and rinsed with clean water. When not in use, the balloons should be protected from light, and may be kept with the nose piece in the box provided with each kit. Each balloon may be inflated a maximum of 20 times.

Likely place in therapy

Otovent is designed as a first-line non-surgical, drug-free treatment option for glue ear during or after the period of active observation following diagnosis, to help avoid the need for surgery.

Specialist commentator comments

All 3 specialist commentators noted that parents are interested in using this treatment. One commented that many parents are disheartened when told, in line with NICE guidance, to wait for 3 months before any intervention can be considered. They are keen to try this treatment during this period, particularly because it is a non-surgical option that does not need the high level of monitoring required for hearing aids. Two specialist commentators pointed out that Otovent can easily be incorporated into NHS clinics, along

with information on the effectiveness and instruction on the method. Another commentator noted that if no clinician is available to show how to use it correctly, instructional videos are available on several internet sites.

One specialist commentator noted that, given the self-limiting nature of glue ear, they would normally not prescribe Otovent unless symptoms have been present for several weeks or are causing distress. They would be particularly likely to consider the device in cases severe enough to need referral for possible grommet insertion surgery. Another specialist commentator highlighted the issue of infection control, especially when the balloon has mucus blown into it, or if there is more than 1 child in the same family being treated, and noted the need for advice on cleaning and device allocation.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women
- eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Otitis media with effusion is a common childhood condition. Age is a protected characteristic, defined by the Equality Act (2010).

Evidence review

Clinical and technical evidence

Regulatory bodies

A search of the Medicines and Healthcare Products Regulatory Agency website revealed

no manufacturer Field Safety Notices or Medical Device Alerts for this device. No reports of adverse events were identified from a search of the US Food and Drug Administration (FDA) database: Manufacturer and User Device Facility Experience (MAUDE).

Clinical evidence

A literature search found 124 citations (after removal of duplicates) and a relevant Cochrane review that reported on auto-inflation using Otovent. Studies were included in this briefing if they reported randomised control trials of Otovent in English.

The Cochrane review (Perera et al. 2013) selected randomised controlled trials that compared any form of auto-inflation (including Otovent and other treatments) with no auto-inflation (observation without treatment) in people with otitis media with effusion. Using pooled data from 8 selected trials, the Cochrane review concluded that auto-inflation, with the various methods used in the trials, seemed to have a beneficial effect on the resolution of otitis media with effusion, and could be considered as a treatment during the observation period.

Of the 8 trials identified in the Cochrane review, 4 used Otovent. One of these (De Nobili and Bellomo 2008) was excluded from this briefing because there was no English translation; the remaining 3 studies (Blanshard et al. 1993; Ercan et al. 2005; Stangerup et al. 1992) are included in this briefing, along with a more recent randomised controlled trial that was funded by the National Institute for Health Research Health Technology Assessment programme (Williamson et al. 2015).

The Williamson et al. (2015) study was set in 43 family practices in the UK (tables 1 and 2). Children aged 4 to 11 years with a recent history of ear symptoms and otitis media with effusion in 1 or both ears, confirmed by tympanometry, were allocated to have either auto-inflation using Otovent 3 times daily for 1 to 3 months plus standard care, or standard care alone. Details of standard care were not further described in the study. Clearance of middle-ear fluid at 1 and 3 months was assessed using tympanometry by experts masked to group allocation. Of the 320 children enrolled, those having auto-inflation were more likely to have normal tympanograms at 1 month than those having standard care alone (47.3% [62/131] versus 35.6% [47/132]; relative risk [RR] 1.36) and at 3 months (49.6% [62/125] versus 38.3% [46/120]; RR 1.37). Auto-inflation also produced greater improvements in ear-related quality of life assessed by a validated tool (the OMQ-14, a 14-point questionnaire on the effect of otitis media with effusion). Compliance with Otovent treatment (use of the device 'most' or 'all of the time') was 89% at 1 month and 80% at

3 months. Adverse events were mild, infrequent and comparable between groups.

The Blanshard et al. (1993) trial enrolled 85 children aged between 3 and 10 years, who had chronic otitis media with effusion in both ears and were on the waiting list for grommet insertion surgery at a UK children's hospital (tables 3 and 4). After randomisation, 2 children were excluded from the analysis, leaving 42 children in the intervention group and 41 in the observation group. Those in the intervention group were given Otovent to use 3 times a day for the duration of the study, and children in both intervention and observation groups were then seen at monthly intervals for 3 months for pneumatic otoscopy and tympanometry. For the analysis, the treatment group was split into a high compliance group (greater than 70% compliance; n=19) and a low compliance group (less than 70% compliance; n=23). Compliance was measured as the number of times a child used the device as a percentage of the maximum possible. Statistically significant improvements, in both tympanometry and pneumatic otoscopy, were seen at 1, 2 and 3 months in those using Otovent in the subgroup with greater than 70% compliance when compared with the observation group. No statistically significant differences were seen between the low (less than 70%) compliance group and the observation group. No adverse treatment effects were seen.

The Ercan et al. (2005) study aimed to evaluate the longer-term effects of auto-inflation using the Otovent device on the need for surgical implantation of grommets (tables 5 and 6). The trial enrolled 60 children aged from 4 to 10 years with chronic otitis media with effusion in at least 1 ear (93 ears in total). The children were randomly divided into intervention and control groups using the total number of affected ears. The intervention group had auto-inflation 3 times a day for 6 weeks with nasal saline irrigation, and the control group had nasal saline irrigation alone for 6 weeks. Compared with the control group, the auto-inflation group showed a statistically significantly lower need for ventilation tubes (grommets) than the control group at 3 months ($p=0.017$), 6 months ($p=0.040$), and 9 months ($p=0.015$). Except for at the third month, the auto-inflation group showed statistically significantly higher recovery rates from effusion than the control group.

The Stangerup et al. (1992) study was done to evaluate the effect of Otovent as a treatment for secretory otitis media (tables 7 and 8). One hundred children recruited from an ear, nose and throat hospital in Denmark were consecutively randomised to treatment and control groups and results were reported by ears (124 in total). The children were aged between 3 and 10 years and were entered into the study after having had secretory otitis media in 1 or both ears for at least 3 months, as verified by tympanometry.

Tympanometry was repeated at 2 weeks and at 1, 2, and 3 months. After 2 weeks of auto-inflation, 33 ears (65%) improved, 17 (33%) remained unchanged and 1 (2%) deteriorated. In the control group, 15% of ears improved, 71% remained unchanged, and 14% deteriorated ($p<0.001$). The children in the auto-inflation group who still had type C2 tympanograms after 2 weeks were asked to continue using Otovent for at least a further 2 weeks. After further treatment of 27 ears, 7 (26%) improved and 20 (74%) remained unchanged. In the control group (55 ears), 14 ears (26%) improved, 33 (60%) remained unchanged and 8 (14%) deteriorated. No statistically significant differences were shown after 2 or 3 months.

Recent and ongoing studies

No ongoing or in-development trials on Otovent nasal balloon for otitis media with effusion were identified.

Costs and resource consequences

According to NHS reference costs 2013–2014, NHS trusts and NHS foundation trusts in England did an annual total of 22,809 operations for the insertion of grommets, at an average cost of £802 per operation (Department of Health 2015). Introducing treatment with Otovent during the initial period of observation does not involve increased costs of monitoring above the cost of the device. Otovent might reduce costs by reducing the need for surgical intervention.

In England in 2014, 10,088 Otovent devices were dispensed at a net ingredient cost of £49,431 (Health and Social Care Information Centre 2015).

No changes would be needed in the organisation or delivery of current services and no other facilities or technologies would be needed.

Strengths and limitations of the evidence

The evidence included in this briefing is drawn from randomised controlled trials, the preferred study design when comparing treatments. The Cochrane review on auto-inflation concluded that although pooled estimates of its effect favoured the treatment, there was no statistically significant effect on middle ear function as measured by tympanometry. The review deemed none of the included studies to be of high quality;

all of the studies were relatively small, had limited treatment duration and short follow-up periods. Of the studies included in the Cochrane review that used Otovent as the intervention, only Ercan (2005) assessed the effect on the need for surgery in the longer term. Although Otovent is intended for use in adults as well as children, no studies were found that assessed its effectiveness in adults.

The Williamson et al. study (2015) enrolled more children and was of a higher quality than the studies included in the Cochrane review, with a reduced risk of bias. The study was an economic assessment of treatment options during the 3-month observation period, and did not follow up participants to consider the long-term cost-effectiveness implications associated with any eventual grommet insertion surgery.

Using the Cochrane Collaboration 'risk of bias' tool, the risk from generation of the randomised sequence was rated as low in the Blanshard et al. (1993) and Williamson et al. (2015) studies, and unclear in the Stangerup et al. (1992) and Ercan et al. (2005) studies. The risk from failing to conceal the treatment allocation was unclear in all studies except Williamson et al. (2015) where it was rated as low. The risk from comparability of groups pre-test was rated as unclear in all the studies except Stangerup et al. (1992) where it was rated as low. The risk from failing to blind the outcome assessment was rated as unclear in all studies. The risk from incomplete outcome data was rated as low in all studies except Stangerup et al. (1992), for which it was rated as high due to 42% attrition in the intervention arm and 67% attrition in the control arm. The risk from selective reporting was rated as low in all of the studies. For the studies included in the Cochrane review (Blanshard et al. 1993; Ercan et al. 2005; Stangerup et al. 1992), the review authors assessed the risk of bias, and the same methodology was applied by the External Assessment Centre to assess the Williamson et al. (2015) study.

Relevance to NICE guidance programmes

NICE has issued the following guidance:

Otitis media with effusion in under 12s: surgery (2008) NICE guideline CG60

References

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Table 1: Overview of the Williamson et al. (2015) study

Study component	Description
Objectives/ hypotheses	To study the efficacy of nasal balloon auto-inflation in children with otitis media with effusion in primary care.
Study design	Open randomised controlled trial with 2 arms: auto-inflation with standard care, and standard care alone. Standard care was not described further.
Setting	43 family practices from 17 primary care trusts in the UK between January 2012 and February 2013.
Inclusion/ exclusion criteria	Children were eligible for inclusion if they were attending school and aged 4 to 11 years; had a history of hearing loss or other relevant ear-related problems in the past 3 months; and had objective otoscopic and tympanometric confirmation of otitis media with effusion in at least 1 ear. Children were excluded if they had current clinical features of acute otitis media (such as ear pain, fever or otoscopic features of acute inflammation); recent or planned ear surgery; a known latex allergy; or a recent nosebleed.

Primary outcomes	The difference between the intervention and control groups in the proportion of children showing definite tympanometric resolution of pressure in at least 1 affected ear at 1 month.
Secondary outcome	Ear related quality of life using OMQ-14.
Statistical methods	Modified intention to treat analysis. The relative effect of auto-inflation on the primary outcome at 1 month and at 3 months was estimated using a generalised linear model for binary data with log-link function, and adjusted for baseline covariates (tympanometric baseline severity, age, sex and primary care trust).
Patients included	320 school children aged 4 to 11 years with glue ear in at least 1 ear.
Results	Of the 320 children enrolled, those having auto-inflation were more likely than controls to have normal tympanograms at 1 month and at 3 months.
Conclusions	Auto-inflation in children aged 4 to 11 years with otitis media with effusion is feasible in primary care and effective both in clearing effusions and improving symptoms and ear-related child and parent quality of life.
Abbreviations: OMQ-14, 14-point questionnaire on the effect of otitis media with effusion.	

Table 2 Summary of results from the Williamson et al. (2015) study

	Otovent plus standard care	Standard care	Analysis
Number of children	160	160	
Primary outcome:			
Tympanometric resolution at 1 and 3 months (percentage of children)	1 month: 47.3% (62/131)	1 month: 35.6% (47/132)	1 month: RR 1.36; 95% CI 0.99 to 1.88; p=0.06

	3 months: 49.6% (62/125)	3 months: 38.3% (46/120)	3 months: RR 1.37; 95% CI 1.03 to 1.83; p=0.03
Secondary outcome:			
Ear-related quality of life (OMQ-14 score; mean \pm SD)	Baseline: -0.07 \pm 1.00 (153/160)	Baseline: -0.04 \pm 0.95 (153/160)	Adjusted between-group difference in change from baseline in OMQ-14 score (an ear-specific quality of life measure) -0.42; 95% CI -0.63 to -0.22; p<0.001
	3 months: -0.70 \pm 1.01 (127/160)	3 months: -0.37 \pm 1.06 (121/160)	
Compliance	1 month: 89% 3 months: 80%	Not applicable	Not applicable
Patients reporting serious adverse events	No serious adverse events reported	No serious adverse events reported	Not applicable
Abbreviations: CI, confidence interval; OMQ-14, 14-point questionnaire on the effect of otitis media with effusion; RR, relative risk; SD, standard deviation.			

Table 3 Overview of the Blanshard et al. (1993) study

Study component	Description
Objectives/ hypotheses	To assess the effects of using Otovent on children on the waiting list for grommet insertion.
Study design	Randomised controlled trial with 2 arms; auto-inflation group and observation group.
Setting	Bristol Children's Hospital, UK from July to December 1991, with final follow-up in March 1992.

Inclusion/exclusion criteria	Children were eligible for inclusion if they were aged 3 to 10 years with confirmed bilateral type B or C2 tympanograms on 2 occasions separated by at least 3 months. Children were excluded if they had previously been treated by adenoidectomy or tonsillectomy or had chromosomal or craniofacial abnormalities.
Primary outcomes	Improvement in tympanometric findings defined as the number of ears converting from type B or C2 to type A or C1. Type A is classed as normal. Clearance of fluid on pneumatic otoscopy.
Statistical methods	The tympanometric results were analysed using the Mann–Witney rank sum test. The otoscopy results were analysed using the Chi-square test. Compliance was measured as the number of times the device was used as a percentage of the maximum possible. For analysis, the children in the treatment group were split into a high compliance group (compliance greater than 70%; n=19) and a low compliance group (compliance less than 70%; n=23). Results were also analysed on an intention-to-treat basis.
Patients included	A consecutive series of 85 children meeting the selection criteria was selected from the waiting list for grommet insertion surgery.
Results	Statistically significant improvement was seen in the high compliance group. This was detected on the outcome measures of tympanometry and pneumatic otoscopy after 1, 2 and 3 months.
Conclusions	Auto-inflation can be an effective short-term treatment for children with OME when used regularly under supervision.
Abbreviations: OME, otitis media with effusion.	

Table 4 Summary of results from the Blanshard et al. (1993) study

	Otovent group	Observation group	Analysis
Number of children	n=42	n=41	166 ears assessed at entry to study.

Primary outcome:			
Tympanometric results (Type A or C1 at 1, 2 and 3 months; % of ears)	1 month: HC: 32.4% ¹ LC: 12.5% ¹	1 month: 8.9% ¹	Statistically significant improvement in the HC group compared with the observation only group at: <ul style="list-style-type: none"> • 1 month: p<0.001 • 2 months: p<0.05 • 3 months: p<0.05. No statistically significant difference between the LC and observation only groups. The analysis by intention to treat showed a significant improvement at 1 month (p<0.01).
	2 months HC: 29% ¹ LC: 0% ¹	2 months: 13.5% ¹	
	3 months: HC: 26.4% ¹ LC: 2.3% ¹	3 months: 5.2% ¹	
Clearance of fluid on pneumatic otoscopy at 1, 2 and 3 months (% of ears)	1 month: HC: 47.4% (18/38) LC: 12.5% (5/46)	1 month: 14.3% (11/82)	Statistically significant improvement in the HC group compared with the observation only group at: <ul style="list-style-type: none"> • 1 month p<0.001 • 2 months p<0.001 • 3 months p<0.01. The analysis by intention to treat showed statistically significant improvements at 1 and 2 months (p<0.05).
	2 months: HC: 44.7% (17/38) LC: 7.1% (3/46)	2 months: 10.8% (8/82)	
	3 months: HC: 36.8% (14/38) LC: 4.6% (2/46)	3 months 10.5% (8/82)	

Patients reporting serious adverse events	No adverse events reported	No adverse events reported	Not applicable.
Abbreviations: HC, high compliance subgroup; LC, low compliance subgroup.			
¹ Calculated by the authors of this briefing.			

Table 5 Overview of the Ercan et al. (2005) study

Study component	Description
Objectives/ hypotheses	To evaluate the long-term effects of auto-inflation on reducing the need for insertion of ventilation tubes in children with chronic otitis media.
Study design	Randomised control trial with 2 arms; a treatment group having auto-inflation and nasal saline irrigation, and a control group having only nasal saline irrigation.
Setting	Istanbul, Turkey; January 2002 to April 2004 with 3 month follow-up.
Inclusion/ exclusion criteria	Children with MEE and free of signs of otitis media were included. Children were excluded if they had any of the following conditions: hypersensitivity or significant adverse reactions to penicillin; previous tonsillectomy or adenoidectomy; previous ear surgery other than tympanocentesis or myringotomy with or without tube insertion; history of seizure disorder, diabetes mellitus, asthma needing daily medication, or any health condition that could make entry potentially dangerous; medical conditions with a predisposition for MEE, such as cleft palate, Down's syndrome, congenital malformations of the ear, cholesteatoma, or chronic mastoiditis; severe retraction pockets; acute or chronic diffuse external otitis; perforation of the tympanic membrane; intracranial or intra-temporal complications of MEE; upper respiratory obstruction attributable to tonsil or adenoid enlargement or both with cor pulmonale, sleep apnoea, or severe dysphagia; history of varicella exposure within the past 30 days (if never had clinical varicella or varicella vaccine) or clinical varicella within the past 3 weeks; history of measles exposure in the past 30 days; or immunisation within the past 30 days.

Primary outcomes	Surgical insertion of ventilation tubes in the eardrum. Recovery rate from effusion.
Statistical methods	Chi-square test.
Patients included	60 children aged 4 to 10 years, diagnosed with chronic otitis media with effusion.
Results	In the auto-inflation group, there was a statistically significant decrease in the need for the insertion of ventilation tubes compared with the control group at 3, 6 and 9 months.
Conclusions	Auto-inflation reduces the need for insertion of a ventilation tube, both in the short and long term. Children should be followed as long as they are at risk of recurrence.
Abbreviations: MEE, middle ear effusion.	

Table 6 Summary of results from the Ercan et al. (2005) study

	Otovent plus nasal saline irrigation	Nasal saline irrigation	Analysis
Number of ears	n=48	n=45	
Primary outcomes:			
Cumulative number of ears requiring ventilation tube insertion after 3, 6 and 9 months	3 months: 37% (18/48)	3 months: 62% (28/45)	3 months: p=0.017
	6 months: 43% (20/46)	6 months: 65% (28/43)	6 months: p=0.040
	9 months: 43% (20/41)	9 months: 75% (30/40)	9 months: p=0.015
Recovery rates from effusion at 3, 6 and 9 months	3 months: 52% (25/48)	3 months: 31% (14/45)	3 months: p=0.108
	6 months: 52% (24/46)	6 months: 45% (16/45)	6 months: p=0.010

	9 months: 75% (22/42)	9 months: 20% (8/40)	9 months: p=0.002
Patients reporting serious adverse events	No serious adverse events reported	No serious adverse events reported	Not applicable

Table 7 Overview of the Stangerup et al. (1992) study

Study component	Description
Objectives/ hypotheses	To evaluate the effect of auto-inflation as a treatment option for secretory otitis media.
Study design	Randomised controlled trial with 2 arms; an auto-inflation group and a control group observed without treatment.
Setting	Ear nose and throat hospital in Denmark; June to December 1988. Two weeks of auto-inflation with a further 2 weeks if symptoms did not improve. Followed up at 1, 2 and 3 months.
Inclusion/ exclusion criteria	Inclusion criteria included unilateral or bilateral secretory otitis media for at least 3 months, and aged between 3 and 10 years. No exclusion criteria were stated.
Primary outcomes	Tympanometric resolution at 2 weeks, and at 1, 2 and 3 months after study entry.
Statistical methods	Statistical analysis was done using the Mann-Whitney rank sum test.
Patients included	100 children aged 3 to 10 years.
Results	Of 100 children enrolled, those doing auto-inflation 3 times per day were more likely than controls to have improved tympanograms after 2 weeks of treatment. A statistically significant difference between the treatment and the control groups remained at 1 month but was not apparent at 2 and 3 months.

Conclusions	Children from the age of 3 years may benefit from auto-inflation. Because of the short-term nature of the treatment effects, repeated use is necessary.
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Table 8 Summary of results from the Stangerup et al. (1992) study

	Otovent	Control	Analysis
Number of children (ears)	n=50 (51)	n=50 (73)	
Primary outcomes:			
Tympanometric resolution at 2 weeks	Tympanometric conditions improved in 33 (65%) ears, unchanged in 17 (33%), and deteriorated in the remaining 1 (2%) ear.	Tympanometric conditions improved in 11(15%) of ears, unchanged in 52 (71%), and deteriorated in the remaining 10 (14%).	At 2 weeks, p<0.001.
Tympanometric resolution at 1 month for children who showed no improvement at 2 weeks	n=27 ears Tympanometric conditions improved in 7 (26%) ears, unchanged in 20 (74%) ears.	n=55 ears Tympanometric conditions improved in 14 (26%) ears, unchanged in 33 (60%), and deteriorated in the remaining 8 (14%) ears.	At 1 month, p<0.05.
Tympanometric resolution at 2 and 3 months	At 2 months 20.9% had type A or C1 tympanograms.	At 2 months 15.8% had type A or C1 tympanograms.	No significant differences between groups at 2 and 3 months.
	At 3 months 17.1% had type A or C1 tympanograms.	At 3 months 14.2% had type A or C1 tympanograms.	
Patients reporting serious adverse events	No serious adverse events reported.	No serious adverse events reported.	Not applicable.

¹ The percentages were recorded incorrectly in the abstract. These are the values recorded in the results section of the paper. These have been verified by the authors of this briefing based on the numbers given in the paper.

Search strategy and evidence selection

Search strategy

Medline and Embase search strategy

1. exp otitis media/
2. (glue and ear).tw.
3. (otitis adj media).mp. or (glue adj ear).tw. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, nm, kf, px, rx, an, ui]
4. exp middle ear/
5. (SOM or OME).tw.
6. ((secretory or serous) adj otitis).tw.
7. (middle and ear*).mp. or (eustachian and tube*).tw. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, nm, kf, px, rx, an, ui]
8. middle ear ventilation/
9. aeration/
10. valsalva maneuver/
11. (autoinflate* or ((auot or ear* or ME or air) and (inflate* or aerat*))).tw.
12. ((nose or nasal) and balloon).tw.

13. valsalva.tw.

14. (insufflat* or popper).tw.

15. (open* or eustachian*).tw.

16. otovent.tw.

17. exp ear disease/

18. 6 and 17

19. 4 and 7

20. 18 and 19

21. 1 or 2 or 3 or 5 or 20

22. 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16

23. 21 and 22

24. (balloon or otovent).tw.

25. 21 and 24

Cochrane Library search strategy

Search date: 25/11/2015 15:18:30.500

#1 otovent (Word variations have been searched)

#2 balloon and (otitis or (glue adj ear)) (Word variations have been searched)

#3 autoinflation and (otitis or (glue adj ear))

#4 #1 or #2 or #3

Evidence selection

The inclusion criteria were as follows:

- Population: adults and children with chronic otitis media.
- Intervention: Otovent nasal balloon.
- Comparator: surgery (grommets), hearing aid, adenoidectomy, watchful waiting, other methods of autoinflation.
- Outcomes: tympanometric resolution, audiology, adverse effects, quality of life, days with hearing loss/earache, pain, days requiring pain relief, sleep disturbance, days off school.
- Study design: randomised controlled trial.
- Non-English language studies were excluded.

About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and **are not formal NICE guidance**.

Development of this briefing

This briefing was developed for NICE by the Birmingham and Brunel Consortium. The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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Additional information about the Williamson et al. (2015) study and comments on a draft of this briefing were kindly provided by:

- Jane Vennik, Faculty of Medicine Primary Care and Population Sciences, University of Southampton

Declarations of interest

No relevant interests declared.

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