



**Bedfordshire Clinical Commissioning Group**  
**Bedfordshire, Hertfordshire, West Essex and Milton Keynes**  
**Priorities Forum Statement**

**Procedure funded subject to Audit**

<b>Number</b>	<b>72</b>
<b>Subject</b>	<b>Grommet insertion in adults</b>
<b>Date of decision:</b>	<b>January 2017</b>
<b>Date refreshed:</b>	<b>September 2018</b>
<b>Date review due:</b>	<b>September 2021</b>

**GUIDANCE**

**Criteria for the funding of grommet insertions in adults:**

- 1) Otitis media with effusion (OME) that meets the following criteria:
  - a) Persisting after a prolonged period of watchful waiting/active observation of at least 4 months, (NB watchful waiting is not appropriate if malignancy suspected)
  - b) There is a definitive diagnosis of OME and
  - c) It persists;

OR

- 2) Severe pain-due to air pressure changes when flying or in hyperbaric treatment. The severity and frequency of flying should be discussed with the patient and balanced against the possible complications associated with grommets;

OR

- 3) Re-insertion of ventilation tubes- where it has been inserted and fallen out- a 2nd or 3rd grommet may be inserted if they still meet one of the above criteria.

OR

- 4) The patient has severe retraction of the tympanic membrane, if the clinician feels this may be reversible and reversing it may help avoid erosion of the ossicular chain or the development of cholesteatoma

**NB:** Patients who do not meet the above criteria may be considered on an individual basis where the GP/Consultant believes exceptional circumstances may exist. In patients who suffer from subjective feelings of pressure or eustachian tube dysfunction-like symptoms, treatable underlying causes should be ruled out.

## **Evidence for the use of grommets as a surgical intervention in otitis media with effusion:**

Most, if not all of the studies available relating to grommet insertion are actually studies conducted in children with hearing loss due to glue ear.

A systemic review by **Mcdonald et al 2008** (looking at two studies) showed that grommets have a significant role in maintaining a disease free state in the first 6 months after insertion. They conclude that further research is required to investigate the effects beyond 6 months and that clinicians should consider the possible adverse effects of grommet insertion before surgery is considered.

**Browning et al 2010** assessed the effectiveness of grommet insertion compared with myringotomy or non surgical treatment in children with otitis media with effusion. They concluded that grommets have a significant role in maintaining a disease-free state in the first 6 months after insertion. Further research is required to assess the effects beyond 6 months and that the adverse effects of the procedure should be considered before insertion.

Whilst the outcome of otitis media with effusion (OME) in children is generally good. Research into the indications in adults is scarce even for use in otitis media. Grommet insertion in adults for recurrent otitis media with effusion is perhaps based on specialist experience underpinned by studies on children.

**Yung et al 2001** studied ventilation tube insertion in 53 adult patients at Ipswich Hospital between 1996 and 1997. Of the 53 patients, 28 had previous history of ventilation tube insertion.

Furthermore at 15-27 months following ventilation tube insertion, the ventilation tube had already extruded in 31 patients and the OME had already occurred in 19 of these. Endoscopic examination revealed that many patients still had evidence of inflammation at the lateral nasal wall (26.4%) and at the eustachian tube orifice (51%). In addition they found a strong history of atopy in the patients studied. They concluded that adult OME may have underlying pathology that could lead to re-occurrence of OME following tube extrusion.

### **Adult symptoms and their cause**

Symptoms commonly blamed on middle ear problems or “Eustachian tube dysfunction” include pain in and around the ear, muffled hearing with or without a measurable hearing loss, and entirely subjective symptoms such as pressure, imbalance and tinnitus.

Unfortunately, the blanket pseudo-diagnosis of “Eustachian tube dysfunction” is often made without adequate expertise and knowledge. Alternative specific causes of these symptoms such as headaches, temporomandibular joint dysfunction and referred pain (including from oropharyngeal malignancy) need to be excluded by careful specialist history, examination and audiometry before the diagnosis of a middle ear cause can be safely established.

It is unsurprising that the scientific literature relating to adult grommet insertion is of poor quality, given the often non-specific nature of the symptoms and diagnosis for which grommet insertion is proposed.

**Evidence for use in Eustachian tube dysfunction (ETD):**

No valid evidence to date exists which proves that grommet use in adults which is effective.

**Evidence for use of Grommets in Meniere's disease:**

Meniere's disease is a disease of the inner ear affecting hearing and balance and tends to get worse over time. The cause is thought to be an abnormality of the homeostasis of the fluids in the various compartments of the inner ear. Disordered physiology causes abnormal osmotic pressures that cause episodic rupture of inner ear membranes and transient disturbance of inner ear function.

One study looking at how effective grommets are in Meniere's disease was highlighted in the literature search:

**Ogawa et al 2015** evaluated the effectiveness of tympanostomy tube placement in controlling symptoms of intractable Ménière's disease. 15 patients with intractable Ménière's disease underwent tympanostomy tube placement in the affected ear. Post-operative changes in vertigo attacks and hearing level were recorded, and were evaluated according to American Academy of Otolaryngology-Head and Neck Surgery criteria.

At 12 months after treatment, 3 patients (20%) showed complete control of vertigo, 7 (47 %) showed substantial control and 2 (13 %) showed limited control; 3 patients (20%) required other treatment. At 24 months after treatment, 7 patients (47 %) showed complete control of vertigo, 3 (20%) showed substantial control and 1 (7%) showed limited control; 1 patient required other treatment 15 months after tympanostomy tube placement. They concluded that there is no definite pathophysiological explanation for the effect of tympanostomy tube placement in reducing vertigo attacks. This treatment is not effective for all patients with intractable Ménière's disease. However, tympanostomy tube placement might be an additional surgical therapeutic option to consider prior to contemplating other, more invasive treatments. More studies are needed.

Grommets are also inserted in Meniere's patients to allow treatment with intratympanic gentamicin and steroids, for which there is increasing evidence of effectiveness.

**Flanagan 2006, Postema 2008 (see reference list below) Evidence for subjective feelings of pressure:** No evidence relating to the treatment of this specific symptom. When not associated with any demonstrable middle ear abnormality, other causes of sensation and pressure should be considered including temporomandibular joint dysfunction and muscular tension.

**Evidence for use of grommets for pain on flying:**

There is one description of a systematic evaluation of the management of otic barotrauma using modified intravenous cannula. **Zhang et al 2013** showed that using a modified 24-gauge IC cannula for tympanotomy tube placement provided middle ear ventilation. 191 tubes were placed for otalgia because of hyperbaric oxygen therapy, 58 tubes were inserted for air travel prophylaxis and 22 tubes were placed for management of otic barotrauma post-flight. All the patients who had this procedure for prophylaxis experienced regular otic barotrauma symptoms during air travel prior to tube placement. All patients were reviewed at 6 weeks post procedure. This technique worked effectively in 99%, though after 6 weeks 88% of the tubes were found to be extruded.

They concluded that given the safety, effectiveness, low risk of complications it provided a simple yet effective therapeutic option for otic barotrauma.

**Conclusions from research literature:**

There is no obvious reason to suppose that treatment of middle ear effusion in adults with proven hearing loss and tympanometric evidence of middle ear effusion will be less successful than similar treatment in children, for which there is considerable evidence of effectiveness, although specific evidence in adults is lacking.

National guidance advises that management of adults with symptoms that might be diagnosed as “ETD” should focus on determining first the correct underlying cause. There is a high level of uncertainty about the cause of symptoms sometimes attributed to “ETD” in the absence of proven hearing loss and tympanometric evidence of middle ear effusion. It is therefore not surprising that the lack of published research into adults with what is likely to be a variety of ill-defined symptoms and even more poorly defined diagnoses means the benefits, harms and cost of myringotomy with or without grommet insertion as a means of relieving these symptoms is unknown.

Treating glue ear in children is pivotal as time is critical. The aim is to prevent long term disability, which may arise from impaired speech, language and educational development. The indication in adults is different, the development has already been achieved and language acquisition has taken place. The aim in adults as far as glue ear is concerned is to treat glue ear (if it is recurrent and does not resolve after active observation). Of course watchful waiting is never appropriate in instances where an underlying pathology (under lying malignancy) is suspected.

An important second consideration is that of whether the glue ear is unilateral or bilateral. Unilateral glue ear in children rarely causes developmental problems and may not require surgical treatment immediately. However unilateral hearing loss in adults does cause a disability and may require intervention.

Grommets are also inserted for a variety of other indications though because of the disparate nature of the symptoms and underlying diagnoses there is no scientific evidence relating to these.

The emphasis should be on making the correct specific diagnosis rather hoping that a grommet will improve symptoms in the absence of a clear diagnosis. The lack of evidence of efficacy of grommet insertion in the absence of clear evidence of hearing loss and middle ear abnormality must be carefully discussed by the treating consultant and the patient as part of the consent process.

Although there is not much literature evidence for grommet use to help manage symptoms of pain associated with pressure change in flying and hyperbaric treatment, grommets can be thought of as effective since a working grommet is bound to prevent the pressure gradient in the middle and outer ear. The severity and frequency of flying should be discussed with the patient and balanced against the possible complications associated with grommets.

## References:

- **Browning GG**, Rovers MM, Williamson I, Lous J, Burton MJ. Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children. *Cochrane Database of Systematic Reviews* 2010, Issue 10. Art. No.: CD001801. DOI: 10.1002/14651858.CD001801.pub3.
- **Llewellyn A**, Norman G, Harden M, Coatesworth A, Kimberling D, Schilder A, et al. Interventions for adult Eustachian tube dysfunction: a systematic review. *Health Technol Assess* 2014;18(46).
- **McDonald S**, Langton Hewer CD, Nunez DA. Grommets (ventilation tubes) for recurrent acute otitis media in children. *Cochrane Database of Systematic Reviews* 2008, Issue 4. Art. No.: CD004741. DOI: 10.1002/14651858.CD004741.pub2.
- **Ogawa Y**, Otsuka K, Hagiwara A, Inagaki A, Shimizu S, Nagai N, Itani S, Saito Y and Suzuki M (2015). Clinical study of tympanostomy tube placement for patients with intractable Ménière's disease. *The Journal of Laryngology & Otology*, 129, pp 120-125. doi:10.1017/S0022215115000079.
- NICE guidance: Grommet use in Meniers disease 2012: <https://www.nice.org.uk/guidance/ipg426>
- NICE guidance: Otitis media with effusion under 12s :<https://www.nice.org.uk/guidance/cg60/resources/otitis-media-with-effusion-in-under-12ssurgery-975561238213>
- **Yung M.W.** et al. Adult-onset otitis media with effusion: results following ventilation tube insertion. *Journal of Laryngology & Otology*, November 2001, vol./is. 115/11(874-8).
- **Zhang Q**, Banks C, Choroomi S, Kertesz T. A novel technique of otic barotrauma management using modified intravenous cannulae. *Eur Arch Otorhinolaryngol.* 2013 Sep;270(10):2627-30. doi: 10.1007/s00405-012-2301-3. Epub 2012 Dec 4. PubMed PMID: 23208527.
- **Flanagan S**, Mukherjee P, Tonkin J. Outcomes in the use of intra-tympanic gentamicin in the treatment of Meniere's disease. *The Journal of laryngology and otology* 2006;120:98- 102.
- **Postema RJ**, Kingma CM, Wit HP, Albers FWJ, Van Der Laan BFAM. Intratympanic gentamicin therapy for control of vertigo in unilateral Meniere's disease: a prospective, double-blind, randomized, placebo-controlled trial. *Acta Oto-Laryngologica* 2008;128:876- <http://sydneyentclinic.com/sean-flanagan/patient-resources/menieres-disease/>

**Human Rights and Equalities Legislation has been considered in the formation of this statement**