The clinical and cost effectiveness of surgical insertion of grommets for otitis media with effusion (glue ear) in children

Key points

- Otitis media with effusion (OME) is common in children. Most cases resolve spontaneously. Persistent (>=3 months), bilateral hearing loss (>=25 dB) is the major concern for OME.
- There is good evidence that surgical insertion of grommets provides short-term benefit in correcting hearing loss associated with OME. The benefit diminishes with time.
- Adjunct adenoidectomy provides a small additional benefit in hearing. Evidence is insufficient to ascertain possible long-term benefits of adjunct adenoidectomy combined with grommet insertion.
- Good quality, long-term trials have demonstrated that watchful waiting (delayed insertion of grommets if OME remains unresolved) compared to immediate insertion of grommets does not result in disadvantage in language, behaviour or social development for children with persistent bilateral OME diagnosed under 3 years old who do not otherwise have disabling conditions.
- It is uncertain whether the safe use of watchful waiting is generalisable to older children and children who have already shown disruptions in language and behaviour development at diagnosis.
- Limited, preliminary evidence suggests that surgical insertion of grommets without adenoidectomy may be cost-effective compared to doing nothing after 3 months of watchful waiting.

Health technology description

Grommets (ventilation or tympanostomy tubes) are small plastic or metallic tubes that are inserted through the tympanic membrane (eardrum) following myringotomy, a procedure that involves creating a hole in the eardrum and draining fluid in the middle ear. The rationale for grommet insertion is to prevent fluid accumulation and to help pressure regulation in the middle ear. The operation lasts approximately 20 minutes. It can be done under local anaesthetic although more often it is carried out under general anaesthetic as the patients are predominantly young children. Once inserted, grommets stay in place for typically 6 to 12 months before eventually being ejected as the eardrum heals naturally. About 20-50% of children may require re-insertion of grommets after tube extrusion due to relapse of otitis media with effusion (OME – see ‘Epidemiology’ section below). The insertion of grommets can be carried out in conjunction with surgical removal of adenoid glands (adenoidectomy) or occasionally tonsils (tonsillectomy). The aim of combining procedures is to reduce subsequent upper respiratory infections, which are frequently associated with OME.

Current Scottish guidelines exist with regard to the diagnosis and management of childhood otitis media in primary care, but these do not cover the use of grommets for OME. Large variations in the rates of surgical insertion of grommets among regions in Scotland and England in the early 1990s led to the necessity of the procedure being questioned in many cases, and to advocating a watchful waiting strategy to reduce surgery rates. A period of watchful waiting (regular monitoring of hearing level without other intervention) before surgical intervention has been adopted in recent guidelines. Most non-surgical interventions including decongestants, antihistamines, mucolytics, steroids and antibiotics are either ineffective, of unknown effectiveness or of limited short-term benefit. Hearing aids and auto-inflation (blowing up a balloon through a nostril) are other potential options.

Epidemiology

Otitis media is middle ear inflammation, which can occur with or without symptoms. Acute otitis media has rapid onset of signs and symptoms such as purulent middle ear effusion (pus), earache and fever, and is frequently associated with upper respiratory tract infections.
infections. Otitis media with effusion, or ‘glue ear’, refers to a chronic disease state with the accumulation of fluid in the middle ear that is usually (but not always) absent of the signs and symptoms of an acute infection. The main symptom associated with OME is hearing loss. Acute otitis media can occur (in some case repeatedly) during a course of OME, and it is not always possible to distinguish between them.

OME is very common in young children. It has been estimated that 80% of children have had at least one episode of OME by the age of 4, and 15-20% of children aged between 2 and 6 suffer from this condition at any point in time7. The prevalence and incidence drops substantially afterwards. The duration of OME is generally short, but 5-10% of OME last 1 year or longer2. Half of the ears in preschool children affected by OME may resolve spontaneously within 3 months, although about half of the ears that recovered may have a further episode8. The major concern of OME in children is persistent (>=3 months), bilateral hearing loss of >=25 decibels (dB), which could affect the children’s language and social development and lead to learning and behavioural difficulties (a hearing loss of 30 dB can mean that a normal conversation sounds like a soft whisper)4. The causal relationship between hearing loss associated with OME and adverse developmental outcomes is still a subject of much debate9.

Clinical effectiveness

The most recent systematic review on the use of grommets for OME is a Cochrane review by Lous and colleagues1. Evidence presented in this section is based on this review (literature search to March 2003) and supplemented by evidence published since from randomised controlled trials (RCTs) and other reviews covering general management of OME that have applied robust methodology for evidence synthesis4,5,10.

The efficacy of grommets in terms of correcting hearing loss has been demonstrated in early RCTs in which a grommet was inserted into one ear of a child who suffered from bilateral OME while the other ear of the same child was served as the control. Ears with grommets inserted (without adenoidectomy) had improved hearing level of 7 to 9 dB, on average, compared to ears without grommets in the first 6 months after surgery1. Significant differences exist in the magnitude of observed improvement between some of the trials at 4 - 6 months (range 5 to 19 dB). Differences between treated and untreated ears appeared to decrease with time across studies, with an average difference of approximately 4 dB at two years and no significant difference at five years. Combining adenoidectomy and grommet insertion had only very small additional benefit with regard to improvement in hearing level compared to grommet insertion alone (<5 dB)4. It was not possible to assess potential long-term benefits of adding adenoidectomy (reduction in upper respiratory infection and re-insertion of grommets) in the identified reviews due to lack of evidence4,10.

More recent RCTs have randomised children rather than ears and have compared bilateral insertion of grommets (without adenoidectomy) to watchful waiting. Statistically significant improvement in hearing and reduction in the proportion of time with effusion were observed in the grommet groups compared to watchful waiting groups up to two years1. Many of the trials also assessed the children’s language development, behaviour and quality of life. Results cannot be combined as the trials differed in study design and used different outcome measures. In two trials, infants and children under 3 years old with persistent OME were identified through population screening11,12. No significant difference between grommet groups and watchful waiting groups was found in any measures of language, quality of life1,11, cognitive or psychosocial development, behaviour or academic achievement throughout long-term follow-up (to 9 to 11 years of age in one of the studies)13. An approximate 3-month delay in language development (of marginal statistical significance) in the watchful waiting group compared to the grommet group was observed at 9 months in another trial in which children (mean age 3 years) with persistent bilateral OME, hearing loss and disruptions to speech, language or behaviour were recruited14. The difference between groups diminished at 18 months, by which time 80% of the children in the watchful waiting group had grommets inserted. The findings suggested that the timing of surgical insertion of grommet may not be crucial in terms of long-term language development1.

In an RCT comparing laser myringotomy with grommets (randomisation by ears) in children with persistent bilateral OME, myringotomy alone was less effective than grommets15. This is consistent with findings from a previous review4. A further UK-based RCT (TARGET trial) comparing non-surgical management, bilateral grommets and bilateral grommets plus adenoidectomy in children aged 3 to 7 has been completed but the full results have not yet been published16,17. No trials have compared grommets with hearing aids or autoinflation.
Safety
A systematic review of published randomised studies and case series investigated sequelae of surgical insertion of grommets. Common sequelae included otorrhea (discharge from ears) during postoperative period (16% of patients) and beyond (26%), tympanosclerosis (scarring of tympanic membrane, 32%) and focal atrophy (25%). Less frequent but more serious sequelae included perforation of tympanic membrane and cholesteatoma (abnormal growth of skin and accumulation of debris in the middle ear), both of which occurred more frequently with long-term tubes compared to short-term tubes. Grommet insertion increased the risk of tympanosclerosis by more than three times compared to controls in RCTs, although the clinical impact is uncertain as tympanosclerosis varies in severity and does not always associate with hearing loss. A very high rate of otorrhea (83% over one year) following grommet insertion and associated increased usage of antibiotics has been observed in a recent RCT in children under 3 years old.

Economic implications
The number of grommet operations (including insertion, maintenance and removal of grommets in both children and adults) in Scotland was 2,895 in 2006. The number has fallen by approximately 40% compared with a total of 5,150 operations in 1999 (ISD Scotland). According to the Scottish National Tariff 2006-07, the average cost per spell for minor ear procedures (Healthcare Resource Group C55, which covers grommet insertion) is £853.

Several cost studies and cost-effectiveness studies have been undertaken, but only one from the UK perspective may be generalisable to current practice in Scotland. This economic evaluation, which is contained within a draft guideline, compared four alternative strategies for the treatment of OME after 3 months of watchful waiting: do nothing, hearing aids, grommets, and grommets plus adjuvant adenoectomy. The results suggest grommets are cost-effective compared to ‘do nothing’. Limitations of this economic evaluation include use of unpublished data to estimate quality-adjusted life year gain and lack of evidence for accurately estimating the effectiveness of the ‘hearing aids’ and ‘grommets plus adenoectomy’ strategies. The unit cost for grommet insertion was estimated at £662 based on the National Tariff 2006/7 (England).

Further information
The National Institute for Health and Clinical Excellence is currently developing a guideline for surgical management of children with OME for the NHS in England, Wales and Northern Island. The guideline is expected to be issued in February 2008.

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