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OME (Glue Ear)/ Adenoid and Grommet: Position Paper ENT UK 2009

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Role of surgery in treating glue ear

The only effective intervention for treating childhood hearing loss caused by glue ear (otitis media with effusion; OME) is the insertion of grommets, (ventilation tubes). In selected cases removal of the adenoid from the back of the nose, adjacent to the Eustachian tube opening (which allows air pressure equilibration) is also recommended. Grommet insertion and adenoidectomy work by reducing low grade infective biofilm ¹ load in the back of the nose, and causing a massive increase in oxygen tension in the middle ear; this in turn, further inhibits inflammation mucin gene activity and hence the formation of middle ear fluid (glue)². Most grommet and adenoid procedures are carried out as day cases with very little systemic morbidity or risk.

Intervention criteria

In 2008, the National Institute for Health and Clinical Excellence (NICE) published guidance following expert statistical and health economic review of the optimum international scientific evidence (CG60, Surgical management of OME). NICE states that children who will benefit from surgical intervention are those with persistent bilateral glue ear, documented for a period of 3 months or more, and a hearing level in the better ear of 25–30 decibels hearing loss or worse, averaged at 0.5, 1, 2 and 4 kHz. (For reference, a 16 to 25 dB hearing loss may be mimicked by plugging the ears with the index fingers). At even 16dB, a child can miss 10% of the speech signal even when the listener is 4 feet away. Thus, in a classroom environment, a 25 - 30dB loss presents an appreciable educational difficulty.

The rate of UK surgical intervention for childhood glue ear has fallen steadily over the past 15 years. Adenoidectomy rates fell dramatically in the late 1990's from over 16,000 procedures per annum, and in 2008-09 there were 5529 adenoidectomy operations in children <15 years ³. Childhood grommet insertion has also fallen from over 43,300 operations in 1994-95 to under 25300 in 2008-09 – a 42% reduction, largely due to the better understanding of the natural history of glue ear and the role of 'watchful waiting'.

Watchful waiting or 'active monitoring'

Watchful waiting⁴ is now recognised as an essential, preliminary period of observation with monitoring of hearing loss, since research by ENTUK surgeons, funded by the MRC (the TARGET multicentre trial ⁵) has shown that 50% of children with a bilateral hearing loss of at least 20dB are likely to recover to normal with no treatment in the first three months after diagnosis. The remaining 50% with persistent hearing loss, concerns about speech, language or other associated problems are those potentially eligible for surgical intervention. In the persistent cases, of course, surgical intervention is inevitably delayed by this watchful waiting policy, leading to concerns that the UK surgical cut backs imposed over the last decade might have been excessive ⁶, driven by cost-cutting rather than clinical evidence. This was the finding in Australia, where an independent medical investigation concluded that there was now actually an under-utilisation of ear nose and throat surgery in children - i.e. children requiring surgery were going untreated.

Limitations of RCTs of surgical intervention due to parental choice

The UK TARGET study was a randomised trial design of surgical treatments for glue ear versus non-intervention, and final results reporting is imminent. The delay in the MRC team's publishing the overall trial outcome is partly because almost 60% of children with glue ear who were randomly selected into the 'no-surgical treatment' limb were switched out of the nonsurgical group by their parents, who decided their children should undergo surgery rather than suffer continuing hearing loss for the purposes of the research study. In other studies of similar high quality, up to 85% of parents of children allocated to the 'no treatment' group requested a move to the treatment group.

The fact that parents tend to switch children out of no treatment into surgery for glue ear has two important implications. Firstly, of course it underlines the level of concern and the recognition of the effectiveness of surgical intervention on the part of parents. Less obvious, but equally important is the fact that not all studies properly report the results according to who switched from no surgery to have surgery. The statistical impact of this habit is to underestimate the difference between the surgery and no surgery groups, as those gaining surgical benefit continue to be analysed as part of the no treatment group.

Implications for children of severe rationing of surgery for glue ear

ENTUK is therefore alarmed to learn that non-medical 'consultants' on Health Service resource allocation have recently stated that the treatment of children's hearing impairment is largely 'unnecessary'. One problem for commissioners scrutinising the results of surgery is that sound is measured by the decibel scale which is logarithmic; the 2005 Cochrane review showed about 9dB improvement from grommets in the first six months after operation, 6dB in the next.. The raw numbers look unimpressive – but due to the logarithmic decibel scale, even a 3dB increase in sound equates to a doubling of intensity and hearing sensitivity. After 12 months there is, predictably little residual difference, in some series, between treated and control groups, as the hearing in both groups is now normal. Most parents (and teachers) do not want a child to spend a year in a school classroom with subnormal hearing.

Many other quoted studies include no hearing test data, as the children recruited were too young to perform the test. In this context, early, active management is supported by the testament of adults with glue ear ⁷, who regularly present for treatment and well articulate the daily functional impact of a middle ear effusion. Any specific rationing of children's glue ear treatment, imposed by public health policy, would appear to represent a form of age discrimination favouring adults at the expense of children.

Earlier this year, McKinsey submitted a vision of wholesale withdrawal of 90% of NHS funded surgical treatment for hearing-impaired children (Table 1).

Table 1

Extract from Table “Up to £700m could be saved if PCT’s decommissioned some procedures”: 2009 report by McKinsey management consultants commissioned by the DH, as published in the *Health Service Journal*, 10 Sept 2009

“Relatively ineffective”	Max potential reduction in procedures (%)	Max potential savings (£m)
Tonsillectomy	90	45
Back pain injections and infusions	90	24
Grommets (glue ear)	90	21

ENTUK is concerned that there is no scientific basis for selection of the 10% of English children still in future to be judged ‘worthy’ in the eyes of the management consultants to receive definitive therapy. Parents, paediatricians, audiologists and otolaryngologists do not want children to be disadvantaged. The surgical alternative - to provide all children with glue ear with NHS digital hearing aids is neither cheap for providers nor acceptable to the vast majority of service users. Health economic modelling by NICE is fanciful in its speculative and evidence-free cost estimation of this alternative. At the end of the day, most of us, given the choice, would prefer not to have to wear a hearing aid when a safe and effective day case surgical treatment fixes the problem as a day case procedure.

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