Quality in Health Care 1992;1:266–270

Effectiveness Bulletin

Surgical interventions for glue ear: what form will a quality service take?

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This review is based on *Effective Health Care*, Bulletin No 4.

Glue ear (otitis media with effusion (OME)) is a condition characterised by the presence of fluid in the middle ear cavity. It is the most common cause of hearing impairment[1] and reason for elective surgery[2] in children. Glue ear can result in a hearing impairment (measured in decibels of hearing loss (dB HL)) of 0 to 50 dB HL with an average of 20 dB HL,[3 5] though it is unclear the degree to which this affects the functioning of the child (disability).[6]

The rate of surgery for glue ear has greatly increased over the past 25 years and has been described as "an epidemic"[2] which does not seem to reflect significant changes in the underlying prevalence of the condition. The overall annual rate of surgical treatment in England and Wales is about 5/1000 children aged under 15 years.[7 8] There are large geographical variations in the rate of surgery and in the proportion of operations undertaken as day case procedures (fig 1), which partly reflects differences in clinical decision making, fashions for surgery of the nasopharynx or tympanic membrane, and relative supply of facilities.

Because of the number of children who receive surgery for glue ear and the resources involved it is important to try and determine how much of this surgery is really necessary and to develop means by which unnecessary interventions can be minimised. In other words, assessing the effectiveness and improving the appropriateness of surgery must be attempted.

This paper describes the main findings of a recent review of published scientific reports relating to surgical treatment of glue ear.[7] The methods used in the review have been previously described.[9]

Impairment and disability

Although the relation between glue ear and hearing impairment is well established, there is less evidence about any effect on the function or disability of the affected child. Several disabilities may result from persistent hearing impairment (for example, compromised levels of social functioning, language competence, and speech production and learning or behavioural difficulties). Although there are many reports examining these links, most studies are of poor quality, small, and include children who have had surgery for glue ear and therefore do not give a clear indication of what would have happened without treatment. Although some disability was associated with glue ear in a large prospective study,[10] there is insufficient evidence to show a causal link between glue ear and significant disability in children. In a comprehensive review of this topic Haggard and Hughes stated that if such a link does exist it is probably the result only of an extremely persistent history of hearing impairment starting at an early age.[1]

Hearing loss will not have the same effect on the functioning of each child and, unless it is likely to result in some form of disability such as impaired educational or social functioning, is not necessarily an indication for major intervention. In addition, since the condition is usually episodic, with few children experiencing bilateral glue ear for more than a few months, even if some short term mild disability occurs it may be followed by a period when the child rapidly "catches up." Most studies that have examined the epidemiology of glue ear or effectiveness of treatment do not use the broader outcomes necessary to measure disability. Without this information hearing impairment has to be used as a proxy measure for disability.

Several characteristics of the natural history of glue ear influence the question of improving the appropriateness of surgery. Figure 2 shows the results of following up a cohort of 2 year old children whose ears were tested every three months for glue ear. About 27% of ears were affected by OME at the age of 2 years; the condition spontaneously remits with time. The distribution of the duration of glue ear was very skewed, with a median duration of three months or less,[11] with only 5% of children having glue ear persisting for more than one year.[11 12] Many children who have not had a previous episode develop the condition as they get older. Several children whose ears improve then experience a recurrence, which also remits.

Therefore in a cross section of young children a significant proportion will have glue ear, some with a first or a recurrent episode of variable duration. The condition is common in young children, with a peak prevalence at age

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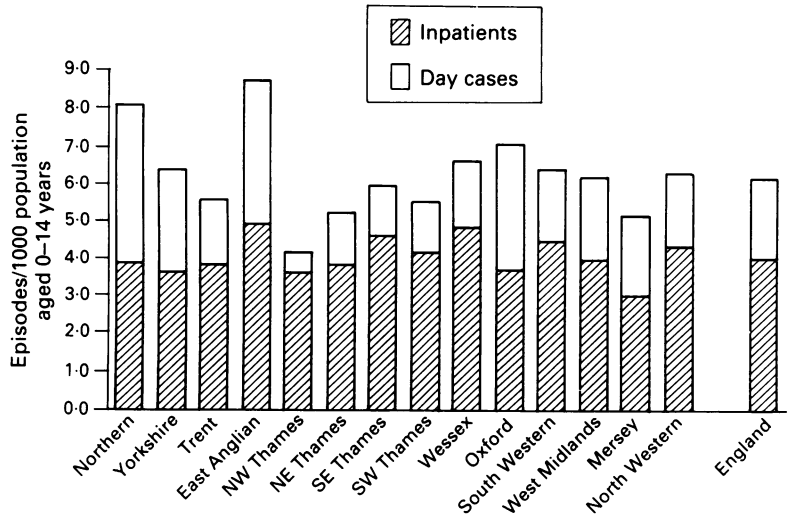

Source: Latest unpublished estimates from the Department of Health (Hospital episodes system)

Fig 1 Rates of surgery for otitis media and mastoiditis (predominantly for glue ear) in children aged 0–14 years by region, England, 1989–90

2 years of around 20% and a second peak at age 6.[13] This does not give a good picture of need for surgery since very few of these episodes persist and only about half are associated with a hearing loss of at least 25 dB, thought to be a reasonable indicator of possible disability. Unilateral hearing impairment (even when persistent) is not necessarily a cause for concern as normal hearing in the non-affected ear eliminates the likelihood of disability.

It is important that clinical services be provided to allow those with a persistent and significant hearing loss to be identified, because they are the most likely to be at risk of disability and the most likely to benefit from intervention. The object of diagnosis is to determine whether glue ear is present, to measure the associated hearing loss, and to ensure that this hearing loss is not due to other causes. No single investigation can achieve this, but adequate diagnosis can be obtained with results from some combinations of the following methods: history, otoscopy, audiometry, and tympanometry.

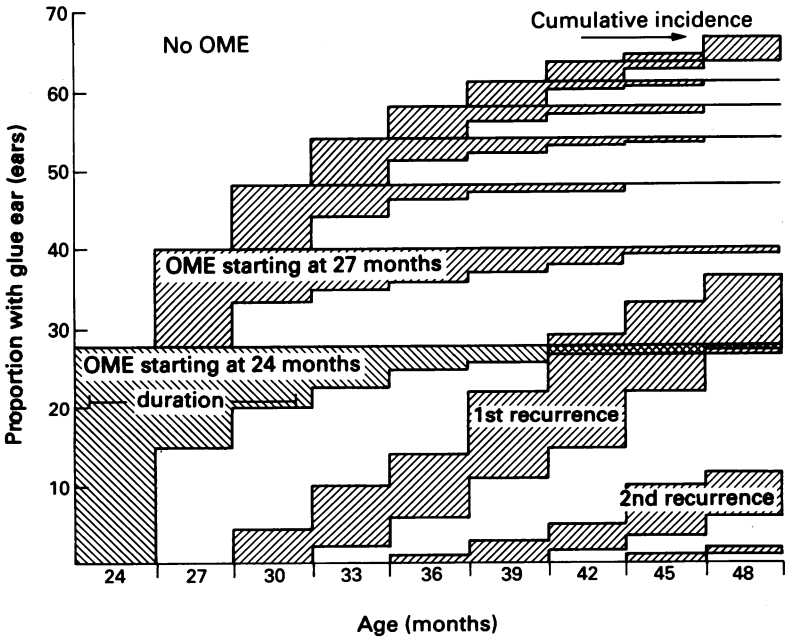

Fig 2 Natural history of glue ear (otitis media with effusion (OME))[11]

Surgical removal of the content of the middle ear cavity (myringotomy immediately before insertion of grommets) provides the standard confirmation of the presence of glue ear, though not of hearing impairment. Most dry taps (where glue is not found at surgery) are likely to be due to poor assessment and diagnosis and not (as often claimed) to anaesthesia with nitrous oxide.[7]

Effectiveness of treatment

Properly designed randomised controlled trials provide the most reliable evidence of the effectiveness of heath care interventions.[9] Nineteen published (or soon to be published) randomised controlled trials have examined the effectiveness of surgical interventions for glue ear,[7] including various combinations of surgical techniques: myringotomy, grommet insertion (tympanostomy tube/ventilation tube), adenoidectomy, and tonsillectomy. The effectiveness of medical approaches is controversial and not reviewed here. We have assumed that medical options have been exhausted before surgery is considered.[14]

When several randomised controlled trials examining the effectiveness of an intervention exist their results are often pooled by means of formal quantitative meta – analysis to obtain a more precise summary estimate of treatment effect.[15] However, the variation between the trials in the populations studied, study design, policy on repeat treatments, comparisons, and outcomes used is such that combining the results would be unhelpful and misleading.[16 17] However, the trials do provide useful evidence about the effectiveness of different interventions for glue ear; a description of each is given in *Effective Health Care*, Bulletin No. 4.[7]

Three of the trials are particularly informative because they report hearing level as an outcome measure and compare treatment with a non-treatment group of ears or children. They also represent the range of current practice in Britain.[18–20] Figure 3 shows the estimated effects of combinations of surgery from these three trials. Both grommets[18–20] and adenoidectomy[18–22] each are effective in reducing mean hearing impairment. However, the mean reduction is estimated to be <12 dB HL at six months and <6 dB HL at 12 months for either treatment strategy.[7] The clinical significance of this degree of improvement is not clear. The combined procedure of grommet insertion and adenoidectomy does not seem to improve hearing significantly more than with either grommets or adenoidectomy alone. Myringotomy alone is not an effective treatment in restoring hearing levels in children with glue ear,[18 22 23] and there is no added benefit of tonsillectomy with adenoidectomy.[24]

The reduction in hearing impairment in children receiving surgical treatment compared with untreated controls declines with

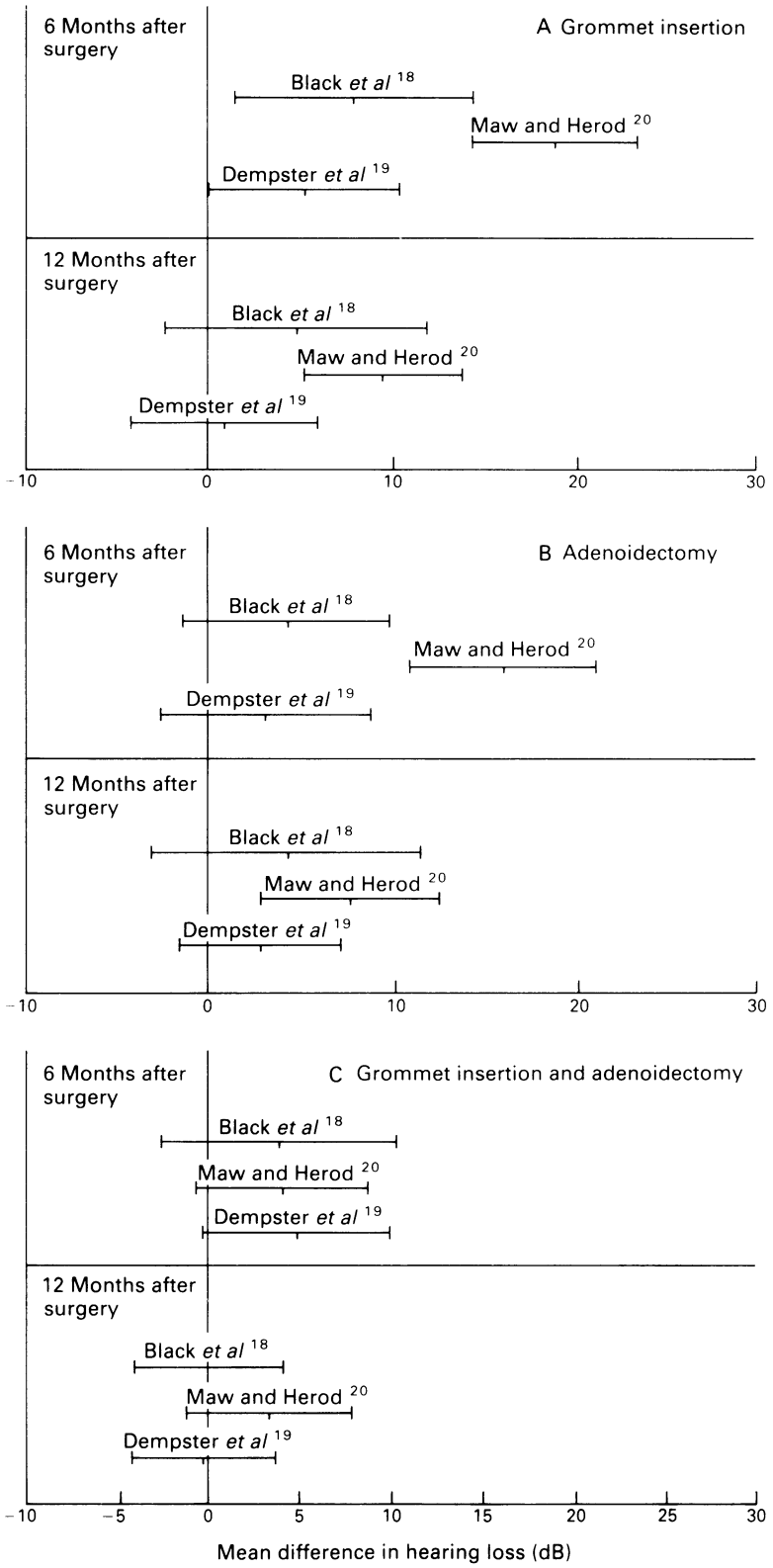

Fig 3 Mean improvement in hearing loss after surgery: (A) grommet insertion, (B) adenoidectomy, and (C) grommet insertion plus adenoidectomy versus adenoidectomy alone. Mean difference in hearing loss = mean hearing loss without surgery minus mean loss with surgery (A, B) or mean loss with adenoidectomy minus mean loss with grommet insertion plus adenoidectomy (C); bars are 95% confidence intervals

time after surgery owing to recurrence of glue ear in some of those treated and spontaneous improvement in the controls.

The small mean improvement in hearing with surgical treatment masks the large variation in the treatment effect between children. Some children show no improvement at all whereas others derive large benefits. Because the studies are too small and not designed for subgroup analysis there is no good evidence of which factors may help predict which children with glue ear will benefit most, so improving the appropriateness of surgery.

Implications for quality of services

If children with glue ear and a bilateral hearing impairment of ≥25 dB HL are not treated immediately but monitored (watchful waiting) to establish whether the condition is persistent (for example, lasting three to six months), fewer will be treated, because of spontaneous resolution. This would differ from the delay currently experienced before surgery because of waiting lists. Children are often not adequately assessed near the time of treatment to ensure that surgery is still appropriate; hence the importance of watchful waiting.

If a period of watchful waiting is introduced the subset of children eventually treated will be those more likely to benefit from surgery, but because they have had to wait longer they may experience an extended period of hearing impairment with any subsequent disability. Therefore there is a trade off in benefits: the longer the period of watchful waiting, the less surgery will be needed but the longer the wait for those with persistent hearing impairment who are eventually treated.

The aim of watchful waiting is to delay the decision to operate until need has been better established by criteria such as persistence and severity. To prevent this period extending the total period of waiting for those who eventually have surgery a provisional waiting list should be used. A child should be put on a provisional waiting list after initial audiological assessment indicates a potential need for surgery and should remain on this list during the period of watchful waiting.

Retesting before surgery will reduce the percentage of children found to have no glue in their ear at the time of surgery (dry taps). If a child is found not to have bilateral glue ear at myringotomy there is currently no justification to proceed further with the intervention. Although the condition may recur there is no reliable way of predicting whether this will occur for an individual child. The occurrence of dry taps indicates failure of the watchful waiting procedure to ensure persistence and thus is potentially useful as a measure in audit.

Audit may be useful in ensuring that surgery is carried out only in those who are likely to benefit most from treatment and that it is effective in improving hearing. The following indicators may be useful in the audit process in improving quality: preoperative audiological measurements to indicate persistence (watchful waiting), postoperative audiological measurements to indicate benefit, and the dry tap rate.

A final assessment should be performed before surgery to reduce unnecessary surgery. Preoperative, postoperative, and a six month measurement of hearing loss is necessary to determine the benefits of the operation related

to severity of the original impairment and whether a grommet is in place and functioning.

A protocol introducing a period of watchful waiting may lead to a considerable reduction in surgical activity, where such a strategy is not already standard practice. The size of the reduction in activity will depend upon the current organisation and delivery of the service. However, the resource savings from reducing activity in glue ear may be difficult to realise, for three reasons. Firstly, surgeons may maintain levels of activity by reducing waiting lists or increasing work in other areas. Secondly, the variable costs of ear, nose, and throat sessions are probably small relative to the fixed costs, and thus the savings achievable from marginal reductions of activity may be small in the short term. Thirdly, improving audiological services and referral protocols may, in some localities, result in satisfying previously unmet need, which will increase appropriate surgical activity, particularly in younger patients.

Purchasers and providers should scrutinise local practice and develop protocols with ear, nose, and throat surgeons, general practitioners, senior clinical medical officers, community paediatricians, audiologists, and other relevant professionals. This protocol should clarify the pathway of referral and treatment of patients in primary and secondary care, improve the quality of assessment, and reduce unnecessary duplication of investigations. The box describes the issues of quality which could be considered when devising local protocols.

Possible elements of a protocol for a quality service for children with glue ear

- Good access to and explicit referral criteria for high quality audiological services
- Full assessment of hearing impairment attributable to glue ear at the beginning and end of a period of watchful waiting, by an appropriate range of tests
- The development of a provisional waiting list for the watchful waiting period to reduce the delay for those subsequently confirmed as needing surgery
- Generally agreed criteria for surgery, including persistence and severity of hearing loss; hearing loss should be measured and glue ear confirmed shortly before surgery
- A schedule for follow up, including audiological testing

Considerable advantages are offered by day case surgery,[25] and grommet insertion/myringotomy is currently recommended as a day case procedure.[26] The proportion of grommet insertions undertaken as day case procedures varies widely.[25] Many surgical procedures in children may be undertaken as day cases,[27] and there are indications that some adenoidectomies may be suitable as day case procedures.[28]

Despite 19 randomised controlled trials the evidence for the effectiveness of surgical interventions is still confused. A 12 dB improvement in hearing[7] is of uncertain value and masks a range of responses. Large multicentre trials examining the effectiveness of a range of interventions using broader outcome measures are required. Alternative interventions, including advice and support for parents and teachers, parental cessation of smoking, use of temporary hearing aids and non-invasive physical auto-inflation of the eustachian tube should all be investigated as alternatives to surgery.

We thank the many people who helped in preparing the fourth bulletin of *Effective Health Care* and the following who acted as consultants: Dr N Black, Professor G G Browning, Professor M P Haggard, and Mr A Richard Maw. The views expressed are those of the authors .

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