Effective HEALTH CARE

The Treatment of Persistent Glue Ear in Children

Are surgical interventions effective in combating disability from glue ear?

- Glue ear is the most common cause of hearing impairment and reason for elective surgery in children. There are doubts whether current high levels of surgery are necessary.
- The average annual rate of surgical treatment for glue ear in England is about 5/1000 children under the age of 15. There is a large regional variation in rates of surgical treatment for glue ear.
- Most episodes of glue ear are of short duration and spontaneously resolve. There is insufficient evidence to demonstrate a causal link between glue ear and significant disability.
- Grommets and adenoidectomy, alone or in combination, are equally effective and reduce mean hearing impairment by less than 12 decibels. There is a large variation in the effect between children. The clinical significance of small improvements is uncertain.
- Myringotomy alone, and tonsillectomy alone or in combination, are ineffective interventions.
- Introducing a period of *watchful waiting* is likely to decrease surgical activity for glue ear, with potential savings but improved access to quality audiology may increase resource use.
- Purchasers should develop protocols in conjunction with relevant professionals which should include direct access to audiological services for general practitioners, and the use of a *provisional waiting list* during a period of *watchful waiting*.
- Large multi-centre trials examining the effectiveness of a range of interventions using broader outcome measures are required.

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A BULLETIN ON THE EFFECTIVENESS OF HEALTH SERVICE INTERVENTIONS FOR DECISION-MAKERS

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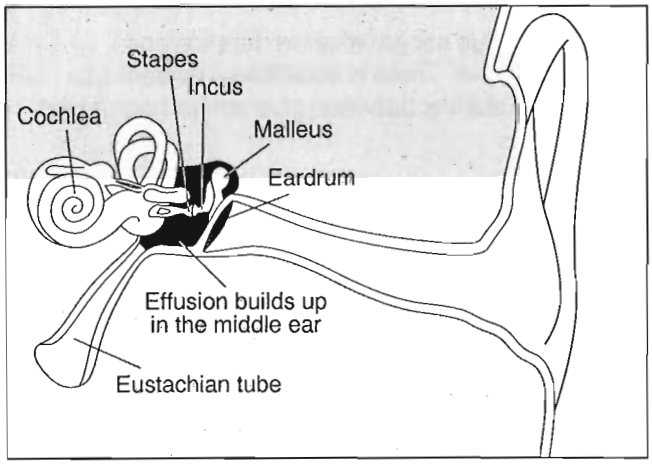
A glossary of medical terms used is given on page 10).

A. GLUE EAR: IMPAIRMENT AND DISABILITY

Glue ear (otitis media with effusion, OME) is the most common cause of hearing impairment and reason for elective surgery in children. There is insufficient evidence to demonstrate a causal link between glue ear and significant disability. There are doubts as to whether current high levels of surgery are necessary.

Figure 1 *Glue (effusion) in the middle ear.*



A.1 Glue ear is a condition characterised by the presence of fluid (effusion) in the middle ear cavity. It is the most common cause of hearing impairment[1] and reason for elective surgery[2] in children.

The *Effective Health Care* bulletins are based on a systematic review and synthesis of literature on the clinical effectiveness, cost-effectiveness and acceptability of health service interventions. Relevant and timely topics for review are selected by a Steering Group comprising managers, directors of public health and academics. Selection of topics takes into account the following criteria: resource implications, uncertainty about effectiveness, and the potential impact on health. The review and synthesis of the literature is carried out by a research team using established methodological checklists, with advice from expert consultants for each topic. The bulletins represent the views of the *Effective Health Care* research team.

A.2 Glue ear affects the functioning of the ear and 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]. The detrimental effect of the hearing impairment on the functioning of the child is referred to as disability[6].

A.3 The rate of surgery for glue ear has greatly increased over the last 25 years and has been described as "an epidemic"[2]. This increase does not appear to reflect significant changes in the underlying prevalence of the condition. Because of the large resources devoted to surgery for glue ear it is important to try to determine how much of this surgery is really necessary and to develop means by which unnecessary interventions can be minimised.

A.4 A number of disabilities may result from persistent hearing impairment (eg compromised levels of social functioning, language competence and speech production, and learning or behavioural difficulties). Whilst there is a sizeable literature examining these links, the vast majority of studies are of poor quality, small size, and include children who have had surgery for glue ear, and therefore do not give a clear picture of what would happen without treatment. Although some disability was associated with glue ear in a large prospective study[7] there is insufficient evidence to demonstrate a causal link between glue ear and significant disability in children. In a comprehensive review of this literature Haggard and Hughes state that if such a link does exist it is only likely to be the result of an extremely persistent history of hearing impairment starting at an early age[1].

A.5 Most studies examining the epidemiology or effectiveness of treatment for glue ear do not use the broader outcomes necessary to measure disability. In the absence of this information it becomes necessary to use hearing impairment as a proxy measure for disability.

A.6 A persistent (ie greater than 3 months) bilateral hearing impairment of 25-30 dB HL is sometimes thought sufficiently serious to justify the consideration of surgery. A hearing loss of 30 dB HL can mean that a normal conversation sounds like a soft whisper (see Table A.1).

Table A.1 *Guide to the clinical significance of different levels of hearing loss*

Jet takeoff (from 60 m)	130 dB
Shot gun blast	100 dB
Car horn at 6 m	90 dB
Inside sports car at 50 mph	80 dB
Loud thunder	70 dB
Normal conversation	60 dB
Typical room	40 dB
Soft whisper at 1.5 m	30 dB
Open country	10 dB

Source: Rosenberg[8]

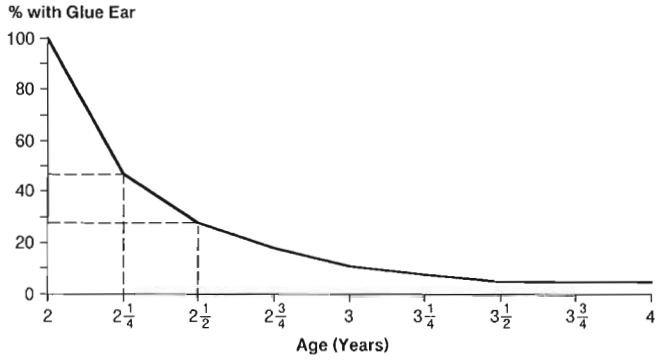
A.7 Unilateral hearing impairment (even when persistent) is not necessarily a cause for concern as normal hearing in the non-affected ear eliminates the likelihood of disability. Similarly, where the condition resolves and then subsequently recurs disability is only likely when this leads to a period of persistent hearing loss.

B. SIZE OF THE PROBLEM

At any point in time around 5% of children aged between 2 and 4 years are likely to have a bilateral hearing impairment as a result of glue ear which persists for at least three months. Most episodes are of short duration and resolve spontaneously.

B.1 Glue ear resolves spontaneously in the majority of children although recurrence is common. Most episodes are of short duration[9]: around 50% of affected ears resolve spontaneously after three months and only 5% of children will have glue ear for a period of a year or more (see Figure 2)[9,10]. In the vast majority of children glue ear will not persist beyond early childhood.

Figure 2 *Spontaneous resolution of glue ear in a cohort of two-year olds.*



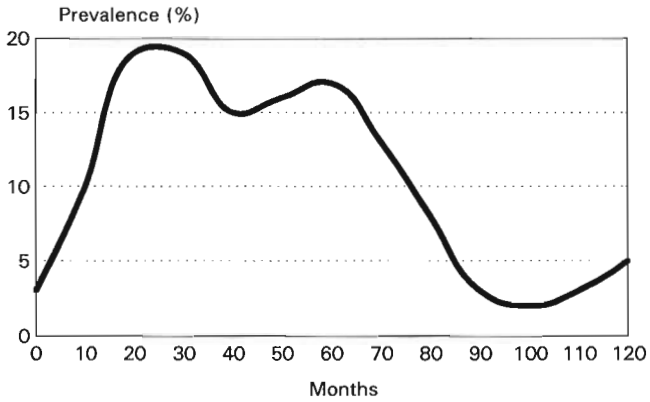
Source: Zielhuis[9].

B.2 Because of the nature of the condition, definition of the number of new cases per year (incidence) and the total percentage of children affected (prevalence) is more complicated than in a more stable condition. Incidence and prevalence studies have been conducted among different populations, using different designs and criteria, making comparison difficult[1].

B.3 *Natural history* Several longitudinal studies[9,11–13] provide information on the natural history of glue ear. The results of one of these studies[9], based on three-monthly measurements on 1217 ears in Dutch children aged between 2 and 4 years, is summarised in Appendix I.

B.4 *Incidence and prevalence* Around 42% of three year old children may begin an episode of glue ear over the next 12 months (incidence), with more cases occurring in winter[14]. Because these episodes are generally of short duration, the percentage of children with glue ear at any point in time (prevalence) is significantly lower. The pooled results of selected prevalence studies demonstrates a peak of 20% at around two years of age, with a second peak in the sixth year[15]. These results are presented in Figure 3.

Figure 3 *Prevalence of glue ear.*



Source: Zielhuis *et al.*[15].

B.5 Around 20% of a cohort of Dutch school children aged two years were found to have glue ear (as measured by bilateral flat type B tympanograms: see D.5) From this it is estimated that around 6% of children aged two years have a bilateral hearing impairment of at least 25 dB HL, which persists for at least three months (see Appendix II).

B.6 *Risk factors* The main risk factors for the development and detection of glue ear include younger age, gender (more common in boys than girls), sibling history, season (greater occurrence in winter and spring), bottle feeding, attendance at day care, and parental smoking[7,14,16–22].

B.7 Anatomical abnormalities of the face such as cleft palate, reduced post-nasal space and certain genetic syndromes (eg Down's, Turner's, Hunter's, fragile X) and abnormality of the skull base and nasopharynx are also associated with an increased risk and duration of glue ear[23,24].

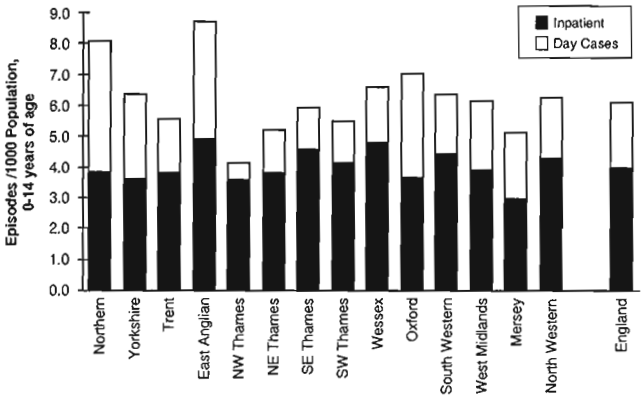
B.8 Persistent glue ear which results in surgery is more common in boys than girls, and higher in social class I than social class V[2]. It is also associated with an older sibling (especially of the same sex) having had surgery[25]. It is doubtful whether this reflects real differences in need: demand for surgery is influenced by a range of factors such as parental expectations, interaction with the clinical judgements of general practitioners (GPs) and the availability of services[26].

C. CURRENT RATES OF SURGERY

The average rate of surgical treatment for glue ear in England is estimated to be 4.7/1000 children under the age of 15 per year. There is a large regional variation in rates of surgical treatment for glue ear which reflects, in part, differences in clinical decision-making.

C.1 In order to estimate the surgical treatment rate for glue ear, data from the Hospital Episode Statistics for 1989/90 which are classified as Otitis Media and Mastoiditis are applied to OPCS regional population estimates (Figure 4). Because these include conditions other than glue ear and so overestimate actual rates a downward adjustment is made using detailed data from Yorkshire region.

Figure 4 *Surgical treatment rates for otitis media and mastoiditis in the under-15s by region, 1989/90.*



Source: Latest unpublished estimates from the Department of Health (Hospital Episodes System).

Treatment episodes for otitis media and mastoiditis are predominantly for the condition of glue ear.

C.2 The average rate of surgical treatment for glue ear in England is estimated to be 4.7/1000 children under the age of 15 per year, although there is a large variation across the country (see Figure 4)[27]. This is consistent with variation within Scotland in routinely collected data and data from the Yorkshire region. These variations are due to a range of factors including screening policy, culture, referral practice and surgical decision-making, and supply and organisation of services. There is uncertainty as to what rate is appropriate.

C.3 *Day case surgery* Figure 4 also shows a variation in the proportion of children treated as in-patient and day cases. There are considerable economic advantages offered by day case surgery[28] and grommet insertion/myringotomy is currently recommended as a day case procedure[29]. There is a large variation in the proportion of grommet insertions which are undertaken as day cases[28]. Many childhood surgical procedures may be undertaken as day cases[30] and there are indications that adenoidectomy may be suitable for day case treatment[31].

D. DIAGNOSIS AND ASSESSMENT

Four main methods are used for assessing the need for surgery. No single investigation can identify children most likely to benefit from surgical interventions.

D.1 It is important to identify those with a persistent and significant hearing loss because they are most likely to be at risk of disability, and therefore most likely to benefit from intervention. The object of diagnosis is to determine whether glue ear is present, measure the associated hearing loss, and ensure that this hearing loss is not due to other causes. No single investigation can achieve this, but adequate diagnosis can be made using results from some combinations of the following four methods: history, otoscopy, audiometry, and tympanometry.

D.2 *History* Retrospective information about the symptoms and persistence of hearing impairment may be obtained from parents, but it is not known how well this correlates with disability. There are likely to be differences in the severity at which parents consult their GP.

D.3 *Otoscopy* Otoscopy is observation of the ear drum using an otoscope. In glue ear the tympanic membrane may appear dull and retracted. Fluid levels or bubbles may be visible, and mobility of the drum can be assessed by a pneumatic otoscope. The accuracy of this procedure depends upon the skill and experience of the user. A sensitivity of around 90% and a specificity of around 75% has been described by skilled users for this procedure[32–35].

D.4 *Audiometry* Audiometric tests (which measure hearing across a range of frequencies), carried out by suitably trained staff with the necessary equipment under appropriate conditions, can detect a conduction defect in the middle ear. Reliable audiograms are more difficult to obtain before the age of four years. Technological advances such as the IHR-McCormick Automated Toy Discrimination test[36] and the more widely used Visual Reinforced Audiometry reduce the age at which audiometric testing can be undertaken. Audiograms are also useful in indicating the degree to which hearing impairment may be attributable to other causes.

D.5 *Tympanometry/impedance audiometry* is a convenient and rapid method of assessing the functioning of the middle ear[34]. Tympanometry measures the ability of the ear drum to react to sound energy but does not directly measure hearing impairment. It can be reliably used in children over the age of around seven months[1].

D.6 The new microtympanometers have the potential to help GPs make an initial diagnosis of glue ear and so guide referral. However to achieve the 49% predictive

value described in Appendix II they require a range of measurement of −400 to +200 mm H_2O, a specification which is not universal[37]. Equipment with a smaller range will not be able to distinguish between established glue ear and transitional stages of the disease[1]. The indiscriminate use of tympanometry for surveillance purposes in general practice might lead to over-referral[38] and it should only be used where concern is sufficient to justify testing.

D.7 Surgical removal of the content of the middle ear cavity immediately prior to grommet insertion (myringotomy/tympanocentesis) provides gold standard confirmation of the presence of glue ear, although not of hearing impairment. Most dry taps (ie myringotomy where glue is not found) are likely to be due to poor assessment and diagnosis and not (as is often claimed) caused by nitrous oxide anaesthesia (see F.5).

E. IMPROVEMENT IN HEARING AFTER SURGERY

Grommets and adenoidectomy, alone or in combination, reduce mean hearing impairment in children with glue ear by less than 12 dB. The effect of treatment diminishes with time.

E.1 Properly designed randomized controlled trials (RCTs) provide the most reliable evidence of the effectiveness of health care interventions[39]. There have been 19 published (or soon to be published) RCTs which examine the effectiveness of surgical interventions for glue ear (see Appendix IV)[41–63]. These examine 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. It is assumed that medical options have been exhausted before surgery is considered[40].

E.2 There are a number of methodological problems in the design of RCTs which examine the effectiveness of surgical interventions for glue ear. Spontaneous remission, recurrence, and large variations in the degree and persistence of hearing impairment all contribute to the difficulties of providing adequate controls in trials.

E.3 Spontaneous remission and other complicating factors may be controlled for by applying different treatments to the right and left ear of each child with bilateral glue ear, one ear acts as the control or comparison for the other[64]. However, matching ears assumes that the intervention in one ear does not affect the other. This may not be the case since the brain may compensate for poor hearing by enhancing hearing in the treated ear so producing an over-estimate of the likely effect of treating both ears. This possibility has not been adequately studied.

E.4 Appendix IV summarises the main features of each of the 19 RCTs which examine the effectiveness of surgical interventions for glue ear. The rest of this section presents the clinically important findings of the review of this literature.

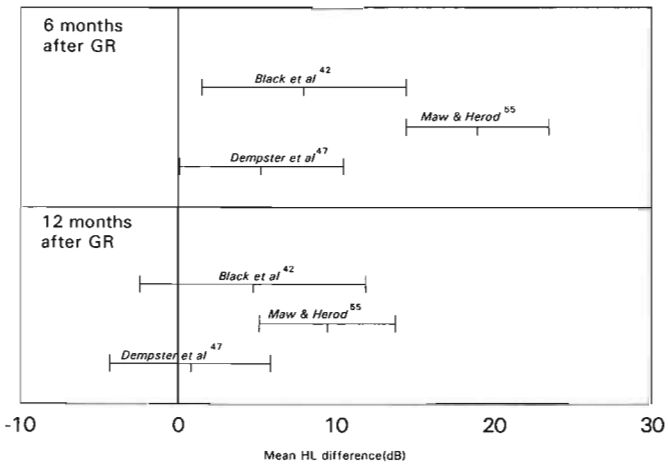
E.5 When there are several RCTs examining the effectiveness of an intervention their results are often pooled by means of meta-analysis in order to get a more precise summary estimate of treatment effect[65]. Such, however, is the variation between the trials in the populations studied, study design, policy on repeat treatments, comparisons made, and the outcomes presented, that the use of formal meta-analysis to combine the results of the majority of the trials is unhelpful[66,67]. However, the trials do provide useful evidence about the effectiveness of different interventions for glue ear.

E.6 Three of the RCTs are particularly informative because they report hearing level as an outcome measure and compare treatment with a no treatment group of ears or children. They also represent the spectrum of current practice in Britain[42,47,55]. Table E.1 and Figures E.1-1 to E.1-5 show the estimates of the effect of different interventions on hearing loss at 6 months and 1 year from these trials[42,47,55].

E.7 Both grommets[42,47,55] and adenoidectomy[42,46,47,55] each reduce mean hearing impairment in children with glue ear. However the mean reduction is estimated to be less than 12 dB HL at 6 months and under 6 dB HL at 12 months for either treatment strategy.

E.8 There is a large variation in the treatment effect between children. The clinical significance of small improvements is not clear (see A). Because, however, the studies are too small and not designed for subgroup

Figure E.1-1 *Mean HL improvement and 95% confidence interval after grommet insertion (GR) compared to no treatment (NT).*



Mean HL difference (dB) = (Mean HL in NT group)−(Mean HL in GR group).

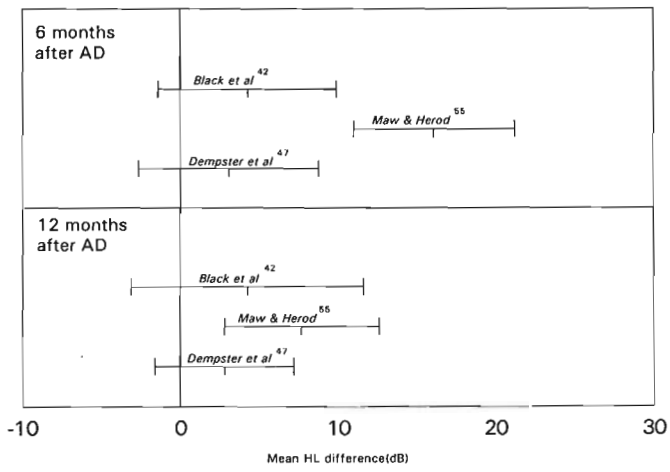
Table E.1 *Improvement in hearing loss (dB HL) after surgery in children with glue ear in three RCTs*

First author	Black[42]	Maw[55]*	Dempster[47]*
Children age:	4–9	2–9	4–9
Dry tap rate:	34%	0%?	0%
Repeated intervention:	Excluded	54% reinsertions	Avoided
Pre-operative mean dB HL:	28.2	32.8	32.4
Intervention:	(MY+GR)/NT	(MY+GR)/NT	(MY+GR)/NT
sample size (no. of ears):	37/37	43/43	35/35
At 6 months			
Mean(SD) dB HL in GR group	-(14.3)	17.5(9.8)	15.8(10.3)
Mean(SD) dB HL in NT group	-(14.3)	36.5(11.9)	21.1(11.7)
Improvement in mean dB HL(SE)	8.0(3.3)	19.0(2.3)	5.3(2.6)
At 12 months			
Mean(SD) dB HL in GR group	-(15.6)	17.5(8.6)	17.6(11.2)
Mean(SD) dB HL in NT group	-(15.6)	27.4(12.1)	18.4(10.6)
Improvement in mean dB HL(SE)	4.8(3.6)	9.5(2.2)	0.8(2.6)
Intervention:	AD/NT	AD/NT	AD/NT
sample size (no. of ears):	37/37	34/45	37/35
At 6 months:			
Mean(SD) dB HL in AD group	-(12.3)	20.4(11.3)	18.0(13.0)
Mean(SD) dB HL in NT group	-(12.3)	36.5(11.9)	21.1(11.7)
Improvement in mean dB HL(SE)	4.3(2.9)	16.1(2.6)	3.1(2.9)
At 12 months:			
Mean(SD) dB HL in AD group	-(16.2)	19.7(10.4)	15.6(8.4)
Mean(SD) dB HL in NT group	-(16.2)	27.4(12.1)	18.4(10.6)
Improvement in mean dB HL(SE)	4.3(3.7)	7.7(2.5)	2.8(2.3)
Intervention:	(AD+MY+GR)/(MY+GR)	(AD+MY+GR)/(MY+GR)	(AD+MY+GR)/(MY+(GR)
sample size (no. of ears):	37/37	34/45	37/35
At 6 months			
Mean(SD) dB HL in AD + GR group	-(10.3)	16.4(8.0)	13.2(9.0)
Mean(SD) dB HL in GR group	-(10.3)	17.5(9.8)	15.8(10.3)
Improvement in mean dB HL(SE)	2.1(2.4)	1.1(2.0)	2.6(2.3)
At 12 months			
Mean(SD) dB HL in AD + GR group	-(11.6)	16.4(8.0)	15.9(8.4)
Mean(SD) dB HL in GR group	-(11.6)	17.5(8.6)	17.6(11.2)
Improvement in mean dB HL(SE)	2.4(2.7)	1.1(1.9)	1.7(2.3)

Key: AD: adenoidectomy; dB HL: decibel hearing loss; GR: grommet insertion; MY: myringotomy; NT: no treatment.

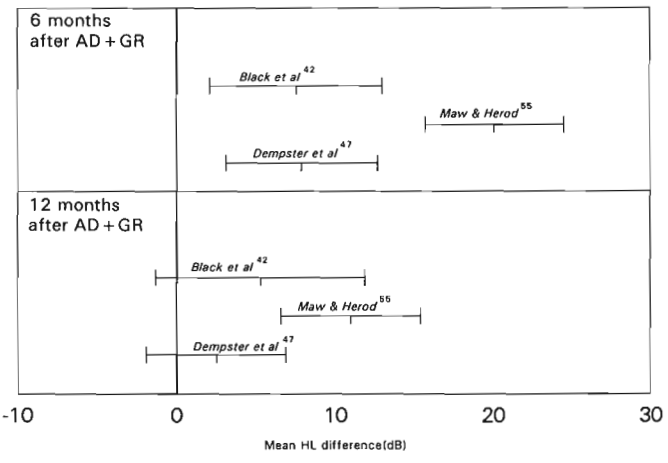
* In Maw[55] and Dempster[47] the standard errors for the improvement in mean hearing loss between groups are based upon unmatched analysis because the standard error based upon the matched analysis was not reported in the original papers: this results in a widening of the confidence intervals.

Figure E.1-2 *Mean HL improvement and 95% confidence interval after adenoidectomy (AD) compared to no treatment (NT).*



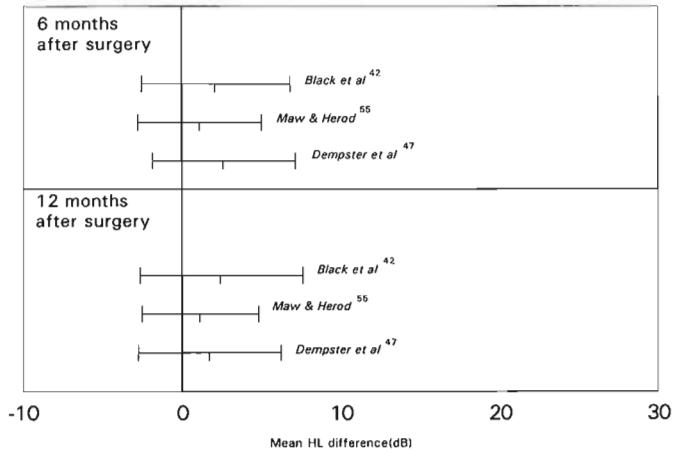
Mean HL difference (dB) = (Mean HL in NT group)−(Mean HL in AD group).

Figure E.1-3 *Mean HL improvement and 95% confidence interval after adenoidectomy plus grommet insertion (AD+GR) compared to no treatment (NT).*



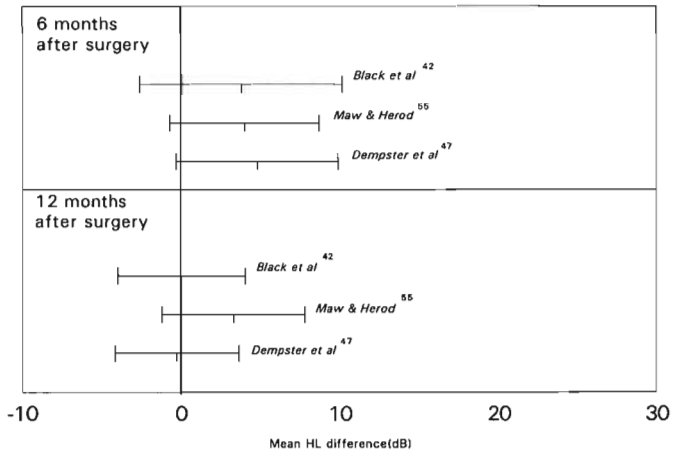
Mean HL difference (dB) = (Mean HL in NT group)−(Mean HL in AD + GR group).

Figure E.1-4 *Mean HL improvement and 95% confidence interval after adenoidectomy and grommet insertion (AD + GR) compared with GR alone.*



Mean HL difference (dB) = (Mean HL in GR group)−(Mean HL in AD + GR group).

Figure E.1-5 *Mean HL improvement and 95% confidence interval after adenoidectomy and grommet insertion (AD + GR) compared with AD alone.*



Mean HL difference (dB) = (Mean HL in AD group) − (Mean HL in AD + GR group).

analysis there is no good evidence about which factors may help predict which children with glue ear will benefit most.

E.9 The added benefit of combining grommet insertion and adenoidectomy treatments compared to either treatment alone is very small. It has been suggested that adenoidectomy may result in longer benefit and therefore reduce the need for re-insertion of grommets[55]; this, however, needs confirmation by further long-term studies.

E.10 Reduction in hearing impairment as a result of surgical treatment declines as the period after surgery increases, due to recurrence of glue ear in the treatment group and spontaneous improvement in the untreated controls.

E.11 Myringotomy alone is not an effective treatment in restoring hearing levels in children with glue ear[42,53,54].

E.12 There is no added benefit of tonsillectomy in conjunction with adenoidectomy in the treatment of children with glue ear[56].

E.13 Grommets temporarily improve hearing when in place and functioning[42,45,52,55,59]. The aim is that they stay in place until the condition spontaneously improves. Some children receive repeat grommet insertions if bilateral hearing impairment returns after the grommet is extruded. Different designs of grommets stay *in situ* for differing periods in the ear-drum. Longer term grommets may have a longer treatment effect, but will lead to a higher level of complications[68]. Ideally the type of grommet used should reflect the remaining period of hearing loss. However, because there are no reliable indicators of the likely persistence of hearing loss, shorter term grommets (extruding after 6 months) are commonly used. Repeat testing after they have dropped out can be used to determine whether the episode has resolved spontaneously, at which point the decision whether to repeat grommet insertion can be made.

E.14 *Side effects of surgery* Grommet insertion leads to tympanosclerosis[43,45,47,53,69]. The long term consequences of tympanosclerosis are unclear: the only study to follow up for sufficiently long was small and failed to show any effect on hearing impairment or other pathology after 15 years[69]. Grommet insertion also leads to a slightly increased incidence of chronic perforation and possibly cholesteatoma which are more serious conditions of the middle ear[43,45,47,53,69]. There are also the more general slight risks of treatment under general anaesthetic, the psychological trauma of hospitalisation and operation, and a slight risk of haemorrhage with adenoidectomy[31].

E.15 Infection is common among those receiving grommets, with between 20% and 35% of children likely to experience a discharge from an ear after grommet insertion[70–72], of which around 5% are likely to be persistent[70]. There is no evidence that surgical interventions for glue ear prevent the development of chronic suppurative otitis media.

E.16 A recent questionnaire examining clinical practice indicates that around 95% of ENT surgeons advise children with grommets not to swim, or put considerable limitations upon their swimming because of the risk of infection[73]. There is no evidence from case reviews or from prospective studies that swimming adversely effects infection rates in children with grommets, and advising these children not to swim puts needless limits upon normal functioning[74,75].

F. WHEN IS TREATMENT APPROPRIATE?

A period of *watchful waiting* (continued observation and testing) may reduce surgery rates, but may delay treatment for the minority of children who stand to gain most from surgery. This may be avoided by the use of a *provisional waiting list*.

F.1 Because of the characteristics of this condition, in which a significant proportion of children recover quickly without surgery (spontaneous resolution), there is uncertainty when treatment is appropriate (see Figure 2). Fifty per cent of cases resolve after a three-month period; after six months around 75% resolve spontaneously. Some of those who spontaneously resolve will have a recurrence (see Appendix I). In a survey of consultant otolaryngologists 36% of respondents stated that they schedule patients for surgery at the first appointment.[76]

F.2 If children with glue ear and a bilateral hearing impairment of 25 dB HL or more are not treated immediately, but monitored over a period of time (*watchful waiting*) to establish that the condition is persistent, fewer will be treated because of spontaneous resolution. Although there is often a considerable delay 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*.

F.3 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 to wait longer, they may experience an extended period of hearing impairment with any subsequent disability. There is, therefore, 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.

F.4 The aim of *watchful waiting* is to delay the decision to operate until need has been fully established using criteria such as persistence and severity. In order 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 *provisionally* put on a waiting list after initial audiological assessment indicates potential need for surgery and remain on this list during the period of *watchful waiting*.

F.5 *Dry taps* Retesting prior to surgery will reduce the percentage of children found to have no glue in their ear at the time of surgery (dry tap). If a child is not found to have bilateral glue ear at myringotomy there is currently no justification for proceeding further with the intervention. Although the condition may recur in future there is no reliable way of predicting whether this will occur for an individual child. Dry taps indicate failure of the *watchful waiting* procedure to ensure persistence.

F.6 The assertion that some dry taps are the result of nitrous oxide anaesthesia is not supported by the evidence[77–79] and a recent study which appeared to demonstrate this relationship used equipment which was unable to distinguish between an established glue ear and transitional stages of the disease (ie between a type B and C_2 tympanogram)[80].

F.7 *Long term effects* Any long term physical damage to the ear as a result of the presence of 'glue' is negligible when compared to the risks associated with intervention, and so does not by itself justify surgical intervention[7,43–45,47,52,62,69].

G. QUALITY AND AUDIT

Indicators of service quality are useful in audit and in the specification of services in order to ensure a quality service for children with glue ear.

G.1 Audit may be useful in ensuring that surgery is only carried out on those who are likely to benefit most from treatment and in ensuring that the surgery is effective in improving hearing. The following indicators can be useful in the audit process in improving quality: pre-operative audiological measurements to indicate persistence, post-operative audiological measurements to indicate benefit, and the dry tap rate.

(i) *To ensure sufficient persistence and severity* A period of *watchful waiting* is required, (eg at least two audiological tests over a period of three to six months) to ensure that those with a mild hearing loss (eg less than 25 dB HL bilateral hearing loss) or children in whom persistence has not been demonstrated, do not automatically receive surgery.

(ii) *To minimise the dry tap rate* A final assessment should be performed prior to surgery to reduce unnecessary surgery.

(iii) *To measure the benefit* Pre-operative, post-operative and six-month measurement of hearing loss is necessary to give information on the benefits of the operation related to severity of the original impairment and whether a grommet is in place and functioning.

H. COST ANALYSIS

Introducing a period of *watchful waiting* is likely to decrease surgical activity for glue ear, with potential savings. Improved access to quality audiology may increase resource use.

H.1 Currently, no reliable costings of surgical procedures are available. Extra-contractual referral (ECR) tariffs are crude measures of cost. However, taking an average of these charges reduces the effect of other influences and mean ECRs are used here (in the absence of more accurate data) as a preliminary estimate of cost.

H.2 A survey, which included one hospital from each English region, reported a mean ECR for grommet insertion of £307, varying from £162 to £582[81]: similar values are reported by providers in the Yorkshire region (see Table H.1).

Table H.1 *The average ECR price for procedures* associated with glue ear in the Yorkshire region (1992/3 prices)*

	In-patient £	Day Case £	Proportion as day case†	Average £
Myringotomy	521	245	0.48	389
Grommet insertion‡	420	237	0.64	303
Adenoidectomy	624	367	0.00	624
Tonsillectomy	768	368	0.22	680

* in 0–14 year olds.
† multiple procedures are conducted on an in-patient basis and are charged as the sum of the prices of the individual procedures, although this may over-estimate actual costs
‡ includes myringotomy
Source: Information Management, Yorkshire Health.

H.3 Improving assessment in order to increase the appropriateness of surgery requires good access to quality audiological services. In some areas this will involve expanding and improving paediatric audiological services. In addition, the number of audiological assessments will probably increase. The cost of a full paediatric audiological assessment has been estimated at between £40 to £70[82].

H.4 Hospital activity data for the Yorkshire region indicates that in the year 1990/91 3106 grommet insertions and 1197 adenoidectomies were performed for glue ear (Table H.2). This ratio of grommet to adenoidectomy treatment rates is similar to that reported in Scotland. Activity rates and the ratio of day cases to in-patient cases is similar in the Yorkshire region to the average in England and so data from this analysis can be usefully extrapolated. Applying these rates to the population of England and Wales indicates that the current expenditure on NHS surgical treatment of glue ear is around £30M.

H.5 A protocol introducing a period of *watchful waiting* may lead to a considerable reduction in surgical activity, where such a strategy is not already normal practice. The size of the reduction in activity will depend upon the organisation and delivery of the service.

H.6 The savings from reducing activity in glue ear may be difficult to realise for a number of reasons:

(i) surgeons may maintain levels of activity by reducing waiting lists or increasing work in other areas;
(ii) the variable costs of ENT 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;
(iii) improvement in audiological services and referral protocols may, in some localities, result in the satisfaction of previously unmet need which will increase appropriate surgical activity, particularly in the younger age group.

I. RECOMMENDATIONS FOR HEALTH CARE COMMISSIONING

Purchasers should develop protocols with ENT surgeons, GPs, SCMOs, community paediatricians, audiologists and other relevant professionals. These should include direct access to audiological services for GPs, and the use of a *provisional waiting list* during the period of *watchful waiting*.

I.1 Purchasers and providers should scrutinise local practice and develop protocols with ENT surgeons, GPs, senior clinical medical officers (SCMOs), community paediatricians, audiologists, and other relevant professionals. This protocol should clarify the pathway of

Table H.2 *Treatment levels and charges for glue ear*

Procedures*	Procedures in Yorkshire	Estimated procedures per district (Popn 250 000)	Estimated procedures in England and Wales	ECR tariff £, 1992/3†	Estimated charge £, 1992/3
Myringotomy	122	8	1660	463	770 000
Grommet	3106	208	42 270	347	14 670 000
Adenoidectomy	1197	80	16 290	624	10 160 000
Tonsillectomy	471	32	6410	768	4 920 000
Total	4951	328	66 630		30 520 000

* 4951 procedures performed in 3443 treatment episodes.
† Day case/in-patient weightings are different to Table H.1 because combined procedures are included.

referral and treatment of patients in primary and secondary care, improve the quality of assessment, and reduce unnecessary duplication of investigations. The following should be considered:

(i) good access to and explicit referral criteria for high quality audiological services (see D);
(ii) full assessment of hearing impairment attributable to glue ear at the beginning and end of a period of *watchful waiting*, using an appropriate range of tests (see F.2);
(iii) the development of a *provisional waiting list* for the *watchful waiting* period to reduce the time until surgery for those who are later found to need surgery;
(iv) generally agreed criteria for surgery based on history of hearing difficulty and disability, together with demonstration of persistence and severity of hearing loss, with findings from otoscopy and tympanometry. This should include the measurement of hearing loss and confirmation of the presence of glue ear shortly before surgery (see F.4);
(v) a schedule for follow-up which will include testing (see E.13).

I.2 When audiological assessment indicates the presence of glue ear and a bilateral hearing impairment which meets the criteria in the local protocol, and other approaches are unsuccessful or inappropriate, the child should be placed on a *provisional waiting list* for surgery during which a period of *watchful waiting* will commence. A subsequent affirmative audiological investigation should then be obtained before surgical treatment.

I.3 The arrangements for post-operative follow-up should be included in the protocol, as some children (those most likely to incur disability) may require further treatments if hearing impairment returns.

J. RESEARCH RECOMMENDATIONS

Large multi-centre trials examining the effectiveness of a range of interventions using broader outcome measures are required.

J.1 Despite 19 RCTs the evidence for the effectiveness of surgical interventions is still confused. A 12 dB improvement in hearing is of ambiguous value and masks a range of responses. Research is required to:

(i) identify sub-groups likely to benefit most from surgical intervention;
(ii) assess the feasibility and effectiveness of alternative strategies such as hearing aids and support and advice to parents and teachers. A promising non-surgical alternative is the use of an autoinflation balloon (Otovent)[84,85]. However, the longer term benefits of this need evaluation;
(iii) investigate the effect of reduced parental smoking (passive smoking) upon the course of glue ear;
(iv) examine the development, implementation, and impact of introducing clinical protocols for the assessment, referral, treatment, and follow-up of glue ear.

J.2 This research should use broader measures of outcome than just hearing loss, which are more sensitive to areas of potential disability, eg linguistic, educational, and other social variables, including parental/child subjective assessments.

J.3 In order to recruit enough children and to reflect a range of settings (and therefore improve the ability to generalise) studies should be carried out on a multi-centre basis.

J.4 Cost-effectiveness should be assessed in future trials in order that scarce resources may be used effectively.

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Glossary

Acute otitis media (AOM): characterised by the presence of an acute onset of symptoms (pain/fever) and signs (red, bulging, ear-drum). Episodes of AOM may be more common in children with persistent glue ear[1].

Adenoidectomy is the surgical removal of the adenoids which is thought to reduce eustachian tube dysfunction.

Chronic suppurative otitis media: a persistent infection of the middle ear which can lead to structural damage and worsening deafness.

Grommets are frequently administered in conjunction with myringotomy in the treatment of glue ear. They are small ventilation tubes which are surgically implanted in the ear-drum.

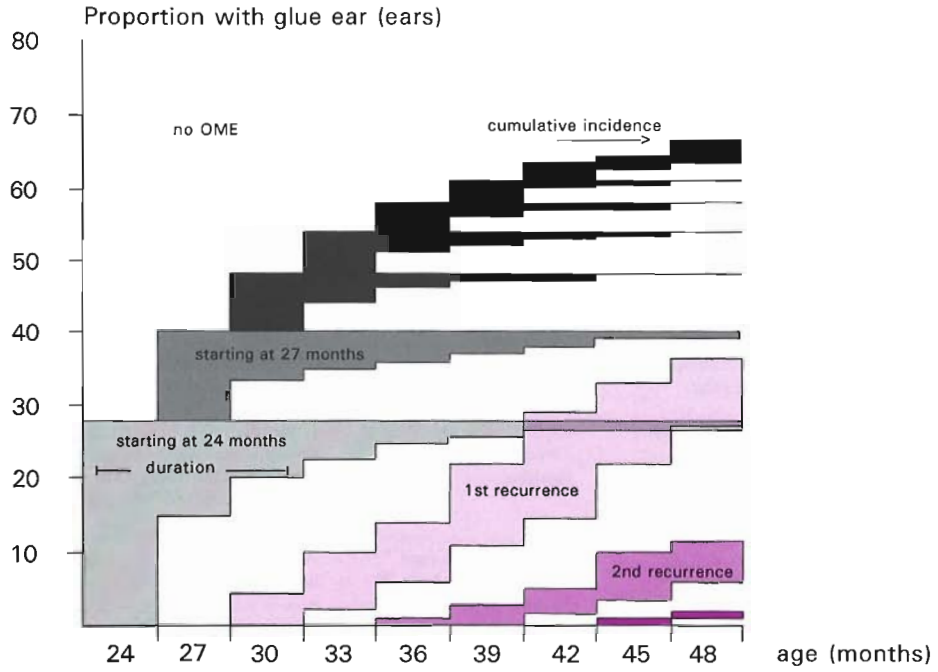
Myringotomy is the surgical removal of fluid from the middle ear.

Otitis media with effusion (OME): glue ear or presence of fluid in the middle ear cavity which is common in early childhood. OME is a blanket term which includes secretory otitis media and serous otitis media with effusion.

Tympanosclerosis is a disorder of the ear-drum.

APPENDIX I

Figure Ap. 1 *Natural history of glue ear.*



Source: Zielhuis[9].

Figure Ap.1 shows the results of following up a cohort of 2-year-old children whose ears were tested every 3 months for glue ear. About 27% of ears were affected by OME at the age of 2 years; these spontaneously remit over time. Many children who have not had a previous episode develop the condition as they get older. Several ears which improve then experience a recurrence which also remits. Therefore, a cross-section of young children will show a significant proportion of ears with glue ear, some with a first or a recurrent episode of variable duration.

APPENDIX II

Proportion of children (2 years old) with persistent bilateral type B tympanogram[9]	10%
Proportion of children (3–12 years) with type B tympanogram who have HL ≥ 25 dB[83] (positive predictive value)	49%
Proportion of children (3–12 years) without type B tympanogram who have HL ≥ 25 dB	2%

APPENDIX III

Important features of the three principal RCTs referred to in Table E.1:

(i) In Black *et al.*[42] 34% of ears did not contain glue at the time of surgery (dry taps) and these ears were included in the analysis as this was a 'pragmatic' trial evaluating surgery as practised in a real clinical setting[86]. These results may therefore underestimate the effect of surgery on more severely affected children with glue ear.

(ii) In Maw and Herod[55] children who had dry taps on myringotomy were excluded from the trial and 41% of children had a grommet reinserted. The treatment effect was higher in this than the other two trials. This was due in part to the poor spontaneous improvement in the untreated control group. Evidence about the natural history (see Figure 2) of glue ear suggests that a significant level of spontaneous improvement will occur, but in this study the untreated control group actually deteriorated in the first six months. The study may therefore overestimate the treatment effect.

(iii) In Dempster *et al.*[47] children who had dry taps on myringotomy were excluded from the trial and the pre-operative hearing impairment was greater than in the other trials. Repeat surgery was avoided during follow-up. The improvement in hearing impairment in this trial is likely to be an underestimate of the effect which would result if grommet reinsertion is employed.

APPENDIX IV

Summary of randomized controlled trials which examine the effectiveness of surgery for glue ear

Author Intervention = *n* (number of subjects)	Children characteristics	Outcome measures	Main results/conclusions
Archard[41] uMY+AD?+TO? = 24 (ears), +AD?+TO? = 24(ears) patients were own control.	Aged 4–10 with 20 dB HL hearing impairment in both ears; no previous ENT surgery. Dry tap rate: 63%?	Audiometry at 1 month and on various occasions between 3–12 months.	The difference in hearing gain in operated and control ears were similar ($P>0.5$) at 1 and 3–12 months. Simple myringotomy performed once in children is harmless but without value as a form of treatment. * Small study size; high dry tap rate; unknown influence of adenoidectomy and tonsillectomy.
Black *et al*[42] AD+bMY+uGR = 37, AD+uMY+uGR = 38, bMY+uGR = 37, uMY+uGR = 37.	Aged 4–9 with bilateral glue ear. Excluded: surgery for other purpose. Dry tap rate: 34% ears dry.	Mean change in audiometric score; % of abnormal tympanograms; % of parents had unfavourable opinions at 7 weeks, 6, 12, 24 months.	Grommet insertion improves hearing in the short term (6 months) compared with no surgery. Mean hearing gain in patients treated with MY+GR was 11.7 dB HL at 7 weeks ($P<0.05$), 8.0 dB HL at 6 months ($P<0.05$), and 4.8 dB HL at 12 month ($P>0.05$). The addition of an adenoidectomy will not improve hearing but increases the likelihood of normal function of the middle ear. Follow up rate: 85% at 12 months, 61% at 24 months. * High dry tap rate.
Bonding *et al*[43] Tos *et al*[44] AD+bMY+uGR = 224 (ears), AD+bMY = 224(ears), Patients were own control.	Mean age 5.0, with bilateral glue ear. Dry tap:?	% ears with average hearing threshold > 20, 30, and 40 dB HL; Mean hearing thresholds; % of tympanogram types; % of pathological types of *pars tensa* at 3, 6, 9, 12 months, 1–3, 6–7 years.	At 1–3 year follow up: Insertion of grommets yields better hearing results than myringotomy if the grommet is functioning: the ears with hearing impairment ≥ 30 dB HL was 1% in ears with grommets and 19% in ears without grommets ($P<0.01$). 23% GR insertion to control ears and 10% reinsertion to GR ears during follow up. Complication: tympanosclerosis 48% in GR ear and 10% in other side; periodic aural discharge 14% in GR ear. At 6–7 year follow up: Tympanosclerosis in 59% of the children on the side with GR insertion and 13% in the contralateral ear ($P<0.001$). The hearing impairment caused by tympanosclerosis <0.5 dB HL and not significant. * Lost to follow up: 14% at 1–3 years, 35% at 6–7 years.
Brown *et al*[45] AD+uMY+uGR = 60 (ears), AD = 60 (ears). patients were own control.	Aged 4–10 with glue ear in both ears. Dry tap rate:?	Mean hearing level; Mean middle ear pressures; % sequelae at 3, 6 months and 5 years.	There was no statistical difference between the postoperative results at 6–12 months. The mean hearing impairment was 11.4 dB HL for the grommet ear and 16.6 dB HL for the control ear at 3 months, 17 dB HL and 14 dB HL respectively at the 5-year follow-up. At 5 years 42% tympanosclerosis and 13% thin scars in the grommet ear but none in the control ear. * 8% lost to follow up; small study size.
Bulman *et al*[46] AD+MY+GR = 16 (ears)? AD+MY = 16 (ears)? AD = 16 (ears)? MY+GR = 16 (ears)? MY = 16 (ears)? NT = 16 (ears)? Patients were own control.	Aged 4–9 with bilateral hearing impairment due to OME. Patients with recurrent earache, febrile illness, or symptoms of nasal obstruction were excluded. Dry tap:?	Audiometry (sum of 0.5, 1, 2, 4 kHZ threshold divided by 10 to form a score), otoscopy at 2 days, 3, 6, 9, 12, 24 months.	The ears with grommets were significantly better than other groups before 6 months ($P<0.05$). Adenoidectomy has no benefit immediately but produces a significant benefit at 3 and 6 months. 40% of patients need re-treatment within one year. * Small study size; dry tap rate? Complications ? Validity of 'score'?
Dempster *et al*[47] (in press); AD+MY+GR = 37 (ears), AD = 37 (ears), MY+GR = 35 (ears), NT = 35 (ears).	Aged 4–9 with otoscopic evidence of bilateral OME, PTA hearing impairment ≥ 25 dB HL, air bone gap ≥ 15 dB HL, type B or C2 tympanogram. Excluded: previous ENT surgery, additional symptoms requiring surgery, cleft palate. Dry tap rate: 0%.	1. Changes in the mean air conduction thresholds at 6, 12 months post-surgery; 2. persistence of OME clinically and tympanometrically; 3. otoscopic evidence of tympanic membrane abnormality post-operatively.	Improvement in hearing: at 6 months post-operatively there is an additive effect of adenoidectomy on grommet insertion in boys ($P<0.01$): at 6 months the improvement in air conduction for the boys in the no-treatment group is 9.2 dB HL, grommet 17.0 dB HL, adenoidectomy but no-grommet 16.6 dB HL, and for adenoidectomy with grommet 21.6 dB HL. The results for the girls is similar at 15.3, 19.3, 12.6, and 15.3 dB HL respectively because of the higher natural resolution rate in them. At 12 months post-surgery 31% tympanosclerosis in grommet alone; 46% in AD + GR; 0% in AD alone or NT. Retraction: 11% in AD; 6% in AD+GR; 3% in GR alone or NT. * Repeated surgery avoided; 8% lost to follow up.
Fiellau-Nikolajsen *et al*[48, 49] AD+bMY = 20, bMY = 22.	Aged 3 with type B tympanometry. Dry tap: ?	PTA, tympanometry, otomicroscopy at 1, 3, 6 and 21 months postoperatively.	No significant difference in middle ear status (tympanogram type) between two groups. Changes in hearing level were not reported. * Small study size.

Author Intervention = *n* (number of subjects)	Children characteristics	Outcome measures	Main results/conclusions
Gates *et al*[50, 51] bMY = 127, bMY+GR = 150, AD+bMY = 151, AD+bMY+GR = 150.	Aged 4–8 with persistent OME (not necessarily bilateral). Excluded: previous ENT surgery, cleft palate, major chronic illness, or who required daily medication. Dry tap: 32%.	Time with effusion; time with HL ≥ 20dB HL; time with recurrent effusion; No. of retreatments. Otoscopy and tympanometry at every 6 weeks for 2 years; audiometry at every second visit.	At the end of study, pure tone averages improved for all groups over the 2 year follow-up, though the improvement was significantly smaller for those in group 1 than those in group 2–4 combined (5 v 12 dB HL, $P<0.05$). There were no significant differences in hearing level among group 2–4. In groups 1 through 4 the mean % of time with any effusion was 49, 35, 30, 26 ($P<0.001$). 19% retreatment; Purulent otorrhoea: 22% in MY, 29% in MY+GR, 11% in AD+MY, and 24% in AD+MY+GR. * 18% lost to follow up; 27 patients crossover to other group but analysed by intention-to-treat.
Lildholdt[52] AD+MY+GR = 150 (ears), AD + MY = 150 (ears). Patients as own control.	Aged 1–10 with middle ear pressure below 150 mm water on both sides; up to 15 dB HL variation between ears. Dry tap: effusion confirmed by myringotomy.	The mean value of middle ear pressure; % flat tympanogram; hearing impairment (PTA); otomicroscopic findings after 3 weeks, then every 3–6 months for 5 years (mean 3.2 years).	The improvement in hearing was better in the ears with grommet *at 3 weeks* ($P<0.001$) postoperatively, but no significant difference after 3 weeks ($P>0.05$). The use of grommet insertion involves a high risk of complications and sequelae which may result in chronic middle ear disease. 17% repeated operation. 23% of the grommet ears were characterised at the final check-up as 'normal' by means of otomicroscopy, in contrast to 83% of the intact ears. * 89% follow-up rate.
Mandel *et al*[53] Severe hearing impairment: MY+GR = 11 MY = 12 Without severe hearing impairment: MY+GR = 30; MY = 27; NT = 29.	Aged 7 months–12 years with OME unresponsive to medical therapy. Severe hearing impairment: PTA-HL > 20 dB HL bilaterally or > 40 dB HL unilaterally. Excluded: systemic illness, history of ENT surgery, severe upper airway obstruction, structural middle ear abnormality, etc. Dry tap rate: ?	Tympanometry, audiometry monthly for 3 years. Life table analysis: time until treatment failure, time until recurrence of OME or AOM.	*At 2 months* post-operatively the MY+GR group showed marked improvement in hearing: the mean Speech-Recognition Threshold (SRT) was 7 dB HL in MY+GR group and 17 dB HL in MY or NT group for those without significant hearing impairment at entry ($P<0.01$); SRT was 5.5 dB HL in MY+GR group and 26.8 dB HL in MY alone group for those with significant hearing impairment at entry ($P<0.01$). The time until half of tubes were nonfunctional was 14.2 (0.49) months (median 50% GR reinsertion at least once during 3 years study. Of 34 patients in the GR group who completed 3 years in the study, 68% had at least once episode of otorrhoea through a tube. 2 subjects with GR developed persistent otorrhoea through a tube and required hospitalisation. *Only the data during the first 2 months reliable since patients in MY and NT group received GR insertion eventually.
Mandel *et al*[54] MY+GR = 37 MY = 39 NT = 35.	Aged 7 months to 12 years with OME lasting at least 2 months. Excluded: previous ENT surgery, acute AOM or purulent rhinitis, PTA >35 dB HL, etc. Dry tap rate: ?	Pneumatic otoscopy, tympanometry, ME muscle reflex testing, audiometric testing monthly for 3 years.	Within 4 months after surgery, the mean SRTs in MY and NT groups showed no statistically significant change between the entry and follow-up evaluations. The MY+GR group showed a marked improvement in hearing (6.6 dB HL at 4 months v 19.1 dB HL at entry, $P<0.001$). MY+GR resulted in less time with effusion than did either MY alone or NT. 2 subjects developed chronic suppurative otitis media with GR in place; 13% tympanic membrane perforation in MY+GR. * Excluded children with HL > 35 dB HL bilaterally.
Maw *et al*[55, 56] ADTO+uMY+uGR = 47, AD+uMY+uGR = 47+23, uMY+uGR = 56+19.	Aged 2–9 with bilateral OME, PTA HL > 20 dB HL, abnormal tympanometry. Excluded: spontaneous resolution during the preoperative period, upper airway obstruction from gross adenoidal hyperplasia. Dry tap rate: dry tap excluded.	Clearance of effusion; impedance change; audiometric hearing gain at 6 weeks, 6, 9 months, 1, 2, 3 years post-operatively.	Both operative groups (ADTO and AD) had advantages in hearing gain over the no-surgery group at 6 and 12 months and no significant difference between two surgical groups: for ears without MY+GR, the mean HL was 18.8 dB HL in ADTO group, 20.4 dB HL in AD group, 36.5 dB HL in no-surgery group at 6 months, and 21.0 dB HL, 19.7 dB HL, 27.4 dB HL respectively at 12 months post-operatively. In no-surgery group, the mean HL was 17.5 dB HL at 6 and 12 months in ears with grommet, compared to 36.5 dB HL ($P<0.001$) at 6 months and 27.4 dB HL ($P>0.05$) at 12 months in ears without grommet. With the exception of adenoidectomy at three years the clearance and the impedance change due to both surgical groups are statistically significant compared with the no-surgery group. Reinsertion of GR: 34% in ADTO, 26% in AD, 54% in no-surgery group ($P<0.01$). * The improvement in HL in operated ears compared to unoperated ears may be mainly caused by a worsening hearing impairment or less spontaneous improvement in HL in unoperated ears.
Paradise *et al*[57] (failed GR)+AD = 52 (failed GR) = 47.	Aged 1–15 with additional, well documented episode of OM *after extrusion of grommets*.	% time with OM or OME; No. of grommet insertions, other otoscopic findings at 1, 2, 3 years.	Hearing acuity was related to the presence or absence of OM, and not to whether or not subjects had received AD (*no figure reported). AD subjects had cumulatively 47% less time with OM than control during 1st follow-up year (15.0% *vs* 28.5%, $P = 0.04$), and 37% less time during 2nd follow-up year (17.8% *vs* 28.4%, $P = 0.005$). During 3rd year, no substantial difference between two groups. * Blindness? Rate of follow up: 87% at 1st year, 73% during 2nd year, 53% during 3rd year.

Author Intervention = *n* (number of subjects)	Children characteristics	Outcome measures	Main results/conclusions
Rach *et al*[58] bGR = 22 NT = 21 Normal = 9.	Aged 4 with bilateral OME: type B tympanogram, Dutch-speaking, not treated for OME before. 9 children without OME as reference. Excluded: congenital ear disorders, cleft palate, chronic diseases, etc. Dry tap rate: ?	Dutch version of the Reynell developmental Language Scales-revised (RDLS-r) test at 6 months. ENT examination at 3, 6 months. Tympanometry monthly for 6 months.	*Language development* seems to be slightly faster after GR insertion compared to non-treatment (not statistical significant: verbal comprehension, $P = 0.74$; verbal expression, $P=0.60$). The rate of improvement is still lower than the development in children without OME (not significant). 40% of ears in non-treatment group become normal (type B tympanometry) by the end of study. 80% of grommets remained *in situ* for at least 3 months, 60% *in situ* for the whole study period. * Hearing level was not available; small sample and short follow up.
Richards *et al*[59] AD+TO?+MY+GR = 57 (ears), AD+TO?+MY = 57 (ears). patients as own control.	Aged 4–12 with bilateral OME (confirmed by myringotomy) and no previous ENT surgery.	Otoscopy: position of grommet, PTA at 3, 6, 12 months after surgery.	The mean pre-operative HL was 26.6 dB HL for ears with grommet, 28.0 dB HL for ears without grommet ($P = 0.4$). The corresponding mean HL was 9.2 dB HL and 16.2 dB HL at 3 months ($P<0.0001$), 10.9 dB HL and 15.5 dB HL at 6 months ($P<0.001$), 11.5 dB HL and 14.6 dB at 12 months ($P<0.01$). Grommet tube extrusion rate: 15% at 3 months, 44% at 6 months, 76% at 12 months. Otorrhoea 19% during 1 year follow-up. * 5% lost to follow-up.
Roydhouse[60] AD+MY+GR = 50, MY + GR = 50.	Aged 3–14 with OME. Excluded: recurrent tonsillitis, cleft palate, acute mastoiditis. 5 subjects lost to follow up.	Otoscopy, tympanometry, ears without fluid, perforations, repeat grommet insertion at 1–6 years.	The cure rate was similar in each of the operation groups with a greater relapse rate in the non-adenoidectomy groups who required 9% more grommet reinsertion. * No result of hearing changes reported.
Rynnel-Dagoo *et al*[61] AD+GR? = 37 + GR? = 39.	Aged 1–12 with OME. Excluded: severe nasal obstruction, recurring adenoids, diabetes. Dry tap rate: ?	Otoscopy, PTA at 6, 12, 24 months.	Improvement rate of nasal obstruction was better among the operated than among the unoperated children during 1st year (61% v 41%, $P=0.04$) but no significant difference during 2nd year (63% v 55%, $P = 0.24$). There was no significant difference in the incidence of common cold, serous and purulent otitis media, and moderate hearing impairment. * Small study size; blindness?
To *et al*[62] AD+MY+uGR = 54 (ears), AD + MY? = 54 (ears). Patients as own control.	Aged 4–14 with OME which has not responded to medical therapy. Excluded: difference of HL between two ears > 6 dB; grommet insertion for retraction or thinning of the drum. Dry tap rate: ?	Audiometry, tympanometry at 3, 12 months post-operatively.	Mean pre-operative HL was 33.5 dB. At 3 months the mean HL in ears with the grommet improved significantly more than the other side (17.1 dB HL v 21.4 dB HL, $P<0.05$) but at 12 months there was no significant difference between the two sides (17.6 dB HL v 19.0 dB HL, $P>0.10$). Time grommet *in situ*: mean of 11.2 months. Complications: Perforation – 1 ear with grommet; Retraction segments – 2 ears with grommet and 1 ear without grommet; Tympanosclerosis – 9 ears with grommet and 1 ear without grommet. * Recovery in ears without GR caused by AD or MY?
Widemar *et al*[63] AD+bMY+GR? = 24 (39 ears), bMY + GR? = 35 (56 ears).	Aged mean 5.5 with OME, no AD previously; impairment of drumhead combined with conductive deafness > 20 dB HL; middle ear pressure < 1.5 kPa. Fluid confirmed by MY.	The state and mobility of the eardrum, a pure tone average audiogram, middle ear impedance. Only the findings at 2-years reported.	No significant difference between the two groups was found with respect to any of the studied parameters. No immediate surgical complications. * Small study size.

The only studies which report that the post-operative assessment was carried out by people unaware of the operative sub-group (blinded) were Gates[50,51] and in the otoscopic measurement in Maw[55,56].

Key:

AD	adenoidectomy
bGR	bilateral grommet insertion
bMY	bilateral myringotomy
HL	hearing level
NT	no surgical treatment
PTA	pure tone audiometry
TO	tonsillectomy
uGR	unilateral grommet insertion
uMY	unilateral myringotomy
?	not everybody or not sure
*	comments

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