

A randomized study of the surgical management of children with persistent otitis media with effusion associated with a hearing impairment

J. H. DEMPSTER, F.R.C.S.,* G. G. BROWNING, M.D.,* S. G. GATEHOUSE, Ph.D.**

Abstract

The object of this study was to compare the effect on the hearing of the insertion of a grommet, with or without adenoidectomy, against a non-surgically managed control ear in children with persistent hearing impairment due to otitis media with effusion.

Seventy-eight children (44 boys, 34 girls, mean age 5.8 years) with documented bilateral otitis media with effusion associated with a bilateral hearing impairment (pure tone average air conduction thresholds over 0.5, 1 and 2 kHz of ≥ 25 dB HL) over a three month period were admitted to a randomized, controlled trial. Each child was randomized to have or not to have an adenoidectomy. The ears in each child were then randomly allocated to have a grommet (tympanostomy tube) inserted. The children's hearing status was reviewed six and 12 months post-operatively. During follow-up, should a child redevelop a persistent bilateral hearing impairment (as defined above) for three months they were managed with a hearing aid. Thus no child had repeat insertion of a grommet.

Surgery of each type had an effect on the hearing and the presence of otitis media with effusion at six months post-operatively but not at 12 months when it was no different from natural resolution.

If resolution of the otitis media with effusion is the outcome measure, then adenoidectomy alone is significantly better than no surgery but only in boys rather than in girls. Even in boys it only resolves about 60 per cent of effusions. However, when combined with a grommet (one insertion) adenoidectomy gives no greater resolution (89 per cent compared with 86 per cent).

If improvement in hearing is the outcome measure, the overall results are similar. Adenoidectomy alone has an effect but if a grommet is inserted, adenoidectomy in addition does not improve the overall effect. However, these findings are not the case when analysed regarding the sex of the subject mainly because of the higher natural resolution rate in girls. In them, at six months surgery of any type or combination has no effect whereas in boys there is an additive effect of adenoidectomy on grommet insertion. Hopefully further studies can be conducted in larger numbers to investigate the differing effect in boys and girls suggested in this study.

Key words: Otitis media with effusion; Ventilation tubes; Adenoidectomy; Hearing aid

Introduction

Despite there having been several randomized controlled trials of surgery for childhood otitis media with effusion the optimum form of management remains uncertain. In reviews (Bodner *et al.*, 1991; Stephenson and Haggard, 1992) a total of 12 such trials have been identified, but they have all been criticized for some aspect of their design and/or analysis. The main controversy centres around the relative roles of adenoidectomy and the insertion of a grommet (tympanostomy, ventilation tube). Adenoidectomy requires a general anaesthetic and usually an overnight stay in hospital but the surgical complications are negligible. Grommets can be inserted under a local, intravenous or general anaesthetic as a day case but at least 25 per cent have recurrent infection around the tube, about 50 per cent have a permanently scarred tympanic membrane and up to 3 per cent a permanent perforation (Hughes *et al.*, 1974; Gates *et al.*, 1987; Mandel *et al.*, 1989). Because of the high natural spontaneous resolution rate of otitis media with effusion, a

good randomized controlled trial, as well as controlling for adenoidectomy, has to have a control ear in which there has been no surgical intervention. Only four of the 12 randomized controlled trials had a non-treated control ear (Bulman *et al.*, 1984; Maw and Herod, 1986; Gates *et al.*, 1987; Black *et al.*, 1990).

In any randomized controlled trial it is important to define the relevant inclusion criteria and outcome. Whilst surgery for otitis media with effusion is carried out for many reasons, the associated hearing impairment is generally considered to be the most important. In order to find the optimum form of management to mitigate this, the randomized controlled trial has to have audiometric entry and outcome criteria reported by conventional methods such as air conduction thresholds and air-bone gaps. Only two of the aforementioned four studies do this. In one of these (Black *et al.*, 1990) at the time of surgery 34 per cent of ears did not have middle ear fluid and these ears were not excluded from the analysis. Hence there is only one study (Maw and Herod, 1986) in which the effect on the hearing

From the Department of Otolaryngology*, Royal Infirmary, Glasgow and the Scottish Section of the MRC Institute of Hearing Research**. Accepted for publication: 30 November 1992.

threshold in ears with proven otitis media with effusion were randomly assigned to have a grommet inserted with or without adenoidectomy, and having a no-surgery ear to compare it with.

Once an individual has been randomly allocated to a surgical treatment group, it is important to be informed of any subsequent management. It is most surgeons' practice to re-insert a grommet if it is extruded or becomes blocked, provided the indications for surgical management remain. In a randomized controlled trial such re-intervention criteria have to be clearly defined, especially as in the Maw and Herod (1986) study 41 per cent of children had the grommet re-inserted. Unfortunately, they did not define the audiometric requirements for revision procedures, simply stating that they required 'revision procedures to restore hearing acuity'.

Hence although it might be argued by those that have not scrutinized the randomized controlled trial literature in depth that there is no need for yet another study, it was our opinion that the topic was important enough, the defects in a very high proportion of the previous studies serious enough, that another was amply justified.

Subjects and methods

The paediatric clinic at Glasgow Royal Infirmary serves as a secondary centre for general practitioners and senior clinical medical officers to refer children between the ages of three and a half and 12 years with a suspected hearing impairment. At Glasgow Royal Infirmary all such children routinely undergo pure-tone audiometry in a sound-proofed booth and tympanometry. Over the period August 1986 to February 1989, children with otoscopic evidence of bilateral otitis media with effusion that satisfied the following criteria were referred to an otitis media with effusion clinic:

- (a) pure tone air conduction thresholds average over 0.5, 1 and 2 kHz of ≥ 25 dB HL;

- (b) an air-bone gap over 0.5, 1 and 2 kHz of ≥ 15 dB;
- (c) Type B tympanogram (Fiellau-Nikolajsen, 1983).

The following were exclusion criteria for referral:

- (1) previous adenoidectomy or aural surgery;
- (2) additional symptoms requiring surgical intervention, e.g. recurrent sore throat;
- (3) cleft palate.

The condition was explained to the parents, who were told that surgery would be offered 12 weeks later if the condition remained unresolved. No specific treatment was given during the intervening period.

Twelve weeks after their identification, the children were reassessed, and if they still satisfied all the referral criteria they were considered to have persistent, bilateral otitis media with effusion associated with a hearing impairment. If otoscopy by a previously validated otoscopist (JHD with a 92 per cent sensitivity and a 90 per cent specificity) confirmed the presence of bilateral otitis media with effusion, the parents were asked if they were willing to let the child enter a randomized study of surgical management, for which Ethical Committee approval had been given. During the 18 month period 80 such children were identified and the parents of 78 (98 per cent) agreed to their involvement.

These 78 children were then admitted to hospital within ten days and randomly allocated by a serially numbered envelope system to have an adenoidectomy under a general anaesthetic or no adenoidectomy. The ears in each child were then randomly allocated by a similar process to have no ear surgery or to have a unilateral Shah grommet inserted following a radial myringotomy with aspiration of fluid. In children in whom an adenoidectomy was not being performed, the operation was performed under intravenous anaesthesia (Ketamine, 1-2 mg per kg).

Thus, the effect of adenoidectomy on the resolution of otitis media with effusion could be made by comparing the non-grommeted ear between children. In addition, the

TABLE I
CHARACTERISTICS OF THE 72 SUBJECTS IN THE STUDY. THE AIR CONDUCTION (AC) AND AIR BONE GAP (ABG) IS THE MEAN AT 0.5, 1 AND 1 KHZ. PERCENTAGES IN PARENTHESIS

	Subjects			
	No adenoidectomy		Adenoidectomy	
	No grommet	Grommet	No grommet	Grommet
Total no.	35		37	
Boys/girls	23/12 (66/34)		17/20 (46/54)	
Age (years)				
Mean \pm 1 SD	5.7 \pm 1.2		5.9 \pm 1.4	
Range	4-9		4-9	
	Ear			
	No adenoidectomy		Adenoidectomy	
	No grommet	Grommet	No grommet	Grommet
AC dBHL				
mean + 1 SD				
Boys	31.3 \pm 7.0	32.5 \pm 6.1	32.5 \pm 11.6	33.9 \pm 12.1
Girls	34.4 \pm 7.2	35.6 \pm 6.5	32.2 \pm 7.1	29.3 \pm 4.9
Overall	32.4 \pm 7.1	33.5 \pm 6.3	32.4 \pm 9.3	31.4 \pm 9.1
Range	25-50	25-47	25-65	25-63
ABG dB				
mean + 1 SD				
Boys	31.1 \pm 7.6	31.7 \pm 6.3	31.5 \pm 9.2	33.1 \pm 10.1
Girls	34.2 \pm 5.6	35.1 \pm 7.1	32.1 \pm 8.0	28.9 \pm 7.4
Overall	32.2 \pm 7.0	33.0 \pm 6.7	31.8 \pm 8.5	30.8 \pm 8.9
Range	15-45	20-43	18-48	18-60

TABLE IIA
BREAKDOWN ACROSS THE FOUR TREATMENT ARMS FOR OTOSCOPIC AND TYMPANOMETRIC FINDINGS AT SIX AND 12 MONTHS POST-OPERATIVELY.
NUMBERS WITH PERCENTAGES IN PARENTHESES

	No adenoidectomy		Adenoidectomy	
	No grommet	Grommet	No grommet	Grommet
6 Months				
Otoscopy:				
Resolved	9 (26)	11 (31)	18 (49)	5 (14)
Persistent OME	26 (74)	5 (14)	19 (51)	4 (11)
Grommet <i>in situ</i>	N/A	19 (54)	N/A	28 (76)
Tympanometry:				
Resolved	7 (21)	4 (12)	15 (41)	1 (3)
Persistent OME	28 (79)	12 (34)	22 (59)	8 (21)
Grommet <i>in situ</i>	N/A	19 (54)	N/A	28 (76)
12 months				
Otoscopy:				
Resolved	13 (37)	13 (37)	20 (54)	16 (44)
Persistent OME	22 (63)	11 (31)	17 (46)	9 (24)
Grommet <i>in situ</i>	N/A	11 (31)	N/A	12 (31)
Tympanometry:				
Resolved	11 (32)	8 (23)	19 (51)	7 (19)
Persistent OME	24 (68)	16 (46)	18 (49)	19 (50)
Grommet <i>in situ</i>	N/A	11 (31)	N/A	12 (31)

TABLE IIB
OTOSCOPIC RESOLUTION RATES TO SHOW THE EFFECT OF ADENOIDECTOMY IN BOYS AND GIRLS. NUMBERS WITH PERCENTAGES IN PARENTHESES

	No adenoidectomy		Adenoidectomy	
	No grommet	Grommet	No grommet	Grommet
6 Months				
Otoscopy: Boys				
Resolved	4 (18)	N/A	10 (59)	N/A
Persistent OME	19 (82)	N/A	7 (41)	N/A
Otoscopy: Girls				
Resolved	5 (42)	N/A	12 (60)	N/A
Persistent OME	7 (58)	N/A	8 (40)	N/A

effect on the hearing of grommet insertion alone, adenoidectomy alone, and of adenoidectomy with grommet insertion could be assessed by making a comparison with a non-treated ear (including the avoidance of nitrous oxide general anaesthetic).

The children were reviewed regularly but no further surgical management was invoked in order that the management strategy remained unaltered. If the child redeveloped a bilateral impairment of ≥ 25 dB HL and this persisted for three months then a hearing aid was issued. This occurred in three (4 per cent) of the children in the study. In no child was a grommet re-inserted. At six and 12 months post-surgery, the presence or absence of otitis media in the non-grommeted ear was recorded by the validated otoscopist who was blind as to whether adenoidectomy had been performed and by tympanometry. At these times, pure-tone audiometry was repeated.

Preliminary inspection of the hearing levels on a retrospective basis of children undergoing surgery for otitis media with effusion in the preceding period showed that a study with two levels of a main effect required a sample size of 80 subjects to detect a 5 dB difference in threshold levels at $\alpha < 0.05$ with a power of 80 per cent. The statistical methods used varied with the type of analysis being carried out and are detailed in the results section.

Results

Eighty children satisfied the entry criteria and the parents

of 78 of them agreed to participate. Six children defaulted either at the six or 12 month assessment visits, leaving 72 (92 per cent) children with complete clinical, audiometric and tympanometric data for the pre-operative and these post-operative visits. The characteristics of the 72 children are shown in Table I, broken down by adenoidectomy *versus* no adenoidectomy, and for the randomization by ear within subjects to grommet *versus* no grommet. The randomization achieved adequate balance across the four treatment arms.

Fluid was aspirated from all (100 per cent) of the ears that had a grommet inserted. The grommet was inserted in 36 left and 36 right ears. There were no immediate post-operative complications. Table IIA shows the otoscopic and tympanometric findings for the six month and 12 month follow-up visits. Until a grommet is extruded or becomes non-functioning, it is not possible to assess whether a grommeted ear has an effusion or not. At the six month follow-up visit, 54 per cent of the grommeted ears in the no adenoidectomy group were still *in situ* and functioning as evidenced by tympanometry while the figure for the adenoidectomy group was 76 per cent. At the 12 month follow-up visit, 31 per cent were still functioning for both the no adenoidectomy and adenoidectomy groups. These percentages are not significantly different, with the obvious exception that the proportion still functioning at 12 months was less than at six months.

From Table IIA it can be seen that:

TABLE III
 AUDIOMETRIC RESULTS FOR THE FOUR TREATMENT ARMS AT SIX AND 12 MONTHS POST-OPERATIVELY. THE AIR CONDUCTION (AC) AND AIR BONE GAP (ABG) ARE THE MEANS AT 0.5, 1 AND 2 KHZ. PERCENTAGES IN PARENTHESIS

	No adenoidectomy		No adenoidectomy	
	No grommet	Grommet	No grommet	Grommet
AC dBHL				
mean ± 1 SD				
6 months	21.1 ± 11.7	15.8 ± 10.3	18.0 ± 13.0	13.2 ± 9.0
12 months	18.4 ± 10.6	17.6 ± 11.2	15.6 ± 8.4	15.9 ± 8.4
ABG dB				
mean ± 1 SD				
6 months	22.6 ± 11.0	17.3 ± 11.3	20.4 ± 11.5	14.5 ± 8.3
12 months	17.2 ± 10.0	17.9 ± 9.9	17.2 ± 10.6	16.5 ± 8.1
Improvements in AC dB				
mean ± 1 SD				
6 months	11.3 ± 11.0	17.8 ± 10.3	14.4 ± 11.6	18.2 ± 10.1
12 months	14.0 ± 12.1	15.9 ± 10.9	16.8 ± 10.7	15.5 ± 10.0
AC dB bands:				
6 months				
>15	12 (34)	19 (54)	18 (49)	24 (65)
15-24.9	9 (26)	9 (26)	13 (35)	10 (27)
≥25	14 (40)	7 (20)	6 (16)	3 (8)
12 months				
<15	16 (46)	21 (60)	21 (57)	18 (49)
15-24.9	11 (31)	5 (14)	9 (24)	13 (35)
≥25	8 (23)	9 (26)	7 (19)	6 (16)

1. For the non-grommeted ears the resolution rate of otitis media with effusion is similar otoscopically and tympanometrically both at six and 12 months. (At six months tympanometrically all ears with OME were Type B, and at 12 months 79 per cent were Type B and 21 per cent Type C).
2. There is an apparent increase in the rate of resolution of otitis media with effusion in the adenoidectomy (no grommet) group as opposed to the no adenoidectomy (no grommet) group at six months (49 per cent *versus* 26 per cent). This was less marked at 12 months (54 per cent *versus* 37 per cent).

This apparent increase was investigated analytically using a logistic regression procedure, with resolution of otitis media with effusion as the dependent variable and adenoidectomy *versus* no adenoidectomy, age less than 5 years *versus* older than 5 years, and boys *versus* girls as the independent variables. This yielded a significant interaction ($p < 0.02$) between adenoidectomy (*versus* no adenoidectomy) and gender (boys *versus* girls) in the direction of poorer resolution rate in the no adenoidectomy

boys. This is illustrated in Table IIB where the rates of otoscopic resolution of otitis media with effusion are tabulated separately for boys and girls to show the effect of adenoidectomy. The resolution rates in the no adenoidectomy girls (42 per cent), adenoidectomy girls (60 per cent), adenoidectomy boys (59 per cent) are similar and contrast markedly with the low resolution rate of 18 per cent in the no adenoidectomy boys. The effect was not apparent at 12 months. There was no effect of age in the regression analysis.

Table III shows the audiometric results at six and 12 months post-operatively for a variety of hearing indices. These can be presented as the mean air conduction or air-bone gap at a particular visit, the improvement in air conduction from the pre-operative levels or the percentage of subjects with hearing levels within a particular band. This comprehensive tabulation facilitates cross comparison with other surgical series, but for analytical purposes some representations are superior.

Whilst categorical representation of the results (for example, the percentage of patients with a mean hearing level ≥ 25 dB which was one of the entry criteria for this study) has an apparently high degree of face validity as an outcome measure, it is perhaps not the most appropriate as:

1. The categorization at, for example, 25 dB contains no inherent rationale (i.e. there is no category boundary at 25 dB which makes an ear with thresholds at 25.1 dB *categorically* different from an ear with thresholds at 24.9 dB, whereas a boy is *categorically* different from a girl).
2. The collapse of continuous data into hearing bands is analytically insensitive. For example, it does not distinguish between a shift from 26 dB to 24 dB and one from 26 dB to 15 dB.

In addition, the use of air-bone gap as an outcome measure introduces the vagaries of bone conduction which are greater than air conduction measurements, so an index

TABLE IV

SUMMARY OF THE ANALYSIS OF VARIANCE ON ALL 72 SUBJECTS SHOWING (A) THE PARAMETER ESTIMATES AND THEIR SIGNIFICANCE LEVELS AND (B) THE ADJUSTED MEAN IMPROVEMENT IN THE AIR CONDUCTION THRESHOLDS FOR (CO-VARIATES) FOR THE SIGNIFICANT EFFECTS. THE DEPENDENT VARIABLE IS THE IMPROVEMENT IN AIR CONDUCTION THRESHOLDS SIX MONTHS POST OPERATIVELY

Effect	Parameter estimate	S.E. of estimate	Significance
Adenoidectomy	1.3	1.8	N.S.
Grommet	5.0	1.8	$p < 0.01$
Sex	0.4	1.8	N.S.
Adenoidectomy by sex	9.3	3.7	$p < 0.02$
Grommet by sex	2.9	3.6	N.S.
Adenoidectomy by grommet	2.1	3.6	N.S.

TABLE V

BREAKDOWN OF AUDIOMETRIC RESULTS FOR THE FOUR TREATMENT ARMS WITH THE BOYS AND GIRLS ANALYSED SEPARATELY. THE AIR CONDUCTION (AC) AND THE AIR BONE GAP (ABG) IS THE MEAN AT 0.5, 1 AND 2 KHZ

	Boys				Girls			
	No adenoidectomy		Adenoidectomy		No adenoidectomy		Adenoidectomy	
	No grommet	Grommet	No grommet	Grommet	No grommet	Grommet	No grommet	Grommet
	<i>n</i> = 23		<i>n</i> = 17		<i>n</i> = 12		<i>n</i> = 20	
Improvements in AC(dB) mean \pm ISD								
6 months	9.2 \pm 11.0	17.0 \pm 10.1	16.6 \pm 10.0	21.6 \pm 8.6	15.3 \pm 10.1	19.3 \pm 11.0	12.6 \pm 12.8	15.3 \pm 10.6
12 months	12.8 \pm 12.2	15.5 \pm 11.5	17.7 \pm 10.9	15.3 \pm 12.3	16.3 \pm 12.2	16.7 \pm 10.0	15.9 \pm 10.8	15.8 \pm 7.8

based purely on air conduction thresholds is likely to be more stable. The improvement in the air conduction thresholds from the pre-operative visit to either the six or the 12 month post-operative visit provided the best approximation to a normal distribution. It therefore is less likely to be contaminated by outliers or non-homogeneity of variance and is used in this study in the statistical analyses, although the other appropriate parameters yielded almost identical results.

A multivariate analysis of variance and co-variance was then carried out with improvement in the air conduction thresholds as the dependent variable and adenoidectomy *versus* no adenoidectomy, grommet *versus* no grommet, boys *versus* girls, age under 5 years *versus* older than 5 years as factors in the analysis (age was retained as a categorical rather than continuous variable to facilitate the entry of interaction terms into the model), with grommet *versus* no grommet specified as a within subject rather than a between subject factor. In addition, the two- and three-way interactions between the factors were entered into the analysis. Table IV summarizes the analysis of variance for the six month post-operative visit and shows that there is a significant main effect of grommet *versus* no grommet and a significant interaction between no adenoidectomy *versus* adenoidectomy and boys *versus* girls. The adjusted means for the improvement in air conduction levels at six months were 134 dB in the no grommet and 18.3 dB in the grommeted ears. The trend to greater resolution with adenoidectomy in boys than girls is illustrated, the means in boys being 19.1 and 13.1 dB for adenoidectomy *versus* no ade-

noidectiony against 14.0 and 17.3 dB in girls. At 12 months there were no significant main effects or interactions for the improvement in air conduction as would be predicted from the almost identical values between management strategies for improvement in air conduction at 12 months in Table III.

Because of the sex interaction at six months, it was decided to analyse the boys and girls separately. Table V shows the mean air conduction and mean air-bone gap separately for boys and girls at the six and 12 month post-operative visits. Inspection of the pre-operative air conduction levels shows that the original balance of the study is retained for boys, but that for girls the design begins to break down with relatively fewer hearing impaired girls in the adenoidectomy-with-grommet subgroup. At six months post-operation the improvement in air conduction for the boys in the no-adenoidectomy no-grommet group is 9.2 dB, no-adenoidectomy but grommet 17.0 dB, adenoidectomy but no-grommet 16.6 dB, and for adenoidectomy with grommet 21.6 dB. The results for the girls is much more similar at 15.3, 19.3, 12.6 and 15.3 dB respectively, which may in part be due to the breakdown of balance in the design. For all subgroups at 12 months post-operatively the improvements in air conduction thresholds have broadly stabilized.

Table VI summarizes the analysis of variance performed separately for boys and girls using Scheffe's test for multiple *a posteriori* comparisons. For the boys there is a significant main effect of adenoidectomy *versus* no adenoidectomy and for grommet *versus* no grommet but there is no significant interaction of the two procedures. The adjusted means of these effects are also shown in Table VI. For girls there is no significant effect of either adenoidectomy or grommet insertion or any significant interaction. Thus for the boys a clear picture emerges with a significant, separate and additive effect of both adenoidectomy and grommet. This is not the case with girls. However, this lack of effect must be interpreted with caution due to the uneven balance of the randomization as shown in Table V. How-

TABLE VI

SUMMARY OF THE ANALYSIS OF VARIANCE FOR BOYS AND GIRLS SEPARATELY SHOWING (A) THE PARAMETER ESTIMATES AND THEIR SIGNIFICANCE LEVELS FOR BOYS AND GIRLS AND (B) THE ADJUSTED MEAN IMPROVEMENT IN AIR CONDUCTION FOR THE SIGNIFICANT EFFECTS FOR BOYS. THE DEPENDENT VARIABLE IS THE IMPROVEMENT IN AIR CONDUCTION THRESHOLDS SIX MONTHS POST-OPERATIVELY

(a) Parameter effects and significance levels			
Effect	Parameter estimate	S.E. of estimate	Significance
Boys			
Adenoidectomy	6.0	2.3	<i>p</i> < 0.01
Grommet	6.6	2.3	<i>p</i> < 0.005
Girls			
Adenoidectomy	-3.3	2.9	N.S.
Grommet	3.2	2.8	N.S.
(b) Adjusted mean improvement in air conduction (dB) in boys			
	No adenoidectomy	Adenoidectomy	
No grommet	9.4	15.8	
Grommet	16.4	22.4	

TABLE VII

NUMBER OF EARS WITH OTOSCOPIC COMPLICATIONS AT SIX AND 12 MONTHS. PERCENTAGES IN PARENTHESES

	No adenoidectomy		Adenoidectomy	
	No grommet	Grommet	No grommet	Grommet
Tympanosclerosis				
6 months	0 (0)	7 (20)	0 (0)	15 (40)
12 months	1 (3)	11 (31)	0 (0)	17 (46)
Perforation/retraction				
6 months	1 (3)	2 (6)	1 (3)	2 (8)
12 months	3 (9)	2 (6)	4 (11)	4 (11)

ever, the subgroup of girls who fail to improve are in the adenoidectomy-no-grommet group and pre-operatively these were comparable to, for example, the no-adenoidectomy-no-grommet group. Thus the breakdown in design cannot be used to explain all of the absence of findings for the females.

Table VII shows the percentage of ears with complications at six and 12 months.

Discussion

The findings of this study are in some aspects similar and in some dissimilar to other randomized controlled studies of surgery for otitis media with effusion in children. In common with other studies (Kilby *et al.*, 1972; Lildholdt, 1983; Maw and Herod, 1986) the effect of surgery, whether it be adenoidectomy or grommet insertion, is mainly evident six months post-operation. At 12 months the spontaneous resolution rate of the otitis media with effusion and the associated hearing impairment is so high that surgery has a lesser if any effect. In common with other studies (Maw and Herod, 1986; Gates *et al.*, 1987; Mandel *et al.*, 1989), the most effective overall surgical intervention regarding both resolution of the effusion and improvement in the hearing is the insertion of a grommet (ventilation tube) albeit that this is associated with at least a 30 per cent incidence of tympanosclerosis and a 3 per cent permanent perforation rate. Like some studies (Maw and Herod, 1986; Gates *et al.*, 1987), the addition of adenoidectomy has a small additive effect.

How this study is different is that the effect appears to be restricted to boys and not to girls, albeit the numbers on which this was based may be considered relatively small. The different effect would appear to be because the natural resolution rate at six months is considerably better in girls than in boys. Thus without surgery the fluid has resolved at six months in 42 per cent of girls as opposed to 18 per cent of boys. At that time the associated hearing impairment has improved by 15 dB in girls as opposed to 9 dB in boys. Whilst this study did not set out to examine the differing effect of sex of the child there is considerable evidence that the natural history between sexes is different. Longitudinal studies (Fiellau-Nikolajsen and Lous, 1979; Teele *et al.*, 1989) have shown that in boys the effusion persists for a significantly longer period of time than in girls.

In addition if otitis media with effusion were to be more persistent in boys than in girls, one would expect that in randomized controlled studies, where persistent hearing impairment documented over a three month period was an early criterion for inclusion in the study, there would be more boys than girls. In this study the ratio was 1.3:1 which is the same as in that of Lildholdt (1983). In other studies the ratio was even higher, being 1.5:1 in Gates *et al.* (1987) and 2:1 in Mandel *et al.* (1989).

As with any different but potentially important finding it is imperative that the quality of the study and its methods of analysis is looked at closely. In this study the follow-up rate was good (92 per cent), all the ears that had a grommet inserted had fluid aspirated and the effect of surgery was not confounded by the reinsertion of grommets which in other trials can be as frequent as 40 per cent of ears. Multiple methods of statistical analysis were used in the current study and each of them confirmed the effect of surgery in boys but not in girls. The sole cautionary element in the

analysis is the fact that ears in girls having grommet along with adenoidectomy had marginally, but not significantly, better hearing than the other ears. Hence the potential for improvement was less.

In this study, repeat intervention was only carried out if the child failed the initial entry criterion again by having a bilateral 3/12 persistent hearing impairment of 25 dB HL or greater. This was strictly applied and only 5 per cent of children necessitated further management, in this case by the provision of a hearing aid. This contrasts markedly with other studies where reintervention is usually by reinserting a grommet and the reinsertion rates vary between 50 and 22 per cent (Gates *et al.*, 1987; Mandel *et al.*, 1989).

In conclusion it would appear that for boys with persistent otitis media with effusion with an associated hearing impairment of 25 dB HL or greater, documented to persist over a three month period or longer, grommet along with adenoidectomy compared with either alone and against natural resolution is the surgical management of choice to resolve the effusion and improve the hearing. Until further evidence is submitted, it is suggested that surgery in girls be considered with greater caution because of the likelihood that natural resolution occurs quicker than in boys.

References

- Black, N. A., Sanderson, C. F. B., Freeland, A. P., Vessey, M. P. (1990) A randomised controlled trial of surgery for glue ear. *British Medical Journal* **300**: 1551–1556.
- Bodner, E. B., Browning, G. G., Chalmers, F. T., Chalmers, T. C. (1991) An attempted meta-analysis: continued uncertainty in surgeries for otitis media in children. *Journal of Laryngology and Otology* **105**: 812–818.
- Bulman, C. H., Brook, S. J., Berry, M. G. (1984) A prospective randomised trial of adenoidectomy versus grommet insertion in the treatment of glue ear. *Clinical Otolaryngology* **9**: 67–75.
- Fiellau-Nikolajsen, J. (1983) Tympanometry and secretory otitis media. *Acta Otolaryngologica (Stockholm) Supplement* **394**.
- Fiellau-Nikolajsen, J., Lous, J. (1979) Prospective tympanometry in 3-year-old children. *Archives Otolaryngologica* **105**: 461–466.
- Gates, G. A., Avery, C. A., Prihoda, T. J., *et al.* (1987) Effectiveness of adenoidectomy and tympanostomy tubes in the treatment of chronic otitis media with effusion. *New England Journal of Medicine* **317**: 1444–1451.
- Hughes, L. A., Warder, F. R., Hudson, W. R. (1974) Complications on tympanostomy tubes. *Archives Otolaryngology* **100**: 151–154.
- Kilby, D., Richards, S. H., Hart, G. (1972) Grommets and glue ears: two-year results. *Journal of Laryngology and Otology* **86**: 881–888.
- Lildholdt, T. (1983) Ventilation tubes in secretory otitis media. A randomised, controlled study of the course, the complications, and the sequelae of ventilation tubes. *Acta Otolaryngologica Supplement* **398**.
- Mandel, E. M., Rockette, H. E., Bluestone, C. D., *et al.* (1989) Myringotomy with and without tympanoplasty tubes for chronic otitis media with effusion. *Otolaryngology — Head and Neck Surgery* **115**: 1217–1224.
- Maw, A. R., Herod, F. (1986) Otoscopy, impedance, and audiometric findings in glue ear treated by adenoidectomy and tonsillectomy. A prospective randomised study. *Lancet* **i**: 1399–1402.
- Stephenson, H., Haggard, M. (1992) Rationale and design of surgical trials for otitis media with effusion. *Clinical Otolaryngology* **17**: 67–78.
- Teele, D. W., Klein, J. O., Rosner, B. (1989) Epidemiology of otitis media during the first seven years of life in children in Greater Boston: A prospective, cohort study. *Journal of Infectious Diseases* **160**: 83–94.

Address for correspondence:
 Professor G. G. Browning,
 Department of Otolaryngology,
 Royal Infirmary,
 Castle Street,
 Glasgow G4 0NB.