

## A conservative approach to the management of otitis media with effusion in cleft palate children

A. K. ROBSON F.R.C.S.,† J. D. BLANSHARD F.R.C.S.,† K. JONES B.Sc., M.C.S.T.,\* E. H. ALBERY B.Sc., M.C.S.T.,\* I. M. SMITH F.R.C.S.,† A. R. MAW M.S., F.R.C.S.†

### Abstract

Otitis media with effusion (OME) is almost universal in children born with a cleft palate. Early placement of a ventilation tube to alleviate hearing problems is common. A retrospective study has been carried out to assess whether the practice of tube placement only for definite clinical indications is successful in terms of subsequent hearing levels and speech and language development. This was assessed by a case note review, analysis of speech therapy data and by means of a special follow-up clinic.

There was no difference in speech development between those treated with tube insertion for OME and those untreated. Audiological thresholds were worse in the treated group. A similar number in each group required regular speech therapy. More abnormal otological findings were present at follow up in those who had tubes inserted, some of these were directly attributable to the presence of tubes.

A conservative management of OME in cleft palate children, with tube insertion for only definite clinical indications, is an appropriate management, and will lead to fewer otological complications of tube insertion.

### Introduction

It is generally accepted that Otitis media with effusion (OME) is very common in children who are born with cleft palate (Stool and Randall, 1967). Paradise *et al.* (1969) demonstrated the universality of OME in 50 patients studied. Doyle *et al.* (1980) has shown that the major factor in the pathogenesis of OME is the limited ability to open the Eustachian tube actively on swallowing. It has been suggested that early placement of ventilation tubes with replacement as necessary be carried out in order to prevent both the long-term complications of OME, and the untoward effects of the hearing loss on language and speech development (Paradise and Bluestone, 1974). Other authors have made similar recommendations (Bluestone and Klein, 1983; Moore *et al.*, 1986) and this practice of early ventilation tube insertion, often at the time of palate repair, has become widely accepted.

More recently in this country, Grant *et al.* (1988) found OME to be present in 97.4 per cent of children with cleft palate aged less than 20 months. Based on the same study, Dhillon (1988) has proposed insertion of a long-term ventilation tube at the time of lip or palate repair, preferring it to a short-term ventilation tube in order to minimize further tube insertions.

However, others have recommended a more cautious approach (Crysdale, 1976). Such a view is based on the knowledge that, even in children with cleft palate, effusions resolve spontaneously and that tube insertion is not without complications. In particular the use of the 'Goode' type long term tympanostomy tube is associated with a higher incidence of complications, such as persistent tympanic membrane perforations, than the short

term ventilation tubes (Rothera and Grant, 1985). Hawthorne and Parker (1988) found an incidence of residual perforation following removal or extrusion of the tube to be 30 per cent and advised against the indiscriminate use of the Goode tube. Weigel *et al.* (1989) compared the complications occurring as a result of placement of four different types of tympanostomy tube and found an increased incidence of otorrhoea when the Goode T-tube was used; this tube was more likely to stay in the tympanic membrane for more than one year and was the only tube in the study associated with residual perforations.

Treatment regimes for OME even in the non-cleft population varies between districts and even within districts (Smith and Maw, 1991). Management should vary according to the duration and severity of the hearing loss, the degree of speech and language impairment and the extent of the detrimental effect it has on the child's schooling. These are imprecise guidelines of the need for and timing of ventilation tube insertion for OME.

A proportion of children will have speech problems as a direct consequence of the cleft palate related to articulation difficulties or velopharyngeal insufficiency. These problems may be exacerbated by a conductive hearing loss.

The otological management policy for children with cleft palate in our unit has been to closely monitor all children from the time of palate repair. Ventilation tubes are inserted as and when clinically indicated, on the basis of hearing loss, recurrent otalgia, poor schooling or behavioural problems. Ventilation tubes are not routinely inserted at the time of cleft surgery. We have carried out a retrospective study to investigate the otological, audiolog-

ical and communicative status of such children and to assess whether there is any difference between those who have had tubes inserted and those who have had no treatment to their ears for OME. Speech therapy assessments are used where available to help define the outcome of treated and untreated patients.

### Patients and methods

There were 192 patients from the County of Avon operated on by one plastic surgeon in the department of Plastic Surgery at Frenchay Hospital between 1976 and 1988 for cleft lip, cleft palate or a combination of cleft lip and palate. Some patients were not resident in the Bristol area, so there were no relevant case notes available for them. Children with cleft lips only and any with coexistent craniofacial abnormalities such as Down's syndrome were excluded from the study. Children were managed in a similar way to all non cleft children with OME as outlined above. Ventilation tubes were not routinely inserted at the time of palate repair.

Case notes on as many of the patients as possible were scrutinized to obtain the following details; type of cleft and age at repair, frequency of aural symptoms (deafness, otalgia and otorrhea) and the tympanic membrane findings on examination. The number and type of tube insertions (as well as the indications for insertion) were noted together with any complications arising from tube insertion. Details of any speech or language impairment were noted and all audiological and tympanometric results were recorded.

All children with repaired cleft palate underwent speech therapy assessment at 2½ years of age and again at five years. If children were managing well at school their speech and language development was considered to be adequate. An experienced speech therapist assessed the state of the velopharyngeal sphincter and graded palatal insufficiency as nil, variable (nil to slight), slight, moderate or severe. Language was assessed using the Reynell test of verbal comprehension and expression (Reynell, 1987).

The children's parents were invited by a postal invitation accompanied by a stamped addressed envelope to bring their child to a special follow up clinic. The purpose of this clinic was to obtain up to date information on the child's aural symptoms and signs, to complete a pure tone audiogram if old enough to co-operate, and to carry out tympanometry. Hearing, language and educational development were assessed subjectively by asking parents if their child's hearing, schooling (if appropriate) and reading were above average, average or below average. They were also asked whether their child's speech development was adequate, delayed or hypernasal and whether the behaviour was normal or bad. Results were analysed using the Chi-squared test, applying Yates' cor-

rection where appropriate. Audiometric results were analysed using the t-distribution, expressed as 95 per cent confidence intervals.

### Results

The case notes of 74 patients who had previously undergone surgery for cleft palate were available for study. The otological management had been under the care of a single consultant otolaryngologist (ARM). Three had submucous clefts, and one had 'minor palatal surgery', so these four patients were excluded from the study (Table I), leaving a total of 70 patients.

Of these patients 38 (54 per cent) had grommets inserted into one or both ears on more than one occasion. Details are shown in Table II. Of these 38, 10 (26.3 per cent) had long term ventilation tubes ('Goode tubes') inserted once or more often. Of these 10 patients one had to have a left myringoplasty eighteen months after a Goode tube had been inserted into that ear. One patient had bilateral Goode tubes inserted into dry middle ears. He has had subsequent episodes of otalgia and otorrhea necessitating removal of the tubes. One child was noted at the follow-up clinic to have perforations surrounding the tubes which were still in place. Two children had persistent otorrhea from the ear with the tube, and one child was noted to have extensive tympanosclerosis in the tympanic membrane.

Of the 38 patients with ventilation tubes, 47 per cent had one or more complication noted in the last recorded entry in the case notes, including one perforation. This compares with a 9 per cent complication rate of the 32 patients not having ventilation tubes inserted. Using the chi-squared test with Yates' correction this was statistically significant ( $p < 0.005$ ). In view of the retrospective nature of this study the incidence of asymptomatic complications such as atelectasis, retraction or tympanosclerosis may be higher.

Only one patient had a grommet inserted at the time of palate repair.

Tympanograms had been obtained on every patient at least once. OME was never demonstrated at routine examination either otoscopically or tympanographically on nine (12 per cent) patients although only one patient had adequate details to show that effusions had never been present from infancy through to seven years of age.

### Speech therapy results

Thirty-nine children had speech therapy assessment at 2½ and five years of age. No formal speech therapy assess-

TABLE I  
DETAILS OF 70 PATIENTS UNDERGOING CLEFT PALATE REPAIR

	Treated group n = 38	No treatment n = 32
Age range	2-13	6 months-12 years
Age mean	6.3	5.2
M:F sex ratio	22:16	14:18

TABLE II  
DETAILS OF 38 OTOLOGICALLY TREATED PATIENTS WITH CLEFT PALATE

No. of grommet insertions: range = 1-4	
mean = 1.66	
No. of patients having Goode tubes: 10 (26.3%)	
Mean age at first grommet insertion = 2.8 (range 1-8)	
Otological findings:	No.
Atelectasis	2
Retraction	7
Tympanosclerosis	6
Otorrhea	2
Perforation	1

ment was made before 2½ years. All those who were graded as having moderate or severe velopharyngeal insufficiency underwent pharyngoplasty. Twelve per cent of children underwent such surgery and it was successful in all cases (Table III).

Sixty-two per cent of 2½ year olds and 79 per cent of five-year-olds did not require any speech therapy. The presence or absence of velopharyngeal insufficiency did not correlate with the severity of middle ear disease (as determined by the requirement for tube insertion).

Twenty-five of these 39 patients (64 per cent) required ventilation tube insertion and 12 (48 per cent) required tubes to be inserted before their first speech therapy assessment. Table IV shows the breakdown of communication disorders as assessed at speech therapy.

Eight patients required regular speech therapy at five years of age. Of these, five had therapy for cleft related articulation problems, and three for phonology and learning difficulties.

Table V compares the speech therapy requirements between those operated upon for OME and those not requiring tube insertion at any stage. There is no significant difference in the number requiring regular speech therapy in each group (chi-squared with Yates' correction,  $p > 0.5$ ).

### Follow-up clinic results

Fifty-nine of the 70 patients attended the special follow up clinic (84 per cent). Thirty-one had had tubes inserted and 28 had not had any surgical treatment. In both groups there was a similar proportion with complete palatal defects (Fig. 1). The age range in the surgically treated group was 3–15 (median 6) and in the untreated group 1–14 (median 6).

OME was present in 16 (52 per cent) of the treated group and nine (32 per cent) of the untreated group. There was no significant difference between the treated and untreated groups (chi-squared with Yates' correction,  $p < 0.5$ ). Three patients in the latter group are on the waiting list for tube insertion. In the treated group the average number of tube insertions was 1.5, and eight patients had tubes *in situ* at follow up. Nine of the treated children had Goode type tympanostomy tubes inserted.

The otological complications are shown in Table VI which show a higher incidence of complications in the treated group. There were three perforations in the treated group, one already discussed, with bilateral perforations around Goode tubes. One child had undergone a myringoplasty on an ear in which ventilation tubes had been inserted on three occasions.

A pure tone audiogram was carried out on 28 of the 31 treated patients and 21 of the 28 untreated patients. The mean hearing loss over the frequencies 500, 1,000 and

2,000 Hz was 22 dB in the treated group (range 11–44, 95 per cent confidence intervals 18–24.6) and 15 dB in the untreated group (range 6–27, 95 per cent confidence intervals 12.8–18.45).

Figure 2 shows that there is no difference between the two groups in terms of schooling, speech attainment and behaviour levels.

### Discussion

This study suggests that selective insertion of ventilation tubes in children with repaired cleft palate is an effective and appropriate way of managing the OME that is almost universally associated with cleft palate. The treated and untreated groups have a similar age range and sex match so are broadly comparable.

The presence of middle ear fluid *per se* should not be an absolute indication for ventilation tube insertion. Ninety per cent of middle ear effusions following acute suppurative otitis media resolve within three months. We have shown in long-term studies of non-cleft patients with bilateral OME in which one ear was left to resolve spontaneously that at one year the rate of spontaneous resolution is 20 per cent increasing to 35 per cent at two years and 60 per cent at three years (Maw, 1988). Furthermore some effusions are unassociated with significant hearing loss and other subjective effects on the child's development. Ventilation tube insertion is known to be associated with long-term complications such as tympanosclerosis, atelectasis and perforation, some of which themselves result in long term hearing loss.

With regard to ventilation tube insertion, the average number of insertions of 1.66 (Table II) is similar to the average number of grommet insertions in noncleft children with OME. Curley (1986), in a study of 630 children undergoing myringotomy, calculated a mean number of insertions of 1.7. However the mean age at first insertion was 2.8 years in our study compared to a figure of 5 years 7 months in her study. This earlier age of insertion may be due to either or both of two factors; either the presence of OME is recognized earlier due to the routine review of all cleft patients from infancy, or the persistent fluid earlier in life leads to more developmental problems at an earlier age than in the noncleft population.

The high complication rate in the treated group is of concern, and may be an underestimate due to the retrospective nature of the study. One cannot be certain if the complications are secondary to the disease process or to the surgical treatment itself. However all untreated patients apart from one had persistent OME but they only had a documented incidence of complications of nine per cent.

The higher complication rate in the treated group was also noted at the follow-up clinic. In 9 of the 12 patients

TABLE III  
EXTENT OF VELOPHARYNGEAL INSUFFICIENCY

	at 2½ years	at 5 years
Normal	57%	61%
Variable	14%	24%
Phoneme specific	5%	3%
Slight	12%	12%
Moderate	7%	0
Severe	5%	0

TABLE IV  
BREAKDOWN OF COMMUNICATION DISORDERS AS ASSESSED AT SPEECH THERAPY

	at 2½ years	at 5 years
Cleft related articulation	21%	14%
Phonological	14%	0
Language difficulties	17%	5%
Learning difficulties	0	3%

TABLE V  
COMPARISON OF SPEECH THERAPY REQUIREMENTS BETWEEN THOSE HAVING TUBE INSERTION AND THOSE NOT REQUIRING VENTILATION TUBES

	Surgery	No surgery
No. requiring regular speech therapy	10 (40%)	5 (36%)
No. requiring 'review' speech therapy	1 (4%)	0
No speech therapy needed	14 (56%)	9 (64%)
	25	14

with tympanic membrane retraction, it was noted to be anterior or anteroinferior, *i.e.* the site of ventilation tube insertion. In two the retraction was posteroinferior, while there was only one case of attic retraction.

Perhaps the most worrying observation at the clinic was the presence of bilateral perforations around Goode tubes that were still *in situ*. In the light of a previous study on the use of long term tympanostomy tubes in non-cleft patients, Goode tubes are now rarely used in our department (Hawthorne and Parker 1988).

The audiological outcome at the follow-up clinic was satisfactory both subjectively and objectively in both groups.

From the parental reports, only seven of the 59 patients were below average at school or playschool, and all of these patients had been treated with ventilation tubes. Gordon *et al.* (1988) in an older group of cleft patients found a normal audiogram in 93 per cent of these adolescents; a normal audiogram was defined as an average of

pure tone threshold below 20 dB over the frequencies 500, 1,000 and 2,000 Hz. In our study, 29 of 49 patients who had an audiogram at follow-up had a normal audiogram by these criteria. Although Gordon *et al.* (1988) noted that grommet insertion did not result in better long-term hearing he still advocated routine insertion at the time of lip or palate repair. Bennett (1972) showed that 50 per cent of cleft patients continued to have otological problems despite, or maybe due to, otological treatment. The statistical difference in the range of means of audiograms between the two groups must be interpreted with caution. The untreated group may have had less severe OME than the treated group, or surgical treatment may itself have contributed to the greater hearing loss in that group.

Hubbard *et al.* (1985) studied two groups of cleft palate patients, one with early aggressive surgical treatment for OME and one group where surgical intervention was reserved until clinically indicated by symptoms. This latter practice is similar to the management of our group and to that of Crysedale (1976). They compared the otological, audiological and developmental status in the two groups. There was no significant difference between the otological or audiological status in the two groups. Speech development was assessed by testing the accuracy of consonant articulation, where it was found that those treated aggressively by otological surgery did better than those that had been treated expectantly. Cognitive, language, and psychosocial development were not adversely affected by expectant treatment. Children in our study did not appear to differ in terms of hearing, schooling or reading development, whether they had been surgically treated or not.

Relatively few children in our study required speech therapy, and most who did needed it for cleft related articulation, rather than phonological, language or learning difficulties (Table IV). One would expect a higher number of children requiring therapy for these latter three problems if they had serious hearing problems.

**Conclusion**

We have shown that routine insertion of ventilation tubes at an early age, merely in the knowledge that a child has a cleft palate and therefore will develop hearing problems, is unnecessary in terms of audiological and developmental outcome. The incidence of the complications in treated patients is much higher than in untreated patients, and in particular the use of a long term Goode type tympanostomy tube is not to be recommended.

The management of OME in patients with cleft palate should consist of regular follow up from infancy and insertion of ventilation tubes as and when indicated by the

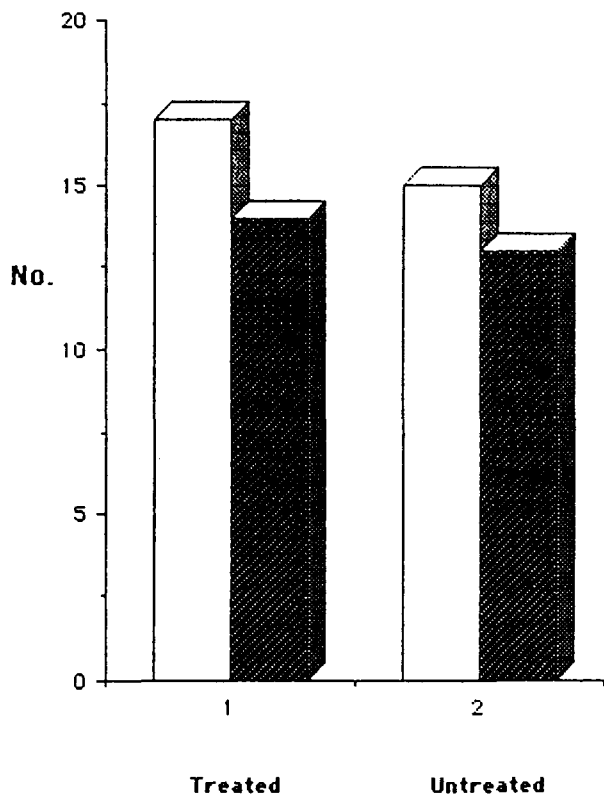


FIG. 1

Bar chart to show proportion of complete (clear box) to incomplete (shaded box) cleft palates between the treated and untreated groups.

TABLE VI  
FOLLOW UP CLINIC; COMPLICATIONS OF OME AND ITS TREATMENT

	Treated group n = 31	Untreated group n = 28
Otorrhoea	5	1
Otalgia	7	3
Perforated tympanic membrane	3	1
Retraction	12	2
Tympanosclerosis	8	0

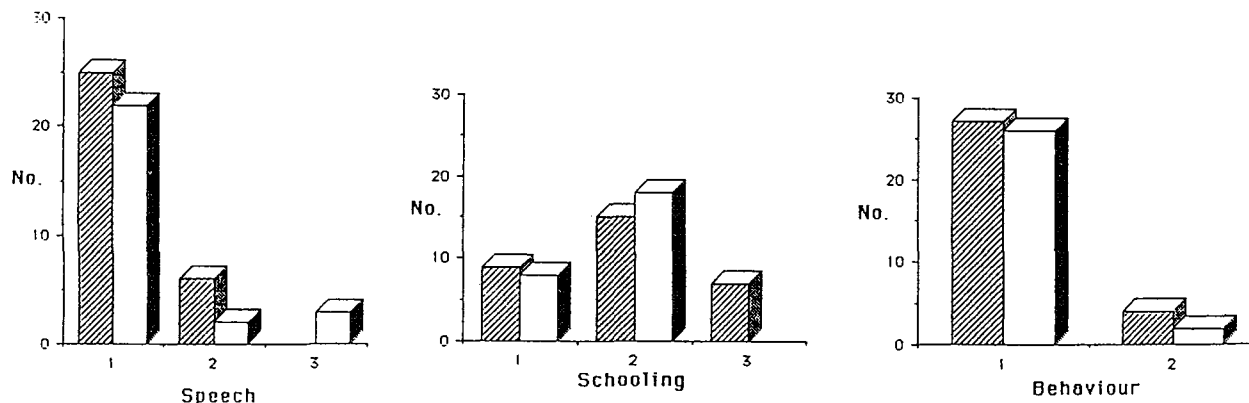


FIG. 2

Bar chart to compare speech development, schooling and behaviour between the two groups.

Key: shaded box = treated group  
clear box = untreated group  
Speech: 1 = Normal  
2 = Poor  
3 = Hypernasal  
Schooling: 1 = Above average  
2 = Average  
3 = Below average  
Behaviour: 1 = Normal  
2 = Poor

degree of hearing loss, delayed speech or language development and behavioural problems.

### Acknowledgements

The authors thank Mr R. W. Pigott F.R.C.S., F.R.C.S. (I) for allowing us to report on his patients and for his help in the preparation of this paper and to Mr B Vinayak F.R.C.S. for help with statistical analysis.

### References

- Bennett, M. (1972) The older cleft palate patient. *Laryngoscope*, **86**: 1217–1225.
- Bluestone, C. D., Klein, J. O. (1983) Otitis media with effusion, otosclerosis and eustachian tube dysfunction. In *Paediatric Otolaryngology*. (Bluestone, C. D., Stool, C. E. eds.), W. D. Saunders: Philadelphia.
- Crysdale, W. S. (1976) Rational management of middle ear effusions in the cleft palate patient. *Journal of Otolaryngology*, **5**: 463–467.
- Curley, J. W. A. (1986) Grommet insertion; some basic questions answered. *Clinical Otolaryngology*, **11**: 1–4.
- Dhillon, R. S. (1988) The middle ear in cleft palate children pre and post palatal closure. *Journal of the Royal Society of Medicine*, **81**: 710–714.
- Doyle, W. J., Cantekin, E. I., Bluestone, C. D. (1980) Eustachian tube function in cleft palate patients. *Annals of Otolaryngology and Laryngology*, **89** (Supplement 68): 34–40.
- Gordon, A. S. D., Jean-Louis, F., Morton, R. P. (1988) Late ear sequelae in cleft palate patients. *International Journal of Paediatric Otorhinolaryngology*, **15**: 149–156.
- Grant, H. R., Quiney, R. E., Mercer, D. M., Lodge, S. (1988) Cleft palate and glue ear. *Archives of Diseases in Childhood*, **63**: 176–179.
- Hawthorne, M. R., Parker, A. J. (1988) Perforations of the tympanic membrane following the use of Goode type long term tympanostomy tubes. *Journal of Laryngology and Otology*, **102**: 997–999.

Hubbard, T. W., Paradise, J. L., McWilliams, B. J., Elster, B. A., Taylor, F. H. (1985) Consequences of unremitting middle ear disease in early life. Otologic, audiologic and developmental findings in children with cleft palate. *New England Journal of Medicine*, **312**: 1529–1534.

Maw, A. R. (1988) Early and late effects of surgery for otitis media with effusion. In *Recent Advances in Otitis Media* (Lim, D. J., ed.) B. C. Decker Inc., Toronto: 282–285.

Moore, I. J., Moore, G. F., Yonkers, A. J. (1986) Otitis Media in the cleft palate patient. *Ear Nose and Throat Journal*, **65**: 291–295.

Paradise, J. L., Bluestone, C. D., Felder, H. (1969) The universality of otitis media in 50 infants with cleft palate. *Pediatrics* 1969, **44**: 35–42.

Paradise, J. L., Bluestone, C. D. (1974) Early treatment of the universal otitis media of infants with cleft palate. *Pediatrics*, **53**: 48–54.

Reynell, J. K. (1987) *Reynell Developmental Language Scales*. (second revision, Huntly M.) NFER-Nelson.

Rothera, M. P., Grant, H. R. (1985) Long term ventilation of the middle ear using the Goode T-tube. *Journal of Laryngology and Otology*, **99**: 335–337.

Smith, I. M., Maw, A. R. (1991) Secretory otitis media: a review of management by consultant otolaryngologists. *Clinical Otolaryngology*, **16**: 266–270.

Stool, S. E., Randall, P. (1967) Unexpected ear disease in infants with cleft palate. *Cleft Palate Journal*, **4**: 99.

Weigel, M. T., Parker, M. Y., Goldsmith, M. M., Postma, D. S., Pillsbury, H. C. (1989) A prospective randomized study of four commonly used tympanostomy tubes. *Laryngoscope*, **99**: 252–256.

Address for correspondence:

A. R. Maw M.S., F.R.C.S.,  
Department of Otolaryngology,  
Clinic 11, Level 6,  
Bristol Royal Infirmary,  
Bristol BS2 8HW.

**Key words:** Otitis media with effusion; Cleft palate; Ventilation tube.