Sequelae of otitis media with effusion among children with cleft lip and/or cleft palate

P. SHEAHAN, A.W. BLAYNEY, J.N. SHEAHAN & M.J. EARLEY

Department of Otolaryngology, The Children's Hospital, Temple Street, Dublin, Department of Mathematics, National University of Ireland, Galway, and Department of Plastic Surgery, The Children's Hospital, Temple Street, Dublin, Ireland

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Otitis media with effusion (OME) is common among children with cleft palate, and may lead to such long-term consequences as hearing loss, tympanic membrane retraction, and chronic otitis media (COM). In total, 104 children with cleft lip and/or palate treated for OME at our institution were reviewed. Mean duration of follow-up was 6.9 years, and mean age at latest follow-up was 9.6 years. The incidence of COM was 19%, and the incidence of cholesteatoma was 1.9%. Ears showing such long-term sequelae of OME as hearing loss, tympanic membrane retraction, and chronic otitis media, were noted to have undergone a significantly greater number of ventilation tube insertions than ears not showing these sequelae. Our findings would suggest that a conservative approach to the management of OME in children with cleft palate is more likely to be beneficial in the long term.

Keywords: cleft palate, otitis media with effusion, chronic otitis media, cholesteatoma, ventilation tubes, hearing

The association between cleft palate and otitis media with effusion (OME), hearing loss, and chronic otitis media (COM) is well documented.1–3 OME is reported to be almost universal among infants with cleft palate.1,2 A high incidence of OME and hearing loss is also found among young children with cleft palate, even after surgical repair of the cleft,3–5 whereas in older children and adults, hearing loss is frequently related to the presence of tympanic membrane retraction, tympanic membrane perforations, and other chronic changes.2,6 The main reason for the increased incidence of OME seen in children with cleft palate would appear to be due to failure of the Eustachian tube to open, consequent to abnormal insertion of the tensor and levator palati muscles, resulting in functional tubal obstruction and negative middle ear pressure.7 Other suggested contributory factors include failure of the Eustachian tube to close,8 abnormal Eustachian tube compliance,9 increased propensity to middle ear infection,10 and associated abnormalities of the craniofacial skeleton, including reduced mastoid depth and height.11

It has been suggested that the presence of chronic tubal dysfunction and OME in childhood may cause changes in the middle ear, which are favourable for the later development of cholesteatoma, non-cholesteatomatous chronic otitis media, and tympanic membrane perforations.12,13 However, there is a lack of evidence to suggest that aggressive treatment of otitis media in young children with cleft palate by repeated ventilation tube insertion leads to improved hearing or decreased incidence of COM in the long term.5,14 On the contrary, a higher incidence of tympanic membrane abnormalities and hearing loss has been reported among ears undergoing ventilation tube insertion than among ears not undergoing this procedure.5,14

The purpose of the present study is to examine the outcome of treatment of OME in children with cleft palate treated at our institution and followed up for several years. The incidence of development of COM and other sequelae of OME such as tympanic membrane retraction and hearing loss is determined,
and related to the demographic features of the children and the treatment administered.

Methods

Between 1990 and 1995, 343 children born with cleft lip and/or cleft palate underwent surgery at The Children’s Hospital, Temple Street, Dublin, for lip repair, palate repair, closure of palatal fistula, pharyngoplasty, or alveolar bone grafting. It was possible to obtain the medical charts of 250 of these; 43 of these children had cleft lip, 117 had cleft palate (15, submucous), and 90 had cleft lip and palate (four, submucous cleft palate). Most children with cleft lip had undergone lip repair at the age of 3 months using the Millard rotation advancement technique, whereas most of those with cleft palate underwent palate repair at a much older age.

In total, 104 of these children attended the otolaryngology service at The Children’s Hospital, Temple Street. The other 146 had attended otolaryngology services elsewhere.

The mean age of the children when first seen by the otolaryngological service was 2 years and 8 months. The mean duration of follow-up was 6 years and 11 months. The mean age of the children when last seen was 9 years and 7 months. In total, 53 of the children were male and 51 were female; three had cleft lip, 46 had cleft palate (five, submucous), and 30 had cleft lip and palate (two, submucous cleft palate). Most children with cleft lip had undergone lip repair at the age of 3–4 months using the Millard rotation advancement technique, whereas most of those with cleft palate underwent palate repair between the ages of 8–12 months using the von Langenbeck technique. A smaller number of children had undergone palate repair using the Veau technique with fracture of the hamulus. Some of the children with submucous cleft palate had undergone palate repair at a much older age.

Assessment of the otological status of the children attending the otolaryngology clinic included assessment of the condition of their tympanic membranes, documentation of the presence of recurrent episodes of acute otitis media or other problems, as well as assessment of their hearing. Chronic otitis media (COM) was considered to be present in ears with cholesteatomas, fixed deep retraction pockets (Sade grade IV), or persistent (>3 months) tympanic membrane perforations. Ears showing lesser degrees of retraction, including myringoincudostapedopexy, or persistent (>3 months) otitis media with effusion, were considered to have an abnormal tympanic membrane appearance. Ears showing the presence of tympanosclerosis alone were not necessarily considered to have an abnormal appearance, as this finding has not been suggested to be a risk factor in the development of chronic ear disease.12

The children’s hearing was assessed on the basis of pure tone audiograms that had been performed during their attendance at our clinic. Children with a hearing loss of less than or equal to 20 dB were considered to have normal hearing, and children with a hearing loss of greater than 20 dB were considered to have reduced hearing.

Statistical Analysis

To test the association between abnormal tympanic membrane appearance and reduced hearing, Fisher’s exact test was used. The association between abnormal tympanic membrane appearance and history of ventilation tube insertion, and between reduced hearing and history of ventilation tube insertion, was tested using both Pearson’s chi-squared contingency table test and the Mann–Whitney U-test for comparison of population medians. Because the Mann–Whitney test utilizes the ordered nature of the value of the previous number of ventilation tube insertions variable, and hence is expected to be more powerful than the chi-squared test, which uses only a nominal scale for the ventilation tube categories, the results of the Mann–Whitney test only are reported.

The statistical tests used assume a random sample of measurements. However, because a possible correlation existed between the data points taken for the left and right ears in the same individual, and which would thus violate the randomness of the sample, separate analyses were performed on right and left ears. We assume that as long as these give results that are consistent with one another, they will support our overall findings.

Results

The presence of OME was documented at some point in 99 out of the 104 children who attended our service, and 90 of these underwent ventilation tube insertion on at least one occasion. COM developed during the period of the study in 20 children. In five children, no episode of OME was documented at any point during the study.

Otitis Media with Effusion

In total, 79 children had OME without progression to COM; 42 of these were boys and 37 were girls; three had cleft lip, 46 had cleft palate (five, submucous), and 30 had cleft lip and palate (two, submucous cleft palate); 19 (24%) gave a history of recurrent acute suppurative otitis media; 70 of these children underwent ventilation tube insertion. The mean age at first intubation was 3.4 years (range 4 months–8.5 years) (Fig.1). The mean number of tubes inserted per ear was 2.1 (Fig. 2).

At the end of follow-up, 33 children (42%) had otoscopically normal tympanic membranes. In eight (10%), an abnormal otoscopic finding was present on one side, whereas in 29 (37%), an abnormal finding was present on both sides; of these were on the waiting list for further grommet insertion. The other nine children had grommets in situ when last seen. There was no significant difference between the groups of children with OME and those with COM with respect to the sex of the children, the type of cleft,
or history of recurrent episodes of acute suppurative otitis media (Table 1).

Recent audiograms were available on 58 of the children with OME (excluding the nine who had grommets in situ at last follow-up). These audiograms were performed on ears without grommets in situ and a mean of 3.4 years subsequent to the most recent grommet insertion. In total, 29 children (50%) had normal hearing (23 with normal tympanic membranes, two with a unilateral abnormal tympanic membrane appearance; and four with bilateral abnormal tympanic membrane appearances); 12 (21%) had a unilateral hearing loss (one with normal tympanic membranes and a unilateral sensorineural hearing loss, five with a unilateral abnormal tympanic membrane appearance; and six with bilateral abnormal tympanic membrane appearances). The mean hearing loss in these children was 32 dB; and 17 (29%) had bilateral hearing loss (one with normal tympanic membranes and a bilateral sensorineural hearing loss, and 16 with bilateral abnormal tympanic membranes). The mean hearing loss in these children was 37.5 dB.

The incidence of sensorineural hearing loss in ears with otitis media with effusion was 1.8% (three out of 158) (overall incidence 1.4%).

**GOODE T-TUBES**

Out of the children undergoing ventilation tube insertion, 10 were intubated with Goode T-tubes. Altogether, 17 ears underwent T-tube insertion: six had previously been intubated with Shepherd grommets. Three patients developed perforations after tube extrusion; one of these healed spontaneously, leaving two persistent perforations, (12%). Three others had abnormal tympanic membranes, and 11 had normal tympanic membranes. At the last follow-up, hearing was within normal limits in 15 out of the 16 ears tested.

**CHRONIC OTITIS MEDIA**

In total, 20 children (19%) developed chronic otitis media (six bilateral). Eight of these children were boys and 12 were girls: 13 had cleft palate (two, submucous) and seven had cleft lip and palate. Seven (35%) gave a history of recurrent acute suppurative otitis media. All had suffered from OME before developing chronic otitis media. In total, 25 out of the 26 ears with chronic otitis media had previously undergone ventilation tube insertion. The mean age at first tube insertion was 2.4 years, and the mean number of tubes per ear was 2.3.

| Table 1. Numbers of patients with cleft palate with normal tympanic membranes, abnormal tympanic membranes, and chronic otitis media |
|-----------------------------|-----------------|-----------------|-----------------|-----------------|
| Sex                         | Bilateral normal TMs | Unilateral abnormal TM | Bilateral abnormal TM | Chronic otitis media |
| Male                        | 17              | 4               | 14              | 8               |
| Female                      | 16              | 4               | 15              | 12              |
| Type of cleft               |                 |                 |                 |                 |
| Cleft lip                   | 2               | 0               | 0               | 0               |
| Cleft palate                | 18 (3)          | 4               | 20 (2)          | 13 (2)          |
| Cleft lip + palate          | 13              | 4               | 9 (1)           | 7               |
| History of recurrent ASOM  | 6 (18%)         | 4 (50%)         | 6 (20%)         | 7 (35%)         |
| % Ears with normal hearing†| 94% (47 out of 50) | 28% (2 out of 7) | 28% (14 out of 50) | 12% (3 out of 25) |

†Figures in brackets indicate number of submucous clefts included in overall figure.
†Excludes patients with grommets in situ or with no follow-up audiogram available.
TM = tympanic membrane.
Excludes patients with grommets in situ at last follow-up.

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Two children (1.9%) had a cholesteatoma. One of these was an attic cholesteatoma occurring in a girl with cleft lip and palate, who underwent a modified radical mastoidectomy at the age of 9 years, and the other was a posterosuperior retraction pocket cholesteatoma occurring in a boy with cleft palate who underwent canal wall-up mastoidectomy at the age of 8 years. Seven further children had a fixed posterosuperior retraction pocket (bilateral in two), whereas the other 11 had a central tympanic membrane perforation (bilateral in three). One of the patients with cholesteatoma also had a central tympanic membrane perforation in the opposite ear, giving a total of 26 ears with chronic otitis media (two cholesteatoma; nine, posterosuperior retraction pockets; 15, central tympanic membrane perforations).

In addition to the six children with bilateral chronic otitis media, three others had an abnormal finding in the opposite ear (retraction or effusion). One other had a grommet in situ. The mean hearing loss in ears with a posterosuperior retraction pocket was 38 dB, and in ears with a central tympanic membrane perforation the mean hearing loss was 33 dB.

**LONG-TERM OUTCOME OF CHILDREN WITH OME AND COM RELATED TO TREATMENT ADMINISTERED**

There was a highly significant correlation between ears with an abnormal tympanic membrane appearance and reduced hearing ($P = 0.000$ for left ears and $P = 0.000$ for right ears). In addition, ears with an abnormal tympanic membrane appearance were found to have undergone a significantly greater number of ventilation tube insertions than ears with a normal tympanic membrane appearance ($P = 0.0071$ for left ears and $P = 0.003$ for right ears) (Tables 2 and 3). Ears with reduced hearing were also found to have undergone a greater number of ventilation tube insertions than ears with normal hearing ($P = 0.0546$ for left ears and $P = 0.0014$ for right ears) (Tables 2 and 3).

**Discussion**

**OTITIS MEDIA WITH EFFUSION**

Otitis media with effusion is a common problem among children with cleft palate. The main consequence of OME for most affected children is a mild-to-moderate conductive hearing loss. However, persistent OME during childhood has also been linked to the development of chronic otitis media in later life. Furthermore, because the hearing loss associated with OME commonly affects children at an age of rapid speech, language, and social skills acquisition, concerns have been raised regarding the possible long-term consequences of OME on speech, language, cognitive development, intelligence, and behaviour.
The almost universal presence of OME among infants with cleft palate has led some authors to advocate early insertion of ventilation tubes in all children born with this condition.\(^1\)\(^2\)\(^21\)\(^22\) However, although ventilation tube insertion may correct the hearing deficit associated with OME in the short term, in the long term, this hearing gain is not maintained.\(^19\) Moreover, ventilation tube insertion has not been shown to prevent progression to chronic otitis media. On the contrary, ventilation tube insertion has been reported to give rise to such complications as focal tympanic membrane atrophy, tympanosclerosis, tympanic membrane perforation, and even cholesteatoma.\(^6\)\(^14\)\(^23\)\(^26\) Therefore, before recommending the routine use of ventilation tubes in all children with cleft palate, consideration should be given to their likely long-term effects, as well as to the potential long-term consequences of untreated childhood OME.

The long-term consequences of untreated childhood OME is a controversial area, with many of the earlier studies examining this question hampered by serious design flaws.\(^17\) In 1983, Hubbard et al.\(^18\) reported their findings among 24 closely matched pairs of children with repaired palatal clefts. One member of each pair had been treated at an institution where routine ventilation tube insertion was performed as early as feasible, and the other at an institution where ventilation tube insertion was only performed in children who showed overt symptoms of otitis media. Thus, one member of the pair had undergone first tube insertion at a mean age of 3 months, whereas the other had undergone first tube insertion at a mean age of 31 months. The authors assumed that OME had been persistently present from birth among the children undergoing later tube insertion. At the time of assessment (mean age 9 years), the children undergoing early tube insertion had slightly less impaired hearing and significantly better consonant articulation than the children undergoing later tube insertion, however, no significant differences were found with respect to verbal IQ, social quotient or behaviour. The authors concluded that early, persistent, untreated OME may result in impairment of hearing and of speech, but does not affect cognitive, language, or psychosocial development. Later, in 1999, Maw et al.\(^19\) reported the results of a prospective randomized controlled trial comparing the results of early treatment of OME by ventilation tube insertion with a policy of ‘watchful waiting’, wherein the children were re-evaluated 9 months later and ventilation tube insertion performed at that stage only if OME was still present. At 9 months, language skills in the watchful-waiting group lagged slightly behind those in the early surgery group, however, at 18 months, the groups did not differ significantly, and 15% of the watchful-waiting group had avoided surgery. Finally, in 2001, Paradise et al.\(^20\) reported the results of another prospective study comparing early to delayed tube insertion for OME. This randomized controlled trial involved 402 children developing OME within the first 3 years of life, drawn from a larger group of 6350 healthy infants enrolled within 2 months of birth and followed up continuously at monthly intervals. The mean age at randomization was 15 months. By the age of 3 years, there was no significant difference between the groups with regard to speech, language skills, cognitive development, or behaviour, and 66% of the late treatment group had avoided surgery. The results of these studies would thus suggest that a conservative approach to the management of OME in young children is not likely to have deleterious long-term consequences.

The long-term consequences on the tympanic membrane of aggressive surgical treatment of OME constitute another controversial area. Focal atrophy and tympanosclerosis are well documented complications of ventilation tube insertion.\(^23\)\(^24\) Persistent perforations may also occur, particularly after repeated tube insertion, after intubation at a young age, or after intubation with long-stay tubes such as Goode T-tubes.\(^24\)\(^26\) Persistent perforation rates of 9–30% have been reported with Goode T-tubes.\(^27\)\(^28\) Cholesteatomas have also been reported as a complication of ventilation tube insertion, and are also reported to be more common after Goode T-tube insertion.\(^26\) However, atrophy, retraction, and chronic otitis media may also develop as sequelae to persistent childhood OME in ears that have never been intubated.\(^12\)\(^13\)

The long-term consequences of ventilation tube insertion are likely to be of particular importance among children with cleft palate. A higher incidence of abnormal tympanic membrane appearance among ears previously treated by ventilation tube insertion was noted by Ovesen and Blegvad-Andersen\(^6\) among a series of 44 11-year-old children with repaired cleft palate, whereas a higher rate of tympanic membrane complications and a worse audiological threshold among children previously treated by ventilation tube insertion was also reported by Robson et al.\(^14\) among a series of 70 children with repaired cleft palate. However, it is unclear whether the children who did not undergo ventilation tube insertion had ever suffered from OME. In addition tympanosclerosis was considered to constitute an abnormal tympanic membrane appearance. However, tympanosclerosis is known to show little tendency to progress or give rise to COM\(^12\)\(^13\)\(^23\) and has generally minimal effect on hearing.\(^23\)

The present study differs from these other studies in a few important respects. In the first instance, ours was a larger group (104 children) undergoing a longer period of follow-up (mean 6.9 years). Second, nearly all the children in our series (99 out of 104) had OME documented, and most (90 out of 104) had previously undergone ventilation tube insertion. Third, because we were primarily interested only in those changes in the tympanic membrane, such as retraction, or ‘pexi’\(^12\) that may be considered risk factors for the possible progression to chronic otitis media,\(^12\) we did not consider the presence of tympanosclerosis alone to necessarily constitute an abnormal tympanic membrane appearance.
In the present study, ears with an abnormal tympanic membrane appearance had undergone a greater number of ventilation tube insertions on average than ears with normal tympanic membranes \((P < 0.0071)\). Not surprisingly, there was a highly significant correlation between abnormal tympanic membrane appearance and reduced hearing \((P = 0.000)\). Moreover, right ears with reduced hearing had undergone a greater number of ventilation tube insertions on average than ears with normal hearing \((P = 0.0014)\), although this was not quite significant for left ears \((P = 0.0546)\). Because the data on which the \(P\)-values for right and left ears are calculated is not independent, there is no obvious way to combine these two \(P\)-values into one overall measure of significance. However, the magnitude of the \(P\)-value for right ears is extremely small, and that for left ears is only barely outside the usual 0.05 level of significance. Such results would be consistent with an association being present between increased number of previous ventilation tube insertions and reduced hearing.

The correlation between a greater number of ventilation tube insertions and a higher incidence of abnormal tympanic membrane appearance and hearing loss reported by the present study is notable, however, the retrospective nature of the present study makes it impossible to determine the degree to which this is due to a greater number of ventilation tube insertions per se or to a more severe underlying inflammatory process that was reflected by the greater number of tubes. Nevertheless, there is some evidence that as children with repaired cleft palate get older, their otological status improves.\(^5\)\(^29\) Thus it would seem reasonable to try to manage their OME during their early years in a way that risks causing as little long-term damage as possible. Furthermore, given that the evidence would suggest that a conservative approach to the management of OME is safe and without deleterious long-term consequences\(^18\)\(^20\) and, given that other forms of aural rehabilitation, such as hearing aids, are also readily available, it would seem prudent to advocate a conservative approach to the management of OME in children with cleft palate.

**GOODE T-TUBES**

The use of Goode T-tubes among patients with persistent OME, including patients with cleft palate, has been advocated by some authors.\(^30\) However, our experience is limited to 10 patients (17 ears). The reason for our general reluctance to use the Goode T-tube or other long-stay tubes was because of our own anecdotal experience of their complications, and because of the numerous reports in the literature regarding their high complication rate.\(^25\)\(^28\) The results of the present study, wherein ears undergoing a greater number of ventilation tube insertions showed a higher incidence of abnormal appearance and reduced hearing, would serve to affirm our reluctance to use these tubes in children with cleft palate.

**CHRONIC OTITIS MEDIA**

The prevalence of chronic otitis media and cholesteatoma is high among patients with cleft palate, with the reported prevalences of cholesteatoma ranging from 0.9% to 9.2%.\(^31\)\(^33\) In the present study, 20 out of 104 patients followed up at our department developed chronic otitis media (19%), with two developing a cholesteatoma (1.9%). Excluding patients with cleft lip, the incidences of COM and cholesteatoma in cleft palate were 20% and 2% respectively. These figures are in broad agreement with those of Dominguez and Harker,\(^32\) who reported an incidence of cholesteatoma among children with cleft palate in Iowa of 2.6%, and Moeller,\(^33\) who reported an incidence in Norway of 0.9%. Our figures do not account for those children attending otolaryngology services elsewhere, some of whom may never have developed ear problems, and so may well represent a slight over-estimate of the incidence of COM in cleft palate. On the other hand, as the children in our study become older, it is possible that further cases of COM and cholesteatoma may develop.

**Conclusion**

Otitis media with effusion is common in young children with cleft palate, however, as children get older, their otological status frequently improves. A higher incidence of tympanic membrane retraction, chronic otitis media, and hearing loss may be expected in ears treated with a greater number of ventilation tube insertions among children with cleft palate. However, a conservative approach to the treatment of otitis media with effusion in children is safe and without adverse long-term effects. Furthermore, aural rehabilitation in the form of hearing aids provides a feasible alternative to surgery. Our data would support a conservative approach to the treatment of OME in children with cleft palate. Ventilation tubes should only be inserted when there is objective evidence of hearing loss, and of persistence of the effusion for more than 3 months, and only after the reasons for surgery and the non-surgical alternatives have been discussed with the child’s parents.

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