Conservative management of otitis media in cleft palate

Richard Shaw¹, David Richardson¹, Siobhan McMahon²

¹ Maxillofacial Unit, University Hospital Aintree, Liverpool, UK; ² Department of Speech & Language Therapy, Royal Liverpool Children’s NHS Trust – Alder Hey, Liverpool, UK

SUMMARY. Aims: Eustachian tube dysfunction affects nearly all children with cleft palate but its management is controversial. Some units perform routine prophylactic grommet insertion at the time of palate repair, whilst others are more conservative, inserting grommets only when signs and symptoms of otitis media with effusion are present. This study aims to present outcome data from one cleft team practising a conservative approach. Design: This is a retrospective study in which consecutive palate repairs over 10 years are analysed and compared with previously published data. The spectrum of clefting and severity (LAHSHAL), otological and speech outcomes were recorded. Patients were excluded if incomplete data was available, and if sensorineural deafness or syndromic clefting was present. Results: Data is presented for 72 of 109 consecutive patients and the 37 excluded patients are discussed. Following a conservative approach to otitis media with effusion, 29% of cases required grommets. The use of grommets seemed to be more common in those with more severe clefting. Despite this, the group receiving grommets had better speech results than those who did not, although this improvement was not statistically significant. Conclusions: There is no evidence of poor overall otological outcome in this series. The data demonstrates that those receiving grommets had better results despite more severe clefting. © 2003 European Association for Cranio-Maxillofacial Surgery.

Keywords: Cleft palate; Otitis media; Grommet; Speech

INTRODUCTION

Cleft palate individuals have very high rates of otitis media with effusion. This condition is caused by inadequate Eustachian tube ventilation of the middle ear and results in a retracted tympanic membrane with multiple air/fluid levels (Fig. 1). Paradise et al. (1969) demonstrated this problem to be “universal” whilst more recent studies have reported rates of 97% (Grant et al., 1988) and 92% (Schonweiler et al., 1994). It has been demonstrated that language development depends more on hearing ability than severity of cleft or surgical repair (Schonweiler et al., 1994). Whilst it is known that repair of the cleft palate improves the ventilatory function of the Eustachian tube (Bluestone et al., 1975), it has not been demonstrated that the surgical method used has any further influence despite differences in muscle positioning during surgery (Ganeren et al., 2000).

Considerable debate exists over the use of ventilation tubes (grommets), and in particular, the values of prophylactic grommets at the time of palate repair. Paradise and Bluestone (1974) have suggested a policy of early grommets (Fig. 2) and replacements as necessary in attempt to reduce long-term otologcal complications and minimize their effects on speech and language development. Whilst this philosophy has gained some support (Moore et al., 1986; Gordon et al., 1988; Merrick et al., 2001) a more conservative approach is favoured by others (Crysdale, 1976). The morbidity of repeated grommet insertion with regard to persistent perforations and scarring of the tympanic membrane has been highlighted (Weigel et al., 1989). Robson et al. (1992) advocate a conservative approach and demonstrates a higher incidence of otologcal complications in those receiving grommets but no benefit in terms of hearing, school achievement, speech or behaviour.

Hubbard et al. (1985) has reported a direct comparison between the two methods. This small, retrospective case matched study compared the outcome of two adjacent cleft units adopting differing policies to grommet insertion. In one unit, all 24 patients had early grommet insertion, replacement as required, and a proactive approach to detect and treat effusions and infection. In the other unit, 24 matched individuals received grommets in line with non-cleft otologcal practice, i.e. only for otorrhea, pyrexia or otalgia. The prophylactic grommet group had slightly better hearing and consonant articulation but there were no differences in cognitive, language or psychosocial development. The authors do not conclude which method they subsequently favour. Clearly there is a need for further research in this field.

In this paper, the results of a retrospective audit of 10 years cleft palate surgery by one surgeon using Delaire’s method of repair are presented (Delaire and Precious, 1985). In this unit, no prophylactic grommets were inserted and whilst there was ENT input to the cleft clinic, grommets were only prescribed for those individuals with symptomatic otitis media with effusion, i.e. otalgia, otorrhea, pyrexia or symptomatic conductive hearing loss.
MATERIAL AND METHODS

A retrospective audit was carried out within a cleft unit on 109 consecutive children undergoing cleft palate repair from 1987 to 1997. Surgery was carried out by a single surgeon using Delaire’s technique (Delaire and Precious, 1985).

Of the 109 operated cases, 12 had moved away or had inadequate or missing notes. Of the 97 remaining, 12 were excluded from this study due to recognized syndromes (4 cases), severe learning disorder (6 cases) and/or sensorineural deafness (4 cases) leaving 83 for whom speech results were sought. Speech records were inadequate in 11 cases due to poor co-operation or missed appointments leaving 72 patients with complete data.

The severity of clefting in each case was recorded by the “LAHSHAL” classification and the age at time of palate repair recorded. The number of cases in each group was: cleft soft palate only 15 (21%), hard and soft palate 21 (29%), unilateral lip, alveolus and palate, 28 (39%), bilateral lip, alveolus and palate 8 (11%).

Speech was assessed using the “Cleft Audit Protocol for Speech” (Sell et al., 1994). Resonance and articulation assessments were carried out by the cleft unit speech and language therapist (S.MeM.) at the age of 3–4 years. This simple scoring gives values for each child. (Resonance, 0 = normal, 1 = mild or inconsistent disorder, 2 = moderate disorder, 3 = severe disorder. Articulation errors, 0 = normal, 1 = mild, 2 = moderate, 3 = severe). In those cases where children had secondary speech surgery (24 patients (33%)), the speech was re-assessed following this surgery. The data was recorded from case notes, cleft department database, speech and language therapy records and collated on a computerized database.

RESULTS

Use of grommets

Of the 72 patients, 20 (28%) received grommets at least once and the remaining 52 (72%) never received grommets.

Table 1 and Fig. 3 demonstrate that severe clefts appear more likely to have grommets inserted. Hence the use of grommets seems at least partly predicted by the severity of clefting, but this correlation did not reach the level of statistical significance. Statistical analysis using chi-squared test for linear trend in use over the severity groups, \( p = 0.30 \).

SPEECH OUTCOME

Resonance

Table 2 and Fig. 4 show that patients who received grommets differed little in terms of hypernasality

Table 1 – Number receiving grommets by severity of clefting

<table>
<thead>
<tr>
<th>S</th>
<th>HS</th>
<th>LAHS</th>
<th>LAHSAL</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grommets</td>
<td>2 (13%)</td>
<td>5 (24%)</td>
<td>11 (39%)</td>
<td>2 (25%)</td>
</tr>
<tr>
<td>No grommets</td>
<td>13 (87%)</td>
<td>16 (76%)</td>
<td>17 (61%)</td>
<td>6 (75%)</td>
</tr>
</tbody>
</table>
from those who did not. Mann–Whitney test (of resonance outcome distribution for grommets vs. no grommets): $p = 0.92$. Further analysis grouping resonance outcome into two groups of normal/mild and moderate/severe again shows no statistical difference (Fishers exact test $(2 \times 2$ table: grommets $(Y/N) \times$ outcome $(N/M, M/S))$: $p = 0.76$).

However, Table 3 shows that, in more severe cases of clefting the resonance outcome seemed better for those who received grommets. This benefit in speech, however, was not statistically significant. For milder clefts (S or HS), Mann–Whitney test: $p = 0.36$ and Fishers exact test $(2 \times 2$ table): $p = 0.38$. For more severe clefts (LAHS or LAHSHAL), Mann–Whitney test: $p = 0.28$ and Fishers exact test $(2 \times 2$ table): $p = 0.22$.

**Articulation**

Table 4 and Fig. 5 show patients who received grommets seemed to have better speech articulation although these differences did not reach statistical significance. Mann–Whitney test (of outcome distribution for grommets vs. no grommets): $p = 0.34$. Further analysis grouping resonance outcome into two groups of normal/mild and moderate/severe again shows no statistical difference (Fishers exact test $(2 \times 2$ table: grommets $(Y/N) \times$ outcome $(N/M, M/S))$: $p = 0.41$).

Further, it seemed that patients with more severe clefts may have received more grommets (Table 1) and separately that having grommets inserted may yield better articulation outcomes (Table 4). Table 5 of articulation outcome vs. grommet use vs. cleft severity does not demonstrate a significant correlation. For milder clefts (S or HS), Mann–Whitney test: $p = 0.62$ and Fishers exact test $(2 \times 2$ table): $p = 0.69$. For more severe clefts (LAHS or LAHSHAL), Mann–Whitney test: $p = 0.51$ and Fishers exact test $(2 \times 2$ table): $p = 0.71$.

**DISCUSSION**

The number of patients excluded from this study because of the cleft being part of a syndrome, sensorineural deafness or severe learning disorder seems high (13%). This is due to the involvement of

**Table 2 – Grommet use versus speech outcome: Resonance**

<table>
<thead>
<tr>
<th>Grommets</th>
<th>Speech outcome – resonance</th>
<th>% Moderate or severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes (20)</td>
<td>7 9 3 1 20</td>
<td></td>
</tr>
<tr>
<td>No (52)</td>
<td>20 18 11 3 27</td>
<td></td>
</tr>
</tbody>
</table>

**Table 3 – Use of grommets and resonance outcome according to cleft severity**

<table>
<thead>
<tr>
<th>Cleft severity</th>
<th>Grommets</th>
<th>Speech outcome – resonance</th>
<th>% Moderate or severe</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Normal</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>S or HS</td>
<td>Yes (7)</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>No (28)</td>
<td>13</td>
<td>8</td>
</tr>
<tr>
<td>LAHS/LAHSHAL</td>
<td>Yes (13)</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>No (24)</td>
<td>7</td>
<td>10</td>
</tr>
</tbody>
</table>
the maxillofacial team in both the supra-regional paediatric craniofacial unit and the cleft unit. The spectrum of clefting in the remaining patients is, however, more typical, and indeed almost identical to a recently presented UK series (Merrick et al., 2001).

The incidence of grommet insertion at 28% is in keeping with other series reporting on conservative management of OME (e.g. Robson et al. (1992) report an incidence of 26%). Assuming the findings of Paradise et al. (1969), Grant et al. (1988) and Bluestone et al. (1975) are correct, the majority of the remaining 72% had endured the first few years of life with sub-clinical otitis media with effusion. The more enthusiastic proponents of prophylactic grommets may regard this as supervised neglect. However, the crucial issue is to what extent this otitis media with effusion damages hearing, and consequently speech, language and development, and moreover, to what extent grommets are effective in preventing this damage. The use of routine grommets necessitates extra costs and risks morbidity associated with additional surgery even when carried out at the time of palate repair. The use of prophylactic grommets also raises the issue of whether to re-operate if grommets are shed, but the child remains asymptomatic.

Comparisons with other series must be made with caution due to differences in clinical management and study design. However, in a series of 53 cleft palate repairs all subject to prophylactic grommets (Merrick et al., 2001), 15 (28%) required repeated grommet insertion on one or more occasions. Assuming criteria for clinical otitis media with effusion were similar in both studies, this suggests that grommets are ineffective in preventing subsequent otitis media with effusion once shed. Clearly other benefits may prevail whilst grommets are in place, but lack of standardization between measures of hearing and speech make comparisons very difficult.

An association of symptomatic otitis media with effusion and cleft severity seems intuitive, but has not been demonstrated at a statistically significant level in this data. Whilst this is in agreement with other series (Schonweiler et al., 1994), it would be interesting to study this further with more sophisticated measures of severity such as cleft diameter.

Unfortunately, audiograms were available in an insufficient proportion of case notes to analyse usefully. This is just one of the difficulties encountered as a result of the retrospective nature of this study. In the absence of audiometric data, we have presented speech outcome data. The use of speech outcome as a surrogate for hearing, whilst not ideal, has some validity, as speech and language development is known to be strongly correlated to hearing.

In terms of resonance, it is not surprising that grommets are ineffective in improving speech. Velopharyngeal incompetence and consequent hypernasality are characteristic of unrepaired or inadequately repaired cleft palates and may be seen in children with perfect hearing. In terms of articulation, it seems that the use of grommets leads to better outcome, although this correlation failed to reach a level of statistical significance.

The difficulties in reaching conclusions in heterogeneous conditions such as cleft lip and palate are also apparent in this study. In an attempt to make comparisons between categories of cleft severity or speech outcome, the numbers within each subgroup became too small to yield statistically significant results.

Table 4 – Grommet use and speech outcome: Articulation

<table>
<thead>
<tr>
<th>Grommets</th>
<th>Speech outcome – articulation</th>
<th>% Moderate or severe</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Normal</td>
<td>Mild</td>
</tr>
<tr>
<td>Yes (20)</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>No (52)</td>
<td>10</td>
<td>23</td>
</tr>
</tbody>
</table>

Fig. 5 – Percentage of patients with and without grommets in each articulation group.

Table 5 – Use of grommets and cleft severity according to articulation outcome

<table>
<thead>
<tr>
<th>Cleft severity</th>
<th>Grommets</th>
<th>Speech outcome – articulation</th>
<th>% Moderate or severe</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Normal</td>
<td>Mild</td>
</tr>
<tr>
<td>S or HS</td>
<td>Yes (7)</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>No (28)</td>
<td>5</td>
<td>12</td>
</tr>
<tr>
<td>LAHS/LAHSHAL</td>
<td>Yes (13)</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>No (24)</td>
<td>5</td>
<td>11</td>
</tr>
</tbody>
</table>
Within the limitations of this study, there seems to be some benefit to those children who received grommets. Whilst this benefit is not conclusively proven, in the context of the debate concerning the use of prophylactic grommets at the time of palate repair, there is a compelling argument for randomized prospective trials in this field.

CONCLUSIONS

- The incidence of symptomatic otitis media with effusion necessitating grommet insertion in this series of cleft palate patients was 28%.
- Based on this study, there is some evidence of improved articulation in those patients who received grommets.
- Due to the power limitations, retrospective design and paucity of audiometric data, it is difficult to recommend change in practice based on these findings.
- Prospective, standardized or multi-centre audit with universal audiometry for cleft palate patients, in addition to speech results may yield more definitive conclusions.
- Progression to a randomized controlled trial seems desirable given the diversity of opinion in this field.

Acknowledgements

Thanks are due to Mr. Derek Lowe, medical statistician, Congleton, Cheshire for his assistance in the preparation of this paper.

References


R.J. Shaw
Specialist Registrar in Oral & Maxillofacial Surgery
Maxillofacial Unit University Hospital Aintree
Longmoor Lane Liverpool
L9 7AL
UK

Tel: +151-529-5280
Fax: +151-529-5288
E-mail: richardjohnshaw@hotmail.com

Paper received 17 September 2002
Accepted 23 July 2003