Complications of Ventilation Tube Insertion in Children With and Without Cleft Palate A Nested Case-Control Comparison

Ian Smillie, MRCS Ed; Sophie Robertson; Anna Yule; David M. Wynne, FRCS; Craig J. H. Russell, FRCS

IMPORTANCE Optimizing hearing in patients with cleft lip and/or palate (CLP) by early recognition and management of otitis media with effusion is essential for speech development. Some evidence has suggested higher complication rates from ventilation tube (VT) insertion in patients with CLP and has led to a trend not to treat these patients surgically. However, studies have failed to match comparison groups for age and sex.

OBJECTIVE To compare complication rates from VT insertion in pediatric patients with and without CLP.

DESIGN, SETTING, AND PARTICIPANTS The study used a nested case-control design to evaluate 60 pediatric patients with CLP who underwent VT insertion at a children's hospital. The control group of age- and sex-matched patients was selected from a database of 2943 VT insertions.

INTERVENTIONS All patients were administered general anesthesia and underwent VT insertion by a pediatric otorhinolaryngology (ENT) team.

MAIN OUTCOMES AND MEASURES The primary outcomes were numbers of otorrhea complications. Secondarily, rates of attendance at an ENT clinic specifically for complications were evaluated. Finally, numbers of complications other than otorrhea were assessed but not statistically analyzed owing to the varied types and low numbers in each group.

RESULTS The control cohort had 151 documented cases of otorrhea compared with 121 in the CLP group (ratio 1.25:1); the difference between groups was not statistically significant (P = .52). There was no significant difference in mean ENT clinic visits per patient for complications between groups (0.80 in the CLP group, 0.78 for controls) (P = .66). Regarding complications other than otorrhea, the control group reported more than the CLP group (43 vs 25; ratio, 1.7:1).

CONCLUSIONS AND RELEVANCE Complication rates of VT placement among patients with CLP were not higher than those among patients without CLP. Therefore, treatment with VT insertion should be administered to patients with CLP under the same guidelines as for those without CLP. Indeed, there could be an argument for a shift in practice toward more aggressive treatment of patients with CLP, who are already vulnerable to speech and social developmental delay.

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Complications of Ventilation Tube Insertion

Left lip and/or palate (CLP), also referred to as oro facial clefting, is the most common craniofacial anomaly identified at birth. With an incidence of 1 in 700 births, CLP accounts for 1000 new cases in the United Kingdom annually. Orofacial clefts have functional and aesthetic implications for a child that require intensive multidisciplinary input to address.

Optimizing hearing in patients with CLP is essential to avoid problems in speech development in a group already disadvantaged. This may involve the use of hearing aids or surgical intervention with ventilation tube (VT) insertion. Otitis media with effusion (OME) and recurrent acute otitis media (AOM) are the most common reasons for conductive hearing loss in children. This hearing impairment is variable in clinical course but can have detrimental effects on speech development.

The cumulative prevalence of both OME and AOM in pediatric patients with CLP is 90% to 100%, with problems developing at a younger age than in children without CLP. Current literature recommends VT insertion for OME causing significant conductive deficit for more than 3 months or recurrent AOM totaling more than 4 episodes per year.

Complications associated with VT insertion have been reported as high as 80%. The most apparent complication reported to cause significant patient morbidity is otorrhea. Studies have suggested that otorrhea rates are higher in patients with CLP than in those without. In addition, it has been suggested that speech outcomes are poorer in children with DLP who receive surgical intervention for middle ear disease. This has caused significant controversy over the optimal management of conductive hearing loss in this group and ultimately has led to a trend not to insert VTs in patients with CLP even if they meet the criteria defined in national guidelines.

However, studies have failed to match control groups for age and sex. The aim of the present study is to assess if there is a significant difference in complications from VT insertion in patients with and without CLP who are matched for age and sex.

Methods

There is no institutional review board at the Yorkhill Royal Hospital for Sick Children, but all participants or their parents or guardians provided written informed consent for participation in this study at the time of surgery.

The study used a nested case-control design that individually matched children with CLP and those without CLP for age and sex. Sixty patients with CLP underwent insertion of VTs between May 2002 and October 2012 at the Royal Hospital for Sick Children, Glasgow. All of these patients also underwent CLP corrective surgery at the same institution.

A control group of children without CLP was selected from a database of 2943 VT insertions over the same period at RHSC by matching patients for age and sex. The patients were matched initially for sex and then for age at the time of VT insertion (all matched control patients were aged within 0.1 years of their corresponding patient with CLP). Hospital notes were reviewed for data relating to otorrhea and otorhinolaryngology (ENT) clinic attendance (follow-up and complication-specific visits). In addition complications other than otorrhea were noted.

The primary outcome was otorrhea, which was defined as discharge from the ear (excluding wax), whether clear or mucopurulent. There was no subdivision made on possible infective origin because microbiology findings were not available for most patients. The secondary outcome assessed was attendance at an ENT clinic for complications, defined as appointments specifically arranged on an urgent basis for complications and distinct from scheduled CLP follow-up visits. The 2 outcomes were subject to a Wilcoxon signed rank test to assess for statistically significant difference between the CLP and non-CLP groups.

The correlation between age and otorrhea rates was also assessed using a Spearman rank correlation coefficient. Other complications documented at ENT clinic visits are reported but not statistically analyzed.

Results

Sixty patients with CLP underwent VT insertion between May 2002 and October 2012 at the Royal Hospital for Sick Children Glasgow. The male to female ratio was 1.22:1; median age at the time of surgery was 3.5 years (age range, 0.6-10.4 years). Patients were assessed for significant comorbidities, but there were no exclusions made from either group of patients.

Total complications for patients with CLP were 146, with a mean of 2.4 complications per patient. In comparison, the control group had 194 complications, with a mean of 3.2 complications per patient. Figure 1 illustrates the complications in each study group.

Otorrhea rates were higher in the non-CLP cohort, with 151 documented episodes occurring in the 60 patients compared to 121 in the study group. The mean number of otorrhea episodes per patient in the CLP group was 2.0 compared with 2.5 in the non-CLP group. Interestingly, 23 in the CLP group (38%) and 24 in the non-CLP group (40%) had no otorrhea reported. There was no significant difference between otorrhea rates in CLP and non-CLP patients.

Figure 1. Otorrhea and Other Complication Rates in Patients With and Without CLP

Illustrated are the numbers of total complications, including otorrhea, occurring in all study participants. CLP indicates cleft lip and/or palate.
the 2 groups (Wilcoxon signed rank test, $P = .52$). The number of other reported complications (Table) was higher in the non-CLP than in the CLP group, with totals of 43 and 25, respectively (ratio, 1.7:1). This was not analyzed for statistical significance owing to the varied complications reported and low numbers in each group.

Table. Complications Other Than Otorrhea Reported in Clinic Visits Identification of the complications reported in clinic visits. CLP indicates cleft lip and/or palate.

<table>
<thead>
<tr>
<th>Other Complications</th>
<th>CLP</th>
<th>Non-CLP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Otalgia</td>
<td>10</td>
<td>17</td>
</tr>
<tr>
<td>Retracted tympanic membrane</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Tympanic membrane perforation</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Blood in canal</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Grommet occlusion-wax</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Tinnitus</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Tympanosclerosis</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Attic crust</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Posterior pars tensa cholesteatoma</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Attic retraction</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Granulation tissue</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Edema of ear canal</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>25</td>
<td>43</td>
</tr>
</tbody>
</table>

Illustrated are the mean numbers of otorrhea complications per patient found in each age group. CLP indicates cleft lip and/or palate.

Otorrhea numbers were higher in children younger than 2 years in both groups. This is illustrated in Figure 2, which shows the mean otorrhea rates for both the CLP and non-CLP groups. The highest mean otorrhea rate was in patients without CLP aged 1 to 1.9 years (7.0 documented cases of otorrhea per patient). There was a significant negative correlation between increased age and otorrhea rate, (Spearman $\rho = -0.275$; $P = .02$). When we evaluated otorrhea rates by patient sex, we found no significant differences ($P = .79$) (Figure 3).

Patients with CLP had more ENT visits for general review per patient than did those without CLP (4.6 vs 3.6). However, we found no significant difference in ENT attendance specifically for complications (0.80 non-CLP vs 0.78 CLP) (Wilcoxon signed rank test, $P = .66$). Mean follow-up for patients with CLP was 2.95 years, which was longer than the 2.2 years for the non-CLP group.

Illustrated are the numbers of total complications, including otorrhea, occurring in all study participants, subdivided by patient sex. CLP indicates cleft lip and/or palate.

### Discussion

It is essential to maximize hearing in pediatric patients with CLP to avoid delays in speech and social development. This may involve the use of hearing aids or surgical intervention with VT insertion. The high incidence and resolution of OME in children suggests that this is a natural phenomenon, but some patients are at greater risk of language delays and behavioral problems. This creates controversy over the optimal management of OME in these patients.

Current guidelines in the United Kingdom call for VT insertion in children (1) who have experienced significant conductive hearing loss due to OME for greater than 3 months or (2) who have had AOM episodes totaling 4 per year or 3 within 6 months. A Cochrane review has contradicted this guidance, reporting no significant benefits over the first postoperative year, but this study did not assess patients at increased risk of developmental delay such as patients with CLP.

Specific to patients with CLP, higher complication rates and poorer speech outcomes have been reported after VT treatment for OME vs patients without CLP. However, most CLP studies have been widely criticized for their poor design or small sample size. It is therefore more appropriate to evaluate conclusions on VT insertion from the higher-quality studies not specific to CLP.

Previous comparative studies comparing children with and without CLP have suggested higher complication rates in the CLP group, but the control groups were not matched for age or sex. These comparative studies suggest that there is insufficient evidence on which to base the clinical practice of early VT placement for OME or AOM in children with CLP. However, the present study, the first to our knowledge to match both age and sex, contradicts the previous evidence. We have demonstrated that there is no statistically significant differ-
ence between the CLP and non-CLP group for otorrhea or ENT attendance for complications.

This disparity arises from the effects of patient age and sex on complications. It is imperative to age match because studies have shown that younger age at VT insertion is directly linked to higher complications rates.14 This is a very important variable because patients with CLP tend to be diagnosed and treated for OME or AOM at a younger age. Our results support this with a finding of negative correlation between increased age and otorrhea. The importance of sex matching has been demonstrated in previous studies as well, with higher complication rates reported in boys than in girls.15 Interestingly, our results showed no statistically significant difference by sex.

Conclusions

To our knowledge, this is the first study to match patients with CLP and non-CLP controls for both age and sex. Our findings, therefore, are the best evidence available to measure the effect of CLP on complication rates. Ultimately, this study has shown that complications are not higher within the CLP treatment group, and therefore patients with CLP should be treated for AOM and OME in the same way as non-CLP patients. Indeed, there could be an argument for a shift in practice toward more aggressive treatment in the CLP group that is already vulnerable to speech and social developmental delay.