



Otorrhea in Infants with Open Cleft Palate

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Abstract

Introduction: The purpose was to compare the frequency of otorrhea in infants with ventilation tubes (VT) who had an unrepaired cleft palate (OCP) to those with intact palates (IP).

Study Design: Retrospective chart review.

Methods: This was a retrospective chart review of 134 infants under 8 months of age presenting to a tertiary care institution between 2003 and 2012 for VT insertion.

Results: This group included 63 infants with OCP and 71 infants with IP. There were more boys in the OCP group, and the children were younger than the IP group (4.5 versus 6.2 months, $p < 0.005$). OCP patients were more likely to have clinic visits for otorrhea, as 60% did, than were infants in the IP group, where 38% did ($p < 0.005$). Twenty-two percent of the OCP patients had 3 or more clinic visits for otorrhea versus 6% of the IP group ($p < 0.005$). No IP patients had prolonged otorrhea (duration > 1 month) while 20.6% of the OCP did ($p < 0.005$). VT were extruded or blocked at one year in 36% of the OCP group versus 18% of the IP group ($p < 0.05$).

Conclusions: Overall, VT outcomes were poorer in infants with unrepaired cleft palates than in infants with intact palates. Clinic visits were more likely, resulting in more resources being required for their care.

Introduction

Children with cleft palates have poor Eustachian tube function and typically develop middle ear effusions and potential hearing loss soon after birth [1]. With the advent of newborn hearing screening and state laws regarding rehabilitation of infants with hearing loss, there has been a sense of urgency to clear the middle ear effusions in cleft palate patients. Typically, Ventilation Tubes (VT) is placed at the time of palate repair. Some children will come to the operating room long before the palate repair is scheduled, sometimes for cleft lip repair at a few months of age, or for other unrelated procedures. VT can be placed in conjunction with these procedures, months before the palate is repaired. There is evidence in the literature that these children have a higher rate of otorrhea prior to palate repair than they do after [2], but whether the rate is higher than in infants overall is not known. The purpose of this study was to compare the frequency of otorrhea among infants less than 8 months of age who either had an open cleft palate (OCP) or an intact palate (IP) in order to predict further health care needs and outcomes.

Method

Patients less than 8 months of age who underwent ventilation tube placement at a tertiary care center between 2003 and 2012 were reviewed. The study population included patients who had an unrepaired cleft palate at the time of surgery, and the control population included those patients who did not have a diagnosis of cleft palate, or who had the cleft palate repaired at the time of VT placement. All patients had evidence of bilateral middle ear effusions (OME) and hearing loss for at least 3 months, or a history of at least 3 episodes of acute otitis media in the preceding 6 months. This was a retrospective chart review. VT was placed under general anesthesia. Middle ears were suctioned after a radial myringotomy was made, and an Armstrong grommet was placed.

Ofloxin drops were instilled immediately after VT insertion, and instructions to parents were to place the drops twice daily for three days post-op. Data collected included age at time of surgery, gender, reason for VT placement, type of effusion present at the time of surgery, number of ENT clinic visits where otorrhea was noted, presence of persistent otorrhea of at least 3 continuous weeks duration, whether the VT was blocked or extruded at the 6 month post op mark, and comorbidities. Data was analyzed with SPSS 20. This study was approved by the Institutional Review Board at Penn State Hershey Medical Center (ID # 39063).

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Table 1: Comparison of study groups.

Comparison of study groups	OCP group	IP group	Significant difference
N	63	71	-
Mean age (months)	4.5	6.2	p < 0.005
Gender	70% male	52% male	p < 0.05
# Clinic appointments for otorrhea (mean N)	1.62	0.65	p < 0.005
No visits for otorrhea (%)	40	62	-
1-2 visits for otorrhea (%)	38	32	-
3+ visits for otorrhea (%)	14	6	-
6+ visits for otorrhea (%)	8	0	-
Prolonged otorrhea (%)	21	0	p < 0.005
VT blocked or extruded prior to 1 year (%)	36	18	p < 0.05

OCP, Open Cleft Palate; IP, Intact Palate

Results

136 children between the ages of 2.28 months and 7.9 months who had bilateral VT placed between April 2004 and May 2012 were identified. Two patients had no follow up at this institution and so were not included in the data analysis. Sixty-three (47%) had an open cleft palate (OCP group) at the time of VT placement, and 71 (53%) did not (IP group). Of those in the OCP group, 52 had a cleft lip repaired at the time of VT placement, and 9 had an isolated cleft palate. All patients had OME of 3 or more month's duration with failed hearing screen in clinic at the time of assessment. In the IP group, 21 had a cleft palate repair done at the time of VT placement, and 50 had no cleft palate. Of this latter group, 38 had VT because they had flat tympanograms and failed newborn hearing screen after 3 months, and 12 had VTs for recurrent acute otitis media.

The group was composed of 81 boys and 52 girls (Table 1). There was a significant difference in gender between the OCP and IP groups (p < 0.05) as there were more boys in the OCP group. Mean age was 0.45 years (5.4 months), 4.5 months in the OCP Group, and 6.2 months in the IP Group, which was a significant difference (p < 0.005).

Most children had Armstrong grommets placed. One child in the OCP group had an umbrella tube placed in one ear since the canal was too small to admit an Armstrong grommet. Overall, 20% had purulent effusions at the time of VT insertion, 44% had mucoid effusions, 20.5% had serous effusions, and 14% had no effusions. The percentages for each group are listed in Table 2. There was a significant difference in the distribution of types of effusion at the time of VT placement (p < 0.05). There were more mucoid effusions among the children with OCP, and more clear ears among children in the IP group.

The average number of otolaryngology clinic appointments where otorrhea was treated either within the first year after VT or prior to cleft palate repair (whichever came first) was 1.62 in the OCP Group, and 0.65 in the IP Group. In the OCP Group, 2 patients had not been seen in follow-up in the otolaryngology clinic. The number of appointments for otorrhea ranged from 0 to 11. Forty percent had no visits for management of otorrhea, 38% had 1 or 2 clinic visits for otorrhea, and 22% had between 3 and 11 visits where otorrhea was treated. In contrast, 62% of the IP Group had no visits where otorrhea was treated. 32% had 1 or 2 clinic visits with otorrhea, and 6% had between 3 and 5 visits for otorrhea. The frequency of clinic visits for

otorrhea was significantly higher in the OCP Group (p < 0.005).

Thirty-five percent of the OCP Group patients with 3 or more episodes of otorrhea had purulent effusions at the time of VT insertion; 46% had mucoid effusions, and 8 % had either a serous effusion or clear ears. One third (33.3%) of the OCP Group patients who had a purulent effusion at the time of surgery subsequently had 3 or more episodes of otorrhea, compared to 20% of patients who had mucoid effusions. Only 3 patients in the IP Group had 3 or more episodes of otorrhea, 2 had mucoid effusions, and one had a purulent effusion at the time of surgery.

Prolonged otorrhea, defined as otorrhea lasting a month or more, occurred in 13 of 125 (10.4%) patients for whom we had complete data (Table 3). All of these patients were in the OCP Group, 21.3% of that group. This was a significant difference between the groups (p < 0.005). Eighty percent of these patients were male. Of these children, 38.5% had purulent effusions at the time of VT insertion, while 61.5% had mucoid or serous effusions. One third of the children in the OCP Group with purulent effusions at the time of VT placement had prolonged otorrhea at some point in the next year. VT that were blocked or extruded prior to one year occurred in 36% of the OCP Group and 18% of the IP Group, which was significantly different (p < 0.05).

Of the OCP group (n = 63), 36 (57%) had passed a Newborn Hearing Screen (NHS), 23 (37%) had not at the time of tube insertion, and there was no information for 4 patients. None passed a hearing screen at the pre-op appointment. Within the first year after tube insertion, 35 (56%) passed a hearing screen, usually DPOAEs. Nineteen (30%) did not pass although they were tested. Ten patients did not get tested, either because of otorrhea at each visit, absence of audiological evaluation at a Cleft Palate Clinic visit, or failure to follow up. Fifteen (65%) of the 23 patients who had not passed a NHS subsequently passed within the first year after ventilation tube insertion, representing 24% of the whole group.

Discussion

There is really no dispute that children with open cleft palates typically have OME – in Valtonen's small study of 42 children with cleft palate, the incidence was 98% [3]. Robinson's study showed that OME persisted in 70% of children after cleft palate repair when VT were not placed [4]. Some older studies advocated conservative management because children with cleft palate and greater number of ventilation tube insertions were perceived to have frequent

Table 2: Comparison of type of middle ear effusion at time of VT placement.

Type of effusion at tube placement	OCP group n = 63(%)	IP group n = 71(%)
Mucoid	52	40
Serous	22	19
Purulent	23	18
No effusion	3	23
OCP - Open Cleft Palate, IP - Intact Palate		

Table 3: Intra-op effusions in patients with prolonged Otorrhea.

Type of effusion at tube placement	OCP group with prolonged otorrhea n = 13 (%)	% with prolonged otorrhea out of Total OCP
Mucoid	50	10
Serous	11.5	2
Purulent	38.5	8
No effusion	0	0
OCP - Open Cleft Palate; IP - Intact Palate		

complications of OME such as hearing loss, tympanic membrane retraction and chronic otitis media [5]. A retrospective review in 1992 suggested that children with cleft palates and VT insertion had worse hearing, more otologic abnormalities, and no better speech development than similar children without VT insertion [6]. However Valtonen “et al.” [3] subsequently showed that hearing outcomes at age 6 were the same for ventilated children with or without cleft palates. In his group of patients, children had VT placed at 6 months under local anesthesia, then cleft palate repair at 12 months. This group advocated early VT placement because they could not demonstrate any significant difference in long term otologic outcomes between cleft palate and non-cleft palate patients [3]. More recently, Klockars and Rautio found that when VT were placed in cleft palate patients at age 4 months, over half had benefit, defined as absence of OME at one year of age, absence of re-tympanostomy before age one, and absence of tympanic membrane perforation [7]. If palate repair occurred early, at 4 months versus 12 months, outcomes were even better on these parameters, with 86% having benefit as defined above [7].

The American Academy of Otolaryngology-Head and Neck Surgery Clinical Practice Guidelines recommend that VT be placed when children have bilateral OME for 3 months or more and documented hearing loss [8]. This is because of the low rate of spontaneous timely improvement and the lack of other non-surgical options for treatment [8]. Rosenfeld analysed the literature in 2001 and reported a chronic otorrhea rate of 3.8% in children who had VT placed. Just over 7% had recurrent otorrhea, and 26% had at least 1 episode [9]. A more recent study of 1184 children (none of whom had cleft lip or palate, Trisomy 21 or immune deficiency) revealed that 12% had recurrent (> 3 episodes in 6 months or > 4 episodes in 12 months) otorrhea and 4% had at least one episode of chronic (> 4 weeks) otorrhea [10]. 67% had at least one episode of otorrhea in the year following VT placement. Episodes of otorrhea were more common in younger patients, in those who had recurrent otitis media as the reason for VT insertion, those who had frequent URTIs, and children who had older siblings in the household [10].

A recent Cochrane Review suggested that several maneuvers were associated with reduction in the frequency of otorrhea in the 2 weeks following VT placement. These included: multiple saline washouts at surgery, a single application of antibiotic/steroid drops at surgery, prolonged use of the same drops, and prolonged use of

oral antibiotics/steroids. The first 2 options were considered the best choice because they were unlikely to cause complications [11]. The situation in children with open cleft palates is different since none of these children will have normal Eustachian tube function. In 1991 a four member case series was published showing that otorrhea resolved after cleft palate repair [12]. These authors postulated that nasopharyngeal reflux through patulous Eustachian tubes accounted for the otorrhea in these cases [12]. This finding was supported by a study of 33 cleft palate infants with VT in place whom Curtin “et al.” [2] monitored for 6 months before and 6 months after cleft palate repair. They found that 43% had 2 or more episodes of otorrhea before repair, and only 6% had 2 or more episodes of otorrhea after repair of the palate.

In our study, among the 63 patients with OCP and VT, we found a higher incidence of otorrhea than we found for similarly aged children without an open cleft palate, 63% versus 38%. Our OCP group is more likely to require frequent visits for this problem, 22% versus 6% of their unaffected peers. However, none of our IP patients in this group had chronic otorrhea. With a rate of 4% as stated in van Dongen “et al.” [10], we would have expected at least 2 children in this group to have chronic otorrhea.

This was a retrospective study, limited by the quality of medical records available to us. It’s likely that the number of clinic visits for otorrhea is under-reported since patients may have been seen by primary care personnel for this problem, and this information may not appear in our records.

What is the impact of a child with recurrent or chronic otorrhea on the family? Very few families would not seek a medical opinion for a child with otorrhea, particularly if they had undergone ear surgery. There is no known quality of life instrument for this kind of problem, but we know from this data that it results in frequent clinic visits that would not have been needed if the child was left with OME and its potential hearing loss. This requires time off work for the parent, loss of income, fees related to the visits and prescribed antibiotics, and concern about the child’s hearing. Another issue is the conflict between medical opinions regarding management of otorrhea. Most patients with chronic otorrhea will be cultured, have culture directed antibiotics prescribed, and may even go on to further medical management of the perceived infection, when in reality the source of the problem is mechanical. These negatives need to be balanced

with the positives of improved hearing and speech development. In our study, we could only prove that 56% of OCP patients had normal hearing prior to palate repair. The prevalence of normal hearing may be higher, particularly if otorrhea is intermittent and short-lived, but we were not able to show this. This need for ongoing health care is balanced against the potential speech delay that might be sequelae of clearing middle ear effusions later, such as at the time of cleft palate - rather than cleft lip - repair. Speech delay may also require health care consumption for resolution. To answer the question of whether early or later VT placement in children with cleft palate has a better outcome - for all of the possible variables mentioned above - would require a large randomized controlled trial; in a society that emphasizes early hearing rehabilitation, this will not ever be deemed ethical.

Conclusion

Infants under 8 months of age who have VT and an open cleft palate have a much more complicated course than do children with intact palates. Parents and pediatricians should be aware of the relatively high incidence of otorrhea in these children, and the fact that only about half of these children will have normal hearing proven before the time of their palate repair.

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