RESEARCH ARTICLE

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Otorrhea in Children with Cleft Palate and Ventilation Tubes: A Retrospective Study

Julie Mortier [a], Olivier M. Vanderveken [a,b], An Boudewyns [a,b]

[a] Antwerp University Hospital, Department of Otorhinolaryngology Head and Neck Surgery, Antwerp, Belgium

[b] University of Antwerp, Faculty of Medicine and Translational Neurosciences, Antwerp, Belgium

an.boudewyns@uza.be

Keywords

Cleft palate; Ventilation tubes; Otitis media

Abstract

Background
Otitis media is common in children with cleft palate and associated with hearing loss and reduced quality of life. Placement of ventilation tubes is the first-line treatment to resolve middle ear effusion, but it may be associated with prolonged or recurrent otorrhea. This study aimed to evaluate the burden of parent-reported and physician-confirmed otorrhea in children with cleft palate.

Methods
We conducted a retrospective review of children with cleft palate managed by a multidisciplinary cleft team over a two-year period. Data collected included the incidence and duration of otorrhea, microbiological findings, and treatment.

Results
Thirty-nine children were included. Over one-third (38.5%) failed newborn hearing screening due to early-onset middle ear effusion. Ventilation tubes were placed at 6 months of age during definitive lip closure or at 9 months during soft palate closure. Otorrhea occurred in 28% of patients at the first postoperative visit and in 67% during follow-up. The median duration of otorrhea was 22 days (IQR 14–53). *Staphylococcus aureus, Streptococcus pneumoniae*, and *Haemophilus influenzae* were the most frequent pathogens. Eighteen children required repeat placement, and 27 patients still had at least one tube in situ at 12-month follow-up.

Conclusions
All children with cleft palate required ventilation tube placement due to middle ear effusion. Postoperative otorrhea was frequent, prolonged, and recurrent. Parents should receive appropriate counselling about the increased risk of postoperative otorrhea and the need for prompt management. Further studies are needed to identify strategies to reduce postoperative otorrhea in this population.

Background and Rationale

Otitis media with effusion is defined as the presence of fluid in the middle ear without signs or symptoms of acute infection. It is diagnosed by one or more of the following: reduced tympanic membrane mobility on pneumatic otoscopy, reduced tympanic membrane mobility on tympanometry, opaque tympanic membrane or a visible air-fluid interface behind the tympanic membrane on binocular micro-otoscopy (1, 2).
Children below the age of seven years are at increased risk of otitis media because of their immature immune system and poor function of the Eustachian tube, a slender connection between the middle ear and the nasopharynx that normally ventilates the middle ear space and equalizes pressure with the external environment. Host-related risk factors such as age, sex, cleft palate, genetic predisposition or environmental risk factors such as seasonality, day care attendance, or tobacco smoke exposure may contribute to otitis media (3, 4).
Ventilation tube (VT) insertion is the surgical placement of a tube through a myringotomy incision for purposes of temporary middle ear ventilation. Ventilation tubes are recommended to treat otitis media with effusion in children who have bilateral effusion persisting for 3 months or longer and associated hearing loss. These tubes typically stay several months depending on tube design and placement location in the tympanic membrane. Insertion is usually associated with an improvement in quality-of-life and alleviation of the hearing loss (1, 5). Tympanostomy tube sequelae are common but generally transient (otorrhea) or usually do not affect function (myringosclerosis, focal atrophy, or shallow retraction pocket of the tympanic membrane). The most common sequela of tympanostomy tubes is otorrhea. In the general population of children, it is seen in approximately 16% within 4 weeks of surgery and in 26% at any time that the tympanostomy tube remains in place (1, 6).

In nearly all infants and children with cleft palate, otitis media with effusion occurs due to abnormal tensor veli palatini muscle insertion and resultant Eustachian tube dysfunction (ETD). Multiple cohort and longitudinal studies report prevalence rates ranging from 76% to over 90% in the first two years of life among children with cleft palate (7, 8). Management in this population includes early VT placement, but this comes along with a higher incidence of protracted otorrhea afterwards. Moreover, many children with cleft palate may require repeated VT placement increasing the risk of short term (e.g. otorrhea) and long-term sequelae (e.g. tympanic membrane perforation, atelectasis...)

TABLE 1: Overview of collected patient data variables.

Demographic data	Gender
	Unilateral or bilateral CLP / CP
	Age at first ventilation tube placement
	Result of neonatal hearing screening
	Comorbidities
Perioperative data	Type of ventilation tube
	Type of middle ear effusion (as described in surgical procedure report)
	Type of antibiotic ear drop in the initial postoperative period
Postoperative data	Doctor visit with otorrhea
	Unilateral or bilateral otorrhea
	Culture result (if available)
	Treatment: local and/or oral antibiotics
	Additional treatment

(9). Preventive measures and effective treatments, such as the use of topical antibiotics, are essential to mitigate complications and improve outcomes (4).
In a systematic review by Felton et al. concerning the role of VT placement in children with cleft palate, otorrhea was the primary side-effect observed following the procedure (9). The authors found a reduction in the incidence of otorrhea with increasing age. Almost 75% of children had otorrhea within the first year after surgery. In a study by Curtin et al. in 33 children, the incidence of otorrhea after ventilation tube placement was higher before cleft palate repair than after the repair, suggesting a beneficial effect of palate closure on the frequency of otorrhea (10). Earlier VT placement resulted in better speech and hearing outcomes (9). In 2017, Nogan et al. conducted a retrospective study in children with cleft palate and concluded that almost one third of patients experienced postoperative otorrhea and methicillin-resistant *Staphylococcus aureus* (MRSA) was the most commonly cultured micro-organism (11). A recent retrospective cohort study by Solis et al. also showed *S. aureus* was the most common organism in children with and without cleft palate with 49% being methicillin-resistant (MRSA) (12).
Episodes of otorrhea in children with cleft palate are rarely self-limiting and typically require a visit to an ENT specialist for clinical assessment with suction cleaning of the fluid. Samples are taken for microbiological analysis and treatment is adjusted accordingly. Repeated visits impose a substantial burden on the patient and the caregivers.
This study aims to document the occurrence and duration of otorrhea following ventilation tube (VT) placement in children with cleft palate.
The primary endpoints are the incidence of postoperative otorrhea, defined as [1] the proportion of patients who develop otorrhea lasting more than one week after primary VT placement, and [2] the proportion of children who experience otorrhea during the follow-up period beginning one month after VT placement.
The secondary endpoints include the frequency of otorrhea episodes, their duration, and the associated microbiological findings.

Material and methods

This is a retrospective analysis of the incidence of parent-reported and physician-confirmed otorrhea after VT placement in children with cleft palate at the ENT department of the University Hospital of Antwerp (UZA).

Study population

Forty children, with either cleft palate or cleft lip and palate, undergoing surgery at the University Hospital of Antwerp (UZA), and born in the year 2022 – 2023, were included. Children with associated congenital ear malformations or syndromic forms were excluded. Reconstructive surgery for children with cleft palate is performed by the maxillofacial surgeons at UZA. Children with a cleft lip and palate undergo definitive lip closure near the age of six months. Closure of the soft palate is performed at the age of nine to ten months, and closure of the hard palate is done near fifteen months of age. All children receive a course of peroral antibiotics (amoxycillin/clavulanic acid at a daily dose of 50/12,5 mg/kg/day in three doses) during the first postoperative week in line with the postoperative management protocol for cleft surgery. Children with isolated cleft palate who fail the newborn hearing screening because of middle ear effusion will receive VT tubes at the age of six months. Those who pass the neonatal hearing screening will receive their first set of VT at the time of soft palate closure unless clinically indicated otherwise.
At the outpatient visits micro-otoscopy is performed by the attending ENT surgeon with suction cleaning of any debris/otorrhea from the outer ear canal. Swabs for microbiological examination are taken.
The study protocol was approved by the Ethics Committee of the Antwerp University Hospital (project ID 6650 and EDGE 3747). Informed consent is waived for retrospective studies.

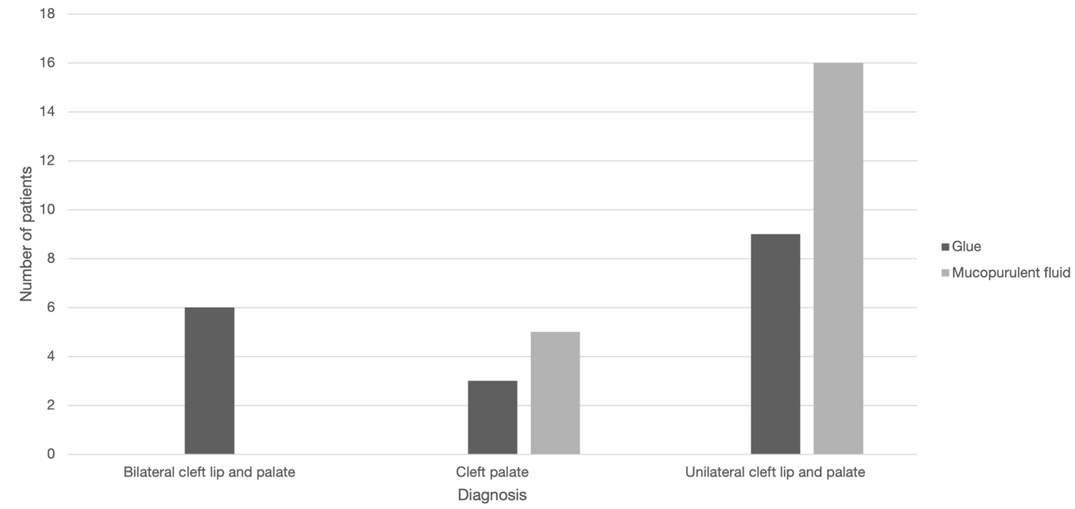
Data Analysis

Study specific data handling information

A database was constructed with demographic data, surgical details, otorrhea episodes and treatment. The electronic patient file (EPD) was used to capture study related data. All the data were stored in REDCap. Table 1 presents an overview of the collected data.

Statistical analysis

Descriptive statistics, including the median, 25th and 75th percentiles for non-normally distributed data or mean and standard deviation for normally distributed data, were used to summarize the distribution of continuous measures. The distribution of parameters was compared between independent groups (for example cleft lip and palate or cleft palate) using Kruskal-Wallis test. Statistical significance was defined as a two-tailed $p < 0,05$. Statistical analysis was performed with SPSS (version 29.0.1.0).



GRAPH 1: Distribution of type of middle ear effusion among different cleft types.

Results

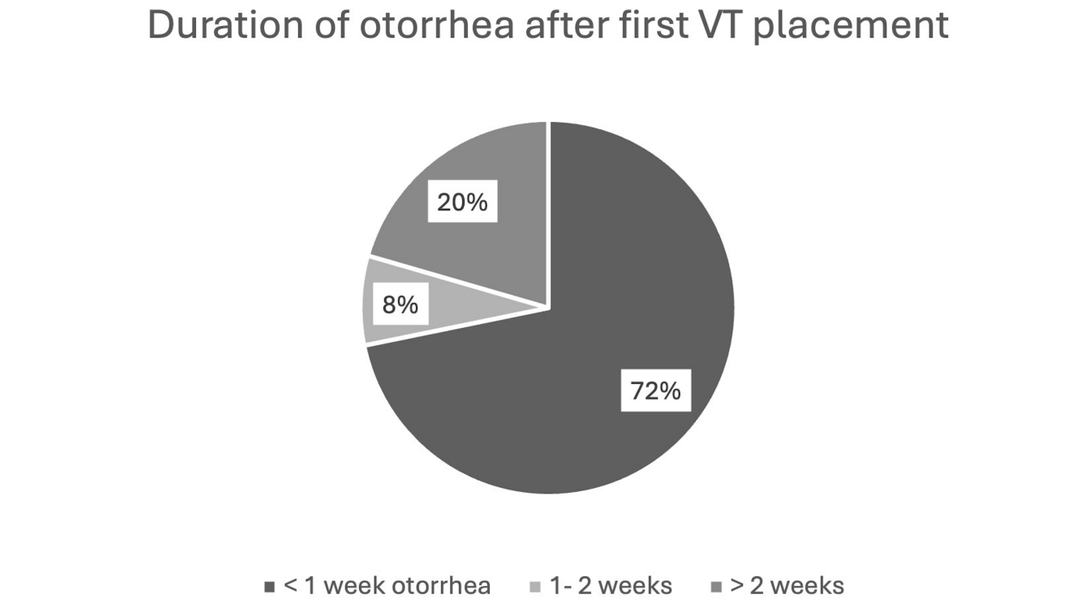
Patient demographics

In total 60 children underwent primary cleft surgery between 2022 and 2023. A total of 39 patients were included based on the inclusion and exclusion criteria. Sixteen patients were female, and twenty-three patients were male. Eight patients presented with an isolated cleft palate, twenty-five patients had unilateral cleft lip and palate, and six patients had bilateral cleft lip and palate. Mean follow-up time was 369 days (± 203). Two patients were lost-to-follow up.
All patients underwent neonatal hearing screening using Automated Auditory Brainstem Response technology. Most patients were tested "pass". Fifteen out of 39 patients (38,5%) had a "refer" in one or both ears. Among these referrals, twelve patients presented with middle ear effusion in both ears. Another three patients had middle ear effusion only present in the left ear. Mean auditory brainstem response (ABR) after referral was 35 dBnHL for the right ear (± 15 dBnHL) and 40 dBnHL for the left ear (± 11 dBnHL). If patients were referred for both ears (n=8), middle ear effusion was always present and mean ABR threshold for both ears was 43 dBnHL (± 10 dBnHL).

Twenty-one patients received VT at the time of definitive lip and nose repair at a mean age of 5,9 months (±1,1). Nine patients received their first pair of VT at the time of closure of the soft palate at a mean age of 8,4 months (±1,6)). All patients received Shepard VT. In 18 patients sticky glue and in 21 patients mucopurulent fluid was aspirated during the procedure (see Graph 1).

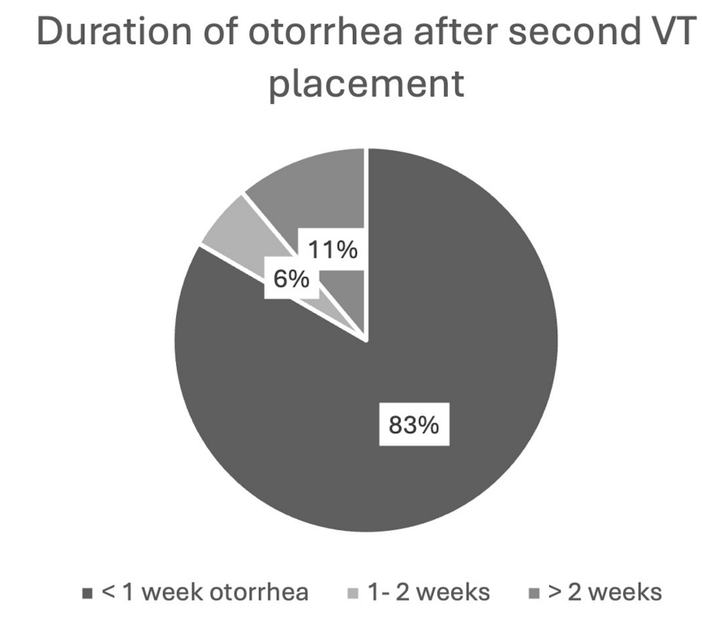
Twenty-one patients received ciprofloxacin drops post-operatively, 17 patients received Fluimucil ear drops (acetylcysteine-thiamphenicol), and one patient received a prescription for ciprofloxacin-dexamethasone ear drops. Eleven out of 39 (28.2%) patients had otorrhea at the first post-operative visit, which took place on average 10 days after surgery. Median duration of otorrhea in the right ear was 22 days [14;53] and in the left ear 32 days [17;67]. During the postoperative course, ear drops were often switched based upon clinical evolution at the discretion of the treating physician (see Graph 2 & 3).

At the time of closure of the hard palate at a mean age 17 months (±2,5), 18 patients received new VT (13 bilaterally, 5 unilateral). Eleven patients received a second set of Shepard VT. Other types included Titanium (n = 3) and Duravent (n = 3) VT. In seven patients sticky glue was aspirated from the middle ear, in five patients mucopurulent fluid was aspirated. Six patients had granulation tissue in the middle ear. Local treatment was given at the discretion of the surgeon who placed the VT.
Twenty-six patients had at least one episode of otorrhea during follow-up (66,7%) (see graph 4 and 5). Twelve patients had bilateral otorrhea, fourteen patients had unilateral otorrhea. An independent-samples Kruskal-Wallis test demonstrated a significant difference in the number of episodes between patients with unilateral cleft lip and palate, bilateral cleft lip and palate and isolated cleft palate ($p = 0,049$). However,

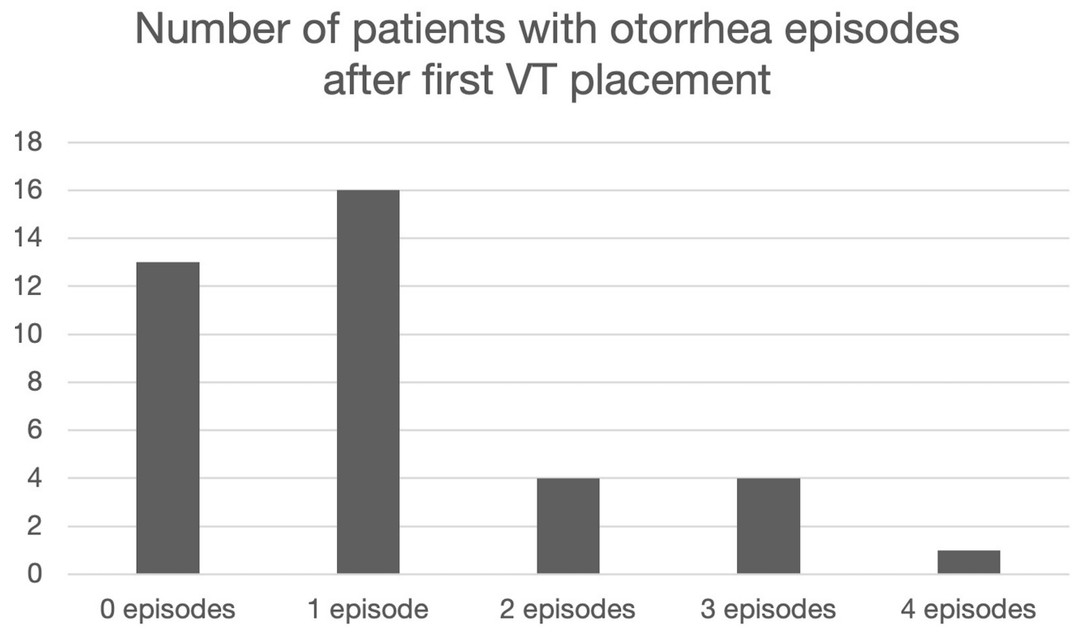


GRAPH 2: Duration of otorrhea after first VT placement: number and percentage of patients.

in pairwise combinations these differences were not significant. See Graph 5. Graph 6 shows the distribution of otorrhea episodes according to age at VT placement for the entire study period. Most patients who presented with an episode of otorrhea during follow up, had already started treatment before a clinical check-up was scheduled by the parents (69,2%). *S. aureus* (n = 5), *Streptococcus pneumoniae* (n = 4) and *Haemophilus influenzae* (n = 3) were the most common cultured organisms. However, only in ten out of 17 patients (58,8%) a result could be obtained by taking a culture sample.



GRAPH 3: Duration of otorrhea after second VT placement: more children experience: number and percentage of patients.



GRAPH 4: Number of otorrhea episodes after first VT placement.

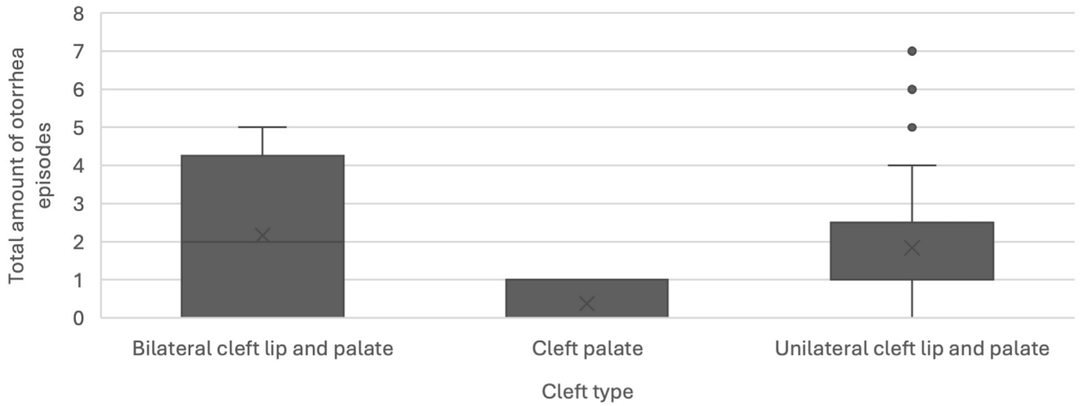
Three patients received an oral antibiotic (2 patients received amoxicillin and 1 patient amoxicillin with clavulanic acid) because of persistent (more than 2 weeks otorrhea) and in nine patients additional treatment was started. In eight patients oral administration of ketotifen was started, in one patient prophylactic treatment with co-trimoxazole given. Mean duration of first otorrhea after second placement of VT could be calculated from six patient records and was 15 days (± 11).

Ten patients had a second episode of otorrhea during follow-up. In four patients, both ears were affected, six patients had unilateral otorrhea. Six patients already started treatment before their clinical visit. Culture showed no causative organism in two patients. In one patient *Candida parapsilosis* was grown. In the second patient *Staphylococcus epidermidis* and *Cutibacterium acnes* and *H. influenzae*. In the last patient *S. pneumoniae* and *Escherichia coli* were cultured. All patients were at first solely treated with topical antibiotics. Two patients received additional treatment, which was prophylaxis with co-trimoxazole according to body weight and ketotifen.

Six patients had a third episode of otorrhea. In two patients both ears were affected, four patients had unilateral otorrhea. Half of these patients already received treatment before visiting the clinic, using ciprofloxacin ear drops. A clinical culture was collected from one patient upon hospital presentation, from which *S. pneumoniae* and *H. influenzae* were isolated. Two patients had a fourth episode of otorrhea, one already received ciprofloxacin before visit and with resolution after visit. One of the patients was not yet treated before visit and culture showed S. aureus, *S. pyogenes* and *H. influenzae*. This patient had a fifth and sixth episode of otorrhea, for which eventually co-trimoxazole antibiotic treatment was started.

Three patients received bilateral VT for a third time at a mean age of 18 months (± 15 days) at the time of closure of the hard palate. In one patient mucopurulent fluid was aspirated, in one patient sticky glue was aspirated and in one patient granulation tissue was encountered. One patient had otorrhea from the left ear at the first post-operative visit and was treated with antibiotic ear drops (acetylcysteine-thiamphenicol).

At the final visit after a median duration of 11 months follow-up, 10 patients had no VT in place, 25 patients still had both VT present, and 2 patients had one VT present. Two patients were lost-to-follow up. At the final visit, audiometric assessment indicated mild hearing loss, with a pure-tone average of 27 dBHL (±5 dBHL) in free-field test conditions (n = 23). One child underwent auditory brain stem responses which showed normal hearing thresholds in both ears at the final visit. In three children, oto-acoustic emissions were present in both ears. In one child, oto-acoustic emissions were present only in the left ear. Ear-specific pure tone audiometry was performed in six children and showed a pure-tone average of 27 dBHL (±11 dBHL) for the right ear and a pure-tone average of 23 dBHL (±3 dBHL) for the left ear. Three children did not undergo audiometric



GRAPH 5: Number of otorrhea episodes among different cleft types.

assessment at the final visit.

Discussion

A notably high incidence of otorrhea was observed following VT placement in children with cleft palate. Despite early intervention and standard postoperative care, more than two-thirds of patients developed otorrhea during the follow-up from one month after first VT placement. Episodes were frequently recurrent, often bilateral, and commonly triggered treatment initiation before formal clinical evaluation. Cultures regularly revealed the typical otopathogens. While most cases responded to topical antibiotics, a substantial subset required additional or prolonged therapy. These findings underscore the persistent vulnerability of children with cleft palate to postoperative otorrhea and the considerable management burden it imposes.

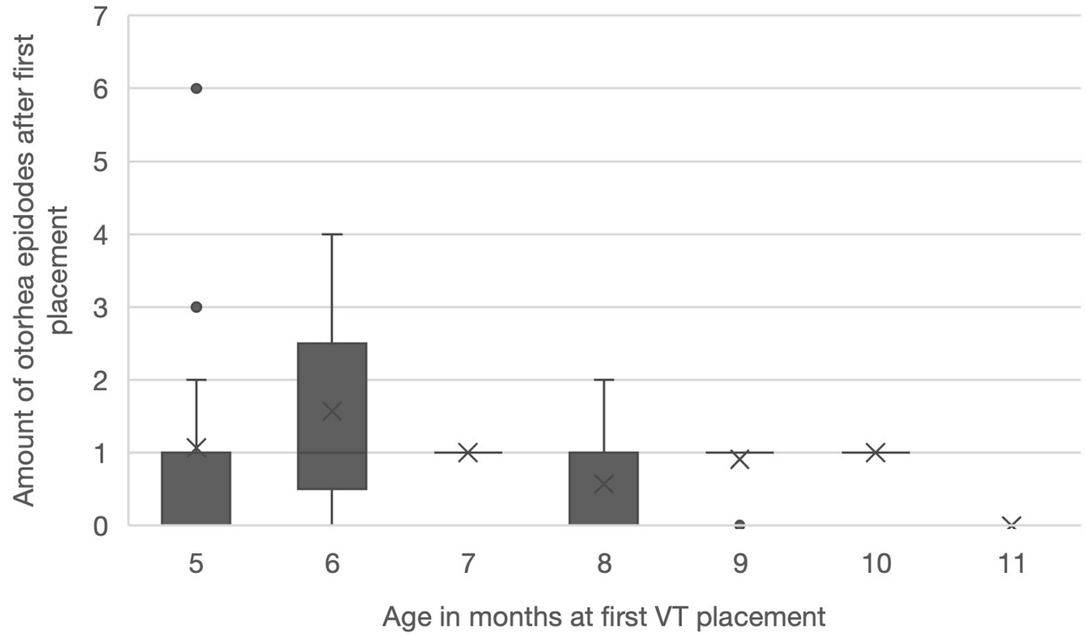
Historically, otolaryngologists have approached VT placement in infants with cleft palate with caution, largely due to concerns about intractable otorrhea resulting from nasopharyngeal reflux through patulous, poorly functioning Eustachian tubes (13). The present study systematically evaluated the incidence, clinical course, and microbiological profile of postoperative otorrhea in this high-risk population. Our findings reinforce the well-established pathophysiological basis of Eustachian tube dysfunction in children with cleft palate and demonstrate that surgical intervention alone does not mitigate this inherent susceptibility. Consistent with previous literature, children with cleft palate exhibited substantially high otorrhea rates. *S. aureus* and *S. pneumoniae* emerged as prominent pathogen, and resistance to fluoroquinolones—commonly used as first-line topical therapy—remains a growing concern (12).

In our cohort, twenty-eight percent of children developed otorrhea by the first postoperative visit, and sixty-seven percent experienced at least one episode during follow-up. These results closely mirror those of Felton et al., who reported otorrhea in nearly 75% of patients within the first year after VT placement, with gradual improvement as the Eustachian tube function matured (9). Curtin et al. similarly demonstrated higher otorrhea rates prior to palate repair, followed by a decline after (10). Early VT placement (often before or at the time of lip repair around 5–6 months, or at soft palate closure around 9 months) aligns with contemporary approaches advocating timely intervention to prevent early conductive hearing loss. However, this strategy inevitably coincides with a period of maximal ETD, thereby amplifying infection risk (9, 14, 15). Our data clearly confirm this trade-off: early placement was associated with frequent early otorrhea and repeated treatment adjustments.

Notably, the median duration of early postoperative otorrhea was prolonged, suggesting both delayed presentation and impaired middle ear clearance due to persistent ETD. The frequent initiation of treatment by parents prior to clinical assessment highlights commendable vigilance, but also exposes the need for clearer, standardized guidance to ensure timely and appropriate management.

Recurrent otorrhea was the rule rather than the exception. Ten children experienced a second episode, six patients a third, and several progressed to four or more episodes. This relentless recurrence reflects the chronic nature of middle ear disease in cleft palate patients. Ventilation tube insertion does not correct the underlying ETD, which often persists, well beyond hard palate closure. Consequently, these children remain prone to recurrent infections, biofilm formation on tubes, and persistent middle ear effusion. While previous studies suggest a higher disease burden in bilateral or isolated palatal clefts compared with unilateral clefts, our subgroup sizes were insufficient to confirm this association (16). Larger cohorts are needed to determine whether cleft extent independently predicts otorrhea recurrence.

Microbiological analysis identified *S.aureus, S.pneumoniae*, and *H. influenzae* as the predominant organisms, aligning with both classic otitis media pathogens and prior cleft-specific studies. Only 58.8% of cultures yielded pathogen growth, reflecting the practical difficulties of obtaining uncontaminated



GRAPH 6: Distribution of otorrhea episodes according to age at VT placement for the entire study period.

samples from actively draining ears. The predominance of *S. aureus* is particularly noteworthy. Previous studies, including those by Nogan et al. and Solis et al., have similarly identified *S. aureus* as the most frequently isolated organism in patients with cleft palate, often with a high prevalence of methicillin-resistant strains (MRSA) (11, 12). Methicillin resistance was not systematically assessed in the present study, the recurrent nature of infections however suggest a potential role for tube-associated biofilm formation. These findings underscore the importance of careful antimicrobial selection, particularly regarding postoperative topical therapy (11).

Only three children required systemic antibiotics during initial episodes, confirming that topical therapy remains effective in most cases. Oral antibiotics were appropriately reserved for prolonged otorrhea, in line with established otolaryngology guidelines (3, 17). Adjunctive treatments such as ketotifen were occasionally employed because the treating physician considered allergic upper airway symptoms or allergic mucosal inflammation to contribute to Eustachian tube dysfunction. The rationale was that its antihistamine and mast cell–stabilizing properties might reduce nasopharyngeal mucosal oedema, although evidence supporting its use for otitis media with effusion or prevention of post-tympanostomy otorrhea is limited. Co-trimoxazole was prescribed selectively by the treating physician in children considered at increased risk of recurrent bacterial middle ear infections, reflecting individual clinical judgment rather than a standardized treatment protocol (18). Similarly, acetylcysteine-thiamphenicol antibiotic ear drops were used in some patients according to physician preference and we acknowledge that this is not the first-line choice of local treatment for postoperative otorrhea (1). There is a need for standardized, evidence-based protocols.

This study yields several clinical implications. Early and recurrent otorrhea should be anticipated rather than regarded as exceptional. Families must be proactively educated on early recognition, proper ear canal cleaning—such as the use of tissue spears prior to drop administration—and clear thresholds for seeking medical review (1). Topical antibiotics remain the cornerstone of treatment, but microbiological sampling should be strongly encouraged in recurrent or refractory cases. Given the high recurrence rate, close follow-up and readiness for repeat VT placement are essential in this population.

A major strength of this study lies in its real-world clinical data from a single tertiary cleft centre with standardized surgical techniques, postoperative care, and audiological follow-up. The inclusion of microbiological findings further enhances its clinical relevance. Limitations include the relatively small sample size, retrospective design, variable timing of culture sampling, and limited follow-up duration.

Future research should prioritize larger, multicentre cohorts to clarify demographic and cleft-related risk factors. Standardized postoperative pathways, including parental education materials and prophylactic strategies, warrant evaluation. Additionally, the impact of tube design, long-term hearing and speech outcomes, and novel interventions such as probiotic ear drops deserves further exploration (19).

Conclusion

Children with cleft palate face a persistently high risk of postoperative otorrhea following VT placement, with early onset and frequent recurrence. The microbiological landscape is dominated by classic otopathogens, particularly *S.aureus*, necessitating targeted and judicious antimicrobial therapy, preferably local therapy. Importantly, despite the high otorrhea burden, hearing outcomes remained favourable at final follow-up. This suggests benefits of VT placement outweigh the burden in this specific population. Optimizing postoperative management and empowering parents through clear guidance are critical to reducing complications, limiting treatment burden, and safeguarding auditory and speech development in the long-term. Further research on pre- and postoperative strategies to diminish the burden of postoperative otorrhea are warranted.

Statements

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