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Cleft palate and ventilation tubes: a prophylactic dilemma

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Abstract

Objective. This study aimed to understand, in a long-term follow-up study, whether the placement of grommets had been necessary after cleft palate surgical correction.

Method. A case–control, retrospective study was carried out on consecutive paediatric patients who underwent surgical repair of a cleft palate.

Results. The study population included 138 patients, divided into 2 groups: group 1 – patients in whom grommets were placed at the time of cleft palate surgery, and group 2 – patients in whom grommets were not placed at the time of cleft palate surgery. During the follow up, in groups 1 and 2, 65.2 per cent and 67.8 per cent, respectively, did not need subsequent grommet placement after cleft palate surgery.

Conclusion. Of patients, 56.5 per cent did not need ventilation tubes at any point during follow up. The placement of grommets is not innocuous; therefore, its use at the time of cleft palate surgical repair should be reconsidered.

Main Article

Dr A Machado takes responsibility for the integrity of the content of the paper

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Introduction

Cleft lip and cleft palate are congenital anomalies that contribute to the burden of family members and the patients themselves. During childhood, management of these anomalies involves several surgical procedures, such as cleft lip repair and cleft palate repair, and as they are known for their association with additional congenital anomalies or genetic syndromes, sometimes other invasive procedures are required.[1,2]

The abnormal positioning of the orbicularis oris muscle results in an obvious lip and nasal defect, and feeding and speech problems. In addition, an abnormal tensor veli palatine function is almost universal in the cleft lip and palate population, giving rise to Eustachian tube dysfunction and middle-ear effusion.[3–6]

Otitis media with effusion involves the collection of fluid in the middle ear for three or more months, often causing damage to the eardrums or acute middle-ear infection.[7] It appears that middle-ear pathology is practically universal in patients with cleft palate. According to the literature, the incidence of ear pathology in this population can reach 90 per cent, which reinforces the need for close surveillance of these patients.[8–11] Several articles reinforce the placement of ventilation tubes routinely, with a statistical argument and with a view to preventing otological complications, improving hearing acuity, and optimising speech and language development.[12–14]

However, ventilation tube placement is not innocuous. The most frequent complication of this surgical procedure is transient otorrhoea (often treated with topical antibiotics); to a lesser extent, there is obstruction of the ventilation tube lumen, formation of granulation tissue, migration of the tube to the middle ear, myringosclerosis, atrophy or a retraction pocket at the myringotomy site, and tympanic perforation after tube extrusion.[15–17]

Our goal was to understand, in a long-term follow-up study, whether ventilation tube placement had been necessary after cleft lip and palate surgical correction.

Materials and methods

Study design

A retrospective study was carried out in the ENT department of a tertiary centre to review the clinical files of paediatric patients who had undergone cleft palate surgical repair.

In order to investigate, in a long-term study, whether ventilation tube placement had been necessary after cleft lip and palate surgical correction, we evaluated the long-term results of two groups: group 1 consisted of patients with ventilation tubes placed at the same time as cleft lip and palate correction surgery performed because of otological pathology (chronic otitis media with effusion or repeated acute otitis media); and group 2 comprised patients with no otological diagnosis and no ventilation tube placement at the same time as the cleft lip and palate correction surgery. Long-term complications associated with ventilation tube placement were also recorded.

Study population

The study included patients, aged under 18 years, with a diagnosis of cleft palate, or cleft palate and cleft lip, who underwent surgical correction at our centre, from 2012 to 2016. A minimum six-year ENT follow up was also mandatory. Patients with incomplete clinical records or follow-up data, and those with a history of prematurity, immunodeficiencies or syndromic pathology, were excluded a priori.

Variables evaluated

This study assessed patient age at repair of the cleft palate and cleft lip, gender, and type of cleft according to the Veau classification (I–IV). We also considered the need for ventilation tubes at the same time as surgical correction of the cleft palate, the subsequent need for ventilation tubes during follow up, any complications, the number of tubes placed, and the indication for ventilation tube placement. We also checked whether any otological surgery was necessary during the follow-up period.

To this end, we divided the interventional patients (who underwent correction of the cleft palate) into two groups: group 1 consisted of patients with ventilation tube placement at the time of surgical correction of the cleft palate, with indications of acute recurrent otitis media or otitis media with chronic effusion;[18] and group 2 comprised patients with no ventilation tube placement at the time of surgical correction of the cleft palate because of a lack of criteria.[18] This group division aimed to establish whether there is a clinical advantage in placing ventilation tubes at the same time as the cleft palate repair surgery.

Statistical analysis

Statistical analysis was performed using SPSS® software, version 28. Normality was assessed using the Kolmogorov–Smirnov, Shapiro–Wilk and Levene tests. For normally distributed values, descriptive results are expressed as mean ± standard deviation. The independent *t*-test and Mann–Whitney test were used to compare continuous variables between groups. A Pearson correlation co-efficient and Kendall's Tau-b analysis were used to examine the relationship between two related variables. A chi-square test was used for comparison between two attributes. The normality of the samples was assessed by histogram and plot visual analysis, and according to this, a non-parametric test – the Mann–Whitney test – was our test of choice for comparison between sides. The McNemar test was used to analyse paired nominal data. A two-sided *p*-value of less than 0.05 was considered statistically significant.

Results

Study population

Our study population comprised 138 patients, 76 males (55.1 per cent) and 62 females (44.9 per cent) (Table 1).

According to the Veau classification (Table 2), 14 patients (10.1 per cent) had a type I cleft, 36 (26.1 per cent) had a type II cleft, 56 patients (40.6 per cent) had a type III cleft and 32 (23.2 per cent) had a type IV cleft (Table 1).

According to the Mann–Whitney test ($U = 150.00$, $p = 0.756$), there was no association, in our sample, between the cleft type (based on the Veau classification) and the laterality of the otological pathology.

Table 1. Population characteristics

Characteristic	Cases (*n* (%))
Gender	
– Male	76 (55.1)
– Female	62 (44.9)
Type of cleft*	
– I	14 (10.1)
– II	36 (26.1)
– III	56 (40.6)
– IV	32 (23.2)
Surgical indication for VT placement	
– Chronic OME	49 (81.7)
– Repeated AOM	11 (18.3)
Groups evaluated†	
– Group 1	23 (16.7)
– Group 2	115 (83.3)

*According to Veau classification. †Group 1 = grommets placed at the time of cleft palate surgery; group 2 = grommets not placed at the time of cleft palate surgery. VT = ventilation tube; OME = otitis media with effusion; AOM = acute otitis media

Table 2. Veau classification of cleft palate

Type	Structures affected
I	Soft palate
II	Hard & soft palate
III	Hard & soft palate with pre-palatal unilateral cleft
IV	Hard & soft palate with pre-palatal bilateral cleft

Group 1 comprised 23 patients (16.7 per cent) and group 2 consisted of 115 patients (83.3 per cent) (Table 1).

Indication for ventilation tube placement

Ventilation tubes were placed in 60 patients. Of these, 81.7 per cent underwent ventilation tube placement because of chronic otitis media with effusion and 18.3 per cent because of repeated acute otitis media (Table 1). All grommets were placed in an anteroinferior position.

Time of ventilation tube placement

In group 1, 15 patients (65.2 per cent) did not need subsequent ventilation tube placement, whilst 8 patients (34.8 per cent) needed subsequent ventilation tube placement (Table 3). In group 2, 78 patients (67.8 per cent) did not need subsequent ventilation tube placement, whilst 37 patients (32.2 per cent) needed subsequent ventilation tube placement (Table 3).

According to the McNemar test ($p = 0.003$), there was an increase of 21 per cent in the need for ventilation tube placement with the recommended approach.

During follow up in ENT and paediatric surgery departments, both groups being considered, the placement of ventilation tubes was necessary in 45 patients (32.6 per cent). Thirty-seven (26.8 per cent) of these patients had not undergone a previous myringotomy, with subsequent ventilation tubes placed at the time of the cleft lip and palate surgical

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Table 3. Comparison of ventilation tube placement or non-placement at time of surgical correction and during follow up

VT at time of CLP surgical correction?	VT placement during follow up*?		
	No	Yes	Total
No	78 (56.5)	37 (26.8)	115 (83.3)
Yes	15 (10.9)	8 (5.8)	23 (16.7)
Total	93 (67.4)	45 (32.6)	138 (100.0)

Data represent numbers (and percentages) of cases. The McNemar test ($p = 0.003$) indicated a statistically significant difference between group 1 (grommets placed at the time of cleft palate surgery) and group 2 (grommets not placed at the time of cleft palate surgery), in terms of our intervention with ventilation tube placement. *In ENT and paediatric surgery departments. VT = ventilation tube; CLP = cleft lip and palate

correction; the remaining 8 patients (5.8 per cent) had already undergone ventilation tube placement when correcting the cleft lip and palate (Table 3).

Number of ventilation tubes placed

The number of times ventilation tubes were placed ranged from one (19 patients) to four (1 patient) (Table 4).

In eight patients, it was necessary to place ventilation tubes at surgery and during follow up (Table 3).

Complications of ventilation tube placement

Regarding complications relating to ventilation tube placement during the follow-up period, otorrhoea was present in 30 per cent of patients (18 patients), myringosclerosis was present in 23.3 per cent (14 patients) and mesotympanic perforation occurred in 10 per cent (6 patients); 3.3 per cent (2 patients) had synchronous myringosclerosis and tympanic perforation (Table 5).

We found no association between ventilation tube placement and the development of otological complications according to the chi-square test ($F(4) = 2.224$, $p = 0.626$).

Additional otological surgery

Regarding the need for other ear surgery during the follow-up period, four patients underwent type 1 tympanoplasties, two patients underwent closure of a tympanic perforation, four patients had long-lasting T-tubes placed, and one patient underwent a closed mastoidectomy (Table 6).

Discussion

This study is the first to be carried out in Portugal, at a tertiary centre, to assess the outcomes of placing Sheppard ventilation tubes in patients with cleft palate and otological pathology versus no prophylactic placement of ventilation tubes at the time of cleft lip and palate correction. The paper also provides a reflection on the approach taken so far.

Table 4. Number of subsequent ventilation tube placements

Number of placements	Cases (*n* (%))
One	19 (47.5)
Two	10 (25)
Three	10 (25)
Four	1 (2.5)

Table 5. Complications of ventilation tube placement

Complication	Cases (*n* (%))
Myringosclerosis	14 (23.3)
Tympanic perforation	6 (10)
Otorrhoea	18 (30)
Myringosclerosis & tympanic perforation	2 (3.3)

The minimum follow-up period considered in this study was agreed to insofar as it guaranteed the peak of otitis media with effusion (OME), which, in the non-cleft palate population, is between three and seven years. Contributory factors include upper respiratory tract infection and narrow upper respiratory airways. Several risk factors were identified, such as patient age of under six years, low socio-economic grouping, frequent upper respiratory infections and household smoking.[19]

A child's Eustachian tube is not fully developed, and is shorter, more horizontal and with a narrower opening to the nasopharynx than that of an adult. An upper respiratory tract infection causes swelling and inflammation, which leads to negative pressure in the middle ear. In addition, given all the anatomical considerations described above, viruses and bacteria from the upper respiratory tract easily pass into the middle-ear cavity, causing middle-ear infection with effusion.

In children with cleft lip and palate, the abnormal reflux of food and fluid from the mouth into the nasal cavity caused by velopharyngeal insufficiency can result in inflammation and oedema of the Eustachian orifices and hypertrophy of the adenoid pads, leading to tubal obstruction, secondary OME and higher rates of OME in these patients.[20–23]

The orifice of the Eustachian tube in cleft lip and palate patients is smaller and located postero-inferiorly, such that the levator sling obstructs rather than lifts the opening during phonation or swallowing, resulting in subsequent OME. This generalised orofacial anatomical dysfunction may explain the lack of a statistically significant association between the laterality of the otological pathology and the type of cleft palate.[24–30]

The McNemar test findings indicated that watchful waiting is necessary because of the high complication rates of myringotomy with ventilation tube placement (78 patients did not need the initial placement of ventilation tubes, nor did they need any during the follow up). According to the same test ($p = 0.003$), there was an increase of 21 per cent in the need for ventilation tube placement with the personalised strategy recommended. However, there is consensus that the placement of ventilation tubes as a prophylactic measure should be carefully considered – the complications of this procedure are not innocuous, which justifies an initial assessment in this regard. The authors consider it important that in 56.5 per cent of patients, a previous ENT observation without indication for

Table 6. Other ear surgical procedures performed during follow up

Surgical procedure	Cases (*n* (%))
Type 1 tympanoplasty	4 (6.7)
Long-term ventilation tube	4 (6.7)
Canal wall up mastoidectomy	1 (1.6)

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ventilation tubes did not translate into a subsequent intervention, either ventilation tube placement or another type of ear surgery already accounted for in this article. It was assumed by the authors that this expectant attitude allowed time for rehabilitation following paediatric surgery, and that the functioning of the Eustachian tube, either for this reason or because of its verticalisation with age, may lead to resolution of the otological pathology in question (Table 3).

Importantly, it is documented in the literature that OME persists in more than 90 per cent of patients who undergo palatoplasty, reflecting poor basic functioning of the Eustachian tube.[20–30]

Of patients who underwent cleft lip and palate repair surgery in the present study, 56.5 per cent did not need ventilation tube placement, suggesting that the repair of the distorted anatomy can contribute to better middle-ear ventilation, with a low incidence of pathology in the area.

At our institution, after the third set of short-term tubes were placed, associated with persistent OME, we opted for the placement of long-term tubes. Some patients in our sample who had had more than three short-term ventilation tubes did not have long-term ventilation tubes – these patients were treated in the private system using a different approach from the one recommended at our centre. However, we believe it was pertinent to include these patients in our sample, as they complied with the inclusion criteria initially recommended.

The multidisciplinary assessment should not be underestimated – not only in the case of otological pathologies, but also for velopharyngeal insufficiency and columella detachments, the latter of which represent burdens for both patients and caregivers.

In addition, from a medico-legal perspective, we should protect ourselves as physicians, and always avoid iatrogenic damage in practice. These data can help us to achieve the best outcome for the patient – the core of our practice – whilst protecting ourselves from legal issues that could emerge from inappropriate surgery.

- Abnormal tensor veli palatine function is nearly universal in cleft palate and lip patients, resulting in Eustachian tube dysfunction and middle-ear effusion
- In this study, 56.5 per cent of patients did not need transtympanic tubes during follow up, hence otological pathology is not universal in cleft palate patients
- This novel study assessed the outcomes of placing transtympanic tubes in cleft palate patients in Southwest Europe
- A complete otolaryngological evaluation before and after surgery offers good results in the management of these complex patients
- Such evaluation also allows an approach tailored to the otological pathology

Regarding study limitations, we must point out its retrospective nature, even though the existence of complete information which allowed us to optimise conclusions regarding our casuistry was assured a priori. The audiological outcomes were assessed to report the clinical and audiological significance of procedural complications, despite not being the main purpose of this study. The type of cleft palate found is related to the degree of differentiation of our centre – tertiary – and in this regard, it may have translated a bias of convenience, and not efficiently translated the Portuguese and southwestern European reality.

In line with Alper *et al.*, the authors agree that the reliable identification of markers or characteristics of patients with a cleft palate who present a high or low future risk of OME can allow better guidance for these patients.[31]

Conclusions

We found that 56.5 per cent of patients with surgical correction of a cleft lip and palate did not need ventilation tubes at any point during the post-operative follow up. Otological pathology is not a universal condition in patients with cleft palate, and this should also be considered. In addition, complications of ventilation tubes should be considered in the management of patients with cleft lip and palate. The positioning of ventilation tubes in cleft lip and palate patients can translate into otological complications, and this only reinforces the need for proper surveillance by an experienced otolaryngologist, who ideally forms part of a multidisciplinary team. A complete otolaryngological evaluation before and after surgery provides a means of offering the best results in the management of these complex patients and of tailoring an approach for the otological pathology itself.

Competing interests. None declared

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