MIDDLE EAR DISEASES AND THE EFFICACY OF VENTILATION TUBE INSERTED IN TO OTITIS MEDIA IN CHILDREN WITH CLEFT PALATE

Tang Xuan Hai[1], Phan Quang Trung [2], Ha Cuc[3], Tran Minh Long[4]
1.2.3. 4.Nghe An Obstetrics and Pediatrics Hospital
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Abstract:

Objectives: Cleft palate is associated with middle ear diseases, but the magnitude of this problem is not generally well appreciated. This study aimed to describe the middle ear status and to evaluate the results of ventilation tube insertion in children with cleft palate.

Methods: A cross-sectional cohort study was conducted to investigate 78 children with cleft palate (CP). These patients underwent otoscopy and tympanometry to assess middle ear status. When chronic otitis media with effusion (OME), recurrent otitis media, or atelectasis were diagnosed, ventilation tube insertion (VTI) and palatal repairation were performed simultaneously. The study was carried out in Nghe An Obstetrics and Pediatrics Hospital from January 2023 to December 2024.

Results: The sex ratio was 1:1; the mean age of the patients was 34.59 months (13 months – 13 years old). Middle ear diseases occurred in 60.26% of patients with Cleft palate, with the incidence of OME and atelectasis being 30.76% and 24.35%, respectively. Type B tympanograms were most frequently observed (66.23%). The rate of post-VTI otorrhea was 10.34%, while the rate of tube extrusion after 3 months was 8.66%.

Conclusions: We assessed the efficacy of ventilation tube insertion (VTI) in eliminating otitis media with effusion (OME) in patients with Cleft palate undergoing palatal repair. The results indicated that VTI is effective in eliminating OME in these patients.

Keywords: Cleft palate, otitis media with effusion, ventilation insertion.

1. Introduction:

Cleft lip and palate are among the most common congenital malformations, with an overall incidence of around 1 in 700 individuals [1].

Middle ear diseases are a well-known complication of cleft palate; however, the extent of this issue is often underappreciated. These conditions typically include otitis media with effusion

[1] * first author: Tang Xuan Hai; Phone number: 0912379583; Email: bstangxuanhai@gmail.com
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(OME), recurrent otitis media, and atelectasis. They frequently present with hearing loss, but may also lead to language delays and hinder educational development [2]. Approximately 90% of infants with Cleft palate develop OME by the time of birth [3].

Although the exact mechanism underlying the development of otitis media with effusion (OME) is not fully understood, dysfunction of the Eustachian tube, which connects the middle ear to the postnasal space, is believed to play a fundamental role. The Eustachian tube functions to equalize pressure on either side of the tympanic membrane, preventing the development of negative pressure in the middle ear. In children, the Eustachian tube is less efficient, leading to a greater tendency for negative middle-ear pressure and fluid accumulation. This dysfunction is further exacerbated in children with Cleft palate due to impaired function of the muscles originating from the palate, which are responsible for opening the Eustachian tube orifice [4].

Over the past several decades, significant advances have been made in the understanding and surgical management of Cleft palate. The disease is no longer considered unmanageable, thanks to the cooperation of a multidisciplinary team, including a pediatric otolaryngologist, a plastic surgeon and a speech therapist [5]. Various palatal repair procedures have been developed, with encouraging results in terms of cosmetic and functional outcomes. However, the ventilation function of the middle ear does not show proportional recovery compared to other outcomes following palatal repair, as some patients with cleft palate continue to develop otitis media with effusion (OME). Under these circumstances, ventilation tube insertion (VTI) has been proposed as a potential solution for OME in children with cleft palate, who are at high risk for complicated

OME and may require further VTI, as recommended by the American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF).

A systematic review by Ponduri et al. concluded that there was insufficient evidence to support routine early prophylactic placement of grommets in infants with cleft palate during palate repair and recommended selective treatment for cases of hearing loss or clinically evident effusion. Similarly, other authors suggested that selective therapeutic VTI be performed based on symptomatic middle ear disease or hearing loss [6].

This cross-sectional cohort study aims to provide a clear overview of middle ear conditions in children with Cleft palate at Nghe An Obstetrics and Pediatrics Hospital and the outcomes of VTI in these patients.

2. Materials and methods

Data for this study were obtained from the records of patients with Cleft palate who were admitted to Nghe An Obstetrics and Pediatrics Hospital between January 2023 and April 2024.

An information letter with an opting-out form was provided to the parents of all patients aged 0-16 years old. Children with Cleft palate, with or without Cleft lip were eligible for inclusion. They underwent otoscopy and tympanometry to evaluate middle ear status. If chronic otitis media with effusion (OME), recurrent otitis media or atelectasis was diagnosed, ventilation tube (VT) insertion and palatal repair were performed concurrently. A total of 78 patients matched the inclusion criteria. All data were processed anonymously. Statistical analysis was performed by SPSS.25 software.

3. Results

3.1. Patient characteristics

3.1.1. Gender: Of the 78 children included, 42 were male (53.84%) and 36 were female (46.16%), resulting in a male-to-female ratio of 1:1.

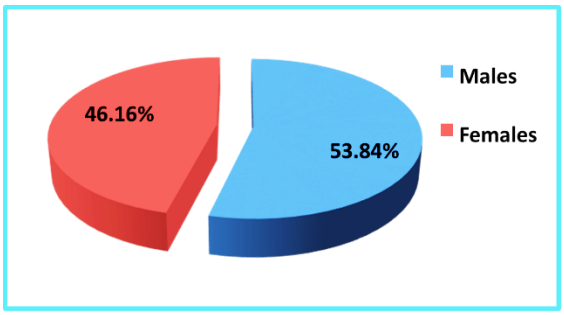

Chart 1. Demographic data: Gender

1.1. 3.1.2. Ages: The mean age of the patients was 34.59 months (13 months – 13 years old)

3.1.3. Otoscopic findings:

A description of the actual middle ear status is listed in Chart 2.

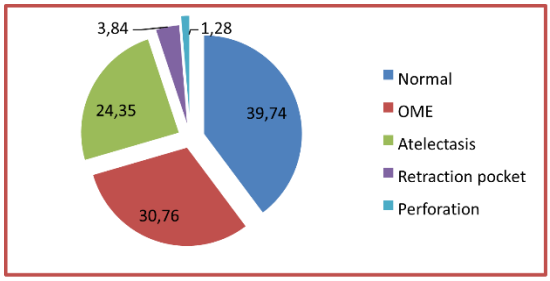

Chart 2. Otoscopic findings in cleft palate children

3.1.4. Tympanometric findings in cleft palate children:

Tympanograms were classified according to the Jerger classification. Examinations of 156 ears (78 patients) revealed that type B tympanograms were the most common, occurring in 66.23% of cases. A description of the tympanogram is shown in Chart 3.

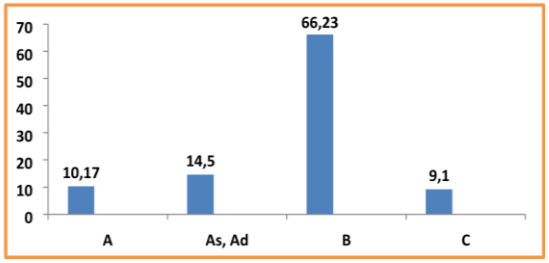

Chart 3. Tympanometric findings in cleft palate children

We have 47 of the 78 children had middle ear conditions. In this group, 3 had developed retracted pockets, 5 had atelectatic tympanic membrane grade III, IV, and 1 had a tympanic membrane perforation. These patients were not indicated for ventilation tube insertion. 9 patients refused treatment and were lost to follow-up. Finally, 29 patients (58 ears) underwent the

cleft palate surgery and ventilation tube insertion simultaneously. A follow-up examination was performed at 3 months after surgery.

3.1.5. Post operation:

3.1.5.1. Results of palate repair:

Table 1. Results of palate repair

Result	n	%
Complete closure	24	82.75
Fistula	5	17.25
Total	29	100

The success rate of palate repair was 82.75%

3.1.5.2. Otoscopic findings after surgery:

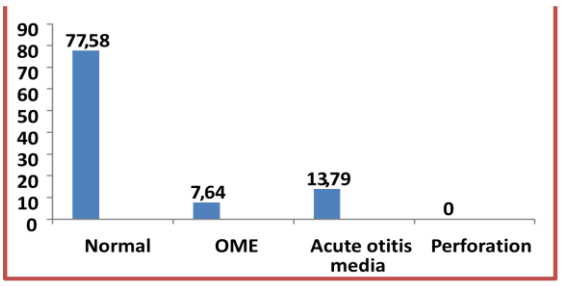

Chart 4. Middle ear status after surgery

After 3 months of surgery, the rate of the normal middle ear was 77.58%, and the recurrence rate of OME and acute otitis media was 7.64% and 13.79%, respectively. No patient had developed tympanic membrane perforation.

3.1.5.3. Complications of VTI:

Table 2. Complications of VTI

Complication	n	%
Otorrhea	6	10.34
Tympanosclerosis	5	8.62

Post-VTI otorrhea is regarded as the most common complication of tympanostomy tube placement. The incidence of otorrhea after the procedure in the study was 10.34%.

3.1.5.4. The ventilation tube status:

Table 3. The ventilation tube status

VT extrusion	n	%
No	53	91.38
Yes	5	8.62

The rate of extrusion tube after 3 months was 8.66%;

4. Discussion

This study involved 58 participants, with a male-to-female ratio of 1:1. Cooper et al. found that the prevalence of Cleft palate was greater in males than in females, but the inter-ethnic prevalence in Asia could not be accurately analyzed due to the inconsistency of available data.

The incidence of middle ear disease in patients with Cleft palate was 60.26%, with the incidence of OME and atelectasis at 30.76%, and 24.35%, respectively. This is consistent with

Flynn and Moller's research which found that the middle ear disease rate in Cleft palate children was 74.7% [7]. According to Hoai An Nguyen, the incidence of OME in cleft palate patients is three times higher than the normal rate. The highest incidence of OME occurred in the age group under 6 years, with a point prevalence of 66.7% [8].

In our results, the ratio of type B and C tympanograms were 66.23% and 9.1%;

Previous studies of Cleft palate only analyzed the types of tympanogram without considering the normal values of tympanometry. This is consistent with Zheng's research, which found that abnormal tympanogram occurred in 34% of children under 1 year old, increasing to 65% for children under 5 years old, 41% in children aged 6 years, and 30% in children aged 8 to 11 years [9].

Of the 29 patients who underwent both palate repair and VTI, 82.75% achieved a good surgical outcome. Oroantral-fistula was observed in 17.25% of Cleft palate repairs, and these patients were reoperated.

Post-VTI otorrhea is the most common complication following tympanostomy tube placement, with its incidence varying from 3.4% to 74% [10]. In our study, the incidence was 10.34%, which was consistent with previous findings' data. As the ventilation tube creates a direct communication between the middle-ear cavity and the external ear, otorrhea, which largely results from the inflammation of the eustachian tube and the middle ear due to the common cold, is inevitable. Fortunately, most cases of otorrhea are simple and manageable by using ototopical drips or water precautions.

The incidence of recurrent OME and otitis media was 21.43%. According to Saranyoo Suwansa-Ard's research, the incidence of OME after palatoplasty and myringotomy with VTI was 54.2%. This happens around 7 months after VT slips off, with initial management often being conservative. Risk factors associated with recurrent OME included: complete Cleft palate, twostage palatoplasty and VT extrusion [11]. The rate of VT extrusion after 3 months is 8.66%, which was consistent with Thanh Thai Le's research (VT extrusion rate was 4.4% after 3 months and 18.3% after 6 months) [12]. VT extrusion is the main cause of OME after palatoplasty and myringotomy with VTI. After palatoplasty, the recovery of the muscles involved in Eustachian tube function typically requires 1-2 years [13]. The limitation of our study was the short-term follow-up.

5. Conclusions:

The efficacy of ventilation tube insertion for eliminating otitis media with effusion in patients with Cleft palate undergoing palatal repair. The results suggested that VTI is effective in eliminating OME in this patient group.

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