Kulak Burun Bogaz Ihtis Derg 2013;23(5):268-274 doi: 10.5606/kbbihtisas.2013.52724 

***Original Article / Çalışma - Araştırma***

# Incidence of otitis media with effusion and long-term clinical findings in children with cleft lip and palate types

## Yarık dudak ve damak tipi olan çocuklarda efüzyonlu otitis media insidansı ve uzun dönem klinik bulgular

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**Objectives:** This study aims to investigate the incidence of otitis media with effusion and to report long-term clinical findings in children with cleft lip and palate types.

**Patients and Methods:** Between March 2000 - October 2010, medical data of 175 patients (84 females, 95 males; mean age 8 years; range, 4 to 20 years) who were operated due to otitis media with effusion with long-term follow-up data were retrospectively analyzed.

**Results:** A total of 105 patients had a complete cleft lip and palate. In the first examination, 134 patients had ear effusion, the eustachian tube were not patent in 146 patients, and middle ear pressure was measured as -200 and below in 121 patients. After the operations, the eardrums had ear effusion in 89 patients, in 93 patients middle ear pressure was lower than -200, and 11 patients had chronic otitis media in the final examination.

**Conclusion:** Our study results suggested that there was a statistically significant relationship among the middle ear disease, function of eustachian tube, treatment outcomes, middle ear pressure, cleft palate type and bilaterality of the disease. We believe that it is of utmost importance as it may affect the treatment process and the patient follow-up in such patients.

*Key Words:* Cleft palate; otitis media; ventilation tube placement.

**Amaç:** Bu çalışmada yarık dudak ve damak tipi olan çocuklarda efüzyonlu otitis media insidansı araştırıldı ve uzun dönem klinik bulgular sunuldu.

**Hastalar ve Yöntemler:** Mart 2000 ve Ekim 2010 tarihleri arasında efüzyonlu otitis media nedeniyle ameliyat edilen ve uzun dönem takip verileri mevcut olan 175 hastanın (84 kadın, 95 erkek; ort. yaş 8 yıl; dağılım 4-20 yıl) tıbbi verileri retrospektif olarak incelendi.

**Bulgular:** Toplam 105 hastada tam yarık damak-dudak vardı. İlk muayenede 134 hastanın kulak efüzyonu vardı, 146 hastada östaki tüpü patent değildi ve ölçülen orta kulak basıncı 121 hastada -200 ve altında idi. Ameliyatlardan sonra, son muayenelerinde ise 89 hastada kulak efüzyonu vardı, 93 hastada orta kulak basıncı -200 ve altında idi ve 11 hastada kronik otitis media vardı.

**Sonuç:** Çalışma bulgularımız orta kulak hastalığı, östaki tüpü fonksiyonu, tedavi sonuçları, orta kulak basıncı, yarık damak tipi ve hastalığın iki taraflı olup olmaması arasında istatistiksel açıdan anlamlı bir ilişki olduğunu gösterdi. Bunun tedavi sürecini ve hasta takibini etkileyebildiği için bu tür hastalarda çok önemli olduğu kanısındayız.

*Anahtar Sözcükler:* Yarık damak; otitis media; ventilasyon tüpünün takılması.

Available online at
www.kbbihtisas.org
doi: 10.5606/kbbihtisas.2013.52724
QR (Quick Response) Code

Received / *Geliş tarihi:* May 05, 2012 Accepted / *Kabul tarihi:* July 25, 2013

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Cleft lip and palate (CLP) is an anomaly resulting from non-fusion of the lip and palate during fetal development. It is among the most common anomalies affecting approximately one in 500 births.[1] Due to incomplete palatal closure, difficulties arise with the development of feeding, speech, language, dentition, facial structures and hearing. Specifically, the development of hearing is affected as children with cleft lip and palate and cleft palate universally present with otitis media with effusion (OME),[2-8] often within the first six months of life.[3,5] Otitis media with effusion presents with fluid in the middle ear and is not accompanied by signs or symptoms of acute infection. The high prevalence of OME in children with CLP is due to Eustachian tube dysfunction. The muscles responsible for opening the Eustachian tube are the tensor veli palatini and the levator veli palatini.[9] The lateral point of insertion causes lack of anchorage which does not allow proper opening of the Eustachian tube. Therefore, the opening of the Eustachian tube is compromised and the middle ear cavity is not properly ventilated. This lack of ventilation leads to negative pressure and results in a retracted tympanic membrane and secretion of mucous from the tissues through osmosis into the middle ear cavity.[10] Otitis media with effusion can lead to conductive hearing loss which can be persistent or recurrent, variable in degree and affect one or both ears.[11,12] The majority of the current research on the prevalence of OME in children with CLP has been conducted retrospectively with data collected through medical records or surveys.[8,13,14] Four studies have prospectively gathered data on children with CLP and demonstrated a higher prevalence of OME in children with CLP though abnormal tympanometry or abnormal otomicroscopy.[6,12,15,16] However these studies examined children younger than the documented peak prevalence of 4-6 years of age.[8] In the present research, long-term treatment results, complications and the necessity for a tube application in these patients are explored.

## PATIENTS AND METHODS

We retrospectively scanned files of palatoplasty patients operated on for the last 10 years (March 2000 - October 2010). Patients with long-term follow-up of at least five years were considered for inclusion and were invited for final examination and comparison of their results. One hundred and seventy-five patients (84 female, 95 male; median age 8 years; range 4 to 20 years) whose follow-up examinations were done regularly were included.

The age and gender, type of cleft lip-palate, surgeries conducted, ear examinations, Eustachian tube function, middle ear disorders, number of ventilation tube applications, and bilaterality of pathology were noted. Tympanometry was performed to measure Eustachian functions and middle ear pressure.

The type of cleft lip and palate, determined as follows: *(i)* cleft palate and cleft lip together *(ii)* cleft lip only *(iii)* cleft palate only; soft and hard palate involvement; and unilaterality and/or bilaterality, were noted. Ear examinations specific to their state, middle ear pressures, state of tube placement or presence of ventilation tube, kind of treatments rendered in postoperative follow-ups, emerging complications and their final examinations were also recorded and analyzed.

**Statistical analysis**

Chi square and Mann Whitney U tests were used.

## RESULTS

One hundred five patients (58.8%) had a complete cleft lip and palate, while 26 patients (14.5%) had a cleft lip only. Forty-four patients (24.4%) had a cleft of the soft and hard palate (incomplete cleft palate), and four patients (2.3%) had a cleft of the soft palate (submucosal) and cleft lip. One hundred and twenty-one patients (67.6%) had bilateral pathology, 58 patients (32.4%) had unilateral pathology.

On first examination 134 patients (74.3%) had ear effusion with increased vascularization, while 45 patients (25.7%) had a normal eardrum. The Eustachian tubes were not patent in 146 patients (81.6%) whereas and patent in 33 patients (18.4%).

Ventilation tubes were placed once in 73 patients (40.7%); twice in 18 patients (10.1%); and thrice in five patients (2.8%). Tube placement was not needed in 83 patients (46.4%), especially those with cleft lip only.

Middle ear pressure was measured as -200 and higher (considered normal) in 58 patients (32.4%); while it was -200 and lower in 121 patients (67.6%).

On final examination, 89 patients (49.7%) had ear effusion and 11 patients (6.2%) had a ventilation tube. There was tympanic membrane retraction in

**Table 1.** Tympanic membrane pathology and cleft palate-lip type during the first examination

| First examination (eardrum) | Submucosal cleft palate | | Incomplete cleft palate | | Complete cleft palate | | Only cleft lip | | *Total* |
|---|---|---|---|---|---|---|---|---|---|
| | n | % | n | % | n | % | n | % | % |
| Normal | 2 | 4.4 | 10 | 22.2 | 12 | 26.7 | 21 | 46.7 | 100 |
| Pathology (+) | 2 | 1.5 | 34 | 25.4 | 93 | 69.4 | 5 | 3.7 | 100 |
| *Total* | 4 | | 44 | | 105 | | 26 | | |

18 patients (10%), with adhesion in one patient (0.5%). Eleven patients (6.2%) had chronic otitis media (COM), with cholesteatoma detected on follow-up examinations in three patients (1.7%) who were operated on.

Statistically-important relations were found between the pathology of eardrum, function of the Eustachian tube, number of tube applications, middle ear pressure, presence of pathology on final examination, final middle ear pressure and cleft lip-palate type and laterality.

Comparing tympanic membrane pathology and the type of cleft lip-palate during the first examination, a majority of patients with eardrum pathology had complete cleft palate-lip ($p<0.001$); while patients with cleft lip only had normal tympanic membranes and half of the patients with submucous cleft had eardrum pathology; this relationship was significant (Table 1).

Concerning the relationship between Eustachian tube function and cleft palate lip type, the Eustachian tube was not patent in the majority of patients with complete cleft palate; patent in the majority of patients with cleft lip only; and patent in half of the patients with submucosal cleft palate, which was again statistically significant ($p<0.001$) (Table 2).

Patients in need of tube placement were also mostly those with complete cleft lip-palate; the majority of those with more than two tube placements were complete cleft patients, while 11.1% of these patients had incomplete clefts which was statistically important ($p<0.001$) (Table 3).

Seventy percent of patients with middle ear pressure less than -200 had complete clefts, and there was negative pressure in some incomplete cleft patients as well. Middle ear pressure (MEP)

**Table 2.** Eustachian tube function and cleft palate-lip type

| Eustachian tube | Submucosal cleft palate | | Incomplete cleft palate | | Complete cleft palate | | Only cleft lip | | *Total* |
|---|---|---|---|---|---|---|---|---|---|
| | n | % | n | % | n | % | n | % | % |
| Not patent | 2 | 4.4 | 38 | 26 | 100 | 68.5 | 6 | 4.1 | 100 |
| Patent | 2 | 6.1 | 6 | 18.2 | 5 | 15.1 | 20 | 60.6 | 100 |
| *Total* | 4 | | 44 | | 105 | | 26 | | |

**Table 3.** Number of tube application and cleft palate-lip type

| Tube application | Submucosal cleft palate | | Incomplete cleft palate | | Complete cleft palate | | Only cleft lip | | *Total* |
|---|---|---|---|---|---|---|---|---|---|
| | n | % | n | % | n | % | n | % | % |
| 0 | 3 | 3.6 | 20 | 24.1 | 34 | 41 | 26 | 31.3 | 100 |
| 1 | 1 | 1.4 | 21 | 28.8 | 51 | 69.8 | – | – | 100 |
| 2 | 0 | 0 | 2 | 11.1 | 16 | 88.9 | – | – | 100 |
| >2 | 0 | 0 | 1 | 20 | 4 | 80 | – | – | 100 |
| *Total* | 4 | | 44 | | 105 | | 26 | | |

**Table 4.** Middle ear pressure and cleft palate-lip type

| MEP | Submucosal cleft palate | | Incomplete cleft palate | | Complete cleft palate | | Only cleft lip | | *Total* |
|---|---|---|---|---|---|---|---|---|---|
| | n | % | n | % | n | % | n | % | % |
| MEP >200 | 2 | 3.4 | 13 | 22.4 | 20 | 34.5 | 23 | 39.7 | 100 |
| MEP <200 | 2 | 1.7 | 31 | 25.6 | 85 | 70.2 | 3 | 2.5 | 100 |
| *Total* | 4 | | 44 | | 105 | | 26 | | |

MEP: Middle ear pressure.

was greater than 200 in patients with cleft lip only, which was again statistically important (p<0.001) (Table 4).

Comparing tympanic membrane pathology during the last examination and lip-palate pathology, the majority of patients with middle ear pathology were complete cleft palate-lip patients which was statistically important (p<0.001) (Table 5).

Most patients with middle ear pressure less than -200 had complete cleft lip-palate which is statistically important (p<0.001) (Table 6).

Patients with bilateral cleft were diagnosed with higher ear pathology which was again statistically important (p<0.001) (Table 7).

With regard the relationship between number of tube applications and laterality of pathology, more than one tube application was required in patients with bilateral cleft, which was statistically important (p<0.001) (Table 8).

Chronic otitis media was detected in 10.3% patients who had ventilating tubes for effusion in the middle ear. Examination results indicated that 24.7% of these patients still had effusion (p<0.001). In 76.9% of patients with chronic otitis media, there was a tube application history which was statistically important. In 46.3% of patients who had effusion without tube application, the pathology is still present. Normal eardrums were seen in 97.6%, while 2.4% patients had ear effusion (p<0.001).

## DISCUSSION

The relationship between cleft palate, ear disease and hearing loss was already reported long ago.[2-3] It was claimed that otitis media is present in cleft lip-palate patients and hearing loss varies between 0-90%.[17]

**Table 5.** Final examination and cleft palate-lip type

| Ear examination | Submucosal cleft palate | | Incomplete cleft palate | | Complete cleft palate | | Only cleft lip | | *Total* |
|---|---|---|---|---|---|---|---|---|---|
| | n | % | n | % | n | % | n | % | % |
| Pathology (–) | 2 | 2.2 | 24 | 26.7 | 40 | 44.4 | 24 | 26.7 | 100 |
| Pathology (+) | 2 | 1.9 | 20 | 18.9 | 65 | 60.3 | 2 | 18.9 | 100 |
| *Total* | 4 | | 44 | | 105 | | 26 | | |

**Table 6.** Final middle ear pressure and cleft palate-lip type (MEP>200: normal)

| MEP | Submucosal cleft palate | | Incomplete cleft palate | | Complete cleft palate | | Only cleft lip | | *Total* |
|---|---|---|---|---|---|---|---|---|---|
| | n | % | n | % | n | % | n | % | % |
| MEP >200 | 2 | 2.4 | 20 | 23.8 | 38 | 45.2 | 24 | 28.6 | 100 |
| MEP <200 | 2 | 2.1 | 24 | 25.3 | 67 | 70.5 | 2 | 2.1 | 100 |
| *Total* | 4 | | 44 | | 105 | | 26 | | |

MEP: Middle ear pressure.

**Table 7.** First examination and unilateral or bilaterality of pathology

| Ear examination | Unilateral eardrum pathology | Bilateral eardrum pathology | *Total* |
|---|---|---|---|
| | % | % | % |
| Normal | 66.70 | 33.30 | 100 |
| Pathology (+) | 16.90 | 83.10 | |

The failure of Eustachian tube' function may trigger middle ear infection. Recurrent infections eventually impair hearing function. The Eustachian tube has three physiological functions related to the middle ear: aeration, protection from nasopharyngeal secretion and drainage.[18] The function of the tensor veli palatini is to open the Eustachian tube.[19]

The tensor veli palatini and tensor tympani muscles stem from the first branchial arch and are innervated by the same nerve. The concordant functioning of these muscles enables drainage of the middle ear secretion. It is claimed that these muscles enable cleaning of the middle ear by increasing middle ear pressure. Failure of these muscles in cleft palate patients results in collapse of the Eustachian tube.[19]

In addition to dysfunctional tensor veli palatini muscle in patients with cleft palate, a more collapsible Eustachian tube, alterations in skull base, pharyngeal anatomy, and a blocked Eustachian tube orifice at the nasopharyngeal end lead to malfunction of the Eustachian tube.[20-22]

It has not been thoroughly accepted that early and routine tube application may trigger hearing problems in these patients, as tubes are placed for all types of cleft palate-lip patients in many countries. Robson et al.,[14] Seagle et al.[23] have detected abnormal otologic findings in patients who received direct tube application. Tube application may create negative effects on middle ear pressure and hearing ability. In our study, there was a history of tube application in 76.9% of patients with chronic otitis media, which is statistically important.

Most patients diagnosed with chronic otitis media in their last examination had tube application history which indicates the fact that tube application is not such an innocent practice ($p<0.001$) (Table 9).

Otitis media with effusion occurs in the majority of patients with cleft palate. In these patients middle ear disease persists longer and leads to higher incidences of conductive hearing loss and cholesteatoma formation.[24] We found that cholesteatoma was detected in three patients (1.7%).

**Table 8.** Tube application and unilateral or bilaterality of pathology

| Tube application | Unilateral | Bilateral | *Total* |
|---|---|---|---|
| | % | % | % |
| 0 | 59.50 | 40.50 | 100 |
| 1 | 9.60 | 90.40 | 100 |
| 2 | 11.10 | 88.90 | 100 |
| >2 | – | 100 | 100 |

**Table 9.** Final ear examination and tube application

| Ear examination | Ventilation tube (–) | Ventilation tube (+) | *Total* |
|---|---|---|---|
| | % | % | % |
| Normal | 65.20 | 34.80 | 100 |
| Ear effusion | 45.50% | 54.50 | 100 |
| Chronic otitis media | 23.10% | 76.90 | 100 |

In a study conducted in Turkey, patients who were operated during the first two years of life had less middle ear problems compared to those without palatoplasty. In the current study, all patients were operated on, and middle ear problems were mostly seen to recur in patients with complete cleft on long-term follow-ups.[25]

Management strategies for otitis media in cleft palate children vary among different teams internationally. Ventilation tube insertion may occur routinely at the time of palatoplasty or selectively on a separate occasion if symptomatic middle ear disease develops. Some teams feel that the frequency of OME in cleft palate is such as to warrant early tympanostomy tubes and report good audiological outcomes.[26]

The most difficult problem in the follow-up of patients with cleft lip and palate is the decision whether they need routine tube application versus simple follow-up. Our study demonstrated that on long-term follow-ups of complete cleft patients, otitis media was still present. Hence, if eardrum pathology is found during the first examination of these patients, tube application and strict follow-up is required. If there is incomplete cleft in the patient but no eardrum pathology, follow-up alone is sufficient. In submucosal clefts or cleft lip only, tube application is rarely needed. The most important point here is that patients should also be monitored attentively by an otorhinolaryngologist since this is the only way to apply the right treatment, avoid unnecessary tube applications and potential complications.

Recent studies (especially in China) show high rates of middle ear diseases.[27] Some studies recommend placing tubes because of less complications,[28] other studies recommend placing tubes in symptomatic cases.[29] Still other studies recommend tubes for patients with small mastoids.[30] As described, there are still a lot of questions about such children.

We found evidence to suggest that individual cleft types have statistically-significant effects on middle ear disease. Therefore, patients with complete cleft palate require the placement of tube with no question whereas those with cleft lip only, submucous or incomplete cleft palate and unilateral pathology can be followed if their ear examinations are normal. In that way, the ratio of complications stemming from tube application can be lessened.

In conclusion, cleft palate type and laterality of pathology are indicative in treatment. Cleft palate teams need to follow-up all such children beginning at birth and going into adulthood.

**Declaration of conflicting interests**

The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

**Funding**

The authors received no financial support for the research and/or authorship of this article.

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