INTRODUCTION

Cleft palate (CP) is a developmental splitting or gap in the palate. It results in eustachian tube dysfunction and possible otitis media with effusion (OME). OME is defined as non-purulent effusion of the middle ear, with no sign and symptoms of acute infection. The purpose of the present study was to determine the incidence of otitis media with effusion in children who present with cleft palate. Otitis media with effusion is a common cause of hearing impairment in children with factors like, the amount and viscosity of middle ear fluid, duration, and the extent to which middle ear becomes filled with fluid, which influences the degree hearing loss. As the hearing loss is fluctuating in nature it is suggested that its impact may be greater than that of permanent hearing loss. This hearing loss might cause adverse effects on speech and language development leading to learning and behavioral issues. Thus, it is very important to establish the incidence/ frequency of OME in children with cleft palate in our setup which can in turn help formulate policy for early identification of cases of OME with CP and timely treatment and rehabilitation of otologic, audiologic, speech & language impairments and handicaps.

Interestingly 82% of the infants born with cleft lip and palate (CLP) do not have OME at birth, however, they get it within first 06 months of life. Later, OME is seen frequently in children presenting with cleft palate and it also results in chronic otitis media, conductive hearing loss (CHL) and sensorineural hearing loss (SNHL). Existing literature shows great disparity in the frequency of OME among cleft palate children ranging from 7.14% to 76.1%. Considering this disparity in the existing literature this study was conducted in the Department of Otolaryngology, Capital Hospital, Islamabad to obtain local statistics which could provide baseline statistical data about the magnitude of the problem, enabling early diagnosis and intervention to prevent hearing and speech language handicaps.

The objective of this study was to determine the frequency of OME in children in cases which present to us with cleft palate.

MATERIAL & METHODS

In this Cross-sectional study, study population comprised of cases who presented in the Department of Otolaryngology, Capital hospital, Islamabad with Cleft palate over a period of five years from 1st May 2007 to 30th April, 2012. Cases were collected by Non-Probability, Consecutive Sampling technique. Sample size was calculated using 95% confidence level and 5% margin of error, taking an expected frequency of OME to be 7.14% (least among all) among children with cleft palate using the Kish Leslie’s formula for cross sectional studies. One hundred and two (102), cases comprising of both gender, aged between 2 to 12 years, who presented with cleft palate were included in the study. Children who received a course of antibiotic before presentation, diabetics and cases using long term steroids for any underlying condition were excluded from the study.

After approval of institutional ethical research committee study was initiated. A parental informed consent was
taken for data collection for research, following which otoscopy followed by impedance measurements were done in all patients, and presence or absence of otitis media was noted. Data collected was entered and analyzed through SPSS version 20 and statistical tests were applied. Numerical variable i.e., Age was presented by Mean $\pm$SD and categorical variables like Gender and Otitis Media were presented by Frequency and Percentage. Data was stratified for Age and Gender to address effect modifiers. Post-stratification chi-square test was applied taking p value $<$0.05 as significant.

RESULTS

The study population comprised of N=102 cases of cleft palate. Their age ranged from 2 years to 12 years with a mean of 7.71$\pm$3.38 years. Majority of the patients were aged between 10-12 years (47.0%), followed by 2-5 years (27.5%) and 6-9 years (25.5%) Gender distribution showed a male preponderance with 66 males (64.7%) and 36 females (35.5%) with male to female ratio M: F = 1.83:1 (Table 1). In the 102 cases of cleft palate, otitis media with effusion was diagnosed in 74 (72.5%) cases. There was no statistically significant difference in the frequency of OME across age (p=0.988) and gender (p=0.956). This study had limitation since surgical confirmation of OME was not done.

Otitis media with effusion is a common cause of hearing impairment in children. The sequelae of OME can result in chronic otitis media, conductive and sensorineural hearing loss. OME commonly develops within first 06 months of life. However, OME is very common before first birthday i.e., occurs at least once in 90% of CLP population, and occurs in 97% till the age of 2 years. Since wide disparity exists in the existing literature regarding frequency of OME from 7.14% to 76.1%, it was imperative to establish the incidence/frequency of OME in children with cleft palate to obtain basic statistical data about magnitude of problem in our setup. This will in turn help in early diagnosis and intervention and thereby reduce burden of disability.

In a Chinese study, Kwan et al., (2011) reported a mean age of 7.34$\pm$2.95, which is in line with our study (Mean age 7.71$\pm$3.38). As regards presentation in different age groups [10 – 12 years (n=48, 47.1%), 2 -5 years (27.5%) and 6 -9 (25.5%)], almost similar age group distribution was reported by Narayanan et al., (2013) in a study on Indian children. A male preponderance was noted (M : F = 1.83 : 1), with slight variation to ours in studies done by Kwan et al., in a Chinese study (1.66:1), Jajja et al., in a Pakistani study (1.47:1), and Ahmed et al., in an Indian study (2:1). However, an equal gender distribution (1:1) was reported by Viswanathan et al.(2008) in an Indian study. In contrast to our study female preponderance was reported by Khan et al., (1.2:1) in Indian study, Bukhari et al., (1:1.4) and Elahi et al., (1:1.2) in a Pakistani study. OME was diagnosed in 74 (72.5%) children who presented with cleft palate, with no statistically significant difference in the frequency of OME across age (p=0.988) and gender (p=0.956) groups. Our results are in conformity with those of Chen et al., (71.92%), Kwan et al., (76.1%) in Chinese population, Narayanan et al., (68.2%) and D’Mello et al., (75%) in Indian and Yabe et al., (69%) in Japanese population. Much higher frequency (90%) of OME has been reported previously by Lau et al.,, and much lower frequency of 7.14% has been reported by Khan et al., in India. The findings of the present study are in line with those of previous studies in other populations.

**Table 1: Demographics of the study sample**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Participants (n = 102)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Years)</td>
<td>7.71$\pm$3.38 (2 - 12)</td>
</tr>
</tbody>
</table>

- 2 – 5 years: 28 (27.5%)
- 6 – 9 years: 26 (25.5%)
- 10 – 12 years: 48 (47.0%)

**Table 2: Frequency of OME in children with cleft palate**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Participants (n = 102)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>74 (72.5%)</td>
<td>-</td>
</tr>
<tr>
<td>Age Groups</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- 2 – 5 years</td>
<td>20/28 (71.4%)</td>
<td></td>
</tr>
<tr>
<td>- 6 – 9 years</td>
<td>19/26 (73.1%)</td>
<td>0.988</td>
</tr>
<tr>
<td>- 10 – 12 yrs</td>
<td>35/48 (72.9%)</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Male</td>
<td>48/66 (72.7%)</td>
<td>0.956</td>
</tr>
<tr>
<td>- Female</td>
<td>26/36 (72.2%)</td>
<td></td>
</tr>
</tbody>
</table>

**DISCUSSION**

This study comprised of one hundred and two (n=102) children with cleft palate with an age range of 2 - 12 years (Mean of 7.71$\pm$3.38 years). Majority were aged between 10-12 years (47.0%), followed by 2-5 years (27.5%) and 6-9 years (25.5%). Gender distribution showed a male preponderance (M: F = 1.83:1). The frequency of otitis media with effusion was found to be 72.5% (n=74) with no statistically significant difference in the frequency of OME across age (p=0.988) and gender (p=0.956). This study had limitation since surgical confirmation of OME was not done.

Since wide disparity exists in the existing literature regarding frequency of OME from 7.14% to 76.1%, it was imperative to establish the incidence/frequency of OME in children with cleft palate to obtain basic statistical data about magnitude of problem in our setup. This will in turn help in early diagnosis and intervention and thereby reduce burden of disability. A male preponderance was noted (M : F = 1.83 : 1), with slight variation to ours in studies done by Kwan et al., in a Chinese study, Jajja et al., in a Pakistani study, and Ahmed et al., in an Indian study. However, an equal gender distribution (1:1) was reported by Viswanathan et al.(2008) in an Indian study. In contrast to our study female preponderance was reported by Khan et al., (1.2:1) in Indian study, Bukhari et al., (1:1.4) and Elahi et al., (1:1.2) in a Pakistani study. OME was diagnosed in 74 (72.5%) children who presented with cleft palate, with no statistically significant difference in the frequency of OME across age (p=0.988) and gender (p=0.956) groups. Our results are in conformity with those of Chen et al., (71.92%), Kwan et al., (76.1%) in Chinese population, Narayanan et al., (68.2%) and D’Mello et al., (75%) in Indian and Yabe et al., (69%) in Japanese population. Much higher frequency (90%) of OME has been reported previously by Lau et al.,, and much lower frequency of 7.14% has been reported by Khan et al., in India. The findings of the present study are in line with those of previous studies in other populations.
thus appears a frequent finding in children presenting with cleft palate with a frequency of 72.5%, in our setup, therefore routine screening and management of this complication in such patients is very important to reduce the associated morbidity and hearing handicap, which if not catered to at this stage can result in hearing and speech language impairment and handicaps. Due to fluctuating nature of hearing loss associated with OME, the impact may be greater than that of permanent hearing loss and it might lead to other sequelae like adverse effects on speech, language, development, balance and culminating in learning and behavioral problems. This study has clinical relevance to rehabilitation because without knowing the true incidence/frequency of OME with cleft palate in our setup, timely initiation of Eustachian tube rehabilitation (ETR) and other surgical and medical treatment of OME cannot be initiated in a timely manner. The study has also implications for future research, and further study is required on the timing of Eustachian tube rehabilitation (ETR) in cleft palate cases.

CONCLUSION

The incidence of otitis media with effusion was found to be 72.5% in children presenting with cleft palate. There was no statistically significant difference in the frequency of OME across age (p=0.988) and gender (p=0.956) groups. This indicates a huge burden of hearing and speech disabilities which will occur if it is left unidentified and untreated. Therefore timely identification and intervention is essential to reduce the burden hearing and speech disabilities.

REFERENCES


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