

The prevalence of otological manifestations in children with cleft palate

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Abstract

Aims i) To determine the prevalence of the various otological manifestations that occurred in children aged between 1 to 5 years, presenting to the Departments of ENT and Plastic Surgery with overt cleft palate. ii) To evaluate the possibility of the association of the different otological manifestations in relation to the various types of cleft.

Materials and methods A cross sectional study was performed on children with cleft palate presenting to the Otorhinolaryngology and Plastic Surgery OPDs of KLE Society's Dr. Prabhakar Kore Hospital and MRC (KLESP-KH & MRC) (a tertiary referral centre), Belgaum between February 1, 2007 and January 31, 2008. Data was collected by clinical ear examination and evaluation of tympanometry reports.

Results Prevalence of external ear abnormalities in the studied population was 13%. More than 55% of the participants' ears were diagnosed clinically with OME. There was no statistically significant association between type and side of cleft with the presence of OME.

Conclusion External ear deformities are more prevalent in the cleft palate population than the general population. There was a high prevalence of OME in concordance with previous studies. The prevalence of other otopathology was

rare. There was no association of the type or side of palate cleft with OME.

Keywords Cross-sectional studies · Ear diseases · Cleft palate

Introduction

The management of cleft affected children is a multidisciplinary affair with inputs from various specialties. Despite having a well documented relationship of cleft palate with middle ear effusion [1–3], little data exists regarding otopathology in Indian children with cleft palate. We had noticed clinically a high number of children with non-syndromic cleft palate having external ear abnormalities. Existing studies do not document the status of the external ear in children with cleft palate [4–6] even though there have been case reports suggesting presence of external ear deformities in individuals with cleft palate [7]. Therefore, to obtain the relevant data and to systematically document the clinically significant otopathology in the child with cleft palate, a cross sectional study was undertaken.

Materials and methods

A randomized cross-sectional study of 50 children in the age group of 1–5 years with overt cleft palate presenting to the outpatient departments of ENT and Head and Neck Surgery, and the Cleft and Craniofacial surgery unit of the Department of Plastic Surgery at KLES PKH & MRC Belgaum, between February 1, 2007 and January 31, 2008.

Inclusion criteria: i) Presence of cleft palate/cleft lip – palate ii) Age between 1 and 5 years

Exclusion criteria: i) Voluntary consent not obtained from parents/guardian ii) Age <1 year and >5 year iii) Submucous cleft palate

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Data collection: Data was collected using a pre-designed and tested format after obtaining the written informed consent of the parent / guardian. History was taken from the responsible parent or guardian accompanying the child. Clinical examination of the children was performed using standard techniques described in literature including pneumatic otoscopy. A qualified audiologist performed hearing assessment. For the purpose of the study, the response of the child to the clap test was recorded.

Data analysis: Analysis of the data was done using Microsoft Excel 2003 Worksheets. Pearson's Chi Squared test with Yates correction (where appropriate) was used as a test of association when required. An association was considered as significant when the probability of null hypothesis (P) was less than 0.05 (5%).

Ethical issues: Permission was taken from the institutional ethics committee before beginning the data collection. Since the participants of this study included the children and the parents/guardians of the participants, consent was obtained from the parents/guardians.

There remains no agreement as to the appropriate treatment for OME, and no widely accepted protocol exists. The children were advised conservative management and the parents/guardians were explained the option of tympanotomy, the need to wait and watch – and were offered consultation at the Department of Otorhinolaryngology.

Results

Fifty children aged between one to five years were randomly selected among those children with cleft palate attending KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum between February 1, 2007 and January 31, 2008. They were examined for their otological status and the results were analysed.

The mean age of the studied population was 839.56 days on the date of examination. Most of the children (78%) were aged between one to three years (Table 1). There were 33 males (66%) and 17 females (34%) included in the study. The sex ratio of the studied population was M:F = 1.94:1. Majority of the children studied came from the poorer socioeconomic class of 3 (48%) and 4 (34%).

18 of the participants had undergone previous surgery for cleft palate (36%), of whom 17 had undergone repair by two flap palatoplasty. One participant had undergone repair by Langenbeck technique. None of the participants had undergone surgery for correction of velopharyngeal incompetence.

The majority of the participants of the study had cleft lip and palate (80%), and about 20% had cleft palate only. Left cleft palate was commoner than right (1.47:1) among those with cleft lip and palate; whereas, bilateral cleft was more common among those with cleft palate only deformity.

Four children had a history of ear problems, ranging from 3 to 22 months in duration. Only one child had received medical treatment for ear problem, whereas the other three had received no treatment. None of the parents had noticed any hearing difficulty in their children at the time of evaluation.

Thirteen of the 100 ears examined were found to have abnormalities in the external ear (Table 2, Fig. 1). 7 ears (3 right and 4 left) were microtic, making microtia the most common external ear deformity. 3 ears were diagnosed as a bat ear, there were 2 ears in one child with preauricular skin tags, and one external ear was atretic, giving a diagnosis of anotia. There was hard, impacted wax in 33 of 100 ears on initial examination which was removed with the help of a Jobson Horne Probe. The tympanic membrane could not be examined in 4 of 100 ears, a failure rate of otoscopy of 4%. One ear had fungal otitis externa with fungal ball visible in the external auditory canal. One child with acute otitis media had frank mucopurulent discharge in the canal. There was no statistically significant association between the presence of external ear abnormalities and type of cleft in the studied population ($X^2 = 0.766$, $P > 0.1$).

55.2% ears were diagnosed with otitis media with effusion (Table 3). 39 ears (40.6%) were found with a normal appearance of the tympanic membrane. Both ears of one participant were diagnosed with acute otitis media, with active mucopurulent discharge and central perforations of the pars tensa. One ear of another child had a retraction of the pars flaccida, the floor of which could not be made out. This child was diagnosed with chronic otitis media of the squamosal type. One ear had white plaques on the pars tensa, with a scarred appearance suggestive of chronic middle ear disease – was diagnosed as having tympanosclerosis. All ears with OME were found to have dull or bluish tympanic membrane. No ear had air bubbles or an air fluid level.

There was an increasing prevalence of OME among the age groups, with about 45% of the 1 to 2 year group

Table 1 Age distribution of study population

Age (years)	Number
1 to 2	22
2 to 3	17
3 to 4	5
4 to 5	6

Table 2 Prevalence of external ear abnormalities

Abnormality	Rt	Lt	Bilateral
Anotia	1	0	0
Microtia	3	4	3
Bat ear	2	1	1
Preauricular skin tags	1	1	1
Total	7	6	5

affected, and 83% of the 4–5 year group affected with OME. There was no statistically significant association of presence or absence of OME with – age [X^2 (with Yates correction) = 4.296, $P > 0.1$], breastfeeding ($X^2 = 0.188$, $P > 0.5$), method of feeding ($X^2 = 2.57$, $P > 0.5$, X^2 with Yates' correction), position while feeding ($X^2 = 0.94$, $P > 0.5$) side of palate cleft ($X^2 = 0.674$, $P > 0.5$), type of cleft palate ($X^2 = 0.886$; $P > 0.1$, < 0.5) or previous surgery for cleft palate ($X^2 = 0.738$; $P > 0.1$, < 0.5).

All the children were evaluated by clinical free field audiometry by an experienced audiologist; but no child was noted to have a clinically significant hearing loss. Response to clap test was noted as normal in 47 of the 50 children. 3 children had equivocal response on clap test, and were uncooperative for subjective hearing assessment.

Tympanometry was performed in 88 of 100 ears, and the reports were analyzed (Table 3). Tympanometry could not be performed satisfactorily in 12 ears due to problems like microtia/anotia/lack of fit of the transducer. Of the 88 ears evaluated, most of the ears – 57(64.77%) had a B type of curve, 18 (20.5%) ears had A type of curve. As curve was observed in 6 ears, D type of curve in 4 ears, Ad in 2 and C curve in 1 ear. Majority of the ears with Type B curve were diagnosed with OME on clinical examination. There was a statistically significant association between the type of curve on tympanometry and the clinical diagnosis of OME (X^2 (with Yates correction) = 13.8, $P < 0.02$).

Discussion

There is lack of uniformity of the age of participants in previous studies, and there is also a lack of age stratified data available in the literature. Examination methods, principles and ethical issues vary for individuals of different age groups. Therefore, to eliminate these problems, a specific age group of preschool age children (age from 1 to 5 yrs) was selected for this study. In the sample obtained, majority (78%) of individuals were in the age group of one to three years. Possible reason for this age distribution is that – most of the children coming to the OPD were preoperative or postoperative groups for follow-up. It is possible that the skewed data availability is due to this factor influencing studies performed elsewhere also. Studies in other age groups, and in the community – especially in the adult un-operated group are required to complete the picture.

It is challenging to obtain the cooperation or to examine the children of this age group [8]. Hearing assessment is difficult, and subjective tests like pure tone audiometry are not possible in this age group. However, observation of the child's response to auditory stimulus will give a working idea of the auditory status of the child [8]. In this study, hearing assessment was done by a qualified audiologist, and only the response of the child to a loud auditory stimulus (clap test) was noted. Cooperation of the child for use of the Valsalva maneuver is not feasible in this age group. There-

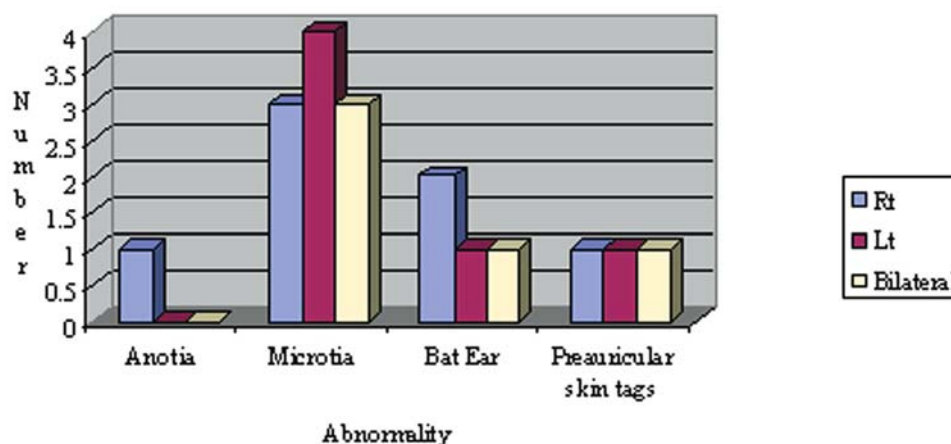


Fig. 1 External ear abnormalities

Table 3 Results of tympanometry

Curve	Number	Percentage
A	18	20.45
As	6	6.82
Ad	2	2.27
B	57	64.77
C	1	1.14
D	4	4.55

fore, pneumatic otoscopy was used as a test of tympanic membrane motility.

The reported prevalence of cleft lip and palate in the community is with the ratio of 2:1 for males versus females. Isolated cleft palate alone is reported to occur more commonly in females [9]. In this study, sex distribution of the participants M:F was 1.94:1. The most prevalent type of cleft in the studied sample was with cleft lip and palate. Therefore the sex distribution is likely due to the predomi-

nance of this type of cleft in the studied sample. This sex distribution does not correlate with that reported by other studies, which have reported a female preponderance [4–6]. The reason for this is likely to be a difference in the sample studied.

Majority of the children in the sample studied (82%) were from the poorer socioeconomic class (class 3 and class 4). Frequent upper respiratory tract infections, crowded living conditions and poor nutrition are problems faced by children in these classes. These factors also play an important role in the development of chronic middle ear disease [10]. It is also likely that repeated surgery and follow-up needed for management of the cleft child is likely to place a significant burden on the family. It would be wiser to choose a conservative method of management of OME in this group than to opt for tympanostomy tube placement which would need frequent follow-up.

There was no significant association found between surgical repair and the absence of OME. Previous studies have documented some beneficial effect of surgery on OME in the short term but equivocal results in the long-term [11–13]. Our study corroborates this finding. However, in our study, the mean postoperative period was 130.9 days, (about 4 months). A longer postoperative period would be needed to document long-term benefits of palate closure on the prevalence of OME.

Only 8% children had a history of ear problems, and among them, only one (2%) had a past history of medical treatment. There was no history of hearing problems obtained from the parents of the participants. Previous studies have documented the absence of clinically significant hearing loss in children with cleft [13–15]. Some investigators have, however, commented on varying degrees of hearing loss found in children with cleft palate [4, 12, 16].

Isolated case reports point to a possibility of association of cleft palate with external ear abnormalities [7]. Some cleft associated syndromes like the hemifacial microsomia syndrome are associated with microtia [17, 18]. In this study, the prevalence of external ear abnormalities was 13%. 7% was due to microtia, 3% was diagnosed as bat ear, and both ears in one child were found with preauricular skin tags. None of the children with external ear abnormalities had been diagnosed with a cleft associated syndrome. Therefore, a high prevalence of external ear deformities is probable in children with non-syndromic cleft. Cleft palate only children are more commonly associated with craniofacial syndromes [19]. However, no association was found between external ear abnormality and the type of cleft. There is a possibility that other craniofacial abnormalities may be present in the child with a non-syndromic cleft because of the common genetic basis proposed for clefting and other craniofacial defects [20, 21]. The parents of children with external ear abnormalities were explained about the availability of surgical corrective techniques.

33% of the ears examined had hard impacted wax in the external auditory canal which was removed with the help of a Jobson Horne probe, after appropriate consent was taken. However, the wax could not be removed in 4 ears due to extremely hard nature of the wax and relatively narrow external auditory canal – mainly in children with microtic ears. This led to an otoscopy failure rate of 4% which is less than 8 to 12% as reported in standard textbooks [22].

The reported prevalence of OME in cleft palate children varies from 20 to 80% in different age groups. OME was the commonest diagnosis in this study, with a prevalence of 55.2% which is in agreement with that previously reported. 40.6% ears were clinically normal. 2% ears were diagnosed with acute otitis media, and 1% had chronic otitis media of the squamous type. The prevalence of acute and chronic otitis media is less than 5 to 6% reported by other investigators [4, 5]. This is probably explained by the fact that the studied sample consisted of children predominantly in the age group of one to three years. All ears with OME had a dull bluish appearance with dull or absent cone of light. Air fluid levels or air bubbles were not seen in any ear, suggesting eustachian tube pathology as the predominant cause of OME in these children. Majority (78%) of ears examined did not have any evidence of retraction of the tympanic membrane.

There was no statistically significant association between the presence of OME and the type or side of cleft. This is in agreement with the findings of other investigators [3, 4, 23]. This suggests that Eustachian tube dysfunction, palatine muscle abnormalities and other problems may occur irrespective of the type or side of cleft.

Tympanometry reports of the studied population were examined and the findings were noted. Tympanometry was performed by the audiologist, and the investigators did not have control over the variables influencing these procedures. However, tympanometry is an objective test with a high degree of interoperator agreement. Therefore, it is unlikely that there would have been any variables confounding the result obtained. This similar prevalence of type B curve and a significant association of the type of tympanogram with the presence of OME as diagnosed clinically confirms the high prevalence of OME in the cleft child. The next common curve was a type A curve (20.5%). Type D curve was seen in 4 ears and As curve in 6 ears. Surprisingly, C curve was noted only in one ear, and a majority of ears were in a normal range of middle ear pressure.

A larger sample size would be required to analyze middle ear pathology other than OME due to their low prevalence. This study confirmed the high prevalence of OME in the Indian cleft palate preschool age population. The novel approach of this study was the documentation of findings of the entire ear, not only the middle ear or tympanic membrane. The association of external ear deformities with non-syndromic cleft individuals has not been reported previously. Further investigation into this aspect would bring out new insights into the etiopathology of cleft.

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