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Does cleft palate repair reduce the incidence of middle ear pathology?

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ABSTRACT

Introduction: In an infant, cleft palate usually affects his/her feeding, speech, eustachian tube, and middle ear physiology. The incidence of otitis media with effusion is particularly very high in the children having cleft palate. Repair of cleft palate is believed to reduce this incidence. **Objective:** This study was conducted to assess the effect of cleft palate repair on middle ear physiology. **Methodology:** The study sample was divided into two groups: Group A consists of patients who are 6 years and older with unrepaired cleft palate and Group B of the patients whose cleft palate were repaired before the age of 2 years and completed at least 4 years after surgery. There were thirty patients in each group. All of them were evaluated clinically, by otoscopy and tympanometry. Clinical assessment included examination of the palate in terms of the presence of scarring, fistula, length of soft palate (visual assessment only), mobility of the soft palate, and speech scoring by Pittsburgh weighted speech score. **Results:** About 21% of operated patients had velopharyngeal incompetence. Thirty-four ears (56.6%) in Group A and 24 ears (40.6%) in Group B had normal otoscopy finding. Normal tympanogram (Type A curve) was found in exactly similar proportion of ears examined in both the groups (20% each). **Conclusion:** Early repair of cleft palate did not have any beneficial effect on middle ear pathology.

Key words: Cleft palate, middle ear, otoscopy, tympanogram

INTRODUCTION

Cleft palate and middle ear dysfunction go hand in hand. The children with cleft palate not being repaired up to advanced age, used to have otitis media with effusion or its further complications more frequently in comparison to those having normal palate.[1,2] Timely repair of cleft palate is proposed to improve middle ear physiology and reduce the incidence of otitis media with effusion.[3] Whereas the opinion is divided in this regard as per the reports published in English literature.[4,5] In developing and underdeveloped countries, children with cleft palate only are usually ignored till a later age as compared to those having complete cleft (cleft of lip and palate). The reasons for this are poverty, illiteracy, and most important being ignorance on the part of parents about its effect on speech and middle ear function. The other reason is their apprehension about anesthesia and surgery. This is evident from the studies involving elderly patients having unrepaired cleft palate.[6-8] On contrary, the children with complete cleft are being subjected to surgery by their parents because of the obvious grotesque appearance of their kids. Otoscopy is a basic primary modality of evaluation of external auditory meatus and the tympanic membrane (TM). This also helps in diagnosing the middle ear pathology. Tympanometry is an objective test to assess middle ear function. It is the gold standard investigation in detecting otitis media with effusion.

The present study assessed the middle ear status in children with cleft palate 4 years after the repair and those who are 6 years and older with unrepaired cleft palate. The study endeavored to evaluate the effect of cleft palate repair on middle ear physiology.

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METHODOLOGY

Approval was obtained from the Institutional Review Board after the study was designed. Written consent of parents of participating children below the age of 12 years and from the patients who are above 12 was received before including them in this study. Patients who did not consent to participate and those who do not fit into the age and follow-up period criteria were excluded from this study.

The study sample was divided into two groups: Group A consists of patients who are 6 years and older with unrepaired cleft palate and Group B was composed of the patients whose cleft palate were repaired before the age of 2 years and completed at least 4 years after surgery. There were thirty patients in each group. All of them were subjected to the evaluation clinically, by otoscopy and tympanometry. Clinical assessment of operated patients included examination of palate in terms of the presence of scarring, fistula, length of soft palate (visual assessment only), mobility of the soft palate, and speech scoring by Pittsburgh weighted speech score (PWSS). Velopharyngeal competence of Group B (operated) patients was evaluated from the PWSS score. Middle ear status of all the patients in both the groups were evaluated by otoscopic examination of TM and tympanogram. The anatomy of TM and evidence of middle ear effusion were looked for during otoscopy.

The type of tympanometric curve obtained followed the Lidén and Jerger's classification.[9,10]

The classification of these curves is:

a. Type A: Suggestive of normal middle ear function
b. Type AS: Suggestive of a less compliant middle ear system
c. Type Ad: Suggestive of highly compliant middle ear system
d. Type B (low and high): Low – suggestive of middle ear dysfunction, high – suggestive of grommet or perforation
e. Type C: Suggestive of eustachian tube dysfunction.

Type A curve is considered normal and all others (Types B, C, As, and Ad) as abnormal. Balakrishnan's classification was used in this study to describe the type of cleft lip and palate.[11]

The patients in Group A were subjected to evaluation at the time of their first visit to our cleft center seeking repair of cleft palate. Assessment of patients of Group B was done during their longest follow-up visit beyond 4 years of their surgery for cleft palate.

The results of both the groups were compared, and statistical analysis was done using Pearson's Chi-square test. A significance level of 5% ($P < 0.05$) was adopted.

RESULTS

A total of sixty patients participated in this study with thirty patients in each group. In Group A, twenty patients were male and ten female, whereas in Group B, both the gender had equal distribution (15 each). Sixty ears were subjected to evaluation in Group A and 59 in Group B (one ear was atretic). The mean age was 16.2 years and 11.7 years in Groups A and B, respectively. The mean follow-up was 9.1 years in Group B with a minimum of 4 and a maximum of 28 years.

Cleft anatomy wise, in Group A, 23 (77%) had Group 2 cleft, 6 (20%) had Group 3 cleft, and only 1 (3%) submucous cleft palate. In Group B, 2 patients (7%) had Group 2 cleft and rest 28 (93%) had Group 3 cleft. In the operated group (Group B), 67% of patients underwent the repair of their cleft palate by two flap technique and 6% by horse shoe flap technique. Intravelar veloplasty and fracturing of pterygoid hamulus were a routine in the repair of cleft palate of all these patients. In eight patients (27%), the technique of palate repair could not be elicited because of failure to retrieve their medical records.

The valving mechanism of the velopharyngeal apparatus of the follow-up patients (Group B) as assessed by PWSS showed 22.7% of them to be competent, 26% borderline competent, 30% borderline incompetent, and 21.3% grossly incompetent [Table 1].

Of the total study sample, 51.3% of ears had pathological otoscopic findings and 48.7% had normal. Otoscopy revealed 34 ears (56.6%) in Group A and 24 ears (40.6%) in Group B to be normal. Retraction of TM was the most common otoscopic finding (32%) with perforation of membrane in 5% of ears. Chronic suppurative otitis media (CSOM) was present in 7.5% of ears and cholesteatoma, the unsafe variety of CSOM in 2.5%. Distribution of different pathological findings in both the groups is shown in Table 2. Comparative distribution of otoscopic findings in both the groups is shown in the bar diagram of Figure 1.

Table 1: Speech score in operated group

Score	Interpretation	Percentage
0	Competent	22.5
1-2	Borderline competent	26
3-6	Borderline incompetent	30
7+	Incompetent	21.5

Overall, 80% of tympanogram were pathological with only 20% being normal (Type A curve). Type B curve was the most common type (46.2%), Type C being 22.6% and As and Ad were 11%. Comparing both the groups [Table 3], normal tympanogram (Type A curve) was found in exactly similar proportion of ears examined in both the groups (20% each). Type B curve was found in 50% of Group A, and 42% of Group B. Figure 2 shows the distribution of various tympanometric curves in both the study groups in the form of bar diagram.

The difference in outcome between two groups in terms of otoscopy and tympanometry was found to be statistically not significant (*P* value was 0.07 and 0.99, respectively).

DISCUSSION

The mean age in unrepaired cleft palate group was found to be 16.2 years. This shows a significant number of cleft palate patients in this part of the world carry their deformity till an advanced age. This finding is similar to that of Ramana *et al.*, Narayanan *et al.*, and Zeng.[6-8] Established velopharyngeal incompetence (VPI) was observed in 21.3% of the patients who underwent early repair of their cleft palate. The finding correlates to those mentioned by Krause *et al.*, Morris, and Riski.[12-14] Hosseinabad *et al.* found the incidence of VPI to be 66.5% in their study.[15] This is significantly high in comparison to our result in terms of speech outcome.

Feniman *et al.* observed 84% of alterations in otoscopy (opacification - 83.4%, visible fluid in the middle ear - 1.5%, the eardrum does not move during inflation - 1.8, and retraction - 0.7) and 65% in tympanometric curves (B/38%, A/36.5%, As/21%, C/4%, and Ad/0.5%) in their study.[16] Zheng *et al.* had abnormal tympanometry in 52% of the ears they examined and eardrum retraction to be the most common otoscopic abnormality (50%).[8] They found unsafe ear disease (cholesteatoma) in 6.6% of the ears. The most common otoscopic finding was a mild retraction of membrane (in 50% of the ears), and Type B curve was the most common tympanogram as observed by Ramana *et al.*[6] Similar was the observation of Gautam *et al.* who found abnormal otoscopy in 66.6% and Type B tympanogram in 72.7% of the ears they evaluated.[17] In their series, Lokman *et al.* also observed a very high percentage of abnormal otoscopic findings and the abnormal tympanogram as well (57.6% and 74.2%, respectively).[18] Otoscopy showing retraction of the pars tensa in 55% and an abnormal tympanogram in 67% of cases was observed by Subramaniam *et al.* in their study with cleft lip and palate patients.[19] The findings of our study are consistent with these reports.

Table 2: Otoscopy finding

Otoscopy findings	Group A (%)	Group B (%)
Normal	34 (56.6)	24 (40.6)
Retracted TM	18 (30)	20 (33.8)
TM perforation	3 (5)	3 (5)
Cholesteatoma	1 (1.6)	2 (3.3)
CSOM	5 (8.3)	4 (6.7)
Wax impaction	0 (0)	3 (5)
Total number of ears evaluated	60	59 (1 ear was atretic)

TM: Tympanic membrane, CSOM: Chronic suppurative otitis media

Table 3: Tympanogram

Type of curve	Group A (%)	Group B (%)
A	12 (20)	12 (20)
As	4 (6.6)	6 (10)
Ad	0 (0)	3 (5)
B	30 (50)	25 (42)
C	14 (23.3)	13 (22)

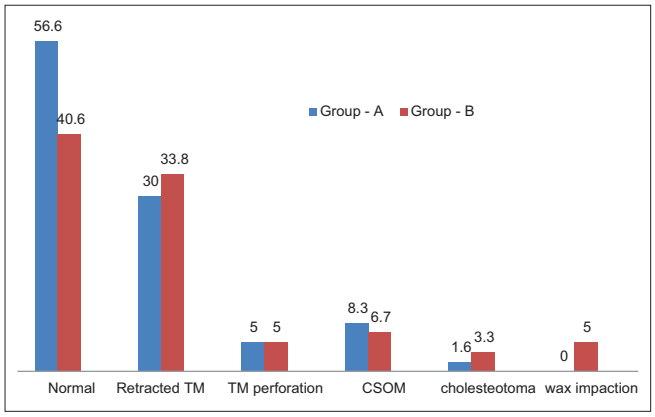

Figure 1: Otoscopic findings (in %)

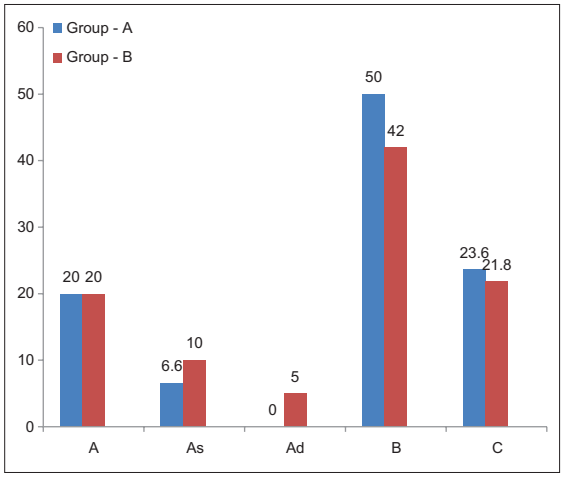

Figure 2: Tympanogram (in %)

Whereas the percentage of abnormal otoscopy and tympanograms in our study is much higher in comparison to those of Narayanan *et al*., Chu and McPherson, and Lima *et al*. all of whom had a lower incidence of these findings.[7,20,21]

Literature is scant on a comparative study of middle ear status of cleft palate patients operated at an early age and those not operated till an advanced age. Tuncbilek found the prevalence of middle ear disease in cleft palate children with "palatoplasty (palate repair before 2 years of age) and no ENT care" to be much lower than the "no palatoplasty, no ENT care" group.[3] Too-Chung also concluded that early closure (before 4 months of age) of the palatal defect reduced middle ear complications significantly.[22] However, the age recommended by the author is too early considering the present global practice and acceptance.

Gopalakrishna *et al*. found cleft palate repair to have no significant effect on the high incidence of serous otitis media in this subset of patients.[23] They included a third subgroup of children having normal palate and observed them to have a lower incidence of serous otitis media in comparison to the children having cleft palate. Similar observation was also made by Lokman *et al*. who found no significant difference between the incidence of middle ear effusion in unrepaired and repaired cleft palates.[18] Lima *et al*. also compared three groups of children - those with cleft palate and low birth weight, cleft palate and normal weight, and the third with normal palate and normal weight.[21] They found no significant difference among these three groups in terms of tympanometry.

The present study compared the status of the middle ear between the group operated at the right age and the group of cleft palate patients not being repaired till an advanced age. We found no significant difference between these two groups. This finding correlates to that of Gopalakrishna and Lokman.

CONCLUSION

Contrary to general belief, this study could not prove the beneficial effect of early cleft palate repair on the eustachian tube function and middle ear pathology. Speech improvement was obvious after cleft palate repair in our study and comparable to the results reported by many cleft and craniofacial centers from across the globe. Small study sample could have influenced the outcome of this study. There could also be other possible factors affecting eustachian tube function apart from cleft palate and tensor veli palatini muscle abnormality in cleft palate patients. Further research in this regard is welcome to establish this fact and guide the cleft surgeons accordingly.

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Conflicts of interest
There are no conflicts of interest.

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