

Original Research Article

Evaluation of Eustachian tube function in patients of cleft palate and effects of palatoplasty on these findings

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ABSTRACT

Background: Isolated cleft palate and cleft palate and cleft lip patients have poor Eustachian tube function which results in hearing impairment that too in the speech formative years. Aim of study was to evaluate tympanometric findings in patient of cleft palate and effect of palatoplasty on both short term and long term postoperatively.

Methods: The subjects consisted of patients attending the cleft lip and palate clinic. This was a combined clinic consisting of department of plastic surgery, department of ENT and department of dental surgery held every month at a tertiary care hospital in Delhi. Study consisted of three groups of patients namely preoperative group, postoperative group and pre-postoperative group.

Results: No significant difference was observed in tympanometric abnormalities in cases of combined cleft lip and palate as compared to isolated cleft palate. After age of 5 months once changes of OME has set in there was no significant change in middle ear findings irrespective of palatal repair.

Conclusions: There is a very high prevalence of otitis media with effusion in these patients. The changes do resolve spontaneously after age of seven, this perhaps is due to combined effect, growth, development and maturity of Eustachian tube and palatal surgery rather than palatal surgery alone.

Keywords: Cleft palate, Eustachian tube dysfunction, Tympanometry

INTRODUCTION

Cleft palate with or without cleft lip is a fairly common congenital anomaly affecting pediatric population. Craniofacial anomalies are classified based on Ritchie's classification into 3 types, that is, group I (comprises of cleft lip only: either left sided, right sided or bilateral), group II (comprises of Cleft of palate alone which can be right sided, left sided or bilateral) and group III (comprises of combined cleft lip and palate, which can be further divided into right sided, left sided or bilateral).

This study included group 2 and group 3 because cleft palate had significant effect on Eustachian tube function which was not the case with isolated cleft lip. Tympanometry is defined as dynamic recording of middle ear impedance with changes in pressure of external ear canal. The technique was sensitive and gave objective evaluation of tympanic membrane integrity, middle ear pressures and Eustachian tube function. Results of tympanometry can be classified according to classification given by Jerger et al into 5 types of

impedance graphs.² The impedance graphs were described as follows:

Type A graph: It represents normal middle ear pressure and normal compliance, with formation of good peak on tympanogram.

Type AS graph: It represents decreased compliance at normal pressure seen in ossicular fixation.

Type AD graph: It represents increased compliance at normal pressure seen in ossicular discontinuity. No identifiable peak on tympanogram.

Type B graph: It represents decreased compliance due to increased middle ear pressure, suggests fluid in middle ear. No peak on tympanogram or flat curve.

Type C graph: It represents increased compliance at negative middle ear pressure seen in Eustachian tube dysfunction. Peak occurs at negative pressure.

Aim of this study was to evaluate the role of impedance audiometry, pre and postoperatively in cleft palate patients with the three primary objectives. First objective was to study the influence of age on tympanometric findings in patients having cleft palate. Secondly was to study tympanometric changes occurring in post-surgical closure of cleft palate and thirdly to determine whether timing of palatoplasty had any bearing on long term tympanometric outcomes.

METHODS

The subjects consisted of patients attending the cleft lip and palate clinic. This was a combined clinic consisting of department of plastic surgery, department of ENT and department of dental surgery held every month at a tertiary care hospital in Delhi. Isolated cleft lip patients were not included in the study as isolated cleft lip doesn't have significant association with middle ear and Eustachian tube problems. The total duration of study was as approximately 1 year which was from October 2010 to October 2011. Period required for analyzing data was about 2 months. Sample size comprised of 63 patients chosen randomly. 63 patients so chosen were divided into three groups. First group had patients who had already undergone cleft palate repair before commencement of study (40 in number) postoperative group. Second group had patients from 10 weeks to 40 weeks (13 in number), having cleft palate but they didn't undergo palatoplasty within stipulated time frame of the study preoperative group. Third group comprised of patients who were planned for surgery and underwent surgery with considerable postoperative period (6 weeks) within the stipulated timeframe of this study (10 in number), pre and postoperative group.

The basis of having three groups

Group 1 analysis: It told us incidence of tympanometric abnormalities in postoperative patients and regression of these abnormalities if any in due course of time.

Group 2 analysis: It told us at what age do the changes in middle ear starts taking place in patients of cleft palate if not surgically corrected.

Group 3 analysis: It comprised of prospective study of patients detected to have tympanometric abnormalities pre operatively and effects of cleft palate repair on these anomalies if any.

Details of patient of cleft palate, cleft type surgery and time since surgery were recorded. Every patient of cleft palate underwent complete ENT examination to ensure that tympanic membrane was intact and ear canal was free of wax, debris. Tympanic membrane status was noted prior to tympanometry. Following ENT examination, patients underwent tympanometry. The pre and post-op group patients had 4 month postoperative time as a standard. The preoperative findings were compared with 4 month postoperative findings for this group.

Statistical analysis

Data so collected was tabulated and analyses statistically. Statistical testing was conducted with the statistical package for the social science system version SPSS 17.0. Distribution of data was not normal so medians (min-max) were used for analysis. Nominal scale variables were described using relative and absolute frequencies (%) and the Chi-square test was used to assess the overall differences between the groups. Proportion test was also used to measure the change in two groups. $P < 0.05$ was considered statistically significant.

RESULTS

Earliest tympanometric abnormalities were seen at age of 4-5 months. At this age normal type A tympanogram changes to B type tympanogram. The type C and type As curves were seen at later age of 9-10 months. Tympanometric abnormalities persisted till age of 6-7 years then tympanogram changed to normal in all cases. Observations were made on preoperative group to determine earliest age at which the changes in tympanometric findings took place. Changes were seen symmetrically in both ears irrespective of side of cleft.

Correlation was done in all 63 patients (126 ears). Table 1 correlates otoscopic findings with tympanometric findings in the given data in all the groups. Otoscopic findings were compared with tympanometric findings. Tympanometric findings were taken as gold standard. Most common finding was dull tympanic membrane with type B curve. Frank bulging tympanic membrane was

seen only in 2 patients. No significant difference was observed in tympanometric abnormalities in cases of combined cleft lip and palate as compared to isolated cleft palate. Palatoplasty seemed to be beneficial in preventing the changes of OME if done early (5 months or even before that). After age of 5 months once changes of OME has set in there is no significant change in middle ear findings irrespective of palatal repair.

Tympanometric findings were correlated with age and findings are given in Table 2 respectively. B type of curve has persisted irrespective of timing of surgery. After the age of six months role of palatoplasty alone in resolution of OME was doubtful.

Table 1: Otosopic findings among the study groups.

Tympanometric findings	Otosopic findings				Total	P value
	Normal tympanic membrane (N=35)	Bulging tympanic membrane (N=2)	Retracted Tympanic membrane (N=36)	Dull tympanic membrane (N=53)		
A	21	0	2	7	30	<0.001
As	4	0	1	2	7	
B	10	2	24	44	80	
C	0	0	9	0	9	
Total	35	2	36	53	126	

Table 2: Correlation of tympanometric findings with age.

Age (in years)	A	B	C	As
0-1	1	9	0	1
1-2	2	17	2	0
2-3	0	6	0	0
3-6	6	21	5	2

DISCUSSION

Ever since Paradise et al have described the universality of OME in cleft palate children way back in early seventies, lots of research has been done in proving this.³ In our study the prevalence of OME (as found out by prevalence of B type of tympanograms) was found in range of 56-65 percent in all 3 groups (Table 2). In pre-postoperative group there was significant increase in number of ears showing type A tympanogram 4 months post-surgery. However in postoperative group longer follow up of cleft palate patients didn't show return to normal tympanogram (at least till 6-7 years of age).

The prevalence of otitis media with effusion in patients of cleft palate was varying in various studies, ranging from 50 to 98 percent. Dhillon showed a striking association of otitis media with effusion is seen with cleft palate.⁴ 50 children were enrolled for the study. In his article 97 percent of children with cleft palate had presence of middle ear effusion as confirmed by myringotomy and micro suctioning. However tympanometry alone could detect fluid in middle ear only in 60 percent of the patients.

64.4 percent prevalence of OME was seen by Zingade et al in his series of 50 children of cleft palate with age group of 1-5 year.⁵

In a large study by Handzic-Cuk et al on 239 patients having cleft palate, type B tympanograms were found in 51.7 percent ears.⁶ Type A tympanograms were found in 41.6 percent ears, while the remainder had type C tympanograms in 6.7 percent. The findings observed in our study are well in agreement with literature data. We could see from literature and our findings that the prevalence of otitis media with effusion in cleft palate patients as detected by tympanometry was around 50-60 percent while after myringotomy and suctioning these can be around 80-90 percent.

In our study tympanometric changes had been recorded in accordance with age of the cleft patient. In the preoperative group it was noted the time at which earliest changes were seen on tympanometry. We can see that till about 4-5 month of age infants had more or less normal appearing tympanogram. After this age the tympanogram showed change to B type. The type As and type C tympanograms were seen less frequently and are noticed after age of 9 months. The prevalence of normal tympanogram (type A) was very less during age of 6 month to age of 7 years after which incidence of type B tympanogram started declining and that of type A started increasing. Therefore it was during the age of speech and language development (age of 8 month to 3 years) that the majority of cleft palate children will have abnormal tympanogram. Young examined cleft palate children

taking into account the various age groups.⁷ His work showed that maximum prevalence of OME was in age group 1-3 years of age after that it fell. After 5 years of age the prevalence fell to 10 percent.

In a study by Cuk et al on 239 cleft palate patients, the frequency of type B tympanogram was 56.3 per cent in the age group one to three months.⁶ The frequency increased to 78.6 per cent at four to six years and decreased to 28.6 per cent at seven to nine years of age and there was a decreasing tendency in the older age groups. In a study by Dhillon it was suggested that presence of fluid was there even before the age of 4 months in cleft palate infants but it was not detected by tympanometry.⁶ The only way to determine fluid was by doing myringotomy and micro suctioning. Hence, according to the author, the fluid was present shortly after birth and will persist till age of 6 years of age.

Feniman et al had also concluded that it was difficult to get a proper tympanometry results by using single frequency probe (226 Hz) in infants below 5 months of age.⁸ Multiple frequency probes have been advocated for very small infants. Therefore single frequency probe was highly unreliable in age below 6 months of age. The tympanometric findings with relation to age of our study were in agreement with those of Cuk et al and Feniman et al.^{6,8}

There was a small but striking observation made in our study. Though the number was very small (two patients), where the patients were operated for cleft palate at the age of five months. The tympanometry in one patient was done four months following the palatoplasty and in other it was done four and a half years after palatoplasty. Both of these cases showed a type A tympanogram throughout the follow up. If this fact was correlated with the patients operated later (after 6 month of age), where the prevalence of B type of curve was seen, one can reasonable conclude that 5 month was the cutoff point where by palatoplasty alone all changes of otitis media with effusion can be prevented.

Effect of palatoplasty on tympanometric outcome was studied in third group (pre-postoperative group) of patients. The patients were followed up for period of 4 months postoperatively and the tympanometric results obtained were compared with preoperative tympanometric findings. The changes were noticed in 3-4 month postoperative period in most of the patients. Longer follow up could not be done in these patients due to paucity of time. Overall there was 15 percent increase in type A tympanogram. And there was 5 percent decrease in type B tympanogram. There was a significant short term benefit of palatoplasty on cleft palate patient.

The long term effect of palatoplasty is studied in group 1 (postoperative group) of 40 children having variable postoperative period ranging from 1 month to 102 months (8.5 years). The tympanometric findings were given in

Table 1. Based on these observations it was observed that palatoplasty doesn't have a significant benefit till about 3 years of postoperative period. After 3 years the incidence of A type of curve increases. This could be the effect of age and maturity of the patient rather than palatoplasty alone.

Our results were in agreement with most of the studies done in this aspect. According to Smith et al palatoplasty was observed to decrease the frequency of middle ear disease and improve hearing compared with untreated cleft palate.⁹ The beneficial effects of palatoplasty on middle ear function were not observed until late in life. Smith et al found that normalization of ET function and resolution of middle ear disease did not occur until a mean of 6 years after palatoplasty. According to RS Dhillon the incidence of OME was only marginally reduced by palatal surgery alone.⁶ The explanation of this lengthy and variable course of improvement in middle ear status was given by Brúlek et al.¹⁰ According to them lengthy and variable time course of this recovery suggested that improvement was not exclusively a result of the surgery performed but was more likely caused by a combination of surgical correction, developmental factors and treatment of middle ear pathology.

The major limitation of the study was timeframe of the study as 1 year was too less to see resolution of tympanometric anomalies irrespective of palatal repair. Other limitation was unavailability of patients younger than 6 months which could have told us beneficial effects of early palatoplasty (before middle ear changes set in).

CONCLUSION

A complete ENT examination is of paramount importance in managing patients suffering from cleft palate. The changes in middle ear start taking place at around 4-5 months of age in cleft palate patient. There is a very high prevalence of otitis media with effusion in these patients. The prevalence of otitis media with effusion is almost hundred percent in these patient especially during the age of speech and language development. The changes do resolve spontaneously after age of seven, this perhaps is due to combined effect of, growth, development and 1 maturity of Eustachian tube and palatal surgery rather than palatal surgery alone. Palatoplasty may have some benefit in preventing the changes of OME in cleft palate patients, if done at the age of 5 month or even before that (before the changes of OME first appear). Palatoplasty alone, after the age of 6 month do not have a significant role in reversal of OME. Pneumatic otoscopy is an important tool in evaluating and managing the patients with cleft palate. If facilities exist patients must undergo tympanometry to assess the middle ear status. Larger studies need to be done regarding role of early palatoplasty before age of 5 month to prevent middle ear effusion. A comparative study needs to be done regarding final hearing outcome in

patients of cleft palate patients with or without myringotomy and grommet insertion.

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