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Tympanogram findings in patients with cleft palates aged six months to seven years

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Abstract. Cleft palate is one of the most common congenital craniofacial deformities. Otitis media with effusion (OME) is a middle ear disease having a prevalence of almost 90% in patients with cleft palates. Tympanometry is a fast, safe, non-invasive, and easy tool for diagnosing middle ear disease qualitatively and quantitatively. Studies have been conducted using tympanometry to detect middle ear conditions in patients with cleft palates, but no research has studied tympanogram findings in patients with cleft palates in Indonesia. The aim of this study is to determine the tympanogram findings in Indonesian children aged six months to seven years with cleft palates. This is a cross-sectional study of 30 patients (17 males and 13 females) with Veau classification of palatal clefts aged six months to seven years (median 26.5 months) who underwent tympanometry examinations using a 226 Hztympanometer. Tympanograms were classified using the Jerger/Liden classification. Examinations of 58 ears found that type B tympanograms occurred most frequently (70.7%). The quantitative values of tympanometry analyzed included SAA (0.1-0.2 cm^3), TPP value (-197.2-(-146.8 daPa)), Vec value (0.5-0.6 cm^3), and gradient value (0.03-0.07 cm^3). Using the Fisher test, a significant relationship was found between age and type of tympanogram ($p = 0.0039$) with the risk of type B and C tympanograms in infants (6-60 months) as high as 4.8 times that of children without cleft palates. The type B tympanogram was most frequently seen in patients with cleft palates aged six months to seven years old with the quantitative values of tympanometry lower than the normal values. Therefore, there was a significant difference in the type of tympanogram seen with age.

1. Introduction

Cleft palate is one of the most common congenital craniofacial deformities worldwide with an incidence of about 0.1-1.1 per 1000 births. It is a palatum formation deformity that occurs at nine weeks of pregnancy and that is classified by anatomy. This deformity is more prevalent among Asian races compared to Caucasian or African races. Cooper *et al.* [1] conducted a literature review of cleft palates in Asia and reported that the prevalence was 1.19 per 1000 births. However, the incidence of cleft palates in Indonesia is unknown [2-4]. The most commonly used classification, especially in ENT Dr. Cipto Mangunkusumo general hospital, is the IOWA classification. However, the IOWA classification classifies cleft lip only. A more representative classification of cleft palates is the Veau

classification which divides cleft palates into four groups. The Plyclinic of Plastic Reconstruction of RSCM Jakarta recorded a total of 13 patients with cleft palates [2-4].

Pathological middle ear disorders often occur in patients with cleft palates. The most common middle ear disorder seen in these patients is otitis media with effusion (OME). The incidence of OME in patients with cleft palates is almost 90% according to some studies. A study by Chen *et al.* [5] of 319 patients with cleft palates in Asia found that the incidence of OME was 71.9%. The reduction in the incidence of OME in Asian patients with cleft palates was caused by the smaller maxillary and mandibular structures in Asian races compared to Caucasians. Although middle ear disorders, especially OME, are often found in patients with cleft palates, ear examinations tend to be performed by surgeons only when ear complaints are made [6-8]. Another middle ear disorder seen in patients with cleft palates is Eustachian tube dysfunction (ETD), especially involving ventilation. ETD results from abnormal insertion of the tensor veli palatini (TVP) and levator veli palatini (LVP) muscles. The abnormal insertion is caused by the musclesthat enter the posterior edge of the hard palate. In 2010, research done by Sheer *et al.* [9] using three-dimensional reconstruction of Eustachian tube (ET) anatomy concluded that in patients with cleft palates, the TVP muscle played a direct role in the ET opening process while the position of the hamular process and the LVP did not affect ET function [10].

Conditions of the middle ear can be evaluated objectively using tympanometry. Tympanograms are one component of a tympanometric examination that can be used as a parameter to assess abnormalities of the middle ear [11-13]. A 226 Hz tympanometer can be used to assess the condition of the middle ear in patients with palatal clefts at the age of six months and over. A226 Hz tympanometer was used by Ramana [14] to examine the audiological findings of patients with unoperated cleft palates. The type B tympanogram is the most common type of tympanogram seen in patients with unoperated cleft palates. However, this study only assessed the type of tympanogram without considering the quantitative values of tympanometry. In Indonesia, research using tympanometry to study middle ear conditions in patients with cleft palates has never been done, so there has been no identification of the type of tympanogram most commonly seen in patients with cleft palates, especially those with unoperated cleft palates. This study will provide an overview of nasal resistance values in patients with unoperated cleft palates. The aim of this study is to determine the characteristics of Indonesian patients with cleft palates based on gender, age, and adenoid hypertrophy by evaluating values for static acoustic admittance (SAA), equivalent ear canal volume (Vec), tympanometric peak pressure (TPP), and gradient. This study also aims to determine the relationship between characteristics of patients with cleft palates aged six months to seven years based on tympanogram findings.

2. Materials and Methods

This cross-sectional study assessed tympanogram findings in patients with cleft palates aged six months to seven years using a 226 Hz tympanometer. The study participants were chosen by purposive sampling and included patients with unoperated cleft palates aged six months to seven years based on physical examination and Veau classification. The parents or guardians of the participants were given an explanation about the research. Otoscopy examinations were performed, and those patients found to have tympanic membrane perforation were excluded from the study. All selected participants underwent tympanometric and flexible nasal endoscopy examinations. The tympanometric printouts were then archived, and the results of the flexible nasal endoscopy examinations were documented.

3. Results and Discussion

3.1 Results

This research included 30 patients with cleft palates from the Polyclinic of Plastic Reconstruction Sub Division, Department of Ear, Nose, and Throat-Head and Neck Faculty Medicine of Universitas Indonesia, the Social Action Foundation in *Hayandra Peduli*, the *Obor Berkat* Indonesia Foundation, the Bina Estetika Clinic, and the *Pembina Penderita Celah Bibir dan Langit-Langit* Foundation

Bandung. The number of male participants (17) was greater than the number of female participants (13), and the median age of all participants was 26.5 months. Veau II classification was the most common finding, occurring in 14 participants. There were eight participants who had adenoid hypertrophy. Ear assessments were performed, and 58 out of 60 ears fulfilled the study criteria. The type B tympanogram was the most common type of tympanogram found and represented 70.7% of the tympanogram findings. This research also analyzed quantitative values of tympanometry consisting of SAA, Vec, TPP, and gradient. There were decreases in all of the quantitative values of tympanometry for the participants compared with the quantitative values of children without cleft palates (Table 1).

Bivariate analysis was performed to identify the relationship between the type of tympanogram and the type of cleft palate, gender, adenoid hypertrophy, and age. The age variable in this study was categorized by referring to the age limit under five years old, which is the most common age for middle ear disorders in patients with cleft palates.This research also analyzed tympanogram type based on an operational definition. An abnormal finding was obtained when a type of tympanogram other than type A was found. In such cases, the type of tympanogram was divided into two groups, type A and type B+C. This analysis was also performed on the variables of the cleft palate types, and as a result, the participant groups were divided into Veau III+IV and Veau I+II groups based on the assumption that the Veau III+IV group had larger palatal defects (Table 2).

The result of Fisher's comparative test showed that there was a statistically significant difference in age with different tympanogram findings ($p < 0.05$). The range of confidence interval (CI) did not cross1.0, so it can be concluded that age is a risk factor. The risk factor of developing type B and C tympanograms in patients aged ≤5 years (6-60 months) was 4.76 times that of patients without cleft palates with 95% CI (1.14-19.96).There was no statistically significant difference between the variables of cleft palate type, gender, and adenoid hypertrophy.

Table 1. Characteristics of SAA, TPP, Vec, and gradient values (n=58)

Variable	Mean (95% CI)
SAA	0.157 (0.107-0.207)
TPP	-171.98 (-197.21-(-146.76))
Vec	0.543 (0.488-0.598)
Gradient	0.051 (0.030-0.072)

Table 2. Bivariate analysis of cleft palate type, age, gender, and adenoid hypertrophy including variables of the types of tympanograms

Variable		Type of Tympanogram					95% CI	
		type B+C		type A		P	Crude	Min	Max
		F	%	f	%		OR		
Cleft Palate Type	Veau III+IV	11	91.7	1	8.30	0.427	3.457	0.400	29.867
	Veau I+II	35	76.0	11	23.9	Ref			
Gender	Male	26	78.8	7	21.2	0.910	0.929	0.256	3.364
	Female	20	80.0	5	20.0	Ref			
Adenoid Hypertrophy	Exist	13	81.3	3	18.8	1.000	1.182	0.276	5.067
	Do not exist	33	78.6	9	21.4	Ref			
Age	≤5 years	40	85.1	7	14.9	0.039	4.762	1.136	19.957
	>5 years	6	54.5	5	45.5	Ref			

3.2 Discussion

This study involved 30 participants with more male participants than female. Cooper *et al.* [1] found that the prevalence of cleft palate was greater in males than in females but that the inter-ethnic prevalence in Asia could not be accurately analyzed because of the inconsistency of available data. In previous research about cleft palates, there was no uniformity in the cleft palate classification system, and therefore, no comparison can be made between this study, which found that the Veau II classification was the most common, and previous studies. Further, there were more participants under five years old in this study (24 samples) than in previous studies. Khayat [15] stated that the adenoid reached its largest size at the age of seven years old. This might have contributed to the difficulty of obtaining samples with adenoid hypertrophy (8 samples) because the adenoid has not yet reached its largest size. The incidence of OME was almost 90%in patients with cleft palates, while the incidence of OME was 71.9% for Asian patients. The sensitivity and specificity of type B tympanograms in diagnosing OME is high enough to allow type B tympanograms to be considered the most common indicator of OME in patients with cleft palates [16].

The previous studies of cleft palates only analyzed the type of tympanogram without considering the normative values of tympanometry. In this study, the proportion of type B and C tympanograms was 85.1% at under five years old and 54.5% above five years (Table 2). This is consistent with Zheng's17research which found fewer abnormal tympanograms after age six. Zheng17associated age with tympanogram findings in 552 patients with cleft palates, and classified type A tympanograms as normal and the other types of tympanograms (type B, C, Ad, and As) as abnormal. Zheng [17], found that abnormal tympanogram findings reached 34% under 1 year old and increased to 65% for children under 5 years old, 41% for children 6 years old, and 30% for children 8 to 11 years old. By six years old, there is maturation of the ET, maturation of neuromuscular control of the soft palate, and decreased frequency of upper respiratory tract infections.

Palatal defects play a role in the occurrence of OME with the assumption that the magnitude of the defect may increase the occurrence of abnormalities in the middle ear. In a narrative review of the pathophysiology of OME in patients with cleft palate, Kuo [18] suggested that the occurrence of OME is associated with velopharyngeal insufficiency caused by a palatal defect resulting in an abnormal reflux of food from the mouth entering the nasopharyngeal area. The prolonged acid exposure from reflux results in inflammation and edema of the tubal orifices of the nasopharynx. This pathophysiology is assumed to explain the role of the palatal defect magnitude in the increased incidence of OME in patients with cleft palates. However, the current studies of OME in patients with cleft palates have not been able to show clear evidence of the association between the magnitude of the palatal defect and the occurrence of middle ear abnormalities. Therefore, it cannot be concluded clinically that the magnitude of the palatal defect can be used as an indicator to determine the presence of middle ear abnormalities in patients with cleft palates. We did not observe an association between adenoid hypertrophy and tympanometry findings in our study. This is in line with the findings in a previous study by Toros [19] on 95 children without cleft palates but with adenoid hypertrophy. There has been no association found between gender and tympanometry findings, despite the overall lower risk of OME in females due to a larger volume of mastoid air cells according to Stanger as cited by Restuti [20]. The characteristics of the participants can be found in all ages but are more frequently found in children under the age of one (6-12 months), with the frequency in males being higher than that in females and only eight participants having adenoid hypertrophy. In the assessment of the quantitative values of tympanometry, there was a decrease in all values, SAA, TPP, Vec, and gradient, compared with the normal quantitative values of tympanometry. The age variable was the only statistically significant variable for the type of tympanogram, with a risk factor for an abnormal tympanogram finding 4.8 times greater in children under five years. This research is preliminary. Further research must be done to determine the prevalence of OME in patients with cleft palates in Indonesia and to collect basic data for multi-center research.

4. Conclusion

The type B tympanogram is the most frequent type of tympanogram finding in Indonesian patients with cleft palates aged six months to seven years, with the quantitative value of tympanometry being lower than the normal value. There is a significant association between age and type of tympanogram with children under five years old diagnosed with cleft palates having a 4.8 times greater risk of having abnormal tympanogram findings.

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