



(RESEARCH ARTICLE)



The Compatibility of Preoperative Temporal Bone CT Scan Interpretation and Intraoperative Findings in Chronic Suppurative Otitis Media at Dr. Zainoel Abidin Hospital Banda Aceh

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Abstract

Introduction: Chronic suppurative otitis media (CSOM) is middle ear and mastoid infection that causes hearing loss globally. Computed Tomography (CT)-Scan of the temporal bone is useful for assessing the pathogenesis of the disease and estimating the prognosis. In addition, evaluation of CT-Scan in patients with CSOM is useful for selecting the appropriate surgical procedure to minimize post-surgical complications. This study aims to assess the suitability of temporal CT-Scan interpretation to intraoperative findings in CSOM patients.

Methods: This is an observational study with cross-sectional design conducted at the Dr. Zainoel Abidin General Hospital, Banda Aceh. The components of suitability evaluation include cholesteatoma, scutum erosion, ossicles, tegmen tympani, facial canal, posterior wall and sigmoid sinus wall. The interpretation suitability of temporal CT-Scan and intraoperative findings was performed using the Kappa test.

Results: A total of 18 CSOM patients were involved in this study with a mean age of 32.44 years and dominated by the safe type with a percentage of 55.6%. Interpretation of ossicular erosion based on temporal CT scan has very strong suitability with the intraoperative findings with $k=0.88$ followed by posterior wall erosion ($k=0.684$), scutum erosion ($k=0.679$), tympanic tegmen erosion ($k=0.455$) and facial canal erosion ($k=0.341$). The findings of cholesteatoma and erosion of the sigmoid sinus wall had a very low suitability ($k<0.001$).

Conclusion: Temporal CT scan in CSOM patients has relatively good suitability with intraoperative findings in evaluating erosion of the ossicles, posterior wall, and scutum. Another examination modality is necessary to assess and improve the accuracy of disease pathogenesis.

Keywords: CSOM; Temporal CT scan; Intraoperative findings; Cholesteatoma

1. Introduction

Chronic suppurative otitis media (CSOM) is an infectious disease of the middle ear and mastoid mucosa and is very common in developing countries [1]. Data from the World Health Organization (WHO) about 65-330 million people in the world suffer from CSOM accompanied by otorrhoea, 60% of them (39-200 million) suffer from significant hearing loss. WHO also estimates that 28,000 deaths annually are due to complications of otitis media and a disease burden of more than 2 million DALYs (Disability Adjusted Life Years) [2,3]. The prevalence of CSOM in developing countries such as Malaysia, the Philippines, Thailand and others is still relatively high, amount 2-4% compared to developed countries

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in Europe such as England, Denmark, Finland and others, which is around 0.4% which is relatively low. More than 90% of the burden is borne by countries in the Southeast Asia and West Pacific region, Africa, and some ethnic minorities on the edge of the Pacific. CSOM is rare in America, Europe, and the Middle East, and Australia. The incidence of CSOM is higher in developing countries due to low socioeconomic standards, poor nutrition and lack of health education [2,4,5]. CSOM is divided into 2 types, safe type (benign) and dangerous type (malignant). In safetytype of CSOM, surgical therapy is indicated if the perforation persists for more than 3 months and causes clinical signs such as recurrent or persistent otorrhea and hearing loss to progressive hearing loss. Dangerous type CSOM is CSOM containing cholesteatoma [6–8]. One of the things that must be prepared before CSOM surgery is the mastoid HRCT of the coronal axial section without contrast with a thickness of 0.6 mm. Temporal bone CT scan is not the main modality in the diagnosis of CSOM, but it is useful for preoperative evaluation in planning surgical action. CT Scan examination can be in the form of a regular resolution CT Scan and a High Resolution CT Scan (HRCT) [9–11]. Currently, conventional resolution CT scanning is not used because it has limitations in visualizing microscopic anatomical structures of the ear such as the facial nerve canal, tegmen tympani, lateral semicircular canal, sigmoid sinus wall, and external ear bones, which are needed in mapping anatomical structures at the time of ear surgery [12]. The structure of the middle ear is very small and delicate, this has led to the implementation of HRCT examination because it is able to provide an image of a thinner section with a higher resolution than the usual resolution CT scan so that the anatomical picture and the extent of the disease are clearer [8,13,14].

This study was conducted to analyze how the results of the interpretation of the preoperative temporal bone CT scan and intraoperative findings in CSOM can be used as a guide for operators in choosing the surgery to be performed, evaluating the severity of the disease and reducing the risk of postoperative complications.

2. Methods

An observational analytic study with a cross sectional design. The population is CSOM patients who receive treatment at the ENT-KL RSUDZA polyclinic. The sample is CSOM patients who meet the inclusion criteria. Samples were taken for 6 months from November 2020 to April 2021. Patients with a diagnosis of CSOM and will undergo middle ear and mastoid surgery; CSOM who underwent preoperative CT-Scan examination of the temporal bone; and have a complete medical record containing all the data required for the study included in this study.

All data were processed using a computer and processed with statistical package for social science (SPSS) software for windows version 20. The suitability analysis of this study was carried out using the nominal variable suitability test using the McNemar test followed by the Kappa test. If the result of Mc.Nemar's calculation is less than 0.05 then there is a difference between the interpretation of preoperative temporal bone CT Scan and intraoperative findings in CSOM, whereas if it is more than 0.05 then there is no difference between the interpretation of preoperative temporal bone CT Scan and intraoperative findings in CSOM. Kappa value guidelines are used if the kappa value 0.8-1 means there is a very strong suitability, the kappa value 0.6-0.8 means there is a strong suitability, the kappa value 0.4 -0.6 means there is a conformity medium, kappa value between 0.2-0.4 means low suitability, and kappa value below 0.2 means very low suitability.

3. Result

Table 1 Characteristics of study subjects

Characteristics	n	%
Age group		
< 18 y.o.	4	22.2
≥ 18 y.o.	14	77.8
Sex		
Male	9	50
Female	9	50
CSOM		
Benign	10	55.6
Maligna	8	44.4

Mean age (mean ± SD): 32,44 ± 14,71

Most of the study subjects were dominated by the adult age group (77.8%) with a mean age of 32.44 years. The proportion of male and female sex in this study was the same with a ratio of 1:1. There are more safe type CSOM patients than dangerous type CSOM with a percentage of 55.6% (**Table 1**).

A total of 8 CSOM patients, based on CT-Scan, who had cholesteatoma were also proven to have cholesteatoma based on intraoperative findings with a prevalence of 44.4%. Based on the results of the Kappa test, it is known that the cholesteatoma findings between the CT-Scan examination of the temporal bone and the intraoperative findings show a value of <0.001 which can be interpreted as having a very low concordance (**Table 2**).

Table 2 Analysis the concordance of cholesteatoma findings between preoperative temporal bone CT scan and intraoperative findings

Cholesteatoma		Intraoperative	
		Pos	Neg
CT Temporal	Pos	8 (44.4)	10 (55.6)
	Neg	0	0

Kappa: < 0,001; McNemar-Bowker test: -

A total of 3 CSOM patients, based on CT-Scan, who had scutal erosions were also proven to have scutal erosions based on intraoperative findings with a prevalence of 16.7%. In addition, as many as 13 CSOM patients based on CT-Scan no scutal erosions were also proven not to have scutal erosions based on intraoperative findings with a prevalence of 72.7%. Based on the results of the Kappa test, it is known that the concordance of the findings of scutal erosion between the CT-Scan examination of the temporal bone and the intraoperative findings shows a value of 0.679 which can be interpreted as having a strong congruence (**Table 3**).

Table 3 Analysis the suitability of scutal erosion findings between preoperative temporal bone CT-Scan and intraoperative findings

		Scutum Erosion	Intraoperative	
			Pos	Neg
CT Temporal	Pos		3 (16.7)	1 (5.6)
	Neg		1 (5.6)	13 (72.7)

Kappa: 0.679 SE (0.210); McNemar test: 1,000

A total of 9 CSOM patients, based on CT-Scan, who had ossicular erosions were also proven to have ossicular erosions based on intraoperative findings with a prevalence of 50%. In addition, as many as 8 CSOM patients who based on CT-Scan did not have ossicular erosions were also proven not to have ossicular erosions based on intraoperative findings with a prevalence of 44.4%. Based on the results of the Kappa test, it is known that the correlation between the findings of ossicular erosions between the CT-Scan examination of the temporal bone and the intraoperative findings shows a value of 0.889 which can be interpreted as having a very strong concordance (**Table 4**).

Table 4 Analysis of the concordance of the findings of ossicular erosion between the preoperative CT-Scan of the temporal bone and the intraoperative findings

Ossicle Erosion		Intraoperative	
		Pos	Neg
CT Temporal	Pos	9 (50)	0
	Neg	1 (5.6)	8 (44.4)

Kappa: 0.889 SE (0.107); McNemar test: 1,000

A total of 1 CSOM patient, based on CT-Scan, who had tympanic tegmen erosion was also proven to have tympanic tegmen erosion based on intraoperative findings with a prevalence of 5.6%. In addition, 15 CSOM patients who based

on CT-Scan showed no tympanic tegmen erosion were also proven to have no tympanic tegmen erosion based on intraoperative findings with a prevalence of 83.3%. Based on the results of the Kappa test, it was found that the correlation between the findings of tympanic tegmen erosion between the CT-Scan of the temporal bone and the intraoperative findings showed a value of 0.455 which could be interpreted as having a moderate agreement (**Table 5**).

Table 5 Analysis of the suitability of the findings of tympanic tegmen erosion between preoperative temporal bone CT scan and intraoperative findings

Tympanic Tegmen Erosion		Intraoperative	
		Pos	Neg
CT Temporal	Pos	1 (5.6)	2 (11.1)
	Neg	0	15 (83.3)

Kappa: 0.455 SE (0.305); McNemar test: 0.5

A total of 1 CSOM patient, based on CT-Scan, who had facial canal erosion was also proven to have facial canal erosion based on intraoperative findings with a prevalence of 5.6%. In addition, as many as 14 CSOM patients based on CT-Scan no facial canal erosion were also proven to have no facial canal erosion based on intraoperative findings with a prevalence of 77.8%. Based on the results of the Kappa test, it was found that the conformity of the findings of facial canal erosion between the CT-Scan of the temporal bone and the intraoperative findings showed a value of 0.341 which could be interpreted as having low concordance (Table 6).

Table 6 Analysis of the suitability of the findings of facial canal erosion between preoperative CT-Scan examination of the temporal bone and intraoperative findings

Facial canal erosion		Intraoperative	
		Pos	Neg
CT Temporal	Pos	1 (5.6)	3 (16.7)
	Neg	0	14 (77.8)

Kappa: 0.341; SE (0.261); McNemar test: 0.25

A total of 3 CSOM patients, based on CT-Scan, who had posterior wall erosion were also proven to have posterior wall erosion based on intraoperative findings with a prevalence of 16.7%. In addition, as many as 13 CSOM patients based on CT-Scan no posterior wall erosion were also proven not to have posterior wall erosion based on intraoperative findings with a prevalence of 72.7%. Based on the results of the Kappa test, it is known that the correlation between the findings of posterior wall erosion between the CT-Scan examination of the temporal bone and the intraoperative findings shows a value of 0.684 which can be interpreted as having a strong agreement (**Table 7**).

Table 7 Analysis of the concordance of posterior wall erosion findings between preoperative temporal bone CT scan and intraoperative findings

Posterior Wall Erosion		Intraoperative		Total
		Pos	Neg	
CT Temporal	Pos	3 (16.7)	2 (11.1)	5 (27.8)
	Neg	0	13 (72.2)	13 (72.2)

Kappa: 0.684 SE (0.200); McNemar test: 0.500

There were no CSOM patients, based on CT-Scan, who had sigmoid sinus erosion also proven to have sigmoid sinus erosion based on intraoperative findings (**Table 8**).

Table 8 Analysis of the concordance of findings of sigmoid sinus erosion between preoperative temporal bone CT scan and intraoperative findings

Sigmoid Sinus Erosion		Intraoperative		Total
		Pos	Neg	
CT Temporal	Pos	0	2 (11.1)	2 (11.1)
	Neg	0	16 (88.9)	16 (88.9)

Kappa: <0,001; McNemar test: -

However, as many as 16 CSOM patients, based on CT-Scan, no sigmoid sinus erosion were also proven not to have sigmoid sinus erosion based on intraoperative findings with a prevalence of 88.9%. Based on the results of the Kappa test, it is known that the concordance of the findings of sigmoid sinus erosion between the CT-Scan of the temporal bone and the intraoperative findings shows a value of <0.001 which can be interpreted as having a very low concordance (**Table 8**).

4. Discussion

A total of 18 study subjects who met the inclusion criteria were included in this study. Most of the study subjects were dominated by the adult age group (77.8%) with a mean age of 32.44 years. There are more safe type CSOM patients than hazard type CSOM with a percentage of 55.6%. Cholesteatoma is a cystic lesion formed by abnormal accumulation of keratinized squamous epithelium in the middle ear, epitympanum, mastoid cavity, petrous apex, or temporal bone [15].

The main pathogenesis theories of cholesteatoma include; invagination, invasion or migration of the epithelium, squamous metaplasia, and ingrowth of papillaries resulting from hyperplasia. The bluestone classification further classifies cholesteatoma based on its location and invasion [16,17]. Classification consists of: Stage 1: cholesteatoma confined to the middle ear (hypoepitympanum and mesoepitympanum), without erosion of the ossicular chain; Stage 2: stage 1 with erosion of one or more ossicles; Stage 3: involves the middle ear and mastoid gas cell system without erosion of the auditory ossicles; Stage 4: same as stage 3 but with erosion of one or more ossicles; Stage 5: extensive cholesteatoma of the middle ear, mastoid, and other parts of the temporal bone, whose extent is not fully accessible for surgery (eg, medial to the labyrinth), with one or more ossicles involved with or without a labyrinthine fistula; Stage 6 is the same as stage 5, but the cholesteatoma extends beyond the temporal bone [15,18].

4.1. Analysis the concordance of cholesteatoma findings between preoperative temporal bone CT scan and intraoperative findings

Based on temporal bone CT scan, all patients in this study had CSOM with cholesteatoma (100%). On intraoperative findings, 44.4% of patients had proven cholesteatoma and intraoperative findings without cholesteatoma in 55.6% of patients. The Kappa test showed a very low concordance between the findings of cholesteatoma between temporal and intraoperative CT scans. This may be due to controversy regarding the ability of preoperative CT scanning to determine whether the soft tissue density in the middle ear or mastoid cells is a cholesteatoma, granulation tissue or mucoid secretion. Currently, soft tissue erosion of adjacent bony structures is generally interpreted as an indication of a cholesteatoma. Other studies have also identified cholesteatoma on the basis of the destruction of bone in the surrounding tissue. CT scan has not been able to distinguish cholesteatoma from other tissues such as granulation tissue, fibrous connective tissue, mucosal edema, and fluid effusion. Cholesteatoma can damage bone so that the findings of ossicular erosion, tympanic tegmen erosion, labyrinth erosion, and wall erosion will be very helpful in indicating the presence of cholesteatoma [16].

4.2. Analysis the suitability of scutum erosion findings between preoperative temporal bone CT-Scan and intraoperative findings

The results of the CT scan of the temporal bone in this study, showed as many as 4 patients with CSOM with a picture of scutum erosion, but only 3 patients who were proven to have scutum erosion based on intraoperative findings. The rest had no scutum erosions on CT scan, there were about 13 patients who also proved to have no scutum erosions based on intraoperative findings. This study showed that there was a strong concordance between the findings of scutum erosions on temporal and intraoperative CT scans. HRCT has a sensitivity and specificity of 95% and 100%, respectively, in detecting scutum erosions. The false-negative findings seen in the study results were associated with soft tissue density in the mesotympanum that precluded visualization. A similar study has also reported high sensitivity and

specificity values, explaining that scutum involvement is most commonly seen at the attic stage early in the disease course and is most commonly associated with pars flaccida cholesteatoma [4,19].

4.3. Analysis the concordance of the findings of ossicular erosion between the preoperative CT-Scan of the temporal bone and the intraoperative findings

A total of 9 CSOM patients had ossicular erosions on temporal CT examination and all of them were proven to have ossicular erosions based on intraoperative findings. In addition, as many as 9 CSOM patients based on CT-Scan did not have ossicular erosion, but only 8 patients were proven to have no ossicular erosion based on intraoperative findings. The concordance of the findings of ossicular erosion between the CT-Scan of the temporal bone and the intraoperative findings in this study was included in the very strong category. However, in this study, erosion of the ossicles was not described separately into malleus, incus, and stapes erosions but as erosion of a single ossicle chain.

O'Reilly et al reported that a CT scan can show the auditory ossicles clearly in 50% of cases. Mafee et al succeeded in defining the ossicular condition in 89% of cases. Tatlipinar et al correctly determined the condition of the ossicular chain in the rate of 85.1% of cases. There are still differences in the interpretation ability from previous studies, but the interpretation of CT Scan can be more precise if the radiologist knows about the patient's clinical condition. In addition, results will improve if the otolaryngologist and radiologist work together in interpreting CT images [16]

In the study of Irwan et al, ossicular erosion occurred in 141 patients (55.95%). Austin- Kartush type D is the most numerous. Abdullah et al reported that the most common finding of ossicular damage was incus damage (87%). Varshney et al reported 85% of the intraoperative findings of CSOM with ossicular damage and 25% were Austin-Kardish type D [15].

The literature reports varying degrees of concordance with preoperative ossicular evaluation on CT scans with intraoperative findings. In our study, these ossicles or ossicles were not assessed separately but as a single ossicular chain [16]. This study used a 0.6 mm CT scan of the temporal bone so that the concordance between CT and intraoperative findings was quite high. However there was 1 false negative case finding due to the partial volume effect found. This false negative result may be due to the partial volume effect and however can be improved by using a finer CT scan section [20,21].

4.4. Analysis the suitability of findings of tympanic tegmen erosion between preoperative temporal bone CT scan and intraoperative findings

Temporal bone CT scan in this study showed tympanic tegmen erosion in 3 CSOM patients, but only 1 CSOM patient was proven to have tympanic tegmen erosion based on intraoperative findings, while two cases were false positive. A total of 15 CSOM patients who based on CT-Scan did not have tympanic tegmen erosion, all of them were proven to have no tympanic tegmen erosion based on intraoperative findings with a prevalence of 83.3%. Kappa test showed the concordance of the findings of tympanic tegmen erosion between the temporal and intraoperative CT-Scan examination into the moderate group. Zia Ng Hui et al also reported a relatively higher k value of 0.76. This discrepancy may be due to the difference in the time interval between surgery and the CT scan as the disease has progressed. In Agarwal's study, sensitivity was lacking (38.9%) because not all tympanic tegmen erosions were identified correctly on CT scan but specificity was high [14].

4.5. Analysis the suitability of findings of facial canal erosion between preoperative CT-Scan examination of the temporal bone and intraoperative findings

Temporal bone CT scan of 4 CSOM patients who had facial canal erosions, only 1 CSOM patient was proven to have facial canal erosions based on intraoperative findings (5.6%). In addition, as many as 14 CSOM patients based on CT-Scan no facial canal erosion were also proven to have no facial canal erosion based on intraoperative findings with a prevalence of 77.8%. Based on the results of the Kappa test, the concordance of the findings of facial canal erosion between the temporal CT scan and the intraoperative findings was low.

The study of Karki et al reported that the extent of erosion to the facial canal was observed on CT scan in 5 patients (7.69%) and this finding was appropriate and appropriate when observed during surgery. Mafee et al said CT was very accurate in the diagnosis of facial canal erosion. In his study, erosion of the horizontal section of the facial canal was correctly diagnosed in three out of four cases with a sensitivity of 100% and a specificity of 75% [21]

Mardassi et al reported that CT had poor sensitivity of 60% and was mostly seen in pars tensa cholesteatoma. In Sirigiri et al, O'Reilly et al, and Jackler et al, CT was able to diagnose dehiscence in the horizontal section of the facial canal with

a sensitivity of 60% and specificity of 90%. Some of these results are in accordance with the results in this study where in determining positive cases of facial canal erosion there were still 3 false positive cases indicating low sensitivity, but successfully predicting correctly all cases of negative facial canal erosion which indicated high specificity [21].

4.6. Analysis of the concordance of posterior wall erosion findings between preoperative temporal bone CT scan and intraoperative findings

Based on a CT scan of the temporal bone, it was found that 5 CSOM patients had posterior wall erosions, but only 3 patients were proven to have posterior wall erosion based on intraoperative findings with a prevalence of 16.7%. In addition, as many as 13 CSOM patients based on CT-Scan no posterior wall erosion were also proven not to have posterior wall erosion based on intraoperative findings with a prevalence of 72.7%. Based on the results of the Kappa test, it was found that the concordance of the findings of posterior wall erosion between the temporal and intraoperative CT-Scan examinations was 68.4% ($k=0.68$) or a strong concordance.

Pramod et al stated that HRCT has a low sensitivity of 72.7% and a high specificity of 100% in detecting posterior wall erosion. There were 4 false negative cases found on CT and evidenced by intraoperative findings. These four cases were the majority in atticointral CSOM with pars flaccid cholesteatoma. There were 15 cases having positive findings of intraoperative posterior wall erosion with only 10 cases detected on HRCT. However, Nanjaraj et al said that CT had a higher sensitivity of 92% and specificity of 91% in finding posterior wall erosions [19].

4.7. Analysis the concordance of findings of sigmoid sinus erosion between preoperative temporal bone CT scan and intraoperative findings

CT Scan examination of the temporal bone of CSOM patients in this study showed that there were 2 CSOM patients who had a picture of sigmoid sinus erosion but were not proven to have sigmoid sinus erosion based on intraoperative findings. The rest, 16 CSOM patients who based on CT-Scan did not have sigmoid sinus erosion were also proven to have no sigmoid sinus erosion based on intraoperative findings with a prevalence of 88.9%. The concordance of findings of sigmoid sinus erosion between temporal and intraoperative CT scans was very low.

A previous study by Walshe et al reported that, they did not detect sigmoid sinus erosion using CT. In the study of Aylin et al, CT was able to detect erosion of the sigmoid sinus wall with a sensitivity of 31% and a specificity of 99% was observed in 1 of 20 cases.¹⁶ There are some differences in the results from previous studies. Rogha et al evaluated 36 CT scan images of CSOM and assessed the correlation with intraoperative findings and found excellent radio- surgical correlations for the sigmoid plate (kappa statistics, $k=1,000$), posterior wall erosion ($k=0.92$), and scutum ($k=0.83$). The CT-intraoperative correlation was good for the tegmen tympani ($k=0.71$) and malleus ($k=0.61$). The radio-surgical correlation was moderate for the mastoid trabeculae ($k=0.58$) and semicircular canals ($k=0.47$). Radio-surgical correlation was poor for incus $k=(0.36)$, stapes ($k=0.27$), and facial canal ($k=0.2$) [20].

Rokaya et al., HRCT showed the sensitivity, specificity, positive predictive value, negative predictive value and sequential accuracy values were 87.5%, 85.7%, 87.5%, 85.7% and 86.7% in diagnosing CSOM with cholesteatoma. HRCT showed sensitivity and specificity of 85.7% and 87.5% in the identification of malleus erosion, sensitivity and specificity of 86.7% and 80%, in the identification of incus erosion, respectively. HRCT showed a specificity of 85% with a relatively low sensitivity of 70% in the identification of stapes erosions. HRCT showed sensitivity and specificity of 83.3% and 95.8% in diagnosing tegmen tympanic erosion, respectively. HRCT showed the highest sensitivity (100%) and specificity (100%) in diagnosing erosion of the sigmoid sinus plate and mastoid cortex. HRCT showed relatively low sensitivity of 66.7% and 75% in diagnosing facial canal erosion [22].

The high value of the sensitivity and specificity of preoperative CT scans and the percentage of conformity with intraoperative findings, it can be concluded that CT scans are very helpful in establishing the diagnosis and decision making for surgery in cases of CSOM with cholesteatoma. Perioperative CT scan examination can accurately predict the extent of disease spread and is very helpful for detecting scutal erosion, ossicular erosion, tympanic tegmen erosion, facial canal erosion, posterior wall erosion of the tympanic cavity. However, it cannot differentiate cholesteatoma from mucosal disease (granulation tissue or mucoid secretion), and it is still difficult to predict sigmoid sinus erosion [20]

5. Conclusion

This study showed that preoperative temporal bone CT scan has a high accuracy value in assessing the scutum, ossicles, tympanic tegmen and posterior wall, while assessing cholesteatoma and sigmoid sinus is still low. CT

scan of the temporal bone in patients with CSOM can be a guide in clinical importance for the assessment of cholesteatoma and other structures.

Compliance with ethical standards

Acknowledgments

We would like to express our sincere to all the study participants who granted their consent to be enrolled. The authors also appreciate and thank to Otorhinolaryngology-Head and Neck Department for helping this study.

Disclosure of conflict of interest

The authors have declared that no competing interests exist in this study.

Statement of ethical approval

The Study has been approved by the Health Research Ethics Committee of the Faculty of Medicine at Universitas Syiah Kuala with a number of ethical contributions KEPPKN registration number 1171012P (Description of ethical expedited number: 136/EA/FK/-RSUDZA/2020).

Statement of informed consent

All authors declare that informed consent was obtained from all individual participants included in the study.

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