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Quality of Life Score Difference Based on Chronic Otitis Media Outcome Test-15 (COMOT-15) Questionnaire on Chronic Supurative Otitis Media Patients with and without Cholesteatoma at Sanglah General Hospital

E. P. Setiawan and M. R. R. D. Meregawa

ABSTRACT

***Introduction*: Chronic suppurative otitis media (CSOM) is a chronic infection in the middle ear with perforation of the tympanic membrane and persistent or intermittent secretion from the middle ear which is more than two months. It causes a pathological condition in the ear which results in limited hearing function in a person and will affect the quality of life of the patients. Quality of life assessment is carried out to assess the patient's condition and an instrument is needed to be able to evaluate the condition of CSOM patients. Currently, there are several questionnaires that can be used to assess the quality of life of people with CSOM. One of them is the Chronic Otitis Media Outcome Test (COMOT-15) which is a valid measuring tool to subjectively assess the quality of life of people with CSOM.**

***Methods*: This study was an observational study with a cross sectional study design.**

***Results*: There was a difference in quality-of-life scores between CSOM patients with and without cholesteatoma types with mean score 26.87 (95% CI 22.28- 31.47) (p<0.001).**

***Conclusion*: There was a difference in quality-of-life scores between CSOM patients with and without cholesteatoma types at Sanglah General Hospital, Denpasar.**

Keywords: Cholesteatoma, chronic supurative otitis media, cholesteatoma, quality of life.

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E. P. Setiawan*
Otorhinolaryngology-Head and Neck Surgery Department Sanglah General Hospital, Denpasar, Bali, Indonesia.
(e-mail: ekaputra.tht@gmail.com)
M. R. R. D. Meregawa
Otorhinolaryngology-Head and Neck Surgery Department Sanglah General Hospital, Denpasar, Bali, Indonesia.
(e-mail: rarameregawa@gmail.com)

****Corresponding Author***

I. Introduction

Chronic suppurative otitis media (CSOM) is a chronic infection in the middle ear with perforation of the tympanic membrane and secretions that occurs continuously or intermittently in more than two months. Chronic suppurative otitis media is considered to be one of the most common causes of deafness with a prevalence of between 1-46% [1]. According to the World Health Organization (WHO) in 2004 around 65-330 million people in the world suffer from CSOM accompanied by otorrhoea, especially in developing countries [2]. In Indonesia, the prevalence of CSOM was 3.1%. In Jakarta, the prevalence of CSOM in 2012 was 3.4% [3], [4].

Chronic suppurative otitis media is divided into 2 types, namely benign and malignant types. In the benign type of CSOM, it was found that the tympanic membrane perforation occurs in the pars tensa and the ossicles are intact, whereas the perforation of malignant type of CSOM is at attic or marginal part of tymphanic membrane and cholesteatoma debris can be found [1], [5].

Chronic suppurative otitis media causes pathological conditions in the ear that result in functional limitations of hearing in a person and will affect the quality of life of the sufferer [6], [7]. Quality of life assessment is carried out to assess the condition of the patient and an instrument is needed to be able to evaluate the condition of CSOM patients. Chronic Otitis Media Outcome Test (COMOT-15) is a valid measuring tool to subjectively assess the quality of life of CSOM patients [8]. Research on differences in the quality-of-life scores of patients with benign and malignant CSOM based on the COMOT-15 questionnaire has not been widely conducted abroad. Likewise, in Indonesia and Sanglah General Hospital has never been done. Therefore, it is necessary to conduct research to determine the difference in the quality-of-life scores based on the COMOT-15 questionnaire in patients with benign and malignant CSOM.

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II. Materials and Methods

The design of this study is an observational study with a cross-sectional approach. The sample including the entire population of CSOM patients at Sanglah General Hospital from January 2017 until March 2021 which was selected by stratified random sampling and met the inclusion and exclusion criteria. We included patients who had been diagnosed with chronic suppurative otitis media with perforation of the tympanic membrane and history of discharge from the ear for more than 2 months either continuously or intermittently, patients who had complete medical records including identity, name, age, gender, and types of CSOM, as well as patients who are at least 18 years old. We excluded patients who refused to participate (interviewed) after proper informed consent, patients diagnosed with a malignancy in the ear, patients with congenital abnormalities, disability, and systemic comorbidities, and patients who were uncooperative and uncommunicative. Then samples in the benign and malignant CSOM group were taken through a stratified random sampling system to obtain 33 samples in each group.

Patients who met the inclusion and exclusion criteria were included in the study sample and data were recorded and interviews were conducted to assess the quality of life in patients with benign and malignant CSOM using the Chronic Otitis Media Outcome Test-15 (COMOT-15) questionnaire. All data obtained were then analyzed using SPSS 24.0 software. There were 3 types of variables in this study. The independent variables were benign type CSOM and malignant type CSOM while the dependent variable was the quality of life of CSOM patients which was measured by COMOT-15 questionnaire. The confounding variables were age, gender, education and occupation.

III. Results

Based on the research, it was found that descriptive data analysis was carried out on the characteristics of the research subjects. Characteristic data obtained in the form of numerical data scale as described in Table I.

TABLE I: Comparison of Characteristics of Research Subjects Based on Research Groups

Variable	CSOM type		P-value
	Benign (n=33)	Malignant (n=33)	
Age (year old)			
Mean±SD	40,67±12,20	40,73±11,71	0,984
Gender			
Male	15 (45,5%)	16 (48,5%)	
Female	18 (54,5%)	17 (51,5%)	0,805
Educational status			
Elementary school graduate	3 (9,1%)	3 (9,1%)	
Junior high school graduate	4 (12,1%)	6 (18,2%)	
Senior high school graduate	11 (33,3%)	13 (39,4%)	0,692
Undergraduate	15 (45,4%)	12 (31,3%)	
Occupation			
Housewife	0 (0%)	2 (6,1%)	
Seller	4 (12,1%)	2 (6,1%)	
Student	2 (6,1%)	1 (3%)	
Housemaid	0 (0%)	1 (3%)	
Farmer	3 (9,1%)	1 (3%)	
Civil servant	6 (18,2%)	6 (18,2%)	0,255
Private employees	15 (45,5%)	16 (48,5%)	
Unemployment	1 (3%)	2 (6,1%)	

Based on the table above, in this study, the average age of patients with benign CSOM was 40.67 years and malignant type CSOM was 40.73 years. Based on gender, in benign CSOM, 18 women or 54.5% and men 15 or 45.5%. In malignant type CSOM, the number of men is 16 people or 48.5% and women are 17 people or 51.5%. For the level of education, in the benign CSOM group, 3 people graduated from elementary school or 9.1%, 4 people graduated from junior high school or 12.1%, 11 people graduated from high school or 33.3% and 15 people graduated from college. or 45.4%. In the malignant type CSOM group, 3 people graduated from elementary school or 9.1%, 6 people graduated from junior high school or 18.2%, 13 people graduated from high school or 39.4% and 12 people graduated from college or 31.3 %.

Based on occupation, there were no benign CSOM sufferers as housewives, while in the malignant type CSOM group there were 2 people or 6.1% as housewives. There are 4 people or 12.1% who work as traders in the benign type CSOM group and 2 people or 6.1% in the malignant type CSOM group. In the benign type CSOM group, there are 2 people or 6.1% status as students and 1 person or 3% in the malignant type CSOM group. There is 1 person or 3% who works as a helper in the malignant type CSOM group, and no one works as a helper in the benign CSOM group.

In the benign type CSOM group, there are 3 people or 9.1% who work as farmers and 1 person or 3% in the malignant type CSOM group. There are 6 people or 18.2% of CSOM patients with benign and malignant types who work as civil servants. In the benign type CSOM group, there were 15 people or 45.5% who worked as private employees and 16 people or 48.5% in the malignant type CSOM group. There were 1 person or 3% of patients in the benign CSOM group who did not work and 2 people or 6.1% in the malignant CSOM group.

Comparison of quality of life scores based on COMOT-15 in CSOM patients with Benign and Malignant Types can be seen in Table II.

TABLE II: The Comparison of Quality of Life Scores Based on COMOT-15 In CSOM Patients with Benign and Malignant Types

Variable	CSOM Type		Mean Difference	95%CI	P-value
	Benign (n=33)	Malignant (n=33)			
COMOT-15 score	26,42±9,34	53,30±9,34	26,87	22,28-31,47	<0,001

Based on Table II, it is found that the comparison of quality-of-life scores based on COMOT-15 in benign CSOM is 26.42±9.34 and 53.30±9.34 in the malignant type with a mean difference of 26.87 95% Confidence Interval of 22.28 - 31.47. The difference in quality-of-life scores based on COMOT-15 can be seen in Fig. 1.

The significance of differences in quality of life based on the COMOT-15 questionnaire questions in patients with benign and malignant CSOM can be seen in Table III.

Based on Table III, it is known from each question item that the p-value <0.001 which means that there is a significant difference in the benign and malignant CSOM group when viewed from each item on the COMOT-15 questionnaire. For question item number 15, namely the number of patient visits

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to the doctor because of the ear in the last 6 months, all CSOM patients with benign and malignant types said they had visited the doctor 4 times in the last 6 months.

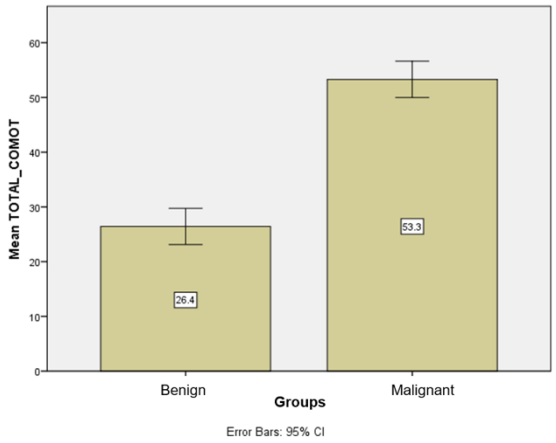

Fig. 1. Comparison diagram of quality of life based on COMOT-15 score between benign and malignant types of CSOM.

TABLE III: SIGNIFICANCE OF DIFFERENCES IN QUALITY OF LIFE BASED ON THE COMOT-15 QUESTIONNAIRE QUESTION ITEMS IN CSOM WITH BENIGN AND MALIGNANT TYPES

Question Items	P-value
Discharge from the ear	<0,001
Ear pain	<0,001
Ear fullness	<0,001
Ears ringing	<0,001
Headache	<0,001
Hearing loss	<0,001
I'm having a hard time understanding someone talking with a greater distance	<0,001
I'm having trouble understanding the conversation in a noisy environment	<0,001
I have a hard time understanding when some people talking at the same time	<0,001
Hearing loss makes me depressed	<0,001
Due to hearing loss, I am afraid of misunderstanding people other	<0,001
My hearing loss causes a state that embarrassing	<0,001
I'm worried that my ear problems will increase in the future	<0,001
Overall assessment of the impact of ear disease on quality of life	<0,001

IV. DISCUSSION

This study was conducted to determine and assess the comparison of the quality of life of patients with benign and malignant types of CSOM. This research is an observational study with a retrospective study design. The study was conducted at the ENT clinic of Sanglah Hospital Denpasar with the affordable population being patients with CSOM at the ENT clinic of Sanglah Hospital. A total of 33 patients with benign and malignant CSOM were taken in this study using a stratified random sampling method and then asked questions according to the COMOT-15 questionnaire.

Chronic suppurative otitis media is a chronic inflammation of the middle ear with perforation of the tympanic membrane and a history of discharge from the ear for more than 2 months, either continuous or intermittent. There are 2 types of CSOM, namely the benign type and the malignant type. Chronic suppurative otitis media causes pathological conditions in the ear that result in functional limitations of hearing in a person and will affect the quality of life of the sufferer. This results in problems during communication that can hinder social interaction and daily life both at work and in activities. In children, it can affect language skills, communication, psycho-social, cognitive development and ultimately lead to learning disorders and decreased achievement in school. In adults, the decline in communication skills due to lack of hearing will lead to depression, anxiety, and social withdrawal.

A. Characteristics of Research Subjects

Chronic suppurative otitis media (CSOM) is a disease with a high prevalence and is estimated to increase so that it becomes a burden on the community's economy. WHO estimates that CSOM has an incidence ranging from 65-330 million worldwide? In developing countries, CSOM ranges from 1-46%. In Indonesia in 2012, the prevalence of CSOM was around 5.4% at all ages compared to neighboring countries such as Thailand, the Philippines, and Malaysia with the prevalence of CSOM ranging from 2.4%.

Based on the characteristics table of research subjects in 33 patients with benign and malignant CSOM, the mean age in benign CSOM was 40.67±12.20 years and in malignant CSOM it was 40.73±11.73 years. The youngest age in both groups was 18 years. In this study, the age distribution between the benign and malignant CSOM groups was not much different. These results are not much different from those obtained in a study conducted by [9] who reported in his study the average age in benign CSOM was 39.1 years and in malignant CSOM 35.7 years. Reference [10] reported the mean age of the study subjects was 44.6 years with an age range of 18-70 years. Reference [11] stated the average age of the research subjects was 52 years with an age range of 18-75 years. Slightly different results were obtained in the study of [12] who stated that the average age of the research subjects was 24.32 years with an age range of 18-61 years.

In benign CSOM, 15 men or 45.5% were found and 18 women or 54.5% were found. Meanwhile, in the malignant type of CSOM, there were 16 men or 48.5% and 17 women or 51.5%. The results of this study are not much different from the results of research from [9] in each group, the research subjects were male in the benign type CSOM group 16 (57.1%) people and the malignant type CSOM group 17 (60, 7%) people. The research subjects were female in the benign type CSOM group 12 (42.9%) people and the malignant type CSOM group 11 (39.3%) people. In research [11] obtained different results were from 90 research subjects, 44 people (48.89%) were male and 46 (51.11%) were female.

Based on the level of education in benign and malignant CSOM, there were 3 elementary school graduates (9.1%), 4 junior high school graduates (12.1%), and 6 (18.2%) malignant types. SMA level graduates in the benign type are 11 people (33.3%) and the malignant type is 13 people (39.4%), college graduates in the benign type are 15 people (45.4%) and the malignant type are 12 people (31.3%).

Based on occupation, there were no benign CSOM sufferers as housewives, while in the malignant type CSOM group there were 2 people or 6.1% as housewives. There are 4 people or 12.1% who work as traders in the benign type CSOM group and 2 people or 6.1% in the malignant type CSOM group. In the benign type CSOM group, there are 2

people or 6.1% status as students and 1 person or 3% in the malignant type CSOM group. There is 1 person or 3% who works as a helper in the malignant type CSOM group, and no one works as a helper in the benign CSOM group.

In the benign type CSOM group, there are 3 people or 9.1% who work as farmers and 1 person or 3% in the malignant type CSOM group. There are 6 people or 18.2% of CSOM patients with benign and malignant types who work as civil servants. In the benign type CSOM group, there were 15 people or 45.5% who worked as private employees and 16 people or 48.5% in the malignant type CSOM group. There were 1 person or 3% of patients in the benign CSOM group who did not work and 2 people or 6.1% in the malignant CSOM group.

This will certainly affect the quality of life of patients with CSOM. Occupational factors, especially formal work, will have a better socioeconomic life so that they can be more aware and understand and will have more routine control in maintaining ear health. The factor of higher education level will certainly have an effect because the higher the level of education, the patient will tend to understand, realize, and follow the rules in handling the disease. The higher a person's level of education, the more they will consider the importance of the value of health so that they will take better care of their health than those with lower education. In this study, there were no significant differences in the benign and malignant CSOM group in variables, age, gender, education, and occupation. So that the role of confounding variables in this study can be removed.

B. Differences in Quality-of-Life Score Based on COMOT-15 between Benign and Malignant CSOM

In this study, the mean quality of life score in benign CSOM was 26.42±9.34 and in malignant CSOM the mean score was 53.30±9.34. Based on the independent t-test, the mean difference between benign and malignant CSOM was 26.87 (95% CI 22.28-31.47). The difference in the quality-of-life scores between the benign and malignant types showed a significant difference, namely the p-value < 0.001. This is in accordance with a study conducted by [13] which said that there were significant differences in quality of life between benign and malignant CSOM. Different results were obtained in a study conducted by [11] where it was said that there was no difference in the quality of life between benign and malignant CSOM.

C. Significance of Differences in Quality of Life Based on Question Items in the COMOT-15 Questionnaire on CSOM for Benign and Malignant Types

In this study, there were significant differences between benign and malignant CSOM on items 1-14, with a p-value of <0.001. This is in accordance with a study conducted by [13] which found a significant difference based on the COMOT-15 questionnaire between benign and malignant CSOM. However, different things were obtained by [11] who stated that there was no difference in the quality of life between benign and malignant CSOM.

In question 15 about visits to doctors in the last 6 months, it was found that all study participants made 4 visits in the last 6 months. This can be caused because CSOM is a chronic disease that can cause repeated complaints so that patients require a visit to the doctor to find out their condition and get the right treatment. Handling of CSOM must not only be precise but also requires thorough handling. Handling to completion in question is not only limited to surgery but care and evaluation of the condition of the patient after surgery must also be considered. Thus, it is hoped that proper and thorough treatment can improve the quality of life of CSOM sufferers.

This study has a weakness in relation to the retrospective study design, where data collection is based on medical records and interviews with patients who have completed treatment so that it can lead to the possibility of recall bias because patients who have completed treatment can forget about the conditions experienced before undergoing treatment. In addition, the sample selection using a stratified random sampling system makes the number of samples limited. It is recommended that in this study, samples were selected that had not undergone surgery or used a cohort study to reduce the occurrence of bias. In addition, sample selection can be done using the total sampling method so that the number of samples is larger, and the 95% CI range is shorter.

V. Conclusion

The mean quality-of-life score in benign CSOM was 26.42±9.34 and in malignant CSOM the mean score was 53.30±9.34. The difference in the mean quality of life scores between benign and malignant types was 26.87 (95% CI 22.28–31.47) with p <0.001. This means that there is a significant difference between the quality-of-life scores of patients with benign and malignant CSOM. This can be caused by a lack of knowledge about the disease, especially in patients with malignant types of CSOM, so that patients arrive late to treat their disease which makes their quality-of-life decrease compared to benign CSOM.

A convenient education for patients with chronic suppurative otitis media that with appropriate care and treatment to completion can improve the patient's quality of life. In addition, further research is needed with other methods to be able to determine changes in the quality-of-life of patients from the initial diagnosis to completion of treatment.

Conflict of Interest

There is no conflict of interest in this research.

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