ORİJİNAL ARAŞTIRMA ORIGINAL RESEARCH

DOI10.24179/kbbbbc.2020-79653

Evaluation of the Effect of Chronic Otitis Media Disease Severity on Quality of Life with Chronic Otitis Media Questionnaire Test 12

Kronik Otitis Media Hastalık Şiddetinin Yaşam Kalitesine Etkisinin Kronik Otitis Media Anketi 12 ile Değerlendirilmesi

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ABSTRACT Objective: To evaluate the effect of chronic otitis media (COM) disease severity on quality of life with Chronic Otitis Media Questionnaire Test 12 (COMQ-12). **Material and Methods:** Eighty five patients aged 18 and over who were operated for the first time with the diagnosis of COM were included in the study. The patients were requested to answer the COMQ-12 before surgery. The severity of the disease was determined according to the pre-operative examinations and the findings detected during the operation. The conditions of the tympanic membrane, degree of hearing loss, computerized tomography (CT) findings, surgery findings, type of surgery (canal wall up vs canal wall down), and whether or not mastoidectomy procedure was done were all documented. All the data about examination findings were checked individually with COMQ-12's total score and subscores. **Results:** 85 patients with a mean age of 40.45±13.99 (18-64) were included in the study. The mean total COMQ-12 score was 27.75±11.61 (5-54). No correlation was found between total COMQ-12 score and the degrees of hearing loss (p: 0.709), CT findings (p: 0.715), tympanic membrane perforation type (p: 0.953), tympanic membrane adhesion type (p: 0.147), presence of granulation tissue (p: 0.399), ossicular chain discontinuity (p: 0.748), presence of cholesteatoma (p: 0.784) and type of surgery (p: 0.295). **Conclusion:** The impact of COM on quality of life may not be consistent with the severity of the disease evaluated by physicians. Patients need to be well informed to understand the importance of the disease and possible complications.

Keywords: Otitis media; suppurative; quality of life; questionnaire

ÖZET Amaç: Kronik otitis media (KOM) hastalık şiddetinin hayat kalitesine olan etkisini, Kronik Otitis Media Anketi 12 [Chronic Otitis Media Questionnaire Test 12 (COMQ-12)] ile değerlendirmek. **Gereç ve Yöntemler:** KOM tanısı ile ilk kez opere edilen, yaşları 18 ve üzeri olan 85 hasta çalışmaya alındı. Hastaların, ameliyat öncesi COMQ-12 anketini cevaplamaları istendi. Hastalık şiddeti, operasyon öncesi yapılan tetkiklerinden ve operasyonda tespit edilen bulgulara göre belirlendi. Timpanik membranın durumu, işitme kaybının derecesi, bilgisayarlı tomografi (BT) bulguları, cerrahi sırasındaki bulgular, operasyon şekli ("canal wall up" veya "canal wall down") ve mastoidektomi yapılıp yapılmadığı kaydedildi. Toplanan klinik veriler, COMQ-12 toplam skorları ve alt skorları ile ayrı ayrı karşılaştırıldı. **Bulgular:** Çalışmaya dâhil edilen 85 hastanın yaş ortalaması 40,45±13,99 (18-64) idi. Ortalama toplam COMQ-12 skoru 27,75±11,61 (5-54) olarak bulundu. Toplam COMQ-12 skoru ile işitme kaybı derecesi (p: 0,709), BT bulguları (p: 0,715), timpanik membran perforasyon tipi (p: 0,953), adezyon tipi (p: 0,147), granülasyon dokusu varlığı (p: 0,399), kemikçik zincir kopukluğu (p: 0,748), kolesteatoma varlığı (p: 0,784) ve cerrahi tipi (p: 0,295) arasında korelasyon bulunmadı. **Sonuç:** KOM hastalığının yaşam kalitesi üzerindeki etkisi, klinisyenler tarafından değerlendirilen hastalık şiddeti ile uyumlu olmayabilir. Hastaların, hastalığın önemini ve olası komplikasyonları doğru anlayabilmeleri açısından iyi bilgilendirilmeleri gerekmektedir.

Anahtar Kelimeler: Otitis media; süpüratif; yaşam kalitesi; anket

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Peer review under responsibility of Journal of Ear Nose Throat and Head Neck Surgery.

Received: 19 Oct 2020 ***Received in revised form:*** 12 Jan 2021 ***Accepted:*** 13 Jan 2021 ***Available online:*** 17 Mar 2021

Chronic otitis media (COM) is a disease of the middle ear and mastoid cavities, which is featured by infection and inflammation lasting more than 3 months. COM is characterized by a defect in the tympanic membrane, discharge from the ear, and hearing loss. Although the prevalence of COM varies greatly among countries (0.3-4%), it is more common in developing countries.[1,2]

COM types according to the lesions seen in the middle ear mucosa are; simple COM, COM with inflammatory granulation, and otitis media with chronic cholesteatoma. Especially in COM with inflammatory granulation and cholesteatoma destructive damage to bone tissue (ossicular chain and/or bone walls of the middle ear field) can be observed. The destructive damage to the bone causes increased hearing loss by affecting the ossicular chain and triggers the development of both infratemporal and intracranial complications with temporal bone damage. Inflammatory lesions of the bone tissue of the temporal bone and arterial thrombosis can also cause intracranial complications.[3,4] Surgery remains as the main treatment strategy for COM, especially in patients with cholesteatoma.

Hearing loss, discharge from the ear, pain, and the frequent need for seeking medical care affect the quality of life (QoL) by limiting social interaction and daily activity. Especially hearing loss affects communication skills negatively in social and business life. In addition, the majority of patients find these symptoms socially embarrassing.[5-7]

QoL, enables them to evaluate how the disease affects a person's physical, social, and emotional functions according to their individual values.[8] QoL in COM evaluation has been implemented for approximately 20 years.[1,9,10]

Chronic Ear Survey (CES), Chronic Otitis Media Outcome Test 15 (COMOT-15), Chronic Otitis Media-5, and Chronic Otitis Media Questionnaire Test 12 (COMQ-12) were disease-specific QoL measurement tools.[1,10-13] The aim of this study was to evaluate the effect of COM disease severity on QoL with COMQ-12.

MATERIAL AND METHODS

This study was carried out prospectively between October 2019 and June 2020 with the approval of the Health Sciences University Ankara Training and Research Hospital Clinical Research Ethics Committee (date: 5/9/2019, protocol no: 60/2019). Volunteers aged 18 and over, who underwent tympanoplasty with or without mastoidectomy for the first time with the diagnosis of COM with or without cholesteatoma in our clinic were included in the study. The diagnosis of COM was made with the presence of mucosal damage or inflammation in the middle ear and/or mastoid air cells for at least 3 months. The study was carried out by taking consent of all patients, in line with the Helsinki Declaration Principles.

The Turkish version of the COMQ-12 was applied to patients before the operation. A total of 85 patients were included in the study. All patients underwent otoscopic examination, pure tone audiograms, computerized tomography (CT) of the temporal bone, and tympanoplasty with or without mastoidectomy. The pure tone audiometry was determined by taking the average of the hearing thresholds at 500 Hz, 1000 Hz, and 2000 Hz. The degrees of hearing loss were classified according to American Speech Language Hearing Association criteria.[14] The conditions of the tympanic membrane (size of perforation; plant 2-3 mm, subtotal plant, total, adhesions), degree of hearing loss, CT findings (mastoid aeration and presence of pathological soft tissue), surgery findings (status of middle ear mucosa, ossicular chain, presence of cholesteatoma, and the type of surgery (canal wall up vs canal wall down) were all documented.

All the documented clinical data were compared individually with COMQ-12's total score and subscores.

STATISTICAL ANALYSIS

The data were analyzed using the SPSS version 21,0 software program (Statistical Package for Social Sciences v.21, IBM, Chicago, IL). As descriptive statistics, the mean, standard deviation values, and percentage values were given. The Student t-test was used to compare hearing levels and ages between two

groups. One way ANOVA test was performed for comparing more than two groups. Categorical variables were referred by counts and percentages. By using Fisher's exact chi-square test for categorical variables crosscheck among groups was done. Spearman correlation coefficient (r) was used in order to investigate the correlations among the variables. p value <0.05 was considered statistically significant.

RESULTS

Eighty five patients with a mean age of 40.45±13.99 years (18-64) were included in the study.There was a significant difference regarding age (p: 0.001) Among these 85 patients, 70 had unilateral COM whereas the other 15 had bilateral COM. There was no significant difference between bilateral and unilateral COM groups regarding age and gender (p: 0.071, p: 0.546).

The preoperative mean air conduction threshold for COM patients was 39.27±16.52 dB for the right ear; 41.88±20.43 dB for the left ear. In patients with bilaterally affected ears, the side with worse hearing was included in the study. The hearing loss levels of patients were evaluated as normal hearing in 4 patients, mild in 46 patients, moderate in 19 patients, and severe to profound hearing loss in 16 patients.

There was no significant difference between hearing loss levels, and the total score (p: 0.709) (Figure 1). The mean COMQ-12 total score was 27.75±11.61 (5-54). Average COMQ-12 sub-scores were as follows; symptom score 15.99±7.75 (0-35), life score 4.21±3.10 (0-10), public health score 3.87±2.71 (0-10) and general life score 3.77±1.65 (0-5). There was no significant difference between age, gender, and unilateral-bilateral COM groups in terms of the total score and sub-scores.

In the CT scans, 21 patients had soft tissue densities in the mastoid cavity and middle ear whereas 17 had a sclerotic mastoid cavity. The mastoid aeration of other patients was evaluated as normal. No correlation was found between the total COMQ-12 score and the CT findings (p: 0.715).

The tympanic membrane perforations were central 2-3 mm perforations in 22 patients, subtotal perforations in 41 patients, and total perforations in 9

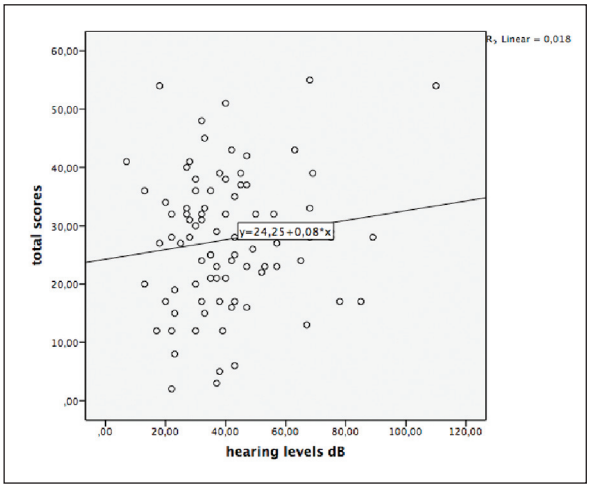

FIGURE 1: Chronic Otitis Media Questionnaire Test 12 total scores and hearing loss levels (p: 0.709)

patients. There was no perforation in 13 patients. The degree of adhesion was grade 4 in 10 patients, grade 3 in 2 patients, and grade 2 in 1 patient. No correlation was found between the total COMQ-12 score, and tympanic membrane perforation type (p: 0.953) or tympanic membrane adhesion type (p: 0.147).

In performed surgeries, it was observed that granulation tissue was present in 16 patients while 29 patients had ossicular chain discontinuity and 19 patients had cholesteatoma. Canal wall up tympanomastoidectomy procedure was performed for 75 patients and the other 10 patients underwent canal wall down procedure. Among patients who had canal wall up procedure, antrotomy was performed in15 of them and mastoidectomy was performed for 10 others.

No correlation was found between total COMQ-12 score and granulation tissue presence (p: 0.399), ossicular chain discontiunity (p: 0.748), cholesteatoma (p: 0.784) and surgery type (p: 0.295) (Table 1). In addition, there was no correlation between the symptom scores related the sub-scores, ear discharge with the presence of granulation tissue (p: 0.363) and surgery type (p: 0.375), hearing loss with ossicular chain discontiunity (p: 0.214), and vertigo with cholesteatoma (p: 0.744).

DISCUSSION

COM is a common disease that affects almost 2% of the global population.[1] Some forms of COM occur

TABLE 1: The distribution of patients and their COMQ-12 total scores according to intra-operative findings.

	Intra-operative Findings							
	Granulation Tissue Presence		Ossicular Chain Discontiunity		Cholesteatoma		Surgery type	
Data	+	-	+	-	+	-	CWU	CWD
Number of patients	16	69	29	56	19	66	75	10
COMQ-12 total scores	29.9±12.7	27.1±11.5	28.2±11.7	27.3±11.7	26.6±8,6	28.3±11.6	28.3±11.4	24.1±14

COMQ-12: Chronic Otitis Media Questionnaire Test 12; CWU: Canal Wall Up; CWD: Canal Wall Down.

with ear discharge, hearing loss, pain, vertigo, facial nerve paralysis, and meningitis. Patients in this group are much more likely to seek medical care and in an effective treatment. Different studies demonstrate that hearing loss caused by COM leads to hearing/speech hassle, language learning problems, cognitive disorders, communication problems, and withdrawal from social activities.[7,13-15] In the first study of QoL in COM patients, CES questionnaire was used.[1] This survey includes the density of symptoms or medical problems but does not include the evaluation of their own by the patients. Therefore, Baumann et al. developed a questionnaire called COMOT-15 that covered the subjectively evaluated disease-specific QOL for COM.[11] About half of the questions in COMOT-15 emphasizes on the hearing assessment.

COMQ-12 was developed in 2014 by Phillips et al. The purpose of developing COMQ-12 was to evaluate the disease severity from the perspective of the patient. That led the patients to prioritize their individual symptoms and allowed them to seek adequate help of their expectations about the disease (Appendix A).[16]

It is a 12-item multiple-choice COM specific health-related QoL questionnaire. COMQ-12 is designed to score the severity and density of the symptoms and their effect on QoL on a scale from 0 to 5. The first 7 questions mainly emphasize the severity of symptoms whereas questions 8 and 9 investigate the density of these symptoms affecting the patients' daily activities at home and work. Questions 10 and 11 evaluate the effect of the disease on public health. The last question, question 12, reveals how the disease influences the patients' general life.

COMQ-12 evaluates hearing loss as well as other symptoms associated with disease in COM patients. Ear discharge (first 2 questions), hearing loss (questions 3 and 4), discomfort in-ear (question 5), vertigo (question 6) and tinnitus (question 7) are symptoms questioned in COMQ-12.[16]

This test has been shown to be a sensitive, valid, and reliable tool to demonstrate the QoL of COM patients.[16]

COMQ-12 has been translated into many languages, including Turkish, and has been found to be a dependable tool for the valuation of health-related QoL in patients with COM.[17-20]

In most QOL measurements for COM, it is generally evaluated if there is any correlation between the changes at hearing levels, and in patients' emotional and social conditions after surgery.[7-21]

In our review of the literature, there was one study that evaluated the association between the QOL measurements and the clinicians' findings before surgery with COMOT-15.[22] The clinicians' findings before surgery were physical examination findings, pure tone average levels, and CT scan findings (presence of cholesteatoma, deterioration at mastoid aeration, and ossicular chain integrity). No correlation was found between clinicians' findings and the QoL scores in that study. The fact that CT has a low level of predictive value and sensitivity in diagnosing cholesteatoma and ossicular chain discontinuity may have led to this result.

Temporal bone CT without contrast is valuable when there is the suspicion of cholesteatoma, and it also provides a detailed view of anatomical structures damaged via the cholesteatoma itself or has a risk of injury during the surgery. On the other hand, different studies reported that the sensitivity of CT may be

APPENDIX A: Original COMQ-12.[16]

Chronic Otitis Media Questionnaire-12 (COMQ-12):

These questions are to find out how badly your ear problems affect you. No machine can do this: only you can tell us. We expect the results from this questionnaire to help us understand which of your ear symptoms is the most important to you. Knowing this will help us improve the ways patients with ear problems are looked after. Please answer the questions below by considering carefully each question asked and then ringing the appropriate number; the numbers each refer to a particular description. There are no right or wrong answers, but please try to think carefully about each question before ringing the appropriate number. Please consider each problem as it has been over the past 6 months.

EXAMPLE:

For the following question, please indicate how often you perform this activity using the scale below and by ringing the appropriate number:

0 Never

1 At least once every 3 months

2 At least once every month

3 At least once a week

4 Most days in the week

5 All the time

How often do you eat toast for breakfast? 0 1 2 3 4 5

A person responding like this conveys (s)he usually has toast but not always.

If you have any problems answering the questions, please ask a member of the clinic staff for help. Thank you

For the following questions, please indicate how severe the various elements described affect you, using the scale below and by ringing the appropriate number:

0 Doesn't bother me at all

1 A minor inconvenience

2 A moderate inconvenience

3 A major inconvenience but I can cope

4 A major inconvenience and I am finding it hard to cope

5 The worst thing that has ever affected my life

Symptom severity:

1. Discharge or drainage from the ear 0 1 2 3 4 5
2. Having a "smelly ear" 0 1 2 3 4 5
3. Hearing problems at home, e.g., requiring the volume of the TV or radio to be turned up 0 1 2 3 4 5
4. Hearing problems when talking to people in groups or when there are noisy surroundings 0 1 2 3 4 5
5. Discomfort in and/or around the ear 0 1 2 3 4 5
6. Dizziness or feeling "off balance" 0 1 2 3 4 5
7. Tinnitus or noises in the ear 0 1 2 3 4 5

For the following questions, please indicate how often the various elements described affect you using the scale below and by ringing the appropriate number:

0 Less frequent than once every 6 months

1 At least once every 6 months

2 At least once every 3 months

3 At least once every month

4 At least once a week

5 Most days in the week

Lifestyle and work impact:

How often have you NOT been able to

low in diagnosis of cholesteatoma and ossicular chain discontinuity.[23-28]

We aimed to evaluate the effect of COM disease severity on QoL with COMQ-12.

Examination of other symptoms besides hearing loss in COMQ-12 suggested that it may also reflect the severity of the disease. Therefore in this study, we examined how the severity of the disease is reflected in

COMQ-12. For the severity of the disease, in addition to the findings obtained before the operation, the operation findings in which the severity of the disease was definitely determined were also used. A significant correlation was present between hearing loss levels and increasing age ($p<0.001$). The fact that hearing loss is higher in older ages may be caused by the increase in age-related hearing loss, the longer duration of COM disease, and inflammation attacks in this process (Figure 2). Although there is no consensus on the cause of sensorineural hearing loss observed in COM, it has been suggested that hearing loss, especially at high frequencies, is caused by toxins passing to the iner ear through the round window membrane eventually causing irreversible damage to the hair cells. The permeability of the round window membrane is known to increase with acute inflammation as seen in COM.[29] In addition, antibiotic drops used for topical treatment can also be ototoxic. Cusimano et al. reported that the degree of sensorineural hearing loss increased with the duration of disease.[30]

Hearing loss caused by COM causes hearing/speech difficulties, attention deficit, language learning problems, cognitive and behavioral disorders, social skill acquisition difficulties and difficulties in providing employment.[5-8] No significant correlation was found between COMQ-12 total scores, and pre-operative and intra-operative findings, or performed operation type. There was no significant correlation between symptom subscores and intraoperative findings, either.

In different studies, the overall scores in COM patients have been shown to be between 22.1 and 33.84.[18,20,22,31] In our study, we also determined the total score to be 27.75±11.61.

Demir et al. determined that the mean score of COMQ-12 was the highest in the cholesteatoma group (33.84) and found that the difference between groups with and without cholesteatoma was statistically significant.[22] However, in separate trials, there was no statistically significant difference between the mean scores of the cholesteatoma and non-cholesteatoma groups.[20,32]

In our study, the impact of COM disease on QoL was not consistent with the severity of the disease evaluated by physicians. This may be because of the location of our hospital (generally low socioeconomic status), a limited number of patients involved in the study, and the characteristics of COM. Further studies can be conducted with more patients in different centers. Patients need to be well informed to understand the importance of the disease and possible complications

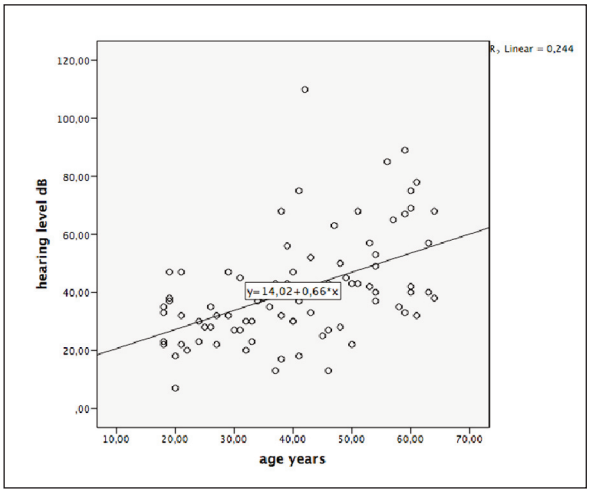

FIGURE 2: The correlation of hearing loss levels and age ($p<0.001$).

CONCLUSION

The impact of COM disease on QoL may not be consistent with the severity of the disease evaluated by physicians. Patients need to be well informed to understand the importance of the disease and possible complications.

Acknowledgments

The authors would like to thank Gülin Gökcen Kesici for their assistance in data management and analysis.

Source of Finance

During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that provides or produces medical instruments and materials which may negatively affect the evaluation process of this study.

Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

Idea/Concept: *Selda Kargin Kaytez;* ***Design:*** *Selda Kargin Kaytez;* ***Control/Supervision:*** *Hatice Çelik, Necmi Arslan;* ***Data Collection and/or Processing:*** *Ramazan Öcal, Songül Dursun;* ***Analysis and/or Interpretation:*** *Selda Kargin Kaytez;* ***Literature Review:*** *Selda Kargin Kaytez, Özlem Akkoca;* ***Writing the Article:*** *Selda Kargin Kaytez, Songül Dursun;* ***Critical Review:*** *Hatice Çelik, Necmi Arslan;* ***References and Fundings:*** *Selda Kargin Kaytez, Ramazan Öcal.*

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