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ORIGINAL ARTICLE

The Factors which Affect Disease-Specific Quality of Life in Patients with Chronic Otitis Media

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Objective: To determine the clinical findings which adversely affect quality of life (QOL) in patients with chronic otitis media (COM) and to assess the relevancy between the severity of those findings and QOL scores.

Study Design: Prospective cohort study with data collection.

Setting: Tertiary referral university hospital.

Patients: The study consisted of 138 patients who admitted to otolaryngology outpatient clinic with the complaints of ear drainage, tympanic membrane perforation, hearing loss, and associated symptoms and had a diagnosis of unilateral or bilateral COM were enrolled in the study.

Main Outcome Measures: The patients were queried for QOL by using a novel survey, namely chronic otitis media outcome test (COMOT). In addition, all the documented physical examination findings and CT findings were compared with QOL score and subscores individually.

Results: There was no difference in total score, ear symptoms score and hearing function score between unilateral and bilateral COM groups except the mental health subscore which revealed statistical significance (p=0.032). In addition, increasing age showed statistical significance for hearing function score(r=0.302 and p<0.001) and total score(r=0.180 and p<0.034). In unilateral COM group, there was significance between hearing function score and hearing level (p=0.033) and between retraction pocket and mental health score (p=0.019).

Conclusion: We concluded that, since the patients' perception to their disease do not necessarily correspond to physicians' evaluation of disease severity, many patients delay in seeking medical treatment. In order to prevent further complications, all patients should be informed not to underestimate their disease.

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Introduction

Chronic otitis media (COM) is a common health problem which affects nearly 2% of population. COM is defined as the chronic infection of middle ear and mastoid mucosa with or without perforation[1]. Although there is no consensus on the duration of symptoms, generally long lasting infection and irreversible mucosal damage over 3 months is accepted as COM in clinical practise[1-3].

Since there are various potential complications and sequales of COM such as, hearing loss, ear drainage, facial nerve paralysis, vertigo, and meningitis, the patients should visit otolaryngology outpatient clinics frequently. These symptoms may more or less compromise the quality of life (QOL) in patients with COM. Especially, hearing loss which is a common clinical finding in those patients, usually interferes with social communication ability beside professional work life[4,5]. Another unpleasant symptom of COM is

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resistant malodorous ear drainage which sometimes causes social withdrawal[6]. In later stages of the disease, some irreversible destructive changes are observed especially in the presence of cholesteatoma. Unfortunately, COM with cholesteatoma does not only affect ossicular chain integrity, but also has potential risks of labyrinthitis, facial nerve paralysis, subperiosteal abcess, cerebrospinal fluid or labyrinthine fistula, and even meningitis[2,3,7].

To evaluate the potential impacts of COM related symptoms to daily functions and social lives of patients, several disease specific surveys were designed previously[1,8,9]. Finally Baumann et al. developed a novel disease specific QOL questionnaire which assesses the severity of subjective symptoms; named as Chronic Otitis Media Outcome Test 15 (COMOT 15). This test was shown to be valid, reliable and sensitive tool for health related QOL in patients with COM[10].

This study was conducted to find out which clinical finding mostly compromises the QOL by using COMOT 15, since COM may have diverse presentations. In addition, we aimed to evaluate any possible discrepancy between patients' perception to their disease and clinicians' assessment of disease severity in respect to clinical findings. Many previous studies revealed that patient based outcomes do not necessarily correspond to clinician based findings and assessment of objective measures together with subjective ones was required[9,11,12]. In our review of literature, there was no other study which evaluated the association between the QOL measurements and clinician based findings before surgical intervention.

The aim of this study is to evaluate which clinical findings mostly affect QOL in patients with COM and to assess the relevancy between the severity of these pathological findings and degree of subjective complaints of patients.

Materials and Methods

This study was planned as a prospective cohort study with data collection and conducted at the Department of Otolaryngology of Uludag University between October 2011 and March 2012. The patients who admitted to otolaryngology outpatient clinic with the complaints of ear drainage, tympanic membrane perforation, hearing loss, and associated symptoms and had a diagnosis of COM were enrolled in the study. The inclusion criteria were as follows: i) duration of symptoms for at least 3 months ii) the presence of infection at middle ear and/or mastoid with or without perforation, iii) age above 18 years old and iv) no previous ear surgery. In total, 138 patients who fullfilled above critearia were included in the study. This study was approved by the ethical committee of Medical School. An informed consent form was assigned by each participant.

All patients underwent general ENT examination including microotoscopy and were evaluated with pure tone audiograms. A high resolution computerized tomography (CT) of temporal bone was performed to all patients in order to determine the presence of cholesteatoma or deterioration of mastoid aeration and to check the integrity of ossicular chain. All the scans were reported by same senior radiologist. In this study, a mean air conduction at frequencies of 0.5, 1, 2, and 4kHz was accepted as hearing threshold. The degrees of hearing loss was classified according to American Speech Language Hearing Association criterias[13]. The status of tympanic membrane, characteristics of ear drainage, status of middle ear mucosa, degree of hearing loss and CT findings were all documented. Furthermore, the stages of atelectasis and retraction pockets were classified according to Sadè classification[14] . The subjective symptoms of these patients were queried with COMOT 15 and symptom severity scores were determined accordingly. COMOT 15 consists of three subscales categorized as ear symptoms (questions 1-6), hearing function (questions 7-9), mental health (10-13). Additionally, 2 more questions about general evaluation of impacts of COM and frequency of doctor visits related to COM were queried[3] (Table 1). Since Turkish translation and validation of Turkish translation was not accomplished yet, the survey was performed by simultaneous translation of English version of the test to each individual patient by the same author each time with a preformed text (M.A.).

Subsequently, disease specific QOL measured with COMOT 15 was analyzed according to instructions in published formula[3]. In addition, any possible correlation between total score and subscores and

Table 1. The chronic otitis media outcome test (COMOT) including 15 questions which assess the severity of subjective complaints of patients.

Chronic Otitis Media Outcome Test - 15(COMOT-15)						
Considering how severe the issue when you experience it and how frequently it happens, please rate each item below on how "bad" it is by circling the number that corresponds with how you feel using this scale:	**No issue at all**	**Very mild issue**	**Mild or slight issue**	**Moderate issue**	**Severe issue**	**Problem as bad as it can be**
1. Discharge from the ear	0	1	2	3	4	5
2. Earache	0	1	2	3	4	5
3. Ear pressure/fullness of the ear	0	1	2	3	4	5
4. Tinnitus (ringing in the ear)	0	1	2	3	4	5
5. Headache	0	1	2	3	4	5
6. Hearing loss	0	1	2	3	4	5
7. I have difficulties to understand someone speaking from a larger distance	0	1	2	3	4	5
8. I have difficulties to understand something in a noisy surrounding area	0	1	2	3	4	5
9. I have difficulties to understand when people are speaking simultaneously	0	1	2	3	4	5
10. My hearing loss makes me feel depressive /sad	0	1	2	3	4	5
11. Because of my hearing loss I fear to misunderstand other people	0	1	2	3	4	5
12. My hearing loss does cause embarrassing situations	0	1	2	3	4	5
13. I am scared that my ear problems will increase in the future	0	1	2	3	4	5
14. Overall assessment of the impact the ear disease on quality of life	0	1	2	3	4	5
For question 15 please notice that we would like to know the number of your visits to the doctor concerning you ears during the last six months	None	One visit	Two visits	Three visits	Four visits	More than Four visits
15. Frequency of doctor visits for problems with my ear(s)	0	1	2	3	4	5

clinical findings was searched. All the documented clinical data regarding examination findings were compared individually to COMOT 15 scores. The patients were informed about their disease progress and potential harmful sequales related to COM. Among those patients who accepted surgical treatment were given surgical appointments.

Statistical analysis was carried out using SPSS v.13.0 for Windows (SPSS inc., Chicago, USA). Shapiro-Wilk test was used to test the normality of continuous variables. Normally distributed data were presented as mean ± standard deviation and independent samples t-test was used for comparing two independent groups. When the data were not normally distributed non-parametric tests were performed and median, minimum and maximum values were given for continuous variables as descriptive statistics. Kruskal Wallis test was performed for comparing more than two groups. Mann-Whitney's U-test was performed for comparing two groups, also after the Kruskal Wallis test in case of finding significances. Categorical variables were expressed by counts and percentages. Comparisons between the groups were performed with Fisher's exact chi-square test for categorical variables. Correlations between the variables were investigated with Spearman correlation coefficient (r). A p value <0.05 was considered to be statistically significant.

Results

The patients consisted of 61 males and 77 females with an average age of 37.74±13.97 years and increasing age showed statistical significance for hearing function score (r=0.302 and p<0.001) and total score (r=0.180 and p=0.034) (Figure 1 and 2). The comparison analysis between male and female gender showed no significant difference for total score and subscores of QOL (as shown in Table 2).

Among these 138 patients, 90 had unilateral COM whereas other 48 had COM in both ears. There was no significant difference between bilateral and unilateral COM groups regarding gender (p=0.317). In addition, there was no difference in total score, ear symptoms score and hearing function score between unilateral and bilateral COM groups but only the mental health subscore revealed statistical significance (p=0.032) in favor of unilateral COM group (Table 2). Further analysis were performed in two individual groups as unilateral and bilateral COM patients to prevent any possible measurement bias.

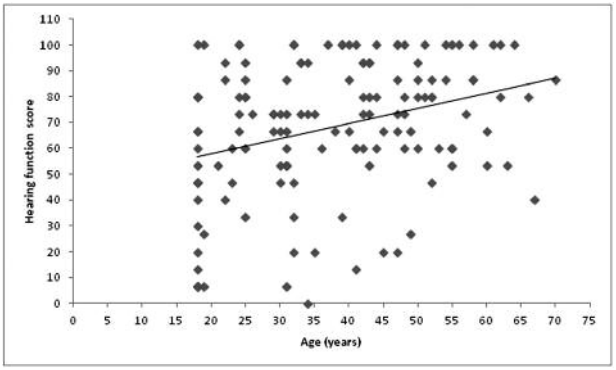

Figure 1. The graph showing the correlation between increasing age and hearing function score with a significance (r=0.302 and p<0.001).

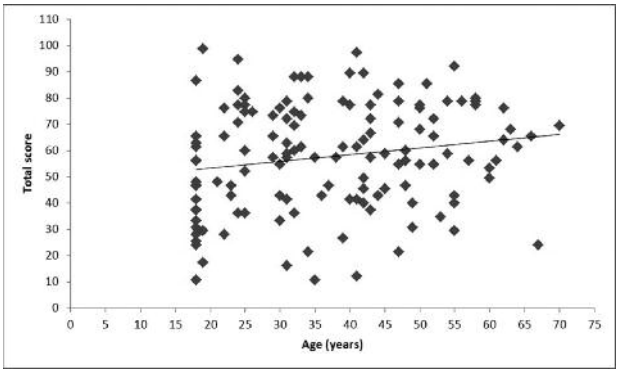

Figure 2. The graph showing the significant correlation between increasing age and total COMOT score (r=0.180 and p=0.034).

The mean air conduction threshold was 46.34 dB for diseased ear in unilateral COM patients. Among these 90 unilateral COM patients; there were 16 slight, 22 mild, and 24 moderate hearing losses whereas other 28 had severe to profound hearing loss. There was no tympanic membrane perforation in 7 of these patients. The characteristic of drainage was serous in 41 patients and mucopurulant in other 29 patients whereas other 20 had dry ear at examination. There was a pathological soft tissue mass filling mastoid cavity and/or middle ear indicating choleasteatoma in CT imagings of 40 patients. However, mastoid aeration was reported to be deteriorated in 75 patients. The ossicular chain was partially eroded in 25 of cases

Table 2. Table showing the distribution of patients and their QOL and subscale scores according to side and gender. '*' refers to statistical significance and values given are median.

COMOT -15 scores	UnilateralCOM	Bilateral COM	Female	Male	Total
Ear symptoms score	50.00	41.66	43.33	53.33	46.66
Hearing function score	73.33	76.66	73.33	73.33	73.33
Mental health score	55.00	75.00*	60.00	70.00	65.00
Total COMOT score	58.66	61.33	57.33	61.33	58.66
Number of Patients	90	48	77	61	138

whereas in 10 patients ossicles were not observed in CT. Moreover, in 77 patients there was no retraction at tympanic membrane while others showed different stages of retraction and retraction pockets. Subsequently, any significant association between these clinical findings and QOL score and subscores were analyzed. There was significance between hearing function subscore and hearing level (r=0.225 and p=0.033) (Figure 3) and between retraction pocket and mental health subscore (p=0.019). But unfortunately, other clinical findings did not show any significance regarding QOL scores (As shown in Figure 4).

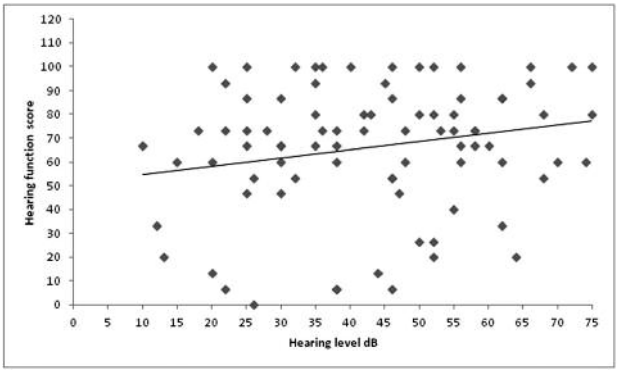

Figure 3. The graph revealing the significant correlation between hearing function score and hearing level in dB for unilateral COM patients (r=0.225 and p=0.033).

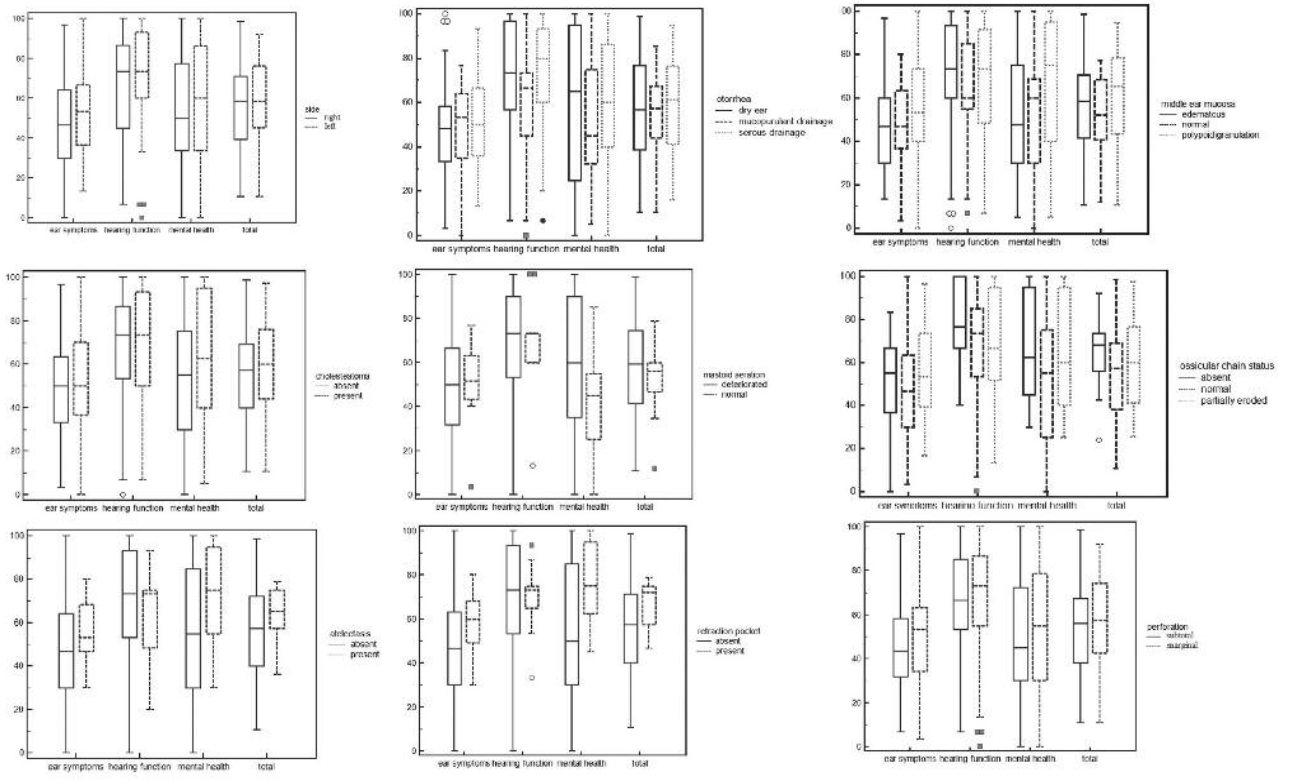

Figure 4. The figure showing the correlation graphs between QOL scores and clinical findings in unilateral COM group.

The mean air conduction threshold was 47.43 dB based on the worse-ear for patients with bilateral COM. Among these 48 bilateral COM patients; there were 6 slight, 12 mild, and 19 moderate hearing losses whereas other 11 had severe to profound hearing loss. Only 4 of the patients had dry ear with no drainage. Cholesteatoma was observed in CT imagings of 19 patients and mastoid aeration was deteriorated in 41 patients. The ossicular chain was partially eroded in 15 of cases whereas in only two patients ossicles were not observed in CT. In addition, there was no retraction in 37 of bilateral COM patients and only three of patients had retraction pockets. The comparison analysis between each clinical finding and QOL scores were all nonsignificant as shown in figure 5.

Finally, we also pointed out that the percentage of dry ear in unilateral COM group was higher than bilateral COM group despite the absence of significance; 22.2% versus 8.3% respectively. In addition, presence of cholesteatoma was not different in between these two groups (p=0.582).

Discussion

Hearing loss is an important determinant of quality of life especially in bilateral COM patients. This does not only restrict their ability to communicate but also deeply affect their professional lives. In addition, some psychological reflections of this handicap such as depression and anxiety disorder may occur. In their study, Newman et al. showed significant correlations between the severity of hearing loss, and emotional and social/situational scores of hearing handicap inventory[15]. Jung et al. reported significant negative correlations between air conduction thresholds, and total survey score and symptom subscale scores for primary surgery group compared to revision ear surgery using chronic ear survey[12]. Baumann et. al. indicated a moderate correlation between objective audiological measurement and subjectively evaluated hearing function after surgery[3]. Similarly, Steward et al. pointed out that emotional hearing status and social/situational hearing status were improved significantly after the treatment of conductive hearing loss ($p<.001$ and $p<.01$ respectively)[8]. In another study, they reported again significant improvements in emotional and social/situational hearing status, however no significant improvement was observed in global QOL score although audiometric studies showed significant improvement after treatment[4]. In addition, Cetin et al. showed significant difference ($p<0.05$) regarding QOL, depression and anxiety levels between patients with acquired hearing loss and normal control group[16].

Most of these above studies were aimed to show improvements in general or disease specific QOL measurements and to evaluate any correlation between

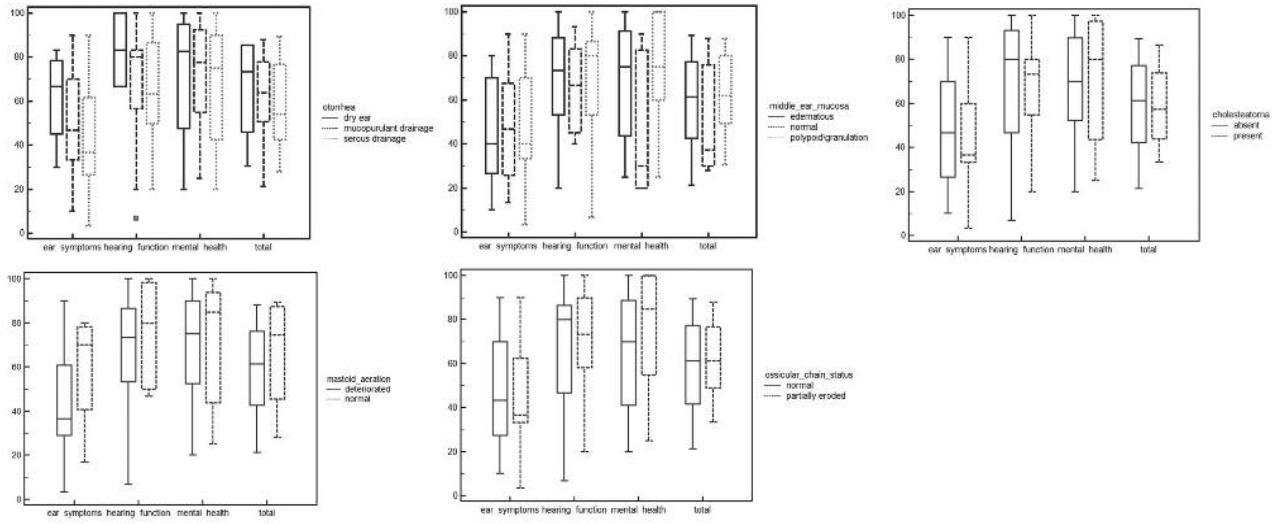

Figure 5. The figure showing the correlation graphs between QOL scores and clinical findings in bilateral COM group.

the changes at hearing levels as functional outcome and the changes of patients' emotional and social status after surgery. However, to the best of our knowledge, our study is the first which evaluates disease-specific and patient-based QOL and compares these scores with physician-based clinical findings including audiometric tests, CT scans, and physical examinations before surgery. In our study, the severity of hearing loss was not correlated with total score but it revealed significant correlation with hearing function subscore in unilateral COM group. In addition, increasing age was significantly associated with hearing function scores which suggests the negative influence of presbycusis. Furthermore, the emotional status of patients was not correlated with the severity of hearing thresholds. Although we expected a possible relation between social life and hearing handicap, this surprising finding suggested that physicians' clinical findings do not necessarily coincide with patient-based complaints. In addition, there was significant difference in mental health score in favor of unilateral COM group compared to bilateral COM patients. This finding supports the previous statement by Steward[8] that although the bilateral hearing loss is not a predictive factor for QOL measures, it effects mental well-being more than unilateral cases.

Cholesteatoma which represents the invasive and erosive form of COM, mostly affects the surgical decision making and influences clinical management. For most ear surgeons, the computerized tomography (CT) of temporal bone is still the most valuable method for assessing middle ear status for preoperative surgical planning. Although in most cases CT imagings enable surgeons to assess mastoid aeration and presence of cholesteatoma, the sensitivity of CT in differentiating cholesteatoma from chronic mucosal disease is controversial. Some studies revealed that preoperative CT findings did not necessarily correlate with operative findings and hence showed false positive results. In their study, Alzouubi et al. showed that cholesteatoma was present at surgery only in half of the cases which cholesteatoma was reported previously by CT scans. In that study, CT scans not only had a low positive predictive value (60.6%) but also had a negative predictive value (70.6%); such as cholesteatoma was present at surgery in 5 cases although its presence was excluded by CT scans. Moreover, the ossicular integrity was correctly assessed in most cases[17]. Similarly, Garber et al. concluded that CT scans should not be relied on to reveal ossicular status or presence of cholesteatoma[18]. In the contrary, Gerami et al. showed that CT had high accuracy in detecting cholesteatoma and ossicular chain erosion, with good correlation between preoperative radiological images and intraoperative clinical findings[19]. We assessed CT scans of temporal bone in order to determine any correlation between quality of life scores and the presence of cholesteatoma, deterioration at mastoid aeration and ossicular chain integrity. Unfortunately, there was no significant correlation in between QOL subscores and CT findings which may be related to low sensitivity and predictive value of CT in the diagnosis of cholesteatoma and ossicular chain. Further evaluation of operative findings in those patients will possibly clarify whether CT scans are not effective in diagnosing cholesteatoma and ossicular chain or the presence of cholesteatoma and eroded ossicles have no influence on QOL .

The impacts of draining ear to patients' social lives are often underestimated. However, this condition usually limits the social and professional activities of patients. In their study, Dornhoffer et al. assessed the QOL changes in 23 patients who underwent revision mastoidectomy surgery for draining cavity. The study showed significant improvements in QOL after surgery and a good correlation between perceived improvement in QOL and improvement in hearing and/or drainage[6] Similarly, Jung et al. reported that after one year of postoperative follow-up, the activity restriction subscale score and total survey score significantly got worse especially in patients who had postoperative clinical problems such as ear drainage, perforation, and retraction[12]. However, there was no significant correlation between ear drainage, perforation and QOL scores in our study. Among unilateral COM patients, ear symptoms subscores of those with mucopurulant drainage were worse than those with dry ears but it did not show significance. This finding suggests the presence of individual differences in how patients perceive their disease and seek for medical treatment.

Conclusion

Patients with COM may have diverse complaints that propel them to visit otolaryngologists. Identifying such factors which seriously disturb the lives of patients is essential for appropriate and timely treatment. Unfortunately, the perception of patients to a disease does not necessarily correlate with the evaluation of disease severity by physicians. Patients may sometimes have serious complications related to COM due to underestimation of symptoms. Nevertheless, since this study reflects only the results which were obtained from a specific population, certain factors such as cultural issues , social and economic status and geographical region of relevant population may all affect these results. Based on the results of this study, we argued that there is not any clinical finding that solely determines QOL in patients with COM and rather that different findings have a cumulative effect on QOL.

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References

1. Nadol JB Jr, Staecker H, Gliklich RE. Outcomes assessment for chronic otitis media: the Chronic Ear Survey. Laryngoscope. 2000;110:32-5.

2. Verhoeff M, van der Veen EL, Rovers MM, Sanders EA, Schilder AG. Chronic suppurative otitis media: a review. Int J Pediatr Otorhinolaryngol. 2006;70(1):1-12.

3. Baumann I, Gerendas B, Plinkert PK, Praetorius M. General and disease-specific quality of life in patients with chronic suppurative otitis media-a prospective study. Health Qual Life Outcomes. 2011:29;9:48.

4. Steward MG, Coker NJ, Jenkins HA, Manolidis S, Bautista MH. Outcomes and quality of life in conductive hearing loss. Otolaryngol Head Neck Surg. 2000;123(5):527-32.

5. Kirkim G, Serbetcioglu B, Odabasi O, Mutlu B. Hearıng loss and communication difficulty in the elderly. Int. Adv. Otol. 2007; 3:126-132.

6. Dornhoffer JL, Smith J, Richter G, Boeckman J. Impact on Quality of Life After Mastoid Obliteration. Laryngoscope. 2008;118:1427-1432.

7. Ceylan A, Bayazıt Y, Yılmaz M, Celenk F, Bayramoglu I et al. Extracranial complications of chronic otitis media. Int. Adv. Otol. 2009; 5(1); 51-55.

8. Steward MG. Outcomes and patient-based hearing status in conductive hearing loss. Laryngoscope. 2001;111:1-21.

9. Vlastos IM, Kandiloros D, Manolopoulos L, Ferekidis E, Yiotakis I. . Quality of life in children with chronic suppurative otitis media with or without cholesteatoma . Int J Pediatr Otorhinolaryngol. 2009;73(3):363-9.

10. Baumann I, Kurpiers B, Plinkert PK, Praetorius M. Development and validation of the Chronic Otitis Media Outcome Test 15 (COMOT-15). Measurement of health-related quality of life in patients with chronic otitis media. HNO. 2009;57(9):889-95. German.

11. Smyth GD, Patterson CC. Results of middle ear reconstruction: do patients and surgeons agree? Am J Otol. 1985;6(3):276-9.

12. Jung KH, Cho YS, Hong SH, Chung WH, Lee GJ, Hong SD. Quality of Life Assessment After Primary and Revision Ear Surgery Using the Chronic Ear Survey. 2010

13. Clark, J. G. Uses and abuses of hearing loss classification. Asha. 1981; 23: 493–500.

14. Sadé J, Avraham S, Brown M. Atelectasis, Retraction Pockets, and Cholesteatoma. Acta Otolaryngol. 1981; 92: 501-512.

15. Newman CW,Weinstein BE, Jacobson GP, Hug GA. The Hearing Handicap Inventory for Adults: pyschometric adequacy and audiometric correlates. Ear Hear. 1990; 11(6):430-3.

16. Cetin B, Uguz F, Erdem M, Yildirim A. The relationship between quality of life, anxiety and depression in unilateral hearing loss. Int. Adv. Otol. 2010; 6(2); 252-257.

17. Alzoubi FQ, Odat HA, Al-Balas HA, Saeed SR. The role of preoperative CT scan in patients with chronic otitis media. Eur Arch Otorhinolaryngol. 2009; 266(6):807-9.

18. Garber LZ, Dort JC. Cholesteatoma: diagnosis and staging by CT scan. J Otolaryngol. 1994;23(2): 121-4.

19. Gerami H, Naghavi E, Wahabi-Moghadam M, Forghanparast K, Akbar MH. Comparison of preoperative computerized tomography scan imaging of temporal bone with the intra-operative findings in patients undergoing mastoidectomy. Saudi Med J. 2009;30(1):104-8.