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Health Related Quality of Life after Canal Wall Down Mastoidectomy with tympanoplasty using the chronic otitis media questionnaire-12 (COMQ12)

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Abstract

Background and objectives: To assess quality of life after canal wall down mastoidectomy in patients operated for chronic otitis media both mucosal and squamosal type.

Methods: Quasi-experimental study design, conducted on fifty patients who were candidates for canal wall down mastoidectomy, between (September, 2016 to September, 2019). All patients were questioned before the operation and one year after the operation using Quality of life questioner for chronic otitis media (COMQ12).

Results: fifty patients, mean age ± SD was 36.52 ± 10.85, The highest proportion (40%) of the sample aged 35-44 years and around half (52%) were male. Mean total score of the COMQ12 before the operation was 25.94, which was decreases to 10.56 after the operation. There was significant improvement in ear symptoms regarding discharging ear and offensive odor post operatively, and also reduction in doctors visit for taking medications and fear from showering, there was non-significant change in questions regarding dizziness, tinnitus and discomfort around the ear, post operatively regarding questions related to the hearing there was significant deterioration post operatively.

Conclusions: Canal wall down with type III tympanoplasty showed a clear decrease in the severity of the ear symptoms, impact on life and work, and health care after surgery. Hearing was the only disabling factor that negatively affect outcome in post-operative quality of life.

Key words: Chronic otitis media; Canal wall down mastoidectomy; COMQ12; Quality of life.

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Introduction

Chronic otitis media (COM) is a clinical condition characterized by inflammation of the middle ear which is associated with otorrhea and perforated tympanic membrane in which, histopathologically there is irreversible tissue changes and the inflammation lasted for more than three months[1] Chronic otitis media is a common disease that affects approximately 2% of the population worldwide[2], still, the incidence of the COM may range from <1% in developed countries up to 4% in developing countries[3]. Chronic otitis media adversely affect the quality of life due to its inconvenient symptoms such as discharging ear, bad odor, hearing difficulty, dizziness, and vertigo. Also, it might have severe complications for example meningitis and brain abscess[4]. The main treatment of COM is surgical therefore mastoidectomy is regarded as common surgical procedures performed in the otology in which diseased mastoid air cells are exenterated [5].In canal wall down mastoidectomy, the posterior bony canal is lowered , the mastoid cavity and the middle ear are changed into a common cavity [6]. Advantages of canal wall down mastoidectomy are easier outpatient follow-up and early identification of cholesteatoma foci or infection, on contrary it has some disadvantages and the most common one is the accumulation of keratin debris and need for frequent cleaning, beside that patients are more susceptible to infection with water exposure, risk of sudden dizziness which is associated with the change of temperature in the external auditory canal and hearing aid discomfort [7] , therefore it is important to assess health related quality of life to evaluate the burden of disease and effectiveness of the treatments. The main objective in the surgery of (COM) is to remove the infection and any associated cholesteatoma and to improve hearing[8]. Until recently, measurement of surgical outcome for chronic otitis media was focused on objective measures using audiometry for hearing level and ear examination looking for discharge, in some cases there was discrepancy between the postoperative audiometric results and patient satisfaction[9], for this reason health-related quality of life (HRQOL) is considered an important method for the clinical assessment and medical research, it is also can be used in the clinical practice to make decisions regarding patient treatment[10].The Chronic Otitis Media

Questionnaire-12 (COMQ-12) was developed by Phillips et al.[11] which used previous three HRQOL questionnaires for COM outcome assessment : Chronic Ear Survey[12], Chronic Otitis Media Outcome Test–15 [13], and Chronic Otitis Media–5 questionnaires [14]. The original version of COMQ-12 is in English, and it has been translated and validated to other languages so that many of COM patients get benefit from it, to this date Dutch, Russian, Portuguese, Servian, Turkish, as well as Indian Kannada versions are available. The aim of this study is to compare disease specific quality of life in patients with COM before and after canal wall down mastoidectomy and tympanoplasty using Chronic Otitis Media Questionnaire-12 questionnaire (appendix A).

Patients and methods

A Quasi-experimental design study done in department of (Otolaryngology-Head and Neck Surgery ,Rizgary teaching hospital) starting from (September 2016 to September 2019) the end date denotes last patient followed up in which involved fifty adults patients who were selected for canal wall down mastoidectomy after being evaluated by taking through history and otomicroscopic examination and diagnosed by senior surgeon after having CT scan of temporal bone and audiometry , all patients questioned by the researcher before the operation using language understood by the patient and one year after the operation, using the original questionnaire about quality of life COMQ12 developed by Phillips et al[11], and the sum of these two scores were compared, those who had lower score indicated that; there was improvement in their quality of life. Exclusion criteria was Congenital cholesteatoma, children (patient younger than 18 years) to get etter response, mentally incompetent and those who had mastoidectomy as an approach for other surgeries. The aim of the study was explained to the participant and written consent was obtained from patients, data were namelessly analyzed and privacy of the data was maintained throughout the study.Standard surgery was performed under general anesthesia and in all cases using a post auricular incision,CWD mastoidectomy performed, facial ridge lowered to the level of lateral semicircular canal, saucerisation of the cavity done, no bony overhangs left, type III tympanoplasty done using temporalis fascia, in case of absence of

stapes superstructure piece of remnant ossicles where placed over the oval window to act as a conducting bridge between the graft and oval window, no obliteration of the neo-mastoid cavity was performed and large meatoplasty done.The Data was analyzed using the Statistical Package for Social Sciences (SPSS, version 22). Wilcoxon signed rank test was used to compare the scores before and after the operation. The effect size was estimated by calculating the R value using a free software. A p-value of ≤ 0.05 was considered statistically significant. Kurdistan Board for Medical Specialization granted approval for this study

.Results

Fifty patients were included in the study. Their mean age ± SD was 36.52 ± 10.85 years, ranging from 18 to 57 years. The median was 37 years. The highest proportion (40%) of the sample aged 35-44 years and around half (52%) were male. And 58% of the patients came from urban areas.

The mean total score of the QoL before the operation was 25.94, which decreases to 10.56 after the operation as presented in Figure(1).

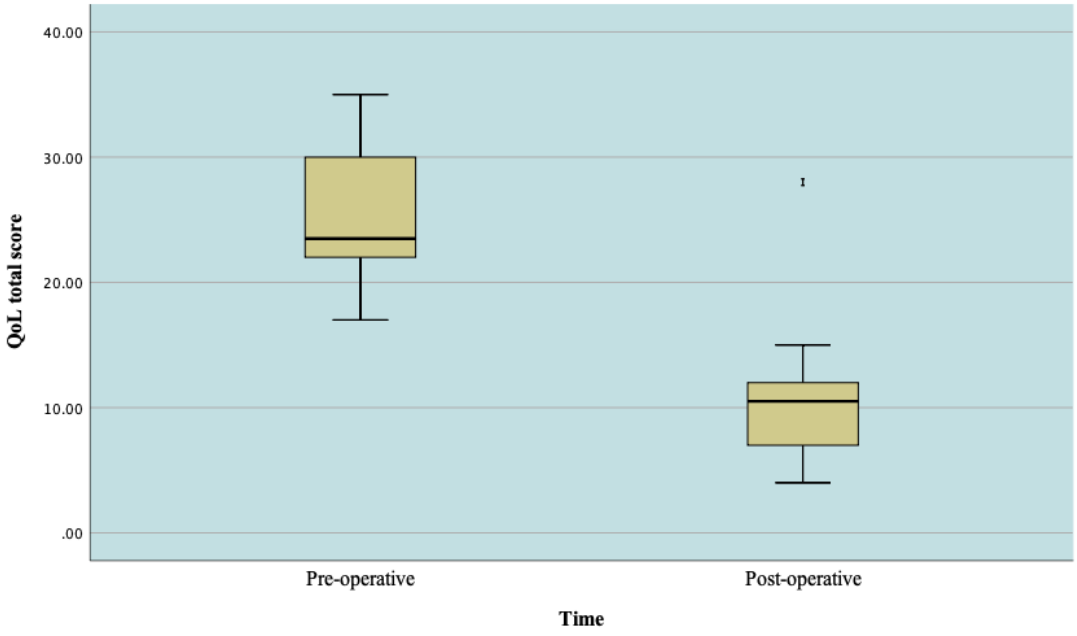

Figure (1): Total QoL scores before and after the operation.

The descriptive statistics for the scores of each of the 12 questions are presented in the mentioned table (1).

Table (1): Descriptive statistics of Quality of Life scores of chronic otitis media patients before and after the operation.

	Pre-operative scores					Post-operative scores				
*	**Mean**	**Median**	**SD**	**Min.**	**Max.**	**Mean**	**Median**	**SD**	**Min.**	**Max.**
Q1	3.70	4.00	0.974	1	5	0.16	0.00	0.468	0	2
Q2	2.74	3.00	1.454	0	5	0.00	0.00	0.000	0	0
Q3	2.22	2.00	.840	0	4	2.60	3.00	1.010	0	5
Q4	2.28	2.50	1.070	0	4	2.84	3.00	1.167	0	5
Q5	0.72	0.00	1.126	0	3	0.80	0.00	1.245	0	4
Q6	0.68	0.00	1.269	0	4	0.32	0.00	0.891	0	4
Q7	0.64	0.00	1.174	0	3	0.60	0.00	1.309	0	4
Q8	1.12	0.00	1.547	0	4	0.56	0.00	0.929	0	3
Q9	2.94	3.00	1.132	0	4	0.40	0.00	0.808	0	3
Q10	3.38	3.00	0.635	2	4	0.76	1.00	0.716	0	2
Q11	3.20	3.00	0.639	2	5	0.30	0.00	0.463	0	1
Q12	2.32	3.00	1.347	0	4	1.22	1.00	1.282	0	4
Total	25.94	23.50	5.37	17	35	10.56	10.50	4.75	4	28

*Note: The 12 questions related to quality of life.

Q1 Discharge or drainage from the ear

Q2 Having smelly ear

Q3 Hearing problem at home eg requiring the volume of TV or radio to be turned up

Q4 Hearing problem when talking to people in groups or when there are noisy surroundings

Q5 Discomfort in and /or around the ear

Q6 Dizziness or feeling of balance

Q7 Tinnitus or noises in the ear

Q8 Perform normal daily activity at home /work

Q9 Wash or shower or bath as you would like to? ie how often have you been fearful of these activities causing ear infection

Q10 How often have you been to see GP about your ear problem?

Q11 How often do you need to take medicine (including ear drops) for your problem?

Q12 To what degree do your ear problems get you down?

The QoL score of question 1 decreased significantly from 3.7 before the operation to 0.16 after the operation (p-value < 0.001). The effect size was large (r = 0.621). The same pattern is for question 2 where the score decreased from 2.74 before the operation to zero after the operation. The effect size was large (r = 0.578). The same pattern is also observed for Q9, Q10 and Q11 where there was significant decrease in the scores after the operation (p < 0.001), and the effect size was also large for each of these questions (r = 0.573, r = 0.634, and r = 0.632 respectively). No significant differences were detected in the scores of three symptoms after the operation, and those were asked about in Q5, Q6, Q7 where the p-values were 0.656, 0.139, and 0.833 respectively.Regarding Q12, there was significant (p-value <0.001) decrease in the score after the operation, but the effect size was not strong (r = 0.368). It is worth to mention that hearing (mentioned in Q3 and Q4) deteriorated after the operation and the QoL scores significantly increased after the operation, but the effect size was weak. The other findings are presented in table (2).

Table (2): Results of the Wilcoxon signed rank test (comparison between the mean ranks before and after the operation).

	p-value*	**Effect size (r)**
Q1	< 0.001	0.621
Q2	< 0.001	0.578
Q3	0.049	-0.197
Q4	0.013	-0.249
Q5	0.656	-0.045
Q6	0.139	0.148
Q7	0.833	0.021
Q8	0.018	0.237
Q9	< 0.001	0.573
Q10	< 0.001	0.634
Q11	< 0.001	0.632
Q12	< 0.001	0.368

Discussion

Chronic suppurative otitis media in developing countries is a frequent disease and canal wall down mastoidectomy regarded as one of the surgical treatments for those patients, we have other surgical options for treatment of COM including canal wall up mastoidectomy and canal wall down mastoidectomy with obliteration which need compliance by the patient for the follow up and second look operation which is not preferred by low socioeconomic patient.In our center because of delayed presentation of the patients, usually they have extensive disease, ignorance of patients, lack of regular postoperative follow up and the preference of a one stage surgery by most of our patients that mandate canal wall down mastoidectomy. When we look to the studies done on this subject, evaluation of COM outcome was narrowed to the measurement of recurrence rate and audiological outcome, these measures do not always represent the patients' symptoms or the patients' perception of their disease and its effect on their life [12], so recently quality of life has been used to assess the impact of the diseases on patients and adding such consideration to the treatment decision process and assessment of operation outcome.The COMQ-12 is newly established HRQOL questionnaire for the assessment of active COM and can be used in both preoperative and postoperative evaluation of patients with COM [11]. Because it is newly developed to the present date in literature, we could not find research papers that evaluate COMQ12 score in patients who had canal wall down mastoidectomy but there is research by Baetens et al[19] who used same questionnaire for mastoidectomy with bony obliteration. In our study total preoperative COMQ12 scores was 25.94 (SD=5.37) and when we compare it to total mean score of other studies that made among patient with COM in its various forms who didn't undergo any sort of treatment as the purpose of these studied was to validate use of COMQ12 in patient with active COM, total scores in following studies are as following: Prabhu et al 24.11 (SD = 5.43)[10], Kong et al (27.92 ± 13.18)[15], Doruk et al (30.64+11.76)[4], Oorts et al. 27.80 (SD=10.51)[16], Quaranta et al. 27.3 (6–53)[17] and Fonseca et al. 29[18].The difference in the COMQ12 scores between these studies which has been done in different countries using deferent languages and our

study is minimum which can be explained by perception of patient to the COM symptoms among different world population, and reveals that our patient where within average scores comparing to international population .In a Dutch version COMQ12, defined cut-off (8) to distinguish between the normal and abnormal health-related quality of life (HRQOL) scores, by using a group of healthy volunteers as well as group of patients with COM[16]. While Doruk et al defined cut-off point of (9) which is slightly higher than the Dutch version[4], the postoperative mean total COMQ12 score in our study was 10.56 (SD= 4.75) which means that our patient achieved near normal scores postoperatively.Regarding the severity of symptoms, its effect on life, work, and health, by the COMQ-12 post operatively showed a significant improvement in most aspects of Quality of life (Q1, Q2, Q9, Q10, Q11). A non-significant difference was observed in symptoms of discomfort, dizziness, and tinnitus (Q5, Q6, Q7), on other hand the hearing (Q3, Q4) there was deterioration in hearing perception. With these results and after a long follow-up, we can come to that result, that hearing remains the only factor that significantly has adverse effect on the long term postoperative HRQOL in patients who had CWD mastoidectomy with Tympanoplasty.Compa ring our findings with Baetens et al. who assessed quality of life in patient who had Canal wall up mastoidectomy with bony obliteration and tympanoplasty using COMQ12, total post-operative score was 9.35 (SD= 7.73) [19] which is close to our result 10.56 (SD=4.75). Historically, CWD has been associated with a poorer quality of life, compared to canal wall up CWU due to the limitations of the wide neo-mastoid cavity[7].However,standardized measurements that obtained through interviews and validated questionnaires was lacking. Lucidi in his study reported absence of a significant difference, in terms of self-perceived quality of life, in patients undergoing CWU compared to CWD [7]. Quaranta et al showed that in terms of quality of life and subjective symptoms, for both intact canal wall mastoidectomy tympanoplasty and canal wall down mastoidectomy tympanoplasty with mastoid obliteration are associated with excellent result[20]. Limitation of our study was small patient sample, more prolonged follow up needed, presence of validated version of questioner in Kurdish and Arabic language make the study free from bias.

Conclusions

Canal wall down with type III tympanoplasty showed a clear decrease in the severity of the ear symptoms, impact on life and work, and health care after surgery. Hearing was the only disabling factor that negatively affect outcome in post-operative quality of life; therefore, COMQ12 is specific for COM patients and reliable measuring score for assessing HRQOL and should be converted from clinical research to clinical practice to provide a personalized assessment for patient COM during their active state of the disease and after chronic otitis media surgery.

Conflict of interests

The authors recorded no conflict of interests.

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APPENDIX A.

Chronic Otitis Media Questionnaire-12:

Response for all questions
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

for question 10 and 11

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

1.	Discharge or drainage from the ear	0	1	2	3	4	5
2.	Having smelly ear	0	1	2	3	4	5
3.	Hearing problem at home eg requiring the volume of tv or radio to be turned up	0	1	2	3	4	5
4.	Hearing problem 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 of balance	0	1	2	3	4	5
7.	Tinnitus or noises in the ear	0	1	2	3	4	5
8.	Perform normal daily activity at home /work	0	1	2	3	4	5
9.	Wash or shower or bathe as you would like to ? ie how often have you been fearful of these activity causing ear infection	0	1	2	3	4	5
10	How often have you been to see GP about your ear problem	0	1	2	3	4	5
11	How often do you need to take medicine (including ear drops) for your problem	0	1	2	3	4	5
12	to what degree do your ear problems get you down	0	1	2	3	4	5