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Original Article

Health Related Quality of Life after the Bony Obliteration Tympanoplasty for COM with Cholesteatoma using the COMQ12 – A Disease Specific PROM

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OBJECTIVES: This study aimed to investigate the effect of canal wall up with bony obliteration tympanoplasty (CWU-BOT) on the health-related quality of life (HRQOL) in patients with chronic otitis media with cholesteatoma by using the chronic otitis media questionnaire 12 (COMQ-12).

MATERIALS and METHODS: This study is a retrospective analysis of the COMQ-12 of 26 patients who completed the COMQ-12 before and after a CWU-BOT with eradication of cholesteatoma followed by obliteration of the mastoid and paratympanic space with bone chips and bone pâté and reconstruction of the tympanic membrane and ossicular chain.

RESULTS: All patients were operated upon in our institute between 2014 and 2017. The median score of the 12 questions was preoperatively and postoperatively calculated, and then compared. A large effect was observed in the total score and the questions about running ear, discharge, and visits to the general practitioner. A medium positive size effect was observed in the questions about hearing in noisy surroundings, discomfort, dizziness, tinnitus, medication use, and the mental aspect of the patient. In the questions about the hearing at home and quality of life and impact on work, we noted a small positive size effect. In 50% of patients, the HRQOL became normal; the remaining 50% improved to a level very close to normal.

CONCLUSION: Canal wall up with bony obliteration tympanoplasty (CWU-BOT) showed a clear decrease in the severity of the symptoms, life and work impact, and health care after surgery.

KEYWORDS: Quality of life, cholesteatoma, bony obliteration tympanoplasty, chronic otitis media

INTRODUCTION

Chronical ear disease affects 2% of the population, and it is associated with material morbidity [1]. Patient-reported symptom appraisal is needed to assess disease severity and to appreciate the results of both surgical and nonsurgical interventions [2]. Chronical ear diseases including chronical otitis media (COM) negatively influence the quality of life (QOL) of patients [1, 3]. This study aimed to investigate the effect of canal wall up with bony obliteration tympanoplasty (CWU-BOT) [4] on the QOL in patients with COM with cholesteatoma.

The chronic otitis media questionnaire 12 (COMQ-12) was developed by Phillips and published in 2014 [5]. This 12-item questionnaire is mixed generic and disease specific. It investigates the symptom severity, life and work impact, and health impact of COM over the past six months. Sufficient consistency and initial validity has been obtained to justify the clinical use of the reduced item set derived from three other questionnaires: the Chronic Ear Survey (CES) [1], the Chronic Otitis Media Outcome Test 15 (COMOT-15) [6], and the Chronic Otitis Media 5 (COM-5) [7] after a literature review [5].

In 2015, a Dutch COMQ-12 version [Appendix A] was validated, and a cut-off value was calculated to distinguish between a normal and abnormal health-related quality of life (HRQOL) in COM using a series of healthy volunteers as well as series of patients

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with COM [8]. In 2017, Philips developed a second questionnaire to overcome the lack of responsiveness, the chronic otitis media benefit inventory (COMBI), which is a dynamic single-shot postoperative tool for the same type of patients [9]. Up to now, no other publication repeated the COMQ-12 patient-reported outcome measure (PROM) before and after surgery for COM with cholesteatoma in the same population.

Our aim was to assess the HRQOL by measuring the patient-reported health and impact on work and social life following CWU-BOT with obliteration of the mastoid and paratympanic spaces for COM with cholesteatoma using a disease-specific PROM questionnaire.

MATERIALS AND METHODS

Study Population

In our institute, patients with COM planned for tympanoplasty routinely complete the COMQ-12 before surgery and at different points in time after surgery. A retrospective analysis of a first cohort of consecutive cases of CWU-BOT with eradication of cholesteatoma followed by obliteration of the mastoid and paratympanic space with bone chips and bone pâté and reconstruction of the tympanic membrane and ossicular chain was planned.

All data were anonymously analyzed. The medical ethics committee of the GZA Ziekenhuizen Antwerp provided the ethics committee approval (180806RETRO).

Statistical Analysis

Power calculation was carried out with the Raosoft® sample size calculator (Raosoft Inc.; Seattle, WA, USA). We accepted a margin of error of 5% and confidence intervals of 95%. Because of the choices and assumptions, the minimum number of subjects to investigate was 25.

Statistical analysis was carried out with Statistical Package for the Social Sciences Statistic version 23 (IBM; Armonk, NY, USA). The Wilcoxon signed rank test with Bonferroni correction was applied to compare the preoperative and postoperative outcome. A p level of less than 0.004 was considered statistically significant. The benchmarks we used to determinate the size effect can be found in Cohen [10] and Rosnow et al. [10]

RESULTS

The study population consisted of 26 patients (13 males, 13 females; average age±standard deviation=35.7±20.6 years; age range=(7.5-77 years)) operated upon in our institute between 2014 and 2017. The mean interval between surgery and completing the questionnaire postoperatively was 2.35±0.64 years (Table 1).

The median score of the 12 questions was preoperatively and postoperatively calculated, and then compared. A significant decrease was achieved in the scores of all questions, except for question 3, 4, 7, 8, and 9 (Table 2). These questions evaluate the hearing situation including the presence of tinnitus or the ability to complete daily activities mostly related to water contact.

Table 1. Demographics

	n	Mean	Median	Standard deviation	Range
Age at surgery (years)	26	35.71	28.69	20.58	7.49-77.00
Completion interval (months)	26	2.28	2.44	0.65	0.69-3.95

n = number of patients

Table 2. Chronic otitis media questionnaire (COMQ-12) results

	Preoperative scores					Postoperative scores				
	Mean	Med	SD	Min	Max	Mean	Med	SD	Min	Max
Question 1	2.19	2.5	1.50	0	5	0.19	0	0.49	0	2
Question 2	2.15	3	1.76	0	5	0.08	0	0.39	0	2
Question 3	2.65	2	1.26	0	5	2.00	2	1.94	0	5
Question 4	3.46	4	1.39	0	5	2.37	2.5	2.13	0	5
Question 5	2.27	3	1.48	0	5	0.77	0	1.07	0	3
Question 6	1.11	1	1.14	0	3	0.23	0	0.62	0	3
Question 7	1.89	1.5	1.51	0	5	1.00	0	1.74	0	5
Question 8	0.69	0	1.29	0	5	0.15	0	0.61	0	3
Question 9	1.73	0.5	2.03	0	5	0.69	0	1.46	0	4
Question 10	1.65	2	1.35	0	4	0.12	0	0.43	0	2
Question 11	2.54	2	1.68	0	5	0.73	0	1.22	0	4
Question 12	2.58	3	1.33	0	5	1.04	0	1.34	0	4
Total score	24.92	23	9.48	11	44	9.35	8.5	7.73	0	28

Med: median; SD: standard deviation; Min: Minimum; Max: Maximum

Table 3. Wilcoxon signed rank test

	p	Significant	R	Effect size
Question 1	<0.001	Yes	0.56	Large
Question 2	<0.001	Yes	0.51	Large
Question 3	0.163	No	0.19	Small
Question 4	0.024	No	0.31	Medium
Question 5	<0.001	Yes	0.49	Medium
Question 6	0.002	Yes	0.43	Medium
Question 7	0.010	No	0.36	Medium
Question 8	0.090	No	0.23	Small
Question 9	0.052	No	0.27	Small
Question 10	<0.001	Yes	0.53	Large
Question 11	<0.001	Yes	0.49	Medium
Question 12	0.001	Yes	0.46	Medium
Total score	<0.001	Yes	0.59	Large

p: probability value; R: coefficient of determination

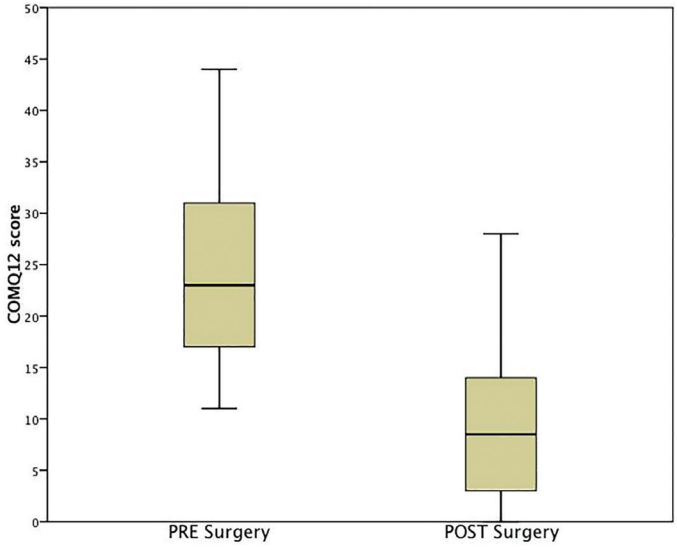

Figure 1. Box and Whisker plots of the *COMQ-12 score* (chronic otitis media questionnaire 12) for 26 patients operated with the canal wall up bony obliteration tympanoplasty technique; *PRE Surgery,* the preoperative COMQ-12 score; *POST Surgery,* the postoperative COMQ-12 score; postoperatively, 50% (n=13) of the patients have a score below the cut-off score of 8 that categorizes them as "normal" concerning health-related quality of life measured with this tool. The other postoperative 50% improved to a level "very close to normal"; bars, minimum to maximum values; rectangles, 25th-75th percentile, bars in rectangles, median value; dots outlying values.

Calculating the regression over time, the curve decreased in all questions, even in the non-significant questions 3, 4, 7, 8, and 9. Based on the Wilcoxon signed rank test, we calculated the effect size of each question and the total score (Table 3). A large effect was observed in the total score and the questions about running ear, discharge, and visits to the general practitioner. A medium positive size effect was observed in the questions about hearing in noisy surroundings, discomfort, dizziness, tinnitus, medication use, and the mental aspect of the patient. In the questions about the hearing at home and QOL and impact on work, we note a small positive size effect.

The previously published cut-off value of 8 for the COMQ-12 was used, which means that a total score of 8 or lower can be categorized as a normal HRQOL [8]. The postoperative evaluation in this study has a mean score of 9.35±7.73, which is not very different from the cut-off value. Between one and two year after surgery, 50% (n=13) of our patients scored "normal" concerning HRQOL measured with this tool. The other 50% scored up to a level "very close to normal." In the latter subgroup, the mean postoperative score was 15.4 (median=14), and the preoperative mean score was 28.2 (median=27). Even though they were not statistically normalized, they still made a significant improvement (p=0.003) (Figure 1).

Analysis of the outliers for each question reveal that patients with disease recurrence (n=1), myringitis, or retraction pockets score less than patients with the absence of these problems.

DISCUSSION

The COMQ-12 is a useful HRQOL questionnaire [5]. At the level of item format, when "before" and "after" are collected on separate occasions or periods, the COMQ-12 is a useful PROMs [12]. In 2017, a new mixed generic and specific dynamic PROMs for adult middle ear disease, named the COMBI, was developed and validated [9]. The COMBI's one-shot format offers convenience over available single-occasion status instruments for chronic middle ear disease that require completion both preintervention and postintervention. Carr et al. [13] stated that expectations and experience determine QOL. Differences obtained by subtraction or baseline adjustment (COMQ-12) may be more bias-free. Hence, we prefer to use the COMQ-12 instead of the COMBI.

This study, which investigated the symptom severity, life and work impact, and health impact of COM over the past six months, by the COMQ-12 preoperatively and postoperatively, showed a significant improvement in almost all aspects and a positive effect for all of the 12 questions. A non-significant improvement was observed in the questions concerning hearing (Q3, Q4, Q7) and lifestyle and work impact (Q8, Q9).

The long-term effect of the CWU-BOT for cholesteatoma concerning safety and hygienic restoration is well established [14-16]. The relative impact of the hearing situation becomes more and more important in the resulting postoperative situation [4, 17]. A postoperative hearing situation with an air-bone gap within 20 dBHL is achieved in only 50%-60% of the adult patients operated with the CWU-BOT technique [4, 18]. The hearing remains thus an unresolved limiting factor, especially in children operated for extensive cholesteatoma, and it is therefore possibly the most important negative influencing factor for the HRQOL [18]. The data of Lailach et al. [19] confirm this finding. They obtained similar results concerning hearing using the COMOT-15 questionnaire. With 7 out of 15 items asking about the hearing situation, this questionnaire is highly overweighed concerning the hearing aspect in HRQOL in COM.

Based on preliminary results of very long follow-up, we can carefully predict that the questions that evaluate the hearing (Q3, Q4) might remain the only significant factors that negatively influence the long-term postoperative HRQOL in patients operated for cholesteatoma with the CWU-BOT. However, these COMQ-12 data are only postoperative and not comparable with a preoperative score. Secondly, the

mean age at the moment of questionnaire completion was 28 years (range 14-32), and the mean age at the time of surgery was 11.4 years (range 6-16); so the patients were children at time of the operation, and the operation was performed with a mean of 17 years before completing the questionnaire [20]. Nowadays this type of analysis could have been performed with the COMBI [9, 21].

In this relatively short-term study, other factors than hearing also influenced the results. Beside the presence of recurrence, myringitis, or retraction pockets, patients with COM with cholesteatoma who underwent ear surgery could stay anxious to have a recurrence of disease or infection. They might be very careful not to have water contact; they might avoid dusty environment and noisy situations especially in the first year after surgery. Long-term analysis could give more information about this possible effect. We hope to report further on this in the near future.

To better understand the HRQOL patient-reported outcome measure of our patient, we now introduced a protocol in our clinical practice. Preoperatively, patients are asked to complete the COMQ-12. Postoperatively, patients complete the COMQ-12 together with the follow-up MRI at 1, 3, and 5 years postoperatively. Patients who do not complete the COMQ-12 preoperatively or who were operated before the start of our protocol are asked to complete the COMBI postoperatively at the same intervals. With this protocol, we expect to obtain an improved insight in the HRQOL of our patients.

CONCLUSION

The COMQ-12 preoperatively and postoperatively in patients operated for COM with cholesteatoma with the CWU-BOT technique to evaluate the HRQOL showed a clear decrease in the severity of the symptoms, life and work impact, and health care between one and two years after surgery. Of the patients, 50% became normal concerning HRQOL; the remaining 50% improved to a level very close to normal.

Ethics Committee Approval: The ethics committee approval for this study was received from the Ethics Committee of GZA Ziekenhuizen Antwerp (180806RETRO).

Informed Consent: Written informed consent was received from the patients who participated in this study.

Peer-review: Externally peer-reviewed.

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Conflict of Interest: The authors have no conflict of interest to declare.

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APPENDIX A. Original COMQ-12 (Phillips et al., 2014)

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:

8. Perform your normal daily activities at home /work? 0 1 2 3 4 5
9. Wash or shower or bathe as you would like to? i.e., how often have you been fearful of these activities causing an ear infection? 0 1 2 3 4 5

Health service impact:
10. How often have you been to see your GP about your ear problems? 0 1 2 3 4 5
11. How often do you need to take medicines (including eardrops) for your ear problem? 0 1 2 3 4 5

For the following question, please indicate how bad things are, on a scale of '0' to '5'.
'0' means not at all, and '5' means the worst you can ever imagine:

General:
12. To what degree do your ear problems 'get you down'? 0 1 2 3 4 5
Please check that you have produced an answer to every question and do ask for help if you find it hard.
Thank you very much for taking part.