Investigating characteristics of health-related quality of life in different types of chronic middle ear disease

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Abstract

Objectives: To investigate characteristics of health-related quality of life and evaluate the association between health-related quality of life (HRQoL) and hearing among different types of chronic middle ear diseases (CMED). Design: Prospective longitudinal cohort study. Setting: Tertiary referral centre. Participants: Adult patients undergoing surgical treatment for CMED. Main outcomes measures: Pure-tone audiometry, Zurich Chronic Middle Ear Inventory (ZCMEI-21). Results: A total of 108 patients (55 females, 53 males; mean age 51.0 years [SD 15.9]) were included. CMED included COM with cholesteatoma (epitympanic [n = 39]; pars tensa [n = 7]), persistent mastoid cavity (with recurrent cholesteatoma; n = 15; without recurrent cholesteatoma, n = 10), COM without cholesteatoma (n = 22), revision ossiculoplasty for hearing restoration (n = 14), and postinflammatory meatal fibrosis (n = 1). No significant differences between pre- and postoperative air conduction pure-tone average was observed in any type of CMED. Preoperatively, mean ZCMEI-21 score showed statistically significant differences among different types of CMED (p = 0.007) with persistent mastoid cavity without cholesteatoma exhibiting the highest mean ZCMEI-21 score (34.1, SD 7.7) indicating a poor HRQoL. At a mean follow-up period of 183 days, no statistically significant differences in ZCMEI-21 scores among different types of CMED were observed (p = 0.67). Conclusion: This study objectifies differences in HRQoL among different types of CMED. In types of CMED with indication for functional surgery only, such as persistent mastoid cavity without cholesteatoma or ossiculoplasty, the worst HRQoL was observed. Yet, in these types of CMED, HRQoL guides decision for treatment. Moreover, differences in HRQoL among different types of CMED are not closely associated with hearing, but largely depend on other symptoms, such as tinnitus, discharge or vertigo.

INTRODUCTION

Common causes of conductive hearing loss are chronic middle ear diseases (CMED), such as chronic otitis media (COM) with or without cholesteatoma. Without adequate treatment, hearing loss can lead to severely limited communication skills with a negative impact on health-related quality of life (HRQoL).[1] Furthermore, CMED may severely affect HRQoL due to symptoms such as discharge from the ear, otalgia and dizziness.[2] Standardized reporting of HRQoL, but also objective outcomes, such as hearing or surgical techniques, is needed when establishing individual or new therapeutic approaches, including new materials or prostheses as well as novel surgical techniques.[3] Concerning the evaluation of surgical treatments of CMED, it has been shown that the outcome of surgery is influenced by the structures involved into the disease, such as the ossicles.[4,5] It has to be assumed that postoperative hearing improvement by reducing the air-bone gap is an important but not the only factor influencing HRQoL.[2]Therefore, focusing on the audiological outcome as an objective evaluation of the surgical success may lead to misinterpretations.[1] The assessment of HRQoL has gained importance both in clinical studies and in clinical practice and has become an important indicator for the assessment of therapeutic success.[6–12] Standardized questionnaires are used to assess the individual impairment covering everyday situations, communication or social contacts and accompanying symptoms such as tinnitus.[13,14] The Zurich Chronic Middle Ear Inventory (ZCMEI-21) is a validated disease-specific

tool for assessing disease-specific symptoms of CMED and their impact on HRQoL.[6,10,15,16] The ZCMEI-21 features a complete assessment of ear-related symptoms and a comprehensive survey of psychosocial impairment.[6] Recent clinical applications of the ZCMEI-21 led to the assumption, that HRQoL varies among different types of CMED.[17,18] This may be explained by different types of CMED presenting with differing severity of single symptoms such as discharge, vertigo or hearing loss. This study therefore aimed to (i) investigate characteristics of HRQoL and (ii) evaluate the association between HRQoL and hearing among different types of CMED. Since not every CMED necessarily is treated surgically, e.g. persistent mastoid cavities without cholesteatoma or postinflammatory meatal fibrosis (PIMF), HRQoL questionnaires may assist the counselling of the patients and find the correct treatment.

METHODS

Study design and patient selection

In this prospective longitudinal study, adult patients undergoing surgery for CMED were assessed for inclusion. Patients were recruited from a tertiary hospital (RM, NWM). Patients received autologous reconstruction material (local pediculed muscle flaps, bone paté, temporal muscle fascia and cartilage) when the mastoid cavity was obliterated and/or to reconstruct the posterior canal wall. In cases of involvement of the ossicles, ossiculoplasty (TTP-Variac System, Heinz Kurz GmbH, Dusslingen, Germany) was performed to improve the hearing. Patients underwent pure-tone audiometry and completed the ZCMEI-21 both pre- and postoperatively.

Audiometric assessment

All audiometric measurements were performed with calibrated instruments in a sound-proof room (DIN EN ISO 8253) by audiologically trained staff. Measurements included standard pure-tone audiometry, performed with a clinical audiometer (AT1000, Auritec, Hamburg, Germany) in 5 dB steps. Pure-tone average (PTA) of the air conduction (AC) and bone conduction (BC) PTA was calculated from AC and BC thresholds at 0.5, 1, 2, and 3 kHz ($PTA_{0.5\text{-}3kHz}$).

ZCMEI-21 questionnaire

The ZCMEI-21 recently was developed and validated as a disease-specific questionnaire for chronic middle ear disease.[6] It has successfully been applied in first clinical trials.[10,17–19] The ZCMEI-21 consists of four subscales investigating ear specific symptoms, hearing, psychosocial impact and the use of medical resources. Answers are presented using a five-point Likert scale. High scores correlate with a poorer quality of life and the minimal clinically important difference (MCID) of the ZCMEI-21 is estimated at 5 points.[19]

Statistical analysis

All statistical tests were selected before data collection. Statistical analyses were performed using Microsoft Excel (version 15.29, Microsoft Corporation, Redmond, WA, USA) and Prism (version 8, GraphPad Software, La Jolla, CA, USA). The significance level was set to $p < 0.05$. The assumption of normality was tested graphically using quantile-quantile plots. If not otherwise specified, data are presented as mean with standard deviation (SD) or absolute numbers with percentages. A paired sample Student's t-test was performed to compare pre- and postoperative means in AC and BC PTA as well as ZCMEI-21 total scores. For comparison of >2 groups, a one-way ANOVA was performed. Following one-way ANOVA, the Holm-Sidak test was used to compare pairs of means. If applicable, p-values represent p-values corrected for multiple testing.

Data Availability Statement

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

RESULTS

A total of 108 patients (55 females, 53 males) with a mean age of 51.0 (SD 15.9) were included into the study. Indications for tympanomastoid surgery were COM with cholesteatoma (epitympanic [n = 39]; pars tensa [n

= 7]), persistent mastoid cavity with recurrent cholesteatoma (n = 15), COM without cholesteatoma (n = 22), persistent mastoid cavity without recurrent cholesteatoma (n = 10), revision ossiculoplasty for hearing restoration (n = 14), and postinflammatory meatal fibrosis (PIMF) (n = 1). The single patient with meatal fibrosis was excluded from any further statistical analysis. The mean follow-up period between surgery and the postoperative follow-up was 183 days (SD 156 days).

Although a trend to hearing improvement for each diagnosis was observed, no statistically significant differences between pre- and postoperative AC PTA among the groups were found (Figure 1). No difference among the groups was found for the AC PTA shift, i.e. the difference between the pre- and postoperative AC PTA (Figure 1). Further, no significant difference in the shift between the pre- and postoperative BC PTA was found in the entire cohort (mean difference 0.4 dB, SD 12.2 dB, p = 0.71).

The mean preoperative ZCMEI-21 total score was 28.8 (SD 13.9) and decreased to 21.9 (SD 12.9) postoperatively (mean ZCMEI-21 total score difference: -6.9, SD 0.9, $p < 0.0001$). The mean preoperative ZCMEI-21 total score (Figure 2A) in COM with epitympanic cholesteatoma was 29.3 (SD 15.9), in COM with pars tensa cholesteatoma 9.9 (SD 5.3), in persistent mastoid cavity with cholesteatoma 27.5 (SD 16.4), in COM without cholesteatoma 30.9 (SD 9.2), in persistent mastoid cavity without cholesteatoma 34.1 (SD 7.7), and in revision ossiculoplasty for hearing restoration 29.6 (SD 10.9). Statistically significant differences in the preoperative ZCMEI-21 total scores were found between patients with COM with epitympanic cholesteatoma and COM with pars tensa cholesteatoma (p = 0.007), between patients with COM without cholesteatoma and patients with COM with pars tensa cholesteatoma (p = 0.005), between patients with revision ossiculoplasty for hearing restoration and COM with pars tensa cholesteatoma (p = 0.02), between patients with COM with pars tensa cholesteatoma and persistent mastoid cavity without recurrent cholesteatoma (p = 0.004) and between patients with COM with pars tensa cholesteatoma and persistent mastoid cavity with recurrent cholesteatoma (p = 0.046) (Figure 2A).

The postoperative ZCMEI-21 scores did not show any statistically significant differences among any types of CMED (Figure 2B).

Groups showing significantly reduced ZCMEI-21 total scores after surgery indicating an improvement in HRQoL (Figure 2C) were COM with epitympanic cholesteatoma (mean reduction -6.6, p = 0.005), COM without cholesteatoma (mean reduction -8.7, p = 0.0009), and persistent mastoid cavity without recurrent cholesteatoma (mean reduction -10.9, p = 0.04). In all of these three groups, differences not only reached statistical, but also clinical significance as defined by the MCID.

The two symptoms that were hypothesized to be particularly different among the different types of CMED, i.e. ear discharge and vertigo/balance problems, were tested separately. Concerning ear discharge, significant differences among patients with COM with pars tensa cholesteatoma and patients with persistent mastoid cavity with recurrent cholesteatoma (p = 0.04) and between patients with persistent mastoid cavity with recurrent cholesteatoma and patients with revision ossiculoplasty for hearing restoration (p = 0.02) were found preoperatively (Figure 3A). Postoperatively, differences were only found between patients with persistent mastoid cavity with recurrent cholesteatoma and patients with revision ossiculoplasty for hearing restoration (p = 0.04) (Figure 3B). Concerning vertigo, significant differences between patients with COM with pars tensa cholesteatoma and patients with persistent mastoid cavity with recurrent cholesteatoma (p = 0.02) and patients with COM with pars tensa cholesteatoma and patients with persistent mastoid cavity without recurrent cholesteatoma (p = 0.04) were found preoperatively (Figure 3C). Postoperatively, no differences between the groups were found (Figure 3D).

DISCUSSION

Synopsis of key findings

This study reports differing symptoms and different HRQoL depending on the type of CMED. Although an overall clinically relevant improvement in HRQoL[19] was found after surgical therapy, subgroup analysis only revealed significant improvement in COM with epitympanic cholesteatoma, COM without cholesteatoma

and persistent mastoid cavity without recurrent cholesteatoma. No significant improvements were found in COM with pars tensa cholesteatoma, persistent mastoid cavity with recurrent cholesteatoma, and revision ossiculoplasty for hearing restoration. Postoperatively, however, no differences in HRQoL were found.

Comparisons with other studies

Preoperative differences in HRQoL were observed mainly for patients with COM with pars tensa cholesteatoma having a significantly better HRQoL compared to other types of CMED. COM with pars tensa cholesteatoma frequently follows retraction pockets and atelectasis. The latter conditions are commonly followed with regular ENT examinations and therefore, COM with pars tensa cholesteatoma may be diagnosed at an early stage with no or only mild symptoms associated. Moreover, the present cohort of COM with pars tensa cholesteatoma exhibited a relatively moderate preoperative hearing impairment, which may also explain the relatively low impairment of HRQoL. A tendency to higher preoperative HRQoL scores was observed in patients undergoing functional surgery (COM without cholesteatoma, persistent mastoid cavity without recurrent cholesteatoma, revision ossiculoplasty for hearing restoration). This is in line with recent studies showing differing HRQoL in patients with cholesteatoma and persistent mastoid cavity.[17,18] Patients with cholesteatoma tend to score lower in the ZCMEI-21 total score preoperatively and exhibited a smaller change in ZCMEI-21 total scores in comparison to patients undergoing mastoid cavity obliteration.[17,18] Accompanying symptoms of mastoid cavity (caloric vertigo, otorrhea, regular consultations with physicians) may explain higher subjective complaints in contrast to the frequently missing clinical symptoms of cholesteatoma.[17] In this study, the analysis of specific symptoms revealed the highest occurrence of ear discharge and vertigo in patients with persistent mastoid cavities regardless of the presence of cholesteatoma. Worst HRQoL was observed in the cohort with persistent mastoid cavity without cholesteatoma. With the absence of cholesteatoma, surgery should be cautiously indicated, and individual complaints need to be taken into account. In contrast, the treatment indication in presence of cholesteatoma directly arises with the diagnosis and does not depend on the patient's symptoms.[20,21] For other CMED, such as persistent mastoid cavity without cholesteatoma, impairment in HRQoL usually contributes to the decision for surgical treatment.[17]In otology, measuring and analysing HRQoL complements traditional, objective outcomes, such as pure tone audiometry. Even though questionnaires cannot replace a comprehensive clinical history, which also assesses the patient's individual expectations from surgical procedures, validated instruments can be a helpful tool for quantifying HRQoL in clinical practice and research.[6,18,22]

Limitations of the study

This study has the limitation that only a small number of patients was included per single type of CMED. Nevertheless, the data reported in this study encourages future assessment of HRQoL in different types of CMED in larger trials. Furthermore, a selection bias for patients undergoing functional surgery (COM without cholesteatoma, persistent mastoid cavity without recurrent cholesteatoma, revision ossiculoplasty for hearing restoration) is probable as only patients being aware of individual symptoms present to healthcare facilities and are referred for surgical treatment. Nevertheless, the results suggest that functional revision surgery may relevantly improve HRQoL if well indicated.

Conclusion

In conclusion, this study supports the notion of differences in the subjective impairment in HRQoL among different types of CMED. These differences are independent from hearing. HRQoL is therefore not only associated with hearing, but also depends on other symptoms, such as tinnitus, discharge or vertigo. These aspects are considerably important and should be assessed using validated disease-specific questionnaires in clinical practice and research under the aim of supplementing the clinical history and providing standardized patient-reported information.

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FIGURE LEGENDS

Figure 1. Pre- and postoperative hearing (air conduction pure-tone average) among different types of chronic middle ear diseases. Bold horizontal lines, means; whiskers, standard deviation. Ch., cholesteatoma; COM, chronic otitis media; w/, with; w/o, without.

Figure 2. Pre- and postoperative health-related quality of life assessed by the ZCMEI-21 among different types of chronic middle ear diseases. (**A**) Preoperative ZCMEI-21 total scores. (**B**) Postoperative ZCMEI-21 total scores. (**C**) ZCMEI-21 total score shifts. A negative value indicates a postoperative decrease in the ZCMEI-21 total score suggesting an improvement in health-related quality of life. The minimal clinically important difference (MCID) is indicated by the dotted line. Statistically significant differences between mean pre- and postoperative ZCMEI-21 total scores are indicated by asterisks (*, $p < 0.05$; **, $p < 0.01$; ***, $p < 0.001$; for exact p-values, see text). Bold horizontal lines, means; whiskers, standard deviation. Ch., cholesteatoma; COM, chronic otitis media; n. s., not significant; w/, with; w/o, without.

Figure 3. Pre- and postoperative assessment of single symptoms among different types of chronic middle ear diseases. (**A**–**B**) Pre- (A) and postoperative (B) ear discharge as assessed by question 2 (Q2) of the ZCMEI-21. (**C**–**D**) Pre- (C) and postoperative (D) vertigo/balance problems as assessed by question 5 (Q5) of the ZCMEI-21. Bold horizontal lines, means; whiskers, standard deviation. Ch., cholesteatoma; COM, chronic otitis media; n. s., not significant; w/, with; w/o, without.