Faculty of Medicine and Health Sciences

Patient reported outcome for chronic otitis media

Dissertation submitted to obtain the degree of Doctor of Medical Sciences at the University of Antwerp to be defended by

John PHILLIPS

Promoters

Prof. Dr. Vincent Van Rompaey, MD, PhD

Mr. Matthew Yung, MD, PhD

Prof. Dr. Paul Van de Heyning, MD, PhD

Antwerp, 2018

Print: D. Provo Digital printing – Gierle

ISBN 978 90 5728 577 6
NUR 600
Legal Deposit D/2018/12.293/06

Promoters

Prof. Dr. Vincent Van Rompaey, MD, PhD
Dept. of Translational Neurosciences & Otorhinolaryngology
Faculty of Medicine and Health Sciences
University of Antwerp, Antwerp, Belgium

Mr. Matthew Yung, MD, PhD
Department of Otorhinolaryngology, Head and Neck Surgery
Ipswich Hospital NHS Trust, Ipswich, United Kingdom

Prof. Dr. Paul Van de Heyning, MD, PhD
Dept. of Translational Neurosciences & Otorhinolaryngology
Faculty of Medicine and Health Sciences
University of Antwerp, Antwerp, Belgium

Members of the jury

Prof. Dr. Marc Braem
Department of Translational Neurosciences
Faculty of Medicine and Health Sciences
University of Antwerp, Antwerp, Belgium

Prof. Dr. Surbhi Malhotra
Vaccine & Infectious Disease Institute
Faculty of Medicine and Health Sciences
University of Antwerp, Antwerp, Belgium

Prof. Dr. Ronald Pennings, MD, PhD
Department of Otorhinolaryngology, Head and Neck Surgery
Radboud University Medical Center, Nijmegen, The Netherlands

Prof. Dr. Holger Sudhoff, MD, PhD, FRCS (London), FRCPath (London)
Department of Otorhinolaryngology, Head and Neck Surgery
Bielefeld Academic Teaching Hospital, Bielefeld, Germany

Table of contents

Abbreviations

CAPAG: Clinical Audit and Patient Advisory Group

CCES: Chinese Chronic Ear Survey

CES: Chronic Ear Survey

COM: chronic otitis media

COM-5: Chronic Otitis Media 5

COMBI: Chronic Otitis Media Benefit Inventory

COMOT-15: Chronic Otitis Media Outcome Test 15

COMQ-12: Chronic Otitis Media Questionnaire 12

COMQ-14: Chronic Otitis Media Questionnaire 14

CSOM: chronic suppurative otitis media

dB: decibel

ENT: ear, nose and throat

FAC: factor

FAC1: first factor

FAC2: second factor

FAC3: third factor

GBI: Glasgow Benefit Inventory

HHIA: Hearing Handicap Inventory for Adults

HRQoL: health related quality of life

K-CES: Korean Chronic Ear Survey

kHz: kilohertz

MeSH: medical subject heading

N: number

NIH: national institutes of health

NHS: National Health Service

NS: not significant

OME: otitis media with effusion

PC: principal component

PC1: first principal component

PC2: second principal component

PC3: third principal component

PCA: principal component analysis

PRO: patient reported outcome

PROM: patient reported outcome measure

PROMIS: Patient Reported Outcome Measurement Information Systems

PTA: pure tone audiogram

Q: question number

OECD: Organisation for Economic Co-operation and Development

QoL: quality of life

RCOMQ-12: Russian Chronic Otitis Media Questionnaire 12

SD: standard deviation

SE: standard error

SF-36: Short Form 36

SRM: standardised response mean

SNOT-22: Sino-Nasal Outcome Test 22

UK: United Kingdom

US: United States

WHO: World Health Organisation

Preface

Introduction

Objectives

Introduction

According to the World Health Organisation, the global burden of illness from chronic otitis media involves 65-330 million individuals with draining ears, 60% of whom suffer from significant hearing impairment. HRQoL measurements reflect the overall burden of disease from the perspective of the patient rather than the clinician. This makes their acquisition particularly pertinent in otology, where single clinical, radiological, and audiological findings may inter-relate poorly, and poorly predict HRQoL. Furthermore, the use of HRQoL measures has been shown to aid both the patient's prioritisation of their symptoms and the management of their individual expectations. In a wider context, ambitions to publish both patient-reported outcomes and objective health markers for the purposes of benchmarking, improving standards, and determining payment to health-care providers have been set out by some European governments.

The ideal HRQoL questionnaire is based on (1) general knowledge from the literature, (2) the psychometric analysis of large bodies of data on the relevant patients, (3) input from experienced clinicians, and (4) input from patients. However, compromises among many competing suggestions for items are necessary if a short, succinct and efficient user-friendly tool is to result. Physical, social and psychological aspects of disease affect quality of life; all justify some coverage, as chronic middle ear disease effects patients in a multidimensional manner, but these cannot be covered exhaustively in any very short instrument.

It was from this backdrop, that my journey began in the development and testing of two robust disease specific HRQoL instruments for the assessment of chronic otitis media. The product of my initial venture was the COMQ-12. This was appraised using a number of techniques in a variety of populations. Firstly, it was appraised in individuals with chronic otitis media; and secondly it was appraised in normal, apparently healthy, individuals.

In 2006, a prospective UK myringoplasty audit was launched under the direction of ENT-UK's clinical audit and patient advisory group (CAPAG). To understand the role of a HRQoL tool in the context of national audit, outcome data from the UK myringoplasty audit was reviewed together with an appraisal of the infrastructure employed to acquire this data. In addition to this, a systematic review of the world literature was performed to compare the characteristics of various HRQoL tools in this area. In doing this we were able to verify the diversity of the individual questionnaire items, to report the methods employed to evaluate the questionnaire, and to identify areas for development in the future.

To develop the use of our questionnaire outside the UK, the COMQ-12 was translated into Dutch and we appraised its use in a population of individuals attending Antwerp University Hospital. From here, we chose to determine whether the COMQ-12 could be internationally adaptable by determining whether it could be satisfactorily applied to the Russian population. The healthcare system in Russia differs in many fundamental ways to that of the United Kingdom and Western Europe, so as such, provided great insight into

how socioeconomic and cultural factors can affect patient-reported quality of life for COM.

The conclusions of the UK myringoplasty audit and the systematic review suggested that current health-related quality of life (HRQoL) questionnaires lack documented ability to assess 'responsiveness', i.e. changes in outcomes. Dynamic assessment tools, such as the somewhat generic Glasgow Benefit Inventory, already exist as popular 'one-shot' instruments. However, a tool that is both dynamic and semi-specific, focusing on the chief domains affected in chronic middle ear disease had not existed. To address this unmet requirement for chronic otitis media, the COMBI was developed.

Objectives

The following objectives were defined in order to define a stepwise approach to develop two robust HRQoL questionnaires for the assessment of chronic otitis media:

1. **Chapter 1: A new health-related quality of life measure for active chronic otitis media (COMQ-12): development and initial validation.**
    a. To develop a new HRQoL questionnaire for the assessment of active chronic otitis media.
    b. To acquire preliminary data regarding the psychometric data properties of this HRQoL questionnaire.
2. **Chapter 2: COMQ-12 scores in adult patients without chronic middle ear disease.**
    a. To consider COMQ-12 scores in individuals without active COM.
    b. To propose the 'normal' values that should be considered before contemplating surgical intervention in patients with COM.
3. **Chapter 3: Myringoplasty Outcomes in the United Kingdom.**
    a. To determine the outcome of myringoplasty as undertaken by ENT surgeons in the United Kingdom.
    b. To assess the current systems available for providing national outcome data.

4. **Chapter 4: A systematic review of patient reported outcome measures for suppurative chronic otitis media.**
    a. To systematically appraise the world literature to identify existing PROMs for the assessment of outcomes in patients with chronic otitis media.
    b. To verify the diversity of the individual questionnaire items, to report the methods employed to evaluate the questionnaires, and to identify areas for development in the future.
5. **Chapter 5: Development of the Dutch version of the health-related quality of life measure for chronic otitis media (COMQ-12).**
    a. To translate the COMQ-12 into Dutch via a process of translation and back-translation.
    b. To appraise the psychometric properties of the Dutch version of the COMQ-12.
6. **Chapter 6: International application of the Chronic Otitis Media Questionnaire 12 (COMQ-12).**
    a. To translate the COMQ-12 into Russian via a process of translation and back-translation.
    b. To appraise the psychometric properties of the Russian version of the COMQ-12.

7. Chapter 7: The Chronic Otitis Media Benefit Inventory (COMBI): development and validation of a dynamic quality of life questionnaire for chronic ear disease.

a. To produce a change-oriented short-form health-related quality of life questionnaire for the assessment of active chronic otitis media.

b. To appraise this questionnaire for internal consistency and for factor structure.

Chapter 1

A new health-related quality of life measure for active chronic otitis media (COMQ-12): development and initial validation

Parts of this chapter have been published in:

Phillips JS, Haggard M, Yung M. A new health-related quality of life measure for active chronic otitis media (COMQ-12): development and initial validation. Otology & Neurotology. 2014;35(3):454-8.

Abstract

Objective: To develop and document for clinical use a new HRQoL questionnaire for the assessment of active chronic otitis media.

Study Design: Two-centre prospective correlational study.

Setting: Two otology referral centres in England.

Patients: Fifty consecutive adult patients with a history of active chronic otitis media.

Results: Consistency criteria (Cronbach's alpha) and first principle component loadings showed satisfactory scoring with 11 of the original 12 items. A single factor was obtained correlating highly with simple unweighted scoring.

Conclusions: Sufficient consistency and initial validity information was obtained from patients with a history of active chronic otitis media to justify clinical use of the reduced item set and acquisition of further data to refine scoring.

Introduction

Chronic ear disease is associated with material morbidity and affects approximately 2% of the population.[1] From a clinical perspective, a considered appraisal of patient symptoms is needed to assess disease severity, and to appreciate the results of both surgical and non-surgical interventions.[2] The same applies from a research perspective[3], only more formally. In this context, measures of health-related quality of life (HRQoL) allow a systematic replicable appraisal of need for and benefit from treatment. In current health care policy, emphasis has been on remedying the past lack of outcome information as a tool of quality assurance[4] giving rise to the concept of patient-reported outcome measures (PROMs) mostly intended for routine administration and therefore very short. HRQoL, and PROMs (or patient reported outcomes – PROs in the USA), are not interchangeable terms. HRQoL assesses a patient's overall health status, whereas PROMs in their requirement to monitor the outcome of interventions may also include specific symptom items not necessarily of broad value to health. This article is concerned with the development and initial validation of a mixed generic and specific HRQoL questionnaire, ultimately for use as a PROM, but for consistency throughout, the term HRQoL will be used in the text. Furthermore, the preliminary study described within this article does not consider the outcome of a particular intervention; so to refer to this HRQoL questionnaire at this stage as a PROM would be premature.

Methods

The ethical issues in the validation of the COMQ-12 were presented to the UK NHS National Research Ethics Service for approval before acquiring local approvals from the two hospitals' Research and Development departments.

Preliminary scoping and construction of the COMQ-12

1. A literature search and review of questionnaires on symptoms associated of chronic otitis media revealed three meriting close consideration: the Chronic Ear Survey (CES)[1], the Chronic Otitis Media Outcome Test 15 (COMOT-15)[5], and the Chronic Otitis Media 5 (COM-5).[6] All questions were amalgamated to create an initial 'long list' containing 33 questions categorized by theme (See Figure 1). This long list was then further reduced by removing repetitions of near-identical questions.

2. Over a period of 12 months this long list was revised progressively using patients' commentaries on two aspects of the item content: (a) topic relevance to patient's symptoms, and (b) comprehensibility of question wordings.

3. The resulting predecessor to the COMQ-12, the COMQ-14 was a provisional list of 14 items. This was reviewed by members of the Clinical Audit and Practice Advisory Group (CAPAG) of ENT-UK (British Association of Otorhinolaryngology - Head and Neck Surgery), all three authors of this article are current members of this group. These discussions eliminated two items, giving the current version COMQ-12 (Appendix A).

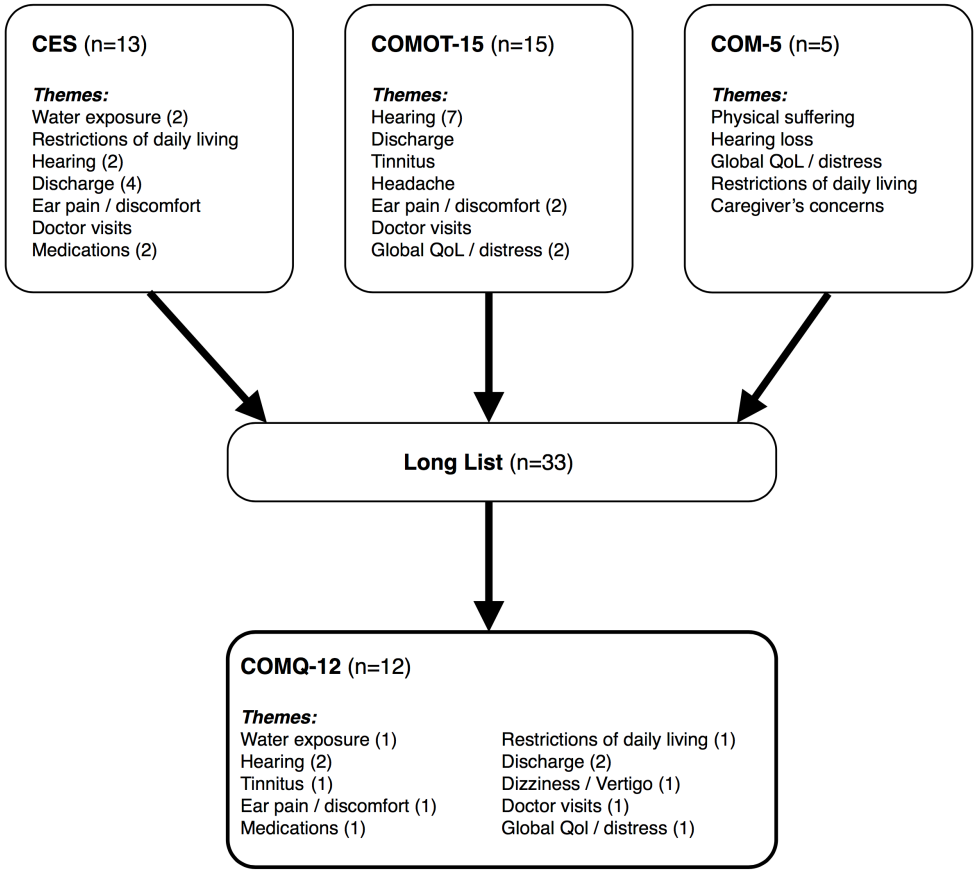

Figure 1. *Process of preliminary scoping and construction of the COMQ-12.*

Reference sample given the COMQ-12 items

A total of 50 patients with a history of active Chronic Otitis Media (27 from Norfolk & Norwich University Hospital NHS Foundation Trust and 23 from Ipswich Hospital NHS Trust) completed the COMQ-12. In addition, a proforma was used to extract supplementary information from the patients' medical records. This information included the patient's audiogram, clinical findings (presence of cholesteatoma, presence of perforation, and current disease activity), and symptom duration documented in the patient's medical record.

Results

Of the 50 patients enrolled in the study, the participants represented a heterogeneous sample of Chronic Otitis Media (COM) patients, the average age was 50(21) years. Participants presented with different forms of COM and at different stages of disease activity. 30% of participants had a wet ear when they completed the questionnaire; 23% of patients had visible cholesteatoma, and 18% of patients had a perforated tympanic membrane. The average COMQ-12 score was 21(14) out of a maximum score of 60. Table 1 displays score averages and distributions for individual COMQ-12 question responses.

Table 1. *Score averages and distributions for individual COMQ-12 question responses.*

Question Number	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12
Mean	1.600	1.700	2.420	2.940	1.660	1.460	1.320	1.300	1.560	1.700	1.860	2.200
Median	1.000	1.000	2.000	3.000	1.000	1.000	1.000	0.000	0.000	1.500	1.500	1.500
Std. Deviation	1.6162	1.7642	1.4581	1.5039	1.5858	1.6563	1.6218	1.8211	2.1205	1.6568	1.9379	1.9060
Variance	2.612	3.112	2.126	2.262	2.515	2.743	2.630	3.316	4.496	2.745	3.756	3.633

Internal Consistency

Cronbach's alpha is a summary index of internal consistency, which also embraces reliability assessing how well the individual component questions of a questionnaire correlate with each other. The Cronbach's alpha was 0.889 for the COMQ-12, indicating high consistency of items as markers of a common underlying severity of COM.

Principle Component Analysis

To further quantify consistency and generate an optimum scoring formula the standard data-reduction technique of principal component analysis (PCA) was used. This allowed us to consider the contribution of each individual question (or item) in generating the questionnaire total, hence potentially to drop uninformative items. The first principal component (PC1), is the dimension of variation underlying the greatest tendency for all items in such a questionnaire to be positively intercorrelated. PCA supported the inclusion of eleven of the twelve questions. Question 11 ('How often do you need to take medicines (including eardrops) for your ear problem?') demonstrated low PC loading, i.e. it added little. However, we decided not to remove this question from the questionnaire, only from the scoring at this stage of development as our panel had considered it a useful part of the clinical record.

Reliability

The design of this preliminary study did not permit gathering of test/re-test reliabilities, so we used the alternative, split-half reliabilities, by correlating the sub-totals for 6 and 5 of the 11 scoring items. To avoid variability that may occur as a result of chance in a particular single split (i.e. 1st vs. 2nd half, odd- vs. even-numbered items) and especially with few items, we used these two methods in addition to 10 further randomly determined divisions. The mean of the 12 split-half reliability correlations was 0.817, demonstrating satisfactorily high reliability.

Item Weighting

The PCA offers optimum weighting of questions for the total questionnaire score. However, the advantage in this over simple totaling of the response values for each individual item was negligible. It was therefore considered overall to be more beneficial to adopt the simpler method of summing the individual question scores as this avoided decimal arithmetic and aided simple application.

Discussion

HRQoL measurements reflect the overall burden of disease from the perspective of the patient rather than the clinician. This makes their acquisition particularly pertinent in otology, where single clinical, radiological, and audiological findings may inter-relate poorly, and also poorly predict HRQoL. Furthermore the use of HRQoL measures has been shown to aid both the patient's prioritisation of their symptoms[7] and the management of their individual expectations.[8] In a wider context, ambitions to publish both patient-reported outcomes and objective health markers for the purposes of benchmarking, improving standards, and determining payment to health-care providers have been set out by some European governments.[9] Patient reported outcome measures are also likely to represent an important part of the revalidation process of doctors in the UK.[10] The COMQ-12 is positioned to contribute to this development.

Item content and ecological validity

The ideal HRQoL is based on (1) general knowledge from the literature, (2) the psychometric analysis of large bodies of data on the relevant patients, (3) input from experienced clinicians, and (4) input from patients.[11] However, compromises among many competing suggestions for items are necessary if a short, succinct and efficient user-friendly tool is to result. Physical, social and psychological aspects of disease affect quality of life; all justify some coverage, as chronic middle ear disease effects patients in a multidimensional manner, but these cannot be covered exhaustively in any very short instrument such as the COMQ-12. As to internal consistency, Cronbach's alpha for the COMOT-12 at .899 compares well with values

reported for the CES (0.83)[12] and COMOT-15 (0.89-0.91)[5] and is well above the conventional minimum of 0.70.

Although the COMQ-12 derives from the CES, COMOT-15 and COM-5, it differs in emphasis from each of these other questionnaires. CES does not include questions related to tinnitus or dizziness, which often figure in patients' symptoms; furthermore the prevalence and significance of these two symptoms in patients with chronic otitis media has been supported in the literature[13,14] and was highlighted in our preliminaries with patients. CES also does not consider the patient's distress or reduction in quality of life; direct judgments of these are considered important elements in HRQoL questionnaires.[15]

Unpublished work has suggested that a favourable outcome of surgery for COM, as reported by the patient, may be more a reflection of an improvement in hearing than an improvement in other ear-related symptoms.[16] COMOT-15 is very heavily oriented to the assessment of hearing, with nearly half of the questions being based on this symptom. Both CES and the COMQ-12 do consider the impact of hearing loss in patients with chronic ear disease, but respect the broader symptom profile via inclusion of diverse items. We found no correlation between hearing level and COMQ-12 scores (for PC r= 0.036, NS; for integer total r=0.022, NS). Given the reliability shown this null finding can be seen positively as non-redundancy with the conventional measure. Unless good reason is found to favour reported over measured hearing as usually obtained, this supports minimal inclusion of questions on hearing loss in a COM questionnaire. In some patients with COM no active infection is present,

and the majority of their symptoms will be related to hearing. A worthy example would be the patient with a long-term self-cleaning retraction pocket that has resulted in erosion of the tip of the incus. In such a patient, the paucity of hearing items entails that the COMQ-12 could not be a sensitive tool to demonstrate improvement in hearing from surgical intervention. Such cases therefore require primary assessment via conventional audiometry, the gold standard mode of assessment in this circumstance.

Neither CES nor COMQ-12 features the symptom of headache, which featured in COMOT-15. During the production of the COMQ-12, patients and professionals alike considered this symptom to be rare. Headache is a fairly common and non-discriminating symptom in the general population, so was omitted.

Generalizability

The study population represented a heterogeneous group compromising of individuals of different ages, disease presentation and disease activity. In view of this absolute outcome totals cannot be broadly applied in a general manner. Further work that considers 'normal' COMQ-12 scores in individuals unaffected by COM, as well as individuals at specific stages of disease is considered a sensible aspiration for future work. Having established largely good basic properties it can now be considered worthwhile to enroll collaborators for assessing further specifications including an assessment of COMQ-12 scores before and after surgical intervention and additional reliability data to address test/re-test variability via a larger scale study.

Applications of the COMQ-12 to audit

For many applications the desirable compromise between length (for precision and reliability) and brevity (with greater user acceptance) is tilted towards minimal respondent burden. It is hoped that the COMQ-12 strikes the right balance, and that its brevity is sufficient to assure acceptance among otologists and patients. For clinical audit purposes, clinical findings, operative details and audiological assessment have been considered essential.[17] However the three-way dissociation between recurrence rates, auditory measurements, and patient reported symptoms cannot be emphasized strongly enough.[18] Thus, with HRQoL measures gaining acceptance among clinicians, the COMQ-12 should complement the data acquired by contemporary clinical audit tools.[17] Furthermore it is hoped that the COMQ-12 will improve general standards of patient care in diverse ways by defining success or failure through the eyes of the patient rather than the clinician.

Conclusions

The COMQ-12 is a new HRQoL questionnaire for the assessment of active chronic otitis media. Sufficient consistency and initial validity information has been obtained to justify clinical use of the reduced item set and acquisition of further data to refine scoring in both a clinical and research setting, an issue to be addressed in a future publication. Subject to satisfactory evaluation of various forms of validity including responsiveness (i.e. contrast between pre- and post- intervention data), it is hoped that the COMQ-12 will be a useful HRQoL questionnaire, particularly as a PROM.

References

1. Nadol JB Jr, Staecker H, Gliklich RE. Outcomes assessment for chronic otitis media: the Chronic Ear Survey. *Laryngoscope*. 2000;110(3 Pt 3):32-5.
2. Koller M, Lorenz W. Survival of the quality of life concept. *Br J Surg*. 2003;90(10):1175-7.
3. Koller M, Klinkhammer-Schalke M, Lorenz W. Outcome and quality of life in medicine: a conceptual framework to put quality of life research into practice. *Urol Oncol*. 2005;23(3):186-92.
4. Black N. Patient reported outcome measures could help transform healthcare. *BMJ*. 2013;346:f167.
5. 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
6. 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.
7. Nies C, Celik I, Lorenz W, et al. Outcome nach minimal-invasiver Chirurgie. Qualitative Analyse und Bewertung der klinischen Relevanz von Studienendpunkten durch Patient und Arzt. *Chirurg* 2001;72: 19–29

8. Koller M, Lorenz W, Wagner K, et al. Expectations and quality of life of cancer patients undergoing radiotherapy. *J R Soc Med.* 2000;93: 621–8

9. Liberating the NHS: Transparency in Outcomes – A Framework for the NHS. Department of Health. 2010.

10. Medical Revalidation – Principles and Next Steps. The report of the Chief Medical Officer for England's working group. Department of Health. July 2008.

11. Dietz de Loos DA, Segboer CL, Gevorgyan A, Fokkens WJ. Disease-Specific Quality-of-Life Questionnaires in Rhinitis and Rhinosinusitis: Review and Evaluation. *Curr Allergy Asthma Rep.*

12. Wang PC, Nadol JB Jr, Merchant S, Austin E, Gliklich RE. Validation of outcomes survey for adults with chronic suppurative otitis media. *Ann Otol Rhinol Laryngol.* 2000;109(3):249-54.

13. Gianoli GJ, Soileau JS. Chronic suppurative otitis media, caloric testing, and rotational chair testing. *Otol Neurotol*. 2008;29(1):13-5.

14. Habesoglu M, Habesoglu TE, Karatas C, Tosun A, Gursel AO, Oysu C. Is there any predictor for tinnitus outcome in different types of otologic surgery? *Eur Arch Otorhinolaryngol*. 2012 Nov 15. [Epub ahead of print]

15. Koller M, Lorenz W. Quality of life: a deconstruction for clinicians. *J R Soc Med*. 2002;95:481-488.

16. Iain Swan. Personal Communication. March 2013.

17. Yung M, Gjuric M, Haeusler R, Van de Heyning PH, Martin C, Swan IR, Tange RA, Huy PT; European Otology Database Project Group. An international otology database. *Otol Neurotol*. 2005;26(5):1087-92.

18. Smyth GD, Patterson CC. Results of middle ear surgery: do patients and surgeon agree? *Am J Otol* 1985;6:276-279.

Appendix A: *COMQ-12*

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 ringer the appropriate number. Please consider each problem as it has been over the past six 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.

Mr John Phillips
Consultant ENT Surgeon
Norfolk & Norwich University Hospital NHS Foundation Trust

For the following questions, please indicate <u>how severe</u> 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 <u>how often</u> 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.

Chapter 2

COMQ-12 scores in adult patients without chronic middle ear disease

Parts of this chapter have been published in:

Phillips JS, Yung MW. COMQ-12 scores in adult patients without chronic middle ear disease. Clin Otolaryngol. 2014;39(6):362-7.

Abstract

Objective: To determine the COMQ-12 score in an adult population without active COM

Study design: Analysis of COMQ-12 scores in participants without active COM

Setting: East Anglia, United Kingdom

Participants: 70 healthy volunteers recruited from two local hospitals

Results: The median COMQ-12 score overall was 2 and the modal score was 0 with 27(39%) participants achieving this score.

Conclusion: We recommend that the 'normal' values defined in this study be seriously considered before contemplating intervention, especially when patients with low scores are considered for surgery.

Background

The Chronic Otitis Media Questionnaire 12 (COMQ-12) is a 12-item multiple-choice disease specific health-related quality of life (HRQoL) questionnaire. Preliminary work on the validation of the COMQ-12 has been completed and has provided the opportunity to examine multiple dimensions of chronic middle ear disease.[1] As part of the development of a HRQoL questionnaire it is essential to establish 'normal' scores as it is this reference point by which realistic goals of treatment, amongst other domains can be measured.

Aim

To identify the COMQ-12 score attributable to subjects who do not have active chronic middle ear disease.

Ethical Considerations

The ethical issues regarding the validation of the COMQ-12 were presented to the UK NHS National Research Ethics Service for approval before acquiring local approvals from the Research and Development departments of the Norfolk & Norwich University Hospital and Ipswich Hospital**.**

Methodology

Healthy volunteers, comprising of hospital staff (doctors, nurses, administrative staff), were provided with the COMQ-12 (See Chapter 1, Appendix A). In addition to completing the COMQ-12, participants were also asked their age, sex and whether that had a history of ear problems other than that of chronic otitis media; this included symptoms of hearing loss, tinnitus, dizziness, childhood ear surgery, childhood ear infections, and episodic acute ear infection. Participants with a history of ear problems other than that of chronic otitis media were included in this study but details with this regard were recorded to enable subgroup analysis. Participants who described a history consistent with chronic otitis media were excluded from the study.

Results

Seventy completed questionnaires were included in the study, these were completed by 18 men and 52 women. The mean age of respondents was 44 (range 19–61). Sixteen of the seventy participants reported a history of ear diseases other than that of chronic otitis media, these are summarised in Table 1.

Table 1. *Summary of causes of ear problems reported by participants.*

Cause of ear problems	**Number of respondents**
Tinnitus	5
History of ear infections	4
Hearing loss	3
Childhood grommets	2
Ear discomfort	1
Impacted wax	1

COMQ-12 scores overall ranged from 0 to 41 with a mean score of 3.4(SD 6.1); for the participants that did not report a history of ear diseases scores ranged from 0 to 15 with a mean score of 1.85(SD 2.94). The median COMQ-12 score overall was 2 and the modal score was 0 with 27(39%) participants achieving this score. The median COMQ-12 score overall is presented rather than the mean score due to the skewed nature of the data. The frequencies of COMQ-12 scores overall are displayed in Figure 1. Of significance, overall, 83% of respondents achieved a score of 5 or less, 93% of respondents achieved a score of 10 or less out of a possible maximum of 60.

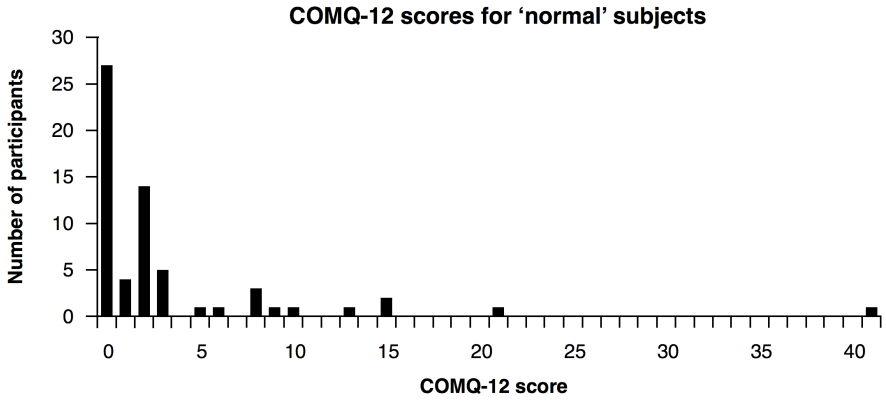

Figure 1. *Frequency of COMQ-12 scores overall amongst all 70 participants.*

Discussion

Chronic middle ear disease is a condition that may be associated with significant morbidity and affects approximately 2% of the population.[2] The COMQ-12 has been developed with the purpose of evaluating overall burden of disease from the perspective of the patient. This benefits the patient by allowing an appreciation of individual patient's prioritisation of their symptoms[3] as well as allowing adequate management of their individual expectations.[4] From a research perspective patient reported outcome measures allow comparison of different surgical and non-surgical interventions for the management of conditions from the patients' perspective. In a more wider context, ambitions to publish both patient-reported outcomes and clinical outcomes for the purposes of benchmarking, improving standards, and determining payment to health-care providers has been set out by the UK Government in its recent White Paper.[5] The role of patient reported outcome measures are likely to represent an important part of the revalidation process of doctors in the UK.[6] As such the COMQ-12 has been introduced as a new component of the common otology audit database.[7]

The initial process of validation has taken place[1], where the COMQ-12 was found to demonstrate high internal consistency with a Cronbach's alpha value of 0.889. The validation of such an assessment tool is not a single isolated process but is a process involving many different stages. A key part of such an assessment is to determine normal values in a population unaffected by the disease state being appraised, this process has been

achieved during the assessment of other otolaryngology HRQoL questionnaires such as the SNOT-22.[8]

Our results suggest that in the population studied the majority of patients would have a COMQ-12 score of 5 or less. Higher reported scores are unlikely to be due to an underlying prevalence of mild hidden chronic middle ear disease, but more likely to be due to some of the individual questions reflecting isolated symptoms unrelated to chronic middle ear disease such as hearing loss and tinnitus which are present in the normal population. To some degree the validity of this study is dependent on how we have defined our 'normal' population. The study population was taken from a cohort of predominantly female participants; however, the age range of these participants was large, ranging from 19 to 61. By selecting participants who were all in employment we have selected those members of the population who are likely to be in better general health than those who are unable to work. In view of these points, a larger study that better represents the UK population as a whole would make for a more representative study.

Conclusions

We recommend that the 'normal' values defined in this study are seriously considered before contemplating intervention, especially when patients with COMQ-12 scores of 5 or under are considered for surgery.

References

1. Phillips JS, Haggard M, Yung MW. A new patient-reported outcome measure for chronic otitis media (COMQ-12): development and initial validation. *Otol. Neurotol*. 2014;35(3):454-8.
2. Nadol JB Jr, Staecker H, Gliklich RE. Outcomes assessment for chronic otitis media: the Chronic Ear Survey. *Laryngoscope*. 2000;110(3 Pt 3):32-5.
3. Nies C, Celik I, Lorenz W, et al. Outcome nach minimal-invasiver Chirurgie. Qualitative Analyse und Bewertung der klinischen Relevanz von Studienendpunkten durch Patient und Arzt. *Chirurg* 2001;72: 19–29.
4. Koller M, Lorenz W, Wagner K, et al. Expectations and quality of life of cancer patients undergoing radiotherapy. *J R Soc Med*. 2000;93: 621–8.
5. Liberating the NHS: Transparency in Outcomes – A Framework for the NHS. *Department of Health*. 2010.
6. Medical Revalidation – Principles and Next Steps. The report of the Chief Medical Officer for England's working group. *Department of Health*. July 2008.
7. Yung M, Gjuric M, Haeusler R, Van de Heyning PH, Martin C, Swan IR, Tange RA, Huy PT; European Otology Database Project Group. An international otology database. *Otol Neurotol*. 2005;26(5):1087-92.
8. Gillett S, Hopkins C, Slack R, Browne JP. A pilot study of the SNOT 22 score in adults with no sinonasal disease. *Clin Otolaryngol*. 2009;34(5):467-9.

Chapter 3

Myringoplasty outcomes in the United Kingdom

Parts of this chapter have been published in:

Phillips JS, Nunney I, Yung MW. Myringoplasty Outcomes in the United Kingdom. Journal of Otology and Laryngology. 2015;129(9):860-4.

Abstract

Objectives: To determine the outcome of myringoplasty as undertaken by ENT surgeons in the United Kingdom. To assess the current systems available for providing national outcome data.

Study design: Prospective national multicentre audit.

Setting: Multiple hospitals throughout the United Kingdom.

Participants: ENT surgeons practicing in the United Kingdom.

Results: Data was prospectively collected over a 3-year period between 1st Match 2006 and 1st March 2009 using the web-based Common Otology Database. In total, 33 surgeons provided valid and complete data for 495 procedures. The overall closure rate for myringoplasty was 89.5%. The average hearing gain for successful primary myringoplasties was 9.14dB (10.62). The Common Otology Database provided an effective platform for capturing outcome data.

Conclusion: Myringoplasty is a safe and effective procedure in the United Kingdom. With the introduction of revalidation by the General Medical Council, participation in national audit will be mandatory in the future. This study demonstrates that performing audit using a web-based audit tool would be fit for such a purpose.

Introduction

In 2006, a prospective UK myringoplasty audit was launched under the direction of ENT-UK's clinical audit and patient advisory group (CAPAG). Following in the footsteps of previous national audits of ear surgery outcomes[1], the primary aim of this venture was to provide individual surgeons with comparative data to allow benchmarking against their peers. Subsequent to the completion of this audit, the opportunity arose to review the outcome of myringoplasty as a whole to provide insight into the success rates and other outcomes measures for UK patients undergoing this surgery by UK surgeons. In the current political climate, it is ever more important to appreciate outcomes, for the benefit of patients, by enabling them to know more about the implications of surgery, as much as for the benefit of surgeons, to allow them insight into factors that may influence the outcomes of this kind of surgery. Outcome data is also being of increasing interest to local and national commissioning groups who require clinical evidence to justify the provision of services.

Data collection

Data was prospectively collected over a 3-year period between 1st Match 2006 and 1st March 2009 using the web-based Common Otology Database. This is a web-based audit tool that allows participants to enter prospective data before surgery, immediately after surgery and at a number of intervals post-operatively. The Common Otology Database is a well-established tool that is widely used amongst ENT surgeons throughout the UK. Data is recorded in a secure and anonymized format to abide with current good practice, the front end of the database is password protected and data is stored in an encrypted format. Participation in the national myringoplasty audit amongst ENTUK members was voluntary rather than compulsory and no funding was required from participants or their employing Trusts.

Data fields regarding patient demographics, risk factors, inter-operative findings, surgical technique, post-operative findings and complications, and pre and post-operative hearing thresholds were recorded. The data fields in the Common Otology Database were determined by CAPAG and tried to minimize the use of free-text fields to encourage uniformity in the way data is recorded. To facilitate this, the database employs the use of multiple dropdown menus and tick-boxes to avoid inconsistencies and to avoid data entry errors.

Post-operative data was recorded between three and six months after surgery. Patients with cholesteatoma, or undergoing ossiculoplasty were excluded. Surgeons with >20% missing follow up data were excluded from

final analysis. Data analysis was conducted in a manner to ensure continued anonymity with respect to both the surgeon and the patient. Statistical analysis was carried out by a medical statistician using statistical software (SAS version 9.3).

In total, 33 surgeons provided valid and complete data for 495 procedures. The overall closure rate for myringoplasty was 89.5%. For primary myringoplasty the closure rate was 90.6%, and for revision myringoplasty the closure rate was 84.2%. Closure rates according to age group are reported in table 1.

Table 1. *Closure rates according to age group.*

Age group	**Primary surgery**		**Revision surgery**	
	N	Closure rate	N	Closure rate
0-9	29	96.6%	3	33.3%
10-13	63	85.7%	10	90.0%
14-16	38	86.8%	6	83.3%
>16	283	91.5%	63	85.7%

The incidence and outcomes of myringoplasty according to the presence of a cleft palate, diabetes or the patient being a smoker are reported in table 2. Table 3 reports the prevalence and outcomes of myringoplasty with respect to the condition of the middle ear mucosa at the time of surgery. The incidence and outcomes of myringoplasty with respect to the location and type of perforation are reported in table 4.

Table 2. *Incidence and outcomes of myringoplasty according to the presence of a cleft palate, diabetes or the patient being a smoker.*

Risk Factor	**N**	**Closure rate**
Cleft Palate	3	66.7%
Diabetes	13	92.3%
Smoking	102	91.2%

Table 3. *Prevalence and outcomes of myringoplasty with respect to the condition of the middle ear mucosa at time of surgery.*

Middle ear appearance	Prevalence	Closure rate
Granulation/hyperplasia	7.1%	82.9%
Oedematous	24.0%	88.2%
Fibro-adhesive	11.3%	89.3%
Tympanosclerosis	4.0%	90.0%

Table 4. *Incidence and outcomes of myringoplasty according to location and type of perforation.*

Perforation	N	Closure rate
Flaccida	3	100.0%
Anterior	191	89.5%
Inferior	160	90.0%
Posterior	210	90.0%
Subtotal	59	79.7%
Total	3	100.0%

The relationship between perforation size and tympanic membrane closure is illustrated in figure 1. The Cochran-Armitage test for trend was applied, and this confirmed a close relationship between perforation size and successful tympanic membrane closure (p=0.0053). The incidence and outcomes of myringoplasty with respect to the type of graft material used are reported in table 5. The prevalence of post-operative complications are listed in table 6, and the post-operative appearances of the tympanic membrane are reported in table 7. The average hearing gain for successful primary myringoplasties was 9.14dB (10.62) and the average hearing gain for successful revision myringoplasties was 7.86dB (12.28). The average hearing gain for unsuccessful primary myringoplasties was 9.16dB (11.09) and the average hearing gain for unsuccessful revision myringoplasties was 12.29dB (7.01).

Table 5. *Incidence and outcomes of myringoplasty according to graft material used.*

Graft material	N	Closure rate
Cartilage	8	75.0%
Temporalis fascia	426	89.9%
Fat	8	75.0%
Periosteum	4	75.0%
Perichondrium & cartilage	11	90.9%
Perichondrium	24	83.3%

Table 6. *Prevalence of post-operative complications.*

Complication	Prevalence
Alteration of taste	1.2%
Facial nerve palsy	0.0%
Intractable tinnitus	0.6%
Vertigo	0.4%
Hearing loss	1.4%
Wound infection	1.4%

Table 7. *Post-operative appearance of the tympanic membrane.*

Tympanic Membrane Appearance	Prevalence
Myringitis	2.2%
Anterior blunting	1.0%
Atelectasis	0.0%
Retraction	0.8%
Lateralization	0.4%
Meatal Stenosis	0.0%
Complete collapse	0.0%
Otitis media with effusion	1.4%

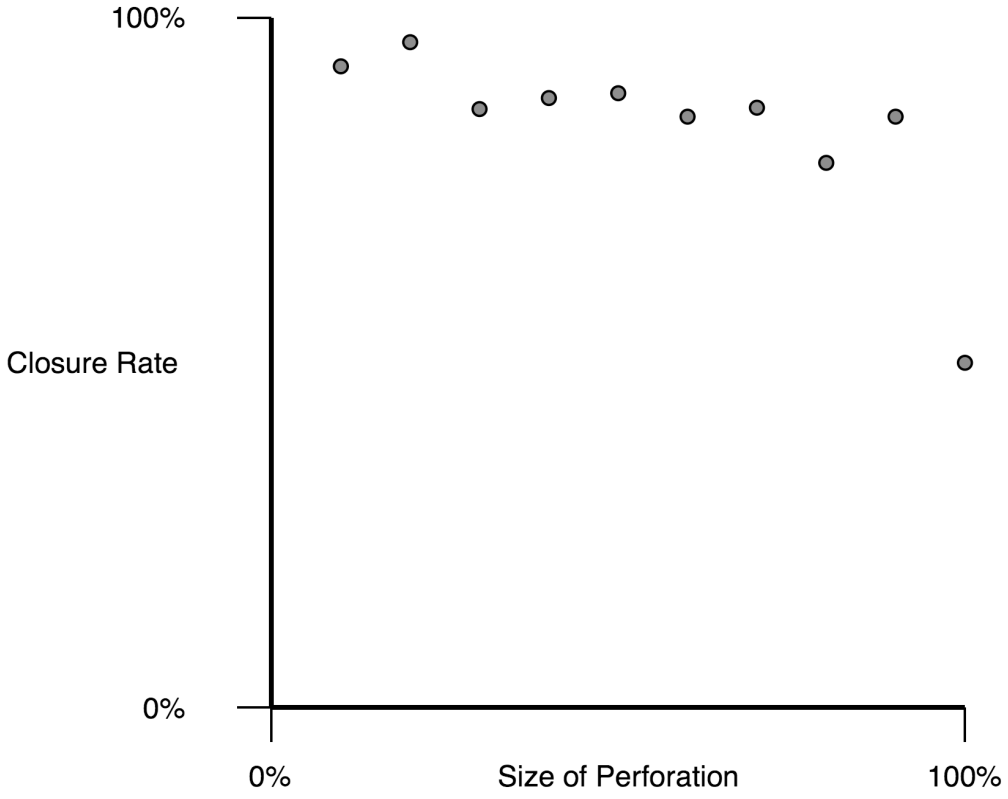

Figure 1. *Relationship between perforation size and tympanic membrane closure.*

Discussion

This national myringoplasty audit represents the most recent prospective appraisal of myringoplasty practice and outcome in the UK. The last national prospective myringoplasty audit in the UK was performed in 1995.[1] This audit reported the outcomes for 495 procedures, however, this is less than half of the number of procedures that were reported in the audit of 1995. The overall closure rate in this myringoplasty audit was 89.5%; this compares with 82.2% in the 1995 audit. This may, however, represent a difference in the specifics of the procedure being performed, the age distribution amongst patients, and perforation and middle ear characteristics rather than due to a true improvement in closure rates over time. When reporting the 1995 audit, Kotecha *et al.* demonstrated an improvement in closure rate from a 1990 national UK retrospective audit.[2] It was proposed that this was due to better recording of perforations as the 1990 audit was retrospective, it was also suggested that modifications in myringoplasty technique had been responsible.

A number of domains were appraised with relation to the outcomes for the patients undergoing myringoplasty in this series, these are discussed individually below.

Implications of age

Upon reviewing the literature, some authors report a lower success graft-take rate for younger children while others report that there is no difference in the graft-take rate between the younger and older children.[3] Otherwise, it has been shown that many children have OME, retraction pocket and

hearing problem even after a successful myringoplasty procedure.[3] Closure rates in children following myringoplasty have been reported to be between 35 and 94 per cent.[4] This variation has been considered to be due to a higher incidence of upper respiratory tract infections and the often immature function of the Eustachian tube.[5, 6] For those children aged over 10 years, closure rates within this series improved with increasing age. However, this may not reflect longer-term closure rates, as it is well appreciated that in children, a proportion of tympanic membranes re-perforate with time.

Implications of smoking

A number of studies have consistently found that closure rates for myringoplasty are lower in smokers as compared with non-smokers.[7, 8, 9] This is considered to be due the effects of smoking on the micro-circulation of the middle ear mucosa. The results of this audit propose average closure rates of over 90% in smokers. This is at odds with the literature, but may not be representative of the longer-term outcomes.

Implications of the location and size of the perforation

Larger and more anteriorly placed perforations are known to be associated with lower rates of successful closure.[1, 5, 10, 11] The results of this audit found that subtotal perforations were associated with slightly poorer rates of closure than anterior, inferior or posterior perforations. There was a 100% closure rate for total perforations, however this is based on only the results of three patients. Generally, there was a gradual and consistent reduction in closure rates as the reported size of the perforation increased.

Influence of graft material

A recent systematic review of morphological outcome (intact ear drum) from cartilage tympanoplasty versus fascia tympanoplasty favoured cartilage tympanoplasty.[12] This finding was not substantiated in this audit, but this may be a consequence of low numbers of patients undergoing cartilage myringoplasty, and the fact that those patients undergoing cartilage tympanoplasty may have been selected due to a perceived poorer chance of success if temporalis fascia were to be used. Pooled data from two randomized controlled trials comparing the graft take rate of cartilage and fascial tympanoplasties have demonstrated no difference in the graft take rate.[13]

Post-operative complications

Complications of myringoplasty are commonly low. Post-operative wound infections, post-operative myringitis and a loss of taste occurred more frequently in patients in this audit as compared with the national myringoplasty audit of 1995 (1.4% vs. 0.8%, 1.2% vs. 0.2%, 2.2% vs. 0.4% respectively). Kotecha *et al.* reported a single facial nerve palsy in their series of around a thousand patients[1], our series reported outcomes for half as many patients and no post-operative facial nerve palsies were recorded. This audit did not distinguish a first side from a second side myringoplasty, it is possible that the effects of damaging both chorda tympani nerves would have been present in patients undergoing second side surgery.

Change in hearing

Previous series looking at hearing improvement after myringoplasty describe a mean hearing improvement of about 8dB[10, 14], this compares well with our results were the average hearing gain for successful primary and revision myringoplasties were 9.14dB (10.62) and 7.86dB (12.28) respectively. Interestingly, patients who had an unsuccessful myringoplasty also experienced an improvement in their hearing.

Although the data produced by this audit may provide food for thought, two shortcomings are particularly worthy of note. Firstly, the data may not truly provide an insight into myringoplasty practice and outcome in the UK as it is likely that only committed otologists have participated in this voluntary exercise. Only those surgeons performing a sufficient number of myringoplasties will have participated, with the occasional myringoplasty surgeon not taking part. Secondly, only short-term data has been appraised and it is appreciated that that longer-term outcomes are poorer.[15] With the introduction of revalidation by the General Medical Council, participation in national audit will be mandatory in the future.[16] This study demonstrates that this audit tool would be fit for such a purpose. It is possible that the completeness of cases reported could be validated using complementary data using Hospital Episode Statistics.

Currently the Common Otology Database provides a web-based tool to support the recording of personal otology surgical outcomes.[17] This tool records pre-operative, intra-operative and post-operative symptoms, findings at operation, details regarding interventions, and audiometric data. In the future this will be supported further with patient-reported outcome

measures data from validated questionnaires such as the COMQ-12 (a health-related quality of life measure for active chronic otitis media).[18] In a more wider context, ambitions to publish patient-reported outcomes for the purposes of benchmarking and improving standards has been set out by the UK Government in its recent White Paper *Liberating the NHS: Transparency in Outcomes – A Framework for the NHS.*[19] It would be hoped that future audits would involve all surgeons that are involved in this kind of surgery and assess longer-term outcomes using a greater variety of methods.

Conclusions

This most recent national ear surgery outcome audit has led to greater insight into the practice amongst UK surgeons, performing myringoplasty on UK patients. Myringoplasty is a safe and effective procedure in the United Kingdom. The role of audit in assessing results for personal reflection is an important consideration for all surgeons and will form an essential part of the revalidation process in the UK in the future. This study demonstrates that performing audit using a web-based audit tool would be fit for such a purpose.

References

1. Kotecha B, Fowler S, Topham J. Myringoplasty: a prospective audit study. *Clin Otolaryngol Allied Sci* 1999;24:126–9
2. Ryan RM, Brown PM, Cameron JM, Fowler SM, Grant HR, Topham JH. Royal College of Surgeons comparative ENT audit 1990 *Clin Otolaryngol Allied Sci* 1993;18:541-6
3. Yung M, Neumann C, Vowler SL. A longitudinal study on pediatric myringoplasty. *Otol Neurotol* 2007;28:353-5
4. Aggarwal R, Saeed SR, Green KJ. Myringoplasty. *J Laryngol Otol* 2006;120:429-32
5. Gersdorff M, Garrin P, Decat M, Juantegui M. Myringoplasty: longterm results in adults and children. *Am J Otol* 1995;16:532–5
6. Caylan R, Titiz A, Fallcioni M, De Donato G, Russo A, Taibah A, *et al*. Myringoplasty in children: factors influencing surgical outcome. *Otolaryngol Head Neck Surg* 1998;118:709–13
7. Lin YC, Wang WH, Weng HH, Lin YC. Predictors of surgical and hearing long-term results for inlay cartilage tympanoplasty. *Arch Otolaryngol Head Neck Surg* 2011;137:215-9
8. Uguz MZ, Onal K, Kazikdas KC, Onal A. The influence of smoking on success of tympanoplasty measured by serum cotinine analysis. *Eur Arch Otorhinolaryngol* 2008;265:513-6
9. Becvarovski Z, Kartush JM. Smoking and tympanoplasty: implications for prognosis and the Middle Ear Risk Index (MERI). *Laryngoscope* 2001;111:1806-11

10. Lee P, Kelly G, Mills RP. Myringoplasty: does the size of the perforation matter?. *Clin Otolaryngol Allied Sci* 2002;27:331–4
11. Scally CM, Allen L, Kerr AG. The anterior hitch method of tympanic membrane repair. *Ear Nose Throat J* 1996;75:244–7
12. Mohamad SH, Khan I, Hussain SS. Is cartilage tympanoplasty more effective than fascia tympanoplasty? A systematic review. *Otol Neurotol* 2012;33:699-705
13. Yung M, Vivekanandan S, Smith P. Randomized study comparing fascia and cartilage grafts in myringoplasty. *Ann Otol Rhinol Laryngol* 2011;120:535-41
14. Palva T, Ramsay H. Myringoplasty and tympanoplasty – results related to training and experience. *Clin Otolaryngol Allied Sci* 1995;20:329–35
15. Halik JJ, Smyth GD. Long-term results of tympanic membrane repair. *Otolaryngol Head Neck Surg* 1988;98:162–9
16. Medical Revalidation – Principles and Next Steps. The report of the Chief Medical Officer for England's working group. *Department of Health* (electronic only), 23 July 2008
17. Yung M, Gjuric M, Haeusler R, Van de Heyning PH, Martin C, Swan IR, *et al*. An international otology database. *Otol Neurotol* 2005;26:1087-92
18. Phillips JS, Haggard M, Yung MW. A new patient-reported outcome measure for chronic otitis media (COMQ-12): development and initial validation. *Otol Neurotol* 2014;35:454-8
19. Liberating the NHS: Transparency in Outcomes – A Framework for the NHS. *Department of Health* (electronic only), 2010

Chapter 4

A systematic review of patient reported outcome measures for suppurative chronic otitis media

Parts of this chapter have been published in:

Phillips JS, Yung MW. A systematic review of patient reported outcome measures for chronic suppurative otitis media. Laryngoscope. 2016;126(6):1458-63.

Abstract

Objective: The purpose of this review was to systematically appraise the world literature to identify existing PROMs for the assessment of outcomes in patients with chronic suppurative otitis media, to verify the diversity of the individual questionnaire items, to report the methods employed to evaluate the questionnaire, and to identify areas for development in the future.

Data Sources: EMBASE (1980-November 2014), MEDLINE (1946-November 2014), CINAHL (1981-November 2014) and PsycINFO (1806-November 2014).

Review Methods: A systematic literature search was independently undertaken by two authors according to predefined inclusion and exclusion criteria.

Results: Nine original articles were identified, which overall outlined the evaluation of four different questionnaires.

Conclusion: This systematic appraisal of the world literature has identified four PROM questionnaires for use in patients with chronic suppurative otitis media. All four questionnaires evaluate reliability and validity using different psychometric methods. The CES questionnaire has been most broadly evaluated and disseminated. All four questionnaires assess static health status. There are many advantages of developing a dynamic 'one-hit' questionnaire to assess the health status of patients having undergone an intervention for chronic suppurative otitis media.

Introduction

Over the last decade there has been an increasing interest in, and demand for, well-constructed instruments to define surgical and non-surgical outcomes from a patient's perspective. Patient reported outcome measures (PROMs) have provided an easily accessible solution and currently play a significant role in the assessment of outcome for reflective practice, audit, and research.[1, 2, 3] In the United Kingdom, the role of PROMs for revalidation is likely to present as a mandatory requirement in specialties where these assessment tools exist.[4] In the United States, PROM development represents an important part of the US NIH roadmap, as outlined by the work of the Patient Reported Outcome Measurement Information Systems (PROMIS) initiative.[5] There is an increasing role of PROMs outside the routine healthcare setting, with the pharmaceutical industry also recognising the significant role of PROMs in assessing health improvement.[6]

According to the World Health Organisation, the global burden of illness from chronic suppurative otitis media involves 65-330 million individuals with draining ears, 60% of whom suffer from significant hearing impairment[7]. The purpose of this review is to systematically appraise the world literature to identify existing PROMs for the assessment of outcomes in patients with chronic suppurative otitis media, to verify the diversity of the individual questionnaire items, to report the methods employed to evaluate the questionnaire, and to identify areas for development in the future. The nomenclature employed to define chronic middle ear disease varies worldwide. For consistency, we will use the term chronic suppurative

otitis media throughout this review, as defined by the world health organization[7].

Definitions

The world health organization chronic suppurative otitis media burden of illness document remarks that a variation in the nomenclature used for the classification of this condition is common[7]. As such the terms COM (Chronic Otitis Media) and CSOM (Chronic Suppurative Otitis Media) are often used interchangeably. The condition that we wish to study is as defined by the world health organization as 'a chronic inflammation of the middle ear and mastoid cavity, which presents with recurrent ear discharges or otorrhoea through a tympanic perforation.'. The world health organization accepts that this includes cholesteatoma[7]. For the purpose of writing a search strategy, we used the term chronic otitis media, as this would identify articles relating to chronic otitis media and chronic suppurative otitis media in the broadest fashion. This approach was deemed most appropriate as it provided a highly sensitive search, yet required further manual examination of the search results to allow a specific analysis of the available literature.

Literature search:

A systematic literature search was performed using EMBASE (1980-November 2014), MEDLINE (1946-November 2014), CINAHL (1981-November 2014) and PsycINFO (1806-November 2014). There were no limits imposed regarding language. There were no restrictions regarding the age group of patients studied. The literature search was performed using the Medical Subject Heading (MeSH) search terms: OTITIS MEDIA or MIDDLE EAR DISEASE or CHRONIC OTITIS MEDIA or SUPPURATIVE OTITIS

MEDIA or OTITIS MEDIA CHRONICA or OTITIS MEDIA EXSUDATIVE or OTITIS MEDIA PURULENTA, together with the terms: HEALTH ASSESSMENT QUESTIONNAIRE, STRUCTURED QUESTIONNAIRES, QUESTIONNAIRE and the free text: "questionnaire". All articles identifying a process to assess reliability or validity of a disease specific health-related quality of life (HRQoL) questionnaire for the assessment of chronic otitis media were pursued.

Literature review

Initially 965 articles were identified from the database searches. A process of reference reduction was independently undertaken by both authors according to predefined inclusion and exclusion criteria (Figure 1.). The reference sections of all original articles were hand-searched to identify other potentially relevant articles. The authors were aware of one article that had been accepted for publication at the time of performing this review[8], so this was added to the initial list of included articles. The process undertaken is schematically presented in Figure 2.

Inclusion criteria:

1. Description of a patient completed questionnaire.

2. Reference to a population specifically with chronic supporative otitis media / chronic middle ear disease or a population specifically without chronic supporative otitis media / chronic middle ear disease.

3. Reported outcomes of reliability or validation, including, but not restricted to: test-retest variability, internal consistency, principal component analysis, face and content validation, construct validation, criterion validation, sensitivity analysis.

Exclusion criteria:

1. Chronic otitis media with effusion or recurrent acute otitis media.

Figure 1. *Inclusion and exclusion criteria.*

A total of nine original articles were ultimately identified with no disagreement between the two authors during the process of reference reduction. A judgement was made *a priori* to further assess all studies to verify the diversity of the individual questionnaire items according to the three principle domains proposed by Koller[9], and to identify all methods employed to evaluate the reliability and validity of each questionnaire. An assessment according to Koller was employed as this was considered to be the most suitable method to appraise the material diversity of potential questionnaire items in the context of chronic suppurative otitis media. Questionnaires were assessed specifically with respect to the following characteristics: patient age group, number of items, range of item scoring, method of attaining score totals, the types and outcomes of reliability testing, and the types and outcomes of validity testing. However, the assessment was conducted in an inclusive manner to include all the types of evaluation described within the text of all of the included article.

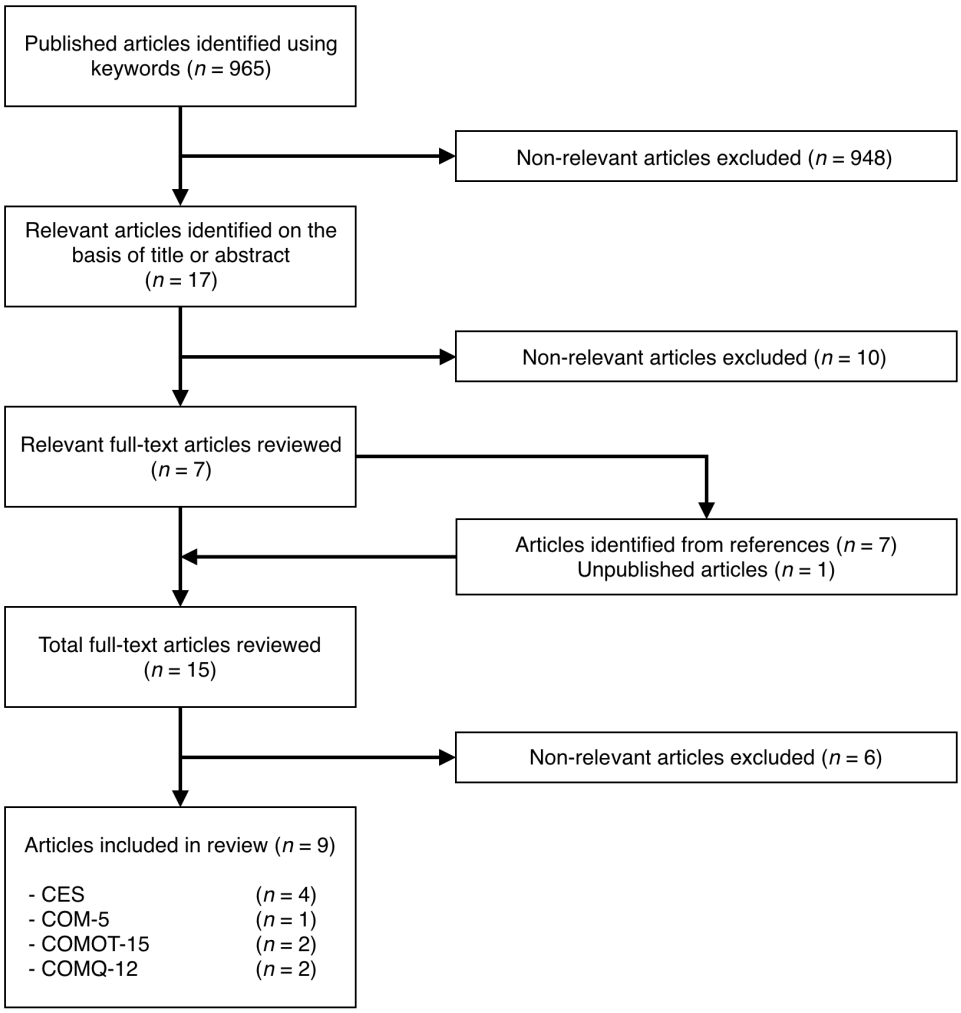

Figure 2. *Process of reference reduction employed during the systematic review of the literature*

Results

Nine original articles were identified[8, 10-17], which overall outlined the evaluation of four different questionnaires – the CES[10-13], the COM-5[14], the COMOT-15[15-16] and the COMQ-12.[8, 17] These articles, together with key findings are reported in Table 1. All four instruments provide a static appraisal of disease specific quality of life. Table 2 categorises the items contained within each questionnaire. The CES was developed in the United States in English[11, 12] for use in adults, but has since been translated and evaluated in Chinese[13] and Korean.[10] Tests for both reliability and formal validation procedures have been employed providing satisfactory scores.[10-13] The COM-5 was developed as an instrument to be used only in children.[14] The COMOT-15 was developed in German for use in adults.[15-16] The COMQ-12 is the most recently described instrument, the COMQ-12 has been developed in English for use in adults.[8, 17] None of the included studies evaluated correlation amongst different instruments.

The outcome of the assessment of questionnaire item diversity is depicted in Table 3. For the domains defined as 'somatic', 'psychological', and 'social'; the COM-5 and COMQ-12 were considered to contain direct questions regarding all three domains. The CES did not contain any direct questions regarding the patient's psychological wellbeing, and the COMOT-15 did not contain any direct questions regarding the patient's social functioning.

Table 1. *Summary of the psychometric properties of identified studies. CCES=Chinese CES; HHIA=Hearing Handicap Inventory for Adults; K-CES=Korean CES; PTA=Pure Tone Audiogram; SF-36=Short Form 36; SRM=Standardised Response Mean.*

Questionnaire	Authors	Population	Questionnaire Language	Items	Range of Scores	Main Methods of Evaluation	No. of Subjects	Major Reported Outcomes
CES	Byun et al. 2011[10]	Adults	Korean	13	0–100	Internal consistency, test-retest reliability, correlation with SF-36	166	Chronbach's $\alpha = 0.850$; test-retest correlation = 0.822 ($P < .001$); high correlation between SF-36 and K-CES
	Nadol et al. 2000[11]	Adults	English			Normal values, internal consistency, test-retest reliability, correlation with SF-36, HHIA and PTA, responsiveness of clinical change	147 (73 at 1 year)	Average score in normal population = 87.8; Chronbach's $\alpha = 0.83$; test-retest correlation = 0.81; no significant postintervention change in SF-36; hearing portions of CES correlated with HHIA ($r = 0.54$, $P = .0005$); SRM = 0.42 (n = 33)
	Wang et al. 2000[12]	Adults	English			Internal consistency, test-retest reliability, correlation with SF-36, responsiveness of clinical change	91	Chronbach's $\alpha = 0.83$; test-retest correlation = 0.91; high correlation between SF-36 and CES; SRM = 0.42
	Wang et al. 2003[13]	Adults	Chinese			Internal consistency, test-retest reliability, correlation with SF-36, responsiveness of clinical change	103	Chronbach's $\alpha = 0.81$; test-retest correlation = 0.98; high correlation between SF-36 and CCES
COM-5	Vlastos et al. 2009[14]	Children	English	5	1 to 7	Internal consistency, test-retest reliability, correlation with Global Ear-related Quality of Life, responsiveness of clinical change	45	Internal consistency "significant correlations" identified; interclass correlation coefficient = 0.73; correlation with Global Ear-related Quality of Life, $r = -0.485$; SRM for tympanoplasty = 1.3; SRM for mastoidectomy = 0.7
COMOT-15	Baumann et al. 2009[15]	Adults	German	15	0 to 100	Internal consistency, test-retest reliability, responsiveness of clinical change	121	Chronbach's $\alpha = 0.89$; test-retest correlation >0.8; SRM = 0.24–0.46
	Baumann et al. 2011[16]	Adults	German			Correlation with SF-36 and PTA	90	No significant postintervention change in SF-36; correlation between air conduction and total questionnaire score at baseline: $r = 0.24$, $P = .02$, and at 6 months: $r = 0.36$, $P = .0005$
COMQ-12	Phillips et al. 2014[17]	Adults	English	12	0 to 60	Internal consistency, content validation	50	Chronbach's $\alpha = 0.889$
	Phillips and Yung 2014[8]	Adults	English			Normal values	70	Average score in normal population: 0 (mode), 2 (median)

All four questionnaires demonstrate a high level of internal consistency with Chronbach's alpha values ranging between 0.81 and 0.89. The paediatric questionnaire (COM-5), contains 5 items; whereas the adult questionnaires (CES, COMOT-15 and COMQ-12), contain between 12 and 15 items. The calculation of score totals involves simple summation for the COMQ-12, whereas further mathematical procedures are required for the other three questionnaires (CES, COM-5 and COMOT-15). All of the adult

questionnaires (CES, COMOT-15 and COMQ-12) allow individual categorical assessment.

Table 2. *Comparison of Items for the CES, COM-5, COMOT-15 and COMQ-12. The numbers within the boxes relate to the number of items within the questionnaire that relate to that particular measure.*

Domain	Measure	CES	COM-5	COMOT-15	COMQ-12
Activity restriction	Water exposure	2	1		1
	Interference with domestic/work/ social activities	1			1
Symptoms	Hearing	2	1	8	2
	Tinnitus			1	1
	Dizziness				1
	Ear discharge	2		1	1
	Pain/pressure/ discomfort	1		2	1
	Headache			1	
	Odor	2			1
	Physical suffering		1		
Use of medical resources	Attending to see a doctor	1			1
	Use of antibiotics	2			1
Other	Emotional		1	1	1
	Overall quality of life			1	
	Caregiver's concerns				
Total		13	5	15	12

Table 3. *Questionnaire diversity assessment.*

	Quality of Life Domain		
Questionnaire	Somatic	Psychological	Social
CES	✓		✓
COM-5	✓	✓	✓
COMOT-15	✓	✓	
COMQ-12	✓	✓	✓

Discussion

In the United Kingdom, the National Health Service has been driving interest in PROMs as indicators for quality of care.[18] Since 2009, surgeons have been encouraged to assess patient reported outcomes on a routine basis for four elective surgical procedures (hip replacement, knee replacement, varicose veins surgery and groin hernia repair).[19] Other surgical specialties, including ENT, have been following suit, with ENT-UK's Clinical Audit and Patient Advisory Committee endorsing specific PROMs for routine use by its members.[20] Here we are providing examples of practice in the authors' home health care system, but progress in this area has progressed steadily throughout health care systems worldwide. Historically many generic forms of outcome assessment have been developed, with the Sickness Impact Profile (SIP)[21] and the Nottingham Health Profile (NHP)[22], being good early examples having been developed in the early 1970s. These were considered to be ideally instruments to provide comparisons between diseases or to compare data with population normative values.[23] However, such comparisons are scientifically flawed, as questionnaire items function in different ways within different patient groups.[23] Furthermore, they fail to capture areas of concern to specific patient populations, and therefore lack the responsiveness needed to measure the outcome of effective interventions. In contrast disease-specific outcome measures will only evaluate items that are particularly relevant and meaningful to specific patient populations, allowing greater potential for demonstrating differences between competing therapies. This is an area where generic and organ-specific assessment instruments fail to demonstrate utility as

they fail to appreciate the disease specific effects of the condition being appraised.

Our review has identified four instruments for the assessment of patient reported outcome.[8, 10-17] All four instruments were disease-specific instruments that identified solely to patients with chronic suppurative otitis media. There has been much work performed in the field of quality of life assessment, and particularly with regard to reporting patient outcomes with this regard[9, 24], with Wilson and Cleary initially proposing their conceptual model of patient outcomes in 1995.[24] Wilson and Cleary propose that patient outcomes are to be considered in the perspective of objective findings (biological and physiological variables, e.g. clinical or audiometric measures of middle ear disease severity) in combination with characteristics of the individual (symptom amplification, personal motivation, values, and preferences) and their environment (psychological, social, and economic supports). Similar considerations have been made for quality of life questionnaires in other fields of otolaryngology, such as rhinosinusitis.[25] These characteristics of the individual have been further established in the context of the World Health Organization's concept of health and quality of life[26], where Koller defines the three domain concept of patient reported outcome that are key for self-perceived and self-reported assessment of quality of life.[9] These domains are for somatic symptoms, such as hearing loss, ear discharge and tinnitus; psychological components including emotion, cognition and general consciousness; and social components such as family and work.[9] Only two of the questionnaires (COM-5 and COMQ-12) fulfilled all three of the domains predefined in the methodology for the assessment of questionnaire item diversity.

When specifically considering the different domains and measures employed for each questionnaire, some interesting features have been exposed. All four questionnaires include items related to physical symptoms, whereas only the CES, COM-5 and the COMQ-12 include items related to activity restriction. When considering the use of medical resources, related questionnaire items are only present within the CES and COMQ-12. Whilst it is true that the reason for many of the differences between the only paediatric questionnaire and the three adult questionnaires are necessary, differences related to emphasis between each of the domains for the adult questionnaires was quite stark. For example, the COMOT-15 provided eight items related to hearing, in comparison with two items for the CES and COMQ-12; and only one item for the COM-5. With the differences identified upon comparing these questionnaires, it is evident that each questionnaire will have its own particular sensitivities for certain measures and this would be reflected in the total scores when the questionnaires are used in clinical practice.

The word validation is often used indiscriminately to define a process of survey evaluation, whereas certain tests, such as that of evaluating internal consistency, are not truly tests of validity. The evaluation of survey instruments comes under the branch of survey research known as psychometrics. Generally, this process can be split in to the evaluation of reliability and validity. Reliability takes the form of features such as test-retest reliability, alternate-form reliability, internal consistency, interobserver reliability and intraobserver reliability. Validation on the other hand, takes the form of content validity, criterion validity and

construct validity. Questionnaire validation is not a single exercise and to achieve some forms of validation, such as construct validation, this process involves gathering a group of different types of data, over a multitude of settings and populations over a number of years. Of the four disease specific HRQoL questionnaires identified, all of them reported an evaluation of questionnaire reliability and validity. Three of the four questionnaires provided a broader evaluation of psychometric properties, with the more recently described questionnaire (COMQ-12), describing a narrower range of psychometric tests.

A key aim for any questionnaire would be to be universally accepted. The CES would seem have an advantage with this respect, being written in English, which is widely spoken worldwide, and having been translated into other languages, including Chinese. The COMOT-15, was written in German, and to date has not been translated into any other languages; thus potentially restricting its use.

Considering these questionnaires as a whole, they are all similar in the way they assess static health status. Although this has many advantages, to appraise health improvement, the questionnaire needs to be administered on more than one occasion, and this may have implications for providing additional follow-up appointments if the patient is not reviewed at a particular time, either preoperatively or postoperatively; or if one wishes to appraise the outcome of a patient who has undergone surgery, but not completed, or incompletely completed a pre-operative questionnaire. A solution to this would be to develop a 'one-hit' questionnaire that is

provided post-intervention, that would consider the patient's health status as a consequence of their intervention, be it surgical or non-surgical.

The employment of PROMs, for the appraisal of surgical outcome is in its infancy, and likely to evolve further with time to satisfy a number of diverse medical and non-medical requirements. In the field of otology the integration of PROMs for the assessment of middle ear surgery outcomes is continuing to progress. A consequence of performing the latest UK national myringoplasty audit has been the ability to assess the infrastructure available to perform national audit.[27] Supporting the current dataset of otology outcome data with data from PROM questionnaires has been identified as the next step towards achieving our goals of improving how surgical outcome data is collected and reported.[27]

Conclusions

This systematic appraisal of the world literature has identified four PROM questionnaires for use in patients with chronic suppurative otitis media. Only the COM-5 and the COMQ-12 questionnaires contain questions that fulfil the necessary domains of somatic, psychological and social dimensions of quality of life. All four questionnaires evaluate reliability and validity using different psychometric methods. The CES questionnaire has been most broadly evaluated and disseminated. All four questionnaires assess static health status. There are many advantages of developing a dynamic 'one-hit' questionnaire to assess the health status of patients having undergone an intervention for chronic suppurative otitis media.

References

1. Koller M, Lorenz W. Survival of the quality of life concept. *Br J Surg*. 2003;90(10):1175-7
2. Koller M, Klinkhammer-Schalke M, Lorenz W. Outcome and quality of life in medicine: a conceptual framework to put quality of life research into practice. *Urol Oncol.* 2005;23(3):186-92
3. Black N. Patient reported outcome measures could help transform healthcare. *BMJ*. 2013;346:f167
4. Medical Revalidation – Principles and Next Steps. The report of the Chief Medical Officer for England's working group. *Department of Health*. July 2008
5. Ader 2007. Ader DN: Developing the Patient-Reported Outcomes Measurement Information System (PROMIS). *Med Care* 2007, 45(Suppl 1)
6. Wilke RJ, Burke LB, Erickson P. Measuring treatment impact: a review of patient-reported outcomes and other efficacy endpoints in approved product labels. *Control Clin Trials*. 2004;25(6):535–552
7. WHO. Chronic suppurative otitis media. Burden of illness and management options. 2004. http://http://www.who.int/pbd/publications/Chronicsuppurativeotitis_media.pdf. ISBN_92_4_159158_7.pdf (last accessed 3 June 2015).
8. Phillips JS, Yung MW. COMQ-12 scores in adult patients without chronic middle ear disease. *Clin Otolaryngol*. 2014;39(6):362-7

9. Koller M, Lorenz W. Quality of life: a deconstruction for clinicians. J *R Soc Med*. 2002;95(10):481-8.
10. Byun JY, Cho YS, Chu H, et al. Standardization for a Korean version of chronic ear survey: translation and verification of validity and reliability. *Korean J Oto-rhinolaryngol Head Neck Surg*. 2011;54(11):755-760
11. Nadol JB Jr, Staecker H, Gliklich RE. Outcomes assessment for chronic otitis media: the Chronic Ear Survey. *Laryngoscope*. 2000;110(3, pt 3):32-35
12. Wang PC, Nadol JB Jr, Merchant S, Austin E, Gliklich RE. Validation of outcomes survey for adults with chronic suppurative otitis media. *Ann Otol Rhinol Laryngol*. 2000;109(3):249-254
13. Wang PC, Chu CC, Liang SC, Tai CJ, Gliklich RE. *Annals of Otology, Rhinology & Laryngology*. 2003;112(1):85-90
14. 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;73:363-9
15. Baumann I, Kurpiers B, Plinkert PK,Praetorius M. *HNO* 2009;57(9):889-895
16. Baumann I, Gerendas B, Plinkert P, Praetorius M. General and disease-specific quality of life in patients with chronic suppurative otitis media – a prospective study. *Health Qual Life Outcomes* 2011;9:48

17. Phillips JS, Haggard M, Yung M. A new health-related quality of life measure for active chronic otitis media (COMQ-12): development and initial validation. *Otol Neurotol*. 2014;35(3):454-8

18. Department of Health: Equity and Excellence: Liberating the NHS. London: *Department of Health*; 2010

19. Department of Health: The NHS Outcomes Framework 2012/2013. London: *Department of Health*; 2011

20. https://entuk.org/professionals/clinical_outcomes (Accessed 20th March 2015)

21. Bergner M, Bobbit RA, Kressel S, Pollard WE, Gilson BS, Morris JR: The Sickness Impact Profile: conceptual formulation and methodology for the development of a health status measure. *Int J Health Serv* 1976;6:393-415

22. Hunt SM, McEwen J, McKenna SP: Measuring Health Status London: *Croom Helm*; 1986

23. McKenna SP. Measuring patient-reported outcomes: moving beyond misplaced common sense to hard science. *BMC Med*. 2011;9:86

24. Wilson IB, Cleary PD. Linking clinical variables with health- related quality of life. A conceptual model of patient outcomes. *JAMA: the J Am Med Assoc*. 1995;273(1):59–65.

25. Dietz de Loos DA, Segboer CL, Gevorgyan A, Fokkens WJ. Disease-specific quality-of-life questionnaires in rhinitis and rhinosinusitis: review and evaluation. *Curr Allergy Asthma Rep*. 2013;13(2):162-70.

26. Bowling A. *Measuring Disease. A Review of Disease-specific Quality of Life Measurement Scales.* Buckingham: *Open University Press*, 2001

27. Phillips JS, Yung MW. Myringoplasty outcomes in the United Kingdom. Journal of Otology and Laryngology. *In Press*

Chapter 5

Development of the Dutch version of the health-related quality of life measure for chronic otitis media (COMQ-12)

Parts of this chapter have been published in:

Oorts E, Phillips JS, Van de Heyning P, Yung M, Van Rompaey V. Development of the Dutch version of the health-related quality of life measure for chronic otitis media (COMQ-12). B-ENT. 2015;11(4):291-5.

Abstract

Introduction and aim: Chronic otitis media (COM) can be defined as a variety of symptoms and physical findings that result from prolonged damage to the middle ear by infection and inflammation. The Health-Related Quality of Life measure for Chronic Otitis Media (COMQ-12) is a new questionnaire for the assessment of chronic otitis media, to evaluate the overall burden of disease from the patient's perspective. The aim of this study is to develop and appraise the psychometric properties of the Dutch version of the COMQ-12.

Materials and methods: The Dutch version of the COMQ-12 was obtained by the process of translation and back-translation. Fifty adult patients with a history of active chronic otitis media completed the Dutch version of the COMQ-12. Internal consistency of this questionnaire was evaluated using Cronbach's alpha coefficient.

Results: The average COMQ-12 score was 22.4 (SD 11.9). The internal consistency of the Dutch version of the COMQ-12 proved to be high, with a Cronbach's alpha value of 0,833.

Conclusions: The Dutch version of the COMQ-12 provides appropriate health-related quality of life outcome measures in patients with a history of chronic otitis media. This questionnaire is a useful tool to evaluate the overall burden of disease from the patient's perspective.

Introduction

Chronic otitis media (COM) can be defined as a variety of symptoms and physical findings that result from prolonged damage to the middle ear by infection and inflammation. Different forms of COM exist, for example retraction or perforation of the tympanic membrane, chronic drainage from the ear and presence of cholesteatoma. COM affects approximately 2% of the population and can be associated with significant morbidity.[1] COM is a disabling disease, estimated by the World Health Organisation (WHO) to affect between 65 and 350 million individuals globally, and therefore a leading cause of health care visits and drug prescription.[2]

The Health-Related Quality of Life Measure for Chronic Otitis Media (COMQ-12) is a new questionnaire for the assessment of active chronic otitis media.[3] This questionnaire has been developed to evaluate the overall burden of disease from the patient's perspective. Measures of health-related quality of life (HRQoL) allow a systematic assessment of need for and benefit from treatment. From both a clinical and a research perspective it is important to assess the impact of disease on health-related quality of life. Patient-reported outcome measures (PROMs) are instruments that allow the assessment of outcome for specific interventions. HRQoL measures, such as the COMQ-12, can be employed as PROMs once appropriately evaluated for this purpose. PROMs are useful to compare different types of surgical and nonsurgical interventions. [4]

The original English version of the COMQ-12 was developed by Phillips *et al.*[3] The construction of this questionnaire was based on three other pre-

existing questionnaires: the Chronic Ear Survey (CES)[1], the Chronic Otitis Media Outcome Test 15 (COMOT-15)[5] and the Chronic Otitis Media 5 (COM-5).[6] The initial validation of this original English version has been completed by the group of Phillips, with a Cronbach's alpha value of 0.889, which demonstrates a high internal consistency.[3]

The aim of this study is to validate the Dutch version of the COMQ-12 in a group of COM patients.

The questionnaire

The Dutch questionnaire, like the original English questionnaire, consists of 12 self-rating questions. The patient has to answer to these questions using a six-point scale. Eight questions (1-7, 12) are asking about the severity of complaints, whereas the other four questions (8-11) are about the frequency of acts concerning the ear problems. In these 12 questions, 10 different topics are covered; water exposure, hearing, tinnitus, ear pain or discomfort, medications, restrictions of daily living, discharge, dizziness or vertigo, doctor visits and global quality of life or distress.

The translation process

The Dutch version of the COMQ-12 was obtained by the process of translation and back-translation. The Dutch version was back-translated to English by an independent native English-Dutch speaker. The term 'general practitioner' was changed to 'doctor' because, unlike the United Kingdom, the otorhinolaryngologist might serve as the first-line physician in case of COM. This difference is the result of the country specific health care organization. The final version of the Dutch COMQ-12 is shown in Appendix A.

Subjects

Dutch speaking patients, with a history of active chronic otitis media, who visited the ENT department at the University Hospital in Antwerp between February and July 2014 were asked to complete the Dutch version of the COMQ-12. A total of 50 patients, with different types of COM completed the questionnaire.

Psychometric assessment

Questionnaire reliability was assessed on the basis of internal consistency by calculating Cronbach's alpha. Cronbach's alpha is a coefficient of internal consistency. This index is used as an internal consistency estimate of reliability of test scores, assessing the degree of correlation between the individual component questions of a questionnaire. Coefficients greater or equal to 0.70 are defined as acceptable, those greater than or equal 0.80 defined as good. The data were analyzed using SPSS (SPSS Inc. Chicago, IL, USA).

This group of participants consists of 32 (64%) men and 18 (32%) women, with a mean age of 53 years (range 15 - 82 years). These 50 patients presented with different forms of COM, at different stages of disease activity. We divided the patients in five different subgroups, based on their type of COM (Table 1). Almost 50% of our patients belong to the group of the healed COM (group E), the other half presented with more active pathology.

Table 1: *Study population: COM subgroups*

Group	Description	Total	Postop (%)
A	**inactive mucosal COM** (dry perforation)	9	0
B	**active mucosal COM** (wet perforation)	3	0
C	**inactive squamous epithelial COM** (retraction, atelectasis, epidermosis)	7	2 (28.6)
D	**active squamous epithelial COM** (cholesteatoma)	7	0
E	**healed COM** (intact tympanic membrane, covered perforation, tympanosclerosis)	24	23 (95.8)

The COMQ-12 scores overall ranged from 2 to 51, with a maximum score of 60. The average COMQ-12 score was 22.4 (SD 11.9). For the Dutch version of the COMQ-12, the Cronbach's alpha value was 0.833, indicating that the internal consistency of this questionnaire is high. This means that there is a high degree of correlation between the individual items of the questionnaire.

Discussion

COM is an important pathology with a significant morbidity that is quite common, as it affects approximately 2% of the population.[1] The Health-Related Quality of Life Measure for Chronic Otitis Media (COMQ-12) has been developed by Phillips *et al.*[3] for the assessment of chronic otitis media. This questionnaire is an evaluation tool that assesses the impact of disease on health-related quality of life of the patients, from the patient's own perspective.

The aim of this study was to appraise the psychometric properties of the Dutch version of the COMQ-12. Therefore, the questionnaire has been translated into Dutch and an assessment of its validity was performed based on the internal consistency.

The study population represented a heterogeneous group of COM patients, aged between 15 and 82 years, all with different disease presentation and disease activity. This group is a representative sample for the overall population of patients with chronic otitis media.

The internal consistency of the original English questionnaire has already shown to be high, with a Cronbach's alpha value of 0.889.3 Our study confirms the high internal consistency of the Dutch version of the COMQ-12, with a Cronbach's alpha value of 0.833.

To make an adequate interpretation of the COMQ-12 scores possible, it is important to have a reference point to start from. A study of Phillips *et al.*[7]

determined normal values for the COMQ-12 scores, in an adult population without active chronic otitis media. Seventy healthy volunteers filled in the English version of the COMQ-12. The overall COMQ-12 scores ranged from 0 to 41 with a mean score of 3.4 (SD 6.1). The median score was 2 and the modal score was 0. The results from this study indicate that the majority of patients in an adult population without active COM, would have a score of 5 or less. Phillips *et al.*[7] recommend to consider these normal values in the preoperative setting when patients with COMQ-12 of 5 or less are considered for surgery. For the Dutch version of the COMQ-12 normal values are not yet determined, this is an interesting goal for future work.

The process involved in fully appraising the psychometric properties of a HRQoL questionnaire involves many processes that documents the development of the questionnaire over a period of time. The contemporary process involves assessing both reliability and validity. This study presents preliminary data to support the further assessment of the Dutch version of the COMQ-12. Once patient data and instrument scores are acquired and compared pre-intervention and post-invention, a measured consideration can take place to evaluate the COMQ-12 as a valid tool to assess patient outcome in the form of a PROM.

Conclusions

In conclusion, the Dutch version of the COMQ-12 provides appropriate health-related quality of life measures in patients with a history of chronic otitis media. This questionnaire is a useful tool to evaluate the overall burden of disease from the patient's own perspective**.**

References

1. Nadol JB, Jr., Staecker H, Gliklich RE. Outcomes assessment for chronic otitis media: the Chronic Ear Survey. *Laryngoscope*. 2000;110(3 Pt 3):32-35.
2. Acuin J. Chronic suppurative otitis media. *Clinical evidence*. 2004(12):710-729.
3. Phillips JS, Haggard M, Yung M. A new health-related quality of life measure for active chronic otitis media (COMQ-12): development and initial validation. *Otology & Neurotology* 2014;35(3):454-458.
4. Koller M, Lorenz W. Survival of the quality of life concept. *British Journal of Surgery*. 2003;90(10):1175-1177.
5. 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):889-895.
6. Vlastos IM, Kandiloros D, Manolopoulos L, Ferekidis E, Yiotakis I. Quality of life in children with chronic suppurative otitis media with or without cholesteatoma. *International Journal of Pediatric Otorhinolaryngology.* 2009;73(3):363-369.
7. Phillips JS, Yung MW. COMQ-12 scores in adult patients without chronic middle ear disease. *Clinical Otolaryngology*. 2014;39(6):362-367.

Appendix A: *Dutch version of the COMQ-12*

Met volgende vragen willen we evalueren hoe ernstig uw oorproblemen u beïnvloeden. We verwachten dat deze vragenlijst ons kan helpen te begrijpen welke oorklachten het belangrijkst zijn voor u.

Lees elke vraag aandachtig, beantwoord de onderstaande vragen door het cijfer aan te duiden dat het meest van toepassing is. De cijfers verwijzen telkens naar een specifieke omschrijving. Elke vraag dient u te beantwoorden rekening houdend met de situatie van de afgelopen 6 maanden.

Voor de volgende vragen mag u aanduiden hoe ernstig de verschillende elementen u beïnvloeden. Hierbij maakt u gebruik van de onderstaande schaal en kan u het juiste cijfer aanduiden als antwoord op de vraag.

0 Stoort me absoluut niet
1 Beperkte last
2 Matige last
3 Belangrijke last, maar ik kan ermee omgaan
4 Belangrijke last, en ik kan er moeilijk mee omgaan
5 Het ergste dat me ooit heeft getroffen

Ernst van de klachten:

1.	Oorloop of loopoor	0	1	2	3	4	5
2.	Een slechte geur uit het oor	0	1	2	3	4	5
3.	Gehoorproblemen thuis, bv. luider zetten van radio of TV	0	1	2	3	4	5
4.	Gehoorproblemen tijdens gesprekken in groep of in rumoerige omgeving	0	1	2	3	4	5
5.	Ongemak in en/of rond het oor	0	1	2	3	4	5
6.	Duizeligheid of het gevoel uit balans te zijn	0	1	2	3	4	5
7.	Oorsuizen of geluiden in het oor	0	1	2	3	4	5

Voor de volgende vragen mag u aanduiden hoe vaak de verschillende elementen u beïnvloeden. Hierbij maakt u gebruik van de onderstaande schaal en kan u het juiste cijfer aanduiden als antwoord op de vraag.

0 Minder dan 1 keer elke 6 maanden
1 Minstens 1 keer elke 6 maanden
2 Minstens 1 keer elke 3 maanden
3 Minstens 1 keer elke maand
4 Minstens 1 keer per week
5 Meerdere dagen per week

Levensstijl en werk
Hoe vaak bent u niet in staat geweest om:

8. Uw normale dagelijkse activiteiten uitvoeren thuis / op werk?	0	1	2	3	4	5
9. Wassen of douchen of baden zoals u wenste? Hoe vaak hebt u schrik dat dit een oorontsteking zou kunnen doen ontstaan?	0	1	2	3	4	5

Gezondheidszorg:

10. Hoe vaak bent u bij een arts geweest voor uw oorproblemen?	0	1	2	3	4	5
11. Hoe vaak moet u geneesmiddelen gebruiken voor uw oorprobleem (bv. ook oordruppels)?	0	1	2	3	4	5

Voor de volgende vraag mag u aanduiden hoe slecht uw situatie is op een schaal van '0' tot '5'. '0' betekent niet, en '5' betekent het ergste wat u zich kan voorstellen.

Algemeen:

12. In welke mate maken uw oorproblemen u 'depri'?	0	1	2	3	4	5

Chapter 6

International application of the Chronic Otitis Media Questionnaire 12 (COMQ-12)

Parts of this chapter have been published in:

Kosyakov SIa, Minavnina JV, Phillips JS, Yung MW. International application of the Chronic Otitis Media Questionnaire 12 (COMQ-12). Journal of Otology and Laryngology – In Press

Abstract

Objective: The Chronic Otitis Media Questionnaire -12 (COMQ-12) was developed initially in the UK to assess the patient-reported health-related quality of life (HRQoL) due to chronic otitis media. The aim of this study is to determine whether this tool is applicable to the Russian population, which has a materially different healthcare system.

Materials and methods: 108 patients with different forms of COM completed the RCOMQ-12.

Results: The average RCOMQ-12 score was 19.4 (SD 8.3). The internal consistency of the RCOMQ-12 was high, with a Cronbach's alpha value of 0.860.

Conclusions: The Russian version of the COMQ-12 is found to be a reliable tool for assessment of HRQoL in patients with chronic otitis media. This sets the scene for international collaboration using this tool to assess the effectiveness of surgical treatments even amongst countries with different healthcare system.

Introduction

Chronic otitis media (COM) is a widespread disease that affects up to 2% of the population.[1] There are several forms of COM, each of which is characterized by peculiarities of courses and outcomes. Some forms of COM, due to their asymptomatic courses, may not cause concern initially and, therefore, often remain undiagnosed for years. Other forms of COM occur with a vivid clinical picture expressed by the complaints of the patient and decrease in their quality of life. Patients in this second group are much more likely to seek medical care, require active treatment and may well have high expectations of treatment. It should be noted that patient's expectations can be greater than the initial forecasts of the surgeon. In such situations, an objective tool is required to evaluate the relationship between the pattern of disease perceived by the patient and the pattern of disease, based on objective data. An important objective of surgical intervention in patients with COM is to meet the expectations of the patient. Inevitably, perfectly executed surgery does not always provide a corresponding improvement in the quality of life for the patient. The relationship between patient expectations and surgical expectations has been demonstrated through the use of the health-related quality of life (HRQoL) questionnaires. The Chronic Otitis Media Questionnaire-12 (COMQ-12) was devised in the United Kingdom to assess patient-reported quality of life due to chronic otitis media.[2] The original English version of the COMQ-12 was developed by Phillips *et al.*[2, 3], and compares favourably when compared with other similar HRQoL questionnaires.[4] The COMQ-12 is gaining international recognition and has been translated and evaluated in Dutch.[5]

The aim of this study is to determine whether the COMQ-12 can be truly internationally adaptable by identifying whether it can be satisfactorily applied to the Russian population, which has a different healthcare system. Superficially this exercise provides supportive data to instruct the application of the COMQ-12 in Russia. However, and of greater academic interest, the administration of the COMQ-12 into a healthcare system that differs in many fundamental ways to that of the United Kingdom and Western Europe, provides great insight into how socioeconomic and cultural factors can affect patient-reported quality of life for COM.

Materials and methods

The RCOMQ-12 was developed from the original English version of the COMQ-12. As such the utilization of an established and well-constructed item list allowed consequent adoption of a validated list of 12 questions characterizing all essential experiences of a patient with COM. Each item is assessed on a five-point scale. Eight questions (1-7, 12) describe the severity of the disease, whereas the remaining 4 questions (8-11) describe the frequency of their occurrence. The minimum score possible is 0, and the maximum score possible is 60. To allow comparison with other studies that have translated the COMQ-12 into another language, a consistent approach was employed with respect to the translation and psychometric evaluation processes.[5]

This study was designed and conducted according to the Declaration of Helsinki (1996). Study methodology was approved according to local ethics guidelines. Informed consent was obtained from all individual participants included in the study. In collaboration with the original authors of the COMQ-12, the RCOMQ-12 was translated and evaluated. The RCOMQ-12 was obtained by an established process of translation and back-translation.[6] Russian speaking patients, with a history of active COM, were asked to complete the RCOMQ-12. Consecutive patients were asked to complete the questionnaire over a four-month period. Every patient fully completed the questionnaire, and every questionnaire was included in the analysis. The patient cohort completing the questionnaires represented a heterogeneous group of patients from all social classes, and from a variety of regions within and outside Moscow. Questionnaire reliability was assessed on the basis of

internal consistency by calculating Cronbach's alpha. This index is used as an internal consistency estimate of the reliability of test scores by assessing the degree of correlation between the individual components of a questionnaire. Coefficients greater or equal to 0.70 are considered to be acceptable; while, those greater than or equal to 0.80 are considered to be good. In addition to acquiring questionnaire scores from patients with COM, the RCOMQ-12 was given to sixty healthy volunteers without COM. All data were analyzed using Statistica and GNU R (version 10.0.1011.6, StatSoft, Inc, 2011, Tulsa, Oklahoma, USA).

Results

The study included 108 patients: 49 men (45%) and 59 women (55%), ranging in age from 16 to 84 years. Patients were classified according to their form of COM and whether previous surgery had been undertaken. Four groups of patients were defined: perforated eardrum, cholesteatoma, patients after previous surgery (open mastoid cavity), and patients with adhesives otitis media and fibrosis. The characteristics of these patients are reproduced in table 1. RCOMQ-12 scores ranged from 4 to 43 among all respondents. The average score was 19.4 (SD 8.3). The median RCOMQ-12 score overall was 20. 91% of respondents achieved a score of 30 or less, 55% of respondents achieved a score of 20 or less. For the RCOMQ-12 Cronbach's alpha was equal to 0.860.

Table 1. *Description of patient groups*

Group	Description	Total	Average	Range
A	Perforated eardrum	58 (54%)	18.5	4 to 43
B	Cholesteatoma	21 (19.4%)	21.2	6 to 41
C	Open mastoid cavity	18 (16.6%)	21.8	5 to 37
D	Adhesive otitis media and fibrosis	11 (10%)	16.6	5 to 28

Sixty healthy volunteers without COM were asked to complete Russian version of COMQ-12. RCOMQ-12 scores overall ranged from 0 to 14 amongst all respondents, with a mean score of 3.55. The median RCOMQ-12 score overall was 2.5 and the modal score was 0, with 19 (31.7%)

participants achieving this score. 75% of respondents achieved a score of 5 or less, 95% of respondents achieved a score of 10 or less.

Discussion

HRQoL measurements reflect the overall burden of disease from the perspective of the patient rather than the clinician. This makes the acquisition of this kind of data particularly pertinent in otology, where single clinical, radiological, and audiological findings may inter-relate poorly, and therefore poorly predict HRQoL. The use of HRQoL measures has been shown to aid both the patient's prioritization of their symptoms[7] and the management of their individual expectations.[8] One problem with any HRQoL tool is related to its ability to allow acceptability, reliability and validity across different internationally diverse populations. Patient perception and prioritisation of health can be influenced by many factors. The healthcare system in Russia is different to that of the UK in both the manner that it is funded and the manner that it is administered, this has implications for access to healthcare. It is often considered that those patients who are in a privileged situation may seek intervention at an earlier stage and have greater expectations for outcome than those who are less privileged.

In Russia, health care is funded via a mixed public and private system. Since 1996, the Constitution of the Russian Federation has provided all citizens the right to free healthcare under Mandatory Medical Insurance. State hospitals have been allowed to offer private services, but since 2011 some private providers have been providing services to the state-insured. Health care costs per capita in Russia is much lower than that in Europe, including Eastern Europe. According to the most recent published figures from the Organisation for Economic Co-operation and Development (OECD),

expenditure on healthcare in 2012 was 6.3% of Gross Domestic Product, compared to 9.3% in the United Kingdom.[9] About 5% of the population, mostly in major cities, have health insurance.[10] In 2012, the Russian Federation had 4.9 physicians per 1000 population, a much higher number than the OECD average of 3.2. In addition to this the number of hospital beds in the Russian Federation was 9.3 per 1000 population in 2012, almost two-times greater than the OECD average (4.8 beds) in 2012. However, compared with OECD countries, the Russian Federation has a very high level of mortality and shorter life expectancy. In 2012, life expectancy at birth in the Russian Federation was 70.2 years, ten years lower than the OECD average (80.2 years). Much has changed since the breakup of the former Soviet Union. As is universal around the world, different health care systems face their own particular challenges. To put modern day Russia into context with the former Soviet Union, an excellent history of how healthcare has evolved is detailed by Barr and Field.[11]

The level of primary health care development in Russia is low compared to secondary and tertiary care. The healthcare model in Russia is such that the requirement for surgical treatment has implications that are not only financial. Russia is a huge country; therefore, the population density is lower than that in Europe. A large number of people live in small towns and villages where there are no specialists, and limited emergency care. It is often the case that the nearest major city may be hundreds of miles away. This means that hospital admission requires traveling to a major centres and this results in the necessity to take leave from work and family for many weeks. Furthermore, the duration of hospitalisation in the Russia is much longer than in European countries. The number of doctors in hospitals and

clinics in Russia per patient exceed those for European countries. However, due to reduced efficiency, hospital departments are less able to meet demand.

The COMQ-12 was developed to assess the impact of disease on HRQoL from the patient's perspective.[2] The Russian version of the COMQ-12 has demonstrated a Cronbach's alpha of 0.860; this confirms high internal consistency of the questionnaire and a high degree of correlation between its individual components. This index is used to measure the reliability of test scores: a factor greater or equal to 0.70 is defined as acceptable, equal to 0.80 or more as good. This compares well, with the original English version of the COMQ-12[2] and the Dutch version of the COMQ-12[5]. Table 2 compares the key reliability characteristics of the COMQ-12 for English, Dutch and Russian.

Table 2. *Comparison of internal consistency between different versions of the Chronic Otitis Media Questionnaire-12*

Language	Number of participants	Chronbach's alpha
English	50	0.889
Dutch	50	0.833
Russian	108	0.860

To interpret COMQ-12 scores in the context of inactive disease, the acquisition of data in a healthy population without COM is of great importance. A study by Phillips *et al.* determined normal values for the COMQ-12 scores in an adult population without active COM.[3] We replicated

this study for our population. The results of both studies demonstrated that COMQ-12 scores of 5 or less are characteristic in a healthy population. This finding is interesting not only from the perspective of evaluating a HRQoL assessment tool for COM, but it interesting as it suggests that despite the populations of Russia and United Kingdom demonstrating many cultural differences, when assessing otological and audiological symptoms in healthy populations, outcome scores are comparable. The health and societal implications for this finding reach further than the initial intended objectives of this study, and they are interesting and are worthy of reflection within disciplines outside that of otolaryngology.

Questionnaire development is not achieved by a single study in a single population. A great deal can be achieved via question development across many different centers and across different countries. This process requires the translation from the original questionnaire language to the native language for each individual country, whilst allowing any nuances in language to be interpreted correctly. By having COMQ-12 in different languages, there is an opportunity to evaluate the course of the disease and its outcomes in different social and cultural conditions all around the world. This allows us to obtain a more complete and objective picture of both the studied disease and the instrument employed to compare disease severity and outcome. Robust, valid and reliable questionnaires evolve via a disseminated process that involves many different patient populations over a number of years. Furthermore, there are a multitude of contemporary techniques available to perform psychometric appraisal. This current study represents an important step for the development of the COMQ-12 both in the Russian population and as piece of work to complement ongoing work

in the development of the COMQ-12 as a global tool to assess QoL in patients with chronic otitis media.

In conclusion, the Russian version of the COMQ-12 is a reliable tool for assessment of HRQoL in patients with COM. RCOMQ-12 scores vary amongst different types of COM. Now that the preliminary appraisal of the RCOM-12 has been completed, this tool can be employed in the future to acquire further data to support its role in the planning of surgical treatments and to assess treatment outcomes in the Russian population. The employment of Western European HRQoL instruments in populations that are distinctively different in social, economic and cultural makeup, provides support for using these tools in an 'international' manner for the acquisition of international clinical audit datasets.

References

1. Nadol J, Staecker H, Gliklich R. Outcomes Assessment for Chronic Otitis Media: The Chronic Ear Survey. *Laryngoscope* 2000; 110(S94): 32-35.
2. Phillips J, Haggard M, Yung M. A New Health-Related Quality of Life Measure for Active Chronic Otitis Media (COMQ-12). *Otology & Neurotology* 2014; 35(3): 454-458.
3. Phillips J, Yung M. COMQ-12 scores in adult patients without chronic middle ear disease. *Clinical Otolaryngology* 2014; 39(6): 362-367.
4. Phillips JS, Yung MW. A systematic review of patient-reported outcome measures for chronic suppurative otitis media. *Laryngoscope* 2015; Sep: 15.
5. Oorts E, Phillips JS, Van de Heyning P, Yung M, Van Rompaey V. Development of the Dutch version of the health-related quality of life measure for chronic otitis media (COMQ-12). *B-ENT* 2015; 11(4): 291-295.
6. Rabin R, Gudex C, Selai C, Herdman M. From translation to version management: a history and review of methods for the cultural adaptation of the EuroQol five-dimensional questionnaire. *Value Health 2014*; 17(1): 70-76.
7. Nies C, Celik I, Lorenz W, Koller M, Plaul U, Krack W, et al. Outcome nach minimal-invasiver Chirurgie. Qualitative Analyse und Bewertung der klinischen Relevanz von Studienendpunkten durch Patient und Arzt. *Chirurg* 2001; 72: 19–29.

8. Koller M, Lorenz W, Wagner K, Keil A, Trott D, Engenhart-Cabillic R, et al. Expectations and quality of life of cancer patients undergoing radiotherapy. *J R Soc Med* 2000; 93: 621–628

9. Health policies and data – OECD. http://www.oecd.org/els/health-systems/ Accessed 13th August 2016.

10. Britnell, Mark (2015). In Search of the Perfect Health System. London: *Palgrave*. p. 81. ISBN 978-1-137-49661-4.

11. Barr DA, Field MG. The current state of health care in the former Soviet Union: implications for health care policy and reform. *Am J Public Health*. 1996;86(3):307-12.

Chapter 7

The Chronic Otitis Media Benefit Inventory (COMBI): development and validation of a dynamic quality of life questionnaire for chronic ear disease

Parts of this chapter have been published in:

Phillips JS, Haggard, Spencer H, Yung M. The Chronic Otitis Media Benefit Inventory (COMBI): Development and Validation of a Dynamic Quality of Life Questionnaire for Chronic Ear Disease. Otology & Neurotology – In Press

Abstract

Objective: This study introduces a change-oriented short-form health-related quality of life questionnaire suited to symptoms of adult chronic middle ear disease and its consequences, and describes its properties.

Study Design: Two-centre prospective correlational study primarily for instrument development.

Setting: Two otology secondary care centres in England.

Patients: Fifty-two consecutive adult patients with active chronic otitis media undergoing surgery.

Methods: The 12 items for the Chronic Otitis Media Benefit Inventory (COMBI) were appraised chiefly for internal consistency of resulting score and for factor structure (exploratory factor analysis).

Results: The internal consistency of the COMBI was high within our cohort of patients, with a Cronbach's alpha value of 0.907. The 3-factor solution from factor analysis explaining 73.6% of the variance was readily interpretable in terms of the intended item content: changes in hearing, ear symptoms and daily activities plus healthcare uptake.

Conclusions: The Chronic Otitis Media Benefit Inventory (COMBI), has suitable properties for the dynamic assessment of active chronic otitis media. Initial psychometric appraisal confirms its suitability for early adoption to acquire more comprehensive large-sample information with it and on it, for future refinement and application.

Introduction

Chronic middle ear disease (COM) is associated with material morbidity and affects approximately 2% of the population.[1] The role of patient-reported outcome measures (PROMs) for the assessment of chronic ear disease has been rigorously appraised in a systematic review.[2] This and the conclusions from national audit data[3], suggested that current health-related quality of life (HRQoL) questionnaires lack documented ability to assess 'responsiveness', i.e. changes in outcomes. Dynamic assessment tools, such as the somewhat generic Glasgow Benefit Inventory[4], already exist as popular 'one-shot' instruments. However, until now, a tool that is both dynamic and semi-specific, focusing on the chief domains affected in chronic middle ear disease, has not existed. This article outlines the first stages of development and initial validation of a mixed generic and specific dynamic patient-reported outcome measure named the Chronic Otitis Media Benefit Inventory (COMBI).

The ethical issues involved in the validation of the COMBI were first presented to the UK NHS National Research Ethics Service for approval. Subsequently, local approvals from the Research and Development departments of the two hospitals involved in this study (Norfolk & Norwich University Hospitals NHS Foundation Trust and Ipswich Hospital NHS Trust) were received.

Preliminary construction of the COMBI

At the level of item content, the preliminary version of the COMBI was constructed from the basic 12 item wording in the static instrument Chronic Otitis Media Questionnaire - 12 (COMQ-12). Several pieces of work have supported that content for the purposes of developing a chronic otitis media quality of life instrument.[2, 5, 6, 7] At the level of item format, when 'before' and 'after' data are not collected on separate occasions, items have to elicit a retrospective comparison between two defined occasions or periods. The COMQ-12 item wording was therefore adapted to allow the respondent to report any perceived change in symptoms. Other intervening events are conceivable, but here the prime application envisaged was consequences of a surgical intervention. The common 5-point numerical response format was used, with two anchoring responses of opposite polarities offered, and one response being neutral, viz: 'much better', 'a little or somewhat better', 'no change', 'a little or somewhat worse', and 'much worse'. To generate preliminary totals in the first round of processing, this scoring was adopted at arithmetic face-value (values 1.0 –

5.0), with a lower score indicating a deterioration in symptoms and a higher score indicating an improvement.

Reference sample given the 12 COMBI items

A total of 52 patients undergoing surgery for Chronic Otitis Media (11 from Norfolk & Norwich University Hospitals NHS Foundation Trust and 41 from Ipswich Hospital NHS Trust) completed the COMBI six months after their surgery had been performed (see Table 1).

Table 1: *Age and basic clinical information on the groups of patients from hospitals A and B. Except for: "averages" entries are Ns*

Hospital	A	B
Number of participants	11	41
Male	6	21
Female	5	20
Average Age – Mean (SD)	50.09 (14.71)	47.68 (15.84)
Average Pre-op Hearing Level – Mean (SD)	49.89 (15.60)	49.33 (28.09)
Average Post-Op Hearing Level – Mean (SD)	41.25 (18.05)	45.98 (26.18)
Average Change in hearing level – Mean (SD)	8.64 (12.61)	3.35 (13.36)
Tympanoplasty for non-cholesteatoma	2	13
Mastoidectomy for cholesteatoma	9	20
Revision mastoidectomy & obliteration	0	8

This cohort of patients had not been involved in any other questionnaire studies previously. Responses on these and the Glasgow Benefit Inventory questionnaire (GBI) constituted the focal data. In addition, a proforma was used to provide supplementary information on the patients' medical history and current status. This information included the age and sex of the patient, the indication for surgery, the type of surgery performed, pure tone audiometry (at 0.5, 1.0, 2.0 and 3.0 kHz), and the clinical observations at review. Clinical findings at review included three 3-way categorisations of

the condition of the ear (dry, moist, or infected), status of the ear canal (cavity, no cavity, or obliterated cavity), and condition of the eardrum (intact, perforated, or stenosed).

Data entry and data verification

Patient responses and clinical data were transcribed to a spreadsheet (Microsoft Excel 2016) and then transferred to an SPSS data file for descriptives, regressions and factor analysis. Preliminary checks revealed a strong negative skew, with most responses demonstrating marked improvement of symptoms, implying possible ceiling effects. Correlations and plots were undertaken using raw item scores, which identified a small number of anomalous data points. To provide a comprehensive account of all the data, cases with anomalies were not excluded but subjected to data verification. Two items, each within two patients, so 4 responses (i.e. 4/[52X12] = 0.6 of 1% of total data] were identified as providing strong isolated responses in the opposite direction from their overall trend of response, raising an issue of response confusion. Both patients were contacted and asked to complete their questionnaires again under supervision and their understanding of the questions was checked. Importantly, these instances were not biasing, as not selected on the basis of their implications, e.g. for increasing or reducing correlations as with 'outliers' in a plot; although any corrections would have tended also to raise already existing correlations. This process identified how the wording for certain questions allowed a small number of respondents to confuse the polarity of the response, for example marking 'Much better', when they meant 'Much worse'. The product was a revised format for how the items affected should be presented, so as to allow item completion in the absence

of supervision (see Appendix A) and subsequent development will use and attend further to that.

Preliminary factor analyses

Factor analysis has for over 70 years been the central standard technique for identifying underlying concepts and deriving approximate measures of those, based on weightings of observed variables such as test scores or questionnaire items, according to their patterns of inter-correlation. For a general introduction, see Field (2009).[8] Factor analysis achieves three objectives particularly useful in questionnaire development: (a) it assists dropping of less useful items from the item pool on the basis of a mixture of low reliability and/or validity or inadequate sampling of the underlying domain in the set; (b) it characterises the content covered in a simple, communicable manner via factor interpretation and labelling; and (c) where profile information is desired, it offers a set of optimally weighted sub-totals, the factor scores. In the context of questionnaire development, a 'factor' can be extracted to summarise the covariation in a number of items that share similar qualities with five applications: revision of an item set; underpinning content validity of the total and or the subscores within the item set; saving actual factor scores; justifying simpler scores of item subsets; or scaling items for more precise empirically based scoring for total or subsets/factors.

Checked and verified scores were entered into a preliminary exploratory factor analysis, which gave 3 factors with an eigenvalue >1.00 (one conventional criterion) explaining 73.6% of the variance (for improvement with scaling see later). An eigenvalue is a summary of how much of the

variance in the observed variables a factor explains relative to the number of original variables. Varimax rotation was performed to ensure factor independence, after which the third factor achieved a rotated eigenvalue of 2.047, thus satisfactory strength for factors beyond the first. There was also a simply interpretable factor solution. Four factors would not be supportable on 12 items so only a possible 2-factor solution was checked as alternative; its 2nd factor was not clearly interpretable, so the 3-factor solution was adopted (Table 2).

Table 2: *Varimax item factor loadings as given by the SPSS table 'rotated component matrix'. First principal component and factor loadings of scaled items from the final 3-factor solution are reproduced, with cross-loading items identified in italics. Note that the score coefficients needed to generate a score, although related, are different.*

Scaled Items	FAC 1 (Hearing)	FAC 2 (Ear pathology)	FAC 3 (Healthcare requirements)	1st PC (weighted total)
Q4 ('Hearing in groups')	**0.914**	0.041	-0.061	0.528
Q3 ('Hearing at home')	**0.875**	0.172	0.131	0.687
Q9 ('Water exposure')	**0.802**	0.211	0.300	0.757
Q8 ('Daily activities')	**0.788**	0.083	0.298	0.670
Q1 ('Ear discharge')	0.028	**0.931**	0.190	0.690
Q2 ('Ear odour')	0.118	**0.910**	0.159	0.713
Q5 ('Ear discomfort')	0.130	**0.733**	0.492	0.787
Q6 ('Dizziness')	0.288	**0.694**	0.480	0.849
Q7 ('Tinnitus')	*0.437*	*0.548*	*0.121*	*0.757*
Q10 ('GP attendance')	0.320	0.194	**0.873**	0.767
Q11 ('Drug requirements')	0.012	0.329	**0.811**	0.634
Q12 ('General well being')	*0.522*	*0.364*	*0.595*	*0.844*

FAC, Factor; PC, Principal Component; Q, COMBI Question Number

Item scaling

In the first iteration, the item coding values 1-5 were taken as given, as values on an equal-interval scale. However, most items have plateau-

shaped or sigmoid relationships to the total or underlying factor score, and these shapes differ from item to item. This entails that improvements in item scaling and hence precision and sensitivity of resulting measures (reduction of measurement error) can be made by assigning empirically justified values in place of the *a priori* integer coding values 1-5. For a problem in otology similar to the present one, a full explanation and illustration of item scaling is given in Milovanovic *et al*. (2016).[9] Especially for rare extreme responses, a very large sample is required to produce justified scale values for generalized application to other samples. However extreme responses are also usually rare, so we proceeded also to scale despite this small sample; on balance of efficiency, for frequently occurring levels of response, better measurement for the dimensions receiving a preliminary total will always follow from scaling. For high-loading items, the provisional total adopted for each item was from the factor score on which it loaded highly. For the two cross-loading items, the provisional total adopted for scaling was the weighted total (1st principal component). The high- and cross-loading items (four subsets) are defined typographically in Table 2. For each item, the five possible responses as arithmetical values were replaced by category labels for a 5-level categorical independent variable. New decimal magnitude estimates for each level were then obtained by predicting a group mean score on the respective provisional total; here 'group' is defined as the adventitious set of respondents, responding with the particular response level on the item under examination. For example, in item 9, the scaled values from responses 1, 2, and 3 do not differ reliably, so the implication of the initial face-value scoring that they differ by exactly one unit, is simply incorrect. Hence the general basis of accepting response values as scoring is incorrect. However, where

category estimates do differ reliably, the differences do not have unit value; for example, the non-extreme difference between responses 3 and 4 becomes 1.74 times the extreme difference between responses 4 and 5. The general tendency to 'S-shape' is thus displaced here to a 'valley-bottom plus hillside' shape, with distinct gradation among the common 'improvement' responses, but no resolution in the lower, rarer values. Such clear examples require scaling, so as to make use of the resolution available in the part of the item response range where resolution is available. The relevant item properties (e.g. valley-bottom versus plateau) cannot, without extensive piloting, be identified in advance from the content. This is why the possible advantages of (re-)scaling need to be examined impartially for new datasets.

Next, the factor analysis was re-run on the scaled item values. This total scaling process amplifies the separation of factors and so increases both precision and the inter-correlation for items within a factor, but does not necessarily improve an item's loading on the weighted total. All subsequently reported results use the scaled versions. As preliminary testimony to the value of scaling in contributing to solving the ceiling problem, the total variance explained by the three factors rose after item scaling by 5.1 % to 78.7%, and the 3rd factor's rotated eigenvalue rose from 2.047 to 2.522, indicating that a better-supported measure of this construct is thus achieved.

Results

Consistency and reliability are widely used performance indicators for an item set and its supported measures. The Cronbach's alpha value for all subjects for the total of the 12 raw COMBI items before scaling was 0.907, well within conventionally accepted limits; after scaling it was 0.911. The improvement is negligible for the total score because only 2 of the 12 items were optimised to the total score, and thus the 12 within-factor pairwise item correlations involved are a small proportion of the total of 66 comprising the alpha index. For the 18 GBI raw items, alpha was 0.927. The factor loadings of the scaled items from the final 3-factor solution are reproduced in Table 2. Italicised items 7 and 12 are defined as cross-loading, lacking a single high factor loading that exceeds other loadings by 0.2 or more, but having two moderately high ones. If distinct factor profiles were the main aim, such items would be eliminated from the item pool, but for a generic or semi-generic instrument wishing also to support a total score for simple robust use, such cross-loading is not a problem. Three factor labels were assigned on the basis of shared properties of high-loading items: hearing function (Factor 1: high loading from items 3, 4, 8, 9), ear pathology problems (Factor 2: 1, 2, 5, 6) and healthcare requirement for such problems (Factor 3: 10, 11). These findings for the COMBI, were comparable to the labels assigned for the COMQ-12.

The distributions were highly negatively skewed, reflecting the predominance of 'large improvement' responses. Skew value for the first Principal Component (PC total) was -1.880 and for the 3 factors -.457, -2.305 and -2.014 (all SEs 0.330). Although Cronbach's alpha conventionally

summarises average item-pair correlations to reflect consistency, the use of principal component analysis and factor analysis offers a more fundamental characterisation of patterns of covariation for decisions (e.g. on item inclusion). It also yields scores optimally weighted according to item reliability and specific factor contribution. The skew-values were, as expected, not much improved by item scaling, so required transformation when using parametric statistics. Considering the compressed range of responses from this skew, the alpha and factor analysis results provide satisfactory justification that the respondents' improvement judgements have a valid structure and are not just a matter of feeling non-specifically pleased or wishing to please the clinician.

The Pearson correlation between raw unscaled total of the 12 COMBI items and the 1st PC total (from scaled items) was r=0.983; this is high enough to regard the raw total as an acceptable approximation where computer data entry and statistical analysis are not available, e.g. in routine clinical uses. However, the fact that it is not > 0.99 shows that the Principal Component is different enough to be worth the computation of scaled scores and PC total as preferable for research.

Table 3 shows the Pearson product-moment correlations between the three factors and the other main continuous scores in the data. The first three bold entries on the negative diagonal show correlations between factor scores (not item subsets, but closely approximating those, as the weights for non-loading items on each factor are very low) and also shows facet scores (PC weighted totals with low loaders excluded). A facet score involves only those items known or shown to be closely related to a specific

aspect of a disease, whereas a factor score receives these low weightings from all of the items within the instrument. The correspondences expected in the sense of criterion validity have to be quite high. Indeed, COMBI Factor 1 score (hearing function) correlates highly with the GBI total (r=0.798). This first study was not intended to provide criterion validity on all supported factors and the instrument was designed to complement, not to provide a short alternative to the GBI. In the latter context, the lower correlation of the PC2 with GBI (0.625) is gratifying.

Table 3: *Crossed correlations between COMBI supported scores (factor scores down the rows and discrete item facets across the columns). All COMBI facet scores use item scaling. GBI items are not scaled.*

	Facet PC1	**Facet PC2**	**Facet PC3**	**GBI FAC1**	**GBI FAC2**	**GBI FAC3**	**GBI PC total**
	Q3,Q4, Q8,Q9	**Q1,Q2, Q5,Q6**	**Q10,Q11**				**(18 items)**
FAC 1	**0.963**	0.154	0.180	0.689	0.444	0.058	0.798
FAC 2	0.145	**0.910**	0.284	-0.045	0.152	0.039	0.076
FAC 3	0.190	0.363	**0.916**	0.106	0.210	-0.001	0.211
PC (12 items)	0.753*	0.841	0.764	0.431*	0.465	0.058	0.625*

*correlations are compared in text on cases having one outlier excluded

Table 4 updates the descriptives on the basis of the metrical improvements and distinguishes clinical groups. With such small group Ns, the effect sizes under 0.5 seen for pathology contrasts that are not highly distinct can in general not be statistically reliable. The distributed differences among groups are marginal for Factor 2 overall ($F_{2,49} = 2.628$; p= 0.082); the extreme difference shown between tympanoplasty and revision mastoidectomy is superficially significant (p= 0.036; unrelated t-test, with differing variances assumed) but this does not survive the necessary

adjustment for multiple testing, and there is no strong specific reason to expect such a difference. With a still small sample size, a purely statistical approach to heterogeneous cases has limitations. However, exceptions can be informative: a further patient producing 'anomalies' had responses which on checking proved to be correct. This was the only patient who sustained a persistent perforation after surgery, and the ear was documented as being 'moist', indicating that this low COMBI score was associated with at least partial surgical failure. The potential interest of analysing profile information further via the factor scores remains, but a richer data base and an *a priori* framework for handling such circumstances with very few cases will be required for a validation of subscores.

Table 4: *Change data on 5 main continuous measures. Positive refers to improvement, negative to deterioration*

	Tympanoplasty for non-cholesteatoma N=15	Mastoidectomy for cholesteatoma N=29	Revision mastoidectomy and obliteration N=8
	Mean (SD)	Mean (SD)	Mean (SD)
Average Change in hearing level	5.917 (12.040)	1.897 (12.855)	11.094 (15.747)
Combi FAC1 (Hearing)	0.041 (0.939)	0.005 (0.957)	-0.097 (1.359)
Combi FAC2 (Ear pathology)	-0.447 (1.381)	0.107 (0.794)	0.449 (0.492)
Combi FAC3 (Healthcare requirements)	0.095 (1.375)	0.033 (0.760)	-0.296 (1.037)
Combi PC total (12 items)	-0.201 (1.366)	0.086 (0.845)	0.063 (0.759)
GBI PC (18 items)	0.065 (0.886)	-0.074 (1.090)	0.148 (0.954)

HRQoL measurements reflect the overall impact of disease from the perspective of the patient, complementing the perspective of the clinician. Simple patient-reported outcome measures (PROMs) are consequently becoming increasingly used in routine healthcare settings.[2, 10] In otology, single clinical, radiological, and audiological findings may inter-relate poorly, and also poorly predict HRQoL. However, use of HRQoL measures has been shown to aid both the patient's prioritisation of their symptoms[11] and the clinical management of their individual expectations.[12] Therefore, it is arguable that a developed set of HRQoL measures for routine use in each major group of conditions should be made available for widespread use. In a wider context, an appropriate combination of patient-reported outcomes and objective health markers could underpin institutional benchmarking, improved professional standards, and incentivised payments to health-care providers; such ambitions have been set out by some European governments.[13] The purpose of this study was to assess the preliminary properties and promise of the COMBI questionnaire, and so to determine whether further development with a larger sample size would be a justified investment – for example to achieve reliable and precise scoring for the rarer response categories, mostly corresponding to non-improvement, which though rare remain a matter for concern.

Main findings of the study

Cronbach's alpha values for the total score demonstrated high internal consistency of the COMBI total score, despite its conceptual heterogeneity and the strong 3-factor structure obtained, that would tend to lower

consistency. For discrete sub-sets of similar items as suggested by factor loadings (but not for factor scores themselves), alpha can also be calculated. However, the high overall reliability made this unnecessary here for general preliminary purposes and demonstration of consistency. In a short-form instrument with few items per sub-score, subset alphas for high-loading items will (by definition, if the factor structure is strong), be higher than for the total score but will not themselves be reliable on a modest sample size. Subscore consistency is therefore deferred to the now justified studies with a larger sample.

The 3-factor solution demonstrates that items of similar content co-vary in their response values; this gives preliminary evidence of content validity for the three factors (changes in hearing, in ear symptoms and in healthcare use) as ways in which patients' health-related QoL evolves or is influenced by treatment. Improvements in factor structure after scaling furthermore justify some expectation that profiles of differential improvement could be supported on the 12 items. The correlations between the first COMBI factor and the GBI total, and between the COMBI total and the GBI total are high enough to show some criterion validity, but not so high as to undermine the claim that COMBI particularly captures the main *a* priori health domains of chronic otitis media – although it has to be noted that such claims have not yet been directly tested. Two of the domains included are not specifically present in the GBI, suggesting that COMBI fulfils a niche for adult COM which the more generic GBI does not fill, despite the GBI's established status. The modest correlations other than these are consistent with such complementation, but there is evidence of criterion validity on the total and Factor 1 (hearing function). We leave demonstration of construct validity

to subsequent studies, as we would not expect many convincing relationships between the routine clinical data (static) and the factor scores (dynamic); also, the sample size is small for addressing correlations of this type. Improvement is partly a matter of perception, and the fine detail in the pathology and surgical technique is not very accessible to ordinary self-observation. This makes validity demonstrations problematic. For example, the difference between pre- and post-operative hearing levels and the score for improvement in the hearing factor correlated only very weakly ($r = 0.152$; $p = .282$) due to the small mean and wide variance in such improvement.

Limitations and strengths of the preliminary study

A sample size of only about 50 can offer limited precision and generalizability concerning factor structure, item scale values, or the reliability and validity indices themselves. However, the use of scaling and factor analysis, as among the most powerful techniques available, has made best use of the existing information for making a decision on further investment, and the consequent results are coherent and encouraging. The psychometric appraisal of a quality of life instrument can never be achieved as a single exercise, in a single population, but requires preliminary justification of promise to resource sufficiently large numbers of participants and variables, preferably in distinct clinical populations, addressing reliability and stability of factor structure; plus, other various forms of validity.[14] The present results justify such a programme expansion to multicentre collaborations.

To avoid bias towards favourable responses and thus allow absence of deterioration responses to be truly informative, response options had to be symmetrically distributed about zero change. However, with only 6 levels this led directly to the observed ceiling effect and lack of resolution near it – barely a continuous response dimension. To reconcile these conflicting aims of reasonably few response alternatives, freedom from central tendency bias on improvement ratings, and gradation in the relevant range, the slightly expanded range of 7 response options, (i.e. a 7-point scale) appears to be needed. The response options currently allowed were derived from a well-established questionnaire in this field (GBI) but that precedent did not give pilot warning that this conflict would be encountered in surgical treatment of COM. One advantage of having proceeded to item scaling even on this modestly-sized sample lies in retention of resolution among frequent response alternatives so probable minimisation of the harm done by the skewed distribution and by coarse quantising of what should be a continuous scale. Consequent facilitation of the factor structure has allowed the general promise of the item/format combination to be evaluated, and has justified the pursuit of further such improvements.

A second recommended improvement is more mundane. Any procedure checking data based on observing anomalies must increase the consistency within the data; but it could also introduce bias that enhances effect sizes. For this reason, only one alteration by each of two patients (0.006 of all the data) on confirmation was accepted here; the issue was handled by repeating filling of the questionnaire. The analysis avoided the more common and more dangerous practice of excluding outliers. It is equally possible that some true relationships exist that are actually stronger than

those shown, because undetected milder responding errors would also dilute such relationships. The present data have pointed to the need to preclude such response confusions via refinements of wording and format.

Applications of the COMBI

The COMBI's one-shot format offers convenience over available single-occasion status instruments for chronic middle ear disease that require completion both pre-intervention and post-intervention. Differences obtained by subtraction or baseline adjustment may be more bias-free for research but there are situations where simpler and more accessible methods of questionnaire completion are desired and acceptable.[3] The COMBI should not be considered as an exact replacement for the COMQ-12, but as a complementary tool for use where very simple pre/post comparison is required. The COMBI's brevity and consistent psychometric properties make it potentially very useful for simple applications such as clinical audit.

Conclusions

In a psychometrically rigorous process, we have developed a new partly generic and partly specific dynamic (i.e. change-oriented) patient-reported outcome measure for adult middle ear disease. Initial psychometric appraisal confirms its suitability for early adoption for further evaluation and optimisation of scoring formulae on larger samples and more diverse datasets, and has specified two areas for minor improvements.

References

1. Nadol JB Jr, Staecker H, Gliklich RE. Outcomes assessment for chronic otitis media: the Chronic Ear Survey. *Laryngoscope*. 2000;110(3 Pt 3):32-5.
2. Phillips JS, Yung MW. A systematic review of patient-reported outcome measures for chronic suppurative otitis media. *Laryngoscope*. 2015 Sep 15.
3. Phillips JS, Yung MW, Nunney I. Myringoplasty outcomes in the UK. *J Laryngol Otol*. 2015;129(9):860-4.
4. Robinson K, Gatehouse S, Browning GG. Measuring patient benefit from otorhinolaryngological surgery and therapy. *Ann. Otol. Rhinol. Laryngol*. 1996;105,415–422
5. Phillips JS, Haggard M, Yung M. A new health-related quality of life measure for active chronic otitis media (COMQ-12): development and initial validation. *Otol Neurotol.* 2014;35(3):454-8.
6. Phillips JS, Yung MW. COMQ-12 scores in adult patients without chronic middle ear disease. *Clin Otolaryngol*. 2014;39(6):362-7.
7. Oorts E, Phillips JS, Van de Heyning P, Yung M, Van Rompaey V. Development of the Dutch version of the health-related quality of life measure for chronic otitis media (COMQ-12). *B-ENT* – In Press
8. Field, A. (2009). Discovering statistics using SPSS. *Sage Publications*.
9. Milovanovic J, Filipovic SA, Marchisio P, Haggard MP, Zhang MF, Spencer H; Eurotitis-2 Study Group. Precision-scored parental report questions and HL-scaled tympanometry as informative measures of hearing in otitis media 1: Large-sample evidence on

determinants and complementarity to pure-tone audiometry. *Int J Pediatr Otorhinolaryngol*. 2016;83:113-31.

10. Koller M, Lorenz W. Survival of the quality of life concept. *Br J Surg*. 2003;90(10):1175-7.
11. Nies C, Celik I, Lorenz W, et al. Outcome nach minimal-invasiver Chirurgie. Qualitative Analyse und Bewertung der klinischen Relevanz von Studienendpunkten durch Patient und Arzt. *Chirurg* 2001;72:19–29
12. Koller M, Lorenz W, Wagner K, et al. Expectations and quality of life of cancer patients undergoing radiotherapy. *J R Soc Med*. 2000;93:621–8
13. Liberating the NHS: Transparency in Outcomes – A Framework for the NHS. *Department of Health*. 2010.
14. Terwee CB, Bot SD, de Boer MR, van der Windt DA, Knol DL, Dekker J, Bouter LM, de Vet HC. Quality criteria were proposed for measurement properties of health status questionnaires. *J Clin Epidemiol*. 2007;60(1):34-42.

Appendices

Appendix A: COMBI – Final version

Chronic Otitis Media Benefit Inventory (COMBI)

Phillips JS, Yung MW, Haggard M, Spencer H

The aim of this questionnaire is to find out how your ear problems have affected you since you have had ear surgery performed or another type of intervention.

Please answer the questions below by considering carefully each question asked, and then ticking the appropriate box. There are no right or wrong answers, but please try to think carefully about each question before ticking the appropriate box.

Once you have completed the questionnaire, please check that you have provided an answer to every question and do ask for help if you find it hard.

Symptom severity:

1. Since your operation/intervention, has the discharge or drainage from your ear been better or worse?

5	4	3	2	1
Much Better	*A little or somewhat better*	*No Change*	*A little or somewhat worse*	*Much worse*

2. Since your operation/intervention, how would you define the change in having a 'smelly ear'. Has this become better or worse?

5	4	3	2	1
Much Better	*A little or somewhat better*	*No Change*	*A little or somewhat worse*	*Much worse*

3. Since your operation/intervention, has your hearing at home (e.g. requiring the volume of the TV or Radio to be turned up) got better or worse?

5	4	3	2	1
Much Better	*A little or somewhat better*	*No Change*	*A little or somewhat worse*	*Much worse*

4. Since your operation/intervention, has your hearing when talking to people in groups (or when there are noisy surroundings) got better or worse?

5	4	3	2	1
Much Better	*A little or somewhat better*	*No Change*	*A little or somewhat worse*	*Much worse*

5. Since your operation/intervention, has the discomfort in and/or around the ear got better or worse?

5	4	3	2	1
Much Better	*A little or somewhat better*	*No Change*	*A little or somewhat worse*	*Much worse*

6. Since your operation/intervention, has your dizziness or feeling 'off balance' got better or worse?

5	4	3	2	1
Much Better	*A little or somewhat better*	*No Change*	*A little or somewhat worse*	*Much worse*

7. Since your operation/intervention, has your tinnitus or noises in the ear got better or worse?

5	4	3	2	1
Much Better	*A little or somewhat better*	*No Change*	*A little or somewhat worse*	*Much worse*

Lifestyle, work and health service impact:

8. Regarding your normal daily activities at home and work, would you say that you have had more problems or less problems, since your operation/intervention?

1	2	3	4	5
Much more problems performing activities	*More problems performing activities*	*No Change*	*Less problems performing activities*	*Much less problems performing activities*

9. Regarding your ability to wash or shower or bathe as you would like to since your operation/intervention, have you been more fearful or less fearful of these activities causing an ear infection?

1	2	3	4	5
Much more fearful of getting my ear wet	*More fearful of getting my ear wet*	*No Change*	*Less fearful of getting my ear wet*	*Much less fearful of getting my ear wet*

10. Since your operation/intervention, have you seen your family doctor more often or less often, about your ear problems?

1	2	3	4	5
Much more often	*More often*	*No Change*	*Less often*	*Much less often*

11. Since your operation/intervention, have you needed to take medicines (including eardrops) for your ear problem more often or less often?

1	2	3	4	5
Much more often	*More often*	*No Change*	*Less often*	*Much less often*

General:

12. Since your operation/intervention, have your ear problems 'got you down' more or less than before?

1	2	3	4	5
Much more than before	*More than before*	*No Change*	*Less than before*	*Much less than before*

Chapter 8

General discussion

Future perspectives

Conclusion

This thesis focuses on the development of two HRQoL questionnaires to appraise the multiple domains of chronic otitis media from a patient-focused perspective.

The COMQ-12 (chapters 1 and 2)

The COMQ-12 was the first HRQoL questionnaire that we developed. This was developed following a review of the items employed within contemporary HRQoL questionnaires, and the formation of a long list that represented the themes covered by these questionnaires. Content validation was acquired by engaging with patients and clinicians. The resulting 12-item questionnaire was then tested in two populations: a cohort of patients with COM, and a cohort of healthy volunteers. The results of our first study confirmed that there was sufficient consistency and that there was sufficient validity information to justify further work in both a clinical and research arena. The results of the second study allowed us to broadly define 'normal' values that should be considered before embarking on otological surgery in patients with COM.

The context of HRQoL questionnaires for COM (chapters 3 and 4)

Once we had initiated a program of questionnaire development, it was considered to be an appropriate time to formally reflect on the relative merits of the COMQ-12 in comparison with other available questionnaires. A formal systematic review of the literature was performed to determine the differential qualities, assessment domains, areas of use and psychometric qualities of a questionnaire such as the COMQ-12 in the

modern healthcare setting. In parallel with this, we took the opportunity to report the outcome of the UK myringoplasty audit. These two ventures when appraised together allowed us to truly appreciate where and how our COMQ-12 would feature within the infrastructure of future large scale audits of surgical outcome. The literature review proved the COMQ-12 to fare well in comparison with other COM HRQoL tools, but other more established HRQoL tools had benefited from psychometric appraisal over a longer period of time. In addition to this, one of the HRQoL questionnaires had already been translated into other languages; making it accessible for use outside its original country of production. A finding of both of these pieces of work at the time, was that there was no HRQoL instruments to assess change as a single process; all questionnaires provided absolute values for HRQoL, and therefore required completion in a before and after fashion.

Translation of the COMQ-12 into other languages (chapters 5 and 6)

A key requirement for the international acceptance of a new HRQoL instrument, is to demonstrate that such an instrument is psychometrically acceptable when translated into another language. We embarked on two studies in this respect. In the first instance the COMQ-12 was translated and appraised in Dutch. In the second instance, the COMQ-12 was translated and appraised in Russian. The Dutch study was performed first to confirm adequate consistencies in questionnaire quality with our original questionnaire. Once this was achieved, we progressed to perform the Russian study. It was very satisfying to confirm the properties of the Russian version of the COMQ-12; as the population of Belgium, from a social and

economic perspective, is far more comparable with that of the UK than that of Russia.

The COMBI (chapter 7)

Earlier findings derived from the literature review and the UK myringoplasty audit recommended the development of a 'dynamic' questionnaire, whereby before and after questionnaire completion is not required. The developmental work surrounding the COMQ-12 up to this point provided an excellent foundation to build a 'dynamic' questionnaire. As the original item set of the COMQ-12 had been consistently identified to appropriately represent the QoL of individuals with COM, a new HRQoL questionnaire was developed, using this same item set, but employing a different method of patient response acquisition. This new HRQoL questionnaire was named the COMBI, and underwent satisfactory initial psychometric appraisal and was deemed particularly suitable for use as a clinical audit tool.

Future perspectives

The development of a good quality HRQoL questionnaire cannot be achieved in a single step. Psychometric appraisal involves a continual assessment of reliability and validity. There are many different tests available to determine the functionality of a QoL questionnaire in these respects and it is often necessary to repeat individual tests in different populations, in different circumstances and over many years.

This PhD thesis does not represent the end of a process, but in fact the beginning of a process. Since embarking on the various aspects of HRQoL development for COM, we have had requests from colleagues from around the world, seeking permission to translate our questionnaires and to collaborate on future projects. Currently, the COMQ-12 has been translated, or is due to be translated, into the following languages: English, Dutch, Russian, Greek, Serbian, Portuguese, Chinese, Japanese, French and German.

Enthusiasm for adopting our questionnaires for use outside the UK and outside Europe provides many opportunities for the future; these include:

1. Recognition of the COMQ-12 and COMBI as the prime instruments for determining QoL in individuals with COM.
2. International dissemination of our development work and subsequent international use.

3. The more diverse the applications of the COMQ-12 and COMBI questionnaires, the more opportunities arise to learn about the distinct psychometric properties of these instruments.
4. The provision of a universal tool for the appraisal of QoL in individuals with COM allows a consistent and readily applicable tool for the comparison of COM symptomology and surgical outcomes on a global scale without the restrictions imposed by language.
5. International dissemination allows international collaboration to accumulate very large series of data.
6. The more we learn about the clinical aspects of COM and its treatment from a patient-focussed perspective, the more we can learn about the relative significance of individual symptoms. This will ultimately lead an improvement in the clinical care that we provide to our patients.

At the time of writing this thesis, there have been requests for international collaborations, the development of international outcome standards, and for the application to national research agencies to fund national outcome audits. I am delighted with the achievements of this work so far, and look forward to continuing this work during the rest of my professional career.

Conclusion

- COM is an important condition affecting the middle ear, and is associated with a significant degree of patient morbidity.

- Appraisal of patient reported QoL is important for many different reasons. In particular, the acquisition of patient reported symptoms allows a fair understanding of an individual patient's prioritisation of symptoms, together with their expectations for treatment. Other benefits include the ability to acquire data for benchmarking and to improve standards.

- The COMQ-12 is a 12 item HRQoL questionnaire that provided an absolute value to suggest the QoL in patients with COM. Initial psychometric appraisal has provided consistently positive findings to recommend the COMQ-12 for use in a clinical and research arena.

- The COMQ-12 fares well when compared with contemporary HRQoL questionnaires.

- The COMQ-12 has been successfully translated and applied to two distinctly different populations in Belgium and Russia.

- The COMBI is also a 12 item HRQoL questionnaire that has been derived from work performed during the development of the COMQ-12. The COMBI provides a relative value to suggest the QoL

in patients with COM. Initial psychometric appraisal has provided encouraging data to promote the COMBI for use in clinical audit.

- The COMQ-12 and the COMBI are the two published HRQoL questionnaires that have been produced as an output of this PhD work. They should be considered as complementary tools for the appraisal of COM.

- The development and appraisal of HRQoL instruments is not a single process that takes place at a specific point in time, in a specific population, or by using a specific battery of tests. This PhD thesis documents progress in the development of the COMQ-12 and COMBI. This work will not end here. As HRQoL questionnaire development is an evolving process, we intend to continue our work in the future.

Chapter 9

Summary

Samenvatting

Summary

COM remains an important condition that affects a significant proportion of the world population. In response to an unmet need for a high quality HRQoL questionnaire to appraisal the physical, social and psychological aspects of this condition, we have developed two questionnaires for use in the clinical and research arenas.[1, 2, 3]

The COMQ-12 questionnaire has been developed and successfully tested to provide an absolute value of QoL in individuals with COM.[1, 2] This means that to appreciate the responsiveness from a specific intervention, the COMQ-12 needs to be completed in a before and after manner. The COMQ-12 has been successfully translated and tested in Dutch and Russian.[4, 5]

A systematic review of the world literature and a review of UK myringoplasty outcome data has allowed a dispassionate reflection upon the development of the COMQ-12 questionnaire.[6, 7] As a consequence of this work, the COMBI questionnaire has been developed to provide a relative value of QoL in individuals with COM; this provides an excellent opportunity for use in clinical audit. Both the COMQ-12 and COMBI questionnaires should be considered as complementary tools for the appraisal of COM.

Samenvatting

Chronische Otitis Media (COM) blijft een belangrijke aandoening die een aanzienlijk deel van de wereldbevolking treft. Als antwoord op een onvervulde behoefte aan een kwalitatief hoogstaande en gevalideerde vragenlijst over de kwaliteit van leven om de fysieke, sociale en psychologische aspecten van deze aandoening te beoordelen, hebben we twee vragenlijsten ontwikkeld voor gebruik in klinische en onderzoekscentra.[1, 2, 3]

De COMQ-12 vragenlijst is ontwikkeld en met succes getest om een absolute waarde van ziekte-gerelateerde levenskwaliteit te bieden bij individuen met COM.[1, 2] Dit betekent dat , om de responsiviteit van een specifieke interventie te waarderen, de COMQ-12 moet worden ingevuld voor en na de behandeling. De COMQ-12 werd met succes vertaald en gevalideerd in het Nederlands en het Russisch.[4, 5]

Een systematische review van de literatuur en een beoordeling van de uitkomsten van UK myringoplasty heeft een terugblik op de ontwikkeling van de COMQ-12 vragenlijst mogelijk gemaakt.[6, 7] Als gevolg van dit werk werd de COMBI-vragenlijst ontwikkeld om een relatieve waarde van levenskwaliteit bij patiënten met COM te bieden (de vragenlijst wordt namelijk enkel na de behandeling gegeven) voor gebruik bij klinische audits. Zowel de COMQ-12- als de COMBI-vragenlijsten moeten worden beschouwd als aanvullende instrumenten voor de beoordeling van COM.

References

1. Phillips JS, Haggard M, Yung M. A new health-related quality of life measure for active chronic otitis media (COMQ-12): development and initial validation. *Otology Neurotology*. 2014;35(3):454-8
2. Phillips JS, Yung MW. COMQ-12 scores in adult patients without chronic middle ear disease. *Clinical Otolaryngology*. 2014;39(6):362-7
3. Phillips JS, Haggard M, Spencer H, Yung M. The Chronic Otitis Media Benefit Inventory (COMBI): development and validation of a dynamic quality of life questionnaire for chronic ear disease. *Otology & Neurotology*. 2017;38(5):701-707.
4. Oorts E, Phillips J, Van de Heyning P, Yung M, Van Rompaey V. Development of the Dutch version of the health-related quality of life measure for chronic otitis media (COMQ-12). *B-ENT*. 2015;11(4):291-5
5. Kosyakov SI, Minavnina JV, Phillips JS, Yung MW. Preliminary appraisal of the Russian version of the Chronic Otitis Media Questionnaire 12 (RCOMQ-12). *Journal of Laryngology and Otology*. – In Press
6. Phillips JS, Yung MW. A systematic review of patient reported outcome measures for chronic suppurative otitis media. *Laryngoscope* 2016;126(6):1458–63
7. Phillips JS, Nunney I, Yung MW. Myringoplasty Outcomes in the United Kingdom. *Journal of Otology and Laryngology*. 2015;129(9):860-4.

Addenda

Publications

Awards – visits – conferences – courses

Dankwoord

Publications related to this PhD thesis

1. Phillips JS, Haggard M, Yung M. A new health-related quality of life measure for active chronic otitis media (COMQ-12): development and initial validation. *Otology Neurotology*. 2014;35(3):454-8
2. Phillips JS, Yung MW. COMQ-12 scores in adult patients without chronic middle ear disease. *Clinical Otolaryngology*. 2014;39(6):362-7
3. Phillips JS, Nunney I, Yung MW. Myringoplasty Outcomes in the United Kingdom. *Journal of Otology and Laryngology*. 2015;129(9):860-4
4. Phillips JS, Yung MW. A systematic review of patient reported outcome measures for chronic suppurative otitis media. *Laryngoscope* 2016;126(6):1458–63
5. Oorts E, Phillips J, Van de Heyning P, Yung M, Van Rompaey V. Development of the Dutch version of the health-related quality of life measure for chronic otitis media (COMQ-12). *B-ENT*. 2015;11(4):291-5
6. Kosyakov SI, Minavnina JV, Phillips JS, Yung MW. Preliminary appraisal of the Russian version of the Chronic Otitis Media Questionnaire 12 (RCOMQ-12). *Journal of Laryngology and Otology* – In Press
7. Phillips JS, Haggard M, Spencer H, Yung M. The Chronic Otitis Media Benefit Inventory (COMBI): development and validation of a dynamic quality of life questionnaire for chronic ear disease. *Otology & Neurotology*. 2017;38(5):701-707.

Publications not related to this PhD thesis

1. Phillips JS, McFerran DJ, Hall DA, Hoare DJ. The Natural History of Subjective Tinnitus in Adults: A Systematic Review and Meta-analysis of No-Intervention Periods in Controlled Trials. *Laryngoscope* – In Press
2. Murphy D, Phillips JS. Haemangioma of the Tympanic Membrane. *British Medical Journal* – In Press
3. Millington AJ, Gaunt AC, Phillips JS. Post-tonsillectomy dietary advice: systematic review. *J Laryngol Otol*. 2016;130(10):889-892.
4. Masterson L, Howard J, Liu ZW, Phillips JS. Asymmetrical Hearing Loss in Cases of Industrial Noise Exposure: A Systematic Review of the Literature. *Otology & Neurotology*. 2016;37(8):998-1005.
5. Mohammed H, Briggs M, Phillips JS. Pulsatile tinnitus as the presenting symptom in a patient with posterior reversible encephalopathy syndrome. *European Archives of Otolaryngology*. 2016;273(9):2847-51.
6. Phillips JS. The Modern Management of Meniere's Disease. *ENT & Audiology News - In Press.*
7. Davey S, Kelly-Morland C, Phillips JS, Nunney I, Pawaroo D. Assessment of Superior Semicircular Canal Thickness With Advancing Age . *Laryngoscope*. 2015;125(8):1940-5.
8. Gaunt AC, Neumann C, Phillips JS, Swan I. BAHA surgery in England - variation in service provision for adults across Strategic Health Authority regions revealed by the Hospital Episode Statistics database. *Clin Otolaryngol*. 2015;40(2):159-62.

9. Davies-Husband CR, Phillips JS, Bath AP. Opportunities for certificate of completion of training. *Clin Otolaryngol*. 2015;40(1):66-7.
10. Gaunt AC, Phillips JS. Reconstructed coronal computed tomogram of the temporal bones. *British Medical Journal* – In Press
11. Wasson J, Phillips JS. A break-even analysis of major ear surgery. *Clin Otolaryngol*. 2015;40(5):422-8.
12. Phillips JS. Otitis externa. *Pulse Magazine*.
13. Millington A, Phillips JS. Are current trends in tonsillectomy reflecting the health burden of tonsillitis? *Ann R Coll Surg Engl*. 2014;96(8):586-9.
14. Phillips JS, Gaunt AC, Phillips DR. Otosyphilis – a neglected diagnosis? *Otology & Neurotology* – 2014;35(6):1011-3
15. Davies-Husband CR, Gatenby C, Phillips JS. Tinnitus sound therapy: from the Sony Walkman to the Apple iPhone. *Clin. Otolaryngol*. - 2013;38(6):561-2
16. Gaunt A, Phillips JS, Pawaroo D. Temporal Odontoma - A Unique Finding. *Otology & Neurotology*. 2014;35(4):e153-4
17. Trinidade A, Phillips JS, Bath AP. Day-case tonsillectomy: Is the NHS demanding unobtainable targets? *Annals of the Royal College of Surgeons of England - In Press*
18. Masood A, Phillips JS, Bath AP. Surgical Competency of ENT Trainees and the ISCP'. *Annals of the Royal College of Surgeons of England*. 2014;96:e9-e13.
19. Trinidade A, Robinson T, Phillips JS. The role of caffeine in otorhinolaryngology: guilty as charged? *Eur Arch Otorhinolaryngol.* 2014;271(8):2097-102.

20. Phillips JS. How I Do It: Fasciaform Tympanoplasty. *ENT & Audiology News.* 2013:22(1);104-5

21. Davey S, Phillips JS. A new challenge: the deaf-wannabe. *Clin. Otolaryngol*. 2013;38(1):109-10.

22. Fitzgerald O'Connor EJ, Phillips JS. Transnasal flexible laryngeo-oesophagoscopy (TNFLO) as an adjunct for the surgical correction of choanal atresia. *Journal of Laryngology and Otology*. 2012;126(11):1179-81

23. Phillips JS, Lee J, Currie D, Parker R, Westerberg BD. Gender Bias May Account for Auditory Comprehension Differences. *Hearing Journal.* 2012:65(4);31-34

24. Phillips JS. Expert bias in peer review. *Curr Med Res Opin.* 2011;27(12):2229-33.

25. Meng Z, Liu S, Zheng Y, Phillips JS. Repetitive transcranial magnetic stimulation for tinnitus. *Cochrane Database Syst Rev*. 2011;5(10):CD007946

26. Phillips JS, Mallinson A, Hamid M. Cost effective evaluation of the vestibular patient. *Curr Opin Otolaryngology Head Neck Surg*. 2011;19(5):403-9

27. Phillips JS, Westerberg B. Intratympanic steroids for Ménière's disease or syndrome. *Cochrane Database Syst Rev*. 2011;6(7):CD008514.

28. Phillips JS, Longridge NS, Mallinson A, Robinson G. Reply to: "Response to: Migraine and Vertigo: A marriage of convenience?" *Headache*. 2011;51(7):1173-4

29. Phillips JS, Mason MJ, Dixon H. Middle ear instrument nomenclature: a taxonomic approach. *British Medical Journal.* 2010;341:c5137

30. Phillips JS, Mallinson A. Vertigo. *BMJ* – eLearning educational supplement

31. Phillips JS, Longridge NS, Mallinson A, Robinson G. Migraine and Vertigo: A marriage of convenience? *Headache*. 2010;50(8):1362-5

32. Phillips JS, McFerran DJ. Tinnitus Retraining Therapy (TRT) for tinnitus. *Cochrane Database Syst Rev*. 2010;17(3):CD007330.

33. Phillips JS, FitzGerald JE, Bath AP. The role of the vestibular assessment. *Journal of Laryngology and Otology*. 2009;123(11):1212-5

34. Phillips JS, Hilger AW. Are we performing enough tonsillectomies? *Nature Reviews Clinical Oncology*. 2009;6(8):439-40

35. Phillips JS, Prinsley PR. A unified hypothesis for vestibular dysfunction? *Otolaryngology - Head and Neck Surgery*. 2009;140(4):477-479.

36. Phillips JS, Montgomery PQ. Scale invariance, global warfare and the monthly morbidity and mortality meeting. Clinical Otolaryngology. 2009;34(1):3-5.

37. Phillips JS, Prinsley PR. What role for betahistine in the treatment of Meniere's disease? *Prescriber*. 2009;20(2):35-37.

38. Davies-Husband CR, Phillips JS, Innes AJ. Fluctuating hearing loss associated with Halo vest application. *Journal of Laryngology and Otology*. 2009;123(1):e5

39. Phillips JS, Premachandra DJ. Giant Parotid Mass. *Canadian Journal of Surgery*. 2009;52(1):E21-2

40. Hilton JM, Phillips JS, Hellquist HB, Premachandra DJ. Multifocal multi-site Warthin tumour. *European Archives of Otorhinolaryngology*. 2008;265(12):1573-5

41. Phillips JS. Ear Discharge: Diagnosis and Treatment. *BMJ* – eLearning educational supplement

42. Phillips JS, Yung MW. Incidence of Mastoid Surgery in England: Implications for Training. *Bulletin of The Royal College of Surgeons of England.* 2008;90(7):242-244(3)

43. Phillips J, Ward T, Montgomery PQ. Variations in posttonsillectomy hemorrhage rates are scale invariant. *Laryngoscope*. 2008;118(6):1096-8.

44. Phillips JS, Prinsley PR. Prescribing practices for Betahistine. *British Journal of Clinical Pharmacology*. 2008;65(4):470-1.

45. Bath AP, Phillips JS. Need to Know: Vertigo. *Pulse*. 2008;68(2):35-37

46. Berry N, Phillips JS, Salam MA. Written Consent - A Prospective Audit of Practices for ENT Patients. *Annals Royal College of Surgeons of England.* 2008;90(2):150-2.

47. Gibbins N, Phillips JS, McKiernan DC. A Conservative Approach to Laryngeal Trauma. *Injury Extra*. 2007;38(11):414-416.

48. Phillips JS, Vowler SL, Salam MA. Is training in endoscopic sinus surgery detrimental to patient outcome? *Journal of Surgical Education*. 2007;64(5):278-81.

49. Phillips JS, Yung MW, Burton MJ, Swan IRC. Evidence review and ENT-UK consensus report for the use of aminoglycoside-containing

ear drops in the presence of an open middle ear. *Clinical Otolaryngology*. 2007;32(5):330-6.

50. Prasai A, Phillips J, Jani P. Spontaneous Resolution of a Traumatic Laryngocoele. *Journal of Otolaryngology*. 2007;36(3):E5-8

51. Salem A, Phillips JS, Joseph JA, O'Donovan DG, Jani P. Basal cell adenocarcinoma of the ethmoid sinuses. *Journal of Laryngology and Otology*. 2007;121(9):889-91

52. Phillips JS, Chokkalingam P, McFerran DJ. Advice given to women who are prescribed antibiotics while taking the oral contraceptive pill. *Clinical Risk*. 2007;13(4):133-4.

53. Phillips JS, Pledger D, Hilger AW. Thyrotoxicosis in Anaplastic Thyroid Carcinoma. *Journal of Laryngology and Otology*. 2007;121(7):695-7

54. Phillips JS, Yung MW, Burton MJ, Swan IRC. Use of aminoglycoside-containing ear drops in the presence of a perforation: evidence review and ENT-UK consensus statement
Clinical Audit and Practice Advisory Group Guidelines, British Association of Otolaryngologists – Head & Neck Surgeons (ENT-UK). May 2007. www.entuk.org

55. Phillips JS, Vowler SL, Salam MA. Endoscopic Sinus Surgery for 'Sinus Headache'. *Rhinology*. 2007;45(1):14-9.

56. McFerran DJ, Phillips JS. Tinnitus. *Journal of Laryngology and Otology*. 2007;121(3):201-8.

57. Phillips JS, Yung MW. Distribution of rhinoplasty operations amongst different surgical specialties in the UK. *BMJ*. 23rd October 2006. Rapid Response eLetter.

58. Baguley DM, Phillips J, Humphriss RL, Jones SEM, Axon PR, Moffat DA. The prevalence and onset of gaze modulation of tinnitus, and increased sensitivity to noise following translabyrinthine vestibular schwannoma excision. *Otology Neurotology*. 2006;27(2):220-4.

59. Phillips J, McRae D. Nasal Preparation. *Clinical Otolaryngology*. 2005;30(6):566-7.

60. Phillips JS, King JA, Chandran S, Prinsley PR, Dick D. Cerebral Autosomal Dominant Arteriopathy with Subcortical Infarcts and Leukoencephalopathy (CADASIL) presenting with sudden sensorineural hearing loss. *Journal of Laryngology and Otology*. 2005;119(2):148-51.

61. Phillips JS, Lishman SC, Jani P. Colonic Carcinoma Metastasis to the Thyroid: A Case of Skip Metastasis. *Journal of Laryngology and Otology*. 2005;119(10):834-6.

62. Phillips JS, Gillespie PH, Logan AM. Digital Nerve Blocks - a Cadaveric Study of an Unrecognised Trauma. *Journal of Trauma*. 2005;59(3):770-2.

63. Phillips JS, Jones SEM. Hyperbaric oxygen as an adjuvant treatment for malignant otitis externa. *Cochrane Database Syst. Rev*. 2005;18(2):CD004617.

64. Phillips JS, Baguley DM, Patel H, Moffat DA. Tinnitus evoked by cutaneous stimulation. *Neurology*. 2004;63(9):1756.

65. Phillips JS, Naik M, Innes AJ. Corticosteroids for Supraglottitis. *British Journal of Anaesthesia*. 2004;92(3):545-5.

66. Haywood RM, Raurell A, Perks AG, Sassoon EM, Logan AM, Phillips J. Autologous free tissue breast reconstruction using the internal

mammary perforators as recipient vessels. *British Journal of Plastic Surgery*. 2003;56(7):689-91.

67. Phillips JS, Prinsley PR. Case Report: Sudden Unilateral Deafness after Bilateral Knee Replacement. *Journal of Laryngology and Otology*. 2003;117(4):310-1.

Awards

1. In 2005, I was awarded the Dan Smith Prize for best presentation at the annual regional East Anglia otolaryngology meeting
2. In 2007, I was awarded the Royal Society Medicine Prize for best presentation in the Evidence Based Medicine section
3. In 2007, I was awarded the Clinical Otolaryngology Review Prize for best published Evidence Based Medicine review 2006/2007. This was presented at the Royal Society of Medicine - December 2007

Visits

In 2009 I was given the opportunity to spend a year in Vancouver, Canada on an otology/neurotology fellowship with Dr Brian Westerberg. During this time, I was able to develop my clinical and surgical experience in many areas of otology and skull base surgery. I was also given the opportunity to develop my research interests.

Courses

1. Functional Orthogonal Cholesteatoma Surgery Course and Laser Update. September 2014. London, UK.
2. Endoscopic Ear Surgery Course. July 2014. Manchester, UK.
3. Advanced Surgical Vibroplasty Course. June 2014. Dundee, UK.
4. 15th International Otology Course. June 2013. Beziers, France.
5. 5th Manchester International Phonosurgery Course. March 2013. Manchester, UK.
6. Medico-Legal Training Course. February 2012. London, UK.
7. Generic Instructors Course (GIC-EPLS). September 2011. Cambridge, UK.
8. British Paediatric Otolaryngology Course. March 2011. Glasgow, UK.
9. Changing Roles – Preparing for a Consultant Post. December 2008. Newmarket, UK.
10. Teaching the Teachers to Teach. November 2008. Cambridge, UK.
11. Cutting Edge ENT "Paediatrics". October 2008. Brighton, UK.
12. European Paediatric Life Support Course. October 2008. Norwich, UK.
13. Portmann Course in Otology. June 2006. Institut Georges Portmann, Bordeaux, France.
14. 10th Surgical Course on Tympanoplasty & Mastoidectomy. June 2006. Ipswich Hospital, Ipswich, UK.
15. One Day Symposium on Lacrimal Surgery. March 2006. Ipswich, UK.

16. Head & Neck Dissection Course. June 2005. Copenhagen University Hospital, Copenhagen, Denmark.
17. Laser Safety Study Day. April 2005. St. Thomas's Hospital, London, UK.
18. 22nd International Course in Functional Aesthetic Nasal Surgery. June 2004. University Medical Centre Utrecht, Utrecht, The Netherlands.
19. An Endoscopic Approach to Rhinosinusitis. October 2003. The Institute of Laryngology and Otology. London, UK.

Conferences

1. 12th International Tinnitus Symposium – Faculty Member. May 2017. Warsaw, Poland.
2. British Society of Otology – Annual Meeting. February 2017. London, UK.
3. British Tinnitus Association – Annual General Meeting. September 2016. Manchester, UK.
4. Cholesteatoma 2016. June 2016. Edinburgh, Scotland.
5. 10th International Tinnitus Research Initiative Conference and 1st EU Cost Action (TINNET) Conference. March 2016. Nottingham, UK.
6. 7th International Symposium on Menière's Disease and Inner Ear Disorders. October 2015. Rome, Italy.
7. 3rd Congress of European ORL-HNS. June 2015. Prague, Czech Republic.
8. Politzer Society Meeting. November 2013. Antalya, Turkey.
9. American Academy of Otolaryngology-Head and Neck Surgery Foundation's 2013 Annual Meeting. September 2013. Vancouver, Canada.
10. 7th International TRI Conference on Tinnitus. May 2013. Valencia, Spain.

Dankwoord

I would like to express my sincere gratitude to many individuals for their inspiration and support during the various stages of my PhD work. Firstly, I would like thank Matthew Yung for his inspiration to purse an interest in patient reported outcome measures.

I would like to thank Mark Haggard and Helen Spencer for their significant input and education regarding the mathematical techniques required to analyse the data acquired during the various stages of questionnaire development.

Vincent van Rompaey and Paul Van de Heyning have provided close support during all stages, from conception to the writing of this thesis. Their immense experience in the field of otological surgery has significantly benefitted all the individual projects that have been compiled in this work; this has allowed the efficient and successful completion of this thesis.

Finally, I wish to thank my wife Allyson for her continued support of my academic pursuits.