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Analysis of tinnitus severity and associated risk factors in patients with chronic otitis media: data from the multinational collaborative Chronic Otitis Media Questionnaire-12 study

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Main Article

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Abstract

Background. Subjective tinnitus is a common symptom, and there is often an underlying otological cause. This study investigated the degree of tinnitus-related annoyance in patients with chronic otitis media and analysed whether associations with tinnitus severity exist.

Method. The multinational collaborative Chronic Otitis Media Questionnaire-12 study collected prospective data on 478 adult patients suffering from chronic otitis media across 9 otology referral centres in 8 countries. Based on this dataset, we investigated tinnitus severity using participant responses to item 7 of a native version of the Chronic Otitis Media Questionnaire-12.

Results. With respect to tinnitus severity, 23.8 per cent, 17.4 per cent, 15.5 per cent, and 43.4 per cent of participants reported no, minor, moderate, and major inconvenience or greater, respectively. The absence of ear discharge, absence of cholesteatoma, and poorer disease-specific health-related quality-of-life were associated with increased tinnitus severity in patients with chronic otitis media, whereas age, hearing disability and geographical region showed no association.

Conclusion. This analysis provided novel insight into potential risk factors for tinnitus in patients with chronic otitis media.

Introduction

Tinnitus is defined as the perception of sound in the absence of an external acoustic source. It is a common complaint, with prevalence estimates ranging from 5.1 to 42.7 per cent in the adult population worldwide and a general trend of tinnitus prevalence increasing with age.[1] In most cases, tinnitus is a subjective phenomenon, and there is often an underlying otological problem, most commonly hearing loss related to ageing, noise exposure or acoustic trauma.[2–4] Although some patients with a primary tinnitus complaint have normal hearing thresholds,[5] several studies have shown that perceived tinnitus severity is greater in hearing-impaired individuals than in tinnitus sufferers with clinically normal hearing.[6–8] This is reflected in the use of pure-tone audiometry in addition to psychometric testing using validated patient-reported questionnaires to stratify tinnitus patients and assign specific interventions within tinnitus triage pathways.[9]

Furthermore, several population-based studies have identified a history of middle-ear infection or established chronic otitis media as risk factors for tinnitus.[10–12] Tinnitus is a frequent complaint in patients with chronic otitis media alongside hearing loss and ear discharge.[13,14] Over the last two decades, disease-specific patient-reported instruments have facilitated standardisation of symptom reporting in chronic otitis media, complementing traditional markers of disease activity such as clinical assessment and audiometry. Such tools capture the overall burden of disease from the patients' perspective and provide a comparable measure of health-related quality of life (QoL).[15] Among static instruments for chronic otitis media, three questionnaires assess the degree of annoyance or frequency of tinnitus.[16–18]

In recent years, there have been many studies evaluating the association between tinnitus and a wide range of demographic, socioeconomic, behavioural and clinical factors in

the general population.[10–12,19,20] However, little is known about the factors influencing tinnitus severity in patients with chronic otitis media. The Chronic Otitis Media Questionnaire-12 has recently been appraised in a large multinational study of patients with chronic otitis media from otology centres across eight countries.[21] This dataset presented an opportunity to conduct an exploratory, cross-sectional analysis of tinnitus severity. Therefore, the aim of the present study was to investigate the degree of tinnitus-related annoyance in a large cohort of chronic otitis media patients as well as analyse whether associations with tinnitus severity exist.

Materials and methods

Study design

We used data from the multinational collaborative Chronic Otitis Media Questionnaire-12 study to perform this cross-sectional analysis. The original study was a prospective multicentre cohort study conducted between December 2018 and August 2019 at nine otology units across eight countries (Shanghai, China; Bogota, Colombia; Paris, France; Bari, Italy; Miyazaki, Japan; Wonju, Korea; Istanbul, Turkey; Ipswich and Norwich, UK). The full methodology is available in the overview publication.[21] This study abides by the Declaration of Helsinki (1996). At each study site, collaborating primary authors submitted the protocol to their respective institutional review board, resulting in either study approval or exemption. Informed consent was obtained from all participants before enrolment in the study.

Participants and data sources

Adult patients (aged 16 years or older) with chronic otitis media in one or both ears were invited to complete a respective local version of the Chronic Otitis Media Questionnaire-12.[21] Patients with inactive disease as well as patients who had undergone middle-ear surgery previously were also eligible for inclusion. The original version of the Chronic Otitis Media Questionnaire-12 in English is provided in Appendix 1. The sole exclusion criterion was an inability to comprehend the written language of the translated Chronic Otitis Media Questionnaire-12 as this constituted the focal data. In addition, a standardised proforma was used to provide supplementary information on participant age and gender, pure-tone air conduction threshold audiometry for both ears (at 0.5, 1.0, 2.0, 3.0 and 4.0 kHz) and otoscopic assessment (discharging, dry perforation less than a quarter of the tympanic membrane, dry perforation more than a quarter of the tympanic membrane, non-dry perforation). The presence or absence of cholesteatoma was also noted. No patient identifiable data were captured. Anonymised local data from each study site were securely transferred to the corresponding author (JSP) and assimilated with the UK dataset in this standardised format.

Study variables

The Chronic Otitis Media Questionnaire-12 questionnaire contains an item assessing tinnitus severity over the past six months (item 7). Participant responses were presented using a 6-point Likert scale from 0 to 5, corresponding to 'doesn't bother me at all' and 'the worst thing that has ever affected my life', respectively. A higher item-7 score indicated a greater degree of tinnitus-related annoyance. This became the ordinal outcome variable.

In this study, the following variables were considered as potential risk factors for tinnitus severity: (a) age, (b) overall hearing disability, (c) worse-ear hearing, (d) ear discharge, (e) cholesteatoma, (f) disease-specific health-related QoL and (g) geographical region. Overall hearing disability refers to the degree of binaural hearing loss, calculated by applying the Department of Health and Social Security formula to hearing thresholds determined by pure-tone audiometry using a 4:1 weighting for the better hearing ear: ((4 × average in better ear at 1, 2 and 3 kHz) + (average in worse ear at 1, 2 and 3 kHz))/5. Worse-ear hearing refers to the pure-tone average of hearing threshold levels obtained at all assessed frequencies in the poorer hearing ear. The presence or absence of active ear discharge was determined by clinician-reported otoscopy. Disease-specific health-related QoL was calculated by subtracting the item-7 (tinnitus) score from the total Chronic Otitis Media Questionnaire-12 score. In order to model a geographic effect, we used the following region classifiers: Europe (France, Italy, Turkey, UK) and Asia (China, Japan, Korea).

Statistical analyses

Descriptive analyses of the study participants grouped by tinnitus severity were carried out. An ordinal logistic regression model was used to study the association between the defined variables and tinnitus severity. Two-tailed analyses were conducted, and p-values of less than 0.05 were considered to indicate statistical significance. The odds ratios, both unadjusted and adjusted, and 95 per cent confidence intervals (CI) for tinnitus severity were calculated. Gender was not reported for UK study participants and therefore has not been included as a variable in the present analyses. Descriptive statistics and logistic regression modelling were performed using SAS statistical software (version 9.4 SAS Institute, Cary, USA).

Results

A total of 478 participants from 8 countries were included in the original study. Consecutive sampling was used to recruit patients during routine out-patient consultation in the specified time period. Only patients meeting the pre-defined eligibility criteria were invited to participate. No study participants withdrew consent following enrolment or participation in the study.

With respect to tinnitus severity, 23.8 per cent, 17.4 per cent, 15.5 per cent and 43.4 per cent of study participants ($n = 478$) reported no inconvenience, minor inconvenience, moderate inconvenience, and major inconvenience or greater, respectively. Table 1 shows the full descriptive analyses of participants according to the degree of tinnitus severity.

In the ordinal logistic regression analysis, three variables were found to be significantly associated with increasing tinnitus severity: absence of ear discharge (adjusted odds ratio, 1.78; 95 per cent CI = 1.10–2.86; $p = 0.0182$), absence of cholesteatoma (adjusted odds ratio, 1.77; 95 per cent CI = 1.12–2.82; $p = 0.0155$) and poorer disease-specific health-related QoL (adjusted odds ratio, 1.09; 95 per cent CI = 1.07–1.11; $p < 0.0001$). However, age, overall hearing disability, worse-ear hearing and geographical region showed no association with severity of tinnitus in the adjusted analyses (Table 2).

Discussion

In our multinational cohort of 478 patients with chronic otitis media, 58.9 per cent reported suffering from tinnitus of at least

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Table 1. Distribution of tinnitus severity and associated participant characteristics*

Severity of tinnitus†	Patients (*n* (%))	Age (mean (SD); years)	Hearing‡ (mean (SD); dB)	Overall HRQoL** (mean (SD); score)
0	114 (23.8)	52.8 (19.7)	33.4 (18.5)	16.6 (9.8)
1	83 (17.4)	47.9 (19.1)	33.0 (18.8)	17.4 (9.0)
2	74 (15.5)	46.0 (17.7)	29.0 (15.8)	22.6 (11.3)
3	72 (15.1)	48.7 (17.3)	31.3 (17.2)	24.4 (9.8)
4	71 (14.9)	48.3 (18.1)	31.7 (17.1)	28.6 (9.6)
5	64 (13.4)	43.0 (15.4)	35.1 (22.4)	34.1 (10.9)

*$n = 478$; †Tinnitus severity was determined by participant responses to item 7 in the Chronic Otitis Media Questionnaire-12. Answers were presented using a 6-point Likert scale (0 = no inconvenience, 1 = minor inconvenience, 2 = moderate inconvenience, 3 = major inconvenience but can cope, 4 = major inconvenience and difficulty coping, 5 = worst thing ever affected life); ‡Overall hearing disability as calculated according to the Department of Health and Social Security formula: ((4 x better hearing ear) + (worse hearing ear))/5; **Mean total Chronic Otitis Media Questionnaire-12 score excluding item 7. SD = standard deviation; HRQoL = health-related quality of life

Table 2. Ordinal logistic regression analysis of factors associated with severity of tinnitus in patients with chronic otitis media

Factors	Unadjusted OR (95% CI)	*P*-value	Adjusted OR (95% CI)	*P*-value
Age	0.99 (0.98, 1.00)	0.0033†	0.99 (0.98, 1.00)	0.1092
Overall hearing disability‡	1.00 (0.99, 1.01)	0.9770	1.00 (0.99, 1.02)	0.8472
Worse-ear hearing	1.00 (0.99, 1.01)	0.6876	1.00 (0.99, 1.01)	0.6809
Ear discharge (absent *vs* present)	1.23 (0.80, 1.91)	0.3499	1.78 (1.10, 2.86)	0.0182†
Cholesteatoma (absent *vs* present)	1.96 (1.26, 3.05)	0.0028†	1.77 (1.12, 2.82)	0.0155†
Disease-specific HRQoL**	1.09 (1.08, 1.11)	<0.0001†	1.09 (1.07, 1.11)	<0.0001†
European countries *vs* Asian countries	1.49 (1.06, 2.10)	0.0206†	1.20 (0.83, 1.71)	0.3330
European countries *vs* Colombia	0.29 (0.17, 0.50)	<0.0001†	0.65 (0.36, 1.18)	0.1540
Colombia *vs* Asian countries	5.15 (2.91, 9.12)	<0.0001†	1.85 (0.97, 3.52)	0.0628

*$n = 478$; †Significant *p*-value; ‡Overall hearing disability as calculated according to the Department of Health and Social Security formula: ((4 x better hearing ear) + (worse hearing ear))/5; **Total Chronic Otitis Media Questionnaire-12 score excluding item 7. OR = odds ratio; CI = confidence interval; HRQoL = health-related quality of life

moderate severity. This is consistent with other studies utilising the Chronic Otitis Media Questionnaire-12 questionnaire to assess disease-specific health-related QoL, with mean item-7 scores ranging from 1.32 to 2.86 (minor-moderate tinnitus severity).[17,22–25] In three studies evaluating chronic otitis media patients following middle-ear surgery, a large proportion of patients reported tinnitus pre-operatively (42.7 to 47.6 per cent).[13,26,27] It is evident that tinnitus is a common burden in patients suffering from chronic otitis media alongside hearing impairment and ear discharge. Therefore, in the present study, we sought to determine whether demographic and disease-related factors influence tinnitus severity.

- Epidemiology of tinnitus in patients with chronic otitis media remains unclear
- A cross-sectional analysis of tinnitus-related annoyance in chronic otitis media sufferers was conducted
- Data from the multinational collaborative Chronic Otitis Media Questionnaire-12 study were used
- Presence of ear discharge, cholesteatoma or both is related to a lower degree of perceived tinnitus severity
- Further studies are necessary to validate these associations and understand the psychopathology of tinnitus in patients with chronic otitis media

Several studies have shown that subjective tinnitus improves following middle-ear surgery, and this appears to coincide with hearing restoration.[13,27–30] Guo *et al.*[27] reported that improved low-frequency air conduction hearing was an important factor in post-operative reduction in tinnitus severity, whereas Kim *et al.*[28] proposed that the degree of pre-operative air-bone gap may influence tinnitus outcome following tympanoplasty. The existing literature concerning the possible relationship between improvement in tinnitus severity and audiological outcome in patients with chronic otitis media is limited to small cohort studies within single medical centres, often performed retrospectively.

In comparison, based on a cross-sectional evaluation of tinnitus in a large cohort across nine otology centres, the present study found no significant effect of overall hearing disability and worse-ear hearing on tinnitus severity. Instead, the presence of cholesteatoma and ear discharge was found to be inversely associated with tinnitus severity; that is, chronic otitis media patients with cholesteatoma or discharging ear(s) appear to have less severe tinnitus, which has not previously been reported. In chronic otitis media, both cholesteatoma and persistent otorrhoea through a perforated tympanic membrane indicate an ongoing inflammatory response within the middle-ear cleft. Over time, this can cause ossicular erosion and disruption of the ossicular chain.[31] Tympanoplasty with or without mastoidectomy is the main curative treatment strategy. The primary objectives of middle-ear surgery are complete removal of disease, provision of a dry ear, and preserved or improved hearing levels. From the patients' perspective, alongside subjective hearing improvement and relief from otorrhoea, improvement or resolution of tinnitus may influence post-operative patient satisfaction.[32,33] It is possible that when patients with chronic otitis media have a discharging ear, cholesteatoma or both, there is an expectation that the disease and any associated symptoms are treatable. We propose that such expectations prior to definitive treatment

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may influence patients' perception of the disease and reduce the burden of individual symptoms such as tinnitus. In contrast, patients presenting with tinnitus as their primary otological complaint are more likely to be annoyed or distressed by it.[34]

In large epidemiological studies, tinnitus severity is directly correlated with increasing age.[19,35] In contrast, our data suggest that tinnitus severity may decrease with age, although this association is not significant in the adjusted model. A strong association between poorer disease-specific health-related QoL and tinnitus severity was expected since both variables were determined using component scores of the Chronic Otitis Media Questionnaire-12, which has high internal consistency as demonstrated in the original study and other validation studies.[21,23,24,36]

This study used a single-item measure within the Chronic Otitis Media Questionnaire-12 to determine tinnitus severity in patients with chronic otitis media, focusing on tinnitus-related inconvenience. However, the consensus is that perceived tinnitus severity has multiple dimensions, not only degree of annoyance but also duration, signal intensity or loudness, and associated disability (e.g. sleep disruption).[1,20] Several validated tinnitus-specific measures exist to assess the level of tinnitus-related distress with varying emphasis on different domains of quality-of-life.[37] A single-item measure is therefore unlikely to capture the breadth or complexity of individual experience.[1] Nevertheless, a single question can serve as a useful screening tool, identifying at-risk patients for whom further assessment or characterisation of their tinnitus is necessary. An expectation for all patients with chronic otitis media to complete a battery of symptom-specific instruments in addition to a disease-specific health-related QoL measure (such as the Chronic Otitis Media Questionnaire-12) would only lead to a higher response burden and information overload on the part of the clinician.

One limitation of the present study is that we could not assess the relationship between high frequency hearing loss and tinnitus in our cohort, since pure-tone audiometry was performed between 0.5 kHz and 4 kHz for all study participants. Elevation of hearing threshold levels in high and extended high frequencies (more than 8 kHz) is commonly detected in patients with chronic otitis media and has been noted to persist even after resolution of acute otitis media,[38–41] presumably because of penetration of inflammatory mediators and bacterial toxins into the inner ear via the round window membrane.[42,43] Of note, Cordeiro *et al.*[38] suggested that the presence of persistent tinnitus six months after an episode of acute otitis media may be associated with worse extended high frequency thresholds. Since pure-tone audiometry was limited to air conduction testing only, we were unable to report the air–bone gap. Chronic otitis media patients with predominantly conductive hearing loss are not distinguishable from patients with underlying and perhaps long-standing sensorineural hearing loss, which may represent distinct cohorts of patients with different experiences of tinnitus.

Due to the brevity of tinnitus assessment, we were unable to characterise whether tinnitus was ipsilateral (localising to the ear affected with chronic otitis media), contralateral or bilateral. It is possible that patients with contralateral or bilateral tinnitus may have chronic otitis media plus sensorineural or mixed hearing loss. Patients with bilateral tinnitus are also more likely to report a greater degree of handicap and psychological burden.[44] Further characterisation of tinnitus (e.g. localisation, loudness, pitch) in chronic otitis media sufferers in relation to disease-specific health-related QoL should be explored in future studies.

Another limitation is that we were unable to investigate a wide array of demographic, behavioural and socioeconomic characteristics or patient co-morbidities since the number of variables included in the logistic regression analyses was restricted to data available in the dataset from the original study.[21] For example, we were unable to explore whether there were gender differences in severity of tinnitus since this characteristic was not reported for UK study participants. Nevertheless, this is the first study to examine potential risk factors influencing tinnitus severity in a large, multinational cohort of chronic otitis media patients with prior unknown tinnitus status. The resulting broad range of tinnitus severity within the study population is reflective of real-world clinical practice, thus increasing the robustness of our findings.

Conclusion

This cross-sectional analysis provides novel insight into potential risk factors for tinnitus in patients with chronic middle-ear disease. In summary, both ear discharge and cholesteatoma appear to be inversely associated with perceived tinnitus severity. Patients with poorer overall disease-specific health-related QoL report a greater degree of tinnitus-related annoyance, whereas age, hearing disability and geographical region had no influence. Further studies are necessary to validate these associations and better understand the psychopathology of this common symptom in chronic otitis media.

Competing interests. None declared

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Appendix 1. Chronic Otitis Media Questionnaire-12

Chronic Otitis Media Questionnaire - 12 (COMQ-12)

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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

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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

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For the following questions, please indicate how often the various elements described affect you using the scale below and by ringing the appropriate number:

0 Less frequent than once every 6 months
1 At least once every 6 months
2 At least once every 3 months
3 At least once every month
4 At least once a week
5 Most days in the week

Lifestyle and work impact:

How often have you NOT been able to:

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

Health service impact:

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

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

General:

12.	To what degree do your ear problems 'get you down'?	0	1	2	3	4	5

Please check that you have produced an answer to every question and do ask for help if you find it hard.

- Thank you very much for taking part.

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