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Artículo de investigación científico y tecnológica

Systematization of a database of patients with chronic otitis media in a University Hospital

Sistematización de una base de datos de pacientes con otitis media crónica en un hospital universitario

Eduarda Birck-Lóh*, Giovanna Rasmussen**, João Pedro Pinto-Garcia***, Leticia Oyama****, Henrique Furlan-Pauna*****

* Cajuru University Hospital (HUC), Curitiba, PR, Brazil. ORCID: <https://orcid.org/0009-0006-0808-3949>.

** School of Medicine, Pontifical Catholic University of Paraná (PUCPR), Curitiba, PR, Brazil. ORCID: <https://orcid.org/0009-0006-0446-8622>.

*** School of Medicine, Pontifical Catholic University of Paraná (PUCPR), Curitiba, PR, Brazil. ORCID: <https://orcid.org/0009-0007-6416-1777>.

**** Cajuru University Hospital (HUC), Curitiba, PR, Brazil. ORCID: <https://orcid.org/0000-0003-0873-1492>.

***** Cajuru University Hospital (HUC), Curitiba, PR, Brazil. School of Medicine, Pontifical Catholic University of Paraná (PUCPR), Curitiba, PR, Brazil. ORCID: <https://orcid.org/0000-0002-5575-7030>.

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ABSTRACT

Background: Chronic otitis media (COM) and cholesteatomatous chronic otitis media (CCOM) are chronic inflammatory diseases of the middle ear associated with hearing loss, structural damage, and an increased risk of complications. Eustachian tube dysfunction plays a fundamental role in their pathophysiology; however, standardized clinical information on these patients remains limited. The ChOLE classification and the Eustachian Tube Dysfunction Questionnaire-7 (ETDQ-7) provide standardized tools for clinical characterization and functional assessment. **Objective:** To systematize the clinical and epidemiological data of patients with COM and CCOM treated at the Department of Otolaryngology of Hospital Universitário Cajuru and classify them according to the ETDQ-7. **Study design:** Prospective longitudinal observational study. **Methods:** A structured data collection instrument including clinical and epidemiological variables related to COM, together with the

Corresponding author

Eduarda Birck Lóh.

Email address: draeduardaloh@outlook.com

Address: 300, Av. São José, Curitiba - Paraná, CEP: 80050-350

Phone number: +55 45991526018

ETDQ-7 questionnaire, was administered to all participants. *Results:* A total of 110 patients were included; 61.8% were female, with a predominance of individuals older than 45 years. Otorrhea was the most frequent symptom (44.5%), followed by hearing loss (31.8%) and tinnitus (10.9%). Right-sided involvement was observed in 37% of cases, left-sided involvement in 31.8%, and bilateral disease in 30.9%. Among the items in the ETDQ-7, the highest median scores corresponded to aural fullness, ear symptoms during upper respiratory tract infections, and muffled hearing. *Conclusion:* This database provides a standardized clinical and epidemiological characterization of patients with COM treated at a university hospital. The findings highlight the common presence of symptoms related to Eustachian tube dysfunction and provide a basis for future comparative studies and optimization of patient management.

RESUMEN

Palabras clave (DeCS):

Otitis media, colesteatoma, trompa auditiva/trompa de Eustaquio, base de datos.

Antecedentes: la otitis media crónica (OMC) y la otitis media crónica colesteatomatosa son enfermedades inflamatorias crónicas del oído medio asociadas con pérdida auditiva, daño estructural y un mayor riesgo de complicaciones. La disfunción de la trompa de Eustaquio desempeña un papel fundamental en su fisiopatología; sin embargo, la información clínica estandarizada sobre estos pacientes sigue siendo limitada. La clasificación ChOLE y el cuestionario Eustachian Tube Dysfunction Questionnaire-7 (ETDQ-7) proporcionan herramientas estandarizadas para la caracterización clínica y la evaluación funcional. *Objetivo:* sistematizar la información clínica y epidemiológica de los pacientes con OMC y otitis media crónica colesteatomatosa atendidos en el Servicio de Otorrinolaringología del Hospital Universitario Cajuru y clasificarlos de acuerdo con el cuestionario ETDQ-7. *Diseño del estudio:* estudio observacional prospectivo de tipo longitudinal. *Métodos:* se aplicó a todos los participantes un instrumento estructurado de recolección de datos que incluyó variables clínicas y epidemiológicas relacionadas con la otitis media crónica, junto con el cuestionario ETDQ-7. *Resultados:* se incluyeron un total de 110 pacientes; el 61,8% correspondió al sexo femenino, con predominio de individuos mayores de 45 años. La otorrea fue el síntoma más frecuente (44,5%), seguida de la hipoacusia (31,8%) y el *tinnitus* (10,9%). Se observó compromiso del oído derecho en el 37% de los casos, del oído izquierdo en el 31,8% y enfermedad bilateral en el 30,9%. Entre los ítems del ETDQ-7, las puntuaciones medianas más altas correspondieron a la sensación de plenitud ótica, los síntomas óticos durante las infecciones de las vías respiratorias superiores y la audición amortiguada. *Conclusión:* esta base de datos proporciona una caracterización clínica y epidemiológica estandarizada de los pacientes con OMC atendidos en un hospital universitario. Los hallazgos resaltan la frecuente presencia de síntomas relacionados con la disfunción de la trompa de Eustaquio y constituyen una base para futuros estudios comparativos y para la optimización del manejo de estos pacientes.

Introduction

Chronic otitis media (COM) is histologically defined by irreversible tissue alterations within the middle ear, which may or may not be associated with middle ear effusion and bony erosion (1). Cholesteatomatous chronic otitis media (CCOM), in turn, may be considered an advanced form of COM, additionally characterized by the presence of keratinized squamous epithelium within the middle ear cavity. Although benign, it exhibits locally invasive behavior and marked destructive potential (1).

CCOM may be classified as congenital or acquired. The primary acquired form results from the accumulation of squamous epithelium within retraction pockets of the tympanic membrane, whereas the secondary acquired form arises from epithelial migration into the middle ear cavity through a pre-existing tympanic membrane perforation. In contrast, the congenital form is attributed to the persistence and accumulation of epithelial remnants within the middle ear during embryogenesis (2).

The pathophysiology of COM and CCOM is closely associated with the function of the Eustachian tube, which

plays a critical role in maintaining middle ear homeostasis. In the presence of Eustachian tube dysfunction (ETD), pressure dysregulation, secretion retention, and impaired mucociliary clearance may occur, leading to symptoms such as aural fullness, clicking sensations, otalgia, hearing loss, and tinnitus. These alterations contribute to a persistently unfavorable middle ear environment, characterized by inadequate ventilation and ongoing inflammatory processes (3).

ETD constitutes a major predisposing factor for the development and persistence of COM. The inability to adequately regulate middle ear pressure results in sustained negative pressure, tympanic membrane retraction, and secretion accumulation, thereby creating conditions conducive to chronic inflammation and mucosal remodeling. These alterations may ultimately lead to the development of primary acquired cholesteatoma, as deep tympanic retractions facilitate the accumulation of squamous epithelium within the middle ear cavity (4).

Patients with COM exhibit a heterogeneous clinical and epidemiological profile, often associated with risk factors that contribute to the persistence of middle ear inflammation. A higher prevalence is observed among individuals with a history of recurrent upper respiratory tract infections during childhood, ETD, allergic rhinitis, and chronic rhinosinusitis, as well as socioeconomic factors that may influence access to early diagnosis and appropriate treatment (5).

Clinically, these patients commonly present with recurrent or persistent otorrhea, varying degrees of hearing loss, and structural abnormalities of the tympanic membrane, such as perforations or retraction pockets. Hearing loss associated with COM is predominantly conductive; however, in cases of prolonged or more advanced disease, a mixed component may also occur (5).

The clinical classification of COM and CCOM is essential for both surgical planning and the standardization of outcome assessment across different clinical presentations. In this context, the ChOLE classification system was developed to provide a standardized framework for describing COM and to facilitate comparisons across studies (6).

First introduced in 2016, the acronym “ChOLE” refers to the following components: Ch (cholesteatoma extension), which assesses the extent of cholesteatoma; O (ossicular chain), which describes the status of the ossicular chain after surgery; L (life-threatening complications), which denotes the presence of potentially life-threatening complications; and E (Eustachian tube function), which is related to mastoid cell pneumatization and ventilation. The data used for this classification are derived from intraoperative findings and preoperative temporal bone computed tomography. Each parameter is assigned a specific score, and their sum allows classification of the disease into three stages (6).

Previous studies have demonstrated an association between the ChOLE classification and relevant clinical outcomes, including hearing prognosis, recurrence rates, and the occurrence of complications. Daniel Bachinger et al. reported that hearing outcomes are significantly associated with the “O” and “L” parameters of the ChOLE classifica-

tion, corresponding to ossicular chain status and the presence of complications (7).

The Eustachian Tube Dysfunction Questionnaire-7 (ETDQ-7) was developed to standardize the assessment of symptom severity related to ETD. It consists of seven items that evaluate ETD-related symptoms using a Likert scale ranging from 1 (no problem) to 7 (severe problem). The items assessed are ear pressure, aural fullness, otalgia, symptom worsening during upper respiratory tract infections, tinnitus, clicking sensations, and hearing difficulties (8).

The application of classification systems in patients with COM and CCOM is particularly relevant, as it enables the systematic analysis of surgical outcomes, estimation of prognosis, and standardization of terminology, thereby facilitating communication among surgeons and healthcare centers. Furthermore, the development of structured databases is essential for generating comparative data, enabling the characterization of patient profiles, the evaluation of clinical outcomes, and integration with national and international multicenter studies.

Materials and Methods

An observational, prospective, longitudinal study was conducted involving patients evaluated and followed at the Otorhinolaryngology outpatient clinic of Hospital Universitário Cajuru (HUC), located in Curitiba, Paraná, Brazil. This study aimed to characterize the clinical, epidemiological, and audiological profile of patients with COM/CCOM and to establish a structured database to make possible future analytical studies. Eligible participants comprised adults aged over 18 years with a confirmed diagnosis of COM or CCOM, who provided written informed consent and demonstrated adequate comprehension of the study procedures. Exclusion criteria included individuals younger than 18 years and those who declined to participate.

Data were collected through the administration of a structured questionnaire developed by researchers and implemented via the Jotform® platform. The instrument was completed in real time during outpatient consultations and subsequently organized into a database for analysis. Collected variables encompassed clinical and epidemiological data, including sex, age, race, educational level, comorbidities, history of prior otologic surgery, disease laterality, and presenting symptoms.

Otologic characteristics were also assessed, including the location and size of tympanic membrane perforations. Audiological parameters were collected, comprising air-conduction pure-tone thresholds (at 250, 500, 1000, 2000, 3000, 4000, 6000, and 8000 Hz) and bone-conduction thresholds (at 500, 1000, 2000, 3000, and 4000 Hz), in addition to speech audiometry and immittance measures. Additionally, the ETDQ-7 was administered to evaluate symptoms related to ETD. Interviews were conducted in a private setting, isolated from routine clinic flow, to ensure participants comfort, safety, and data confidentiality.

Descriptive statistical analyses were performed for all variables. Categorical variables were summarized as absolute (n) and relative (%) frequencies. Continuous variables were described using measures of central tendency (mean or median) and dispersion (standard deviation or interquartile range), according to data distribution. Normality was assessed by visual inspection of the histograms and the Shapiro-Wilk test, with a significance level set at 5% ($\alpha = 0.05$). All statistical analyses were conducted using R (version 4.3.2) within the RStudio environment, employing base functions and the “readxl” package.

The risks associated with participation were considered minimal and included potential discomfort during the otorhinolaryngological examination, possible embarrassment related to questionnaire items, and concerns regarding data confidentiality. All appropriate measures were implemented to ensure a respectful, empathetic, and safe approach, with strict protection of participants confidentiality.

No direct benefits were offered to participants as a result of study participation, and this was clearly communicated during the recruitment process. Nevertheless, the study provides relevant indirect benefits to both scientific knowledge and clinical practice, particularly through the development of a structured database comprising detailed information on patients with COM and CCOM. This resource enables a more comprehensive characterization of the clinical and epidemiological profile of the studied population, as well as the exploration of potential associations between clinical features, otoscopic findings, audiological parameters, and ETDQ-7 scores.

Results

A total of 110 participants were included in the analysis. The cohort was predominantly female (61.8%), older than 45 years, and caucasian. About one third of the participants (36.4%) had no comorbidities. Among the participants with comorbidities, the most common was systemic arterial hypertension (36.4%) (**Table 1**).

Table 1. Baseline characteristics of the study population

Characteristic	n (%)
Sex	
Male	42 (38.2)
Female	68 (61.8)
Age group	
18-25 years	10 (9.1)
26-35 years	6 (5.5)
36-45 years	20 (18.2)
46-55 years	26 (23.6)
56-65 years	22 (20.0)
> 65 years	26 (23.6)

Race/ethnicity	
Asian	5 (4.5)
White	66 (60.0)
Mixed	25 (22.7)
Black	12 (10.9)
Not reported	2 (1.8)
Education level	
Incomplete elementary school	21 (19.1)
Complete elementary school	10 (9.1)
High school	20 (18.2)
Higher education	11 (10.0)
Not reported	48 (43.6)
Comorbidities*	
Systemic arterial hypertension	40 (36.4)
Diabetes mellitus	15 (13.6)
Hypothyroidism	12 (10.9)
Dyslipidemia	9 (8.2)
Smoking	8 (7.3)
Generalized anxiety disorder	4 (3.6)
Major depressive disorder	4 (3.6)
Pulmonary disease	4 (3.6)
Chronic kidney disease (CKD)	3 (2.7)
None	40 (36.4)

Note - n = 110.

Percentages may exceed 100%, as a single participant could present more than one comorbidity. Comorbidities with ≤ 2 observations (Alzheimer's disease, schizophrenia, fibromyalgia, previous acute myocardial infarction, pancreatitis, renal transplantation, intellectual disability, neoplastic diseases, rheumatologic diseases, gastroesophageal reflux disease, glaucoma, chronic myeloid leukemia, obesity, Down syndrome, and deep vein thrombosis) are not presented in the table.

Table 2 and **Figure 1** report the main complaints of the participants. Otorrhea was the most common (44.5%), followed by hearing loss (31.8%), tinnitus (10.9%), and otalgia (10%). Dizziness, pruritus, and other complaints represented less than 1% of the observations. Regarding the laterality of the disease, 37% of the participants presented right laterality, 31.8% left laterality, and 30.9% was bilateral. Most participants (70.9%) had no history of previous otologic surgery.

The characteristics of tympanic membranes (TM) perforations, both right and left, are presented in **Table 3**, **Figure 2** and **Figure 3** below. Right-sided perforation occurred in 36.4% of the participants, and most of them showed central topography (53.8%). Left-sided perforation occurred in about 40% of the participants, and most of them also presented central perforation (53.8%).

The results of the audiometry and tympanometry of the right ear are presented in **Table 4** and **Figure 4**. Most of the patients evaluated presented absent ipsilateral (90.9%) and contralateral (93.2%) acoustic reflexes, with about a half (44.8%) presenting a type B tympanogram.

Table 2. Participants chief complaints

Chief complaint	n (%)
Otorrhea	49 (44.5)
Hearing loss	35 (31.8)
Tinnitus	12 (10.9)
Otalgia	11 (10.0)
Dizziness	1 (0.9)
Pruritus	1 (0.9)
No complaints	1 (0.9)
Disease laterality Right	41 (37.3)
Left	35 (31.8)
Bilateral	34 (30.9)
Previous otologic surgery	
Yes	32 (29.1)
No	78 (70.9)

Note - n = 110.

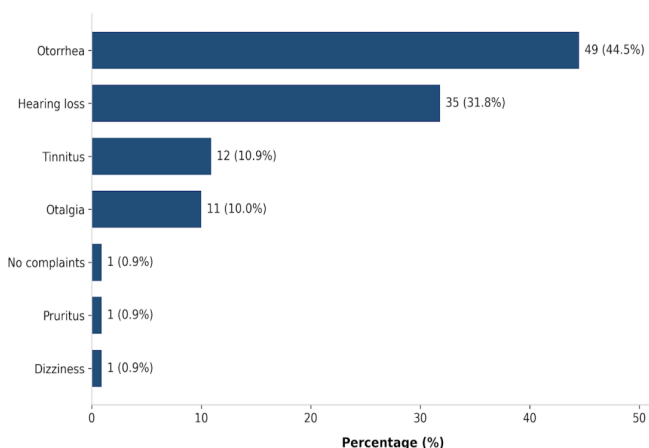


Figure 1. Distribution of chief complaints

Table 3. Tympanic membrane perforation (left and right)

Right tympanic membrane	n (%)
Perforation (n = 99)	
Present	39 (36.4)
Absent	60 (60.6)
Topography of the perforation (n = 39)	
Central	21 (53.8)
ASQ	3 (7.7)
AIQ	6 (15.4)
PSQ	7 (17.9)
PIQ	2 (5.1)
Estimated perforation size (n = 39)	
Total	5 (12.8)
>50%	10 (25.6)
30%-50%	9 (23.1)
10%-30%	12 (30.8)
Punctate	3 (7.7)
Left tympanic membrane	
Perforation (n = 99)	
Present	39 (39.4)
Absent	60 (60.6)
Topography of the perforation (n = 39)	
Central	21 (53.8)
ASQ	6 (15.4)
AIQ	8 (20.5)
PSQ	1 (2.6)
PIQ	3 (7.7)
Estimated perforation size (n = 39)	
Total	6 (15.4)
>50%	10 (25.6)
30-50%	4 (10.3)
10-30%	12 (30.8)
Punctate	7 (17.9)

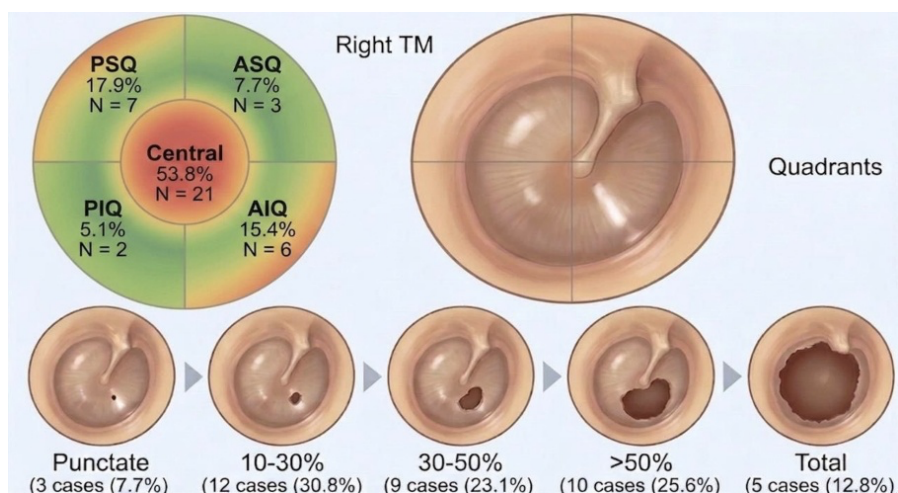


Figure 2. Distribution of perforations on the right tympanic membrane.

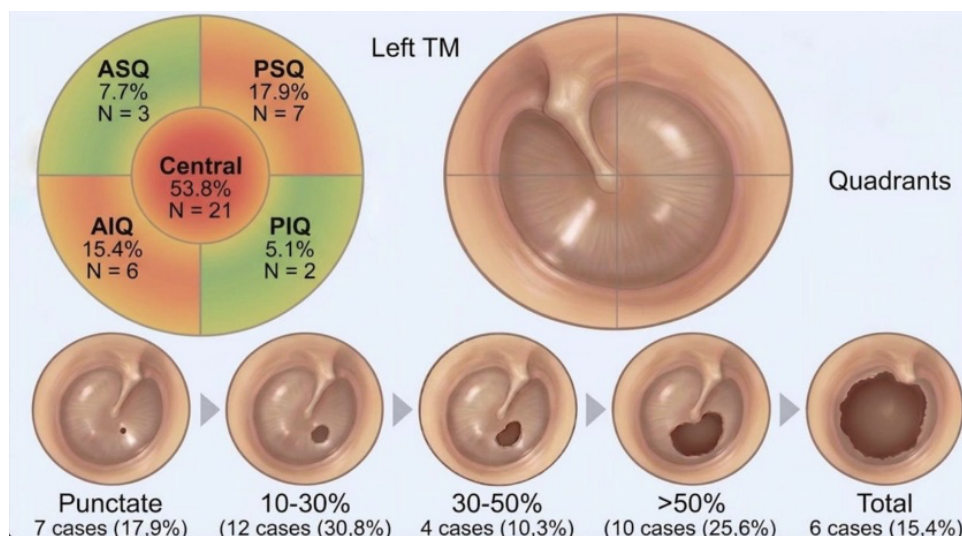


Figure 3. Distribution of perforations on the left tympanic membrane.

The audiometric and tympanometry results for the left ear are shown in **Table 5** and **Figure 5**. Like the right ear, most of the patients evaluated exhibited absent ipsilateral (84.0%) and contralateral (90.1%) acoustic reflexes, with about half (47.7%) presenting a type B tympanogram. Patients with type B tympanogram tended to have higher ETDQ-7 scores.

Table 4. Audiometric thresholds and tympanometry - right ear

AC - dB (n = 94)	
250 Hz	45 (26.25-60)
500 Hz	40 (25-55)
1000 Hz	35 (25-55)
2000 Hz	45 (30-50)
3000 Hz	45 (30-60)
4000 Hz	50 (35-65)
6000 Hz	50 (35-70)
8000 Hz	60 (40-80)
BC - dB (n = 85)	
500 Hz	25 (15-35)
1000 Hz	20 (15-30)
2000 Hz	25 (15-40)
3000 Hz	25 (15-40)
4000 Hz	30 (20-40)
SRT - dB (n = 51)	
SRS (n = 78)	92 (84-99)
Tympanogram type* (n = 87)	
A	23 (26.5)
As	3 (3.4)
Ad	3 (3.4)
B	39 (44.8)
C	4 (4.6)
No seal	15 (17.2)

Ipsilateral acoustic reflex* (n = 77)	
Present	7 (9.1)
Absent	70 (90.9)
Contralateral acoustic reflex* (n = 73)	
Present	5 (6.8)
Absent	68 (93.2)

Note - AC: Air conduction; BC: Bone conduction; SRT: Speech Reception Threshold; SRS: Speech Recognition Score.

Non-parametric numerical data are presented as median (p25-p75). Parametric numerical data are presented as mean (standard deviation).

Categorical data are presented as absolute and relative frequencies - n (%).

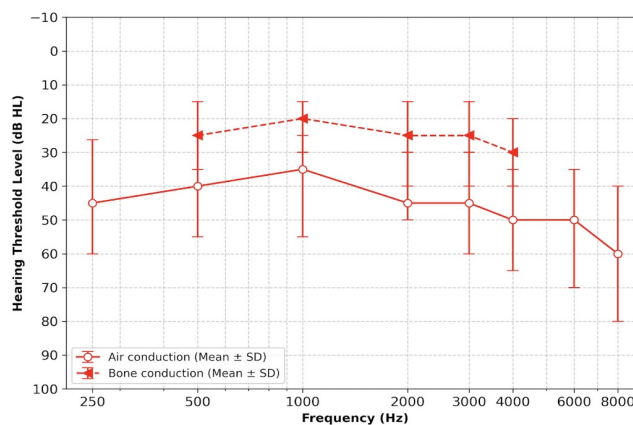


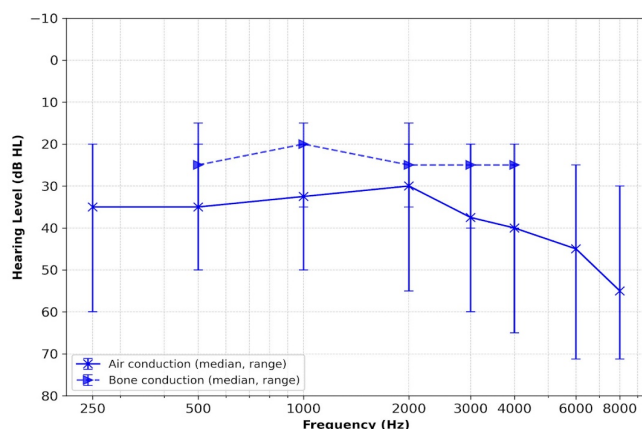
Figure 4. Pure-tone audiogram - right ear.

Table 6 presents the results of the ETDQ-7. Among the questionnaire items, the sensation of clogged ears, the presence of ear symptoms in cases of flu or sinusitis, and the sensation of muffled hearing were the items with the highest median value (5). Ear pain and ear crackling, in turn, were the items with the lowest median value (1).

Table 5. Audiometric thresholds and tympanometry - left ear

AC - dB (n = 92)	
250 Hz	35 (20-60)
500 Hz	35 (20-50)
1000 Hz	32.5 (20-50)
2000 Hz	30 (20-55)
3000 Hz	37.5 (20-60)
4000 Hz	40 (25-65)
6000 Hz	45 (25-71.25)
8000 Hz	55 (30-71.25)
BC - dB (n = 86)	
500 Hz	25 (15-35)
1000 Hz	20 (15-35)
2000 Hz	25 (15-35)
3000 Hz	25 (20-40)
4000 Hz	25 (20-40)
SRT - dB (n = 53)	36.0 (23.7)
SRS (n = 75)	96 (88-100)
Tympanogram type* (n = 86)	
A	21 (24.4)
As	3 (3.5)
Ad	6 (7.0)
B	41 (47.7)
C	3 (3.5)
No seal	12 (14.0)
Ipsilateral acoustic reflex* (n = 75)	
Present	12 (16.0)
Absent	63 (84.0)
Contralateral acoustic reflex* (n = 71)	
Present	7 (9.9)
Absent	64 (90.1)

Note - AC: Air conduction; BC: Bone conduction; SRT: Speech Reception Threshold; SRS: Speech Recognition Score. Non-parametric numerical data are presented as median (p25-p75). Parametric numerical data are presented as mean (standard deviation). Categorical data are presented as absolute and relative frequencies - n (%).

**Figure 5. Pure-tone audiogram - left ear.****Table 6. Eustachian Tube Dysfunction Questionnaire (ETDQ-7)**

ETDQ-7	
Pressure in the ears	2.5 (1-5)
Pain in the ears	1 (1-5)
A feeling that your ears are clogged or "underwater"	5 (1.75-6)
Ear problems when you have a cold or sinusitis	5 (1.75-6.25)
Crackling or popping sounds in the ears	1 (1-5)
Ringing in the ears	4 (1-6)
A feeling that your hearing is muffled	5 (4-6)

Note - ETDQ-7: *Eustachian Tube Dysfunction Questionnaire-7*. Non-parametric numerical data are presented as median (p25-p75). n = 76 (except for "Clicking in the ears," for which n = 75).

Discussion

The analysis of the 110 patients included in this study made it possible to outline a clinical and epidemiological profile compatible with that observed in other tertiary services dedicated to the management of COM and CCOM. The predominance of female patients and those over 45 years old, although not universal, appears similarly in Brazilian series, as described by Silva et al. (9), suggesting that sociocultural factors and patterns of public healthcare service utilization may influence this profile. In contrast, international surveys such as those conducted by Yung et al. (10) demonstrate a more equitable distribution between genders, indicating a possible influence of distinct population and demographic variables.

The most frequent complaints were otorrhea and hearing loss, a classic finding widely described in the literature. Rutkowska et al. (2) emphasize that persistent otorrhea is among the main markers of chronicity of the disease, often associated with tympanic perforation and continuous inflammation of the middle ear. The high proportion of central tympanic perforations observed in our sample resembles the findings of Kuo et al. (11), who indicate that stable perforations reflect established chronic disease, frequently associated with delays in access to surgical treatment, which is a common reality in Brazilian public health services.

The audiometric findings, predominantly characterized by conductive hearing loss, type B tympanogram and absent acoustic reflexes, align with the pattern described by Weiss et al. (12), who highlight the importance of the ossicular chain status and middle ear ventilation in determining auditory prognosis. National studies, such as that of Almeida et al. (13), also indicate similar prevalences of conductive hearing loss in patients with non-CCOM, reinforcing the consistency of the findings in the present sample.

A methodological edge of this study was the inclusion of the ETDQ-7 questionnaire to assess ETD. National literature still lacks studies exploring this association, although international studies such as that of Schilder et al. (3) evaluate ETD as a central element in the pathophysiology of COM. High scores on items related to the sensation of clogged ears,

muffled hearing, and worsening of symptoms during respiratory infections suggest that ETD plays a relevant role in the clinical condition of a portion of patients. These results are in line with the anatomical findings of Pauna et al. (1), who demonstrated structural changes in the protympanum in temporal bones of individuals with chronic disease, possibly correlated with conditions of ineffective ventilation of the middle ear.

The importance of systematized databases for COM studies has been widely discussed in recent literature. Linder et al. (6), in proposing the ChOLE classification, emphasize the need for standardization of clinical and intraoperative records in order to improve comparability between studies and enable more refined prognostic analyses. Although the classification was not applied directly in this study, the structured data collection model adopted establishes a fundamental basis for future investigations within the service, including multicenter analyses.

When comparing the results of this study with case studies from countries with similar healthcare systems, such as India and regions of sub-Saharan Africa, a convergent pattern is observed. Studies by Sarker et al. (14) and Mawson & Fagan (15) report patients frequently presenting with advanced disease, extensive perforations and prolonged intervals until specialized care, characteristics that are similar to the Brazilian context and help explain the breadth of clinical findings observed.

The continuation of the project, with the expansion of the database, will allow investigation of correlations between tubal symptoms, audiological patterns, topography of tympanic perforations and clinical evolution, contributing to the development of increasingly individualized approaches. The structuring of this database also enables the service to participate in national and international collaborative studies, thus strengthening scientific production in the field of otology.

Conclusion

The present study enabled the systematization and organization of a comprehensive database on patients with COM and CCOM treated at the Otorhinolaryngology outpatient clinic of Cajuru University Hospital. The standardized data collection allowed for a detailed characterization of the clinical-epidemiological profile of the studied population, enabling the identification of patterns relevant to disease management within the service context.

The creation of this database represents an essential tool for improving care, allowing for future comparative analyses, the identification of prognostic factors, and a better understanding of the characteristics of the population served. Furthermore, it enables the development of subsequent studies, including the correlation between audiological parameters, clinical findings, and ETD scores, contributing to a more individualized and evidence-based approach.

Conflict of interest

The researchers declare that they have no conflict of interest.

Funding

This study did not receive any type of funding.

Contributions

Eduarda Birck-Loh: Conceptualization, data collection, statistical analysis, drafting of the manuscript and critical review of the manuscript.

Henrique Furlan-Pauna: Critical review of the manuscript and conceptualization.

Giovana Rasmussen: Data collection and drafting of the manuscript.

João Pedro Pinto-Garcia: Data collection.

Leticia Akazaki-Oyama: Development of the data collection form for research.

Ethical considerations

This study was approved by the Research Ethics Committee of Pontifícia Universidade Católica do Paraná (PUCPR) under approval number 51756921.0.0000.002. All participants signed the written informed consent form before participating in the study. The results will be used exclusively for scientific and academic purposes. Participant confidentiality was maintained, and no identifiable information was disclosed.

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