The Journal of International Advanced Otology

J Int Adv Otol 2019; 15(2): 277–82 • DOI: 10.5152/iao.2019.5512

Original Article

Prevalence and Severity of Tinnitus in Otosclerosis: Preliminary Findings from Validated Questionnaires

Piotr Henryk Skarżyński, Beata Dziendziel, Elżbieta Gos, Elżbieta Włodarczyk, Beata Miaśkiewicz, Joanna Jadwiga Rajchel, Henryk Skarżyński

Institute of Physiology and Pathology of Hearing, World Hearing Center, Warsaw, Poland (PHS, BD, EG, EW, BM, JJR, HS)
Institute of Sensory Organs, Kajetany, Poland (PHS)
Department of Heart Failure and Cardiac Rehabilitation, Medical University of Warsaw, 2nd School of Medicine, Warsaw, Poland (PHS)

ORCID IDs of the authors: P.H.S. 0000-0002-4978-1915; B.D. 0000-0001-6607-2355; E.G. 0000-0003-3173-3867; E.W. 0000-0003-3737-5730; B.M. 0000-0003-3407-2355; J.J.R. 0000-0001-5072-8532; H.S. 0000-0001-7141-9851.

Cite this article as: Skarżyński PH, Dziendziel B, Gos E, Włodarczyk E, Maiśkiewicz B, Rajchel JJ, Skarżyński H. Prevalence and Severity of Tinnitus in Otosclerosis: Preliminary Findings from Validated Questionnaires. J Int Adv Otol 2019; 15(2): 277-82.

OBJECTIVES: In addition to progressive hearing loss, subjective tinnitus is one of the primary symptoms of the otosclerosis development. The aim of this study was to evaluate the prevalence and severity of preoperative tinnitus among a group of consecutive adult patients with otosclerosis, using standardized research tools.

MATERIALS and METHODS: The study included 157 cases of clinical otosclerosis (106 women, 51 men). All patients were tested using pure-tone audiometry. The preoperative prevalence and severity of tinnitus were tested using three validated questionnaires: The Tinnitus and Hearing Survey (THS-POL), Tinnitus Handicap Inventory (THI-POL), and Tinnitus Functional Index (TFI-PI).

RESULTS: Preliminary results showed that 107 of 157 patients with otosclerosis (68.2%) had preoperative tinnitus. Of them, 51 (47.7%) had unilateral tinnitus (in the ear that qualified for stapes surgery), and 56 (52.3%) had bilateral tinnitus. The THS results showed that for 23.4% patients, tinnitus was a problem equal to or greater than hearing loss. The average result of the TFI-PI questionnaire was 31.6 points, and for THI-POL, it was 38.6 points, indicating that preoperative tinnitus was moderately severe. The statistical analysis did not reveal a correlation between the tinnitus severity and audiometric results ($p>0.05$). The severity of tinnitus did not differ significantly between men and women ($p>0.05$), although the TFI-PI and THI-POL questionnaires indicated that the tinnitus severity generally increased with age in women, while it decreased in men.

CONCLUSION: This is a scientific study conducted to evaluate the prevalence and severity of preoperative tinnitus in Polish patients with otosclerosis, using three validated questionnaires.

KEYWORDS: Otosclerosis, stapes surgery, tinnitus, questionnaires, adult

INTRODUCTION

Otosclerosis is a chronic pathological process leading to the formation of spongy bone and fixation of the stapes footplate in the oval window [1]. With an incidence of 1%-2% in the white population, otosclerosis is among the most common causes of acquired hearing impairment [2].

In addition to progressive hearing loss, subjective tinnitus is one of the primary symptoms of the otosclerosis development [3-6]. The pathophysiology behind the tinnitus has not been clearly explained, despite ongoing scientific research. The "exchange hypothesis" of tinnitus formation in otosclerosis assumes that the newly formed bone tissue, because of its rich vascularization, leads to pulsatile tinnitus [7]. According to Ismi et al. [6], tinnitus may be a consequence of the reduction of the inner ear fluid vibration or the production of toxic otosclerotic metabolites.

The difficulty in assessing the severity of tinnitus is primarily because it is difficult to measure it objectively [8]. Consequently, there are few scientific publications on the prevalence and severity of tinnitus in patients who are to undergo stapes surgery.

This study was presented at the The 4th International Symposium on Otosclerosis and Stapes Surgery, 5-7 April 2018, Cracow, Poland; 32nd Politzer Society Meeting, 2nd World Congress of otology, 28 May-1 June 2019, Warsaw, Poland.

Corresponding Address: Piotr Henryk Skarżyński E-mail: p.skarzynski@inz.waw.pl

Submitted: 13.04.2018 • **Revision Received:** 25.04.2019 • **Accepted:** 10.05.2019
Available online at www.advancedotology.org

Preoperative measurement of the incidence of tinnitus in the adult population with otosclerosis is important because the number of patients treated for otosclerosis is increasing, suggesting that not only hearing loss but also tinnitus is a significant problem. In terms of treating otoslerosis, current approaches should not only aim to close the air–bone gap, but also to reduce or eliminate coexisting tinnitus [9, 10]. To the authors' best knowledge, no comprehensive study of patients qualified for stapes surgery has been published yet, which, by using a battery of validated research tools, assessed the distress caused by tinnitus. The aim of this study is therefore to evaluate the prevalence and severity of preoperative tinnitus among a group of consecutive adult patients with otosclerosis, using standardized research tools.

MATERIALS AND METHODS

The study included patients qualified for treatment of otosclerosis by stapes surgery. The main inclusion criteria were age ≥18 years, suspected otosclerosis, and no previous stapes surgery (stapedotomy) in the ear eligible for surgery. We excluded patients whose intraoperative images excluded otosclerosis, or who needed a surgical procedure other than stapedotomy. Tinnitus was diagnosed as clinically relevant when it occurred at least once a week and lasted at least 5 minutes. According to the Clinical Practice Guideline on Tinnitus (American Academy of Otolaryngology-Head and Neck Surgery), tinnitus lasting longer than 6 months is classified as chronic [11].

The research was conducted as a part of a standard diagnostic evaluation preceding the stapes surgery. The pure-tone audiometry was conducted in every participant of the study. The mean hearing thresholds for air conduction and bone conduction were determined at 500, 1000, 2000, and 4000 Hz. The air–bone gap was defined as the difference between the average bone conduction threshold and air conduction threshold.

Table 1. List of acronyms and abbreviations

Abbreviation/Acronym	Meaning
TFI-PI	Tinnitus Functional Index—Polish version
TFI-PI I	Intrusive subscale of TFI-PI
TFI-PI SC	Sense of control subscale of TFI-PI
TFI-PI C	Cognitive subscale of TFI-PI
TFI-PI SL	Sleep subscale of TFI-PI
TFI-PI A	Auditory subscale of TFI-PI
TFI-PI R	Relaxation subscale of TFI-PI
TFI-PI Q	Quality of life subscale of TFI-PI
TFI-PI E	Emotional subscale of TFI-PI
TFI-PI T	Total score of TFI-PI
THI-POL	Tinnitus Handicap Inventory—Polish version
THI-POL F	Functional subscale of THI-POL
THI-POL E	Emotional subscale of THI-POL
THI-POL C	Catastrophic response subscale of THI-POL
THI-POL T	Total score of THI-POL
THS-POL	Tinnitus and Hearing Survey—Polish version

Three validated questionnaires-The Tinnitus and Hearing Survey (THS-POL), Tinnitus Handicap Inventory (THI-POL), and Tinnitus Functional Index (TFI-PI)-were used to assess the tinnitus complaint in patients reporting its occurrence. The acronyms and abbreviations are listed in Table 1.

The Tinnitus and Hearing Survey (THS) was published by Henry et al. [12] and adapted into Polish by Raj-Koziak et al. (as THS-POL) [13]. It is a quick and easy screening tool for differentiating hearing loss and tinnitus problems. The sum of the results obtained in Parts A and B allows the clinician to effectively diagnose the patient and choose a treatment direction.

The Tinnitus Handicap Inventory (THI) was published by Newman et al. [14] and adapted into Polish by Skarżyński et al. (as THI-POL) [15]. THI is used to evaluate the severity of tinnitus and the effect of tinnitus on daily functioning. By the criteria proposed by McCombe et al. [16], the results are divided according to a nuisance scale: slight (1-16 points), mild (18-36), moderate (38-56), severe (58-76), and catastrophic (78-100 points).

The Tinnitus Functional Index (TFI) was created by Meikle et al. [17] and adapted into Polish by Wrzosek et al. (as TFI-PI) [18]. The number of points determines the following scale: no problem (0-17 points), small problem (18-31 points), moderate problem (32-53 points), big problem (54-72 points), and very big problem (73-100 points).

Statistical Analysis

A statistical analysis was performed using The Statistical Package for the Social Sciences (SPSS) (IBM Corp.; Armonk, NY, USA) v. 24 program. Variables with a non-normal distribution were analyzed using non-parametric tests: the Kruskal–Wallis test and Spearman's correlation coefficient. The Mann–Whitney U test was used to compare two independent groups. The $p<0.05$ were considered statistically significant.

RESULTS

Prevalence and Severity of Tinnitus

The study group consisted of 157 patients: 106 women and 51 men. The age of patients at the time of surgery ranged from 22 to 75 years (M=46.5, standard deviation [SD]=10.8). The average duration of hearing loss (the time between the detection of hearing loss until surgery) was 10.3 years (SD=10.2).

Seventy-one women and 36 men reported preoperative tinnitus, which was 68.2% of the study group. Tinnitus was equally common among women and men (67.0% of women and 70.6% of men reported chronic tinnitus). The average duration of tinnitus was 81.5 months (minimum 6, maximum 360). Fifty-six patients reported bilateral and 51 patients reported unilateral tinnitus (only in the ear qualified for surgery).

The THS-POL questionnaire indicated that 76.6% of patients had a greater problem with hearing loss than with tinnitus. For 13.1% of patients, tinnitus was more of a problem than hearing loss, and for 10.3%, the negative effects of hearing loss and tinnitus were on the same level. The last part of the THS-POL consisted of questions about

tolerance to sounds, and 53.3% patients indicated they had no problem tolerating sound. For 15.0%, sounds were a small problem, for 14.0% a moderate problem, and for 17.7% a big or a very big problem.

The results of the TFI-PI questionnaire showed that for 29.9% of patients, tinnitus was not a problem, for another 29.9%, it was a small problem, and for 20.6%, it was a moderate, 15.9% big, and 3.7% a very big problem. Based on the mean TFI-PI score (M=31.3; SD=21.4), participants reported that tinnitus was a small to moderate problem in general. The highest mean scores were obtained on the subscales of intrusiveness (M=48.6, SD=25.2), effect on hearing (M=42.2, SD=28.2), and interference with relaxation (M=33.5, SD=27.6).

The THI-POL questionnaire indicated that 14.0% of respondents found that tinnitus impacted slightly on daily life, for 41.1%, it had a mild impact, for 23.4% moderate, for 16.8% serious, and for 4.7%, the impact was catastrophic. The average total score for the group was 38.6 points (SD=21.9), indicating that tinnitus had a moderate impact in limiting daily life activities.

Table 2. Average results of tinnitus severity for subscales of THI-POL divided by gender

	Female			Male		
	M	SD	Me	M	SD	Me
THI-POL F	19.3	11.3	18.0	15.5	10.9	12.0
THI-POL E	11.5	7.7	10.0	9.8	8.0	8.0
THI-POL C	9.6	5.0	10.0	8.9	4.9	8.0
THI-POL T	40.4	21.4	38.0	35.0	22.6	30.0

M: mean; SD: standard deviation; Me: median; THI-POL F: Functional subscale of THI-POL; THI-POL E: Emotional subscale of THI-POL; THI-POL C: Catastrophic response subscale of THI-POL; THI-POL T: Total score of THI-POL.

Table 3. Average results of tinnitus severity for subscales of TFI-PI divided by gender

	Female			Male		
	M	SD	Me	M	SD	Me
TFI-PI I	50.2	26.5	46.7	45.5	22.4	41.7
TFI-PI SC	27.1	25.5	20.0	20.8	18.8	18.3
TFI-PI C	30.7	28.	23.3	18.8	17.9	16.7
TFI-PI SL	22.8	26.5	10.0	21.2	24.4	10.0
TFI-PI A	44.4	30.5	43.3	37.9	23.0	36.7
TFI-PI R	36.0	28.9	30.0	28.6	24.5	26.7
TFI-PI Q	30.7	26.7	27.5	22.3	23.1	15.0
TFI-PI E	27.3	26.7	16.7	19.9	22.6	13.3
TFI-PI T	33.5	23.3	27.2	26.7	16.9	24.2

M: mean; SD: standard deviation; Me: median; TFI-PI I:Intrusive subscale of TFI-PI; TFI-PI SC: Sense of control subscale of TFI-PI; TFI-PI C: Cognitive subscale of TFI-PI; TFI-PI SL: Sleep subscale of TFI-PI; TFI-PI A: Auditory subscale of TFI-PI; TFI-PI R: Relaxation subscale of TFI-PI; TFI-PI Q: Quality of life subscale of TFI-PI; TFI-PI E: Emotional subscale of TFI-PI; TFI-PI T: Total score of TFI-PI.

Tinnitus and Gender

The average tinnitus severity scores from THI-POL and TFI-PI are shown in Tables 2 and 3, respectively. The Mann–Whitney U test showed that there were no significant differences between women and men in tinnitus severity for subscales of THI-POL and TFI-PI.

Tinnitus and Age

Participants were divided into five age groups at 10-year intervals. The average tinnitus severity scores for each age group are presented in Table 4. The correlation between age (years) and tinnitus severity was also investigated: the statistical analysis showed no relationship between age and severity of tinnitus for TFI-PI (χ^2 = 3.72; p=0.445) or THI-POL (χ^2=4.42; *p*=0.352). Only for the emotions subscale of the TFI-PI questionnaire was a significant difference found: χ^2=14.34; p=0.006.

Tinnitus, Gender, and Age

The results of tinnitus severity for women and men are presented in Tables 5 and 6, respectively. Based on both TFI-PI and THI-POL, the severity of tinnitus increased with age in women, but not in men. For each gender, Spearman's correlation coefficient was used to determine the relationship between age and tinnitus severity. A significant correlation was found for women on the functional subscale of THI-POL (*rho*=0.28; p=0.020), meaning that as women get older, they experience greater tinnitus severity in the domain of functioning. The TFI-PI questionnaire showed that older women were particularly susceptible to tinnitus severity in the following areas: hearing (*rho*=0.29; p=0.013), quality of life (*rho*=0.34; p<0.01), and emotions (*rho*=0.33; p<0.01). In men, the only relationship between age and severity of tinnitus was on the relaxation subscale of TFI-PI (*rho*=–0.39; p=0.016). With advancing age, men perceive tinnitus as less troublesome in terms of opportunities for rest (relaxation).

In summary, although the total tinnitus severity result did not differ significantly between men and women (p>0.05), both TFI-PI and THI-POL indicate that tinnitus severity increased with age in women, while in men, it decreased, but only in some areas.

Tinnitus and Audiometric Results

The relationship between audiometric results and tinnitus severity was analyzed. For this reason, an analysis of preoperative audiometric results was performed only in a group of 107 patients with diagnosed tinnitus. Bilateral hearing loss was diagnosed in 94 (88%) patients. The audiometric results for the ear qualified for surgery showed mixed hearing loss in 76 (71%) patients and conductive hearing

Table 4. Average scores of tinnitus severity from the TFI-PI and THI-POL questionnaires divided into five age groups

		TFI-PI			THI-POL		
Age Group	*N*	M	SD	Me	M	SD	Me
20-29	7	21.3	20.7	14.8	28.3	18.4	28.0
30-39	32	28.2	16.8	26.2	34.5	20.7	28.0
40-49	41	32.2	22.4	24.8	40.3	21.7	38.0
50-59	16	32.5	22.4	31.4	45.1	23.7	38.0
60-69	11	40.8	27.8	32.8	41.3	24.4	30.0

M: mean; SD: standard deviation; Me: median

loss in 31 (29%). The average air conduction threshold was M=54.3 dB (SD=15.9), and the bone conduction threshold was M=25.5 dB (SD=12.6). The average air–bone gap was 28.8 dB (SD=8.7). There was no correlation between audiometric results and tinnitus severity measured by TFI-PI and THI-POL (Tables 7 and 8, respectively). Only for the auditory subscale of the TFI-PI questionnaire showed a weak relationship with air and bone conduction thresholds.

DISCUSSION

Preliminary results of our questionnaire study on 157 adults with otosclerosis have shown that 68.2% of patients experience chronic tinnitus before surgery. In the literature, the prevalence of tinnitus in otosclerosis has been determined to be 60%-90%. The prevalence of tinnitus in our study is similar to the results by Gristwood and Venables [19] and Bagger-Sjöback et al. [20], who have used the largest research material. In the Gristwood and Venables study of 1,014 patients, chronic tinnitus was preoperatively diagnosed in 65% of participants. Tinnitus was diagnosed as chronic when it lasted persistently longer than 3 months. This is the only scientific report focused exclusively on the prevalence of preoperative tinnitus in otosclerosis, although the authors did not assess tinnitus severity. The authors investigated the relationship between the results of pure-tone audiometry and the presence of tinnitus. Interestingly, the proportion of patients with tinnitus decreases with the increase in the mean level of air and bone conduction thresholds. The authors also did not explain why the proportion of tinnitus cases initially rises with the air–bone gap level but then falls again at the top level. In our study, there was a lack relationship between audiometric results and tinnitus severity. Although tinnitus often accompanies hearing impairment [21], the correlation between tinnitus severity and hearing thresholds is not obvious. It can be explained by the fact that tinnitus perception and reactions to it are subjective phenomena. With respect to the general population, some authors have attempted to evaluate the potential link between tinnitus distress and an underlying hearing loss. Savastano [22] analyzed the clinical characteristics of tinnitus both in normal hearing subjects and in patients with hearing loss. The hearing impaired patients reported bigger tinnitus discomfort (measured by visual analogue scales, VAS); however, tinnitus handicap (measured by THI) was more severe in normal hearing subjects than in hearing impaired patients. Moon et al. [23] examined the role of hearing loss on the tinnitus symptoms severity in a group of 1,705 patients. Among the groups with low anxiety sensitivity, awareness, and loudness of tinnitus were significantly greater among patients with hearing loss than among those with normal hearing. A large cross-sectional study conducted in South Korea including 11, 266 people investigated the relationship between tinnitus, hearing loss, and the quality of life [24]. In this study, no significant association between the group with hearing loss without tinnitus and the quality of life was noted. The results obtained by Aazh et al. show a significant relationship between the pure-tone average (PTA) and the tinnitus loudness as measured by VAS [5]. However, the relationship was very weak (r=0.022; p<0.001), and statistical significance was probably achieved due to a large sample size. The authors conclude that tinnitus severity and the impact of

Table 5. Average scores of tinnitus severity for women from TFI-PI and THI-POL divided into five age groups

		TFI-PI			THI-POL		
Age Group	*N*	M	SD	Me	M	SD	Me
20-29	7	21.3	20.7	14.8	28.3	18.4	28.0
30-39	20	29.2	19.1	22.0	36.2	19.8	28.0
40-49	26	34.5	24.6	37.4	42.6	21.9	44.0
50-59	10	38.1	19.6	38.8	45.8	21.0	42.0
60-69	8	46.20	31.14	56.80	47.75	25.73	57.0

M: mean; SD: standard deviation; Me: median

Table 6. Average scores of tinnitus severity for men from TFI-PI and THI-POL divided into four age groups

		TFI-PI			THI-POL		
Age Group	*N*	M	SD	Me	M	SD	Me
30-39	12	26.5	12.7	27.8	31.7	22.7	29.0
40-49	15	28.3	17.9	22.8	36.3	21.3	30.0
50-59	6	23.1	25.4	15.4	44.0	30.6	32.0
60-69	3	26.5	5.8	25.6	24.0	6.0	24.0

M: mean; SD: standard deviation; Me: median

Table 7. Correlations between the TFI-PI subscales and average air and bone conduction thresholds, and air-bone gap

	AC		BC		ABG	
	rho	p	rho	p	rho	p
TFI-PI I	-0.05	0.630	-0.04	0.710	-0.04	0.710
TFI-PI SC	0.08	0.413	0.03	0.754	0.10	0.301
TFI-PI C	0.05	0.583	0.01	0.929	0.04	0.701
TFI-PI SL	-0.01	0.960	-0.07	0.508	0.02	0.830
TFI-PI A	0.23	0.019*	0.21	0.031*	0.06	0.551
TFI-PI R	-0.01	0.972	-0.03	0.747	0.04	0.715
TFI-PI Q	0.18	0.066	0.12	0.221	0.11	0.272
TFI-PI E	0.10	0.308	0.11	0.270	0.04	0.678
TFI-PI T	0.10	0.289	0.06	0.516	0.05	0.613

*p<0.05

AC: air conduction thresholds; BC: bone conduction thresholds; ABG: air–bone gap, TFI-PI I:Intrusive subscale of TFI-PI; TFI-PI SC: Sense of control subscale of TFI-PI; TFI-PI C: Cognitive subscale of TFI-PI; TFI-PI SL: Sleep subscale of TFI-PI; TFI-PI A: Auditory subscale of TFI-PI; TFI-PI R: Relaxation subscale of TFI-PI; TFI-PI Q: Quality of life subscale of TFI-PI; TFI-PI E: Emotional subscale of TFI-PI; TFI-PI T: Total score of TFI-PI.

Table 8. Correlations between the THI-POL subscales and average air and bone conduction thresholds, and air–bone gap

	AC		BC		ABG	
	rho	p	rho	p	rho	p
THI-POL F	0.09	0.350	0.13	0.172	-0.03	0.797
THI-POL E	0.06	0.541	0.07	0.494	0.01	0.883
THI-POL C	0.06	0.518	0.05	0.589	0.03	0.794
THI-POL T	0.11	0.284	0.12	0.206	0.00	0.999

AC: air conduction thresholds; BC: bone conduction thresholds; ABG: air–bone gap; THI-POL F: Functional subscale of THI-POL; THI-POL E: Emotional subscale of THI-POL; THI-POL C: Catastrophic response subscale of THI-POL; THI-POL T: Total score of THI-POL.

tinnitus on life were more strongly correlated with tinnitus loudness than PTA. It is worth mentioning that Raj-Koziak et al. [25] demonstrated that the evaluation of tinnitus loudness with VAS could be a useful tool in diagnosing patients and measuring the effects of treatment—but only in patients with normal hearing. The authors suggested that VAS measures of tinnitus loudness in patients with hearing loss might be over-reported because of overlapping complaints related to tinnitus and hearing loss. We can speculate that the assessment of tinnitus severity in otosclerosis patients can only be made by self-report questionnaires. In the study by Bagger-Sjöback et al. on 135 subjects eligible for stapes surgery, 68% reported tinnitus. Bast et al. [26] used 53 patient records to establish the presence of tinnitus in over 80% of their subjects. Similarly, Ismi et al. [6] found that in a group of 69 patients, 87.1% reported tinnitus. The highest percentage of tinnitus, some 90% of patients, was reported in studies by Sobrinho et al. [27] and Rajati et al. [5], who studied 48 and 29 patients with otosclerosis, respectively.

Based on the results from the TFI-PI and THI-POL questionnaires, we have shown that over 40% of adult otosclerosis patients eligible for surgery stapes experience tinnitus on a severity rated as a moderate to very large problem. Therefore, this group of patients expects surgery to not only improve their hearing, but also to reduce the annoyance associated with tinnitus.

Due to the use of slightly different methods and techniques to measure the severity of tinnitus in otosclerosis, a meta-analysis of our results and those from other scientific reports is not possible. Ayache et al. [28] used a self-created 4-point scale (*slightly bothersome, bothersome, irritating, unbearable*) to evaluate the severity of tinnitus. In another three publications, VAS was used to assess the distress caused by tinnitus [20, 27, 29]. Dewyer et al. [30] used VAS to assess the volume of tinnitus, which correlates with the severity of tinnitus as measured by the TFI questionnaire, although they did not provide actual data on the severity of preoperative tinnitus as assessed by the TFI. Bast et al. [26] in a study of tinnitus distress used the Tinnitus Questionnaire created by Goebel and Hiller [31].

Subsequent researchers have adopted the same measurement tools as we used to evaluate the preoperative severity of tinnitus. Rajati at al. [5] used the THI questionnaire to measure the intrusiveness of tinnitus in a group of 26 patients. The authors classified their results according to the 5-point scale of Newman (1996) [14]: 23.1% of the patients fell into the first and second degree of tinnitus severity, 42.3% the third degree, 34.6% the fourth, and no patient reached the fifth degree. These results differ from ours and may be due to the small number of patients they used. Chang and Cheung [32] studied a group of 26 patients with otosclerosis and assessed the severity of their tinnitus using the TFI questionnaire. Unfortunately, no detailed analysis of preoperative tinnitus severity was reported, and although the work referred to the tinnitus severity classification proposed by Meikle et al. [17], the results presented differed from the original source.

The available scientific literature on tinnitus severity in otosclerosis appears to be based largely on questionnaires dedicated to evaluating particular aspects of this ailment. However, in most of these studies, there is no information about whether the research tools used were validated. For the sake of reliability, it is desirable to cross-culturally adapt questionnaires in accordance with international validation guidelines.
Numerous scientific reports on otosclerosis indicate that tinnitus more often affects women than men [4, 5, 19, 26-28, 30], and our research confirms this. The number of women included in our study was nearly twice that of men, but we found that subjective tinnitus was equally common in both genders. The literature on the association between gender and tinnitus in otosclerosis is inconclusive. Some authors claim there is no gender effect [5, 27, 28, 33]. However, Deggoju et al. [29] found that women with otosclerosis are much more likely to have tinnitus than the general population and also than men having otosclerosis. Gristwood and Venables [19] showed a correlation between gender and the occurrence of preoperative tinnitus in otosclerosis: nearly 70% of 663 women and 56% of 351 men reported tinnitus before surgery. The authors did not present any hypotheses on why there was a higher prevalence of tinnitus among women.

In our study, the severity of tinnitus as measured by TFI-PI and THI-POL was not significantly different between men and women, although higher scores were observed in women. It is possible that this difference was due to nearly double the participation of women. Rajati et al. [5] also found no significant gender effect in preoperative tinnitus severity. The findings of Sobrinho et al. [27] were similar, although in the group of patients with the highest preoperative tinnitus severity (defined as 7-10 VAS points), 16 of 19 patients (84.2%) were women.

In terms of patient age, this factor also does not seem to be a predictor of the perceived severity of preoperative tinnitus. However, the TFI-PI questionnaire indicated that the severity of tinnitus did increase with age on the TFI-PI emotions subscale, which gauges the levels of feelings such as fear, anxiety, nervousness, and depressive states. The studies by Sobrinho et al. [27] and Rajati et al. [5] also showed no relationship between age and the severity of tinnitus.

We observed a clear correlation between age, gender, and the severity of tinnitus. In women, the severity of tinnitus increased with age, while it decreased in men. The THI-POL questionnaire showed that as women became older, tinnitus progressively impaired their functioning, meaning social, professional, and physical areas in which problems of disorientation, irritability, weariness, and increased stress arose. The TFI-PI also pointed to the importance of the age factor for women in terms of its impact on the quality of life and emotions associated with tinnitus. We therefore hypothesize that older women are more likely to have problems with adapting to tinnitus, whereas in men, the ability to adapt to tinnitus increases with age.

Although providing valuable knowledge about tinnitus among patients with otosclerosis, the study has several limitations. One of them is assessing the tinnitus complaint only in a group of patients qualified for stapes surgery, which may not reflect the tinnitus complaint met in patients with smaller air–bone gaps (at the initial stage of otosclerosis development) or those not willing to undergo the surgical procedure to improve hearing. Additionally, our current findings concern only the preoperative period, without providing information on the effectiveness of stapes surgery in the postoperative tinnitus cessation. However, knowing that tinnitus is such a prevalent and significant complaint, such investigation is planned as a next step of our research.

CONCLUSION

A major lack of information on the prevalence and severity of tinnitus in otosclerosis has prompted us to conduct, to the best of our knowledge, the first prospective study on the subject. The main con-

sequence of otosclerosis is progressive hearing loss, which also leads to tinnitus, and they both significantly reduce the quality of life. It is therefore advisable to continue studies in this area, since knowledge about tinnitus in otosclerosis can be very useful in qualifying patients for stapes surgery and meeting their expectations about outcomes. This work is a first step toward the next stage of research, which is to evaluate changes in the severity of tinnitus after surgical treatment for otosclerosis.

Ethics Committee Approval: The study was designed and conducted according to the Declaration of Helsinki, with the study protocol reviewed and approved by the Institutional Review Board of Institute of Physiology and Pathology of Hearing (IFPS/KB.05.2017).

Informed Consent: Informed consent was obtained from all individual participants included in the study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – H.S., B.D., P.H.S.; Design - B.D., H.S.; Supervision – P.H.S., B.D., H.S.; Resource - H.S.; Materials - B.D.; Data Collection and/or Processing - B.D., J.J.R.; Analysis and/or Interpretation - B.D., E.G.; Literature Search – B.D., E.G., E.W., B.M., J.J.R.; Writing – B.D., E.G., J.J.R.; Critical Reviews – P.H.S., H.S.

Acknowledgements: The authors express their gratitude to colleagues from the World Hearing Center – Weronika Świerniak and Katarzyna Bieńkowska – for their help in collecting data.

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

Financial Disclosure: The authors declared that this study has received no financial support.

REFERENCES

1. Skarżyński H, Mrówka M, Młotkowska-Klimek P, Sitarz L, Wysocki J, Skarżyńska B. Stapedotomy in advanced otosclerosis and tympanosclerosis. Audiofonologia, 2003; XXIV.
2. Bast F, Weikert S, Schrom T. Treatment of otosclerosis with a superelastic nitinol piston: first results. Indian J Otolaryngol Head Neck Surg 2011; 63: 126-31. [CrossRef]
3. Szymański M, Gołabek W, Mills R. Effect of stapedectomy on subjective tinnitus. J Laryngol Otol 2003; 117: 261-4. [CrossRef]
4. Sparano A, Leonetti JP, Marzo S, Kim H. Effects of stapedectomy on tinnitus in patients with otosclerosis. Int Tinnitus J, 2004; 10: 73-7.
5. Rajati M, Poursadegh M, Bakhshaee M, Abbasi A, Shahabi A. Outcome of stapes surgery for tinnitus recovery in otosclerosis. Int Tinnitus J 2012; 17: 42-6.
6. Ismi O, Erdogan O, Yesilova M, Ozcan C, Ovla D, Gorur K. Does stapes surgery improve tinnitus in patients with otosclerosis? Braz J Otorhinolaryngol 2016; 83: 568-73. [CrossRef]
7. Bartnik G. Szumy uszne i nadwrażliwość słuchowa. In: Skarżyński H, editor. Instytut Fizjologii i Patologii Słuchu. Warszawa; 2010, p.61-3.
8. Raj-Koziak D. Tinnitus in adults - literature review. Now Audiofon, 2016; 5: 24-9.
9. Skarzynski PH, Kochanek K, Skarzynski H, Senderski A, Wysocki JA, Szkielkowska A, et al. Hearing Screening Program in School-Age Children in Western Poland. J Int Adv Otol 2011; 7: 194-200.
10. Skarzynski H, Piotrowska A, Kamyk P, Czupryniak A, Saniewska-Kilim A, Włodarczyk A i wsp. EU Council Conclusion on early detection and treatment of coumminication disorders in children, including the use of e-health tools and innovative solutions. J Hear Sci 2012; 2: 51-2.
11. Tunkel DE, Bauer CA, Sun GH, Rosenfeld RM, Chandrasekhar SS, Cunningham ER, et al. Clinical Practice Guideline Tinnitus. Otolaryngol Head Neck Surg 2014; 151: S1-40. [CrossRef]
12. Henry JA, Griest S, Zaugg TL, Thielman E, Kaelin C, Galvez G, et al. Tinnitus and hearing survey: a screening tool to differentiate bothersome tinnitus from hearing difficulties. Am J Audiol 2015; 24: 66-77. [CrossRef]
13. Raj-Koziak D, Gos E, Rajchel J, Pilka A, Skarzynski H, Rostkowska J, et al. Tinnitus and Hearing Survey: a Polish Study of Validity and Reliability in a clinical population. Audiol Neurotol 2017; 22; 197-204. [CrossRef]
14. Newman CW, Jacobson GP, Spitzer JB. Development of the Tinnitus Handicap Inventory. Arch Otolaryngol Head Neck Surg 1996; 122: 143-8. [CrossRef]
15. Skarzynski PH, Raj-Koziak D, J Rajchel J, Pilka A, Wlodarczyk AW, Skarzynski H. Adaptation of the Tinnitus Handicap Inventory into Polish and its testing on a clinical population of tinnitus sufferers. Int J Audiol 2017: 1-5. [CrossRef]
16. McCombe A, Baguley D, Coles R, McKenna L, McKinney C, Windle-Taylor P. Guidelines for the grading of tinnitus severity: the results of a working group commissioned by the British Association of Otolaryngologists, Head and Neck Surgeons, 1999. Clin Otolaryngol Allied Sci, 2001; 26: 388-93. [CrossRef]
17. Meikle MB, Henry JA, Griest SE, Stewart BJ, Abrams HB, McArdle R, et al. The tinnitus functional index: development of a new clinical measure for chronic, intrusive tinnitus. Ear Hear 2012; 33: 153-76. [CrossRef]
18. Wrzosek M, Szymiec E, Klemens W, Kotyło P, Schlee W, Modrzyńska M, et al. Polish Translation and Validation of the Tinnitus Handicap Inventory and the Tinnitus Functional Index. Front Psychol 2016; 7: 1871. [CrossRef]
19. Gristwood RE, Venables WN. Otosclerosis and Chronic Tinnitus. Ann Otol Rhinol Laryngol 2003; 112: 398. [CrossRef]
20. Bagger-Sjöbäck D, Strömbäck K, Hultcrantz M, Papatziamos G, Smeds H, Danckwardt-Lilliestrom N, et al. High-frequency hearing, tinnitus, and patient satisfaction with stapedotomy: A randomized prospective study. Sci Rep 2015; 5: 13341. [CrossRef]
21. Henry JA. "Measurement" of Tinnitus. Otol Neurotol 2016; 37: e276-85. [CrossRef]
22. Savastano M. Tinnitus with or without hearing loss: are its characteristics different? Eur Arch Otorhinolaryngol 2008; 265: 1295-300. [CrossRef]
23. Moon KR, Park S, Jung Y, Lee A, Lee JH. Effects of Anxiety Sensitivity and Hearing Loss on Tinnitus Symptom Severity. Psychiatry Investig 2018; 15: 34-40. [CrossRef]
24. Joo YH, Han K, Park KH. Association of Hearing Loss and Tinnitus with Health-Related Quality of Life: The Korea National Health and Nutrition Examination Survey. PloS One 2015; 10: e0131247. [CrossRef]
25. Raj-Koziak D, Gos E, Świerniak W, Karpiesz L, Niedziałek I, Włodarczyk E, et al. Relationship Between Tinnitus Loudness Measure by Visual Analogue Scale and Psychoacoustic Matching of Tinnitus Loudness. Otol Neurotol 2019; 40: 16-21. [CrossRef]
26. Bast F, Mazurek B, Schrom T. Effect of stapedotomy on pre-operative tinnitus and its psychosomatic burden. Auris Nasus Larynx 2013; 40: 530-3. [CrossRef]
27. Sobrinho PG, Oliveira CA, Venosa AR. Long-term follow-up of tinnitus in patients with otosclerosis after stapes surgery. Int Tinnitus J 2004; 10: 197-201.
28. Ayache D, Earally F, Elbaz P. Characteristics and postoperative course of tinnitus in otosclerosis. Otol Neurotol 2003; 24: 48-51. [CrossRef]
29. Lima A da S, Sanchez TG, Marcondes R, Bento RF. The effect of stapedotomy on tinnitus in patients with otospongiosis. Ear Nose Throat J 2005; 84: 412-4. [CrossRef]
30. Dewyer NA, Kiringoda R, Kram YA, Chang JL, Chang CYJ, Cheung SW. Stapedectomy Effects on Tinnitus: Relationship of Change in Loudness to Change in Severity. Otolaryngol--Head Neck Surg 2015; 153: 1019-23. [CrossRef]
31. Goebel G, Hiller W. [The tinnitus questionnaire A standard instrument for grading the degree of tinnitus Results of a multicenter study with the tinnitus questionnaire]. HNO 1994; 42: 166-72.
32. Chang CYJ, Cheung SW. Tinnitus modulation by stapedectomy. Otol Neurotol 2014; 35: 1065-9. [CrossRef]
33. Gersdorff M, Nouwen J, Gilain C, Decat M, Betsch C. Tinnitus and otosclerosis. Eur Arch Otorhinolaryngol 2000; 257: 314-6. [CrossRef]