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Unilateral versus bilateral stapes surgery: A comparative study on auditory outcome and quality of life

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ABSTRACT

Otosclerosis is a well-known disease which mainly affects middle-aged female patients, causing conductive or mixed hearing loss. Diagnosis is essentially made through a complete audiometric battery testing, while treatment substantially relies on stapes surgery.

In this study, we analyzed audiometric and Quality-of-Life data from 33 patients in order to refine the surgical indications (unilateral versus bilateral stapes surgery) and assess the best technique (stapedotomy versus partial stapedectomy) and timing of treatment. The original questionnaire OTOS, in the Italian language, was administered to all patients.

In this study, most of the patients were female (18/33), with a mean age of 53 years old. Both surgical techniques appear to be effective with no significant difference in post-operative Air Bone Gap. OTOS questionnaire appeared to be effective in assessing quality of life in patients treated by stapes surgery. Post-operative QoL appeared to be similar in bilaterally and unilaterally operated patients, suggesting that a contralateral intervention after effective surgery should be undertaken only if expressly requested by the patient.

1. Introduction

Otosclerosis is a common disease that appears to be linked to genetical factors, environmental causes and hormonal changes, and clinically affects women more commonly than men (Crompton et al., 2019) (Karosi and Sziklai, 2010). It usually presents with bilateral conductive or mixed hearing loss (HL) and tinnitus (Batson and Rizzolo, 2017), however a unilateral HL may precede contralateral involvement or remain the unique symptom. Diagnosis is based on clinical history and a full audiometric battery testing, including tympanometry and acoustic reflex. No medical treatment has been demonstrated its effectiveness in preventing the disease nor stopping its progressive course so far. The current treatment options include hearing aids and stapes surgery, while cochlear implantation is reserved to cases with severe sensorineural HL (Batson and Rizzolo, 2017) (Foster and Backous, 2018) (Quaranta et al.).

Stapes surgery aims at the improvement of hearing threshold and tinnitus and therefore improve the Quality of Life (QoL) of the patients. In terms of hearing outcome generic health-related quality of life questionnaires have failed (Redfors et al., 2015) (Subramaniam et al., 2006), therefore disease-specific QoL questionnaires have been developed and validated with the purpose of evaluating the overall burden of disease from the perspective of the patient. To the best of our knowledge, no otosclerosis-specific QoL questionnaires have been validated so far in English or Italian language, while the SPOT-25 is a German-born QoL questionnaire (Lailach et al., 2017) that has been translated and validated to these days in Dutch, Danish, French and Greek languages (Beka et al., 2022) (Hildebrandt et al., 2020) (Hildebrandt et al., 2022) (Blijleven et al., 2019) (Gargula et al., 2023).

This preliminary study is concerned with the first use and initial validation of a mixed generic and specific QoL questionary, the OTOS. Furthermore, the QoL score obtained by this questionnaire was correlated with the auditory outcome and used to compare the results of surgery.

Abbreviations: HL, hearing loss; QoL, quality of life; IT, item; PTA, pure tone average; AC, air conduction; BC, bone conduction; ABG, air-bone gap; SD, standard deviation; HPL, hemiplatinectomy; PLT, platinotomy.

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2. Materials and methods

All consecutive patients addressed to stapes surgery in the period between January and October 2021 were prospectively enrolled in the study.

All cases with abnormal tympanic membrane, or evidence of other congenital or acquired middle ear anomalies were excluded, as well as revision surgeries and total stapedectomies. Patients with a follow-up time shorter than 6 months were not considered for the analysis. The study was approved by the local Institutional Review Board (Protocol no. 273/2023) and was carried out in accordance with the Declaration of Helsinki; all patients gave their written informed consent for both the intervention and the study.

Pre-operatively, all patients underwent a full audiometric battery testing and were asked to answer the Italian version of OTOS questionnaire. This is a twenty-question questionnaire divided into four different items (IT): subjective perception of the symptoms referring to the worse ear or to the next-to-surgery one (IT-1, questions 1 to 6); subjective evolution of the symptoms (IT-2, questions 7 to 9); psychological impact of the disease (IT-3, questions 10 to 17); impact on the local health system (IT-4, questions 18 to 20). All questions are referred to the previous twelve months. Each question from IT-1 to IT-3 is scored on a five-point scale from 1 (less burden) to 5 (worse burden); IT-4 questions do not have standardized scores and were not taken into

A Quality of life measurement questionnaire OTOS for otosclerosis suffering patients

ITEM 1: SUBJECTIVE AUDIO-VESTIBULAR SYMPTOMS
Please answer these questions referring to the last 12 months:

1. I feel like my hearing is lower	1 – 2 – 3 – 4 – 5
2. I feel like a whistle (tinnitus) in my ears	1 – 2 – 3 – 4 – 5
3. I suffered from severe vertigo	1 – 2 – 3 – 4 – 5
4. When standing or walking I feel imbalance	1 – 2 – 3 – 4 – 5
5. I make effort in following others talking	1 – 2 – 3 – 4 – 5
6. I must turn up TV or radio volume to understand	1 – 2 – 3 – 4 – 5

ITEM 2: EVOLUTION OF AUDIO-VESTIBULAR SYMPTOMS
Please answer these questions referring to the last 12 months:

7. In the last 12 months, I felt like my hearing got progressively worse	1 – 2 – 3 – 4 – 5
8. In the last 12 months, I felt like my tinnitus got progressively worse	1 – 2 – 3 – 4 – 5
9. In the last 12 months, I felt like vertigo got progressively worse	1 – 2 – 3 – 4 – 5

B Quality of life measurement questionnaire OTOS for otosclerosis suffering patients

ITEM 3: PSYCHOLOGICAL IMPACTION
Please answer these questions referring to the last 12 months:

10. Sometimes I am afraid of not understanding others and feel/being isolated	1 – 2 – 3 – 4 – 5
11. Due to my disease, I make extra-effort in connecting to others	1 – 2 – 3 – 4 – 5
12. Due to my disease, I attend fewer social activities with family and/or friends	1 – 2 – 3 – 4 – 5
13. Due to my disease, I have trouble in public or workspace	1 – 2 – 3 – 4 – 5
14. My ear disease makes me feel sad	1 – 2 – 3 – 4 – 5
15. I fear my symptoms would not improve in the future even in case of surgical intervention	1 – 2 – 3 – 4 – 5
16. I fear the surgery or the post-operative period (also in case of revision surgery)	1 – 2 – 3 – 4 – 5
17. My ear disease worsens my quality of life in any way	1 – 2 – 3 – 4 – 5

ITEM 4: HEALTH SYSTEM IMPACTION

18. In the last 12 months, I had a doctor check my ears…	1 time – 2 times – 3 to 5 times – 5 to 7 times – 8 or more times
19. I use hearing aids…	Yes (one side) – Yes (both sides) – No
20. I have already performed stapes surgery…	Yes – Yes (2 times, same side) – Yes (both sides) – No

Fig. 1. (A) (B) English adaptation of the original Italian version of OTOS questionnaire.

account. (Fig. 1(A)(B) shows the English adaptation and further details of the questionnaire, for better comprehension).

All surgeries were performed by the senior author as an inpatient service by a transcanal microscopic approach under local anesthesia. After the elevation of the tympanomeatal flap and an adequate postero-superior canaloplasty, a control hole was made in the stapes footplate, the incudostapedial joint was separated, the stapedius tendon cut, and the stapes superstructure removed. At this point, the selection of the technique was made intra-operatively in consideration of the width of the oval window: when possible, a stapedotomy was preferred, by enlarging the control hole by the use of a microhook until obtaining a hole diameter at least 0.2 mm

Wider than the prosthesis; in case of partial stapedectomy, the posterior third or half of the footplate was removed by the use of micro-hooks. A Teflon piston was then placed directly into the

Vestibule: a 0.4 mm shaft diameter piston was chosen in case of stapedotomy, while a 0.6 mm one was preferred in case of partial stapedectomy. The oval window niche was finally sealed with autologous fat harvested from the ear lobe, the tympanomeatal flap repositioned and the external auditory canal packed.

At six-month post-operative follow-up all patients were asked to answer the same questionnaire and undertook pure tone audiometry.

All data were collected in an electronic database. The OTOS score was calculated for each item and for each patient (IT-1 range 6–30, IT-2 range 3–15, IT-3 range 8–40) by adding the scores of single questions.

Pure-tone average (PTA) was calculated for both air (AC) and bone conduction (BC) as the mean of 0.5, 1, 2, and 4 kHz thresholds. Air-bone gap (ABG) was calculated as the difference between AC and BC PTAs determined at each evaluation. Post-operative ABG gain was calculated from the difference between pre-operative and post-operative ABGs. Delta-BC was calculated as the difference between the post-operative and pre-operative average BC thresholds at 1, 2 and 4 kHz, as the possible expression of a sensorineural iatrogenic damage. The deepness of Carhart notch was measured in dB at each assessment. All hearing data were presented in accordance with the recommendations from the Hearing Committee of the American Academy of Otolaryngology–Head and Neck Surgery for the evaluation of conductive hearing loss.

3. Calculations

Both hearing results (ABG, ABG gain and BC variation) and QoL data (OTOS IT-1, IT-2 and IT-3 scores) were compared in relation to the timing (pre-versus post-operative), the surgical technique (stapedotomy versus partial stapedectomy) and pre-operative HL (unilateral versus bilateral).

Categorical or dichotomous variables were expressed as absolute number and percentage (N, %). Continuous variables were expressed as mean ± standard deviation (μ ± SD). Mann-Whitney test was used to compare continuous variables (OTOS and hearing outcome) in the two groups of patients (stapedotomy Vs. partial stapedectomy and unilateral Vs. bilateral stapes surgery), while Wilcoxon signed-rank to assess their postoperative variations. A *p-value* < 0.05 was considered as statistically significant. The software Wizard 2 for MacOS [Version 2.0.13 (262)] was used for statistical analysis.

4. Results

A total of 33 patients (18 females and 15 males) were enrolled in the study: 17 subjects (8 females and 9 males) had already undergone a previous stapes surgery on the contralateral side (defined hereinafter as group A) while the remaining 16 (10 females and 6 males) were recently diagnosed with bilateral otosclerosis, i.e. had no previous ear operation (defined as group B).

Mean age was 53.17 years old (range 29–80 years old), and 53,14% were female. Apart from HL, the most common complaint was tinnitus (77.14%), followed by vertigo (22.86%) and fullness (17.14%). A stapedotomy (SPT) was performed in 19 cases (54.29%), while a partial stapedectomy (posterior hemiplatinectomy, HPL) was performed in the remaining 14 cases (45.71%). Mean follow-up time was 7.45 months. These data are summarized in Table 1.

Table 2 reports the hearing and QoL outcome in relation to the surgical timing (Pre-op Vs. Post-op), technique (SPT vs. HPL) and pre-operative HL (Group A Vs. Group B).

Average ABG improved in the post-operative period (p-value <0.001) regardless of the surgical technique or laterality. Fig. 2 summarizes the variation of AC and BC thresholds in pre- and post-operative sets. Average BC PTA was significantly improved post-operatively in the total cohort (25 dB Vs. 29 dB pre-operatively, p-value 0.02), in the platinotomy subgroup (24.79 dB Vs. 30.2 dB, $p = 0.006$) and in group B (26.15 dB Vs. 32.9 dB, $p = 0.027$). Average delta-BC was negative as the effect of the reversal of Carhart effect in all groups. In particular, post-operative BC threshold was reduced in 16 cases (51.4%), unchanged in 3 (8.6%) and slightly worsened (mean 3.75 dB) in the remaining 14 patients (40%), including 2 cases of moderate BC deterioration (+6 dB and +8 dB respectively) (Fig. 3).

No significant difference was found when comparing the mean pre- and post-operative ABGs, ABG gain and delta BC between the two different techniques (SPT Vs. HPL) and side of HL (Group A Vs. Group B).

Pre-operative QoL scores were overlapping between the two techniques, even though worse average pre-operative IT-2 scores were found in Group B when compared to Group A (9.29 Vs. 7.29 respectively; $p = 0.016$). Average post-operative IT-1, IT-2 and IT-3 scores appeared to be significantly improved, regardless of the surgical technique or strategy. No significant difference was observed in terms of post-operative QoL outcome when comparing the two techniques (SPT Vs. HPL) or the side of HL (Group A Vs. Group B).

Table 3 shows a crossed inter-group comparison at different moments in relation to the surgery. In particular, to better understand the impact of stapes surgery on the QoL, the post-operative scores of group A were compared to the pre-operative ones of group B (i.e., bilateral surgery Vs. no surgery) and vice versa (pre-op Group A Vs. post-op Group B). As expected, the post-operative QoL in group A (two operated ears) was significantly better ($p < 0.001$) than the pre-operative one of group B (no operated ear). Surprisingly, also the post-operative scores of group B (one ear which just had surgery) were significantly better ($p < 0.001$) than the pre-operative ones of group A (one ear operated since at least one year and the other one scheduled for next surgery).

5. Discussion

Otosclerosis is well known disease. It usually presents with unilateral

Table 1
Demographics, symptoms, and surgical data of the study population. SD: standard deviation; M: male; F: female; R: right; L: left; CL: contralateral; SPT: stapedotomy; HPL: hemiplatinectomy.

		N (%) or Mean (±SD)
Sex	M	15 (42.86)
	F	20 (57.14)
Age	(years)	53.17 ± 12.25
Symptoms	Hearing loss	35 (100)
	Fullness	6 (17.14)
	Tinnitus	27 (77.14)
	Vertigo/dizziness	8 (22.86)
Side of surgery	R	18 (51.43)
	L	17 (48.57)
Bilateral disease		33 (94.28)
Previous CL surgery	Yes	17 (48.57)
	No	18 (51.43)
Technique	SPT	19 (54.29)
	HPL	16 (45.71)
Follow-up	Mean (min – max)	7.45 months (6–9)

Table 2
Hearing and QoL mean outcome of the study population. Level of significance 95%. SPT: stapedotomy; HPL: hemiplatinectomy; ABG: air-bone gap; BC: bone conduction; IT: item; Red values: statistically non-significant; Green values: statistically significant.

	Mean	SPT	HPL	*p-value*	Group A	Group B	*p-value*	*Non-operated ear*	
PTA Air								***Left***	***Right***
Pre-op.		61.18	58.73	0.547	58.23	62.79	0.302	40.9	40.83
Post-op.		36.12	32.36	0.353	35.15	34.86	0.905	40.18	41
p-value		<0.001	<0.001		<0.001	<0.001		0.438	0.844
ABG									
Pre-op.	30.46	29.84	30.5	0.756	30.59	29.72	0.858		
Post-op.	8.93	10.53	7.39	0.281	9.36	9	0.886		
p-value	<0.001	<0.001	<0.001		<0.001	<0.001			
BC								***Left***	***Right***
Pre-op.	29	30.21	26.75	0.285	26.16	32.89	0.168	30.42	27.4
Post-op.	25	24.79	25.75	0.704	25.09	26.15	0.375	26.99	27.21
p-value	0.020	0.006	1		0.519	0.027		0.812	0.75
ABG gain	21.53	20.42	24.5	0.142	22.88	21.72	0.636		
Delta BC	−4	−5.53	−1.46	0.17	−1.07	−6.13	0.131		

	Mean	SPT	HPL	*p-value*	Group A	Group B	*p-value*
OTOS IT-1							
Pre-op.	19.06	19.59	18.81	0.458	18.5	20.07	0.069
Post-op.	9.9	5.35	3.09	0.458	9.64	8.79	0.427
p-value	<0.001	<0.001	<0.001		<0.001	<0.001	
OTOS IT-2							
Pre-op.	8.09	8.24	8.36	0.781	7.29	9.29	0.016
Post-op.	3.7	1.71	1.36	0.853	3.36	3.57	0.804
p-value	<0.001	<0.001	<0.001		<0.001	<0.001	
OTOS IT-3							
Pre-op.	24.4	24.71	25.36	0.926	24.36	25.57	0.910
Post-op.	13.67	6.06	3.72	0.781	12.79	11.50	0.571
p-value	<0.001	<0.001	<0.001		0.002	<0.001	

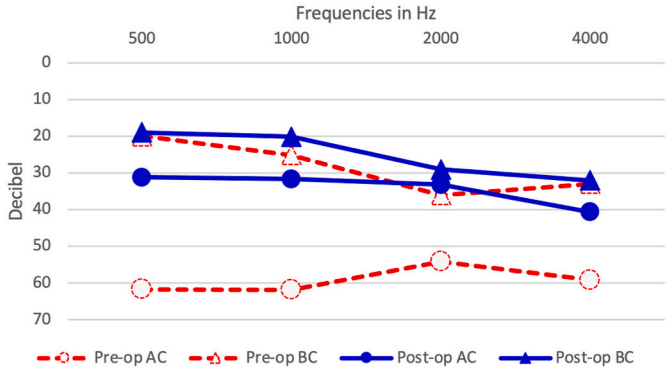

Fig. 2. Mean audiometric test values in dB (y-axis) for frequencies 500–4000 Hz (x-axis).
Legend. Pre-op: pre-operative; Post-op: post-operative; AC: air conduction; BC: bone conduction.

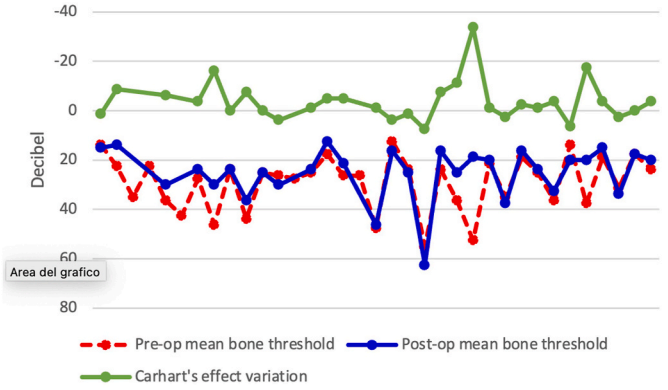

Fig. 3. Comparison between pre-operative and post-operative bone conduction thresholds and relative variation of Carhart effect per patient (y-axis in dB).

or bilateral progressive HL, accompanied by fullness, tinnitus, vertigo or imbalance (Batson and Rizzolo, 2017) (Mahafza et al., 2013). Stapes surgery is often the best option and is indicated in case of air-bone gap greater than 35–40 dB, while cochlear implantation is reserved to cases of advanced otosclerosis (Quaranta et al.) (Bajin et al., 2020) (Quaranta et al., 2005).

Although bilateral hearing loss represent an undoubtful indication, there is still a debate in literature if stapes surgery should be indicated in case of unilateral HL (De Seta et al., 2009). In case of unilateral HL, stapes surgery in comparison to hearing aid has been shown to improve speech discrimination in noise, as well as sound localization and QoL (Molinier et al., 2022).

In case of bilateral otosclerosis poor free-field speech discrimination in noise has been proposed as the main indication for second-side intervention, as this parameter closely reflects the usual listening

Table 3
Crossed inter-group comparison of mean values of OTOS scores at different times. Legend. pre-op: pre-operative; post-op: post-operative; Green values: statistically significant.

	Group A post-op	Group B pre-op	Group A pre-op	Group B post-op
Prosthesis in	Two ears	None	One ear	One ear
OTOS IT-1	9.64	20.07	18.50	8.79
p-value	<0.001		<0.001	
OTOS IT-2	3.36	9.29	7.29	3.57
p-value	<0.001		<0.001	
OTOS IT-3	12.79	25.57	24.36	11.50
p-value	<0.001		<0.001	

conditions in everyday life (De Seta et al., 2009), since traditional audiometric measurements such as tonal audiometry and vocal audiometry do not always correlate with real life conditions.

The use of patient-based questionnaires regarding the QoL and perceived handicap has recently gained increasing attention in the field of otology, in fact QoL assessment may help the surgeon to optimize the quality of treatment.

The Stapedoplasty Outcome Test 25 (SPOT-25) questionnaire was recently developed by Lailach et al. (2017) (Lailach et al., 2018) in German, and translated in different languages (Beka et al., 2022) (Hildebrandt et al., 2020) (Hildebrandt et al., 2022) (Blijleven et al., 2019) (Gargula et al., 2023). It consists of 25 items that explore five domains: hearing function, tinnitus, mental condition, social restrictions and impact of otosclerosis on QoL. Different authors have showed an improvement of post-operative QoL (Beka et al., 2022) (Hildebrandt et al., 2022) (Lailach et al., 2018) (Weiss et al., 2020) (Weiss et al., 2019), however the evaluation of QOL of patients operated with bilateral or unilateral HL has never been reported.

This study presents the first use and initial validation of a mixed generic and specific QoL questionary, "The OTOS". OTOS IT-1 focus on symptoms referred by patients considering the worse or next-to-surgery ear, whereas IT-2 and IT-3 aim to assess overall QoL in patients, focusing on subjective evolution of the pathology in the previous twelve month and global psychological impaction of QoL itself. IT-4 was not taken into account due to lack of applicability, as stated in paragraph 2.

The outcomes of stapes surgery were evaluated, from an audiological and QoL point of view, by comparing the two main surgical techniques (stapedotomy versus posterior hemiplatinectomy) and the effect of surgery in unilateral and bilateral HL.

Postoperatively, average ABG significantly improved in the total cohort as well as in each subset (group A, group B, HPL and SPT), as well as BC threshold improved on average of 4 dB as the expression of the reversal of the Carhart effect. Similarly, average post-operative QoL scores appeared to be significantly reduced if compared to the pre-operative mean scores, regardless of the surgical technique or laterality of HL, suggesting an improvement of QoL.

Pre-operatively IT-2 scores (subjective evolution of the symptoms) were lower in group A if compared to group B: this may be explained by the fact that the previous stapes surgery on the contralateral side may have positively affected the QoL or otherwise it may be a statistical limit of the specimen itself. Post-operative OTOS sub-scores were not significantly different when comparing group A with group B, suggesting a role for stapes surgery in unilateral HL. A crossed inter-group comparison showed an interesting and unexpected result. In particular, a comparison was made between two subgroups of patients which are supposed to have overlapping QoL scores, as they both have undergone one-side stapes surgery at the time of the assessment (group A pre-operatively Vs. group B post-operatively). Surprisingly, significantly better OTOS sub-scores have been found in group B post-operatively if compared to group A pre-operatively. This finding might be explained by the positive psychological effect on the QoL of patients that have just undergone their first stapes surgery or a selection bias may have played a role in this finding, as patients that have already undergone a stapes surgery and that were not completely satisfied with their hearing status may have asked for a contralateral intervention. To verify our preliminary results and hypothesis, further studies are needed, possibly with a larger cohort and a longer follow-up, and by including patients who had already undergone unilateral stapes surgery but refused contralateral surgery.

6. Conclusions

Otosclerosis is a well-known, surgically treatable disease affecting mostly middle-aged patients. Stapes surgery appears to significantly improve both the hearing threshold and the QoL. The results of this study show that bilateral intervention may be redundant, and the eventual indication should be mostly QoL-driven. A first use and validation of the new otosclerosis-specific OTOS questionnaire has been undertaken in this study. Further prospective and ideally multi-centric studies with a larger sample should be made to confirm our results.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Data availability statement

All relevant data is contained within the article. Further inquiries and additional data can be provided by the corresponding author.

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