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Otology

Hearing outcomes and patient satisfaction after stapes surgery: local *versus* general anaesthesia

Risultati uditivi e gradimento nei pazienti operati di stapedoplastica in anestesia locale e generale

Beatrice Giannoni[1,2], Federica Pollastri[1,2], Chiara Adembri[3], Dina Straticò[1], Paolo Vannucchi[1], Alessia Stival[1], Curzio Checcucci[4], Chiara Bruno[5], Rudi Pecci[1]

[1] Unit of Audiology, Careggi University Hospital, Florence, Italy; [2] Department of Neuroscience, Psychology, Drug's Area and Child's Health, University of Florence, Florence, Italy; [3] Department of Experimental and Clinical Medicine, Unit of Anesthesiology, University of Florence, Italy; [4] Department of Physycs and Astronomy, University of Florence, Italy; [5] Unit of Otorhinolaryngology, Careggi University Hospital, Florence, Italy

SUMMARY

Objective. Otosclerosis is a frequent ear disorder causing a stapedo-ovalar ankylosis and conductive hearing loss. Stapedoplasty, performed under both general (GA) and local anaesthesia (LA), is the most advisable surgical solution. Auditory recovery relies on the patient's conditions and on the intervention itself. The aim of our work was to compare hearing outcomes with stapedoplasty performed under GA or LA and to investigate patients' compliance to both methods.

Methods. Fifty-five otosclerotic patients underwent stapedoplasty both under GA (32/55) and LA (23/55). Pre- and post-operative air and bone tone audiometry threshold values as well as the air-bone gap and its closure score, were analysed. All patients filled in a satisfaction questionnaire regarding their concern and level of appreciation of the type of anaesthesia.

Results and conclusions. Our data show that the auditory results with stapedoplasty are good and do not differ between LA and GA. Even considering the advantages and limits of the two methods, one cannot favour one or the other type of anaesthesia. Finally, the patient's satisfaction cannot be considered a criterion of choice, since this was found to be high in both cases.

KEY WORDS: stapedoplasty, otosclerosis, local anaesthesia, general anaesthesia, stapes surgery

RIASSUNTO

Obiettivo. *L'otosclerosi è una frequente patologia otologica che provoca anchilosi stapedo-ovalare e ipoacusia trasmissiva. La stapedoplastica, eseguita in anestesia generale (AG) o locale (AL), è la soluzione chirurgica ideale. Il recupero uditivo dipende da variabili legate al paziente e all'intervento. Scopo del nostro lavoro è stato confrontare i risultati uditivi dopo stapedoplastica eseguita in AG e AL e indagare il grado di soddisfazione dei pazienti nei riguardi delle due metodiche.*

Metodi. *Abbiamo studiato 55 pazienti con otosclerosi sottoposti a stapedoplastica in AG (32/55) e AL (23/55). Abbiamo valutato la soglia audiometrica tonale pre- e post-operatoria, il valore del gap trasmissivo via aerea-ossea e la sua chiusura. I pazienti hanno compilato un questionario di soddisfazione riguardo alla preoccupazione e al livello di apprezzamento del tipo di anestesia.*

Risultati e conclusioni. *I nostri dati mostrano che i risultati uditivi dopo stapedoplastica sono buoni e non differiscono in base al tipo di anestesia. Anche considerando i vantaggi e i limiti delle due metodiche non si può propendere per la scelta dell'uno o dell'altro tipo di anestesia. Infine, la soddisfazione del paziente non può essere considerata un criterio di scelta, poiché questa è risultata elevata in entrambi i casi.*

PAROLE CHIAVE: *stapedoplastica, otosclerosi, anestesia locale, anestesia generale, chirurgia stapediale*

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Correspondence
Beatrice Giannoni
Unit of Audiology, Careggi University Hospital, Florence, Department of Neuroscience, Psychology, Drug's Area and Child's Health, University of Florence, viale Gaetano Pieraccini 6, 50139 Florence, Italy
Tel. +39 055 7948154
E-mail: beatrice.giannoni@unifi.it

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Introduction

Otosclerosis is a dystrophic process of the otic capsule characterised by an abnormal sponge-like bone growth at the middle-inner ear limit that often blocks the stapedo-ovalar joint. At the beginning, hearing loss is solely conductive, but becomes mixed and even pure sensorineural with progression of the disease because of the extension of the pathological process into the cochlea [1,2].

The main treatment for otosclerosis is surgical, namely by stapedoplasty, which has the goal of restoring ossicular chain mobility and hearing performance by the partial or in toto substitution of the stucked stapes with a micro-prosthesis. In the literature, the success rate of modern stapedoplasty has been reported to be 75-94% in terms of hearing recovery [3,4].

Stapedoplasty is a surgical procedure that can be carried out under either local (LA) or general anaesthesia (GA). Over time, it has been seen that the two types of anaesthesia have contrasting advantages and disadvantages, playing an important role in post-operative hearing outcomes.

Historically, stapes surgery was performed under LA, which is advantageous because it allows for communication with the patient about intraoperative hearing changes, vertigo and other symptoms. Conversely, nowadays, GA is preferred. Benefits of GA include patient comfort in terms of anxiety, pain, noise annoyance and vertigo and increased surgeon's safety. Moreover, modern GA techniques can avoid intubation and the use of heavy drugs, thus being less traumatic and allowing a more gradual awakening, resulting in an less invasive procedure overall [5,6].

In the absence of contraindications for GA or LA, the selection of the anaesthesia method should be based upon best hearing outcome evidence.

Remarkably, only a handful of studies have compared outcomes based on the type of anaesthesia, and report conflicting and non-definitive results.

On the other hand, the limited literature does not consider the preference of the patient about the type of anaesthesia and final satisfaction regarding the anaesthetic procedure received.

The aim of our work is to contribute in establishing whether LA or GA performed with the most modern anaesthesiological techniques can influence hearing outcome after primary stape's surgery. Furthermore, considering the anaesthesiological experience and auditory outcomes, we discuss how to better match a patient's wishes and/or needs of the physician's team with the final acceptance of the anaethesia by the patient and the best functional results.

Materials and methods

A retrospective study was performed on 55 patients suffering from documented otosclerosis and undergoing stapedoplasty at the Audiology Unit of Careggi University Hospital in Florence between June 2016 and November 2017. Thirty-two of 55 subjects underwent GA and 23 were operated on under LA.

Surgery was managed by the same "expert surgeon", according to the definition given by Yang [7], in order to avoid bias on comparing different surgical hands. All operations were with conventional footplate drilling and insertion of a Teflon prosthesis. Anaesthesia was always administered by the same anaesthesiology team that is specifically trained for otological surgery.

Demographic data including age, sex and information on general pathological and otological history were collected. The type of anaesthesia used during the operation, audiometric findings before and after surgery and possible complications were evaluated.

When LA was performed, an intravenous sedative such as propofol was administered in a single dose with a peak effect in the first two minutes in order to avoid that the patient felt pain during local infiltrations. A mixture of lidocaine 2% and mepivacaine 2% was used to infiltrate the auditory external canal in six different points (two in the retroauricular sulcus and four around the external auditory meatus, at 12-3-6-9 o'clock); optocaine was then used to inject directly the postero-superior scutum area.

Balanced GA was generally the elective technique for GA: the intravenous analgesic drug (remifentanil) was associated with an inhaler anaesthetic (selfuran). Alternatively, total intravenous anaesthesia was performed with a mixture of propofol and remifentanil. During the intervention, cardiovascular monitoring was ensured together with constant evaluation of normocapnia. When administering GA, in order to have a bloodless operating field, the controlled hypotension technique was adopted, keeping the average blood pressure at values around 60 mmHg. When surgery was performed under GA, the airways were secured with a tracheal tube or with a supraglottic airways device (SAD). Irrespective of the device, it is important to have strict control of the airways, because there is a limited access to the patient's head during surgery and the head is not maintained in a neutral position but rather turned to the left or right. Controlled ventilation is necessary to avoid respiratory depression and hypercapnia, and therefore bleeding in the surgical field [6,8,9].

In our experience, since we have always used a SAD, we avoided neuromuscular blocking agents. Other advantages of SAD also include a smooth emergence from anaesthesia with less chance of coughing and a subsequent increase of ear pressure or bleeding. A standard prophylaxis of post-operative nausea and vomiting was usually carried out associating ondansetron and dexamethasone, irrespective of the type of anaesthesia.

Before the operation (within 3 months) and 1 month after surgery, each patient underwent pure tone audiometry (PTA) testing including detection of air-conduction (AC) and bone-conduction (BC) thresholds values at frequencies of 250, 500, 1000, 2000 and 4000 Hz. AC and BC PTA scores in dB HL, before and after surgery, were calculated as follows:

- AC PTA = (250 KHz) + (500 Hz) + (1000 Hz) + (2000 Hz) + (4000 Hz)/5;
- BC PTA = (250 Hz) + (500 Hz) + (1000 Hz) + (2000 Hz) + (4000 Hz)/5.

Air Bone Gap (ABG) values, in dB HL before and after surgery, were calculated for each frequency and then the mean ABG (μABG) in dB HL before and after stapedoplasty was obtained as follows:

- μABG= [(AC 250 Hz - BC 250 Hz) + (AC 500 Hz - BC 500 Hz) + (AC 1000 Hz - BC 1000 Hz) + (AC 2000 Hz - BC 2000 Hz) + (AC 4000 Hz - BC 4000 Hz)]/5

Before surgery's ABG score was subtracted from after surgery's ABG value, the obtained value representing the ABG Closure (ΔABG) after stapedoplasty.

Results were reported according to AAO-HNS Level 1 Guidelines [10]:

1. dB HL of ABG after surgery;
2. dB HL of ΔABG (ABG Closure);
3. Change in the average postoperative threshold (of minimum audibility) of the bone pathway, expressed as dB HL lost (ΔPTA < -5 dB), recovered (ΔPTA > +5 dB) or unchanged (-5 dB < ΔPTA < 5 dB).

All patients were dismissed on the first post-operative day after having verified the absence of general, audiological and vestibular complications. All returned to visit on the third or fourth postoperative day to extract the swab from the ear canal and to perform the first audiometric testing to rule out early serious hearing complications. During this same visit, the presence of vestibular complications was also investigated by bedside vestibular examination.

All patients were given some rules of conduct to be maintained during the 15 days following the intervention, which consisted essentially in avoiding intense physical exertion and large variations in external or internal ear pressure.

In any case, hearing testing was compared with preoperative values performed one month after the operation.

On admission, a satisfaction questionnaire, in use in our hospital and clinically validated for ophthalmological surgery, concerning the global experience with the anaesthetic technique used, was given to all patients. Before undergoing stapedoplasty, both GA and LA patients were asked to fill in the part of the questionnaire relating to the final choice about the anaesthesiological procedure, namely if it was made on their explicit request or upon the advice of the surgeon or the anaesthetist. The questionnaire also inquired about the degree of concern about the type of anaesthesia, using a scale with values from 1 to 5, where such scores correspond to the minimum and the maximum degree of concern, respectively.

After surgery, at the time of discharge and before postoperative audiometric evaluation, LA patients were asked about pain during local anaesthetic injections and to grade it on a visual scale with values from 1 (no pain) to 10 (very severe pain); in addition, patients were asked if they felt pain even during the remainder of the operation and on what occasion and intensity. At the end of the questionnaire, the presence of nausea or vomiting in the postoperative period was also checked in both groups of patients. Based on personal experience with stapes surgery, patients were also asked to grade their overall satisfaction regarding the anaesthesiological method, scoring it from 1 (poor satisfaction) to 10 (high satisfaction).

Shapiro-Wilk's test was used to check for normality of data. We used unpaired two-tailed Student's t-test and Chi-Squared test to compare continuous and discrete variables, respectively, in the two groups (GA and LA). Comparison between pre and post surgery parameters was performed using a paired sample t test. P-values < than 0.05 were regarded as statistically significant. All statistical analyses were performed using Microsoft Excel 2013, SPSS for Apple iOS (v. 23, SPSS Inc., Armonk, NY) and the open source statistical package R, version 3.4.3 (The R Foundation for Statistical Computing, www.r-project.org).

Results

The mean age of patients was 53.87 ± 9.59 years and a range of 34-73 years. The female to male ratio was 1.5:1 (33 females, 60%, and 22 males, 40%). Thirty-two patients (58.2%) underwent GA (17 females, 53.1%, and 15 males, 46.9%) and 23 (41.8%) were submitted to LA (16 females, 69.6%, and 7 males, 30.4%).

No patient had any notable cardiovascular or respiratory risk factors in their clinical history or reported a significant drug allergy. None in the sample had to be subjected to antithrombotic prophylaxis before the operation, while in all cases a "one shot" antibiotic therapy was administered with amoxicillin/clavulanate 2 g intravenously immediately before surgery. In no case did anaesthetic complications occur during the operation for patients in either group.

In no case, during stapedoplasty, were there serious otologic complications (i.e. gusher, trauma on the ossicular chain, suffering of the facial nerve or inner ear). No patient showed severe hearing (profound hearing loss or anacusis) or vestibular (acute vestibulopathy) consequences after surgery.

Table I. AC single frequency absolutes values and AC PTA scores before and after stapedoplasty. 13,2020 (original approval: Oct 15, 2014).

Frequency	AC threshold before (μ ± SD)	AC threshold after (μ ± SD)	P-value	BC threshold before (μ ± SD)	BC threshold after (μ ± SD)	P-value
250 Hz	56.9 ± 14.73	30.6 ± 10.86	< 0.001*	13.82 ± 5.52	13.98 ± 4.83	0.860
500 Hz	59.7 ± 14.15	33.2 ± 12.25	< 0.001*	19.1 ± 8.28	17.2 ± 6.15	0.040*
1000 Hz	56.8 ± 14.47	32.8 ± 10.35	< 0.001*	22.3 ± 8.32	20.45 ± 7.01	0.020*
2000 Hz	54.2 ± 14.65	35.8 ± 13.01	< 0.001*	33.54 ± 11.21	30 ± 11.05	0.010*
4000 Hz	54.9 ± 22.29	47.3 ± 19.07	0.010*	28.54 ± 14.19	34.9 ± 13.82	< 0.001*
8000 Hz	57.8 ± 21.49	57.4 ± 22.08	0.870	-	-	-
PTA	57.1 ± 13.59	39.5 ± 11.49	< 0.001*	23.45 ± 7.28	23.3 ± 6.49	0.854

BC single frequency absolute values and BC PTA scores before and after stapedoplasty.
*μ: means; SD: standard deviation; *: statistically significant data.*

In no case did the surgical diagnosis differ from the clinical diagnosis of otosclerosis established preoperatively.

After surgery, the AC minimal auditory threshold absolute values were improved for all frequencies for all patients in both groups under examination. Such an improvement was statistically significant ($p < 0.05$) at all frequencies except for 8 KHz. In all subjects, the post-operative AC PTA score was also significantly improved, changing from mean pre-operative values of 57.1 ± 13.59 dB to mean postoperative values of 39.5 ± 11.49 dB (mean PTA improvement of 17.6 dB) (Tab. I).

Regression curves for pre- and post-operative AC PTA values are reported in Figure 1.

In all patients in both groups, BC minimal auditory threshold absolute values were also improved after surgery for all frequencies except 250 and 4000 Hz. Actually, such a gain was significant only for 500, 1000 and 2000 Hz, while the worsening was slightly significant only for the 4000 Hz frequency (Tab. I).

Regression curves for pre- and postoperative BC PTA values are represented in Figure 2.

The results of ABG after surgery (range 2.4-46 dB) were divided in three groups (bands): 0-10 dB HL (first band), 11-20 dB HL (second band) and > 20 dB HL (third band) (Fig. 3).

Regarding the GA group, 13 patients (40.6%) belonged to the first band, 15 (46.9%) to the second band and 4 (12.5%) to the third. Among LA patients, 9 (39.1%) fit in the first band, 10 (43.5%) in the second one and 4 (17.4%) in the third (Tab. II).

Taken together, post-surgical ABG values were not significantly different between patients undergoing GA or LA.

In the entire series, mean ABG was 32.9 dB HL before and 13.0 dB HL after surgery. The difference of ABG before and after stapedoplasty was significant for both groups ($p < 0.001$) (Fig. 4).

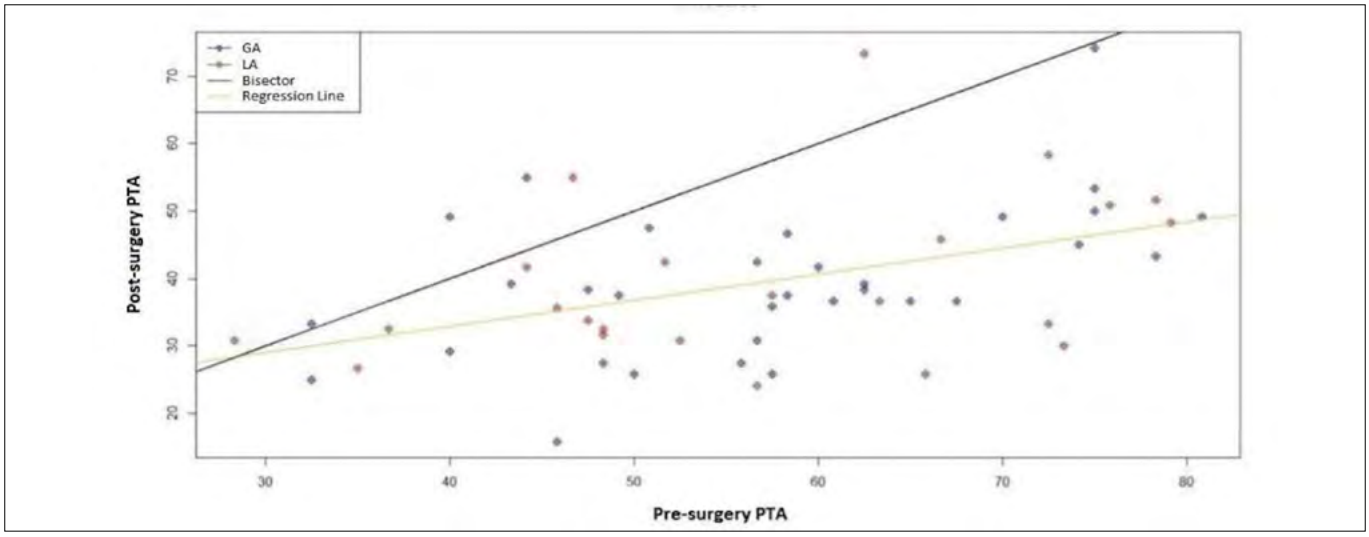

Figure 1. AC PTA values in dB, before (abscissae) and after surgery (ordinates). Density of values is greater under the bisector on the right: higher values were registered for pre-operative PTA. The inclination of the regression line highlights the relationship between the two parameters.

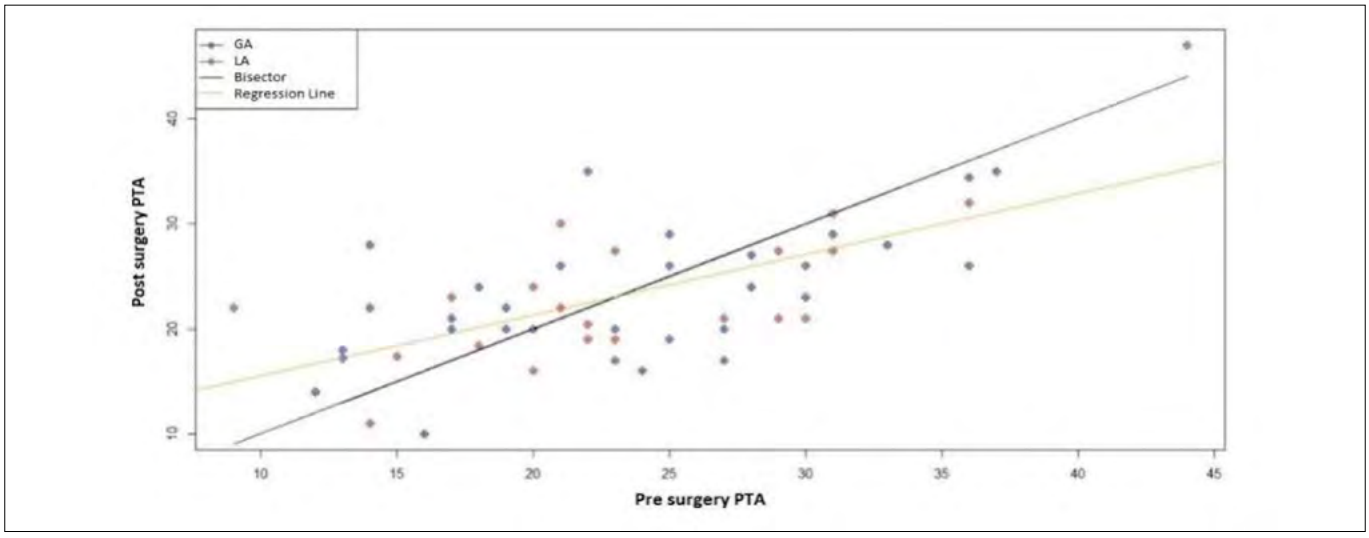

Figure 2. BC PTA values in dB, before (abscissae) and after surgery (ordinates). The concentrated values on the bisector report a weak variation after surgery.

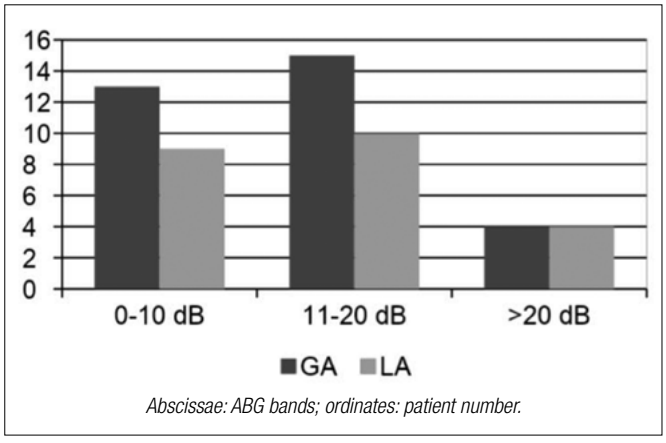

Figure 3. ABG value distribution after surgery in the GA and LA groups.

Table II. After surgery ABG.

ABG after surgery	GA (n = 32)	LA (n = 23)	P-value
0-10 dB	13 (40.6%)	9 (39.1%)	0.261
11-20 dB	15 (46.9%)	10 (43.5%)	
> 20 dB	4 (12.5%)	4 (17.4%)	

ABG: air bone gap; GA: general anaesthesia; LA: local anaesthesia.

ΔABG (ABG Closure) results were divided in bands, as for ABG values, and compared between LA and GA. We found no significant difference between the two anaesthesia groups or the three bands (Tab. III).

After surgery, BC hearing threshold was the third parameter evaluated. By subtracting BC PTA after surgery to BC PTA before surgery, we obtained BC ΔPTA. A worsening BC hearing threshold was found in 16% of the entire series,

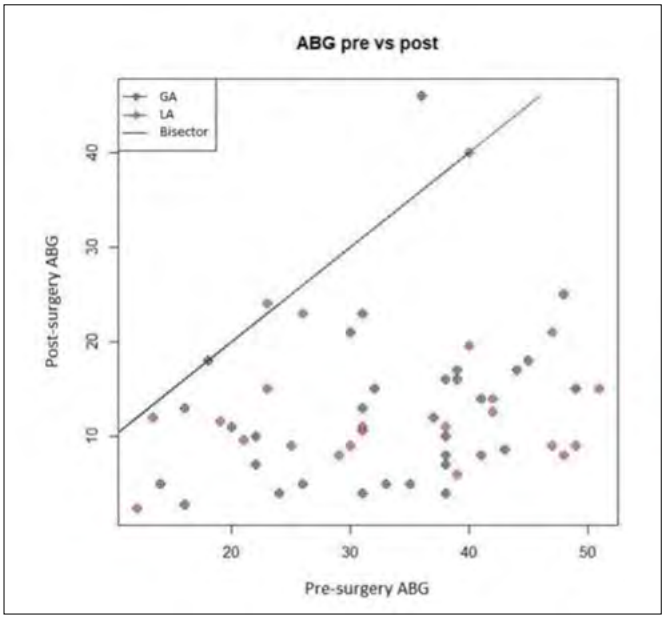

Figure 4. ABG before and after surgery in dB.

Table III. ΔABG (ABG Closure) in dB stratified for bands and anaesthesia groups.

Post-surgical ABG	Mean GA ΔABG	Mean LA ΔABG	P-value
0-10 dB	24.37 dB	25.55 dB	0.800
11-20 dB	19.54 dB	19.79 dB	0.950
> 20 dB	7.5 dB	7 dB	0.960
Tot dB	20.3 dB	19.82 dB	0.890

ABG: air bone gap; GA: general anaesthesia; LA: local anaesthesia.

Table IV. BC ΔPTA after surgery; + ≥ 5 dB = improved by a value greater than or equal to 5 dB; - ≥ 5 dB = worsened by a value greater than or equal to 5 dB: -5 dB < x > +5 dB: substantially unchanged (because changed in negative or positive by a value lower than 5 dB).

BC ΔPTA		n.	PTA (μ ± SD)	P-value
+ ≥ 5 dB	GA	8 (25%)	7.5 ± 1.69	
	LA	3 (13%)	7.67 ± 1.53	0.880
- ≥ 5 dB	GA	5 (15.6%)	-10.25 ± 3.86	
	LA	4 (17.4%)	-9.25 ± 2.87	0.690
± < 5 dB	GA	19 (59.4%)	-0.53 ± 3.22	
	LA	16 (69.6%)	0.85 ± 3.05	0.200

BC: bone conduction; GA: general anaesthesia; LA: local anaesthesia; μ: means; SD: standard deviation.

regardless of the type of anaesthesia. BC hearing threshold was ameliorated by more than 5 dB in 20% and unchanged in the remaining 63.6% of patients. BC ΔPTA values were not significantly different between GA and LA (Tab. IV).

When compared to subjects undergoing LA, patients subjected to GA with BC ΔPTA included in the interval +/-5 dB showed a slightly greater hearing loss on the frequency of 4000 Hz ($p = 0.018$, μGA = -3.12 dB, μLA = -0.33 dB). In 14 patients (25.4%), we observed a sensorineural hearing loss > 15 dB at 4000 Hz.

Regarding the results of the questionnaire in the group of patients operated on under GA, the final decision on the type of anaesthesia was made in 17 of 32 cases (53.1%) at the explicit request of the patient, in 14 cases (43.8%) after the surgeon's advice and in 1 case (3.1%) on the advice of the anaesthetist. The patients' VAS level of concern about GA was 1 point in 16/32 subjects (50%), 2 points in 6/32 (18.8%), 3 points in 5/32 (15.6%), 4 points in 2/32 (6.2%) and 5 points in 3/32 (9.4%), with a mean value of 2.06. After surgery, only 3 of 32 patients (9.4%) reported nausea or vomiting. Overall, the satisfaction score for GA was 10 for 15/32 patients (46.9%), 9 for 10/32 patients (31.3%), 8 in 3/32 cases (9.4%), 7 in 2/32 cases (6.2%) and 6 for the remaining 2 (6.2%). The mean acceptance score for GA was 9.1 and no patient reported satisfaction values below 6.

Among patients undergoing LA, the decision regarding the type of anaesthesia was made by the patient in 11/23 cases (47.8%), after the surgeon's advice in 8/23 (34.8%) and following the interview with the anaesthetist in 4/23 (17.4%). The VAS level of concern for LA was 1 in 19/23 patients (82.6%) and 2 in 4/23 (17.4%), with a mean value of 1.17. During periauricular injections of local anaesthetic, only 4 (17.4%) of 23 patients reported pain. The pain level described by these 4 patients on the VAS scale was 3, 4, 7 and 8 (mean value 5.5). During the surgical procedure, 2/23 subjects (8.7%) reported a pain score of 7 and 8 respectively, and 5/23 (21.7%) referred to discomfort (feeling cold in 1 case, dizziness in 1 patient and worry for noise of the drill in the another 3 cases). In the post-operative period, only 4/23 patients (17.4%) experienced nausea or vomiting. The final satisfaction score for LA was 10 in 8/23 patients (34.8%), 9 in 7/23 (30.4%), 8 in 7/23 (30.4%) and 5 in 1/23 (4.4%), with a mean value of 8.9 points. The comparison between the two groups is reported in Table V.

Three of 55 patients complained of dysgeusia after the operation: one subject, for which during surgery under GA it was necessary to sacrifice the chorda tympani, had this complaint for about one year; the remaining two (one in the GA and one in the LA group) complained of this symptom only for a brief period of time because the nerve was preserved.

None of the patients had prolonged vestibular symptoms after surgery. Upon discharge, 5 patients complained of slight dizziness, although bedside vestibular testing were normal. One patient, suffering from positional vertigo when lying and turning in bed towards the operated side, had signs suggestive of benign paroxysmal positional vertigo. This was resolved by physical therapy and the patient was symptom-free at the first control. Among the 6 patients, 3 underwent GA and 3 LA.

Discussion

The literature that takes into consideration the problem we have faced is scarce and inhomogeneous for the population examined, the objective of the study and the results. In a review of 257 papers comparing hearing outcomes between stape's surgery performed under GA and LA, Wegner found only 3 surveys satisfying eligibility criteria [11]. It was concluded that there was no difference between the two anaesthesiological types in post-operative ABG or in post surgery BC hearing threshold, or post-operative vertigo. However, in one of these 3 studies, Vital found complete hearing loss only among those submitted to GA (3/160 patients, 1.87%) [12]. In another study, Mathews observed that GA allowed better and safer learning for residents [13]. Babighian [14] reviewed 78 revision stapes operations to determine the causes of failure of the first intervention. For such surgery, hearing outcomes were comparable between the two types of anaesthesia. In any case, the author argued that LA should be preferred because it allows better monitoring of the labyrinthine function.

In Wegner's review, only 2 papers reported the description of the anaesthesiological technique. In particular, Mathews used a mix of 1% or 2% lidocaine with 1:100,000 epinephrine augmented by intravenous analgesia and sedation for LA and endotracheal intubation with inhaled and intravenous narcotic agents for GA [13]. Vital described only

Table V. Comparison of questionnaire responses between GA and LA patients.

	Local (n = 23)	General (n = 32)	P-value
Who most influenced the choice of the type of anaesthesia?			
The surgeon	8 (34.8%)	14 (43.8%)	0.188
The anaesthetist	4 (17.4%)	1 (3.1%)	
The patient	11 (47.8%)	17 (53.1%)	
How worried was the patient about having to undergo anaesthesia?			
1	19 (82.6%)	16 (50%)	
2	4 (17.4%)	6 (18.8%)	
3	0	5 (15.6%)	0.051
4	0	2 (6.2%)	
5	0	3 (9.4%)	0.001*
Mean	1.17 ± 0.39	2.06 ± 1.34	
Did you experience pain/discomfort during injection of the local anaesthetic?			
Yes	4 (17.4%)	-	
No	19 (82.6%)	-	-
Did you experience pain/discomfort during the surgery?			
Pain	2 (8.7%)	-	
Discomfort	5 (21.7%)	-	
No	16 (69.6%)	-	-
Did you have postoperative nausea/vomiting?			
Yes	4 (17.4%)	3 (9.4%)	0.379
No	19 (82.6%)	29 (90.6%)	
Overall, how satisfied were you?			
1	0	0	
2	0	0	
3	0	0	0.156
4	0	0	
5	1 (4.4%)	0	
6	0	2 (6.2%)	
7	0	2 (6.2%)	
8	7 (30.4%)	3 (9.4%)	
9	7 (30.4%)	10 (31.3%)	
10	8 (34.8%)	15 (46.9%)	0.554
Mean	8.9 ± 1.2	9.1 ± 1.2	

the method used for LA, which was injection of the external auditory canal with 1% lidocaine with epinephrine 1:100,000 at the bony-cartilaginous junction of the four quadrants [12]. Finally, Loewenthal considered 88 stapedotomies and compared hearing outcomes obtained when performing surgery under GA and LA and by using microdrill and laser techniques for footplate perforation. Outcomes were equally satisfying for both surgical and anaesthetic procedures. However, barely superior outcomes were seen for GA in combination with conventional microdrill [8].

Our cohort is homogeneous for sex and age both absolutely and with respect to the two groups of anaesthesia. Moreover, the sample is in line with what reported in the literature about the demographic characteristics of otosclerosis at the age suitable for stapedoplasty.

Otosclerosis was the only confirmed diagnosis, also surgically. Hearing outcomes after stapes surgery have been globally successful for all patients neither a significant deterioration of hearing nor anacusis.

The absolute AC minimal auditory threshold as well as pre and postoperative AC PTA values significantly improved after surgery in both anaesthesiological groups.

Similarly, by comparing the overall pre and post surgical BC scores between groups, it can be observed that in most cases (83.6%) there was improvement or stability. The only frequency at which a greater worsening was noted, only for GA, was 4000 Hz. On the other hand, this difference is only weakly significant and would need to be confirmed in a larger sample.

The postoperative ABG value was also very restrained (< 20 dB) regardless of the type of anaesthesia chosen. In reality, mean ABG after surgery was 13 dB HL, a value that is very close to that of 10 dB HL, the best value recommended in the literature as the desirable outcome following stapes surgery [10].

Also considering the ABG recovery bands, it can be seen not only that most of patients belonged to the better recovery bands (therefore with smaller ABG and greater ΔABG),

but also that the percentages were equally distributed in the two anaesthetic groups.

From an otosurgical point of view, conducting stapedoplasty under LA, and thus having the patient conscious, has the undoubted advantage of being able to test the patient's subjective hearing after the insertion of the prosthesis. At that time, an awake patient should also report the appearance of vertigo as an expression of a labyrinthine mechanical insult that can be attributed to an excessive length of the piston or to its malpositioning. The lack of subjective hearing recovery, even partial, or the occurrence of vestibular events, may allow the surgeon to check the fit of the prosthesis in order to avoid disturbances or lesions. LA is a non-invasive procedure whose effect is quickly disposed after surgery and in which the drugs used do not usually cause side effects. Moreover, LA does not have the risk of provoking mechanical trauma on the aero-digestive tracts that are capable of provoking voice or swallowing disorders. The use of loco-regional anaesthetic drugs allows the application of this type of anaesthesia even in subjects with significant cardio-circulatory comorbidities and in polytherapy.

On the other hand, LA has some limitations especially related to the difficulty for the patient in maintaining the same position for a long time and in avoiding sudden movements that could be dangerous for the delicate surgical manoeuvers. In addition, LA necessitates a cooperative and relaxed patient and it is thus not recommended for anxious people or for those who have neurological, pneumological or orthopaedic disorders that can limit their compliance to maintain a forced position. The limited duration of the effects of the local anaesthetics, however sometimes does not allow the complete covering of a possible extension of the surgical times in case of complications.

The main advantage of general anaesthesia is to allow controlled management of blood pressure values to limit bleeding in the operating field. In fact, during otosurgery, and especially in stapedoplasty, it is essential to have a clean and bloodless operating field to clearly see landmarks and small middle ear structures, and to avoid aspirating the perilymph from the stapedotomy along with blood. Controlled hypotension is achieved by inhalation anaesthetics such as isoflurane and sevoflurane. When used in moderate concentrations the latter drugs can have a vasodilating effect thus turning down blood pressure levels and resulting in a neuroprotective effect. The hypotensive effect of sevoflurane does not act on cochlear blood flow. At higher concentrations, these anaesthetic agents have a vasodilator effect that can increase cerebral flow and worsen cerebral autoregulation [6,15,16].

Controlling the airways, by means of an endotracheal tube or of a SAD, may be important because during ear surgery there is a limited access to the patient's head since it is always turned sideways. Obviously, GA ensures patient's immobility and is comfortable for patients with anxiety, pain and noise discomfort. Due to the these aspects, unlike LA, GA is also more suitable for residents to acquire practical skills.

Until recently, one of the most significant disadvantages of GA has been to require invasive ventilation manoeuvers and heavy drugs. Nevertheless, the most modern otosurgical GA techniques involve the insertion of a SAD in place of an endotracheal device, also avoiding the risk of injury to surrounding tissues. Using SAD, it is possible to not use muscle relaxants and to employ lower amounts of anaesthetic drugs: this considerably shortens the awakening phase after the operation, making it smoother with less chances of coughing and thus the occurrence of early otologic complications (bleeding, vertigo, hearing loss, prosthesis dislocation). Secondly, during GA the patient is unconscious and, therefore, it is not possible to check subjective hearing performance at the end of the surgical procedure.

In our experience, neither of the two anaesthesiological techniques had ever given rise to serious medical complications, either during or after surgery.

In most cases in our series, the choice of the type of anaesthesia was left as a free choice to the patient, since for these subjects there were no clinical reasons to indicate one over the other. This was the reason why these patients started from an initial condition of serenity and availability. Only for a small number of patients was the decision made by the anaesthetist and/or by the surgeon because of clinical contraindications to GA or due to anatomo-functional or psychological conditions.

The majority of patients in both groups underwent the chosen anaesthesia with a minimum level of concern, further confirming the importance of the patient's independent choice and/or the relationship of trust that must be created between the surgeon and the patient in view of the operation.

Nausea and/or vomiting were infrequent post-operative events in both GA and LA patients. This confirms the opportunity to use antiemetic drugs to control autonomic symptoms due to platinotomy and prosthesis insertion.

Only a small fraction of LA patients reported pain during local anaesthetic injections and/or during the entire surgical procedure. This important result is achieved thanks to the effectiveness of sedation and pain relief therapy which is always used in this type of anaesthesia. This aspect is of fundamental importance in the outcomes of stapedoplasty, since the lowest possible perception of pain allows the patient to remain immobile during the procedure and there-

fore not to invalidate the intervention with sudden movements related to painful symptoms.
In the few cases of discomfort recorded, the most frequent was nuisance to the noise of the drill. However, this never led the patient to make rash movements.
All patients completed the satisfaction questionnaire on the day of discharge even before undergoing the first medication and the first audiogram, on the third-fourth day after surgery. We chose to deliver the questionnaire at that time to prevent the quality of functional results from influencing the patient's responses. Patients in both groups reported a high degree of satisfaction regarding the anaesthetic treatment. Once the quantitative results were obtained, the better the recovery, the greater the patient's satisfaction expressed in the questionnaire.
The latter aspects can be interpreted in the sense that a calm and grateful attitude toward the assistance of the physicians' team can also positively influence both qualitative and quantitative functional recovery after stapedoplasty.
Patients who underwent GA reported a significantly greater degree of concern than those who knew they should only receive LA.
Therefore, the overall hearing outcomes that we found in our cohort are superimposable whether the patient undergoes stapedoplasty in GA or in LA, and therefore there is not the need to choose one or the other method for strictly audiological reasons.
Considering the strengths and weaknesses of one or the other anaesthesiologic technique, we observed that these are equivalent and that even a technique considered invasive until some time ago cannot be considered as such at present, thanks to the airway control devices that makes the procedure only mildly traumatic, and to the use of drugs that are short-lasting.
Finally, patient satisfaction with one or the other type of anaesthesia was the same even if, initially, patients who had to undergo GA were a somewhat more worried.

Conclusions

Stapedoplasty is a safe surgical procedure with considerable benefits on auditory function when the correct indications exist and if it is carried out by highly trained surgeons, independently from the type of anaesthesia.
Our study confirms the limited literature observations that hearing results following stapedoplasty do not differ if surgery is performed in GA or LA. One anaesthetic technique is not to be preferred, even when considering the relative advantages and limitations. With the present analysis, we also wanted to examine the subjective aspects of the patient: evaluation of the degree of satisfaction regarding the type of anaesthesia received, no differences emerged between the two techniques. It can be observed that the choice of the type of anaesthesia, pre-eminently performed by the patient, can introduce a bias in subsequent judgment of the satisfaction of the anaesthesia itself. In reality, in some cases the choice was also made by the audiologist or the anaesthetist, and therefore not entirely free from bias. However, it might be interesting in the future to improve the weight of our conclusions by carrying out double-blind studies and matching patients randomly divided by anaesthetic group.
Therefore, the choice of the type of anaesthesia can objectively continue to be guided on the basis of medical or surgical needs or the patient preference. Nevertheless, working in a university clinical facility and as the modern techniques of GA are now at low risk and very comfortable for the patient, one can lean towards the latter anaesthesiological technique in order to facilitate the training of physicians in specialist training and expand the surgical experience of specialists.

Conflict of interest statement

The authors declare no conflict of interest.

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Author contributions

BG: conceived, designed and wrote the study, elaborated data and interpreted their meaning. FP: designed and wrote the study, contributed to data collection and clinical interpretation. CA: contributed to work's conception and design, performed and supervised anaestethic procedures, contributed to data collection. DS: contributed to data collection and elaboration. PV: performed operations and contributed to data collection. AS: contributed to data collection and elaboration. CC: performed statistical analysis, contributed to data elaboration. CB: contributed to statistical analysis, data elaboration and clinical interpretation. RP: conceived the study, contributed to wrote the paper, data collection and clinical interpretation.

Ethical consideration

This study was approved by the Institutional Review Board for Human Subjects Research for AOU Careggi. Subjects gave informed consent prior to participation (approval numbe 19751/055).
The research was conducted ethically, with all study procedures being performed in accordance with the require-

ments of the World Medical Association's Declaration of Helsinki.

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