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Short-term audiological outcomes of stapedotomy: microdrill at low revolutions versus manual perforator to perform a small footplate fenestra. A prospective observational study

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ABSTRACT:

Introduction: Stapedotomy is currently the surgical technique of choice for treating otosclerosis. Despite this, there is no agreement about the best technique to perform a small fenestra footplate, therefore multiple procedures have been proposed. The aim of this study was to investigate the hearing outcomes of microdrill and manual perforator

Material and Methods: An observational prospective study was carried out on patients who underwent stapedotomy. We analyzed the hearing threshold in two groups of patients according to the way the fenestra footplate was realized by microdrill or manual perforator.

Results: A total of 113 patients were evaluated. Postoperative hearing gain of the microdrill group was 23.29 (18.58) dB HL 95% CI (18.40–28.18), while in the manual perforator group, it was 22.67 (12.91) dB HL 95% CI (19.07–26.26). Both groups were statistically significant. Postoperative bone conductive hearing threshold at the frequencies of 0.5, 1 and 2 KHz and postoperative air conductive hearing threshold at the frequencies of 2 and 4 KHz showed statistically significant differences in the manual perforator group. The closure of air-bone gap was higher in the microdrill group with statistically significant differences.

Conclusion: Both manual perforator and microdrill have good hearing outcomes at six months after surgery. The manual perforator has better audiological outcomes than microdrill. Hence, the manual perforator is a safe technique and can be used in centers that do not have other methods to make the small fenestra.

KEYWORDS: audiology, hearing loss, otosclerosis, stapedectomies, stapes surgery

ABBREVIATIONS

ABG – air-bone gap
ACT – air conduction threshold
BCT – bone conduction threshold
EAC – external auditory canal
MD – microdrill
MMP – microperforator
PTA – pure-tone audiometry
PTA – PTA average
SO – stapedotomy

INTRODUCTION

Since the first surgery for otosclerosis performed in the mid-20th century by Shea [1], it has remained the best method for hearing improvement in the majority of patients with this condition. However, nowadays the tendency is to move away from classical stapedectomy [2]. Considering stapedotomy (SO) as the technique of choice at the present time [3, 4], audiological studies have shown that SO is associated with better results than stapedectomy as well as fewer complications [5].

The performance of small fenestration in the stapes footplate can be carried out in different ways, either with a microdrill, laser, manual perforators or even combining these techniques [6]. The use of laser technology seems to have prevailed over the others. Different types of laser systems, such as KTP, argon, erbium, YAG and CO2 lasers, have been assessed for stapes footplate perforation [7].

However, none of them have demonstrated to be superior to the others in audiological results. In addition, they are not exempt from complications such as heat or pressure trauma [8]. Some centers cannot access the laser technique, and hence the use of microdrills or manual perforator is still an option when performing the fenestra. These methods can be considered when we deal with the tympanic segment of facial nerve dehiscence, in which case the laser cannot be used [9].

Nonetheless, the manual perforator has been considered a more traumatic method to perform the small fenestra in the stapes footplate [10] compared to microdrilling, although the second is more likely to cause acoustic trauma [11]. For that reason, the aim of the study was to evaluate the short-term audiological outcomes in patients who underwent SO due to otosclerosis through the comparison of two methods – low revolution microdrill (MD) versus manual microperforator (MMP).

MATERIALS AND METHODS

An observational, prospective, single-center study was carried out in patients underwent SO surgery at a tertiary referral hospital between December 2015 and May 2019. The inclusion criteria were: adult patients (age over 18) with a clinical diagnosis of otosclerosis confirmed by exploratory tympanotomy. The exclusion criteria were: pediatric patients, adult patients who underwent total or partial stapedectomy, patients in whom the plate graft was used, and patients without fixated footplate during exploratory tympanotomy. Patients who met the criteria were divided into two groups according to the technique for carrying out the small fenestra. In group A the small fenestra was performed by microdrilling and in group B it was made with manual perforators. In both groups, pure-tone audiometry (PTA) was performed at 0.25, 0.5, 1, 2, 4 and 8 kHz for air conduction threshold (ACT) and 0.25, 0.5, 1, 2 and 4 kHz for bone conduction threshold (BCT). PTA was measured prior to surgery and six months after operation. The PTA average (PTAa) for air conductive hearing threshold was calculated using 0.25, 0.5, 1, 2 and 4 kHz. The air-bone gap (ABG) was calculated with the average 0.25, 0.5, 1, 2 and 4 kHz between the BC and the AC at preoperative and postoperative periods.

All surgeries were performed under general anesthesia through the external auditory canal (EAC). A surgical microscope Leica M525 F20 (Leica Microsystems®, Wetzlar, Deutschland) was used. Prior to the incision, a solution of mepivacaine 2% + epinefrin (1:100.000) was subperiosteally infiltrated into the superior ear canal wall. Then, an ear canal skin incision was made allowing for elevation of the tympanomeatal flap to access the middle ear. To visualize the footplate, the posterior external auditory canal bone was removed with a curette. Once the whole chain of ossicles was displayed, the fixing of the staple was checked. A joint knife was used to separate the incudostapedial joint and the stapedial tendon was cut. The crura were fractured and removed before perforating the footplate.

In the group of patients in which the small fenestra was made by microdrill we used a 0.8 mm diameter diamond drill burr (Skeeter®, Otologic Drill System, Medtronic Xomed, Jacksonville, FL, USA) with a speed of rotation of 1200 rpm. In the manual perforator group the fenestra had a 0.8 mm diameter. The prosthesis used was a Fluoroplastic piston of 0.6 mm diameter in all patients (Causse Loop Piston Fluoroplastic, Medtronic Xomed, Jacksonville, FL, USA). In all cases, we measured the distance from the top of the incus to the thin footplate in order to choose the length of the piston. We did not use any sealing material when performing stapedotomy.

Once the prosthesis was in place, the tympanomeatal flap was rebuttoned and the external auditory canal was packed with Gelfoam. All patients were cited in the clinic one week after surgery to rule out complications. They were prescribed ear drops to clean the Gelfoam residue. Subsequently, patients were checked at one month, three months and six months after the surgery. Postoperative PTA was carried out in the last visit.

This study was approved by the ethics Ethics Committee of our hospital (JPGAOST2019). Informed consent was obtained from all patients who participated in the study.

Data were analyzed using the statistical package IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp. Categorical variables are expressed as frequencies and percentages. The Kolmogorov–Smirnov test for normality was used. Analysis of continuous variables was performed by Student's t-test to compare dependet samples and Mann-Whitney U test was used to compare independent samples. A p value < 0.05 was considered statistically significant.

RESULTS

One hundred-thirteen patients met the inclusion criteria; 44 (38.9%) were male and 69 (61.1%) were female, the mean age was 45.94 +(-) 10.91 years (min: 24/max: 77). The left ear was the most common 62 (54.9%).

According to the type of surgical technique, the small fenestra of the footplate was performed using a microdrill in 59 (52.2%) cases and the manual perforator in 54 (47.8%) cases. In 102 cases (90.3%), the prothesis size was 0.6 x 4.5 mm and in 11 cases (9.7%) it was 0.6 x 4 mm.

Preoperative PTAa was 66.17 (18.69) dB HL with a p-value of 0.009 in the MD group and 57.92 (13.11) dB HL with a p-value of 0.008 in the MP group. There were no significant differences between the two preoperative PTAa groups with a p-value of 0.051. The remaining data of the preoperative pure-tone audiometry by frequencies according to surgical technique are shown in Tab. I. Postperative PTAa was 42.57 (22.52) dB HL in the MD group and 35 (17) dB HL in the MP group. Paired samples t-tests showed a hearing gain of 23.29 (18.58) dB HL 95% CI (18.40–28.18) in the MD group with a p-value < 0.001 and a hearing gain of 22.67 (12.91) dB HL 95% CI (19.07–26.26) in the MP group with a p-value < 0.001. Besides, postoperative PTA analysis found statistically significant differences with decreasing intensity in bone

Tab. I. Preoperative PTA according to surgical technique (BCT – bone conductive threshold; ACT – air conductive threshold).

	Mean BCT preoperative dB HL (SD)			Mean ACT preoperative dB HL (SD)		
Frequency (Hz)	Microdrill n = 59	Manual perforator n = 54	p-value	Microdrill n = 59	Manual perforator n = 54	p-value
250	20.78 (11.57)	17.12 (8.36)	0,110	70.86 (18.45)	64.23 (13,55)	0,085
500	31.21 (19.11)	26.44 (11.12)	0,439	69.66 (18.86)	63.56 (12,32)	0,159
1000	34.66 (19.84)	26.54 (10.63)	0,066	66.12 (19.01)	57.50 (13.08)	0,016*
2000	43.79 (20.92)	36.25 (12.59)	0,070	62.24 (20.56)	50.58 (16.49)	0,001*
4000	35.78 (20.47)	27.40 (15.82)	0,033	61.98 (24,58)	53.75 (19,19)	0,090
8000	-	-	-	65.43 (27,74)	57.21 (22,65)	0,203

Tab. II. Postoperative PTA according to surgical technique (BCT – bone conductive threshold; ACT – air conductive threshold)

	Mean BCT postoperative dB HL (SD)			Mean ACT postoperative dB HL (SD)		
Frequency (Hz)	Microdrill n = 59	Manual perforator n = 54	p-value	Microdrill n = 59	Manual perforator n = 54	p-value
250	20.85 (12.28)	15.93 (9.95)	0,054	41,27 (23,60)	36,30 (18,45)	0,255
500	29.58 (14.80)	24.17 (10.80)	0,022	41,61 (22,69)	36,02 (16,72)	0,203
1000	30.25 (16.69)	22.13 (11.39)	0,005	40,17 (23,99)	33,33 (17,64)	0,152
2000	35.09 (17.63)	26.48 (13.34)	0,009	40,34 (23,72)	31,02 (17,54)	0,036
4000	36.61 (22.02)	27.69 (16.24)	0,071	49,49 (27,17)	38,33 (21,41)	0,031
8000	-	-	-	58,93 (25,09)	52,41 (26,45)	0,132

Tab. III. Paired samples t-tests by technique.

	Pre and postoperative air conductive hearing dB HL (SD)					
	Microdrill n = 59			Manual perforator n = 54		
Frequency (Hz)	Mean (SD)	95% CI	P	Mean (SD)	95% CI	P
250	29.39 (22.92)	23.36–35.42	0,000	27.59 (14.73)	23.49–31.69	0,000
500	27.75 (19.38)	22.66–32.85	0,000	27.30 (14.12)	23.37–31.20	0,000
1000	25.60 (19.37)	20.50–30.69	0,000	23.94 (14.53)	19.89–27.98	0,000
2000	21.55 (18.78)	16.61–26.49	0,000	19.51 (15.50)	15.20–23.83	0,000
4000	12.15 (21.40)	6.52–17.78	0,000	15 (17.68)	10.02–19.92	0,000
8000	4.18 (24.49)	-2.43–10.80	0,211	5.19 (20.72)	-0.52–10.96	0,077

Tab. IV. Preoperative and postoperative ABG according to surgical technique (ABG – air-bone gap).

	Mean ABG dB HL (SD)		
	Microdrill n = 59	Manual perforator n = 54	p-value
Preoperative	32.31 (9,18)	33.10 (8.42)	0,641
Postoperative	14.26 (11.01)	19.60 (15.83)	0,038*

Tab. V. Hearing Gain by technique.

	Mean hearing gain dB HL (SD)		
Frequency (Hz)	Microdrill n = 59	Manual perforator n = 54	p-value
250	29.39 (22.92)	27.59 (14.17)	0,007
500	27.75 (19.38)	27.30 (14.12)	0,032
1000	25.60 (19.37)	23.94 (14.52)	0,169
2000	21.55 (18.78)	19.51 (15.50)	0,158
4000	12.15 (21.40)	15 (17.68)	0,094

differences with decreasing intensity in bone conductive hearing threshold (BCT) at frequencies of 0.5, 1 and 2 KHz in favor of the MP. For the postoperative air conductive hearing threshold (ACT), PTA analysis showed statistically significant differences in the frequencies of 2 and 4 KHz in favor of the manual perforator (Tab. II.). Paired samples t-tests were used to analyze air conductive hearing data from each technique. The results were that both techniques improved air gain, except at the 8.000 Hz frequency (Tab. III.).

The mean preoperative of ABG in the MD group was 32.31 +(-) 9.18 dB and in the MP group it was 33.10 +(-) 8.42 dB HL. After surgery the mean ABG in the MD group was 14.26 +(-) 11.01 dB HL and 19.60 +(-) 15.83 dB HL in the MP group, with a significant difference between both groups with p = 0.038. ABG closure was higher in the group of patients where the MD was used (Tab. IV.). The analysis of hearing gain showed a higher value in the MD group, revealing statistically significant differences only in the 0.25 and 0.5 KHz frequencies.

DISCUSSION

Different small fenestra perforation techniques have been described since the introduction of stapedotomy. The greatest number of publications compare results achieved by laser technique with respect to other techniques. However, the laser has not yet demonstrated a clear advantage over other platinum drilling techniques [8]. The use of the manual perforator is still valid as a method for performing SO with good hearing results without greater vestibular complications than other methods such as laser [15].

We decided to use a fluoroplastic piston of 0.6 mm in all cases because they are easy to fit, economical, biocompatible and stable in the long term. In addition, using the same type of piston in both groups would avoid bias in our research.

The piston diameter was 0.6 mm, therefore we considered it necessary to make a slightly larger small fenestra of the footplate for better piston molding. Wegner et al. [12] in a systematic review found no difference between a 0.4-mm-diameter piston and a 0.6-mm-diameter piston. Besides, in all cases we measured the distance from the top of the incus to the thin footplate. The measurement from the outer portion of the incus to the footplate is usually 4.5 mm but may vary from 3.5 to 5.5 mm [13] as we could find in our study data.

We found a decrease in the audiometric thresholds with statistically significant differences in the bone conduction thresholds at frequencies of 0.5, 1 and 2 KHz in the group in which the plate was perforated with a microdrill. This deterioration of the bone conduction threshold in patients where the microdrill was used could correspond to some degree of acoustic trauma, either from the sound of the burr rotation [14], overheating of the drill [15] or movement of perilymph fluids. Other authors such as Gjuric et al. [16] found no differences in the bone conduction threshold regardless of the technique, hence so if there was acoustic trauma it would be similar in both techniques. Somer et al. [17] found that bone conduction was affected in the beginning, but it was able to recover over the weeks. Our study did not analyze the evolution of this phenomenon over time, so we did not rule out that an improvement in the bone threshold could occur over time.

In the analysis of the air conduction threshold we found statistically significant differences in the frequencies of 2 and 4 kHz, presenting a better average with the MD. This may be an indirect sign of high frequencies being affected by the MD. Even though both techniques significantly improve air conduction except in the 8 KHz frequencies, this loss in extended acute frequencies can be partially recovered although it will remain beyond 12 months in most patients [13].

Regarding closure of the ABG, we observed a greater closure in the MD group, being superior in the lower frequencies. Although it was indicative of surgical success [18], we think that the closure may be due to the involvement of the high bone conduction at low frequencies, which is where there is the highest preoperative ABG. Besides, we observed that hearing gain was similar in both groups with merely a minor significant difference in low frequencies in favor of the (MD).

The present study determines that both techniques are useful to make a small fenestra and achieve hearing improvement 6 months after surgery. Nonetheless, the results obtained in the MP group appear safer and slightly superior to the MD technique. Even so, our study presents limitations such as short-term follow-up of patients and the performance of surgery by different surgeons. However, we would like to continue to collect data about hearing outcomes in these patients and include long-term results in our database for future research.

CONCLUSION

Both the microdrill as well as manual perforators allowed to achieve significant hearing improvement. The manual perforator is a safe method for making the small fenestra of the footplate. This may be of use in centers that do not have access to laser or microdrill. We believe that it is necessary to conduct more research to compare the differences between the two techniques.

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