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Comparative Study between Piezosurgery and Conventional Surgical Method in the Treatment of Otosclerosis

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Abstract

Aim: This work aimed to compare Piezosurgery stapedotomy with the conventional approach in the management of otosclerosis in terms of intraoperative time, postoperative complications, and air-bone gap improvement.

Methods: This randomized controlled clinical trial was conducted in Beni-Suef University hospital from August 2021 to June 2022 according to the ethical considerations of the local institutional review board. It included 40 patients suffering from hearing loss due to otosclerosis, diagnosed based on clinical features, audiometry and impedancemetry. Patients were randomly divided into two groups: group P underwent stapedotomy by the Piezosurgery medical device, and group C underwent stapedotomy by the conventional method.

Results: Both groups were matched regarding their baseline characteristics. The air bone gap (ABG) postoperatively reached a mean of 7.7±6.7 dB (median=6) in group P and 7.6±6.8 (median=7) dB in group C, with no significant difference. The percentage of reduction of A-B gap was 76.21%±17.6% in group P (Piezosurgery), while group C (conventional) was 75.8% ±18.7%, with no significant difference. The operative time in group P was (35.5± 4.5) minutes vs (29.7 ±3.2) minutes in group C, with a significant difference. Regarding the complication, there was no significant difference between Piezosurgery and conventional surgery regarding intraoperative and postoperative complications (P-value > 0.05).

Conclusion: This work concluded no difference between conventional techniques and Piezosurgery in (ABG) reduction postoperatively, intraoperative, and postoperative complications, only surgical time was longer in Piezosurgery group and was statistically significant.

Keywords: Piezosurgery, Otosclerosis, Air bone gap.

Introduction

Hearing impairment and loss may occur due to otosclerosis that is characterized by progressive remodeling of the temporal bone at its otic capsule.[1] This disease affects from 0.5% to 1.5% of the population.[2] Otosclerosis is a multifactorial disorder

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related to genetic predisposition and environmental factors.[3] The most commonly affected age is the middle age group especially twenties and thirties with female predominance than males.[4]

Otosclerosis surgical management is an effective and safe method, with good results in improving hearing minimal complications and undesired outcomes.[5] With the improvement of surgery over time, stapedotomy fenestration procedures have changed from using micro-instruments to micro-drills and then laser.[6] However, it is a delicate and difficult surgery; the operation may fail if the prosthetic device was displaced, erosion of the incus bone and with sustained head trauma.[7]The Piezosurgery device is widely used in maxillofacial, oral surgeries, in neuro and orthopedic surgeries.[8]

Piezosurgery otologic surgery allows a fast and feasible intraoperative procedure. It gives a safe and accurate cut, even in unfeasible sites. It offers perfect intraoperative visibility with less blood and without damage to soft tissues such as the blood vessels, nerves and fascia. Its two peristaltic pumps and handpieces allow the completion of surgery without interruptions.[9]

From the point of view of the advantage of Piezosurgery stapedotomy, this work was to compare Piezosurgery stapedotomy with the conventional method in the management of otosclerosis in terms of intraoperative time, postoperative complications, and air bone gap improvement.

Materials and Methods

This randomized controlled clinical trial was conducted in Beni-Suef University hospital from August 2021 to June 2022, including 40 patients suffering from hearing loss due to otosclerosis, diagnosed based on the clinical features, audiometry and impedancemetry.

Patients were allocated randomly into two groups: group P and group C (20 patients in each group) by online GraphPad randomizer as follows:

Group P of patients (20 patients) underwent a stapedotomy operation through the Piezosurgery medical device.

Group C of patients (20 patients) underwent a stapedotomy operation by the conventional surgical method.

Inclusion criteria:

Patients fit for general anaesthesia, aged from 20 to 50 years, from both sexes, with air-bone gap not lower than 20 dB, and tympanometry type A or As with absent acoustic reflex (AR) and pure conductive hearing loss or mixed but with good cochlear function were eligible to be included in the study.

Exclusion criteria:

Patient with poor general health, any problems affecting their balance as fluctuating hearing loss or active endolymphatic hydrops, active infection in the middle or external ear, tympanic membrane perforation, air-bone gap less than 20 dB, younger age less than 20 years or older age more than 50 years, pregnant women, an anomaly of the inner ear, the affected ear is the only hearing ear, type B, Ad or no seal tympanometry, pure sensory-neural hearing loss or mixed hearing loss with poor cochlear function, revision surgery, active otosclerosis were excluded.

Preoperative assessment:

Obtaining full history, complete otorhinolaryngological examination in addition to audiological assessment were performed to all patients. Audiometry and impedancemetry used GSI 33, Grason Stadler, as an Immitancemeter, Madsen Orbiter 922 version 2 as a clinical audiometer, and a sound-treated room were used. In addition to routine pre-operative investigations like complete blood count, random glucose level, bleeding profile, liver function and renal function tests.

Surgical technique:

Operations were done with hypotensive general anesthesia by the same surgeon as follows:

In the first Group (P):

1. Patients were placed in a supine position. The Transcanal approach was used. Then an injection of a vasoconstrictive solution (1ml of saline adrenaline (1:200,000)) in the posterosuperior meatal wall was done.

2. Then, a horizontal incision was performed about 6 mm from the tympanic membrane (TM).
3. A tympano-meatal flap was elevated in the external auditory canal (EAC) posterior region.
4. Exposure of incudostapedial joint and stapedial footplate using Piezosurgery medical device where we used the insert (MP3-a30). The device uses ultrasonic waves at low frequency (24.7-29.5 kHz). The machine is programmed depending on the bone cut density and its applied power is modulated between 2.8 and 16 W. The micro-vibrations generated by piezoelectric handpiece cause linear vibration by the inserts between 60 and 210 µm. The two peristaltic pumps provided with the device are connected to control units and used for irrigation. The speed was adjusted at the lowest level.
5. Then, the mobility of the ossicular chain was tested to check for stapedial fixation.
6. A hole was performed in the stapedial footplate using a Piezosurgery medical device where we used the insert (MD2-08).
7. Placing the Teflon piston prosthesis of 0.6 mm diameter in this hole was performed to become fit around the incus bone at its long process.
8. Cutting the tendon of the stapedius bone using micro-scissors and separating the incudostapedial joint.
9. Carefully fracturing and removing the stapes superstructure were performed.
10. To seal the stapedial footplate, small pieces of fat taken from the ear lobule might be placed.
11. Repositioning the tympanomeatal flap was done, then insertion of Gelfoam® in the (EAC).

12. In the second group (C):

Steps 1, 2 & 3 were the same as in group P.

4- Exposure of incudostapedial joint and stapedial footplate using the conventional surgical curette.

5- Mobility of the ossicular chain was assessed to check for stapedial fixation.

6- A hole was performed in the stapedial footplate using Larkin perforator.

Steps 7, 8, 9, 10& 11 were the same as group P.

Intraoperative and postoperative follow up and assessment:

For all patients: operative duration, operative complications, postoperative complications, and the hearing outcomes were recorded to be compared between both groups. Audiological evaluation as audiometry and impedancemetry was done 2 months postoperative and compared with preoperative.

Statistical analysis of data:

At the end of this study, data were statistically analyzed and presented using mean ± standard deviation (± SD) for scale variables, numbers, and percentages for categorical variables. All statistical calculations were made using computer programs IBM® SPSS® Statistics Version 25. P-values less than 0.05 were considered statistically significant. Scale variables were tested for normality using the Shapiro Wilk test. Normally distributed variables were compared by independent T-test between both groups. At the same time, a non-parametric Mann Whitney U test was used to compare not normally distributed variables. Paired T-test was used to follow the normally distributed A-B gap. The Wilcoxon Signed Rank test was used to follow up on non-parametric ones. The chi-Squared test was used to compare both groups regarding categorical variables. The percentage of reduction of AB gap was calculated as follows; [(preoperative air bone gap – postoperative air bone gap)/ preoperative air bone gap] x 100.

Ethical Considerations:

The protocol of this research had been revised by the research ethics committee of faculty of Medicine of Beni-Suef University. An informed consent was obtained from all patients and all data were anonymous and confidential. The study was conducted according to the ethical principles of Helsinki.

Results

In group P, the average age of patients is (32±5.7) ranging from 25 to 45 years and mostly females 12 (60%). While in group C, there are 7 males (35%) and 13 females (65%), with average age (32±5.9) ranging from 23 to 46 years. No statistically significant differences were seen between both groups (P-value >0.05) regarding their age and gender.

The main preoperative presenting symptoms were deafness in all patients in both groups. Only 5 patients (25%) in the group (P) and 4 patients (20%) in the group (C) complained of tinnitus with no significant difference regarding presentation in both groups, while no recorded cases suffered from vertigo.

In preoperative pure tone audiogram (PTA), the pre-operative mean air conduction (AC) in group P was 47.8±4.2 dB and in groupC was 45.6±5.1 dB.The mean bone conduction (BC) in group P was 16.5±3.4 and 15.3±2.9 dB in group C. The average postoperative AB gap was 31.4±4.4 dB in group P and 30.3±4.6 dB in group C (Table 1).

Two months after surgery, PTA revealed that; the mean AC in group P was 25.1±2.8 dB, and in group C was 23.8±3.1 dB, while the average BC in group P was 17.4±4.9 dB and in group C was 16.2±3.5 dB. The average postoperative AB gap was 7.7±6.7 dB (median=6) in group P and 7.6±6.8 (median=7) dB in group C (Table 1).

A-B gap percentage of reduction (postoperative gap as compared with the original pre-operative gap) was slightly higher among the Piezosurgery as compared with conventional surgery. However, this difference was not significant statistically (P-value=0.820), and percentage of reduction of A-B gap among group P (Piezosurgery) was ranged from 5.4% to 88.89% with an average A-B reduction of 76.21%±17.6%, while for group C (conventional) the percentage of A-B gap reduction was ranged from 0% to 88.89% with an average 75.8% ±18.7% (Table 1).

Table 1. Comparison between both techniques regarding air conduction, bone conduction and air bone gap percentage of reduction

(dB)		Group P (piezo) (no=20)	Group C (conventional) (no=20)	P-value between groups
Mean AC	Pre	47.8±4.2	45.6±5.1	0.144
	Post	25.1±2.8	23.8±3.1	0.172
	P-value Pre vs Post in each group	<0.001*	<0.001*	
Mean BC	Pre	16.5±3.4	15.3±2.9	0.237
	Post	17.4±4.9	16.2±3.5	0.378
	P-value Pre vs Post in each group	0.503	0.381	
A-B gap	Pre	31.4±4.4	30.3±4.6	0.467
	Post	7.7±6.7 (median=6)	7.6±6.8 (median=7)	0.989 (MW)
	P-value Pre vs Post in each group	<0.001* (WS)	<0.001* (WS)	
Percentage of the decline of the AB gap		76.2±17.6	75.8±18.7	0.820 (MW)

AC: air conduction, (BC), A-B gap: air-bone gap, dB: decibel

MW: Mann Whitney U test WS: Wilcoxon Signed Rank test

*P-value is significant

The time of operation was significantly shorter in group C as compared to group P (P-value<0.001). The average time in group P was (35.5± 4.5) minutes vs (29.7 ±3.2) minutes in group C (Table 2).

Regarding the intraoperative complication, there was no significant difference between Piezosurgery and conventional surgery (P-value=0.147). Also, post-operatively the occurrence of tinnitus and dizziness didn't differ significantly between both techniques (Table 2).

Table 2 Comparison between both techniques regarding intra-operative time, intra-operative and postoperative complications

Items	Group P (piezo) (no=20)	Group C (conventional) (no=20)	P-value
Intra-operative time	35.5± 4.5	29.7 ±3.2	0.001*
Corda tympani Injury			0.147
No	20 (100.0%)	18 (90.0%)	
Yes	0 (0.0%)	2 (10.0%)	
Tinnitus	17(48.6%)	18(51.4%)	0.633
No	3(60.0%)	2(40.0%)	
Yes			
Dizziness (mean days ±SD)	1.9± 0.7	1.7± 0.6	0.272
Facial paralysis	0(0%)	0(0%)	---

SD: Standard deviation *P-value is significant

Discussions

Otosclerosis is considered as one of the most One of the most common causes of hearing loss is otosclerosis.[10]Slowing the course of hearing loss is a common goal for early detected cases with fast progression.[11] However, otosclerosis has no known medical treatment.[12]

Different surgical approaches are available as management of otosclerosis like total and partial stapedectomy, as well as stapedotomy.[10]Different variations of stapedotomy are present and even all were tried in the past, however the main principle of this approach is to establish a calibrated hole inside the footplate.[13] The new technique, Piezosurgery depends on a device producing specific ultrasound waves at a frequency (22 000–35 000 Hz) and the generated ultrasonic vibrations are used for cutting and modulation the shape of bones.[14]

We conducted our study intending to compare and evaluate otosclerosis's hearing outcome and complications treated with the Piezosurgery and conventional surgical stapedotomy. In our study, female patients were predominant 25 (62.5%) and male:female ratio was (1:1.7). This observation is consistent with the fact that otosclerosis is more prevalent in females than males[15], which is running with previous reports of a gender bias of 1:1.5-2 in the male to the female prevalence of otosclerosis.[16,17]

According to the current study results, there were considerable improvements in postoperative ABG in both groups of patients. However, no approach outperformed the other in lowering the (ABG). In group A the mean A-B gap was 31.3 dB preoperative and 7.7 dB postoperative. In comparison, in group B the mean A-B gap was 30.3 dB preoperative and 7.6 dB postoperative.

The results of our study corroborated previous research demonstrating the efficacy of stapedotomy using conventional instruments in reducing the (ABG) and improving the status of patients' hearing, as most of patients at all frequencies tested (0.5. 1, 2 and 4 kHz) showed closure of the air-bone gap (0.5. 1, 2 and 4 kHz). Adedeji et al. 2016 found in their study that at (ABG < 10 dB) 61.1% of patients showed complete closure of ABG compared to 1.6% preoperatively and within 20 dB 85.2% showed closure of ABG compared to 4.7% preoperatively (P-value<0.001). More than 94% of patients had improvement in hearing and 81.5% showed closure of the ABG greater than 10 dB

at the postoperative follow-up (mean gain 23.38 ± 12.37 and P-value<0.001.[18]

Sergi et al. 2010conducted a study in Italy and reported progressive closure of ABG starting from the early postoperative follow-up and this improvement continued to increase throughout the late postoperative follow-up(Sergi et al., 2010).[19]Our outcome is matching to the study performed in France by **Vincent et al. 2010**, who found closure of ABG < 10 dB in 63.4% of the studied patients.[20]

The time of operation was significantly shorter in the conventional techniques (29.7 minutes) than the Piezosurgery (35.5 minutes and P-value=0.001).

Despite using the microscope in both studied groups, the time taken for the conventional was significantly shorter than for Piezosurgery. This may be due to the large size of the device's handle, which masks part of the surgical field and the time taken for irrigation in the Piezosurgery to make the surgical field clear. But this was not in line with a finding from Italy that documented the superiority of Piezosurgery over the conventional method regarding the time.[19]Another reasonable cause for using the Piezosurgery technique is relatively new in the study location. More time is needed for the surgeon to be experienced in using it. Therefore, evaluation of success rate of surgery performed at each center is very important.

Regarding the intraoperative complications, cochlear implantation in children showed no side effects on soft tissues like facial nerve and vessel and this could be attributed to once the cutting head loses its contact with mineralized tissue the head becomes inactive producing no damage in case of accidental slipping to the surrounding tissues; that accentuates the safety of the device and makes the Piezosurgery procedure ideal.[21,22]

This was consistent with the finding of this study as no patient experienced an intraoperative injury to chorda tympani in the Piezosurgery technique compared to patients in the conventional group with no significant difference between both groups regarding intraoperative complications.

Literature showed that no side effects were reported with unintentional contact to the facial nerve also with the removal of the tumor showed no impact on the surrounding soft tissue and vascular structures.[9] On examination of operative specimens, no bone necrosis was detected.[23] Such finding may favor the use of Piezosurgery rather than conventional methods as it sounds safer and efficient, especially on the soft tissue. Cranial and inner ear side effects were avoided by absence of micro-vibrations.[22]

The current study had two main limitations, first: the relatively small sample size and second: the cost to use the Piezosurgery is extremely high in comparison to conventional tools.

Conclusion and Recommendations:

Our study concluded that both techniques showed non-significant difference regarding the improvement of postoperative ABG, intraoperative, and postoperative complications. However, the latter consumed more time and the cost of using the Piezosurgery is extremely high compared to conventional tools. Further clinical trials with a larger sample size are recommended. We also recommend that the handle of the device should be smaller to be suitable for microscopic ear surgeries.

Conflict Of Interest: We declare that we have no conflicts of interest.

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