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Original Article

Comparative Analysis of Laser and Non–Laser Stapes Surgeries

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OBJECTIVE: This study aimed to observe differences in the efficacy of laser and surgical treatments of middle-ear conductive hearing loss (MECHL).

MATERIALS and METHODS: A total of 276 ears of 267 patients with MECHL were divided into laser (n=172) and surgical (n=104) treatment groups according to the treatment method. Changes in the air–bone gap (ABG) after treatment and at the time of final follow-up were compared. An ABG value <20 dB was defined as effective and an ABG value <10 dB, significantly effective. The long-term treatment effects were also compared at the time of final follow-up. Additionally, postoperative adverse reactions were recorded for both the groups.

RESULTS: The mean follow-up period was 76.77±43.62 months (range: 12–168 months). No significant difference in ABG was found between the two groups (21.31±11.64 dB vs. 19.14±9.79 dB, p>0.05). However, the laser treatment group showed slightly better results than the surgical treatment group at the final follow-up, although the difference between the groups was not found to be significant (11.69±9.98 dB vs. 12.62±10.94 dB, p>0.05). There was no difference in the long-term treatment effects between the two groups (effective: 87.21% vs. 88.46%, p>0.05; significantly effective: 55.81% vs. 56.73%, p>0.05). The incidence rates of postoperative adverse reactions were not significantly different.

CONCLUSION: The treatment efficacy of laser and surgical treatments for MECHL are similar.

KEYWORDS: Middle-ear conductive hearing loss, surgery, laser

INTRODUCTION

Stapes fixation or deformity is one of the main causes of middle-ear conductive hearing loss (MECHL), wherein otosclerosis accounts for the highest proportion of cases [1]. Otosclerosis is characterized by the spongization of the inner ear capsula ossium and re-ossification that causes ear–bone fixation, resulting in progressive conductive hearing loss and deafness [2]. In 1958, Shea performed the first stapedotomy to treat otosclerosis, which was followed by another report describing the small fenestra technique [3]. In Jordan, a study involving an 8-year postoperative follow-up of patients with otosclerosis found that only 1 among 104 patients developed deafness [4]. Therefore, surgery was a preferred mode of treatment since patients typically obtained satisfactory therapeutic results [5] and the incidence of deafness was less than 1% [6].

The surgical equipment used for stapedotomy also developed from the initial microscopic instruments to miniature ear drills to lasers [7-9], and all above showed the results by instrument. In 1997, Wang first reported the application of a CO_2 laser for stapedotomy in China. In 1999, Hausler first reported the application of an erbium-doped yttrium aluminum garnet (Er:YAG) laser system in stapedotomy and obtained positive results, with an air–bone gap (ABG) of less than 20 dB in 15 cases (ears) [10]; similar findings were first reported in China in 2004. The usefulness of both CO_2 and Er:YAG lasers in stapes surgery have been confirmed with a decrease in the hearing threshold [11]. The 3-year follow-up of patients who received laser treatment showed that the Er:YAG laser was the safest type of pulsation laser for use in ear surgery because no facial nerve paralysis or adverse effects were observed in the inner ear function [12].

A recent meta-analysis summarized that laser treatment offered advantages over non-laser methods, such as preventing footplate fracture and sensorineural hearing impairment [13]. However, a similar analysis remains to be conducted in China. We hypothesized that laser and surgical treatment toward MECHL should reflect the differences in efficacies. This study retrospectively analyzed the short- and long-term hearing results following laser and non-laser stapes surgeries, as well as the effects of cochlear vestibular function and surgical incidents.

MATERIALS and METHODS

General Information

From April 1999 to April 2014, 267 patients with MECHL who underwent stapes surgery were admitted to our hospital (diagnostic criteria and surgical indications included normal tympanic progressive conductive deafness and ABG greater than 15 dB), including

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86 men and 181 women (men–women ratio of approximately 1:2). Among these 267 patients, 9 had bilateral involvement, leading to 276 ears that formed a part of the study. Patients were aged between 11 and 78 years (mean: 46.23±14.75 years; median: 48 years). This study was conducted in accordance with the Declaration of Helsinki. Approval from the Ethics Committee of First People's Hospital University was obtained. Written informed consent was obtained from all the participants.

The mean preoperative air conduction (AC) was 65.53±13.93 dB, mean preoperative bone conduction (BC) was 25.05±12.22 dB, and preoperative ABG was 40.45±10.44 dB. The 172 ears on which laser surgery was performed in our hospital were defined as the laser group, among which 141 ears were treated using an Er:YAG laser from 2000 to 2011 (Zeiss Co.) and 31 ears were treated using a CO_2 laser after 2011 (Lumenis Co.). The 104 ears that underwent surgery in our hospital before October 2000 or underwent the same surgery using non-laser equipment in other hospitals between 2000 and 2014 were included in the non-laser group. The preoperative AC values of the laser (65.04±15.7 dB) and non-laser (66.35±10.38 dB) groups showed no significant difference (U=0.84, <U0.05=1.96, p>0.05). The preoperative BC values of the laser (26.47±13.57 dB) and non-laser (24.01±8.87 dB) groups showed no significant difference (U=1.87, <U0.05=1.96, p>0.05). The preoperative ABG values of the laser (39.81±10.67 dB) and non-laser (41.83±9.98 dB) groups showed no significant difference (U=1.58, p>0.05). The mean ages of the laser (47.60±14.89 years) and non-laser (44.30±14.08 years) groups showed no significant difference (U=1.80, p>0.05).

Two ears suffering from MECHL presented with anterior malleolar ligament ossification, 1 ear showed bone bridging between the stapes and the facial nerve crest, and 4 ears demonstrated superficial nerve exposure covering more than two-thirds of the footplate. Ligament ossification and bone bridging were treated simultaneously using a laser.

Surgical Methods

All the surgeries were performed by experienced surgeons. The 276 ears in consideration underwent surgery under local anesthesia using the small fenestra technique, also known as stapedotomy, in which a laser is used to amputate the stapes head, stapes muscle, rear arch bow, and footplate fenestra. Prior to October 2004, the implanted stapes prosthesis pseudo-covers were self-made, non-slip, hook-type pistons with a piston diameter of 0.5 mm (laser group: 60 ears; non-laser group: 62 ears; total: 122 ears) [14]. Post October 2004, an imported stapes prosthesis was used, with a piston diameter of 0.4 mm (a Pt wire plus poly-material stapes prosthesis provided by Medtronic Inc. was used between 2004 and 2009) (laser group: 54 ears; non-laser group: 20 ears; total: 74 ears); a complete Ti stapes prosthesis (KURZ, Germany) provided by Changning Medical Co. was used from 2009 onwards (laser group: 55 ears; non-laser group: 19 ears; total: 74 ears). During surgery, 6 ears were found to have less severe stapes fixation and smaller ABG (20–30 dB); therefore, stapes mobilization and elevation were performed instead of the insertion of stapes prosthesis [15].

In 11 ears (4%) that underwent surgery in other hospitals, the effects on hearing were not satisfactory (i.e., poor postoperative effects or beneficial effects that had declined soon after surgery) and repeat surgery was performed.

In the repeat surgery, 11 ears (4%) underwent secondary exploration due to poor hearing results after the initial operation.

Endpoints

The primary endpoints included hearing and efficacy. Hearing was defined as the average value of frequencies at 0.25, 0.5, 1, 2, and 4 kHz, with the postoperative recorded value at 2 weeks defined as short-term hearing and the value at the time of final follow-up (≥1 year) defined as long-term hearing. Efficacy was evaluated based on the ABG values as follows: (a) ABG reduced to less than 20 dB was considered a success, (b) ABG above 30 dB or within 10 dB was considered significantly effective, and (c) ABG above 15 dB was considered effective. The secondary endpoints were the duration of the surgery and adverse postoperative effects such as tinnitus, vertigo, and facial paralysis.

Statistical Analysis

The U test and chi-square analysis were used, where $p<0.05$ considered to be statistically significant.

RESULTS

Follow-up assessment was performed on patients for over a year with a mean follow-up period of 76.77±43.62 months (ranging from 12 to 168 months). The comparison of the mean postoperative ABG (20.49±11.01 dB) with the mean preoperative ABG (40.45±10.44 dB) in 276 ears was significantly different (U=21.98, p<0.01). The average ABG (12.03±10.26 dB) was significantly different from the preoperative ABG (U=32.37, p<0.01). A comparison between the postoperative ABG with that recorded at 1-year follow-up showed a statistically significant difference (U=9.32, p<0.01). The grouping analysis showed that the postoperative ABG of the 172 ears of the laser group was 21.31±11.64 dB and that of the 104 ears of the non-laser group was 19.14±9.79 dB, with no statistically significant difference between the groups (U=1.65, p>0.05). The 1-year follow-up ABG in the laser group was 11.69±9.98 dB, which was slightly better than that noted for the non-laser group (12.62±10.94 dB), but the difference was not statistically significant (U=0.71, p>0.05). Among the 276 ears studied, 242 ears were classified as success (87.68%), which included 150 (87.21%) and 92 (88.46%) ears from the laser and non-laser groups, respectively; the chi-square test showed no significant difference (χ^2=0.094, p>0.05). A follow-up ABG value <10 dB was noted in 155 (56.15%) ears, which included 96 (55.81%) and 59 (56.73%) ears from the laser and non-laser groups, respectively; the chi-square test showed no significant difference (χ^2=0.022, p>0.05). There was a significant improvement (of 6–12 dB) in BC postoperatively at all the frequencies examined. For post-stapedectomy patients, a loudness change by 1.5–2.0 points averaged for both the ears in bilateral tinnitus or ~2.5 points in unilateral tinnitus for a clinically significant change in tinnitus severity.

Repeat Surgery

Here, 11 ears (4%) underwent surgery in other hospitals, which were repeated in our hospital due to unsatisfactory hearing effects (i.e., poor postoperative effects or beneficial postoperative effects that had declined soon after the surgery), with 9 (82%) ears subsequently classified as successes. Further, 5 ears that initially showed an improvement demonstrated a decline a few years later with an average ABG reduction of 30 dB. Two ears showed anterior malleolar ligament

ossification and the postoperative ABG dropped to less than 20 dB. Two ears had piston incarceration and, therefore, underwent fenestra dilation and piston replacement, following which the ABG dropped to less than 10 dB. Two ears demonstrated no hearing change after surgery. Eight ears received laser treatment during the repeat surgery, while 3 ears did not.

Upon second exploration of the 11 ears (4%) that underwent repeat surgery due to poor hearing after the first surgery, 9 ears were classified as showing successful results (82%). Among the 11 ears, 8 ears had small fenestra that caused piston incarceration or hook loosening. The ABG values of 5 ears were reduced to less than 10 dB after the second surgery and those of the other 3 ears were reduced to within 20 dB. One ear exhibited anvil loosening in the first surgery and the stapes was not treated; in the second surgery, the ABG value after opening the fenestra and mounting a piston was reduced to within 10 dB. Two ears exhibited wide piston and fenestra adhesion and showed no hearing improvement after the second surgery. Seven ears received laser treatment during the repeat surgery, while four ears did not.

Postoperative Complications

Accidental full footplate dislocation occurred in 3 ears, all of which were part of the non-laser group (3 out of 104, i.e., 3%). In two ears, the periosteum was used to cover the oval window, followed by the piston to support the periosteum. Postoperative hearing recovered and was maintained at an optimal level during long-term follow-up. In the third ear, the piston was first installed followed by the use of the periosteal striga to surround the piston and close the oval window. Severe postoperative vertigo occurred 3 days later during recovery. This patient hurriedly left the hospital 1 week after surgery and undertook a long bumpy overnight train journey, resulting in sudden deafness. Total deafness was noted at the time of review 1 month later, and this was the only case of sensorineural hearing loss (0.4%) in this study.

Long-term sensorineural dysfunction occurred in only 1 ear (0.4%) with the self-made piston in the laser group and occurred 10 years after the second exploration. The patient's postoperative hearing after the first surgery was poor. Piston incarceration, adhesion, and hook loosening were recorded 3 months later. Therefore, the piston was replaced and the ear was classified successful. However, this patient developed sudden deafness 10 years later. The patient's contralateral ear had undergone surgery 20 days prior to the affected ear. In the following 13 years, the hearing was maintained at an optimal level (long-term follow-up ABG: 1 dBHL).

Other minor adverse effects were recorded for 9 ears in the laser group (5%), including 6 ears with anterior footplate ligament extrusion and 3 ears broken while removing the arch bow; all the ears demonstrated successful postoperative hearing. Four ears in the non-laser group (4%) were affected, including 1 ear demonstrating breaking of the footplate, 2 ears with anterior footplate ligament extrusion, and 1 ear with a non-broken arch bow crushed toward the promontory; however, all the ears demonstrated successful postoperative hearing. The chi-square analysis of the number of minor incidents demonstrated a non-significant difference (χ^2=0.054, p>0.05).

In the laser group, 137 ears (80%) had no occurrence of postoperative vertigo, while 35 ears developed slight postoperative vertigo. This remitted 1–5 days later with an average duration of 2.25 days, but had no effect on the patients' daily lives. Three ears (70%) in the non-laser group had no postoperative vertigo, and 31 ears exhibited 1–6 days of vertigo, including 1 case of serious vomiting. The incidence of vertigo seemed to be slightly more in the non-laser group, but no significant difference existed between the two groups (χ^2=3.187, p>0.05).

There were no occurrences of short- or long-term facial paralysis in this study. Among the 27 (10%) ears that demonstrated facial nerve exposure, 4 ears were noted with a footplate covered by more than two-thirds (2 ears in both the groups); 2 ears showed facial nerve deformity in the horizontal pathway involving bifurcation or down-shifting into the bottom of the oval window (1 ear in both the groups) when performing the fenestra opening. Consequently, a fine flat stripper was used to push away the facial nerve in the laser group to provide a sufficient operating field over the footplate; however, blind feeling was required to master the depth and caliber in the non-laser group.

DISCUSSION

Recently, Wegner et al. [13] performed a meta-analysis on 999 cases of laser and non-laser stapes surgeries and found no obvious difference in postoperative ABG reduction or immediate postoperative vertigo, but the sense of tone for MF and HF sounds were better in the laser treatment group than the non-laser treatment group; additionally, the incidence of vertigo was lower [16]. The results obtained in this study also showed that the short- and long-term hearing results of the laser and non-laser group were not significantly different. In addition, there was no difference in the incidence rates of minor adverse events such as postoperative vertigo, facial nerve exposure, injury avoidance, and anterior footplate ligament extrusion between both the groups, which is consistent with the findings of Wegner et al [13].

Wegner et al. [13] proposed that laser surgery was a better choice in preventing footplate fractures than non-laser surgery. Although this study did not find that the non-laser group demonstrated more cases of footplate fracture, it was clear that non-laser surgery required more surgeon experience and skill, while laser surgery was more convenient and secure. For example, footplate mobilization occurred in 3 ears in the non-laser group when performing fenestration, implying that the operating surgeons required advanced skills. However, a method of drilling-piston installation-arch bow amputation was used, which allowed one hand to hook the foot bow such that it would not sink into the vestibule when drilling, while the other hand could perform the fenestration with a one-handed drill. In the laser group, such situations would never occur. Similarly, in dealing with the cases with anterior malleolar ligament ossification, vertigo, and follow-up problems caused by non-laser-assisted malleus processing induced by enormous displacement and shaking of the stapes and piston would be extremely serious [17, 18].

Wegner et al. [13] also concluded that non-laser surgery would have more cases of sensorineural hearing loss. However, the results of this study were different; only 1 case of sensorineural hearing loss occurred 2 weeks later in the non-laser group. Although likely to be caused by a rough, long-distance train journey, it might also be due

to an insufficiently closed oval window after the complete removal of the footplate. After improving the sealing technique, no similar incidents have occurred. Since then, the small fenestra technique was used in non-laser surgeries and the problem of full footplate mobilization has rarely occurred. Only 1 case developed sensorineural hearing loss during the long-term follow-up, 10 years after the laser surgery. A potential reason may be the fact that the hearing results in the 3-month review were poor and adhesions required separation for the replacement of the stapes piston. However, a definitive cause as to why the sensorineural hearing loss occurred 10 years later was not identified. There was no significant difference in the incidence of sensorineural hearing loss between the two groups. As a result, it can be concluded that the incidence of sensorineural dysfunction in the stapes surgery could be greatly reduced by using small fenestra technique and high-quality piston prosthesis. This could lead to significant improvements from the previous reports in which even the most experienced surgeons would inevitably experience an incidence rate of 1%–2% [19, 20], while the incidence in this study was less than 0.4%.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of First People's Hospital divided.

Informed Consent: Written informed consent was obtained from all the participants.

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