Otology

Can the learning curve in stapes surgery predict future functional outcome?

L'analisi della curva di apprendimento della chirurgia dell'otosclerosi può aiutare a predirre i risultati funzionali?

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SUMMARY

Over the last 20 years, the number of stapes operations performed has decreased steadily. This inadequate exposure to stapes surgery poses problems for both trainees and trainers. We retrospectively reviewed the outcomes of stapedotomy performed by a young physician at the ENT Clinic of the "A. Gemelli" Hospital of Rome. We used the technique of "one-shot" CO_2 Laser stapedotomy using a titanium-Teflon piston. For data analysis, we considered the audiograms obtained 24 hours preoperatively and at the last follow-up examination (mean 45 months). Air conduction (AC) and bone conduction (BC) PTA were calculated for 0.25, 0.5, 1, 2 and 4 kHz thresholds. Air bone gap (ABG) were obtained from ACPTA and BCPTA. Postoperative hearing gain was calculated from the ABG before the operation minus the ABG at late follow-up examination. Analysis of outcomes did not show a clear endpoint for the learning curve; complete closure of the ABG was obtained in a large number of patients at the beginning followed by patients who showed a higher ABG. Fortunately, we did not observed any "dead ear". The study supports a learning curve in stapes surgery, but the results can vary widely among surgeries with excellent results followed by others that are not fully satisfactory. Stapes surgery should not be one of the first ear surgeries performed by a young otologist due to the functional outcome expected by patients and the lack of necessary surgical skills.

KEY WORDS: Otosclerosis • Stapedotomy • CO_2 laser • Learning curve • Hearing threshold

RIASSUNTO

Il numero di interventi per otosclerosi è progressivamente diminuito nel corso degli ultimi 20 anni. Questa riduzione crea difficoltà sia al chirurgo esperto ma soprattutto a quello giovane che inizia il suo percorso di formazione. Abbiamo analizzato in maniera retrospettiva i risultati funzionali ottenuti dopo stapedotomia effettuati da un giovane chirurgo presso la Clinica Otorinolaringoiatrica del Policlinico "A. Gemelli" di Roma. La tecnica impiegata è quella della stapedotomia con laser CO_2 e utilizziamo una protesi in teflon e titanio. I risultati funzionali sono stati valutati come riduzione della ipoacusia trasmissiva sulle frequenze comprese tra 250 e 4000 Hz all'ultimo esame eseguito durante il follow-up. L'analisi dei dati non ha evidenziato un momento in cui la curva di apprendimento possa essere considerata conclusa poiché ottimi risultati con una riduzione pressoché completa della ipoacusia trasmissiva si sono alternati con altri i cui risultati funzionali non sono stati altrettanto ottimi. In nessun caso si è comunque registrata una coclearizzazione dell'ipoacusia. Questa analisi supporta l'esistenza di una curva di apprendimento della chirurgia dell'otosclerosi senza però individuare un punto dopo il quale si possa prevedere che i risultati funzionali saranno tutti ottimi. La chirurgia dell'otosclerosi non dovrebbe essere effettuata all'inizio della pratica della chirurgia otologica, data l'aspettativa funzionale che il paziente ripone nell'intervento e la mancanza delle capacità chirurgiche necessarie.

PAROLE CHIAVE: *Otosclerosi • Stapedotomia • Laser CO_2 • Curva di apprendimento • Soglia uditiva*

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Introduction

Stapes surgery is one of the most highly satisfying but technically challenging otologic procedures, and several studies have documented that clinical outcomes are dependent on surgical experience [1 2]. During the last years, the number of stapes surgeries seems to be reduced, and some reasons can explain this trend: fluoridation of water supplies, improvement of quality of hearing aids and increasing number of surgeons. It follows that few cases of otosclerosis present to each surgeon per year leading to problems for acquiring the needed surgical skills for training. On the other hand, the surgical technique and the technological tools have been improved over the decades rendering some tricky points more simple: stapedectomy surgeons changed to the small fenestra technique thus reducing the risk of an inner ear damage; microdrills and lasers allowed to perform safer platinotomy; the self crimping prosthesis have eliminated this dangerous part of the procedure.

We report and analyse the outcomes of our first surgeries for otosclerosis to determine if the functional results can be related to our learning curve and if we can draw some conclusions regarding future teaching activities.

Materials and methods

From January 2008 to December 2011, 171 ears affected by otosclerosis were operated on at the Clinic of Otorhinolaryngology of the Università Cattolica del Sacro Cuore of Rome. There were 125 females and 46 males. The age at the time of surgery ranged between 18 and 74 years, with an average of 45 years (standard deviation 12 years). A diagnosis of otosclerosis was based on a clinical history of progressive hearing loss, normal otoscopic findings, an audiogram showing a mean conductive hearing loss of 20 dB in the range of 0.5 to 4 kHz and absence of cochleostapedial reflexes.

Surgery was performed under local anaesthesia with adequate preoperative sedation. In a few cases, upon the patient's request, general anaesthesia was used. A transcanal approach through an ear speculum was standard. After having visualised and evaluated the ossicular chain, cut the stapedial tendon, separated the incudostapedial joint and removed the stapes arch previously fractured by a hook, perforation of the footplate was obtained with a CO_2 laser using the SurgiTouch system (Lumenis Co., Tel Aviv, Israel) and the "one-shot technique". In all cases, the desired perforation diameter was achieved by a single shot, and in 12 cases, we rounded off the edges with the smallest hook. Usually, we use a power setting of 20 to 22 W with an exposure time of 0.03 to 0.05 second per pulse and a diameter of the shot of 0.6 mm. A 0.4 mm titanium Teflon prosthesis was then inserted in the perforation and crimped to the long process of the incus. The prosthesis diameter is 0.1 to 0.2 mm smaller than the perforation diameter. Finally, the oval window niche was sealed with connective tissue or a blood clot, the tympanomeatal flap was replaced and the ear canal was packed with Merocel.

Audiograms were obtained at least 24 hours preoperatively. Functional results were recorded at the last follow-up examination (mean 45 months; standard deviation 13 months; range 24-70 months). Audiologic evaluation was performed using a tonal audiometric test according to the guidelines of the Committee on Hearing and Equilibrium (1995; American Academy of Otolaryngology Head and Neck Surgery Foundation). Air-conduction and BC pure-tone average (PTA) values were calculated as the mean of 0.25, 0.5, 1, 2 and 4 kHz thresholds. Air-bone gaps (ABG) were obtained from ACPTA and BCPTA thresholds. Finally, the postoperative hearing gain was calculated from the ABG before the operation minus the ABG of the last follow-up examination. Patients were queried about occurrence of nystagmus, vertigo and tinnitus.

Data distribution was preliminarily assessed with a Kolmogorov-Smirnov test. After verifying the normal distribution of data, statistical analysis was performed using a Student's t test when 2 sets of data were compared and a paired, 2-way analysis of variance when more than 2 data sets were compared. The level of significance was set at $p < 0.05$.

Results

Analysis of the data involved the consecutive surgeries performed by a single surgeon younger than 40 years at the beginning of his experience with stapes surgery. Among all the stapedotomies performed, 31 patients were operated on by the same surgeon. Two patients were excluded by the analysis because one patient was lost to follow-up and another was not considered because a stapedectomy was accidentally performed when fracturing the stapes superstructure.

No patient complained of tinnitus, nystagmus, or vertigo. The results are summarised in Figures 1 to 5.

The mean preoperative ACPTA was 55 dB, and the mean preoperative BCPTA was 23 dB. The mean pre-operative ABG was 32 dB (Fig. 1).

At the last follow-up, ACPTA was 31 dB, and BCPTA was 22 dB. Considering each frequency, the postoperative ACPTA improvement was greater at low and middle frequencies than at high frequencies: the ACPTA improvement was 33,

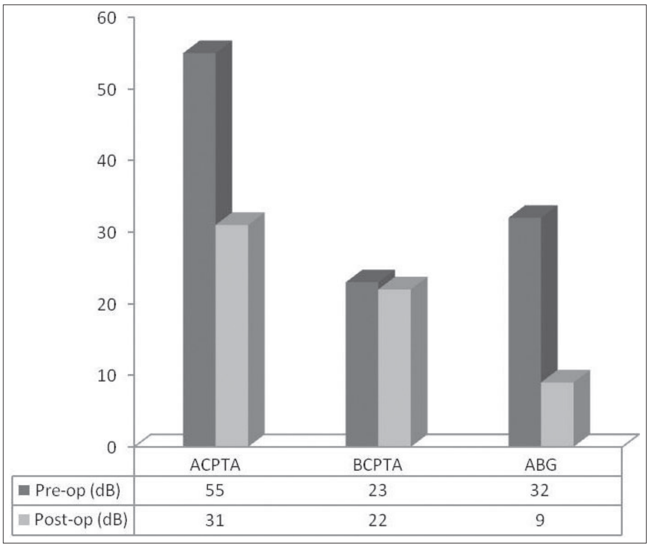

Fig. 1. Histograms show the main outcome of the study.

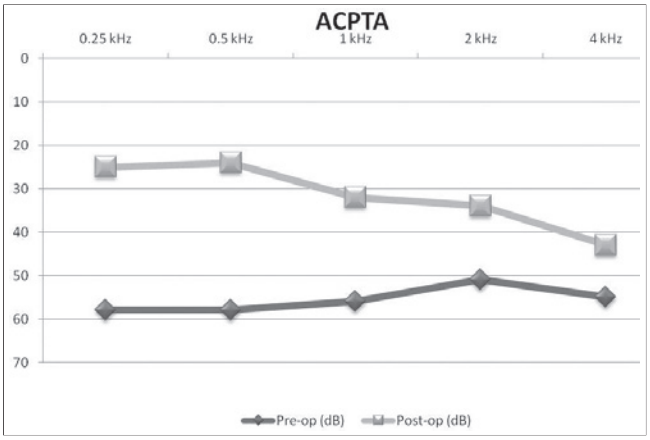

Fig. 2. Mean AC thresholds before and after surgery.

34, 24, 17 and 12 dB at 0.25, 0.5, 1, 2 and 4 kHz, respectively (Fig. 2). Bone conduction PTA remained almost stable at 0.25, 0.5 and 1 kHz, improved by 4 dB at 2 kHz and worsened by 2 at 8 kHz (Fig. 3). The mean post-operative ABG was 9 dB: 18 patients (62%) had an ABG of 10 dB or less; 10 patients (34,4%) presented an ABG between 11 and 20 dB; 1 patient (3,4%) showed an ABG between 21 and 30 dB (Fig. 4). The post-operative ABG for the 29 consecutive patients is reported in Figure 5.

Analysis of variance showed a statistically significant difference between preoperative and postoperative ACPTA ($p < 0.001$); the postoperative ABG also improved significantly compared with preoperative ABG ($p < 0.001$).

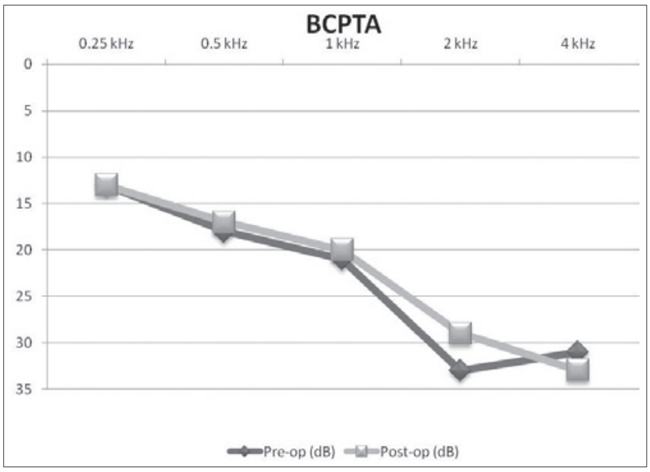

Fig. 3. Mean BC thresholds before after surgery.

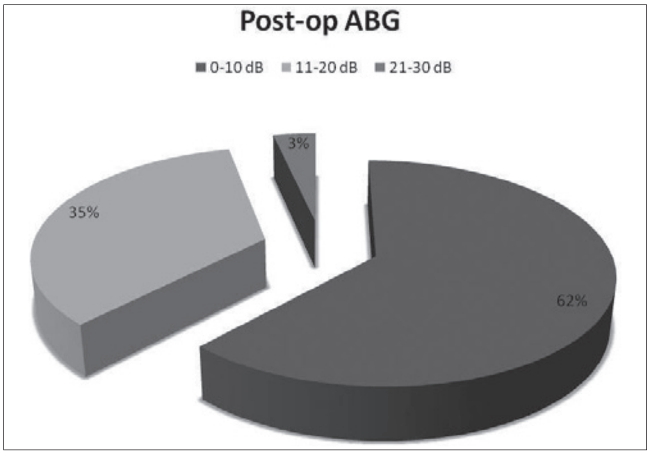

Fig. 4. Distribution of patients by the level of ABG after surgery.

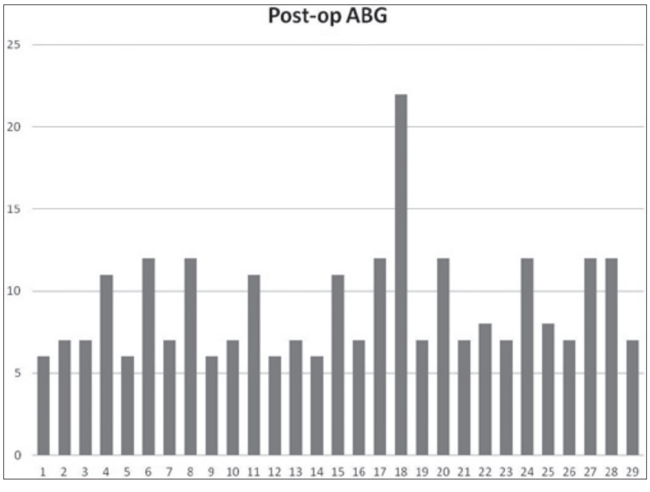

Fig. 5. Post-operative ABG for all patients.

Discussion

When learning a new procedure, performance tends to improve with experience, and graphically plotting performance against experience produces a learning curve. The challenge becomes providing enough time and employing teaching strategies that facilitate universal achievement. Learning differs from surgeon to surgeon, and some surgeons will reach a peak faster than others. The key elements in learning are: unequivocal definition of what is to be learned and how it will be evaluated; allowing trainees to learn at their own pace; assessment of progress with appropriate feedback; and testing that the expert phase has been achieved. Learning a surgical technique is a process that goes through some stages. Didactic phase: study, watch videos and training with instruments and techniques on artificial and cadaver models; training phase: under staff supervision; practice phase: perform the procedure with increasing degrees of independence.

Stapes surgery is regarded as the ideal operation to investigate the learning curve of surgery. It is conceptually simple, but technically difficult. Once the technique is mastered, the results of stapes surgery are predictably good. Furthermore, the outcome of the operation is easily measured and can be compared with gold standard results of stapes surgery that are well documented. However, due to the few cases operated on each year, some otolaryngologists only perform their first complete stapes operation when they become consultants. It is natural that they go through a learning curve before they can achieve good results.

Many authors have reported on the learning curve in stapes surgery: some focused the analysis on the results obtained by residents [3 4], others on the use of laser [5] and others on the decreasing number of surgeries performed with following impact for training [6]. Some authors quantified the learning curve analysing their results: Hughes [1] indicates that it took 50 stapes operations over a 9 year period to obtain a postoperative air-bone gap of 10 dB or better in 90% of patients. Yung reported that the peak on his learning curves appears to be at 60 to 70 cases over a 10 year period: there was no cochlear damage, and 90% of the cases had a postoperative air-bone gap of less than 10 (mean 6) dB. However, such favourable results were not maintained in subsequent cases. Oates, analysing his learning curve, noted two peaks, one at 30 to 40 cases (mean air-bone gap of 5.5 dB) and the other at 70 to 80 cases (mean air-bone gap of 5.2 dB) over a 6 year period. Both authors had a “dead” ear at the early

stage of their learning curve: case 13 for Yung and case 5 for Oates [7]. This volume of surgical experience stands in stark contrast to the number of surgeries performed by residents during training.
The analysis of our first surgeries showed that we achieved a good functional outcome in 29 patients over a 4 year period: the median air-bone gap was 6 dB, 62% of patients showed an air-bone gap less than 10 dB and we had no "dead" ears. However, if we analyse the post-operative air-bone gap of each patients, as shown in Figure 5, we noted that all results except one (patient 18) were acceptable, and that this unsatisfactory result was not at the beginning of our series but later on in the series.
As noted by Yung and Oates, we believe that it is wrong to set a clear endpoint in a functional technique such as stapes surgery, and that it would be better to speak of important milestones during the learning curve. Moreover, it is almost impossible to select the easiest cases for training in stapes surgery: in our series, we had an unintentional stapedectomy (not included in the analysis) and faced complications as intraoperative bleeding and some anatomical anomalies such as a narrow window niche and dehiscent facial nerve protruding over the stapes and the oval window. No preoperative technique, including high resolution CT, can help the young surgeon in diagnosis allowing referral of difficult cases to a more experienced surgeon. Nevertheless, we obtained good results since each surgery was performed under control of a well trained surgeon with immediate feedback. In this way, the young surgeon can feel more comfortable because the trainer can intervene at any time in the operation, if necessary; this is recommended because the well-being of patients is the first priority.
Moreover, the use of laser simplifies the procedure by avoiding manual fenestration of the oval window, which is one of the most challenging and difficult steps of stapes surgery: a small mistake can lead to disastrous results and complete sensorineural hearing loss. We use the CO_2 laser with the SurgiTouch system (Lumenis Co., Tel Aviv, Israel): in this device, the microprocessor-controlled rotating mirrors are synchronised to the laser, guiding the laser beam over the surface enabling a one-shot footplate perforation of a preselected diameter; it also reduces the generation of heat and induction of pressure waves in the scala vestibuli. One shot CO_2 laser stapedotomy can shorten the learning curve for a young surgeon: indeed, the laser allows to perforate the platina avoiding dangerous manipulation, permitting the young surgeon to feel more confident. However, the surgeon has to be aware of the target of the laser beam to avoid damage to surrounding structures. On the other hand, surgeons should know and apply more conventional techniques because the surgery must be concluded even in case of device failure.

Conclusions

Stapedotomy is a highly satisfying but technically challenging otologic procedure, and several studies have documented that clinical outcomes are dependent on surgical experience. There has been an overall decline in volume of stapes surgery, and thought must be given to how to provide trainees with adequate training to perform this surgery safely and effectively. The reality is that the majority of current residency programs are not providing adequate training for stapedotomy. Surgical observation, graded surgical responsibility and temporal bone laboratory experience have remained the mainstay of otological training. For these reasons, we do not recommend to treat otosclerosis at the beginning of the surgical experience: it is desirable to achieve optimal surgical skills in middle ear surgery before dealing with a stapedotomy. We perform surgeries knowing that our first dead ear could be just around the corner, and we believe that the number of surgeries performed is not enough to ensure good hearing results.

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