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Stapes Surgery Outcomes: The Practice of 35 Years

Original Investigation

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Abstract

Objective: The objective of this study was to review patients who underwent stapes surgery in the Hacettepe University Ear Nose Throat and Head and Neck Surgery Department with subgroups, such as type of surgery, prosthesis used in the surgery, rate of revision, and audiological results.

Methods: The data of 35 years were searched, and it was detected that 327 patients (190 females, 137 males) had undergone stapes surgery; the age was ranging between 11-70 years (mean: 39).

In our clinic, stapes surgery is performed mostly by transmeatal incision. After entering the middle ear, we almost always look for stapes mobility. If there is mobility in the incus and malleus and no mobility in the stapes, a small fenestra is performed as stapedotomy and prosthesis and placed between the stapedotomy fenestra and incus long arm. To cover the space near the stapedotomy, small bony fragments are placed. In patients who had preoperative and postoperative audiograms, the mean value of 500, 1000, 2000, and 4000 Hz air-bone conduction thresholds of 199 cases were measured and compared.

Results: In 62% of 327 patients who were operated on, the air-bone gap was less than 10 dB, less than 15 dB in 88%, and less than 20 dB in 94%. In 6% of patients, there was air-bone conduction gap of more than 20 dB. Revision surgery was performed in 20 patients. Of them, air-bone gap closure was achieved in 60%. One patient had sudden sensorineural hearing loss. There was also a perilymph fistula in one patient who had vertigo.

Stapedotomy and using a Teflon piston with autogenous bone are successful methods of recovering conductive-type hearing loss in otosclerosis. In patients with advanced sensorineural hearing loss, a very low air-bone gap or unmeasured air-bone gap is not a contraindication.

Conclusion: Stapes surgery (stapedectomy or stapedotomy) is a successful surgery in the case of conductive-type hearing loss with otosclerosis. Complications, such as total sensorineural hearing loss, facial nerve paralysis, and perilymph fistula, could be seen at variable rates, and the surgeon should be cautious, and the patients must be informed about these complications in the pre-operative period.

Keywords: Stapes, stapedotomy, Teflon prosthesis, juvenile otosclerosis

Introduction

Otosclerosis is a hereditary disorder of the otic capsule that is autosomal dominant with incomplete penetrance. In fact, otosclerosis is the primary otospongiosis of the labyrinthine capsule. At the early stages of the disease, a slight decrease in air conduction is detected by pure tone audiogram. However, in advanced cases with the development of sensorineural hearing loss, mixed-type hearing loss can be seen. Autoimmunity and measles are blamed to be the causes of this disease (1, 2).

There is no difference in the incidence of histological otosclerosis between males and females. But, clinical otosclerosis is more common in females (3).

The prevalence in races is different, and it is more common in Caucasians. The prevalence is about 6.4% in Europe and North America. But, symptomatic stapes fixation is in about only 3 in 1000 persons (4). Otosclerosis is mostly seen at young and middle age. With the increase in data and new diagnostic techniques, the diagnosis of otosclerosis can be made in early age, even in childhood. Although the hearing loss begins mostly in the third decade, the histologic changes begin in puberty and even in early childhood. Stapedial fixation begins in early age in juvenile otosclerosis. In 15.1% of patients with stapedectomy, complaints begin under the age of 18 years; the research about the therapy of juvenile otosclerosis is insufficient (5). Otosclerosis is very rare in children, and stapedectomy in this group is controversial (2).

There is no medical therapy for otosclerosis (5, 6). But, for the treatment of hearing loss in otoscle-

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rosis, research has been made since the first stapedectomy trial of Kessel in 1876 and Miot's stapes mobilization. There have been many periods of tha stapes surgery, such as fenestration by Holmgren, Sourdille, and Lempert, and stapes mobilization by Rosen in 1953. In 1958, Shea proposed stapedectomy, which included the removal of the stapes, closure of the window with a thin slice of connective tissue, and the implantation of a prosthesis from the incus to oval window. This technique continues with minor modifications. Even in more advanced cases, stapedotomy is more popular, and a prosthesis is used. Since the early 1980s, to minimize damage to the inner ear during the operation, various types of lasers have also been used (7).

Methods

Although there were 1247 stapedectomy cases who were operated on in our center and analyzed retrospectively, the data of 327 cases were achieved. The data were evaluated according to age, gender, preoperative and postoperative hearing thresholds, type of surgery, type of prosthesis used, early and late complications, and need for revisions. There were 190 (58%) female patients and 137 (41.9%) male patients. The age was ranging between 11-70 years, and the mean age was 39.

Stapes surgery in our clinic has been made by a transmeatal incision under local anesthesia in the large majority. Ear ossicular chain mobility was checked by taking the nerve chorda tympani forward after entering the middle ear. If the malleus and the incus were mobile and there was no mobility in the stapes, stapedectomy was performed. After removing the stapes suprastructure, a small fenestra at the base of stapes was opened. After the required measurements, a Teflon piston was cut and placed between the stapedotomy fenestra and the incus long arm. To close the remnant of the fenestra, sawdust obtained from the stapedial bone was filled around the hole.

Of the 199 patients having pre- and postoperative hearing tests, the mean value of 500, 1000, 2000, and 4000 Hz air-bone thresholds was taken. This procedure was performed for both the preoperative and postoperative periods. To evaluate the success of the operation, the air-bone conduction gap averages were obtained for preoperative and postoperative bone.

The data was evaluated via SPSS 18 (Statistical Package for the Social Sciences 18, Chicago, Illinois, United States).

Informed consent of all cases was obtained pre-operatively, as their surgical information might be used for the literature without giving any personal information.

Ethics committee approval was obtained from the Hacettepe University Medical Faculty Ethics committee, which was enumerated as GO14/457.

Results

Among the 1247 cases, 327 stapedectomy surgeries with information that could be achieved at our clinic between 1964-2001 were examined retrospectively. There were 190 (58.1%) female patients and 137 (41.9%) male patients. Their ages ranged between 11-70 years; the average age was 39. Also, 155 cases were operated on in the left ear versus 172 on the right. Four patients had previous surgery at another clinic. Three patients received NaF treatment.

The average air-bone conduction gap was 30.5 dB (SD±5.42 dB) in preoperative audiograms. Preoperative ipsilateral reflexes were as follows: at the opposite site in 53.8% of cases, negative in 45.8% of cases, and positive in 0.4% of the cases. When preoperative contralateral reflexes were evaluated, 98.7% of them were negative, 0.4% of them were reversed, and in 0.9%, the on-off phenomenon was observed.

Opposite ear hearing was as follows: 117 (44.5%) patients had otosclerosis follow-up; 62 (23.5%) of them had stapedectomy; 1 (0.3%) had total hearing loss; 2 (0.7%) used a hearing aid; and 81 (30.8%) were identified with normal hearing.

Through the cases, 321 operations (98.1%) were under local anesthesia, and 6 (1.8%) were performed under general anesthesia. A transmeatal incision was used in 325 (99.4%) cases, and an endaural incision was used in 2 (0.6%) cases. Also, 234 operations (71.6%) were performed by specialists, and 93 (28.4%) were performed by resident doctors. CO_2 laser surgery was used in 5 cases. Further, 66 (20.2%) of the cases were stapedectomy, and 261 (79.8%) were stapedotomy. A Teflon piston was used in 298 (98%) surgeries, wire Teflon was used in 5 (1.6%) surgeries, and a homograft bone was used in l case (0.3%). The prosthesis diameter was 0.6 mm in 178 (54.4%) cases, 0.8 mm in 148 (45.2%), and 0.4 mm in 1 (0.3%) case. The length of the prosthesis was ranging between 3.5-5 mm; the most widely used were as follows: 3.5 mm (2.2%), 3.75 mm (9.9%), 4 mm (28.7%), 4.5 mm (25%), 4 , 25 mm (20.4%), 4.75 mm (5.6%), and 5 mm (5.2%).

In closing the oval window fenestra around the piston, stapes sawdust was used in 65.8% of cases, external ear sawdust was used in 0.9%, and Gelfoam and sawdust were used in 33.2% of cases. A vein greft was never used.

Otosclerosis type in surgery was as follows: annular in 123 (41.2%), anterior in 44 (14.8%), biscuits in 3 (1.6%), diffuse in 109 (36.5%), obliterative in 18 (5.5%), and tympanosclerosis in l (0.3%) patient. The round window reflex was normal in 325 (99.4%) of 327 cases and otosclerotic in 2 cases (0.6%). The facial canal was open and prolapsed to the oval window in 6 patients (2.2%). During the operation, 40 (12.2%) patients encountered complications. These complications were incus luxation in 5 (1.5%), floating footplate in 10 (3.1%), chorda tympani injury

in 5 (1.5%), perilymph gusher in 2 (0.6%), loss of prosthesis in 2 (0.6%), tympanic membrane perforation in 13 (4%), and facial nerve damage in 3 (0.9%).

In the postoperative period, 35 (10.8%) patients developed complications. Early sensorineural hearing loss was found in 1 (0.3%) of the patients, late loss was found in 4 (1.2%), conductive hearing loss was found in 20 (6.1%), vertigo was found in 2 (0.6%), tympanic membrane perforation was found in 2 (0.6%), middle ear adhesions were found in l (0.3%), granuloma formation was found in 2 (0.7%), and perilymph fistula was found in 3 (1%) patients. Twenty cases (6.1%) had undergone revision surgery. The average preoperative air-bone gap was 30.5 dB (SD±5.42 dB); the controls were found to be 10.5 dB (SD±2 dB). When we look at the postoperative audiological results, the success rates were as follows: in 62% of cases, the difference was 10 dB or below, 15 dB and below in 88%, 20 dB and below in 94%, and above 20 dB in 6%.

In juvenile otosclerosis cases, there was annular otosclerosis in 3 patients, obliterative-type in 5 patients, and anterior otosclerosis in l patient. Among them, just the patient with anterior otosclerosis had a stapedectomy; the other cases had a stapedotomy. Also, a 0.6-millimeter piston was used in 8 patients, 0.6 mm piston in 1 patient. In the audiological findings in the first 6 postoperative months, the air-bone gap fell below 10 dB in 7 patients. In 1 patient, the hearing gain was only in the low frequencies, and the patient had severe hearing loss at high frequencies. The preoperative and postoperative air-bone gap of 2 patients was continued. These patients had obliterative otosclerosis. Air threshold in 3 of 7 patients having an air-bone gap closure by the surgery fell progressively to the former level. As evidence of the operation, these patients had obliterative otosclerosis. Annular otosclerosis was found in 3 patients.

In 1 of the 7 patients who had complications, sudden vertigo and hearing loss developed after 2 years. A labyrinthine fistula was considered in this patient but was not explored because of late application. This patient had had anterior otosclerosis before surgery and had a stapedectomy.

Transmission of 45 dB of the air-bone conduction was measured in 11 patients; 2 of the patients (18%) were male, 9 of them (82%) were female, and the mean age was 45 (ranging between 30-59). None of the patients received NaF treatment. Three of these patients had a stapedectomy (27%), 8 had a stapedotomy (73%), and in all of them, the Teflon piston prosthesis was used. Complications were seen only in 1 case; a facial nerve injury occurred in this patient. Three operations (27%) were done by residents versus 8 (73%) by specialist doctors.

Preoperative and postoperative bone conduction thresholds in 10 of 11 patients undergoing stapedectomy with progressive hearing loss reached to measurable levels, and air conduction thresholds were elevated. In 5 (45.5%) of 11 patients, diffuse-type otosclerosis was found intraoperatively. Total revision patients accounted for 20 cases; 11 (55%) of them were male and 9 (45%) were female. The distribution of ages of the patients was between 19-62, and the average was 37. Also, 12 (60%) revision cases were on the right ear, and 8 of them were on the left (40%). nine (45%) of the contralateral ears of patients undergoing revision surgery were normal, 2 (10%) had stapedectomy, and 9 of them (45%) had otosclerosis. Further, 18 (90%) of 20 patients had a primary stapedectomy in our center. Two of them (10%) were outside the center. Also, 19 patients (95%) had a transmeatal incision, and 1 (5%) patient had an endaural incision. In 2 operated (10%) patients, no prosthesis was found; in 8 (40%) patients, the prosthesis was displaced, and 10 (50%) patients had the prosthesis were in place. Four (20%) patients had a granuloma, and 1 (5%) patient had a perilymph fistula. Taken out of the previous prosthesis was performed in 8 (40%) patients. One of the patients (5%) had sensorineural hearing loss. One (5%) patient had revision 2 times on the same ear. In this study, exploration was performed in 19 (95%) patients with conductive hearing loss and in l (5%) patient with vertigo.

Dislocation of the prosthesis from oval window was identified in 9 patients, dislocation of the prosthesis from the incus and granuloma of the oval window were identified in 4 patients, and an enclosed oval window was identified in 2 patients.

Sixty percent of the patients had improvement in hearing. None of the patients had total hearing loss. Sensorineural hearing loss occurred in 1 patient. The average postoperative air-bone gap were 26 dB (SD±5dB). One (5%) of the patients with vertigo and 1 (5%) case with perilymph fistula were monitored.

Discussion

Stapedectomy was found to be efficient in the correction of hearing loss caused by otosclerosis after the first time by Shea in 1958. Shea, in 1998, published the results of the last 40 years, and he made all of his surgeries total or partial stapedectomy. Early, the success rate (air-bone gap in speech frequencies of 10 dB or below) was 95.1% and 62.5% in 30 years (6). In this study, the success rates of patients with postoperative audiological were as follows: the difference was 10 dB and below in 62% of cases, 15 dB and below in 88% of the patients, and 20 dB and below in 94% of patients. Air bone gap in 6% of patients was found to be above 20 dB.

In recent years, stapedotomy has been preferred with increasing proportion. Among the causes of this increase are it being less traumatic and providing better hearing in high frequencies. The Fisch (8), Marquet (9), and Causse (10) series support this view. Also, less postoperative sensorineural hearing loss and less dizziness were reported. Persson and colleagues (11) compared total

and partial stapedectomy and stapedotomy results with a 3-year follow-up. In the study, stapedectomy showed better results than stapedotomy in all frequencies. However, in the stapedectomy group, rapid deterioration was observed in hearing thresholds; the deterioration was more pronounced in 4 kHz. In our clinic, stapedotomy was used in 79.8% of cases. When comparing the results of hearing results in stapedotomy and stapedectomy, there was no statistical difference (t-test was used).

Shea had used a vein graft in closure of the oval window. The annular ligament contains elastic fibers with 0.2-mm thickness. A vein graft also contains elastic fibers, and veins obtained from the dorsum of the hand also have 0.2-mm thickness (6). Therefore, it has been preferred in closing the window. Fascia, perichondrium, Gelfoam, blood, and sawdust extracted from the stapes or external ear canal could also be used (5, 6).

Hough (12) reported stapedectomy failures and suggested using tragal perichondrium because of the proximity to the surgical field to create a solid structure on the oval window to prevent displacement of the prosthesis. It was also suggested that it was especially efficient in cases with a defected long arm of the incus.

A Teflon piston prosthesis was used in 98% of cases in our clinic. Teflon is a well-tolerated substance in the middle ear, because it does not give a reaction with tissues. Goldenberg and colleagues (13) made a survey by members of the American Otological Society (AOS); 71% of the members of AOS prefer stainless steel/platinum prostheses. Shea (6) and Causse (14) reported that in their series, they often used a Teflon piston.

There were many studies about the size of the piston and hearing thresholds. In another paper of our center, it was shown that a Teflon piston being 0.8 mm in diameter is more successful than a 0.6-mm Teflon piston (15). Grolman'ın (16) proved in his study about 0.3- and 0.4-mm prostheses that a 0.4-mm diameter teflon piston, especially in low frequencies, was more successful.

Sensorineural hearing loss is a serious complication, even in stapedectomies by experienced hands. Series published in the literature vary between 0.6% to 3% (17). In this study, 0.3% of cases in the early period, l, 2 % cases had delayed sensorineural hearing loss.

Related to juvenile otosclerosis, very few publications were found in the literature (5). In patients under 20 years, surgeons seem to be inclined to a conservative approach. Mostly, two situations are encountered in patients with young age (<20 years): congenital stapes fixation and otosclerosis. In the first one, the diagnosis could be made earlier and is not progressive. Juvenile otosclerosis has a familial history and progressive symptoms. A family history of otosclerosis and progressive illness are helpful in the differential diagnosis (5, 18). Four of 9 patients in this study had a family history. In the pre-operative audiological follow-up of 9 patients, they all had progressive mixed-type hearing loss.

The probability of having bilateral juvenile otosclerosis is 80%, and it is more prominent than adult otosclerosis. In this study, bilateral otosclerosis was found in 6 of 9 patients. In Robinson's study, in 31 patients operated on for otosclerosis under 18 years, 20 of them had bilateral otosclerosis. After the age of 18, patients who undergo surgery in the future develop bilateral disease. If the hearing loss began under 18 years, this ratio rises up to 92% (19).

In patients with juvenile otosclerosis, obliterative otosclerosis is the most commonly seen type. Çöle (20), in 41% of patients with juvenile otosclerosis, and Robinson (19) in 27.8% found obliterative otosclerosis. In our study, 5 of 9 patients had obliterative otosclerosis. The drill should be used in obliterative otosclerosis surgery. For this reason, obliterative otosclerosis surgery in juvenile age is stated to be unnecessary to delay. With the increase in age, the otosclerotic focus in the base of the stapes increases, and surgery would be more difficult (19). Our juvenile study group needed to use the drill.

House (21) recommended delaying surgery in juvenile otosclerosis and, if possible, using bilateral hearing aids. As reason, patients under 20 years of age have the risk of postoperative sensorineural hearing loss. In Robinson's study, this rate increased up to 20%. Lippy et al. (5), in their study, found sensorineural hearing loss of 0.7 dB in 1 year and also stated that it was not different from adults (5, 21). In our study, only 1 patient had high-frequency sensorineural hearing loss in the early postoperative period. At the end of 2 years in this study, hearing had fallen to the preoperative values in 3 patients. In contrast to the sensorineural hearing loss mentioned above, these 3 patients showed decreased airway thresholds.

Robinson (19) examined 4014 stapedectomy patients retrospectively; in 15.1% of patients, the symptoms started under the age of 18. In these patients, only 31 of them (35 ears) had surgery under the age of 18, while the others had amplification or waited for advanced age. Most early age in the patients operated was 5 years of age. In this study, the youngest age was 11 years. Robinson (19), House (21), and Çöle (20) had reported success rates of 100%, 94%, and 97%, respectively. In these patients, the main problem was the potential of serous otitis media and acute otitis media attacks. There are reports about conductive-type hearing loss after surgery to cochlear otosclerosis. Çöle (20) and Robinson (19) identified cochlear otosclerosis rates of 27% and 20%, respectively. In this study, 25% of the patients had cochlear otosclerosis. Among them, the patients operated on due to juvenile otosclerosis should have a long-term follow up.

There are many studies about the diameter of the prosthesis. In our previous study (15), we had compared a 0.6-mm piston with one 0.8 mm in diameter, and the results were more successful in the 0.8 mm group. In the juvenile otosclerosis group, only 1 patient had a 0.8-mm Teflon piston. In this study, only 1 case had a stapedectomy. This patient had developed a labyrinthine fistula.

In routine cases, to lower the air-bone gap below 10 dB difference is considered a criterion for success in severe otosclerosis; to make the patient hear or use a hearing aid should be accepted as success. Compared to the other study, higher success rates have been obtained in this study. Stapedectomy in cases with severe otosclerosis had better results. The patients had better hearing or were able to use a hearing aid. Stapedectomy in severe otosclerosis should be preferred because of economic reasons, patient compliance, and easier rehabilitation (19-21). In the differential diagnosis of other reasons of advanced sensorineural hearing loss and advanced otosclerosis in patients having more than 85 dB conduction hearing loss and having no measurable bone thresholds: 1. positive family history, 2. paraacusis, 3. having benefit from a hearing aid, 4. air-bone conduction gap in previous audiograms, 5. otosclerosis on CT, 6. positive Schwartz sign, and 7. no pathology to make hearing loss. The differential diagnosis should be made especially in patients with cochlear implant candidate (22).

Our results showed that there was no need of a lower limit in bone conduction threshold for stapedectomy. Very low or even not measurable bone conduction thresholds did not create a contraindication for stapedectomy. Increasing levels of postoperative bone thresholds in non-measurable cases can not be explained by the lack of Carhart effect.

For conductive hearing loss after a successful primary stapedectomy or not enough success after primary surgery, revision stapedectomy is needed. The revision stapedectomy surgery technique it is difficult due to the distorted anatomy, and the success will be lower than the primary surgery. The surgeon and the patient should be aware of the risks and problems encountered (23).

Indications for revision surgery are: at least 20 dB of conductive hearing loss in speech frequencies, suspected perilymph fistula, and sudden sensorineural hearing loss. Common reasons of failure in stapedectomy surgery are as follows: prosthetic dislocations, fibrous adhesions, granuloma formation, perilymphatic fistula, incus and/or malleus fixation, incus necrosis, short and long prostheses, and mobilized footplate (23, 24).

In this study, the most common reason leading to revision surgery in patients with conductive hearing loss was a dislocated prosthesis. As a cause of prosthesis dislocation, oval window dislocation and dislocation from the long arm of the incus were observed. According to Pearman (23) and Shea (24), the most common cause was incus necrosis. In this study, the second reason was granuloma formation (20%). In Burtner and Goodman (25) series of 42 patients, the incidence of granuloma formation was 1.8%, and contamination with a foreign body has been suggested as a cause of granuloma formation. Two cases showed bone closure of the oval window. Sheehy et al. (26) and Bhardwaj (27) stated that oval window reopening will cause sensorineural hearing loss.

In this study, sawdust of the stapes suprastructure was placed around the Teflon piston. Thus, he opening around the Teflon piston can be closed well.

Perilymphatic fistula was reported by Sheehy et al. (26) in 16%, Bhardwaj (27) in 1.6%, and Feldman and Schuknecht (28) in 3%. Fistula formation developed more in the Gelfoam group than in the living tissue group (29). In this study, in 1 (5%) patient, the formation of a perilymphatic fistula was monitored.

Shea (24) reported that sensorineural hearing loss after revision surgery could occur more commonly than in primary stapes surgery. In this study, 1 patient (5%) had sensorineural hearing loss. Another factor to keep in mind for each patient is to palpate and monitor the mobility of the ossicular system. The success of revision surgery was 60% in this study. This result can be compared with the results of Crabtree et al. (30) (46%), Sheehy et al. (26) (44%), Burtner (25) (65%), and Dawes (31) (42%).

Conclusion

Stapedotomy and using a Teflon piston with autogenous bone fragments in closing the stapedotomy fenestra are successful methods to recover conductive-type hearing loss in otosclerosis. Stapedotomy in children was found to be as successful as in adults. In patients with advanced sensorineural hearing loss, for stapedotomy, a very low air-bone gap or unmeasured air-bone gap is not a contraindication.

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