Journal of Pharmaceutical Research International

28(6): 1-7, 2019; Article no.JPRI.50453
ISSN: 2456-9119
(Past name: British Journal of Pharmaceutical Research, Past ISSN: 2231-2919, NLM ID: 101631759)

Determining the Incidence of Complications and Their Causes after Stapedotomy in Patients with Otosclerosis

Mohamad Mohseni[1], Ahmad Daneshi[1], Ali Mohamad Asghari[1], Saleh Mohebi[1] and Sara Moradi[1*]

[1]ENT and Head & Neck Research Center and Department, Hazrat Rasoul Hospital, The Five Senses Institute, Iran University of Medical Sciences, Tehran, Iran.

Authors' contributions

This work was carried out in collaboration among all authors. Authors MM and AD designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Authors AMA and SM managed the analyses of the study. Author SM managed the literature searches. All authors read and approved the final manuscript.

Article Information

DOI: 10.9734/JPRI/2019/v28i630222
Editor(s):
(1) Dr. Jongwha Chang, University of Texas, College of Pharmacy, USA.
Reviewers:
(1) S. Sujatha, Government Medical College, India.
(2) Jadi Lingaiah, Kaloji Narayana Rao University of Health Sciences, India.
Complete Peer review History: http://www.sdiarticle3.com/review-history/50453

Original Research Article

Received 14 May 2019
Accepted 24 July 2019
Published 01 August 2019

ABSTRACT

Introduction: In order to treat the symptoms of otosclerosis, various surgical and medical treatments are suggested. Surgical treatments are the choice. This study aimed to determine the incidence of vertigo and its cause in Iran, and the present study focused on this issue.
Methods: This was a prospective cohort study carried out on patients with otosclerosis undergoing stapedotomy referred to Rasoul Akram hospital, Tehran during 2017-18. The patients aged below 18 or those who had a history of vertigo were excluded. Diapasonic and audiometric tests were carried out. The follow-ups included the time of admission (the day after surgery) for the presence of vertigo using visual analogue scale and diapasonic tests, one week after surgery using visual analogue scale and diapasonic tests, and one month after surgery using visual analogue scale and audiometry. The data were imported to SPSS v.22 software and analyzed.
Results: The surgical complications that occurred after stapedotomy for patients in this center were as follows: 12.1%of subjects had vertigo one day after surgery, 8.6% had vertigo one week

**Corresponding author: E-mail: s.moradi22m@gmail.com;*

later, and 1.7% had vertigo one month later, thus, the frequency of vertigo was reduced overtime. Meanwhile, 91.4% of the patients had a better sense of hearing and only 1.7% suffered from tympanic membrane perforation. In 8.6% of subjects, there was a disturbance in the taste. Tinnitus was only observed in 5.2% of the surgical patients in this center. Among women, vertigo was higher one day and one week after surgery. Logistic regression showed that age is significant predictor of dizziness one day after surgery (OR: 1.37, P=0.03).

Conclusion: According to the results, the frequency of vertigo was decreased overtime. In this study, it was found that the complications of stapedotomy surgery were less than other surgical methods, but those who were older had significantly higher vertigo a week and one day after surgery indicating effective role of age on postoperative complications. Those who underwent surgery by tympanomeatal method had a better vertigo one day and one week after surgery.

Keywords: Stapedotomy; tympanomeatal; otosclerosis; SNHL.

1. INTRODUCTION

Otosclerosis is the most common cause of progressive hearing loss in adults. It is typically more common in women [1]. The prevalence of otosclerosis in the normal population is less than 1% [2,3]. There are various surgical and medical treatments. Surgical treatment is the choice, which improves the hearing of almost 95% of patients [4]. Vertigo is one of the complications that can be caused by stapes operation [2,5]. Among other surgical complications, the nervous sensory hearing loss, facial paralysis, tinnitus, tympanic membrane perforation, perilymph fistula, and taste disorder can be mentioned [5]. A small number of patients have noted the postoperative tinnitus which is often associated with serous labyrinthitis. The taste disorder occurs in 9% of patients and is mostly related to elongation of chorda tympani than its perforation. It is often improved within 3-4 months. The perforation of tympanic membrane is often small and marginal with rapidly response. The perilymph fistula is an uncommon post-stapedectomy complication with incidence of 3-9%, in which is much less likely to occur after stapedotomy. A mild vertigo is common after stapes surgery occuring in one per 20 cases. It usually lasts for several hours and is quickly solved but is rarely long or severe. Its control is mainly supportive [1].

In a study by Plaza Mayor G et al., 115 patients were examined and only 2 patients (2.6%) noted vertigo during a 12-month follow-up [6]. In various studies, different causes are noted for vertigo after stapes surgery, including serous labyrinthitis, perilymph aspiration, perilymph fistula, and inner ear trauma, and vertigo can be cured depending on the cause [7,8].

In a study by Magliulo G et al. on 141 patients undergoing surgery, 12 patients (8.5%) had symptoms similar to Benign paroxysmal positional vertigo (BPPV) after surgery and the onset of symptoms varies from day 5 until day 21 after surgery [9]. In another study, 11 patients who had suffered from Sensorineural hearing loss (SNHL) with or without vertigo after surgery underwent MRI, two cases of reparative intravestibular granuloma, a case of intralabyrinthine hemorrhage and a case of bacterial labyrinthitis were reported [10]. Given the differences in the results of studies in this field and the lack of domestic studies on this topic, a study was required to determine the incidence of vertigo and its causes in Iran, and the present study focused on this issue.

2. METHODS AND MATERIALS

This was a prospective cohort study carried out on patients with otosclerosis undergoing stapedotomy referred to Rasoul Akram hospital, Tehran during 2017-18. The patients aged below 18 or those who had a history of vertigo were excluded. Prior to surgery, the Temporal HRCT was carried out for all studied patients. Stapedotomy surgery was performed in patients undergoing total intravenous anesthesia (TIVA) by transcanal or endaural approaches. Twenty one patients received endaural incision in addition to tympanomeatal flap.

The information about the patient and surgery was recorded after the surgery. The follow-up of patients in regard of vertigo was performed by questionnaire, and the diapasonic and audiometric tests were carried out. The tympanic perforation on a visit a month after surgery, postoperative SNHL, prosthesis displacement, postoperative facial paralysis, postoperative tinnitus, postoperative taste disorder, perilymph fistula, and toxic labyrinthitis were evaluated. The vertigo follow-ups included diapasonic tests a

week after surgery using visual scale, diapasonic tests a month after surgery via visual scale, and the audiometry. Moreover, the age, gender of patients and also the side of body suffering from arteriosclerosis were also recorded. The patients who didn't visit for follow-up for any other reason or those who underwent revision surgery were excluded.

2.1 Statistical Analysis

For data analysis, the information recorded in the forms was imported into SPSS v.22 software. First, using descriptive statistics, the frequency of qualitative variables was calculated. Then, the analytical testswas performed on quantitative and qualitative variables of their relationship with the presence of the developmental disorder. In order to investigate the relationship between the studied quantitative variables and developmental disorder, initially the Kolmogorov–Smirnov test was performed to examine the normality of data distribution. The significance level was considered 0.05.

3. RESULTS

In this study, 58 individuals were included in the study, 21 (36.2%) of them were male and 37 individuals (63.8%) were female. The mean age was 30.60±5.98 years. After surgery, it was found in 56 (96.6%) individuals, the improved hearing as gap reduction was above 15 db for 53 subjects (91.4%) and below 15 db for 3 subjects (5.2%). Frequency and percentage of some baseline characteristics of participants are listed in Table 1 and complications were presented in Table 2.

In comparison between the complications, it was found that there was no significant difference in dizziness by gender one day, one week, and one month after surgery (P> 0.05). In those who had a shorter time interval between fenestration and prosthesis insertion, the vertigo a month after surgery was lower (p=0.019). Also, the relationship between tympanomeatal and endeuroral surgery with vertigo at measured times showed that surgical approaches with headache incidence did not show significant relationship between these three times (P>0.05). To investigate the relationship between variables with vertigo during one day after surgery using logistic regression model, there was not a significant relationship between surgical approach, surgeon and gender with vertigo at one day postoperatively (P>0.05) but with an increase in the age unit, the odds ratio of dizziness increased by 1.37 (95% CI, 1.02-1.84) one day after surgery (P=0.03). Table 3 shows the logistic regression model. Patching the prosthesis to connective tissue caused less tympanic perforation, perilymph fistula, and SNLH after surgery (P<0.05). The number of attempts for surgical repair was significantly related to less hearing improvement, higher vertigo after a day and a week, as well as prosthesis displacement (P<0.05).

Table 1. Frequency and percentage of some baseline characteristics of participants

Variable		Frequency (%)
High blood pressure	Negative	58 (96.5)
	Positive	2 (3.50)
Previous SNHL	Negative	58 (96.5)
	Positive	2 (3.50)
Surgical approach	Endaural	19 (32.7)
	Tympanomeatal	19 (67.3)
Blood in the field during prosthesis insertion	Negative	47 (81.0)
	Positive	11 (19.0)
Surgeon	Professor	19 (32.7)
	Fellows	39 (67.3)
Time interval between filtration and prosthetic insertion	5min<	9 (15.5)
	5min>	49 (85.5)
Gaucher disease	Negative	57 (98.28)
	Positive	1 (1.72)
Patching the prosthesis to connective tissue	Negative	53 (91.3)
	Positive	5 (8.7)
Unilateral or bilateral disease	Unilateral conflict	30 (51.7)
	Bilateral conflict	28 (48.3)

Table 2. Frequency and percentage of postoperative complications

Variable		Frequency (%)
Vertigo a day after surgery	Negative	51 (87.9)
	Positive	7 (12.1)
Vertigo a week after surgery	Negative	53 (91.3)
	Positive	5 (8.7)
Vertigo a month after surgery	Negative	57 (98.28)
	Positive	1 (1.72)
Tympanic perforation on a visit a month after surgery	Negative	57 (98.28)
	Positive	1 (1.72)
Postoperative SNHL	Negative	57 (98.28)
	Positive	1 (1.72)
Prosthesis displacement	Negative	56 (96.6)
	Positive	2 (3.4)
Postoperative tinnitus	Negative	53 (91.3)
	Positive	5 (8.7)
Taste disorder	Negative	53 (91.3)
	Positive	5 (8.7)
Perilymph fistula	Negative	57 (98.28)
	Positive	1 (1.72)
Toxic labyrinthitis	Negative	57 (98.28)
	Positive	1 (1.72)

Table 3. Logistic regression model for relationship between vertigo one day after surgery with surgical approach, surgeon, gender, and age

Variable	OR	95% CI		P Value
		Lower	Upper	
Surgical approach	0.16	0.02	1.26	0.08
Surgeon	0.82	0.09	7.16	0.85
Gender	8.68	0.91	82.42	0.06
Age	1.37	1.02	1.84	0.03

4. DISCUSSION

The sensory neural hearing loss is the worst complication after surgery. The prevalence is about 1% and the cause is unknown. It could be mild or exclusively present at high frequencies. In case of clinical suspicion, prednisolone is started for the patient [5]. Another complication is the serous labyrinthitis that is common because of inflammation in the inner ear. Clinically, it is seen as mild imbalance, positional vertigo or mild hearing loss in higher frequencies. The symptoms usually disappear within several days to several weeks. Facial paralysis is another surgery complication that is rare and usually occurs with delay and after the fifth day and remains stable for several weeks [1]. The surgical complications that occurred after stapedotomy for patients in this center were as follows: 12.1% of subjects had vertigo a day after surgery, 8.6% had vertigo a week later, and 1.7% had vertigo a month later, thus, the frequency of vertigo was reduced overtime. Meanwhile, 91.4% of the patients had a better hearing sensation and only 1.7% suffered from tympanic membrane perforation. In 8.6% of subjects, there was a disturbance in the taste sensation that was lower than earlier studies [5]. The new tinnitus was only observed in 5.2%of the individuals in this center.

A study in 2017 indicated that the otosclerosis is the cause of 5-9% of hearing loss. The aim of this study was to evaluate the results of treatment of otosclerosis surgery and to investigate the effect of disease stage, time of symptoms, age and gender on the results. In this study, 105 patients undergoing surgery were investigated. The postoperative hearing status was evaluated. The mean values of air- and bone-conduction (air bone gap) were compared a year after the treatment and at least 4 years after the surgery. The results of this study show that the disease stage, time of symptoms, age and gender had no effect on the results of treatment, but the difference in the mean hearing loss before and after treatment is significant [11]. Meanwhile, in our study, those who were older had significantly higher vertigo a week and a day

after surgery, and it shows that age had been effective on the postoperative complications.

In a study by Wegner in 2018, 230 patients were retrospectively investigated in terms of hearing improvement as a decrease in air bone gap after stapedotomy. In the study, the success rate of surgery was reported 95.7%. In the same study, the tympanic perforation after stapedotomy was reported 1.1% [12]. In the present study, 91.4% of patients had hearing improvement as a decrease above 15 db in air bone gap, but the difference in surgery by attending physicians and fellows was not significant, and their complications were not significantly different. Also, there was a case of postoperative tympanic membrane perforation, which was a marginal microperforation.

In a study conducted in 2017, the results of the auditory and otoacoustic tests (OAE) of stapedotomy were compared. In this study, a total of 18 patients with otosclerosis participated in a cohort study. All patients underwent fenestra drill stapedotomy using the Causse fluroplastic large loop piston prosthesis. The bone audiometries, pure tone air, audiometry, and OAE tests were performed. One year after surgery, these results were compared within the group and between the groups. The similar results of hearing after stapedotomy were found for 0.4 and 0.6 mm prostheses with small but considerable advantages in increasing BC and overclosure parameter for 0.6 mm prosthesis. The difference in OAE test was not found in evaluating the auditory results of stapedotomy, and also, the hearing rate of these individuals had significant results before and after surgery in all tests [13]. In another study that was published by Mohammad Khorsandi et al. in 2018, the medical records of 995 patients with otosclerosis undergoing stapedectomy or stapedotomy was retrospectively investigated. The success rate of surgery in this study was reported 93.4% and it was said that the diameter of the prosthesis had no effect on the success rate, but the female gender and right ear involvement are reported as a prognostic factor in the good surgical outcome [14]. In this study, the size and diameter of the prosthesis were not related to auditory outcome and postoperative complications. The gender of the patient had also no effect on the success rate of the surgery, but the vertigo rate a day and a week after surgery was higher in women.

In a study carried out in 2018 to compare the measurement of the effect of treatment in tinnitus using multi-item outcome instrument, the aim was to determine the minimum important change in tinnitus, in which was clinically significant for patients with otosclerosis. To follow this goal in this study, 95 patients with otosclerosis who were suffering from tinnitus were investigated. They completed the tinnitus performance index before the stapedotomy and three months after surgery. The anchor-based approach using the external criterion (anchor) allows for determining the change in the tinnitus sensation that was significant for patients after stapedotomy. In this evaluation, it was shown that score 8.8 in Tinnitus Functional Index could be the criteria for the effectiveness of stapedotomy in patients with otosclerosis suffering from tinnitus. The hearing problems accompanying tinnitus can affect the concept of tinnitus variations and the hearing rate was also increased in these patients. In this study, 69.4% of individuals felt that their tinnitus was improved after surgery and had a significant difference with the other group [15].

In a study by Cavalcante et al., done as a review of articles, eight papers were investigated on the tinnitus improvement after the stapes surgery. The degree of postoperative tinnitus improvement during this examination was reported 85.52% [16]. In the present study, 84.4% of patients noted the postoperative tinnitus improvement. In two studies by Somers T and Sedwick JD, the comparison of surgical results in two methods of fenestration with micro-drill and CO2 laser was investigated, and no significant difference was reported in the results of the two groups in any of the studies [17,18]. In this study, laser was not used for fenestration in these patients. The only difference in surgical methods in patients in the present study was using both approaches of endaural and tympanomeatal. In the results of the examinations, those who were operated by tympanomeatal method had better vertigo rate a day and a week after surgery.

The studies show that otosclerosis is more prevalent in men than women. In a study in France on the complications of stapes surgery in these patients, 67% of patients were female [1], and in a study in Spain, it was reported 68% [19] as well as occupation has a role in hearing [20]. In the present study, the prevalence was higher in women (63.8%).

A study carried out in 2017 revealed that the surgical intervention was the preferred treatment method for reduced conductive hearing associated with stapedial otosclerosis. However,

given that it is a difficult and delicate method, the surgery might fail for various reasons. Therefore, it is very important to evaluate the success rate of the surgical procedure used in each regional center. The aim of this study was to evaluate the effectiveness of stapedotomy to improve hearing sensation for otosclerotic patients. All cases that were subjected to stapedotomy during 1997-2009 were retrospectively investigated. The preoperative and postoperative evaluations were carried out. None of the studied cases in this study showed a nervous sensory hearing loss caused by stapedotomy. It is concluded that stapedotomy is a safe and effective treatment method for patients with otosclerosis [21].

In a study by Rao in 2018, the complications after endoscopic stapedotomy were investigated in 40 patients. The vertigo and SNHL were reported in five and one patients, respectively. In the present study, there was vertigo a day, a week, and a month after surgery in seven, five and one patients, respectively. A case of SNHL was developed after surgery that did not respond to medical treatment [22].

In 2018, Shiao retrospectively examined 53 patients (56 involved ears). In this study, two methods were conducted by traditional stapes surgery and minimally traumatic stapes surgery. There was no significant difference in the hearing outcomes of patients between the two surgical methods, but the postoperative vertigo rate was lower in patients for whom the soft tissue sealant was used around their prosthesis [23]. In this study, there was no relationship between patching prosthesis to connective tissue and postoperative vertigo rate, but failure to patch around the prosthesis was associated with a higher SNHL.

In case of the association between HTN and otosclerosis, Yutaka performed a study in 2008 on the role of angiotensin II in bone remodeling in 186 patients with otosclerosis and 526 patients in the control group. In this study, the pleomorphism of 3 genes associated with ACE receptor was investigated, and the results of this study showed that there is a significant relationship between the activity of renin-angiotensin system and otosclerosis [24]. In 2009, Isabelle Schrauwen examined the pleomorphism of three genes investigated in the earlier study in a larger sample size and reported that there was no significant relationship between this pleomorphism associated with activity of the renin-angiotensin system and otosclerosis [25]. In this study, in those who had a shorter time interval between fenestration and prosthesis insertion (less than 5 min), the vertigo rate a month after surgery was lower. Also, in patients with higher number of attempts for prosthesis insertion (more than 3 times), the rate of vertigo a day and a week after surgery as well as prosthesis displacement was higher, but the presence or absence of blood in the surgical field during prosthesis insertion was not associated with an increase in complications.

5. CONCLUSION

In the study, the level of complications occurred after stapedotomy in patients with otosclerosis was associated with variables such as age of patient, surgical procedure, number of attempts for prosthesis insertion, as well as the time interval between fenestration and prosthesis insertion.

CONSENT

As per international standard, patient's written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

Human rights were respected in accordance with the Helsinki Declaration 1975, as revised in 1983. All phases of the study were supervised by the Ethics Committee of Iran University of Medical Sciences.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

REFERENCES

1. Flint PW, Haughey BH, Niparko JK, Richardson MA, Lund VJ, Robbins KT, et al. Cummings Otolaryngology-Head and Neck Surgery E-Book: Head and Neck Surgery, 3-Volume Set: Elsevier Health Sciences; 2010.
2. Ealy M, Smith RJ. Otosclerosis. Medical genetics in the clinical practice of ORL. 70: Karger Publishers. 2011;122-9.
3. de Vilhena D, Gambôa I, Duarte D, Lopes GJIjoo. Vestibular disorders after stapedial surgery in patients with otosclerosis; 2016.
4. Dahlin Redfors Y, Möller CJAoo. Rhinology laryngology. Otosclerosis: Thirty year follow up after surgery. 2011;120(9):608-14.
5. Kojima H, Komori M, Chikazawa S, Yaguchi Y, Yamamoto K, Chujo K, et al.

Comparison between endoscopic and microscopic stapes surgery. 2014;124(1): 266-71.
6. Uppal S, Bajaj Y, Coatesworth AJIjocp. Otosclerosis 2: The medical management of otosclerosis. 2010;64(2):256-65.
7. Albera R, Milan F, Giordano L, Riontino E, Lacilla M, Bussi M, et al. Stapedectomy outcome. Comparison of different diameter prostheses. 1997;47:185-90.
8. Nicolás JLL, Cano JG. Possible benefit of calcitonin in the treatment of otosclerosis. 2003;54 (3):169-72.
9. Magliulo G, Gagliardi M, Cuiuli G, Celebrini A, Parrotto D, D'Amico RJJoVR. Stapedotomy and post-operative benign paroxysmal positional vertigo. 2005;15(3): 169-72.
10. Testa JRG, Millas I, De Vuono I, V Neto M, Lobato MJRBdO. Otosclerose: Resultados de Estapedotomias; 2002.
11. Czerwińska G, Ścierski W, Namysłowski G, Lisowska G, Misiołek MJOpTPo. The surgical treatment results of otosclerosis at the Department of Otolaryngology Silesian Medical University in Zabrze in years 2000-2010. 2017;71(2):16-21.
12. Wegner I, Vincent R, Derks LS, Rauh SP, Heymans MW, Stegeman I, et al. An internally validated prognostic model for success in revision stapes surgery for otosclerosis. 2018;128(10):2390-6.
13. Faranesh N, Magamseh E, Zaaroura S, Zeidan R, Shupak AJTJotIAO. Hearing and otoacoustic emissions outcome of stapedotomy: Does the Prosthesis Diameter Matter? 2017;13(2):162-71.
14. Khorsandi A MT, Jalali MM, Shoshi DV. Predictive factors in 995 stapes surgeries for primary otosclerosis. 2018;128(10): 2403-7.
15. Skarżyński H, Gos E, Dziendziel B, Raj-Koziak D, Włodarczyk EA, Skarżyński PHJH, et al. Clinically important change in tinnitus sensation after stapedotomy. 2018;16(1):208.
16. Cavalcante AMG, Silva IMdC, Neves BJ, Oliveira CA, Bahmad Jr FJBjoo. Degree of tinnitus improvement with stapes surgery-A Review. 2018;84(4):514-8.
17. Sedwick JD, Louden CL, Shelton CJAoOH, Surgery N. Stapedectomy vs stapedotomy: Do you really need a laser? 1997;123(2):177-80.
18. Somers T, Vercruysse J-P, Zarowski A, Verstreken M, Offeciers E. Rhinology, Laryngology. Stapedotomy with microdrill or carbon dioxide laser: Influence on inner ear function. 2006;115(12):880-5.
19. Vincent R, Sperling NM, Oates J, Jindal MJO. Neurotology Surgical findings and long-term hearing results in 3,050 stapedotomies for primary otosclerosis: a prospective study with the otology-neurotology database. 2006;27(8):S25-S47.
20. Amani F, Bahadoram M, Hazrati S. Evaluation of occupational injuries among welders in Northwest Iran. Journal of Preventive Epidemiology. 2017;2(2).
21. Alzhrani F, Mokhatrish MM, Al-Momani MO, Alshehri H, Hagr A, Garadat SNJAoSm. Effectiveness of stapedotomy in improving hearing sensitivity for 53 otosclerotic patients: Retrospective Review. 2017;37(1):49.
22. Rao PK, Ramesh Sjjoeom, sciences-jemds d. Endoscopic stapedotomy-our experience. 2018;7(36):3954-8.
23. Shiao A-S, Kuo C-L, Wang M-C, Chu C-HJJotCMA. Minimally traumatic stapes surgery for otosclerosis: Risk reduction of post-operative vertigo. 2018;81(6):559-64.
24. Imauchi Y, Jeunemaître X, Boussion M, Ferrary E, Sterkers O, Grayeli ABJO, et al. Relation between renin-angiotensin-aldosterone system and otosclerosis: A genetic association and in vitro study. 2008;29(3):295-301.
25. Schrauwen I, Thys M, Vanderstraeten K, Fransen E, Ealy M, Cremers CW, et al. No evidence for association between the renin-angiotensin-aldosterone system and otosclerosis in a large Belgian-Dutch population. 2009;30(8):1079-83.

Peer-review history:
The peer review history for this paper can be accessed here:
http://www.sdiarticle3.com/review-history/50453