

Factors Affecting Postoperative Hearing Results in Type IV Tympanoplasty: Preliminary Study of the Influence of External Auditory Canal Packing Material

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ABSTRACT

Background Postoperative hearing results of type IV tympanoplasty have been shown to have poorer results than other reconstruction techniques. There are numerous reports evaluating the factors for hearing improvement. This preliminary study aimed to analyze and determine the factors that affect hearing results.

Methods A total of 80 patients who underwent type IV tympanoplasty were evaluated to participate in this study. The medical records of the candidate patients were collected retrospectively. Fifty out of the 80 recruited patients were excluded due to the following reasons: they could not be followed-up for more than a year after the final operation, their initial surgery was not performed in our department, or they needed a revision surgery. The pre-, intra-, and postoperative factors were evaluated and analyzed using EZR software. Cases were divided into two groups according to postoperative hearing results, and each factor was analyzed univariately. The explanatory variables included in the multivariate analysis were the variables that satisfied $P < 0.1$ in the univariate analysis. Furthermore, all cases were divided into two groups according to the qualitative variables that showed significant difference in the multivariate analysis, and the background factors were evaluated.

Results The results of univariate analysis showed $P < 0.1$ for 'Age' and 'Material of external auditory canal (EAC) packing'. Multivariate analysis showed $P < 0.05$ for both. The comparison between the two packing material groups showed that the gauze group was more likely to have improved hearing than Spongel[®] group, and the ossicular chain condition of the gauze group was maintained better.

Conclusion 'Age' and 'Material of EAC packing' were considered to be significant factors affecting the postoperative hearing results. The selection and use of packing materials that provide stability should be considered to obtain better postoperative hearing results in type IV tympanoplasty.

Key words external auditory canal packing; postoperative hearing; type IV tympanoplasty

The purpose of a tympanoplasty is to address the diseases of the tympanic cavity and to improve hearing. Compared to other reconstruction techniques, Type IV tympanoplasty is reported to be unlikely to improve hearing; hence, studies have been performed to evaluate the factors that affect the postoperative hearing results of type IV tympanoplasty. We performed the tympanoplasty by a standard technique. We used the retroauricular approach, then performed the mastoidectomy on demand, and addressed the diseases in the tympanic cavity under a microscope. The endoscope was used to check the tympanic cavity as necessary. The facial nerve stimulator (NIM response[®], Medtronic, Dublin, Ireland) was used in almost all cases. The external auditory canal and scutum were reconstructed with cartilage when drilled. However, in our previous study on short-term postoperative hearing results of tympanoplasty in 2010,¹ we also found that the hearing results with type IV tympanoplasty were not as good as expected. Therefore, we conducted an exploratory analysis to determine the factors that affect hearing results. The focus of the past reports was often on factors such as intraoperative findings and reconstruction materials. In this study, we aimed to determine the preoperative, intraoperative, and postoperative factors that affect postoperative hearing results.

MATERIALS AND METHODS

A total of 80 patients who underwent type IV tympanoplasty between January 2009 and December 2018 were screened for this study. Patients were included retrospectively based on their medical records. Fifty of the 80 recruited patients were excluded due to the following reasons: failure to follow up for more than 1 year after the final operation, their initial surgery was not performed in our department, or there was a need for revision surgery due to recurrence of cholesteatoma

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Abbreviations: EAC, external auditory canal; JOS, Japan Otological Society

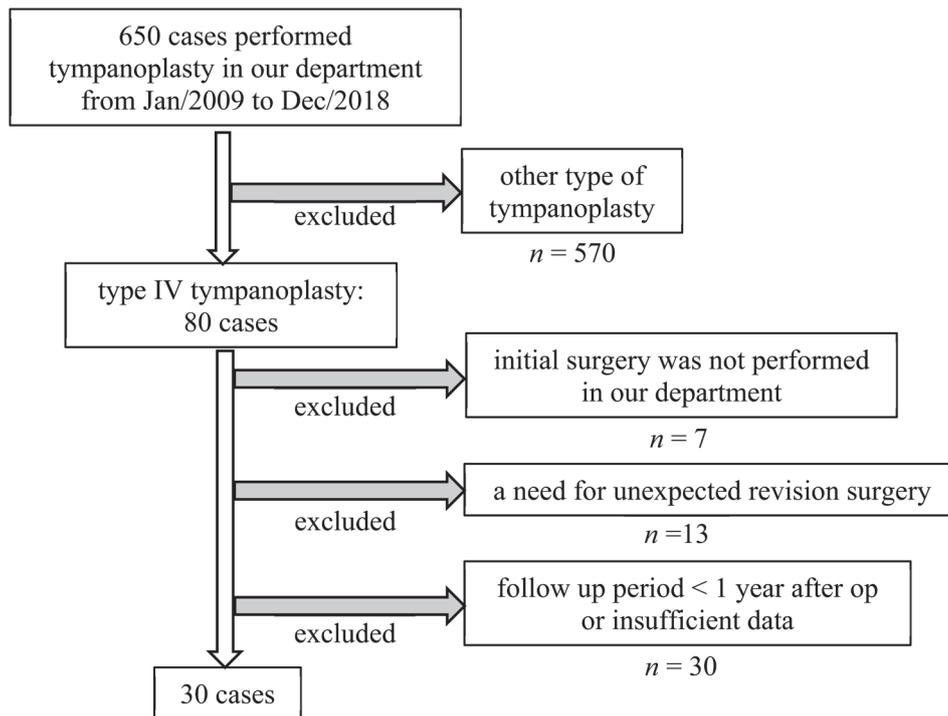


Fig. 1. Flowchart of sample selection.

recurrence and unexpected ossicular discontinuity. Staged surgery case was counted as one case with the initial surgery. Finally, 30 cases were included in this study (Fig. 1). The mean observation period from the last surgery was 60.6 months (12–120 months). There were 18 cases of cholesteatoma (stage I: three cases, stage II: 11 cases, stage III: three cases), five cases of congenital cholesteatoma (stage I: two cases, stage II: two cases, stage III: one case), four cases of adhesive otitis media, and three cases of ossicular malformation. We determined the staging for middle ear cholesteatoma using the criteria of Japan Otological Society (JOS) in 2015.² There were no cases of facial nerve palsy or other serious complications.

We evaluated the following preoperative factors: age, gender, pathology, affected side, and mastoid cells development, the following intraoperative factors: approach, mastoid obliteration, pathological status of stapes, and material of external auditory canal (EAC) packing, and the following postoperative factors: postoperative hearing results, postoperative aeration around stapes, and postoperative ossicular chain condition.

Pathology was further classified into two categories due to its small number: cholesteatoma (including congenital) or others. The development of mastoid cells and pathological status of stapes were further classified into four categories based on the staging and classification

criteria for middle ear cholesteatoma proposed by the JOS in 2015.² Mastoid cells development was classified according to the following criteria; MC0: almost no cell growth, MC1: cellular structures only around the mastoid antrum, MC2: well-developed cellular structures, MC3: cellular structures extending to the peri-labyrinthine area. In addition, mastoid cells development was classified into one of the two subcategories: underdeveloped (MC0, MC1) and well-developed (MC2, MC3). The pathological status of the stapes was classified according to the JOS criteria as follows; S0: no stapes involvement, S1: the superstructure is surrounded by cholesteatoma and granulation, S2: the superstructure is missing but the footplate remains intact, S3: the footplate is involved and indistinguishable; and SN, the stapes is not observed during surgery.² As this study only included cases above S2, all cases were classified as S2 or S3. The intraoperative factor approach was further divided into two types: canal wall reconstruction and canal wall preservation. The material used for EAC packing was either shredded gauze or Spongel® (LTL Pharma, Tokyo, Japan). Postoperative hearing improvement was determined according to the JOS criteria (2010), modified Sakai's criteria.³ The latest hearing results were used as postoperative hearing results. The results were the average of three speech hearing frequencies: 0.5-, 1-, and 2-kHz. The criteria to

Table 1. Background of all cases

Mean age, years (range)	35.9 (4–75)
Gender (male:female)	14:16
Pathology (cholesteatoma:others)	23:7
Affected side (right:left)	12:18
Mastoid cells development (well:poor)	16:14
Approach (CWD or TCA with reconstruction: CWU)	22:8
Mastoid obliteration (yes:no)	9:21
Pathological status of the stapes (S2:S3)	25:5
Material of EAC packing (shredded gauze:Spongel)	21:9
Hearing results (improve:no change or worse)	17:13
Aeration around stapes after surgery (good:poor)	25:5
Ossicular chain condition after surgery (good condition:bad condition)	25:5

CWD, canal wall down; CWU, canal wall up; TCA, trans canal atticotomy.

determine success included any one of the following: A-B gap < 15 dB, average of the postoperative air conducted hearing level of < 30 dB, hearing gain > 15 dB. The A-B gap is the difference between the postoperative air conducted hearing average (HA) and preoperative bone conducted HA. Hearing gain refers to the extent of postoperative air conducted HA improvement from its preoperative state. The overall success rate of the type IV tympanoplasty was 56.7% (17/30). The postoperative aeration around stapes was assessed based on the latest computed tomography images. Postoperative ossicular chain condition was classified into two categories: good (correct position/shift) or bad (fall/discontinuity) condition. For the ossicular chain reconstruction, we used a cartilaginous ossicle prosthesis (Apaceram[®], HOYA Technosurgical, Tokyo, Japan).

The cases were divided into two groups according to postoperative hearing results. To perform multivariate analysis; each factor was initially analyzed univariately. The explanatory variables included in the multivariate analysis were the variables with $P < 0.1$ in the univariate analysis. Statistical significance was considered with P value of < 0.05.

Furthermore, all cases were then divided into two groups according to the qualitative variables that showed significant difference in the multivariate analysis and the evaluated background factors.

The statistical method used were logistic regression analysis, χ -square test, and t test using EZR software.⁴

The study was approved by the ethics review committee at Tottori University (approval number 20A053), and the requirement for informed consent was waived due to the opt-out policy adopted in the study.

RESULTS

The background of all cases is showed in Table 1. Using univariate analysis, one preoperative factor was found to be statistically significant, with P value of < 0.1: age (Table 2). The odds ratio was 1.040, $P = 0.0211$. The lower and upper 95% confidence intervals (CI) were 1.010 and 1.070, respectively. The intraoperative factor with $P < 0.1$ was the material used for EAC packing. The odds ratio was 8.75, $P = 0.0205$. The lower limit of the 95% CI was 1.400 and the upper limit was 54.80. No significant postoperative factor was found (Table 2).

Multivariate analysis

From each result, age and the material of EAC packing were selected as explanatory variables. Multivariate analysis was then performed with the objective variable as postoperative hearing results. All of the variables were considered significant factors affecting the postoperative hearing results (Table 3). Statistical analysis was performed by logistic regression analysis with EZR.

Patient background factors divided by materials of EAC packing

The cases were divided into two groups: the shredded gauze group and the Spongel[®] group, then the patient background factors were analyzed with EZR (Table 4). There were no significant differences in preoperative or intraoperative factors. However, there were significant differences in postoperative hearing results and postoperative ossicular chain conditions. In other words, there were significantly more cases of poor hearing improvement and bad condition of the ossicular chain in the Spongel[®] group.

Table 2. Univariate analysis

	OR	95% CI		P value	
		Lower	Upper		
Pre	Age	1.040	1.010	1.070	0.0211*
	Gender	0.964	0.227	4.10	0.961
	Pathology	1.03	0.186	5.66	0.977
	Affected side	1.120	0.256	4.91	0.880
	Mastoid cells development	0.6	0.140	2.58	0.492
Intra	Approach	0.720	0.137	3.78	0.698
	Mastoid obliteration	0.25	0.0477	1.31	0.101
	Pathological status of stapes	2.250	0.317	16.00	0.417
	Material of EAC packing	8.75	1.400	54.80	0.0205*
Post	Aeration around stapes	0.848	0.120	6.00	0.869
	Ossicular chain condition	7.110	0.686	73.70	0.100

* $P < 0.1$. CI, confidence interval; OR, odds ratio.

Table 3. Multivariate analysis

	OR	95% CI		P value
		Lower	Upper	
Age	1.050	1.010	1.090	0.0225**
Material of EAC packing	12.90	1.450	115.00	0.0220**

** $P < 0.05$. CI, confidence interval; OR, odds ratio.

Table 4. Patient background factors divided by materials of EAC packing

	Gauze ($n = 21$)	Spongel ($n = 9$)	P value
Age, years (average)	34.4	39.3	0.571
Gender (male:female)	9:12	5:4	0.694
Pathology (cholesteatoma:others)	14:7	9:0	0.071
Affected side (right:left)	8:13	4:5	1.00
Mastoid cells development (well:poor)	9:12	5:4	0.694
Approach (CWD or TCA with reconstruction: CWU)	16:5	6:3	0.666
Mastoid obliteration (yes:no)	6:15	3:6	1.000
Pathological status of the stapes (S2:S3)	18:3	7:2	0.622
Hearing results (improve: no change or worse)	15:6	2:7	0.020**
Aeration around stapes after surgery (good:poor)	18:3	7:2	0.622
Ossicular chain condition after surgery (good condition:bad condition)	20:1	5:4	0.019**

** $P < 0.05$. CWD, canal wall down; CWU, canal wall up; TCA, trans canal atticotomy.

DISCUSSION

It has been reported that postoperative hearing results after type IV tympanoplasty have poorer outcomes than other types of reconstruction. Many reports have evaluated the factors for hearing improvement after tympanoplasty. Adkins et al.⁵ found that the age of the patient affected the postoperative hearing results, and Tos⁶ stated that postoperative hearing results were best in patients under 10 years of age and worst in patients over 60 years of age. In Japan, Aoyagi et al.⁷ reported that postoperative hearing in older patients is less likely to improve after tympanoplasty. The reason was that older patients are more affected by repeated inflammation and had a progressive sensorineural hearing loss. In addition, it was also reported that “Pathology”,⁸ “Postoperative aeration around stapes”,⁹ and “Condition of a stapes superstructure”¹⁰ can be significant factors affecting hearing results.

In our study (Table 3), age is found to be an important factor for improvement of hearing, and the results obtained are consistent with previous reports. However, pathology and postoperative aeration around stapes did not show significant differences in postoperative hearing results. This discrepancy may be due to the number of cases and the small number of items in this study, which could have prevented us from performing an adequate analysis for each of these factors. This study was only exploratory, thus, further studies are needed to obtain more accurate results. In addition, it is difficult to evaluate the impact of our results on the pathological status of stapes because it is not possible to obtain reports that are subdivided by the condition of the stapes footplate, as classified by JOS classification (2015).² This may be clarified in the future once the evaluation of this classification becomes widespread and more reports are published.

We found a significant difference in the material of EAC packing group, thus we further examined the background of the patients by dividing them into two groups: the shredded gauze group and the Spongel[®] group. Currently, several packing materials such as hemostatic gelatin sponge (Spongel[®]), medical sponge, chitin wound dressing, and polyglycolic acid sheet have been widely used in middle ear surgery.¹¹ In our department, shredded gauze or a piece of Spongel[®] are used as packing materials. Spongel[®] is used for pediatric patients who cannot tolerate ear treatment, cases with no perforation of the ear canal or tympanic membrane, and staged surgery cases with a well-defined ear canal morphology. Spongel[®] is used because packing with gauze leaves a large amount of lint in the EAC, which is time-consuming to treat, and also causes pain while

cleaning. However, the results showed that there was a high incidence of cases with poor condition of ossicular chain, especially in the Spongel[®] group, and the postoperative hearing improvement was also poor (Table 4). We hypothesized two reasons for the poor condition of ossicular chain in the Spongel[®] group. First is the inadequate compression of the packing. In fact, in cases with large amounts of exudate or postoperative infection, the Spongel[®] can melt and sometimes fall out, leading to inadequate fixation. Second is the difficulty of predicting how large Spongel[®] would expand as it absorbs the exudate. Furthermore, the mastoidectomy on demand, which is often used in our department, may result in a large defect in the EAC wall (even if EAC wall reconstruction is performed). There is a risk of excessive pressure by the Spongel[®] if a vulnerable part of the EAC is created. Since these factors are suspected to affect the stability of the ossicular chain, it was hypothesized that the selection and use of a stable packing material for type IV reconstruction should be studied in the future. Hence, we thought that the gauze might be a better material in type IV tympanoplasty. However, further research is required to prove the postoperative morphologic changes of EAC.

In conclusion, postoperative hearing results was affected by age and the material of EAC packing in the type IV tympanoplasty patients. Although this is an exploratory study and more cases are needed for accurate results, attention must be paid on the selection and use of packing materials that provide stability to obtain better postoperative hearing results.

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