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Original Article

Short–Term Hearing Prognosis of Ossiculoplasty in Pars Flaccida Cholesteatoma Using the EAONO/JOS Staging System

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OBJECTIVES: The aim of the present study was to investigate the prognostic factors for short-term hearing outcomes of ossiculoplasty for primary pars flaccida cholesteatoma according to the European Academy of Otology and Neurotology/Japanese Otological Society (EAONO/JOS) and 2015 JOS staging systems.

MATERIALS and METHODS: A total of 34 patients with primary pars flaccida cholesteatoma who underwent one-stage tympanomastoidectomy with partial ossicular reconstruction using double cartilage block were included in the study. The postoperative pure-tone average air–bone gap (PTA-ABG) was calculated, and two criteria of successful hearing outcomes were defined as ≤10 and ≤20 dB. Patients were classified according to the EAONO/JOS and 2015 JOS staging systems. Cochran–Armitage test was used to statistically analyze staging, and Fisher's exact test was used to analyze other factors.

RESULTS: Successful hearing outcome with postoperative PTA-ABG ≤10 and ≤20 dB occurred in 23.5% and 55.9% of cases, respectively. When postoperative PTA-ABG ≤20 dB was defined as successful, the success rate significantly decreased with increase in EAONO/JOS stage, and S0 pathological status of the stapes (no involvement) was a significantly favorable predictive factor. When postoperative PTA-ABG ≤10 dB was regarded as successful, the significantly favorable predictive factors were S0 pathological status of the stapes and development of mastoid cells with MC2–3 (better developed cells).

CONCLUSION: Favorable prognostic factors for hearing outcomes of tympanomastoidectomy with partial ossicular reconstruction for primary pars flaccida cholesteatoma were low stage following the EAONO/JOS staging system and no stapes involvement and better development of mastoid cells following the 2015 JOS staging system.

KEYWORDS: Cholesteatoma, tympanoplasty, prognosis, hearing

INTRODUCTION

Pars flaccida cholesteatoma (attic cholesteatoma), which originates in a pars flaccida retraction pocket, is a non-neoplastic cystic lesion formed by keratinizing squamous epithelium and keratin debris. It can gradually expand into the middle ear and cause complications by the erosion of the nearby bony structures. There has been no viable non-surgical therapy developed [1]. Thus, tympanoplasty is performed to remove pathological lesions and maintain or improve hearing.

In 2015, the Japan Otological Society (JOS) has proposed staging and classification criteria for middle ear cholesteatoma to provide a basis for meaningful exchange of information pertaining to cholesteatoma treatment [2, 3]. In 2017, the European Academy of Otology and Neuro-otology (EAONO) and the JOS have collaborated and published joint consensus statements regarding the definition, classification, and staging of middle ear cholesteatoma [4].

This study was presented at the "9th EAONO Instructional Workshop", "20th-23th of June 2018", "Copenhagen, Denmark".

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Although various factors affecting the hearing outcomes of tympanoplasty have been reported [5-17], to the best of our knowledge, no study has investigated the favorable prognostic factors for hearing outcomes of ossiculoplasty for middle ear cholesteatoma based on standardized staging and classification criteria. The aim of the present study was to investigate the prognostic factors for hearing outcomes of one-stage tympanoplasty for primary pars flaccida cholesteatoma according to the EAONO/JOS staging system [4], the 2015 JOS staging system [2], and the factors listed in previous reports [5, 6, 8, 10-17].

MATERIALS AND METHODS

Patients

This was a retrospective study. A total of 34 consecutive patients who underwent ossiculoplasty for primary pars flaccida cholesteatoma at a university hospital between April 2013 and July 2017 were included in the study and were followed up for >1 year. All patients underwent one-stage tympanoplasty with mastoidectomy. Cholesteatoma was diagnosed according to the EAONO/JOS joint consensus statements on the definition, classification, and staging of middle ear cholesteatoma [4]. Inclusion criteria only included patients with cartilage ossiculoplasty with partial ossicular reconstruction in the presence of stapes superstructure. The present study was approved by the Institutional Review Board of our university hospital for clinical research (IRB no. 017-0375) according to the tenets of the Declaration of Helsinki. Informed consent was not required for this retrospective study.

Surgical Procedure

All procedures were performed under general anesthesia. A postauricular incision was made, and the cholesteatoma was microscopically removed using a canal wall up (CWU) or canal wall down (CWD) technique. The technique was selected depending on the tegmen height, degree of mastoid cell development, and presence or absence of tegmen destruction. An endoscope was used to examine if there was any residual lesion when the cholesteatoma involved difficult access sites, such as the supratubal recess and sinus tympani. The incus and the malleus head were then removed. A piece of cavum conchae cartilage was harvested and used for ossicular reconstruction. Two small pieces of cartilage were prepared, and a shallow acetabulum was created to receive the stapes capitulum on one of the cartilage pieces. A double cartilage block was interposed between the head of the stapes and the tympanic membrane. When the chorda tympani nerve was preserved, it was positioned on the double cartilage block to stabilize it. A large meatoplasty was performed by removing a segment of the conchal cartilage, and an inferiorly pedicled, periosteal-pericranial flap [18] was used to partially obliterate the mastoid cavity in all patients who underwent CWD tympanoplasty.

Staging and Classification Criteria

The patients were classified according to the EAONO/JOS staging system. The extension of cholesteatoma in each ear was surgically confirmed and scored according to middle ear involvement using the STAM system: S1 (supratubal recess), S2 (sinus tympani), T (tympanic cavity), A (attic), and M (mastoid) (Figure 1) [4]. The staging system for pars flaccida cholesteatoma was as follows: I (cholesteatoma localized in the attic), II (cholesteatoma involving two or more sites), III (cholesteatoma with extracranial complications), and IV (cholesteatoma with intracranial complications) (Table 1) [4]. Mastoid cell development was assessed by preoperative computed tomography and classified into one of the four degrees following the 2015 JOS staging system: MC0 (almost no cell growth), MC1 (cellular structures only around the mastoid antrum), MC2 (well-developed cellular structures), and MC3 (cellular structures extending to the peri-labyrinthine area) (Figure 2) [2]. The pathological status of the stapes was

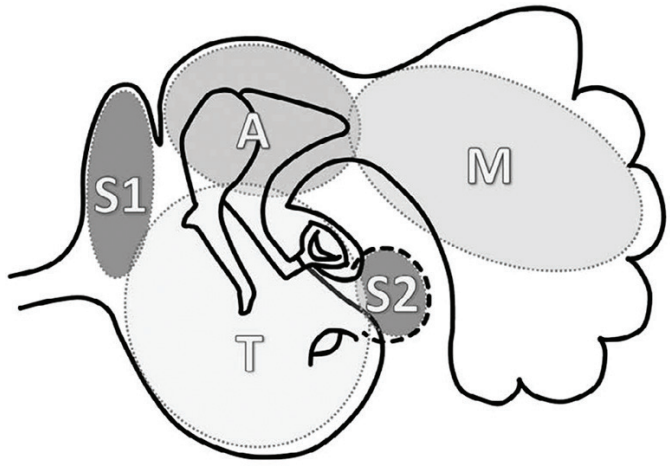

Figure 1. Schematic of divisions of the middle ear space using STAM system: S1, supratubal recess; S2, the sinus tympani; T, tympanic cavity; A, attic; M, mastoid (Adapted from Yung et al. [4] 2017).

Table 1. The EAONO/JOS staging system for pars flaccida cholesteatoma (attic cholesteatoma) (Adapted from Yung et al. 2017 [4])

Stage I	Cholesteatoma localized in the attic
Stage II	Cholesteatoma involving two or more sites
Stage III	Cholesteatoma with extracranial complications or pathologic conditions including
	Facial palsy,
	Labyrinthine fistula: with conditions at risk of membranous labyrinth,
	Labyrinthitis,
	Postauricular abscess or fistula,
	Zygomatic abscess,
	Neck abscess,
	Canal wall destruction: more than half the length of the bony ear canal,
	Destruction of the tegmen: with a defect that requires surgica repair, and
	Adhesive otitis: total adhesion of the pars tensa.
Stage IV	Cholesteatoma with intracranial complications including
	Purulent meningitis,
	Epidural abscess,
	Subdural abscess,
	Brain abscess,
	Sinus thrombosis, and
	Brain herniation into the mastoid cavity.

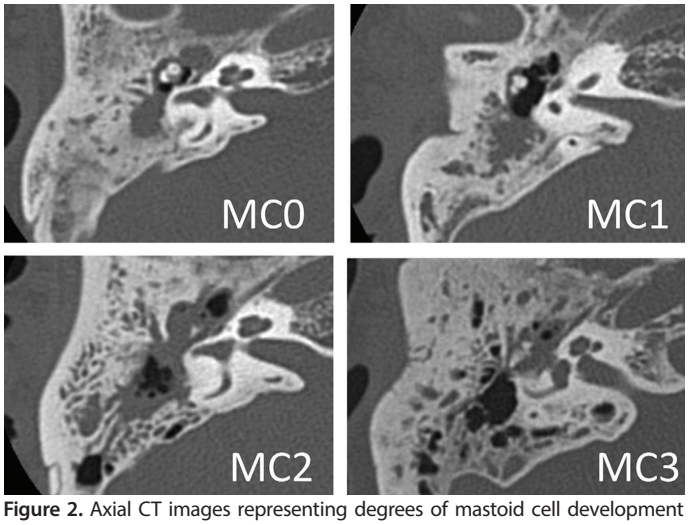

Figure 2. Axial CT images representing degrees of mastoid cell development (MC0-MC3) (Adapted from Tono et al. [2] 2017).

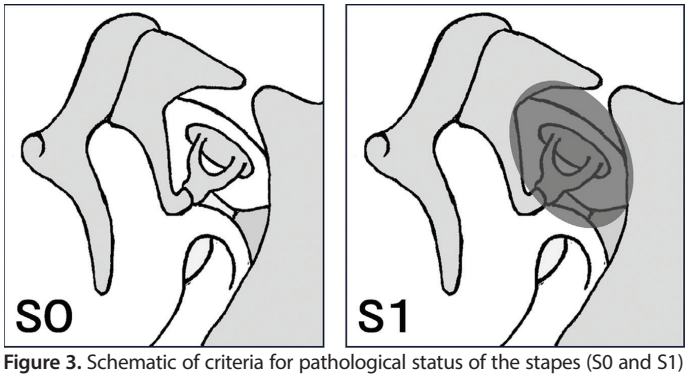

Figure 3. Schematic of criteria for pathological status of the stapes (S0 and S1) (Adapted from Tono et al. [2] 2017).

intraoperatively evaluated and classified into two statuses following the 2015 JOS staging system: S0 (no stapes involvement) and S1 (superstructure surrounded by cholesteatoma and/or granulation) (Figure 3) [2]. The condition of the malleus handle was defined as absent when the malleus handle was eroded due to a lesion or when it was purposefully removed. The tympanic cavity mucosa (e.g., edematous or adhesive) was intraoperatively identified as either normal or diseased.

Hearing Outcome

Hearing outcome was calculated according to the guidelines of the Committee on Hearing and Equilibrium of the American Academy of Otolaryngology-Head and Neck Surgery [19]. Pure-tone air-conduction and bone-conduction thresholds were obtained with thresholds at 0.5, 1, 2, and 3 kHz, which were used to calculate the pure-tone average air–bone gap (PTA-ABG). When 3 kHz was not tested, the mean thresholds at 2 and 4 kHz were used instead, and a four-frequency (0.5, 1, 2, and 3 kHz) PTA-ABG was calculated. Audiograms at ≥1 year but <2 years after surgery were used for determining postoperative short-term hearing results. The two criteria of successful hearing outcomes were defined as PTA-ABG ≤10 and ≤20 dB.

Statistical Analysis

JMP pro 14 (SAS Institute, Inc., Cary, NC, USA) was used for statistical analysis. The prognostic factors for hearing outcomes were analyzed. The prognostic factors were patient age (<60/≥60 years), staging (I-

Table 2. Demographic and clinical data of the patients

Characteristics	No. (%)
Sex	
Male	18 (52.9)
Female	16 (47.1)
Age, years	
median (range)	61.5 (16–87)
<60	15 (44.1)
≥60	19 (55.9)
Staging	
Stage I	5 (14.7)
Stage II	16 (47.1)
Stage III	13 (38.2)
Labyrinthine fistula	3 (8.8)
Destruction of the tegmen	10 (29.4)
Adhesive otitis	1 (2.9)
Stage IV	0 (0)
S1 involvement	
+	1 (2.9)
–	33 (97.1)
S2 involvement	
+	3 (8.8)
–	31 (91.2)
T involvement	
+	5 (14.7)
–	29 (85.3)
M involvement	
+	26 (76.5)
–	8 (23.5)
Development of mastoid cells	
MC0-1	27 (79.4)
MC2-3	7 (20.6)
Pathological status of the stapes	
S0	18 (52.9)
S1	16 (47.1)
Surgical procedure	
CWU	14 (41.2)
CWD	20 (58.8)
Malleus handle	
Present	30 (88.2)
Absent	4 (11.8)
Cholda tympani nerve	
Present	23 (67.6)
Absent	11 (32.4)
Middle ear mucosa	
Normal	30 (88.2)
Diseased	4 (11.8)

CWU: canal wall up; CWD: canal wall down.

IV), S1 involvement, S2 involvement, T involvement, M involvement, development of mastoid cells (MC0-1/MC2-3), pathological status of the stapes (S0/S1), surgical procedure (CWU/CWD), malleus handle (present/absent), chorda tympani nerve (present/absent), and middle ear mucosa (normal/diseased). Cochran–Armitage test was used for statistical analysis of staging, and Fisher's exact test was used for statistical analysis of other factors. A $p<0.05$ was considered statistically significant.

Table 3. Hearing outcomes

	Postoperative data
Mean air-bone gap (SD)	19.2 (10.4) dB
Air-bone gap	
0-10 dB	8 (23.5 %)
10-20 dB	11 (32.4 %)
20-30 dB	11 (32.4 %)
>30	4 (11.8 %)

SD: standard deviation.

Table 4. Analysis of the prognostic factors of hearing outcomes

		p*	
		Postoperative PTA-ABG	
Factors	**Contrast**	**≤10 dB vs >10**	**≤20 dB vs >20**
Age, years	<60	N.S.	N.S.
	≥60		
S1 involvement	+	N.S.	N.S.
	–		
S2 involvement	+	N.S.	N.S.
	–		
T involvement	+	N.S.	N.S.
	–		
M involvement	+	N.S.	N.S.
	–		
Development of mastoid cells	MC0–1	0.0374	N.S.
	MC2–3		
Pathological status of the stapes	S0	0.0425	0.0142
	S1		
Surgical procedure	CWU	N.S.	N.S.
	CWD		
Malleus handle	Present	N.S.	N.S.
	Absent		
Chorda tympani nerve	Present	N.S.	N.S.
	Absent		
Mucosa	Normal	N.S.	N.S.
	Diseased		

PTA-ABG: pure-tone average air-bone gap; N.S.: not significant; CWU: canal wall up; CWD: canal wall down.
* Fischer's exact test

RESULTS

A total of 34 patients were enrolled in the study. The study included 18 male patients. The median age of the patients was 61.5 (16-87) years. The mean follow-up period was 41 (12-63) months. Table 2 shows the demographic and clinical data of the patients. There were no patients with stage IV pars flaccida cholesteatoma. Table 3 shows the hearing outcomes of all patients. Successful hearing outcomes with postoperative PTA-ABG ≤10 and ≤20 dB were observed in 23.5% and 55.9% of the cases, respectively. One out of the 34 patients had revision surgery for a recurrent cholesteatoma 3 years after undergoing CWU tympanoplasty. There were no patients who experienced postoperative complications, such as local flap necrosis, cavity problems, facial nerve paralysis, meningitis, or brain abscess.

Figure 4 and Table 4 show the analysis of the prognostic factors for hearing outcomes. When postoperative PTA-ABG ≤20 dB was used to define successful hearing outcomes, the successful hearing improvement rate significantly decreased with increase in the EAONO/JOS stage (p=0.0249), and the S0 pathological status of the stapes (no stapes involvement) was a significantly favorable predictive factor (p=0.0142). When postoperative PTA-ABG ≤10 dB was used to define successful hearing outcomes, the significantly favorable predictive factors were S0 pathological status of the stapes (p=0.0425) and development of mastoid cells with MC2-3 (better developed mastoid cells) (p=0.0374). The cholesteatoma extent according to the STAM system, surgical procedure, presence of the malleus handle and chorda tympani nerve, and middle ear mucosal status were not significant predictors for any of the criterion of successful hearing outcomes.

DISCUSSION

Many studies have investigated the prognostic factors for a successful ossiculoplasty. The favorable prognostic factors affecting outcomes in ossicular chain reconstruction are a low level of otorrhea [6, 16], the presence of malleus handle [6, 8, 12, 13, 15-17], the presence of stapes super-

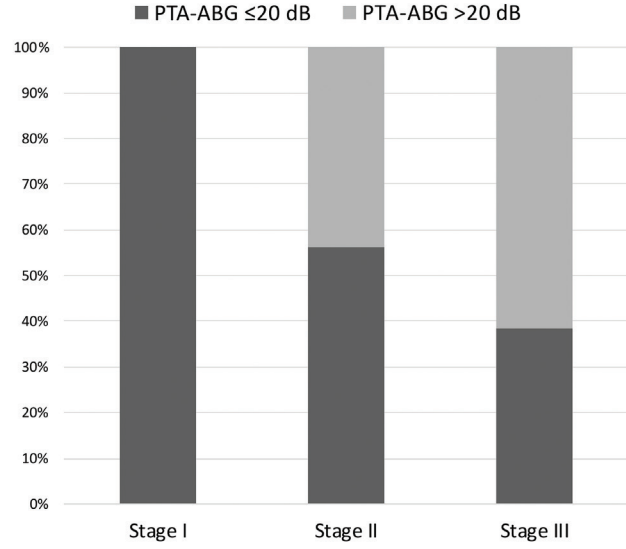

Figure 4. The rate of successful hearing improvement significantly decreased with increase in EAONO/JOS stategе (p=0.0249).

structure [7, 9, 12, 14, 17], normal stapes mobility [12], the presence of chorda tympani nerve [10], normal middle ear mucosal status [12-14, 16], intact canal wall tympanomastoidectomy (CWU) [5, 10, 11, 16], primary surgery [9-11, 16, 17], and local anesthesia [12]. Although various factors that affect postoperative hearing outcomes have been reported, they are not always significant, and the results have been controversial. In addition, many studies have adapted many pathological conditions and used various methods of ossicular chain reconstruction in their studies [6-17], and only a few studies have been limited to cholesteatoma [5].

Hearing outcomes of tympanoplasty for middle ear cholesteatoma are of interest to otologists worldwide. However, there are no common standards for discussion of the postoperative results. The EAONO/JOS and JOS 2015 staging systems for middle ear cholesteatoma have been recently published [2, 4], Hence, postoperative hearing results were studied based on these staging systems. Our research was limited to primary pars flaccida cholesteatoma. Furthermore, the surgical procedure was limited to one-stage tympanomastoidectomy with partial ossicular reconstruction using the double cartilage block in the presence of stapes superstructure to reduce confounders.

In the present study, the postoperative PTA-ABG was 18.0 dB, and successful hearing outcome with a postoperative PTA-ABG ≤20 dB occurred in 55.9% of the cases. According to the literature, the closure of ABG to within 20 dB ranges from 50% to 85.2% using the double cartilage block [20-23]. Our results are in accordance with these studies, although the latter included various pathological conditions other than primary pars flaccida cholesteatoma, and a direct comparison is difficult.

In our study, the rate of successful hearing improvement significantly decreased with increase in EAONO/JOS stage, and S0 pathological status of the stapes (no involvement) was a significantly favorable predictive factor when postoperative PTA-ABG ≤20 dB was considered a successful hearing outcome. When postoperative PTA-ABG ≤10 dB was used to define successful hearing outcome (excellent results), both S0 pathological status of the stapes and development of mastoid cells (MC2-3, better development) were significantly favorable predictive factors. Cholesteatoma and granulation can cause the deterioration of mobility in stapes with S1 pathological status (superstructure surrounded by cholesteatoma and/or granulation). Therefore, the hearing results of cases with S0 might be better than those with S1 status. Mishiro et al. [12] reported that normal stapes mobility is a significantly favorable predictor of ossiculoplasty, and their results are consistent with those reported in the present study. Some authors have demonstrated the important role of postoperative aeration in the middle ear in achieving better hearing outcomes of tympanoplasty [23-25]. Better developed mastoid cells, which indicate good Eustachian tube function, may contribute to aerated tympanomastoid cavities postoperatively. Hence, the hearing outcome of cases with MC2–3 might be better than those with MC0-1.

There was a clear correlation between the rate of successful hearing improvement and EAONO/JOS stage, indicating that the EAONO/JOS stage reflects the hearing prognosis after partial ossiculoplasty for primary pars flaccida cholesteatoma. On the other hand, no correlation was found between hearing outcome and the involvement of particular sites using the STAM system. Surgical procedure, presence of the malleus handle and chorda tympani nerve, and middle ear mucosal status were also not significant predictors of successful hearing in our study. The small sample size and/or some confounders may have been the cause of these factors not being significant.

Our study had some limitations. Since the present study was retrospective, only short-term hearing outcomes were investigated. Moreover, only univariate analysis was performed. Multivariate analysis could not be performed because of the small number of samples. Therefore, confounding factors could not be avoided. Further investigations are required with multivariate analysis of a large number of samples in a prospective survey according to a standardized basis for evaluation, such as the EAONO/JOS staging system, to reveal independent significant prognostic factors of ossiculoplasty for middle ear cholesteatoma.

CONCLUSION

No stapes involvement and low EAONO/JOS stage were the favorable prognostic factors for hearing outcomes of ossiculoplasty with partial ossicular reconstruction for primary pars flaccida cholesteatoma. In particular, there may be a strong association between the accomplishment of excellent hearing results and development of mastoid cells. Therefore, the EAONO/JOS staging and the criteria for evaluation of the pathological status of stapes and the degree of mastoid cell development in the 2015 JOS staging systems may be useful for predicting the prognosis of hearing outcomes of partial ossiculoplasty for primary pars flaccida cholesteatoma.

Ethics Committee Approval: Ethics committee approval was received for this study from the Institutional Review Board of Hokkaido University Hospital for clinical research (IRB no. 017-0375) according to the tenets of the Declaration of Helsinki.

Informed Consent: Informed consent is not necessary due to the retrospective nature of this study.

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Conflict of Interest: The authors have no conflict of interest to declare.

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