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## Factors associated with prolonged duration of post-tympanoplasty local treatment in adult chronic otitis media patients: A retrospective observational study using a Japanese inpatient database

Sayaka Suzuki<sup>a,\*</sup>, Hideo Yasunaga<sup>b</sup>, Hiroki Matsui<sup>b</sup>, Kiyohide Fushimi<sup>c</sup>,  
Tatsuya Yamasoba<sup>a</sup>

<sup>a</sup> Department of Otolaryngology, Head and Neck Surgery, Faculty of Medicine, The University of Tokyo, Tokyo 1130033, Japan

<sup>b</sup> Department of Clinical Epidemiology and Health Economics, School of Public Health, The University of Tokyo, Tokyo 1130033, Japan

<sup>c</sup> Department of Health Policy and Informatics, Tokyo Medical and Dental University Graduate School of Medicine, Tokyo 1130034, Japan

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### ABSTRACT

**Objective:** The occurrence of persistent infection following tympanoplasty has been reported in many studies, and it is important to know the risks for site infection after tympanoplasty. In this study, we aimed to explore the factors affecting early wound complications after tympanoplasty for chronic otitis media.

**Methods:** We conducted a retrospective cohort study using the Diagnosis Procedure Combination database. Data on a total of 13,094 adult patients from 420 acute-care hospitals who received tympanoplasty for chronic otitis media from 2010 to 2013 were extracted. The duration (days) of postsurgical local wound treatment was measured as an outcome, because this duration was assumed to be prolonged by the existence of wound infection. The associations between treatment duration and background characteristics (age, sex, body mass index, smoking status, diabetes mellitus, use of antithrombotic agents, with or without cholesteatoma, duration of anesthesia, academic hospital or not, and hospital volume) were assessed by multivariable linear regression analyses, fitted with a generalized estimating equation to adjust for within-hospital clustering.

**Results:** The median treatment duration in each hospital was 8 days (interquartile range: 7–11). Factors significantly associated with longer treatment duration were: older age (0.2 days for 10-year increase), use of antithrombotic agents during hospitalization (1.8 days), and prolonged duration of anesthesia (vs. <120 min of anesthesia, additional 1, 2, 3, and 4 days for 120–179, 180–239, 240–299, and ≥300 min of anesthesia, respectively). Body mass index and smoking status were not significantly associated with treatment duration.

**Conclusions:** Older age, antithrombotic agents during hospitalization, and longer anesthesia time were independently associated with early local wound complications after tympanoplasty for chronic otitis media.

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## 1. Introduction

Tympanoplasty (TP) is a safe and common procedure for chronic otitis media (COM) with or without cholesteatoma to remove inflammatory lesions of the middle ear, reconstruct the

ossicular chain for improvement of hearing function, and repair perforations of the tympanic membrane [1,2].

A postauricular incision is usually made to harvest an autologous cartilage-perichondrium graft or temporal fascia graft. Early postsurgical local complications, such as wound infection, otorrhea from the outer ear canal caused by infection of the middle ear or mastoid, and graft failure, are troublesome, because they can cause excess healthcare resource utilization for postsurgical local treatment, as well as patient discomfort and inconvenience [3].

Numerous studies assessing the occurrence of persistent infection following TP have produced inconsistent findings, arising

\* Corresponding author at: Department of Otolaryngology, Head and Neck Surgery, Faculty of Medicine, The University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 1130033, Japan. Tel.: +81 3 3815 5411; fax: +81 3 3814 9486.

E-mail address: [sayasuzuki-ky@umin.ac.jp](mailto:sayasuzuki-ky@umin.ac.jp) (S. Suzuki).

from differences in the definition of infection, timing of evaluation, and study period, as well as relatively small sample sizes [3–5]. To our knowledge, there have been no studies on the duration of postsurgical local treatment for site infection. Furthermore, the factors associated with prolonged duration of such treatment remain unknown.

Using a nationwide inpatient database in Japan, the present study aimed to explore the factors affecting early complications after TP for COM. We adopted the duration of postsurgical local treatment as an outcome, as an alternative to the severity of postsurgical infection to be treated.

## 2. Methods

### 2.1. Ethical considerations

We have obtained study approval from the Institutional Review Board of The University of Tokyo. Because of the anonymous nature of the data, the requirement for informed consent was waived.

### 2.2. Data source

We extracted patient data from the Diagnosis Procedure Combination (DPC) database, a national inpatient database in Japan. The DPC database includes administrative claims data and discharge abstract data collected for all inpatients (approximately 6.8 million patients in 2012) discharged from more than 1000 participating acute-care hospitals across Japan. The details are described elsewhere [6].

For each patient, the database includes the following information: age; sex; patient characteristics (weight, height, Brinkman Index); main diagnoses, comorbidities at admission, and complications after admission encoded by International Statistical Classification of Diseases (ICD)-10 codes and text data in Japanese; surgical interventions and medical procedures encoded with original Japanese codes; daily records of drug administration; duration of anesthesia; type of hospital (academic or non-academic); length of stay; and discharge status.

All 82 academic hospitals in Japan are obliged to participate in the DPC database, while the participation of community hospitals is voluntary. The codes related to surgeries, procedures, medications, and anesthesia are almost complete because they are compulsory for healthcare cost reimbursement. To maximize the accuracy of these data, the physicians in charge are required to record the information on diagnoses and therapies with reference to the patients' medical charts [7,8].

### 2.3. Patient selection and characteristics

Data for patients with diagnoses of otitis media (ICD-10 codes: H65x, H66x, H67x) on admission who underwent TP between July 2010 and March 2013 (33 months in total) were extracted.

With the aim of selecting a homogeneous target population with COM, we excluded patients with the following comorbidities: (i) otitis media possibly accompanying acute inflammation in middle or inner ear (ICD-10 codes: H66.0, H830); (ii) benign or malignant tumor (D140, D180, D33.3, D43.3, Q85.0, Cxx); (iii) fracture of skull or facial bones (S02x); and (iv) congenital malformation of ear (Q16x, Q17x). We also excluded: (v) patients who received surgical wound treatment for other surgical sites to selectively identify local wound treatment for TP; (vi) patients who received revision surgery, including second-look procedure for cholesteatoma, because of potentially impaired wound healing after second or subsequent surgery; and (vii) patients under 19 years of age.

The following background characteristics of the patients were assessed: age; sex; body mass index (BMI; kg/m<sup>2</sup>); smoking status

(current or ex-smoker, non-smoker); diabetes mellitus (DM; ICD-10 codes: E10–E14) on admission; middle ear cholesteatoma (H71, “cholesteatoma” written in Japanese); use of antithrombotic agents during hospitalization; duration of anesthesia; and type of hospital (academic or non-academic). Antithrombotic agents contained antiplatelet agents (aspirin, cilostazol, ticlopidine, clopidogrel, sarpogrelate, beraprost, icosapentate) and anticoagulant agents (warfarin, dabigatran, edoxaban, rivaroxaban, apixaban). Hospital volume (HV) was calculated based on the annual number of TPs performed during the study period in each hospital. We trisected hospitals into three HV groups ( $\leq 27$ , 28–51,  $\geq 52$ ). According to the World Health Organization definitions, we classified BMI as underweight ( $< 18.50$  kg/m<sup>2</sup>), normal weight (18.50–24.99 kg/m<sup>2</sup>), or overweight and obese ( $\geq 25.00$  kg/m<sup>2</sup>) [9]. Normal weight was separated into low-normal (18.50–22.99 kg/m<sup>2</sup>) and high-normal (23.00–24.99 kg/m<sup>2</sup>).

### 2.4. Outcome measurement

The primary outcome was duration (days) of postoperative treatment for surgical wound and middle ear (“treatment duration”). Postoperative treatment included sterilization or gauze dressing for surgical wound, or irrigation of the external ear.

### 2.5. Statistical analysis

The continuous variables were compared using a *t*-test. To investigate the correlations between the categorical variables, we calculated Spearman's rho correlation coefficients. We also checked the “variance inflation factors” for each independent variable, to explore the multicollinearity between the independent variables. A variance inflation factor of  $> 10$  was defined to indicate multicollinearity. Multivariable linear regression analyses were performed to investigate the relationships between patient characteristics and duration of postoperative treatment for surgical wound and middle ear. Because the study was based on a multicenter retrospective design, data were structured hierarchically, including patient level and hospital level. Therefore, the patient characteristics or physician practice patterns within the same hospital could have been clustered. To adjust for such within-hospital clustering, we fitted a generalized estimating equation to the multivariable linear regression analyses [10].

The threshold for significance was set at  $p < 0.05$ . All statistical analyses were performed using Statistical Package for Social Sciences software version 20.0 (IBM SPSS Corp., Armonk, NY, USA).

## 3. Results

We identified 16,486 patients who underwent TP for otitis media during the study period. Among them, a total of 3392 patients were excluded for the following reasons: acute suppurative otitis media ( $n = 2$ ); labyrinthitis ( $n = 3$ ); any type of malignancy ( $n = 186$ ); benign middle ear tumor ( $n = 9$ ); glomus tympanicum tumor ( $n = 6$ ); benign neoplasm of cranial nerves ( $n = 2$ ); neoplasm with uncertain or unknown behavior of cranial nerves ( $n = 19$ ); fracture of skull or facial bones ( $n = 5$ ); congenital malformation of ear ( $n = 124$ ); surgical wound treatment for other surgical site ( $n = 453$ ); revision surgery ( $n = 86$ ); and age under 19 years ( $n = 3019$ ). No patients with diagnoses of neurofibromatosis or von Recklinghausen disease were identified. Finally, we selected 13,094 eligible patients from 420 hospitals.

Table 1 shows the patient characteristics. The mean ( $\pm$ SD) age was  $54.8 \pm 16.2$  years. The sex ratio was close to one. More than one-quarter of the patients were overweight or obese. Among the total patients, 60.8% had cholesteatoma, 6.8% had DM, and 1.8% received antithrombotic agents during hospitalization. Most of the TPs were

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