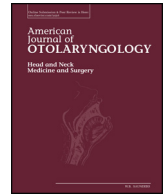




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## Prevalence and incidence of clinically significant patulous Eustachian tube: A population-based study using the Korean National Health Insurance Claims Database

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### ABSTRACT

**Objectives:** The aim of this study is to estimate the entire population-based prevalence and incidence of Patulous Eustachian tube (PET) using the Korean National Health Insurance (NHI) claims database. The annual trends of prevalence and incidence of PET were also investigated.

**Methods:** Retrospective analysis of PET patients was performed between 2010 and 2016, from the NHI claims database. PET patients were defined as those who had at least one service claim with a primary diagnosis under an ICD-10-based PET code (H69.0).

**Results:** During the study period, there were 20,533 new PET patients in Korea. In 2016 there were 4482 incident cases, and the standardized annual incidence rate was 8.8 per 100,000 persons. The standardized annual prevalence rate increased significantly from 7.2 per 100,000 persons in 2010 to 10.3 per 100,000 persons in 2016. The prevalence increased significantly on annual basis, whereas the incidence rate fluctuated over time. Interestingly, the incidence and prevalence of PET in women was almost twice as high as that in men, and peaked in their 20s.

**Conclusions:** This study demonstrated the substantial annual increase of the NHI claims with PET code (H69.0) in Korea from 2010 to 2016. Statistical results based on the NHI claims, we confirmed the high prevalence and incidence rates of clinically significant PET in women than in men. This study only covered patient using the medical service for PET and missed PET sufferers not seeking medical service. However, this study can provide basic epidemiological information on clinically significant PET.

### 1. Introduction

The Eustachian tube (ET) is normally closed, but opens temporarily during swallowing [1]. Patulous Eustachian tube (PET) is a disease that affects patients with auditory symptoms such as aural fullness and autophony of breathing sounds due to persistent opening or inadequate closing of the ET [2]. PET patients also suffer from vestibular symptoms and hearing loss by transferring the movement of ossicles to the inner ear caused by excessive pressure changes in the middle ear [3]. The symptoms are alleviated with the change in position, such as lying down or having the head between the knees while sitting on a chair [4]. The diagnosis of PET can be confirmed by directly observing the inward and outward movement of the tympanic membrane at the same time as

forced nasal breathing [2,4].

Since PET was first described by Jago [5] in 1858, little has been learned about its epidemiology. Although some studies have revealed that PET is associated with pregnancy [6], rapid weight loss [7], mucosal atrophy [8], or muscular dysfunction [9,10], there have been no national population-based epidemiological studies to estimate the incidence and prevalence of PET to date. The aim of this study was to investigate prevalence and the incidence of PET using the National Health Insurance (NHI) claims database. We also investigated the time trends in the prevalence and incidence of PET.

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## 2. Materials and methods

### 2.1. Data source and study population

The data used in this study were extracted from the Korean NHI claims database administrated by the government-affiliated agency under the Ministry of Health and Welfare that administers and supervises all medical activities in Korea. All Korean citizens and registered foreigners must be enrolled in the NHI system, either as an NHI beneficiary or Medical Aid recipient. It is mandatory for all types of healthcare institutions to submit all inpatient and outpatient data to the NHI. Nation-wide inpatient and outpatient data on the demographics, medical service use, medication, transaction information, deductions and claims are coded and registered in the database. The disease codes used in the database are based on the International Classification of Disease, 10th version (ICD-10). The NHI claims database enables easy retrieval and analysis of the information on population-based epidemiological data.

Population-based medical data for patients of all ages with PET were extracted from NHI claims database retrospectively from January 2010 to December 2016. As of 2016, the NHI contained data on 50,763,283 beneficiaries, which represented 97.1% of the total Korean population of 52,272,755. The patients with PET were defined as those who received at least one service claim to a clinic or hospital having a principle diagnosis of PET by an otolaryngologist based on an ICD-10 diagnostic code of PET (H69.0) during the study period. When a physician is consulted at a medical facility in the South Korea, the physician is required to code the most appropriate diagnosis in that situation. These codes are required to be entered based on the ICD-10, which is designed to efficiently manage disease and health problems by the World Health Organization. Therefore, all such records of medical services conducted in the South Korea will be assigned these diagnostic codes and stored in NHI claims database.

We analyzed the data by sex and age for these identified patients with PET, and further used the population data provided by the Korean NHI to determine the incidence and prevalence of PET. These values were considered as the characteristics of clinically significant PET.

Personal information was protected and kept anonymous. This study was approved by the institutional review board of the Pusan National University Hospital (H-1612-012-050).

### 2.2. Statistical analysis

We analyzed the data with respect to prevalence and incidence of PET in Korea from January 2010 to December 2016. All data were analyzed using the SAS software version 9.3 (SAS Institute, Cary, NC). The incidence and prevalence of PET were calculated by analyzing the databases of the patients who were identified through the operational definition described above. Since this study was based on the claims cases that were diagnosed at medical institutions, these values were considered as the characteristics of clinically significant PET. We analyzed the age-standardized rates for the estimation of the exact prevalence and incidence. Prevalence and incidence rate were defined as follows. For age-standardization, the standard population was set based on the most recently surveyed population structure of the Korean National Statistical Office and calculated by the following method:

$$\text{Prevalence rate} = \frac{\text{annual number of PET patient}}{\text{annual number of beneficiaries from NHI claims database}}$$

$$\text{Incidence rate} = \frac{\text{annual number of newly diagnosed PET patient}}{\text{annual number of beneficiaries from NHI claims database without former history of PET diagnosis}}$$

$$\text{Age standardized rate} = \frac{\sum (PkRk)}{\sum Pk}$$

where  $Pk$  is the standard population in sex/age group  $k$ ;  $Rk$  is observed prevalence/incidence rate in sex/age group;  $k$  is the age/sex group [11]. When defining an incident case, the 2-year period prior to 2012 was set as a “wash-out” period to exclude patients who had been diagnosed before. Age- and gender-specific annual prevalence and incidence rates of PET were calculated by dividing the number of patients with PET by the total annual claim population number of NHI beneficiaries for the corresponding year. Incidence and prevalence rates were expressed as the number of cases per 100,000 person-years. Data on the specific number of beneficiaries for each gender and age group were extracted from the database. We analyzed the age-standardized rates for the estimation of the exact incidence and prevalence, and we used population structure information from the National Health Insurance Statistical Yearbook published annually by the Health Insurance Review and Assessment Service. Multivariate Poisson regression analyses were used to calculate sex- and age- adjusted relative risk (RR) with 95% confidence interval (95% CI). A  $p < .05$  was considered statistically significant.

## 3. Results

There were 20,533 new PET patients during the study period from 2012 through 2016. Both the crude and age- and gender-standardized annual prevalence rate of PET was 10.3 per 100,000 persons in 2016. The prevalence of PET was among men and women were 7.2 and 13.4 per 100,000 persons in 2016, respectively. The male and female ratio was 39.9% for males and 60.1% for females. The rates were higher among females during the study period. The analysis of prevalence rates revealed that this measure peaked in the age group 20–29 years for female and decreased thereafter, respectively (Fig. 1). A 43% increase (from 7.2 to 10.3 per 100,000 persons) in the crude annual prevalence of diagnosed PET from 2010 to 2016 (Table 1). The prevalence rate of PET showed an average annual increase of 6.73%. After the direct standardization of the Korean population, the annual standardized prevalence rates increased over time, as well as the discrepancy between crude and standardized annual prevalence rates ( $p < .05$ ). The annual prevalence rates increased from 5.0 to 7.2 per 100,000 persons among male and from 9.6 to 13.4 per 100,000 persons among female. Age- and gender-standardized prevalence and incidence of PET during the study period are described in Fig. 2. Further, the prevalence rate had increased in all age groups, except for those over 70s. In particular, the highest average annual increase was 17.3% in the under 20s (3.7–10.8 per 100,000 persons) (Fig. 3).

Significant interactions in the annual standardized prevalence rates were observed between time, sex and age (Table 2). After multivariate adjustment, the prevalence increased annually with increasing RR as calendar year being treated as an ordinal variable ( $p < .05$ ). In particular, the prevalence was significantly higher among females [RR (95% CI): 1.951 (1.896–2.008), respectively Table 2]. The prevalence rate of PET was also associated with age [RR (95% CI): 1.570 (1.503–1.640), 1.274 (1.218–1.332), 0.985 (0.941–1.032), 0.813 (0.768–0.861), 0.793 (0.754–0.833), 0.530 (0.493–0.570) for the age groups 20–29, 30–39, 40–49, 50–59, 60–69 and  $\geq 70$  years, respectively Table 2]. The prevalence rate was significantly associated with age specific analysis by sex, especially for females [RR (95% CI): 2.293 (2.191–2.339), 1.696 (1.619–1.777), 1.234 (1.175–1.295), 0.895 (0.846–0.949), 0.893 (0.840–0.942), 0.507 (0.470–0.547) for the age groups 20–29, 30–39,

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