

Letters

RESEARCH LETTER

Prevalence of Eustachian Tube Dysfunction in Adults in the United States

The eustachian tube is a dynamic, tubular structure linking the middle ear to the nasal cavity. It ventilates and clears fluid from the middle ear when open, and prevents transmission of pathogens, material, and sounds when closed.¹ Eustachian tube dysfunction (ETD) is a common diagnosis applied to conditions where the eustachian tube is incapable of performing its functions adequately, resulting in symptoms including hearing loss, aural fullness, otalgia, and autophony. Eustachian tube dysfunction occurs with a variable range of severity between 2 distinct subtypes (obstructive and patulous), and patients may fluctuate along this spectrum of disease, even between subtypes. The exact causes of ETD are not clearly understood, but there are associations with inflammatory disease. Eustachian tube dysfunction is diagnosed through a combination of clinical history, physical examination, tympanometry, audiometry, and other tests as indicated. A recently presented clinical consensus statement defined obstructive ETD in terms of medical history and/or evidence of negative middle ear pressure.¹

Existing literature on the prevalence of ETD in adults is sparse, ranging from 0.9% through a clinical definition² to 48.5% via questionnaire among patients with chronic rhinosinusitis.³ One study⁴ investigating visit burden determined that more than 2 million visits per year for adults were related to ETD and related conditions. Herein, we calculated ETD prevalence and population estimates in adults using a representative cross-sectional sample combined with census data. These estimates approximate the burden of ETD among adults in the United States.

Methods | We analyzed data from 9098 adults aged 20 years or older from the 2001 to 2006 and 2009 to 2012 cycles of the National Health and Nutrition Examination Survey, an ongoing cross-sectional study of a representative sample of the non-institutionalized US population. Eustachian tube dysfunction was defined as tympanometric middle ear (peak) pressure less than -100 dekaPascals in either ear in the absence of cold, sinus problem, or earache in the last 24 hours and head cold or chest cold in the last 30 days. Among the initial sample, a total of 5620 adults were included. Demographic characteristics included were age, sex, and race/ethnicity. Population prevalence was estimated employing sample weights using STATA statistical software (version 15.1, Stata Corp) and data were combined with the 2013 to 2017 American Community Survey 5-Year Estimates⁵ to determine population estimates. Analyses were performed between January and May 2019. We used publicly available, deidentified data provided by the National Health and Nutrition Examination Survey. The study was approved by the institutional review board of the

Table. Prevalence and Number of Adults in the United States With Eustachian Tube Dysfunction (ETD)^{a,b}

Characteristic	ETD, % (95% CI)	ETD, No. Millions ^{c,d}
Overall	4.61 (3.99-5.23)	11.01
Age, y		
20-39	3.25 (2.34-4.16)	2.82
40-64	4.59 (3.52-5.66)	4.77
≥65	8.25 (6.54-9.95)	3.94
Sex		
Male	5.28 (4.14-6.41)	6.12
Female	3.95 (3.09-4.81)	4.85
Race/ethnicity ^e		
Non-Hispanic white	4.73 (4.06-5.40)	8.47
Non-Hispanic black	4.81 (3.44-6.18)	1.39
Hispanic	3.06 (1.84-4.27)	1.11

^a National Health and Nutrition Examination Surveys 2001 through 2006, 2009 through 2012 (n = 5620).

^b ETD defined as middle ear pressure less than -100 dekaPascals in either ear in the absence of cold, sinus problem, or earache in the past 24 hours and head cold or chest cold in the past 30 days.

^c Source: US Census Bureau, 2013 to 2017 American Community Survey 5-year estimates.

^d Values do not sum to group total because of rounding.

^e Data on other racial/ethnic groups were not included owing to insufficient numbers. Hispanic represents Mexican-American and other Hispanic groups.

National Center for Health Statistics and all participants provided written informed consent.

Results | In a nationally representative sample of 5620 US adults, the overall prevalence of ETD among adults in the United States was estimated to be 4.6%, corresponding to a total of 11 million affected individuals (Table). Prevalence was higher among older adults and men and lower among those who self-identified as Hispanic.

Discussion | Eustachian tube dysfunction was found to be common in the present study, with a prevalence of 4.6% among US adults. This is substantially higher than a prior estimate of less than 1%,² which used a similar but more inclusive definition. Our findings are comparable to the prevalence of 6.1% determined among US children, using the same definition (<100 daPa),⁶ though ours removed individuals with recent colds or sinus infections to exclude acute ETD.

The major limitation of this study is the diagnosis of ETD by tympanometry alone. In practice, ETD is diagnosed through tympanometry combined with audiometry, patient-reported symptoms, and physical examination. Presentations are heterogeneous owing to differing causes. By accounting only for obstructive ETD by tympanogram findings, excluding patulous and baro-challenge testing, this study takes a conservative approach and likely underestimates the true prevalence of ETD.

In addition, although peak pressure measurements have been used previously to define ETD,⁵ this can underestimate prevalence by excluding individuals with flat (type B) tympanograms, which may correspond to middle ear effusion.

Nonetheless, to our knowledge, these data provide the first nationally representative estimates of the prevalence of ETD among US adults. Studies are needed to identify risk factors and causes, and advance both a clinical and a public health-driven approach to this common disorder.

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Study concept and design: Shan, Ward, Goman, Betz, Nieman.

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Use and Cost of a Hypoglossal Nerve Stimulator Device for Obstructive Sleep Apnea Between 2015 and 2018

More than 17 million patients in the United States have obstructive sleep apnea,¹ a condition associated with sequelae such as daytime somnolence, motor vehicle crashes, and cardiovascular disease.² Continuous positive airway pressure devices are the first-line treatment for obstructive sleep apnea, although the effectiveness of such treatment is often limited by patient noncompliance.² Second-line treatments (eg, oral appliances and palatal surgery) exist, but the available evidence offers limited support for such alternatives.²

In April 2014, the US Food and Drug Administration approved the Inspire II Upper Airway Stimulator (Inspire Medical Systems) for the treatment of moderate to severe obstructive sleep apnea (specifically, apnea-hypopnea index scores between 15 and 65) in adults unable to tolerate continuous positive airway pressure with favorable anatomy (ie, without complete concentric soft palatal collapse).¹ This hypoglossal nerve stimulator (HGNS) is designed to open the airway during sleep by protruding the genioglossus muscle with inspiration. No other manufacturers have received approval to market HGNS devices to date.

A number of major insurers have recently issued positive coverage determinations for the device. However, the cost-effectiveness of the HGNS device remains uncertain.³ We therefore sought to characterize the extent and cost of HGNS use.

Methods | We reviewed publicly available financial statements submitted by the manufacturer to the US Securities and Exchange Commission to assess device use and expenditures.¹ For each year between 2015 and 2018, we extracted the total US and non-US (ie, European) revenues. We then divided revenues by current US and European average selling prices to estimate the number of units sold. Using information provided in Securities and Exchange Commission filings, we additionally estimated the total Medicare payment per HGNS device placement in 2018 and procedural cost drivers (device production cost, manufacturer markup, hospital reimbursement, and physician reimbursement). We used descriptive statistics to characterize trends over time and cost drivers of Medicare payment.

Results | Between 2015 and 2018, global annual HGNS device sales increased 6.3-fold, from 346 to 2175 units; a total of 4459 units were sold during this period. Sales growth was primarily driven by increased utilization in the United States, with a 7.2-fold increase, from 262 units sold in 2015 to 1896 units in 2018 (Figure 1). Total US sales in this period accounted for nearly 85% (3786 units; 84.9%) of global sales.

Between 2015 and 2018, annual US sales revenue increased 7.2-fold, from \$6.1 million to \$44.4 million, totaling \$88.6 million for this period. In 2018, Medicare payment—