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# Complications associated with surgical treatment of sleep-disordered breathing among hospitalized U.S. adults

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#### ABSTRACT

The purpose of this cross-sectional study is to examine the relationship between surgical treatments for sleep-disordered breathing (SDB) and composite measure of surgical complications in a nationally representative sample of hospital discharges among U.S. adults. We performed secondary analyses of 33,679 hospital discharges from the 2002–2012 Nationwide Inpatient Sample that corresponded to U.S. adults ( $\geq$ 18 years) who were free of head-and-neck neoplasms, were diagnosed with SDB and had undergone at least one of seven procedures. Multivariate logistic regression models were constructed to estimate adjusted odds ratios (aOR) and 95% confidence intervals (CI), controlling for age, sex, race/ ethnicity, obstructive sleep apnea (OSA) and obesity diagnoses. Positive associations were found between composite measure of surgical complications and specific procedures: palatal procedure (aOR = 12.69, 95% CI: 11.91,13.53), nasal surgery (aOR = 6.47, 95% CI: 5.99,6.99), transoral robotic assist (aOR = 5.06, 95% CI: 4.34–5.88), tongue base/hypopharynx (aOR = 4.24, 95% CI: 3.88,4.62), maxillomandibular advancement (MMA) (aOR = 3.24, 95% CI: 2.74, 3.84), supraglottoplasty (aOR = 2.75, 95% CI: 1.81, 4.19). By contrast, a negative association was found between composite measures of surgical complications and tracheostomy (aOR = 0.033, 95% CI: 0.031,0.035). In conclusion, most procedures for SDB, except tracheostomy, were positively associated with complications, whereby palatal procedures exhibited the strongest and supraglottoplasty exhibited the weakest association.

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#### 1. Introduction

Sleep disorders are a group of chronic conditions that manifest themselves in difficulty initiating or maintaining sleep and in nonrestorative sleep (Beydoun et al., 2016; Gamaldo et al., 2016). Obstructive sleep apnea (OSA) is a serious and potentially lifethreatening sleep disorder. Falling along the spectrum of sleep disordered breathing (SDB) (Choi et al., 2015), it is characterized by frequent episodes of upper airway (soft palate and/or tongue base) collapse, through intermittent closure of the pharyngeal (nasal, oral, hypo) airway during sleep, which can lead to hypoxemia, hypercapnia, arousal, sleep fragmentation and sleep disruption (Gillis et al., 2016; Strohl et al., 2016). Whereas simple snoring

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results from minimal airway obstruction, OSA results from complete or partial airway obstruction (Goessler et al., 2007).

The obesity epidemic and population aging have rendered SDB, including OSA, a growing public health concern (Eastwood et al., 2011). OSA is an under-appreciated and under-diagnosed, yet highly prevalent sleep disorder, affecting 2–4% of the general population and 37–40% of heavy snorers (Hamans et al., 2010; Pavelec et al., 2016; Strohl et al., 2016). The U.S./European prevalence of OSA is 2–11%, with estimated healthcare costs of \$34 billion (Pavelec et al., 2016). It is estimated that 7–18 million people in the United States are affected by OSA, with the highest prevalence rate among men between the ages of 40 and 65 years (Goessler et al., 2007). If left untreated, OSA could lead to excessive daytime sleepiness, fatigue, headache, poor motor/visual skills, motor vehicle accidents, occupational accidents, lost productivity, neurocognitive impairment, hypertension, stroke, ischemic heart disease, coronary heart disease, arrhythmias, congestive heart

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failure, metabolic syndrome, type 2 diabetes, depression, impotence, decreased quality of life, and death (Gillis et al., 2016; Heidsieck et al., 2016).

Although numerous treatment modalities have been introduced for moderate-to-severe OSA, these are often tailored to the needs of the individual patient (Goessler et al., 2007). The "standard of care" or "first-line" treatment is continuous positive airway pressure (CPAP), which provides a "pneumatic splint" that holds the airway open (Gillis et al., 2016; Pavelec et al., 2016). Safety and effectiveness of CPAP treatment are well-established through its ability to reduce daytime sleepiness and cardiovascular complications (Choi et al., 2013). However, tolerance and long-term adherence to CPAP as prescribed (at least 4 h/night for 5 nights/week) is suboptimal, with an estimated non-adherence rate of 30–50% (Choi et al., 2015; Friedman et al., 2016; Heidsieck et al., 2016; Murphey et al., 2016; Pavelec et al., 2016).

Alternative treatment options for patients who cannot tolerate CPAP include non-surgical treatments such as behavioral modifications (weight loss, avoidance of alcohol and sedative medicine, body position training for sleep) and dental/oral appliances, as well as single-level or multiple-level surgical treatments with or without implantable devices (Hamans et al., 2010). Surgical treatments are designed to increase the dimensions of the upper airway by addressing redundant tissue structures (soft palate, uvula, tongue, tonsils) that may be causing airway obstruction, stiffening the pharyngeal wall and/or increasing muscle tone, without compromising normal functions such as breathing, speaking or swallowing (Goessler et al., 2007; Pavelec et al., 2016). Laserassisted uvulopalatoplasty (LAU), uvulopalatopharyngoplasty (UPPP), maxillomandibular advancement (MMA), tracheostomy, and the Pillar Implant and Upper Airway Stimulation are examples of surgical procedures that are utilized to treat patients diagnosed with OSA (Choi et al., 2013; Heidsieck et al., 2016; Murphey et al., 2016; Pavelec et al., 2016).

Distinct types of surgical procedures (nasal surgery, palatal procedure, tongue base/hypopharynx, maxillomandibular advancement, tracheostomy, supraglottoplasty, transoral robotic assist) are often applied simultaneously to individual patients depending on their specific healthcare needs (Pathak et al., 2015). Unlike CPAP, daily use of equipment is not needed, and non-adherence is therefore not an issue for most of these surgical procedures (Pavelec et al., 2016). However, since sham surgery is often not acceptable as a control group, and since clinical endpoints such as the apnea-hypopnea index (AHI) score may not be the only relevant measure, the longterm success of these surgical procedures remains equivocal (Goessler et al., 2007; Choi et al., 2013). Surgical procedures are often painful, invasive and irreversible and can carry significant morbidity risks, including complications such as infections, hemorrhage, edema, velopalatal insufficiency, thickened secretion, foreign body sensation, speech and swallowing dysfunction (Gillespie et al., 2011; Gillis et al., 2016; Pavelec et al., 2016).

To date, specific complications accompanying surgical procedures performed in adult patients diagnosed with SDB have been identified in the context of small clinical studies that focus on few types of surgical procedures at a time. At the national level, the safety profile of surgical treatments for SDB including OSA has been evaluated using a limited number of perioperative complications among adult (Capobianco et al., 2014) and pediatric (Allareddy et al., 2016) populations. Surgical treatments in the context of hospitalized adult patients diagnosed with SDB have not been characterized in terms of broadly defined complications, namely wound healing, infectious, cardiovascular, respiratory, gastrointestinal, urinary or other types of complications. The purpose of this cross-sectional study is two-fold: [1] to describe the demographic and clinical characteristics of hospitalized adult U.S. patients who had undergone surgical treatments for SDB; and [2] to analyze the relationship between surgical treatments for SDB and a composite measure of surgical complications in a nationally representative sample of hospital discharges among U.S. adults from the 2002–2012 Nationwide Inpatient Sample.

#### 2. Materials and methods

#### 2.1. Data source

The Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Project (HCUP) is a federal--state-industry partnership comprising multiple databases and software tools including the Nationwide Inpatient Sample (NIS), the largest publicly available all-payer database in the United States that can provide national estimates of health care utilization, access, charges, quality and outcomes. NIS consists of a 20% stratified probability sample of community hospitals from the State Inpatient Databases which include all inpatient data currently contributed to HCUP. In 2012, NIS became a sample of discharge records from all HCUP-participating hospitals, rather than a sample of hospitals of which all discharges were kept. The sampling frame of hospitals (or hospital discharges) was divided into strata using five hospital characteristics, namely, ownership/control, bed size, teaching status, urban/rural location and U.S. region. NIS samples were selected with probabilities proportionate to the number of hospitals (or hospital discharges) in each stratum. Between 2002 and 2012, NIS data were collected from ~1000 hospitals annually and the number of states covered by NIS has grown from 35 to 44. The NIS contains clinical, non-clinical and resource use data elements typical of a discharge abstract, including hospital-level and patient-level characteristics. The original research project was approved by an institutional review board with appropriate informed consent procedures in accordance with principles outlined by the Declaration of Helsinki.

#### 2.2. Study population and sample

We performed secondary analyses using a sub-sample from the 2002–2012 NIS data. Eligibility criteria were applied to the 2002–2012 NIS data to define the study population. Hospital discharges were included in the study if they corresponded to adult patients ( $\geq$ 18 years of age) who were diagnosed with conditions broadly referred to as SDB (ICD-9-CM diagnostic codes: 327.23, 327.20, 327.24, 327.29, 780.50, 780.51, 780.52, 780.53, 780.55, 780.56, 780.57, 786.09) using 15 (2002–2008) to 25 (2009–2012) diagnostic (DX) variables in NIS (Griffin et al., 2013; Mokhlesi et al., 2013a, b; Jean et al., 2015; Pathak et al., 2015; Allareddy et al., 2016; Becerra et al., 2016; Gamaldo et al., 2016; Smith et al., 2017) and had undergone at least one of the following types of surgical procedures: nasal surgery (septoplasty (ICD-9-CM procedure codes: 21.5, 21.88); rhinoplasty (ICD-9-CM procedure codes: 21.84, 21.85, 21.86, 21.87)), palatal procedure (palatal surgery (ICD-9-CM procedure codes: 27.64, 27.69, 27.72, 27.73, 27.79, 29.39, 29.4); tonsillectomy (ICD-9-CM procedure codes: 28.2, 28.3); adenoidectomy (ICD-9-CM procedure codes: 28.6); palatal implant/Pillar (ICD-9-CM procedure codes: 27.64)), tongue base/hypopharynx (tongue radiofrequency/midline glossectomy (ICD-9-CM procedure codes: 25.1, 25.2, 25.59, 25.94, 25.99); genioglossus advancement, genioplasty or tongue stabilization (ICD-9-CM procedure codes: 76.63, 76.64, 76.68); lingual tonsillectomy (ICD-9-CM procedure codes: 28.5); hyoid suspension (ICD-9-CM procedure codes: 83.02), maxillomandibular advancement (ICD-9-CM procedure codes: 76.43, 76.46, 76.61, 76.62, 76.65, 76.66), tracheostomy (ICD-9-CM procedure codes: 31.1, 31.2, 31.29), supraglottoplasty (ICD-9-CM procedure codes: 31.69), transoral robotic assist (ICD-9-CM procedure

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