

ORIGINAL RESEARCH

Comparison of readmission and complication rates between traditional sleep surgery and hypoglossal nerve stimulation

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Abstract

Objective: This study aims to compare readmission and complication rates between hypoglossal nerve stimulation (HNS) and traditional sleep surgery (TSS) in the 90-day postoperative period using a federated electronic health record (EHR) database.

Methods: We queried TriNetX, a global federated health research network providing access to EHR data from approximately 70 million patients in 49 large health care organizations to identify individuals who underwent either HNS or TSS for obstructive sleep apnea (OSA) from April 2014 to March 2021. Propensity scores based on demographics and obesity were used to balance groups. We compared the frequency of readmission/representation and surgical-related complication rates between cohorts.

Results: After propensity score matching of HNS versus palatal surgery ($n = 1014$ in each cohort) and HNS versus multilevel surgery ($n = 374$ in each cohort), we found palatal and multilevel surgery had a significantly higher risk of readmission versus HNS (12% vs. 4%, $p < .0001$). Palatal surgery complication rate was also higher than HNS (21% vs. 2%, $p < .0001$). Multi-level surgery results were similarly higher (22% vs. 3%, $p < .001$). The most common diagnoses at ER readmission for TSS were procedural complications and pain, while common diagnoses for HNS readmission were general complaints such as malaise and headache.

Conclusions: Hypoglossal nerve stimulation has lower risk of readmission and postoperative complications than traditional sleep surgery as demonstrated in a large research network database analysis.

Level of Evidence: 3.

KEYWORDS

drug-induced sleep endoscopy, hypoglossal nerve stimulation, obstructive sleep apnea, surgery, upper airway stimulation, UPPP

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1 | INTRODUCTION

Obstructive sleep apnea is a common disorder affecting approximately 13% of men and 6% of women between the ages of 30 and 70.^{1,2} The repetitive upper airway collapse, resultant hypoxemia, and fragmented sleep leads to a host of sequelae including hypercapnia, snoring, hypersomnolence, and hypertension with subsequent cardiovascular disease,^{3,4} which pose significant impairment to patients' health and quality of life (QoL). Continuous positive airway pressure (CPAP) is an effective first-line treatment that has long been considered the gold standard, but its effectiveness has been greatly hampered by under-utilization and intolerance due to discomfort, claustrophobia, and impact on sleep quality.⁵

Traditional sleep surgery (TSS) for OSA targets the removal or repositioning of soft tissue in the upper airway, consisting of palatal, tongue base, or some combination of these two procedures. For years, uvulopalatopharyngoplasty (UPPP) has been the most common surgical procedure for OSA and consistently demonstrated improved mortality and QoL.⁶⁻⁹ In 2007, Pang and Woodson introduced the Expansion Sphincter Pharyngoplasty (ESP), another palatal procedure addressing lateral pharyngeal wall collapse.¹⁰ However, the painful recovery and complication rates of these procedures have been well chronicled, with some patients requiring overnight stays and airway monitoring.¹¹

Tongue base surgery is another treatment option for OSA with a variety of procedures targeting this area including radiofrequency ablation and coblation, hyoid suspension, genioglossus advancement, and partial pharyngectomy, and more recently transoral robotic surgery.¹²

In more severe cases, or where multilevel airway collapse has been diagnosed, multilevel surgery, commonly consisting of various combinations of palatal and tongue base procedures has been undertaken.¹³ The results thus far have been inconsistent, warranting further investigation into more effective interventions.^{14,15}

Hypoglossal nerve stimulation (HNS) is an FDA-approved implantable neurostimulation system (Inspire Medical Systems, Minneapolis, MN) to treat selected CPAP-intolerant OSA by stimulating the distal branches of the hypoglossal nerve. The stimulation leads to selective activation of the genioglossus muscle, resulting in multi-level airway enlargement at the level of the palate and tongue base.¹⁶⁻²³ The Stimulation Treatment for Apnea Reduction (STAR) trial followed these first implanted patients for 60 months, showing sustained improvement in apnea-hypopnea index (AHI) and QoL measures.¹⁷ The ADHERE (Adherence and Outcome of Upper Airway Stimulation for OSA) international registry demonstrated similar improvements in outcomes, in addition to significantly higher therapy adherence and patient satisfaction when compared to historical CPAP average.²⁴ Such studies have supported the use of HNS as a viable and effective treatment alternative to TSS for patients failing CPAP therapy. However, direct comparison between the complication rates between palatal and multi-level TSS and HNS are lacking. We hypothesize that HNS will have lower readmission rates and fewer adverse postoperative outcomes when compared to palate only and multilevel TSS.

2 | MATERIALS AND METHODS

We conducted a retrospective cohort study using data obtained from the TriNetX Research Network (TriNetX, Cambridge, MA). The TriNetX Research Network is a federated system that continuously polls, updates, and aggregates de-identified EHR data from participating health care organizations including hospital, primary care, and specialty treatment providers across a range of geographies and patient populations. TriNetX was reviewed by and received a waiver from Western Institutional Review Board (IRB). As the present study employed only de-identified data available through TriNetX, further IRB approval was not required. Details of the network have been previously published.²⁵ Record search was limited to the time period beginning at the time of FDA approval of HNS in 2014 through March 2021. The EHR data obtained included demographics, diagnoses, procedures, medications, and selected laboratory values. Sleep endoscopy or apnea-hypopnea index was not available in the database. All data analyses were performed within the TriNetX Analytics software, which provides data in summarized tables and does not provide individual patient-level data.

We analyzed data from three cohorts of patients aged 22 and older who received surgical treatment that had a primary diagnosis of OSA (ICD-10: G47.30) that was directly connected with the procedure. The minimum age of 22 was selected to match the FDA minimum age indication for HNS when this study was conceived in 2019. These cohorts were identified by using the procedures CPT codes associated with physician billing and/or ICD-10-PCS codes associated with facility billing. The usage of both CPT (HCPCS Level I) and ICD-10-PCS procedure codes was chosen as a best practice to comprehensively capture procedures when physician or facility billing were in different systems. CPT and ICD-10 have high consistency and using both code sets has been shown to increase the sensitivity of procedural case identification.²⁶ Since HNS was a new surgical option, we decided to compare it to the most commonly performed sleep surgeries prior to HNS, which were palate and multi-level surgeries.²⁷ The three cohorts were patients who underwent palate surgery (palate cohort) those who underwent palate and tongue base surgery (multilevel cohort), and patients who received an HNS device (HNS cohort). The multilevel cohort was defined as having, on the same date, at least one palate surgery procedure from Group 1 in Table 1, and at least one oropharynx/tongue base/hyoid/mandible surgery code (Group 2 from Table 1). Previous literature on complication rates on sleep surgery were used to inform the codes chosen in the tables. Outcomes of interest occurring within the first 90 days after initial surgical treatment were readmission (defined as Emergency Department or inpatient admission), and surgical complications (defined as a diagnosis code, connected with the surgery, of post-procedural bleeding or respiratory complications; difficulty speaking, swallowing, eating, dehydration, and other surgical complications not otherwise classified). To further understand the causes of the readmission, we also examined the most common diagnosis codes that were documented with the readmission.

TABLE 1 Surgical procedure codes

Palatal surgery procedure code (Group 1)	Description
42145	Palatopharyngoplasty
42299	Unlisted procedure, palate, uvula
42140	Uvulectomy, excision of uvula
42281	Insertion of pin-retained palatal prosthesis
0CQ3	Mouth and throat/repair/soft palate
0CQM0ZZ	Repair pharynx, open approach
0CQ33ZZ	Repair soft palate, percutaneous approach
0CQN	Mouth and throat/repair/uvula
0CQN0ZZ	Repair uvula, open approach
0CQ30ZZ	Repair soft palate, open approach
0CTNXZZ	Resection of uvula, external approach
0CTN0ZZ	Resection of uvula, open approach
0CTN	Mouth and throat/resection/uvula
0CU3	Mouth and throat/supplement/soft palate
0CU2	Mouth and throat/supplement/hard palate
0CQ3XZZ	Repair soft palate, external approach
Multi-level surgery procedure codes—Group 2 (at least one palatal code and any of the following)	Description
21199	Osteotomy, mandible, segmental; with genioglossus advancement
41120	Glossectomy; less than one-half tongue
42870	Excision or destruction lingual tonsil, any method (separate procedure)
21685	Hyoid myotomy and suspension
0C57XZZ	Destruction of tongue, external approach
0C573ZZ	Destruction of tongue, percutaneous approach
0C570ZZ	Destruction of tongue, open approach
0CBP3ZZ	Excision of tonsils, percutaneous approach
0CBP0ZZ	Excision of tonsils, open approach
0NQV0ZZ	Repair left mandible, open approach
0CBPXZZ	Excision of tonsils, external approach
0NQTXZZ	Repair right mandible, external approach
0NQVXZZ	Repair left mandible, external approach
0NQ3ZZ	Repair right mandible, percutaneous approach
0NQV3ZZ	Repair left mandible, percutaneous approach

(Continues)

TABLE 1 (Continued)

Multi-level surgery procedure codes—Group 2 (at least one palatal code and any of the following)	Description
0NQTOZZ	Repair right mandible, open approach
0NSX0ZZ	Reposition hyoid bone, open approach
0NSX04Z	Reposition hyoid bone with internal fixation device, open approach
Hypoglossal nerve stimulation procedure codes (Group 3)	Description
64568 AND ...	Cranial nerve stimulator implant
64999 OR 0466T ^a	Implantation of a chest wall respiratory sensor electrode

^aFrom 2014 to 2016, the 64999 code was used for the implantation of the respiratory sensor was 64999. Starting in 2017, a specific code 0466T was created for the respiratory sensor. This code has been used since this time.

2.1 | Statistical methods

Data are presented as mean and standard deviation. Patients who receive different treatments are likely to be different, often resulting in a confounding relationship between patient characteristics and measured outcomes resulting from therapy choices.²⁸ Propensity score matching can be an effective method to reduce the bias in estimating treatment effects as well as reduce the likelihood of confounding when analyzing nonrandomized, observational data.²⁹ Thus, the cohorts were propensity score matched using age, sex, race, ethnicity, BMI category, diagnosis of a metabolic disorder, and diagnosis of obesity or other hyperalimentation. Readmission and complication rates in each cohort were monitored from the first day after surgery (index event) and continuing for 90 days. We used an odds ratio to estimate the relationship between groups and outcomes. To compare outcomes across groups, we used Kaplan–Meier curves and risk differences (via *t*-test). To minimize time-based bias when comparing groups using retrospective EHR data, we limited all cohorts to those receiving treatment during the same time period beginning April 30th, 2014 (after FDA approval of the Upper Airway Stimulator).

3 | RESULTS

From April 2014 through March 2021, there were 1201 HNS, 3364 palate, and 492 multilevel procedures performed among approximately 70 million patients in 49 health care organizations in the database. Overall, the patients were predominantly overweight and obese Caucasian males. Prior to propensity score matching, the HNS cohort was older, had lower BMI, and included more females and non-Hispanic Caucasians than the palate and multilevel cohort (Table 2). After propensity score matching, 1014 patients were compared for

HNS versus palate surgery, and 374 patients for HNS versus multilevel surgery, and were more similar (i.e., not statistically different) in terms of age, race, ethnicity, sex, and obesity diagnosis. Despite propensity score matching, there remained a significant difference in BMI

between the HNS versus palate and multilevel surgery group ($p < .001$), as the HNS cohort had a lower BMI (Table 3).

TABLE 2 Characteristics of cohorts, prior to propensity score matching

	Palate	Multilevel	HNS
Total (n)	3364	492	1201
Age in years	47 ± 13	49 ± 12	60 ± 11
Female (%)	26%	27%	33%
Ethnicity (%)			
Not Hispanic	64%	80%	69%
Unknown ethnicity	28%	16%	30%
Hispanic	8%	4%	1%
Race (%)			
White	68%	75%	86%
Black or African American	14%	11%	3.5%
Unknown race ^a	14%	-	10%
BMI (kg/m ²)	33.3 ± 6.6	32.4 ± 6.2	29.2 ± 3.8

^aNot all race information was reported in TriNetX, so values may not add to 100%.

TABLE 3 Propensity score matching results

	HNS vs. palate		HNS vs. multilevel	
	HNS after matching	Palate after matching	HNS after matching	ML after matching
Total (n)	1014	1014	374	374
Age, years	58 ± 11	58 ± 11	52 ± 12	52 ± 11
White	84%	86%	80%	79%
Black	4%	4%	8%	9%
Unknown race	11%	10%	17%	18%
Non-Hispanic	69%	69%	80%	79%
Female	31%	31%	27%	29%
Metabolic disorder	44%	42%	40%	42%
Overweight	26%	26%	32%	32%
BMI (kg/m ²)	29 ± 4	31 ± 6	30 ± 4	32 ± 6

Procedure	Cohort, n	Outcome, n	Risk (%)	Risk differences vs. HNS (%)
HNS vs. palate				
HNS	1014	35	3.5%	-
Palate	1014	118	11.6%	8.2% (5.9–10.5)*
HNS vs. multilevel				
HNS	374	15	4%	-
Multilevel	374	45	12%	8.0% (4.1–11.9)*

* $p < .0001$.

3.1 | Ninety-day readmission risk

Risk of readmission within 90 days was highest for the multilevel cohort (12.0%), slightly lower for the palate cohort (11.6%), and lowest for the HNS cohort (4%). HNS had a statically significantly lower 90-day readmission risk compared to palatal and multi-level surgery ($p < .0001$). Further details and group comparisons are displayed in Table 4.

Figure 1 shows freedom from readmission over time for all three procedures. The first 10 days following surgery was especially risky for readmission in the palate and multilevel cohorts, as evidenced by the readmission risk curve steeply separating from the HNS curve in the first 10 days after surgery. In contrast, HNS readmission risk appears to be more evenly distributed across the 90-day period.

We examined the most common ICD-10 diagnosis codes documented during the readmission encounter (ED or inpatient admission). For HNS, the most common diagnosis was “general signs and symptoms” such as malaise, headache, edema, and so forth (ICD10: R50-R69). For the palatal surgery, the most common diagnosis was intraoperative or post-procedure complication and disorder of the

TABLE 4 Comparison of 90-day readmission following procedure, propensity matched cohorts

FIGURE 1 Ninety-day freedom from readmission

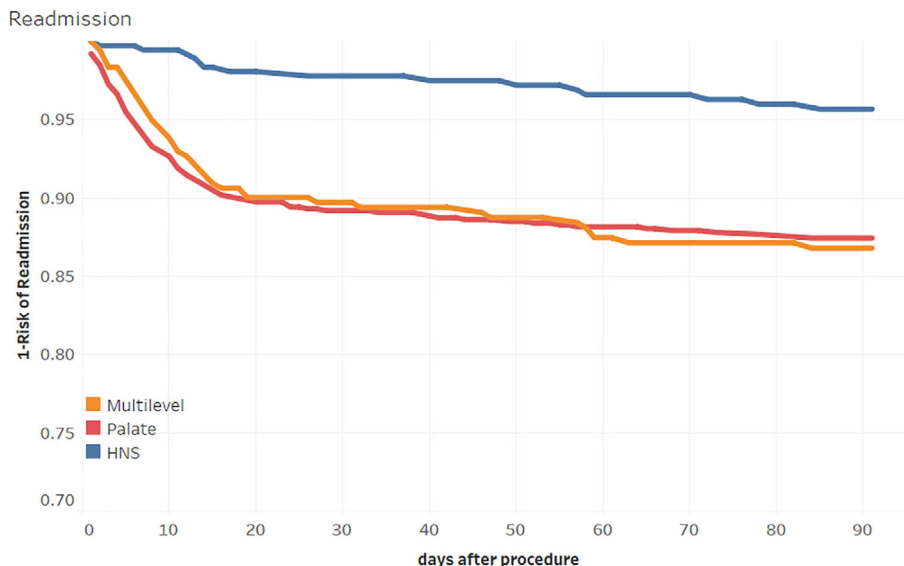


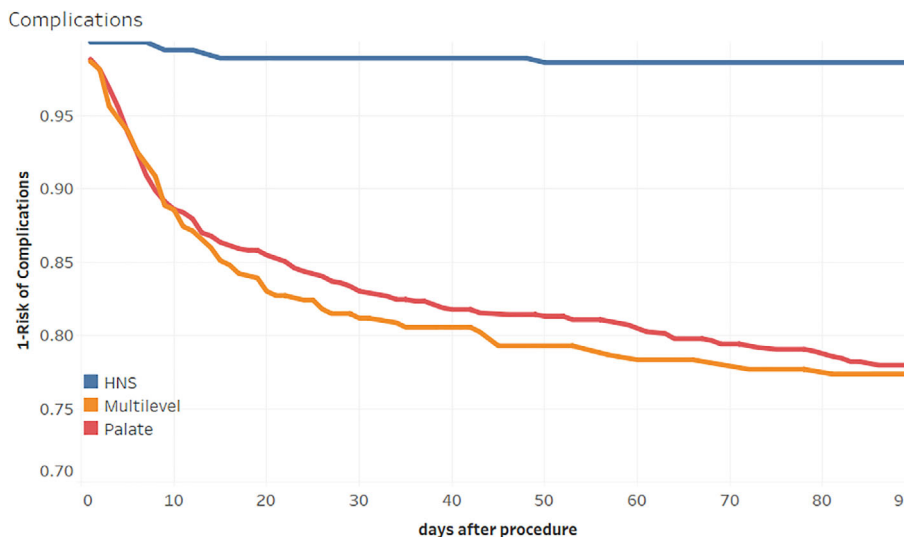
TABLE 5 Comparison of 90-day complications following procedure

Procedure	Cohort, n	Outcome, n	Risk (%)	Risk differences vs. HNS (% , 95% CI)
HNS vs. palate				
HNS	1014	23	2.3%	-
Palate	1014	204	20.1%	17.9% (15.2-20.5)*
HNS vs. multilevel				
HNS	374	10 ^a	3%	-
Multilevel	374	79	21%	18.5% (14.0-22.9)*

^aValues less than 10 are reported as 10, per TriNetX policy.

**p* < .0001.

FIGURE 2 Ninety-day freedom from postoperative complications



respiratory system (ICD10: J95), and for multi-level surgery, the most common was pain (ICD10: G89).

3.2 | Ninety-day postoperative complications

Risk of 90-day surgical complication follows a similar trend as readmission—highest for the multilevel cohort (18.9%), slightly lower

for the palate cohort (15.1%), and lowest in the HNS cohort (2.4%). HNS had a significantly lower postoperative complication rate than palatal and multilevel surgery (*p* < .001). The full results and breakdown are displayed in Table 5. Additionally, Figure 2 demonstrates the freedom from developing a complication in the first 90 days for all three procedures. As with readmission rates, palate and multilevel cohorts have increased risk, and the curve largely separates from the HNS cohort in the first 10 days after surgery. The complication rates

are more evenly distributed across the 90-day period for the HNS cohort.

4 | DISCUSSION

Hypoglossal nerve stimulation has become a well-established option in the surgical armamentarium for patients with OSA failing first line CPAP therapy. HNS has an excellent safety profile as demonstrated across many studies,^{20,21,24} whereas traditional sleep surgery including procedures of the palate and tongue base have known substantial risks of postoperative pain, dehydration, bleeding, and airway obstruction.^{11,30} A recent paper confirms the results of a recent single-site retrospective comparison between sleep surgery and HNS.³¹ The purpose of the present study was a first use of “EHR big data,” across multiple health care systems, using the TriNetX Research Network to retrospectively compare HNS therapy to TSS. Specifically, we examined surgical morbidity, as evidenced by 90-day readmission and postoperative complications. This study represents the largest comparison of its kind to date, with 1014 matched HNS and palate surgery patients and 374 matched HNS and multilevel surgery patients.

Our study's findings of a 2.4% 90-day surgical complication rate for hypoglossal nerve stimulation is similar to other published studies. HNS was FDA approved for the treatment of moderate to severe obstructive sleep apnea in 2014, after publication of the STAR trial data. This multicenter study examined 126 patients undergoing HNS and demonstrated an overall one-year, device-related serious adverse event rate of 2%, which was due to the need for surgical device revision in two patients.

The post-approval multi-institutional observational registry ADHERE enrolled 301 patients and reported on safety outcomes showing that 97% of HNS procedures were completed without report of an adverse outcome. Serious adverse outcomes were rare such as need for revision (1%), tongue weakness (1%), speech or swallow complaints (1%), and pain related to the device (2%).²⁴ A recent meta-analysis pooled data from 7 high-quality prospective studies, finding 12 of 195 patients experiencing 14 serious adverse events (6.1%).³²

Uvulopalatopharyngoplasty was first introduced by Fujita in 1981 and has been widely adopted as one of the most common surgical procedures for treating OSA. UPPP has undergone many modifications, perhaps most notably ESP as described by Pang and Woodson. ESP has largely supplanted UPPP in many centers because ESP rearranges rather than removing tissues, which results in an anterior displacement of the soft palate along with lateral expansion at the level of the velo- and oropharynx.¹⁰

Readmission rates capture both life-threatening and less serious, but still significant, complications that occur after discharge. In this study, we found the 90-day UPPP readmission rate was 12%. A cross-sectional analysis of multistate ambulatory and hospital databases followed 2349 ambulatory UPPP cases and found 9.7% had revisit after surgery. These patients returned to the surgery center (13.7%), emergency room (68.3%) or for inpatient admission (18.1%). The most common reason for revisit was bleeding (38.3%), followed by acute

pain (21.2%) and fever/dehydration (6.6%).³⁰ Baker et al. queried the ACS-NSQIP database for 30-day complications and readmission among patients undergoing UPPP alone, UPPP and nasal surgery, and UPPP and base of tongue (BOT) surgery. Overall complications for UPPP + BOT surgery were highest at 11.4%, followed by UPPP alone (7.1%) and UPPP + nasal surgery (7.0%) however there was no statistically significant difference between these two groups. Readmission rates were reported at 2.8% for UPPP alone and 4.8% for UPPP + BOT surgery.³³

This study showed a higher-than-expected complication rate for palate surgery, compared to existing literature, which may be due to the long-term data captured in an EHR database. Serious complication after UPPP occurs in the operative and perioperative period at a rate of 3.7%–10%.¹¹ The nature of palatal surgery complications found in this study were similar to previous reports. These typically included surgical complications such as bleeding requiring transfusion and/or return to the operating room, infection, wound dehiscence, and respiratory compromise as well as medical complications such as myocardial infarction, stroke, deep vein thrombosis, renal failure, and pneumonia. Kezirian et al. reported that among 3130 men studied, the most serious complications such as hemorrhage, re-intubation, emergent tracheostomy, and cardiovascular complications occurred in a rate of 1.5% of patients, with overall mortality rate in this cohort of 0.2%.

Although several studies have compared outcomes such as AHI reduction between HNS and TSS,^{34,35} there have been few published papers comparing readmission and complication rates. The current study confirms our hypothesis that HNS has lower readmission and complication rates in the immediate postoperative period than palatal and multi-level surgery for OSA. The 90-day readmission rate was lowest among the HNS cohort (4%) when compared to the palatal surgery alone (11%) or multilevel surgery (12%). Similarly, HNS had a statistically much lower rate of complications (2%–3%) when compared to palatal surgery (20%) or multilevel surgery (21%). A strength of this study is the use of a federated EHR system, which reduces selection bias inherent in single or even multi-institutional studies because its data is sourced from diverse sites. The raw, unadjusted demographic data in TriNetX demonstrates that those undergoing HNS are older, have lower BMI, and are more likely to be white than those with palate and multilevel surgery. However, a strength of this study is the ability to match subjects to reduce these confounding factors.

While this study used a large EMR dataset to strengthen its findings, there are limitations in this analysis. The use of the TriNetX database, which only stores diagnosis and procedure codes in an aggregated basis, limits the ability to know whether the patients receiving sleep surgery were not eligible for HNS, and thus a different population, which could bias the outcomes. For example, the TriNetX database does not record the sleep endoscopy results, thus we cannot definitively determine the type of collapse being addressed by either HNS or TSS cohorts. Additionally, this database did not record postoperative AHI, so it is not possible to compare the postoperative outcomes between the groups. One potential weakness of this study is

that the database includes use of CPT and ICD codes, which are reliant on the accuracy of those inputting the data into the EHR system. For example, UPPP and all forms of modified UPPP such as ESP will typically be indistinguishable due to use of the same CPT code, although there may be differing readmission and complication rates between the two palatal techniques. Additionally, there is heterogeneity among the procedures given the diverse sites included and the diversity of individual procedures that can be captured under a single CPT code. Specifically, this brought concern that the multi-level group was defined too broadly, which was accepted as a limitation of a retrospective study of this type.

In this study, we used propensity score matching to attempt to equalize baseline differences between the HNS and surgery groups. Despite best efforts to match the BMI between the two groups, HNS cohort still had a lower BMI than sleep surgery cohorts likely due to insurance coverage policies covering HNS implant in patients with BMI less than 35. The higher average BMI in sleep surgery could have negatively impacted the readmission and complication rates, however, clinical impact of a 2 point BMI difference on readmission and complication rates is unknown.

Another inherent weakness is that this study examines only 90-day complications and readmission, which likely captures the vast majority of adverse events of those undergoing TSS but may underestimate latent HNS complications such as infections, surgical revisions, explant, or device failure which can occur beyond the 90-day period. For reference, the 1-year HNS surgical complication rate was 1.5%,²⁰ and 5-year surgical complication rate was 6%.³⁶ Our definition of HNS and sleep surgery complications during the EHR search was based on previously published complication descriptions for the initial postoperative period, but may not be comprehensive of all complications, especially if the complication was not recorded in the EMR record or did not match the complication codes used in this analysis. Similarly, HNS or sleep surgery complications which do not present to the ER or clinic, or patients who return to a different health system that is not covered by the TriNetX database within 90 days would not be captured by this method. Due to these limitations in methodology, our findings may underestimate both the HNS and sleep surgery readmission and complication rate. While the safety profile of HNS may be higher than TSS, not all patients may qualify for HNS, and those who do not qualify may still require traditional sleep surgery to treat their OSA.

5 | CONCLUSION

Patients undergoing HNS experience lower rates of 90-day readmission and complications when compared to those undergoing palate or multilevel surgery for obstructive sleep apnea. This is the first study to use a federated EHR system to examine adverse events in matched subjects undergoing HNS or TSS for the treatment of OSA and contributes to the evidence that HNS has an excellent safety profile for selected patients who qualify for HNS compared to traditional surgical treatment options.

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CONFLICT OF INTEREST

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