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WILEY

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Background: A bioabsorbable nasal valve implant (NVI) was introduced in 2016 as a minimally invasive solution to nasal valve collapse. Historically the introduction of less invasive procedures performable in-office has resulted in an increase in volume. Our objective is to evaluate this trend as it relates to nasal vestibular repair, and its impact on healthcare utilization.

Methods: We interrogated the Medicare Part B national database for nasal vestibular repair (CPT code: 30465), Unlisted nasal procedure (30999) and septoplasty (30520) from 2010 to 2017. Septoplasty was used as a surrogate for overall nasal procedural rate. Linear regression modeling was used to examine the changes in reported vestibular repair rate adjusting for septoplasty rate.

Results: In the Medicare population, the rate of septoplasty was stable from 2010 to 2017, increasing from 26,962 to 30,194 at an annual rate of 1.1% over this time period. Coding for unlisted nasal procedure increased from 272 to 333 at an adjusted annual rate of 1.1% over this time period. Coding for nasal vestibular repair increased from 2026 to 5331 over this interval at an adjusted annual rate of 0.9% from 2010 to 2016 but significantly increased to 5% between 2016 to 2017 ($P < .0001$).

Conclusion: The reported volume of nasal vestibular repair increased significantly in the year following Food and Drug Administration approval of NVIs. In the absence of a corresponding increase in septoplasty, this temporal relationship suggests that the introduction of NVIs impacted the utilization of this procedural code.

Key Words: Nasal valve repair, septoplasty, Medicare.

Level of Evidence: N/A

INTRODUCTION

A bioabsorbable nasal valve implant (NVI) was approved by the U.S. Food and Drug Administration in June 2016. It was created as a minimal invasive solution to nasal valve collapse and an alternative approach to nasal valve repair (NVR) traditional surgical techniques such as batten grafts, bone-anchored sutures, and lateral crural strut grafts.1-3

Due to its relative simplicity, the NVI can be performed in the clinic under local anesthesia as a stand-alone procedure or in conjunction with turbinate reduction or septoplasty.4 It extends accessibility to new providers and patient populations, including older patients who may otherwise not be good candidates for traditional open NVR. Historically, however, the introduction of newer and less invasive in-office procedures has resulted in an increase in procedural volume.

For example, the total number of sinus procedures in the Medicare population increased at a steady rate of an additional 3.7% from 2000 to 2014, while utilization of balloon sinuplasty has increased at a substantially greater rate of 59% since the introduction of CPT codes for these procedures in 2011.2

Our objective was to analyze trends in nasal valve repair using 2010–2017 Medicare data, with particular attention to the trend pre- and post-introduction of the NVI in 2016. The data was subdivided by state, region, and procedural setting. Additionally, we analyzed trends in usage at the individual physician level based on prior rate of NVR.

METHODS

We conducted a retrospective cohort analysis of the data from the Medicare Provider Utilization and Payment Data: Physician and Other Supplier Public Use File (PUF) from the Centers for Medicare and Medicaid Services (CMS). The Medicare Part B National Summary Data File was also queried to obtain annual procedure data from 2010 to 2017. The total number of Medicare beneficiaries per state and nationwide was obtained from the “Total Number of Medicare Beneficiaries” table from the Kaiser Family Foundation for the years 2012 to 2017. All data was accessed online (https://www.cms.gov/ and http://kff.org/) between June 10, 2019 and July 23, 2019. Procedures codes of interest included nasal valve repair procedures (NVR) (CPT code 30465) and septoplasty (CPT code 30520).
Selection of Participants

Detailed provider and payment data from 2012 to 2017 was obtained from the PUF. Since the PUF does not contain data on providers performing less than 10 of any given procedure, it is a subset of the total Medicare Part B Database. A “septoplasty cohort” was created from providers who performed at least ten septoplasties in any calendar year from 2012 to 2015. Providers in the cohort were defined as +NVR or −NVR based on whether the provider performed at least 10 NVRs in any year from 2012 to 2015.

In 2016 and 2017, there was an additional group of “emerging providers” that was not captured in the cohort due to having not reached the threshold of performing at least 10 septoplasties in a year from 2012 to 2015. This group was composed of 130 and 183 providers who performed at least 10 septoplasties or 10 NVR in 2016 or 2017, respectively.

Study Outcomes

The main outcome variable was the total number of NVR procedures performed annually in 2016 and 2017. We also examined the number of unique providers performing at least 10 NVRs annually during the study period. The number of NVR procedures annually subdivided by state, region, and procedural setting (billing code as in a facility or in an office) was also evaluated.

Analysis

The national total number of NVR was adjusted for the natural increase in overall procedures annually by using the rate of septoplasty as a marker of baseline nasal surgery. This relative NVR rate was calculated by dividing the number of NVRs by the number of septoplasties performed for a given year. The total number of providers billing for NVR or septoplasty and trends in procedural setting were studied. The total number of services rendered nationwide, in each state, and in each of the four U.S. regions (West, Midwest, Northeast, South) as defined by the U.S. Census Bureau were calculated. To account for differences in the population between states and regions, all procedure data was normalized per 10 thousand Medicare beneficiaries to give the number of procedures per 10 thousand beneficiaries (PP10K). The number of NVRs performed by each provider in the cohort was obtained for the year 2016 and 2017. Mean percentage of providers performing NVR and mean NVR procedures per NVR provider in each group was calculated for 2016 and 2017. Generalized estimating equation models were used to test for trend between 2016 to 2017 and test for trend difference across groups while taking into account correlated data within providers across years. Statistics were calculated using SAS 9.3 and R 3.6.1 for Windows.

RESULTS

From 2010 to 2017, the total number of NVR procedures nationwide annually increased from 1972 to 5204 per year. When adjusted for the gradual increase in number of septoplasties, the number of NVR per septoplasty increased from 7.3 per 100 septoplasties in 2010 to 17.2 per 100 septoplasties in 2017. The number of NVR procedures relative to septoplasties increased from 2010 to 2016 linearly at a rate of 0.9% per year (Fig. 1). However, the rate of increase was 5% per year from 2016 to 2017, and this rate of increase was significantly different from the annual rate of increase from 2010 to 2016 (P < .001).

The increased rate of NVR from 2016 to 2017 coincided with a large increase in the number of NVR providers in 2017 compared to 2016. This large increase in NVR providers was not seen for years prior to 2017 (Fig. 2). Of note, the number of providers performing septoplasty, our marker for overall nasal surgery productivity, did not change significantly over the same period.

NVR were increasingly utilized in both the facility and office setting during the study period. Prior to 2016, 4–5% of NVR were performed in office however the rate of office NVR increased to 7% and 9% in 2016 and 2017, respectively.

Additionally, when examining trends in procedural setting, there was a gradual exponential increase in NVR performed in office from 2012 to 2017 (Fig. 3A). Over this time period, NVR performed in facility increased at a mean rate of 9.7% annually from 2012 to 2016. However, the increase was 41.0% from 2016 to 2017 (Fig. 3B).

When examining the trend by region, from 2015 to 2016, the number of NVR per 10,000 Medicare population slightly decreased in the West, Midwest, and Northeast.
but slightly increased in the South (Fig. 4). From 2016 to 2017, this measure increased for all four regions with the greatest increase seen in the South and least in the West. When examining the trend by state, the overall number of NVR per 10,000 Medicare beneficiaries increased nationally but not all states experienced an increase from 2016 to 2017. Idaho, Montana, New Hampshire, Utah, and West Virginia had a slight decrease relative to their Medicare population. The top three largest increases in NVR relative to their Medicare population were Maryland, Texas, and Tennessee.

From 2012 to 2015, 59/1080 (5.5%) of septoplasty providers performed at least 10 NVR procedures in Medicare recipients in any single year during 2012–2015. These stations...
TABLE I. Comparison of Percentage of NVR Providers by NVR Experience and Year.*

<table>
<thead>
<tr>
<th>Group</th>
<th>Year 2016</th>
<th>Year 2017</th>
<th>OR (95% CI) comparing % NVR providers in 2017 vs. 2016</th>
<th>P-value testing trend across years by group</th>
<th>P-value testing for time trend difference among group</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-volume NVR provider</td>
<td>22/59 (37.3%)</td>
<td>23/59 (39.0%)</td>
<td>1.07 (0.62–1.85)</td>
<td>.80</td>
<td>.047</td>
</tr>
<tr>
<td>in 2012–2015</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low- to no-volume NVR</td>
<td>2/1021† (0.20%)</td>
<td>9/1021‡ (0.88%)</td>
<td>4.53 (1.33–15.4)</td>
<td>.016</td>
<td></td>
</tr>
<tr>
<td>provider† in 2012–2015</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional “non septoplasty” providers‡</td>
<td>10/130 (7.7%)</td>
<td>19/182 (10.4%)</td>
<td>1.54 (0.87–2.72)</td>
<td>.14</td>
<td></td>
</tr>
</tbody>
</table>

*High-volume NVR providers defined as those who performed at least 10 septoplasties and 10 NVR any given year between 2012 and 2015.
†These providers performed at least 10 septoplasty during 2012–2015 but did not perform or performed fewer than 10 NVR.
‡These providers either did not practice or performed fewer than 10 septoplasties between 2012 to 2015.

Discussion

There was a sudden increase in the number of NVRs in the Medicare population relative to septoplasties from 2016 to 2017 at the time of introduction of a bioabsorbable NVI (Fig. 1). This increase noticeably coincides with the increase of unique providers from 2016 to 2017 (Fig. 2), while the number of septoplasty providers remained relatively stable. These results show additional utilization for Medicare patients and more unique providers performing NVR after the introduction of a NVI.

Further analysis of the provider profiles shows that the increase in the number of providers performing 10 or more NVI per year after 2016 came from those who previously did not perform 10 or more NVR per year (Table I). While the absolute number of previously –NVR providers who began performing the procedure was small, our analysis showed that providers in this group who started to perform the procedure in 2016 were even more likely to continue in 2017. This is in contrast to the observation that among those who previously performed the procedure from 2012–2015, a similar proportion of providers continued to perform NVR in 2016 and 2017 at high volume (37% vs. 39%). This might suggest that surgeons who used to routinely offer septoplasties without offering NVR were increasingly offering NVI to their Medicare patient population after the NVI introduction in 2016. Also, while the absolute numbers are small, the data represents the first full year of a new product and if trends continued then costs to the health system could be significant.

Out of 182 “emerging” providers who previously had not performed greater than 10 septoplasties between 2012–2015, almost 10% (19/182) performed NVR procedures in 2017 compared to just 3% of providers who were previously performing septoplasty surgery. These providers may have been newly trained surgeons who were more interested in utilizing this new device or may have been surgeons who did no previously offer nasal surgery but began to offer NVI. It should be noted that the mean number of NVR cases per provider was not significantly different across all groups of providers by year (Table II). This supports the notion that the increase in the number of NVR procedures can be evenly attributed to all provider groups and not just a particular group frequently performing the procedure.

The increase in NVR may in part be explained by the ease in which it can be performed that allows more in-office use of NVI outside the operating room (Fig. 3). NVRs were increasingly performed in both facility and office settings, with a sharp increase noted after 2016 in both settings. The rate of increase is more dramatically
noted in the office group. Only 4–5% of NVR was performed in office prior to 2016 whereas this rate increased to 7% and 9% in 2016 and 2017, respectively. We hypothesize that this near 5-fold increase in the number of procedures is due to of the availability of NVI for utilization in office beginning in 2016.

We found a geographical bias in performance of NVR. The number of NVRs per 10,000 Medicare population showed a noticeable spike in all four regions, with the South showing an almost 3-fold increase in the rate of the surgery (Fig. 4). This preferential increase of the new technique is consistent with the previous observation where the greatest percentage of BSP procedures in 2013 and 2014 was performed in the South—with Tennessee and Texas being the two highest in the region in our study.

In a previous study, Venkatraman et al. showed that the nine hospital referral regions with the highest diagnoses of chronic rhinosinusitis were all found in the Southern region. It is possible that nasal valve collapse associated with nasal congestion or rhinosinusitis could be more commonly diagnosed in these regions. Alternatively, it is possible that some of the hospitals have better manufacturer support, flexible structure of adoption and diffusion of the new technology from a health economic standpoint.3

The role of NVI in the treatment of nasal valve collapse remains unclear. Previous studies have proven the clinical efficacy of NVI up to 24 months,4 with the most recent study showing improvement on both physical exam findings as well as patient-reported symptom improvement.5 It should be noted that the patients included in this study were very carefully selected for those who have dynamic lateral wall collapse. Patients who improved with standalone implant placement were more likely to have had prior septoplasty, turbinate reduction, or endoscopic sinus surgery.5 Although considered relatively safe with more than 32,000 implants deployed,6 the true complication rate for this device is still under investigation as only anecdotal complications were reported in the literature.7 Emerging, rapidly adopted surgical technologies have historically been subject to scrutiny, particularly in regards to overutilization. With appropriate patient selection and pre-operative counseling, overutilization of this device can be avoided.

Our study covered the utilization of sinus procedures in a limited demographic of Medicare Part B database. A study of the generally older Medicare population may not be wholly representative of those with dynamic nasal wall collapse. The number of NVI cases may be overrepresented in our dataset because younger, healthier patients likely are better able to tolerate general anesthesia and other aspects of surgery compared to the elderly, and may opt for more traditional methods of NVR. The older age of patients also may overrepresent clinic usage of NVI compared to the facility. In addition, the databases accessed for this study are built around provider billing data and thus fail to include variables that could provide further insight into utilization patterns.2 It is not possible based on the limitations of the dataset to determine whether the popularity of bioabsorbable nasal implants is due to the increased ease of the procedure or broadening of possible surgical candidates. Diagnosis codes are not provided; therefore, we are unable to identify the reasons for the prescribed treatment or at which point in the treatment algorithm the procedure was performed (standalone, previous septoplasty, ESS). When characterizing physician volume, PUF does not include data for surgeons who performed 10 or fewer procedures on Medicare beneficiaries. Therefore, the PUF data available is only a subset of all Medicare data and does not capture procedures performed by providers whose patient population is younger. Medicare data also does not provide any information about outcomes or complication rates. Lastly, it should be noted that recently the American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) recommended to change coding for NVI placement to 30999, which might impact reimbursement structure.8 Further research on the cost effectiveness of NVI, as well as trends in coding patterns of 30465 and 30999, is warranted.

### CONCLUSION

The number of NVRs among Medicare beneficiaries and the number of unique providers increased at the time of introduction of a NVI, while the rate of septoplasty and the number of septoplasty providers remained unchanged. There was geographic disparity in the rate of increase of NVRs, with the South having the greatest increase in the rate of surgery. This temporal relationship suggests that the introduction of NVIs impacted the utilization of this procedural code. Further research following the coding patterns of 30465 and 30999 is warranted in the setting of recent AAO-HNS recommendations to change coding for NVI placement to 30999.

### BIBLIOGRAPHY


