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ORIGINAL ARTICLE

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Real-world evidence analysis of the impact of steroid-eluting implants on healthcare resource use among chronic rhinosinusitis patients undergoing sinus surgery

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ABSTRACT

Objective: To compare healthcare resource use (HCRU) in patients undergoing sinus surgery with or without steroid-eluting sinus implants

Methods: A retrospective, observational cohort study using real-world evidence data (OM1, Inc, Boston, MA, USA) was conducted on adult patients with chronic rhinosinusitis (CRS) with or without nasal polyps who underwent endoscopic sinus surgery between 2014 and 2019 and had at least 18 months of data both before and after surgery. Patients receiving implants ("implant cohort") were matched to patients who did not receive implants ("non-implant cohort") based on a propensity score developed using baseline characteristics. Chi-square for binary variables and analysis of variance tests for continuous variables were applied to compare HCRU measures.

Results: Comparison of the implant ($N = 1983$) and non-implant ($N = 1983$) cohorts during the 18-month follow-up period demonstrated significantly lower HCRU in those receiving implants, including all-cause outpatient visits (94.3% vs. 96.6%, $p < .001$), all-cause otolaryngologist visits (47.3% vs. 59.6%, $p < .001$) and all cause ER/urgent care visits (9.2% vs. 11.8%, $p = .007$), as well as sinus-related endoscopies (39.1% vs. 43.8%, $p = .003$). Although not statistically significant, fewer patients in the implant cohort had undergone repeat surgeries (4.6% vs. 5.3%, $p = .273$).

Conclusion: Patients with steroid-eluting sinus implants had lower HCRU over a post-operative period of 18 months. These findings support the contention that reductions in HCRU may be achieved using steroid-eluting implants during sinus surgery.

WHAT IS KNOWN ON THIS TOPIC

- Chronic rhinosinusitis (CRS) causes severe symptoms that lead to poor quality of life.
- Endoscopic sinus surgery (ESS) is 76–98% effective in improving CRS patients' symptoms.
- Surgical outcomes can be compromised in the immediate post-operative period by scarring, adhesion formation, and early polyp recurrence.
- Oral and topical corticosteroid therapy has become integral to the maintenance of successful surgical outcomes, the management of post-operative scarring and edema, and the prevention of nasal polyp recurrence.
- Steroid-eluting sinus implants have been shown in clinical trials to improve postoperative outcomes after ESS by delivering localized, sustained release of corticosteroids directly onto inflamed sinus tissue.

WHAT THIS STUDY ADDS

- This observational study is one of the first to use real-world evidence to assess the effect of steroid-eluting sinus implants on healthcare resource use (HCRU) in patients with chronic rhinosinusitis who underwent sinus surgery with or without implants.
- Use of implants significantly reduced HCRU, including all-cause outpatient visits (94.3% vs 96.6%, $p < .001$), all-cause otolaryngologist visits (47.3% vs 59.6%, $p < .001$), and all-cause ER/urgent care visits (9.2% vs 11.8%, $p = .007$), as well as sinus endoscopy (39.1% vs 43.8%, $p = .003$).
- Use of implants had no significant effect on sinus procedures such as debridement and polypectomy, as well as sinus-related imaging such as CT, MRI, and x-ray.

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Chronic rhinosinusitis; corticosteroid; mometasone furoate; sinus implant

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Introduction

Chronic rhinosinusitis (CRS) is an inflammatory condition affecting the mucosa of the paranasal sinuses and nasal passages that persists for 12 weeks or longer and causes at least two of the following symptoms: nasal congestion, mucus discharge, facial pain/pressure, decreased sense of smell[1,2]. CRS adds substantial economic cost to the US healthcare system. The direct costs of CRS-related healthcare are estimated to range from $7 to $13 billion per year[3,4]. Patients with CRS refractory to medical treatment may undergo sinus surgery[5]. Sinus surgery is technically challenging, and surgical outcomes may be compromised by a number of factors, such as middle turbinate lateralization, incomplete anterior or posterior ethmoidectomy, scarred frontal recess, and middle meatal antrostomy stenosis[6]. Avoidance of scarring and middle turbinate destabilization during surgery may reduce the failure rate of primary sinus surgery[7,8].

Steroid-eluting sinus implants have been shown in clinical trials to improve postoperative outcomes after sinus surgery by delivering localized, sustained release of corticosteroids directly onto inflamed sinus tissue[9–13]. The implants were shown to reduce the need for post-operative intervention, oral steroid use to resolve recurrent inflammation, and rate of occlusion or restenosis through postoperative day 30[14,15]. A recently updated international consensus opinion of over 140 rhinologists noted once again that the steroid-eluting implants exhibit no significant systemic corticosteroid absorption or ocular toxicity, and found that they offer, in aggregate, a preponderance of benefit over harm[16]. While some clinicians have raised concerns regarding the cost of the steroid-eluting sinus implants, analyses have demonstrated that upfront costs associated with the use of the implants are offset by the downstream savings associated with fewer postoperative interventions[17–20].

The corticosteroid-eluting sinus implants[i] are coated with 370 μg of mometasone furoate and approved by the US Food and Drug Administration (FDA) for use in patients 18+ years of age following sinus surgery in the ethmoid, frontal sinus ostia, and maxillary sinus ostia. Currently, none of the implants are approved for use in the sphenoid sinus. This observational study used real-world evidence (RWE) data to assess HCRU in patients with chronic rhinosinusitis with and without nasal polyps (CRSwNP and CRSsNP) who underwent sinus surgery with or without steroid-eluting sinus implants.

Methods

Study design

This retrospective observational cohort study assessed the frequency of HCRU in adult patients with CRS with or without polyps who underwent ESS between 1 January 2014 to 31 December 2019. Assessments were summarized and compared between patients who received any of the corticosteroid-eluting sinus implants ("implant cohort") and those who received none ("non-implant cohort"). The study population and HCRU parameters were identified from a multisource database containing healthcare claims and electronic medical record (EMR) data in the US. The dataset used for this study is fully de-identified and compliant with the Health Insurance Portability and Accountability Act. A description of the dataset was submitted to an Institutional Review Board for approval, and the dataset was determined to be exempt.

Data source

This study was conducted within the OM1 Real-World Data Cloud (OM1, Inc, Boston, MA). This dataset is derived from deterministically linked, de-identified, individual-level healthcare claims, electronic medical records (EMR), and other data from January 2013 to the present. The EMR data are from sources geographically representative of the US population and include medication history and prescription information, laboratory results, and diagnoses documented by a health care provider. Additional medical and pharmacy claims data are linked to the clinical data to fill gaps in patients' clinical care. The medical and pharmacy claims contain billing and coding history on inpatient and outpatient encounters from acute care facilities, ambulatory surgery centers, and clinics.

Patient selection and cohort assignment

The study population included patients ≥18 years of age who underwent an index sinus surgery between 1 January 2014 and 31 December 2019. Patients were required to have at least one International Classification of Diseases (ICD 9th or 10th Revision) diagnosis code for CRS with or without polyps on or before the date of their sinus surgery. Patients were also required to have claims data at least 18 months before and at least 18 months after their sinus surgery to ascertain baseline characteristics and HCRU, respectively. Sinus surgeries and use of sinus implants were identified within the study population based on the presence of relevant procedure codes on the day of the surgery.

To account for differences in CRS disease severity and other pre-surgery characteristics, patients in the implant cohort were matched to patients in the non-implant cohort on a propensity score (PS) that predicted implant use versus no implant use. The PS was calculated using logistic regression modeling for the probability of receiving an implant. The logistic regression model included the following baseline variables: demographics (age, sex, race), presence of asthma and/or allergic rhinitis, overall comorbidity burden as measured by the Deyo-Charlson comorbidity index (an overall measure of health based on ICD 9th and 10th Revision diagnosis codes for a range of comorbidities)[21,22], year of surgery, duration of the baseline period, and facility type. In addition to the PS, patients in the implant cohort were also exact matched to patients in the non-implant cohort based on the number of prior sinus surgeries and the presence of polyps prior to the index surgery. The surgery that had a corresponding match was defined as the index surgery. Each patient contributed only one index surgery to the final study population. All observed data prior to that index surgery was used to define the baseline variables.

Health care resource use

The following HCRU measures were ascertained in the implant and non-implant cohorts over an 18-month follow-up period after the index surgery: repeat sinus surgery (including traditional sinus surgery, balloon sinuplasty, osteoplastic frontal sinus obliteration, frontal sinus trephination, Caldwell-Luc procedure, or external ethmoidectomy), emergency room (ER)/urgent care visits for any reason, office visits with any provider, office visits with an otolaryngologist, sinus-related procedures (endoscopy, debridement, polypectomy), and sinus-related imaging (CT scan, MRI, X-ray).

Statistical methods

Descriptive statistics were used to summarize baseline demographics, surgery history and clinical characteristics, as well as HCRU during follow-up. For patients with repeat sinus surgery, use of implants and the sinuses operated on were also summarized. Chi-square tests were used to compare the percentage of patients with repeat sinus surgery and other binary measures of HCRU (e.g. % of patients with at least one visit for each visit type (yes/no)) between the matched cohorts. Analysis of variance (ANOVA) was used to compare continuous HCRU measures (e.g. number of visits) between the matched cohorts. Within the 18-month follow-up period, HCRU measures were assessed over 6-month intervals during the following time frames: 0 to 6 months, $>$ 6 to 12 months, and $>$12 to 18 months, and combined 0 to 18 months. All analyses were conducted with SAS 9.4 (SAS Institute; Cary, NC).

Results

The study population comprised 3966 patients: 1983 patients in the implant cohort and 1983 patients in the non-implant cohort. The median time for baseline characteristic ascertainment was 40 months (interquartile range [IQR]: 30–52 months) in the implant cohort and 40 months (IQR: 29–53 months) in the non-implant cohort. The matched cohorts were similar with respect to age, sex, race, and insurance type (Table 1). More patients in the implant cohort than in the non-implant cohort (94.8% vs. 85.1%) underwent sinus surgery involving multiple sinuses (Table 2). More patients in the implant cohort than non-implant cohort had surgery in the maxillary (90.8% vs. 89.2%), ethmoid (76.3% vs. 59.9%), frontal (74.0% vs. 53.0%) and sphenoid (52.8% vs. 38.5%) sinuses. Nearly all index surgeries (99%) were performed in outpatient facilities and the majority were *de novo* (85%). Half of CRS patients in each cohort had polyps and half did not (Table 3). All comorbid conditions were well-balanced between cohorts, including allergic rhinitis (62.5% vs. 62.1%) and asthma (33.4% vs. 35.8%).

During the 18-month follow-up, repeat surgery was rare and occurred at a similar rate in both cohorts (4.6% vs. 5.3%, $p = .273$) with an overall difference of 0.7% (Table 4), corresponding to a 14.1% relative reduction in the implant cohort. Repeat use of implants was reported in 1.4% (28 of 1983) of patients in the implant cohort and none in the non-implant cohort. In both cohorts, the overall revision rate was highest in the maxillary sinus (3.1% vs. 4.4%), followed by the sphenoid sinus (2.0% vs. 1.6%), which remained stable the study duration. Compared to the non-implant cohort, the implant cohort had a significantly lower incidence of healthcare visits (Table 5), including all-cause outpatient visits (94.3% vs 96.6%, $p < .001$), all-cause otolaryngologist visits (47.3% vs 59.6%, $p < .001$), and all-cause ER/urgent case visits (9.2% vs 11.8%, $p = .007$). Significantly fewer patients in the implant cohort required endoscopy (39.1% vs. 43.8%, $p = .003$), whereas debridement, polypectomy and imaging occurred at

Table 1. Demographic characteristics by cohorts.

	Implant		Non-implant	
	N = 1983		*N = 1983*	
	N/Mean	%/SD	N/Mean	%/SD
Age (Mean, SD)	46.9	14.2	47.3	15.2
Sex (*N*, %)				
Female	1069	53.9%	1017	51.3%
Male	914	46.1%	966	48.7%
Race (*N*, %)[a]				
N reported patients	585		551	
Caucasian	493	84.3%	472	85.7%
African American	79	13.5%	59	10.7%
Asian	11	1.9%	13	2.4%
Other	2	0.3%	7	1.3%
Insurance type (*N*, %)[a]				
N reported patients	1482		1572	
Commercial	1318	88.9%	1280	81.4%
Medicaid or Medicare	47	3.1%	131	8.3%
Other	117	7.9%	161	10.2%

Abbreviations: SD, standard deviation.
[a]Percentages were calculated using the N reported patients as the denominator.

Table 2. Characterization of the index sinus surgery by cohort.

	Implant *N = 1983* *N* (%)	Non-implant *N = 1983* *N* (%)
Number of sinuses treated		
Multiple	1879 (94.8%)	1687 (85.1%)
One	104 (5.2%)	296 (14.9%)
Type of sinuses treated[a]		
Maxillary	1800 (90.8%)	1768 (89.2%)
Ethmoid	1513 (76.3%)	1187 (59.9%)
Frontal	1468 (74.0%)	1051 (53.0%)
Sphenoid	1048 (52.8%)	763 (38.5%)
Unknown	11 (0.6%)	87 (4.4%)
Facility type		
Outpatient[b]	1967 (99.2%)	1960 (98.8%)
Inpatient	16 (0.8%)	21 (1.1%)
Unknown	0 (0.0%)	2 (0.1%)
Year of index surgery		
2014	74 (3.7%)	73 (3.7%)
2015	349 (17.6%)	402 (20.3%)
2016	585 (29.5%)	544 (27.4%)
2017	451 (22.7%)	448 (22.6%)
2018	415 (20.9%)	410 (20.7%)
2019	109 (5.5%)	106 (5.3%)
Number of prior sinus surgeries		
0	1694 (85.4%)	1694 (85.4%)
1	248 (12.5%)	248 (12.5%)
2 or more	41 (2.1%)	41 (2.1%)

[a]The OM1 Real-World Data Cloud provides data on the type of sinuses treated, but not on the specific sinus location of implant placement or the type of implant used. None of the studied implants are approved for placement in sphenoid.
[b]Outpatient facility included day surgery and ambulatory services.

Table 3. Baseline characteristics by cohort.

	Implant		Non-implant	
	N = 1983		*N = 1983*	
	Mean/*N*	SD/%	Mean/*N*	SD/%
CRS (*N*, %)				
CRSsNP	995	50.2%	995	50.2%
CRSwNP	988	49.8%	988	49.8%
Deyo-Charlson comorbidity index (Mean, SD)[a]	0.9	1.3	0.8	1.2
Comorbid condition of interest (N, %)				
Allergic rhinitis	1239	62.5%	1232	62.1%
Asthma	662	33.4%	710	35.8%
Sleep disorders[b]	514	25.9%	558	28.1%
COPD	325	16.4%	322	16.2%
Eustachian tube dysfunction	253	12.8%	256	12.9%
Immunodeficiency disorders	57	2.9%	46	2.3%
Sensitivity/allergy to aspirin or NSAIDs	50	2.5%	50	2.5%
Allergic fungal rhinosinusitis	4	0.2%	3	0.2%

Abbreviations: COPD, chronic obstructive pulmonary disease; CRS, chronic rhinosinusitis; CRSsNP, CRS without nasal polyps; CRSwNP, CRS with nasal polyps; NSAIDs, nonsteroidal anti-inflammatory drugs; SD, standard deviation.
[a]The Deyo-Charlson comorbidity index or CCI is a weighted score that is calculated based on the presence of a range of comorbidities recorded in administrative data. The CCI is used to measure burden of disease, with higher scores indicating a more severe level of comorbidity, and consequently a worse prognosis. [20].
[b]Includes sleep apnea, nighttime awakening due to congestion, and snoring.

Table 4. Characterization of repeat sinus surgery during 18 months following the index surgery in the matched cohorts.

	0 to 6 months		>6 to 12 months		>12 to 18 months		Overall (0 to 18 months)	
	Implant *N = 1983* *N* (%)	Non-implant *N = 1983* *N* (%)	Implant *N = 1983* *N* (%)	Non-implant *N = 1983* *N* (%)	Implant *N = 1983* *N* (%)	Non-implant *N = 1983* *N* (%)	Implant *N = 1983* *N* (%)	Non-implant *N = 1983* *N* (%)
Repeat surgery	40 (2.0%)	40 (2.0%)	30 (1.5%)	40 (2.0%)	28 (1.4%)	35 (1.8%)	91 (4.6%)	106 (5.3%)
Characteristics (% among patients with repeat surgery)								
Implant[a]	15 (37.5%)	0	8 (26.7%)	0	5 (17.9%)	0	28 (30.8%)	0
Type of sinus								
Maxillary	23 (57.5%)	31 (77.5%)	25 (83.3%)	33 (82.5%)	17 (60.7%)	30 (85.7%)	62 (68.1%)	88 (83.0%)
Sphenoid	12 (30.0%)	6 (15.0%)	18 (60.0%)	15 (37.5%)	14 (50.0%)	10 (28.6%)	40 (44.0%)	31 (29.2%)
Frontal	2 (5.0%)	1 (2.5%)	0	1 (2.5%)	0	0	2 (2.2%)	2 (1.9%)
Ethmoid	1 (2.5%)	0	0	0	0	0	1 (1.1%)	0
Characteristics (% among the total number of patients)								
Implant[a]	15 (0.8%)	0	8 (0.4%)	0	5 (0.3%)	0	28 (1.4%)	0
Type of sinus								
Maxillary	23 (1.2%)	31 (1.6%)	25 (1.3%)	33 (1.7%)	17 (0.9%)	30 (1.5%)	62 (3.1%)	88 (4.4%)
Sphenoid	12 (0.6%)	6 (0.3%)	18 (0.9%)	15 (0.8%)	14 (0.7%)	10 (0.5%)	40 (2.0%)	31 (1.6%)
Frontal	2 (0.1%)	1 (0.1%)	0	1 (0.1%)	0	0	2 (0.1%)	2 (0.1%)
Ethmoid	1 (0.1%)	0	0	0	0	0	1 (0.1%)	0

[a]Represents patients who underwent a repeat sinus surgery with steroid-eluting sinus implants. Data on specific sinus location of implant placement and the type of implant used were not available in the OM1 Real-World Data Cloud. None of the studied implants are approved for placement in sphenoid.

Table 5. Healthcare visits and procedures during 18 months following the index sinus surgery in the matched cohorts[a].

	Overall (0 to 18 months)		
	Implant *N = 198)* *N* (%)	Non-implant *N = 1983* *N* (%)	*p-value*
Healthcare visits (*N*, %)			
All-cause outpatient	1869 (94.3%)	1915 (96.6%)	<.001
All-cause otolaryngologist	938 (47.3%)	1182 (59.6%)	<.001
All-cause ER/urgent care	182 (9.2%)	234 (11.8%)	.007
Sinus procedures performed (*N*, %)			
Endoscopy	775 (39.1%)	868 (43.8%)	.003
Debridement	384 (19.4%)	361 (18.2%)	.350
Polypectomy	4 (0.2%)	1 (0.1%)	.179
Sinus-related imaging (*N*, %)			
CT	201 (10.1%)	172 (8.7%)	.115
MRI	32 (1.6%)	19 (1.0%)	.067
X-ray	16 (0.8%)	18 (0.9%)	.730

Abbreviations: CT, computed tomography scans; ER, emergency room; MRI, magnetic resonance imaging.
[a]Values represent counts and percentages of patients with at least one visit (or procedure) during the specified time frame. Patients with multiple types of visits (or procedures) are counted under each type.

similar rates in both cohorts. HCRU rate varied over time (Table 6). The implant cohort had a lower percentage of all-cause outpatient visits in the first 6 months (86.3% vs 91.8%, $p < .001$) and a lower percentage of all-cause otolaryngologist visits at all time intervals (44.6% vs 56.3%, $p < .001$ during first 6 months; 19.1% vs 24.5%, $p < .001$ in >6 to 12 months, and 13.8% vs 19.3%, $p < .001$ in >12 to 18 months). A lower percentage of implant cohort patients underwent endoscopy in the first 6 months (32.4% vs 37.1%, $p = .002$).

Discussion

This observational RWE study demonstrated reduction in HCRU during 18-month follow-up among CRS patients who underwent sinus surgery with steroid-eluting sinus implants compared to the matched cohort of those who underwent sinus surgery alone. A lower percentage of the implant cohort than non-implant required all-cause outpatient, all-

Table 6. Healthcare visits and procedures during each 6-month interval following the index sinus surgery in the matched cohorts[a].

	0 to 6 months			>6 to 12 months			>12 to 18 months		
	Implant *N* = *1983* *N* (%)	Non-Implant *N* = *1983* *N* (%)	*p-value*	Implant *N* = *1983* *N* (%)	Non-Implant *N* = *1983* *N* (%)	*p-value*	Implant *N* = *1983* *N* (%)	Non-Implant *N* = *1983* *N* (%)	*p-value*
Healthcare visits (*N*, %)									
All-cause outpatient	1712 (86.3%)	1820 (91.8%)	<0.001	1507 (76.0%)	1549 (78.1%)	0.113	1430 (72.1%)	1449 (73.1%)	.499
All-cause otolaryngologist	885 (44.6%)	1117 (56.3%)	<0.001	378 (19.1%)	486 (24.5%)	<0.001	273 (13.8%)	383 (19.3%)	<.001
All-cause ER/urgent care	68 (3.4%)	100 (5.0%)	0.012	83 (4.2%)	109 (5.5%)	0.054	90 (4.5%)	108 (5.4%)	.189
Procedures performed									
Endoscopy	643 (32.4%)	734 (37.1%)	0.002	329 (16.6%)	356 (18.0%)	0.257	234 (11.8%)	259 (13.1%)	.229
Sinus debridement	348 (17.5%)	321 (16.2%)	0.252	60 (3.0%)	53 (2.7%)	0.504	36 (1.8%)	33 (1.7%)	.716
Polypectomy	3 (0.2%)	0	0.083	0	0	—	1 (0.1%)	1 (0.1%)	1.000
Sinus-related imaging (*N*, %)									
CT	95 (4.8%)	71 (3.6%)	0.057	74 (3.7%)	74 (3.7%)	1.000	60 (3.0%)	48 (2.4%)	.242
MRI	16 (0.8%)	11 (0.6%)	0.334	8 (0.4%)	4 (0.2%)	0.247	9 (0.5%)	5 (0.3%)	.284
X-rays	5 (0.3%)	9 (0.5%)	0.284	6 (0.3%)	6 (0.3%)	1.000	6 (0.3%)	5 (0.3%)	.763

Abbreviations: CT, computed tomography scans; ER, emergency room; MRI, magnetic resonance imaging.
[a]Values represent counts and percentages of patients with at least one visit (or procedure) during the specified time frame. Patients with multiple types of visits (or procedures) are counted under each type.

cause otolaryngologist, and all-cause ER/urgent care visits. They also had fewer sinus-related endoscopies. Most of the differences observed within the first 6 months were statistically significant. The lower percentage of the implant cohort with all-cause otolaryngologist visits remained statistically significant throughout the 18-month follow-up and that with all-cause ER/urgent care visits remained statistically significant up to 12 months. To our knowledge, this is the first study that demonstrated sustained effect of corticosteroid-eluting implants on reduction in HCRU beyond 30 days.

While the observed results did not reach statistical significance, a lower percentage of patients in the implant cohort underwent repeat sinus surgery between 6 and 18 months, and overall. These results are compelling given that a higher percentage of implant patients than non-implant patients had surgery on multiple sinuses, and the extent of sinus surgery was greater in the implant cohort, suggesting higher disease severity among implant patients. Therefore, the reported between cohort differences in HCRU and procedures may underestimate the effect of implant use because patients who received implants may have had more severe disease than non-implant patients. Since the non-implant patients were matched to the implant patients, HCRU reported in the non-implant cohort may not be generalizable to the larger population of less severe CRS patients who do not receive implants during sinus surgery. The long-term revision rate for sinus surgery has been estimated to be greater than 15% over 10 years[23]; the reported rates of 2% within the first 6 months and 5% at 18 months are much lower given much shorter follow-up. Commonly cited factors predisposing patients to the need for repeat or revision sinus surgery include incomplete uncinectomy, retained agger nasi or anterior ethmoid cells, and lateralization of the middle turbinate[24]. The results for repeat surgery observed in this study are unexpected, as most repeat surgeries involved the maxillary and sphenoid sinuses, and the frequency of repeat ethmoid and frontal surgery was negligible. While the uncinate process belongs anatomically to the ethmoid sinus, it is possible that surgeons code removal of retained uncinate process as maxillary sinus surgery, due to the proximity of the uncinate process to the maxillary sinus ostium.

Recent publications have sought to further characterize the safety of steroid-eluting implants by examining post-market data available through the Manufacturer and User Facility Device Experience (MAUDE) database[25,26]. A total of only 28 adverse events associated with implant use were observed from 2011 through 2020, with the most commonly reported adverse events being postoperative infection followed by stent migration[26]. Importantly, attribution of the adverse event to the implant was not established in all cases. Given that an estimated 277,900 implants were used between 2012 and 2016 alone[27], the occurrence of implant-related adverse events is likely to be exceptionally rare. These safety results from post-market analyses echo those observed in clinical trials[9,13] and are consistent with the consensus opinion cited previously finding a preponderance of benefit over harm[16]. The results of this current study are consistent with and extend the results of clinical trials demonstrating the efficacy of steroid-eluting implants in improving postoperative outcomes through postoperative day 30[9–13]. Finally, the reduction in HCRU observed in this study corroborate the overall cost-effectiveness of steroid-eluting implants observed by others[17–20].

This study has several strengths. The OM1 Real-World Data Cloud links patient data across multiple payors for claims and EMR systems, which allows for assessment of HCRU over a longer period (18 months) than would be expected from a closed-claims system of a single payor. Because surgeons may elect to use steroid-eluting sinus implants on patients with more severe CRS, matching methods were implemented so that comparisons were made between cohorts that were similar with respect to measured baseline characteristics. The median length of the baseline period of 40 months allowed for adequate capture of the number of prior sinus surgeries and presence of polyps, and these data were used in addition to the PS to match implant with non-implant patients. The large sample of non-implant patients also gave rise to numerous candidates for appropriate matching to implant patients. Given the study's observational nature using data collected independent of this research question, there should be no differential recording of HCRU or risk factors between the cohorts.

Caution is warranted when interpreting the study results. Although the matched implant and non-implant cohorts were well balanced on measured baseline characteristics, residual confounding by unmeasured characteristics, such as sinus-specific disease, remains possible. This study included patients who met eligibility criteria based on their first and subsequent surgeries. However, patients may have had other sinus surgeries that were not accounted for in this study, including surgeries occurring before January 2013 (earliest date of data availability in the data source), or those performed by a provider not captured by the data source. Although patients were matched on the presence of polyps and other key clinical characteristics, residual confounding by polyp severity or other unmeasured baseline characteristics may remain. Finally, although there is an implicit assumption that clinical practices between the cohorts differ only in their use of steroid-eluting sinus implants, surgeons who use implants may perform more extensive surgery, may have a lower threshold for imaging studies, and may employ a broader armamentarium in postoperative care. These areas may influence outcomes and HCRU but cannot be evaluated in these data and warrant investigation in future studies.

Limitations

There are limitations inherent to retrospective study designs and the secondary use of data. Although the sinuses operated on during the index and repeat surgeries are reported, the data source did not allow for the identification of the specific sinuses in which the implants were placed. Although imaging studies (CTs, MRIs, x-rays) were limited to sinus-related procedures, it is possible that the imaging was done for non-CRS-related sinus issues. Despite the multi-source nature of the data, incomplete data capture may have occurred during the study period. For example, the data show that only 44–59% of patients had an otolaryngology visit, 32–37% of patients had a sinus-related endoscopy, and 16–17% of patients had sinus debridement in the first 6 months following surgery. These values should approach 100% in most clinical practices, suggesting incomplete capture of these encounters. The medication data available were not sufficient to allow for a complete assessment of medications used to treat CRS patients (e.g. oral corticosteroids or antibiotics before and after surgery). Due to the open nature of the claims in the OM1 Real-World Data Cloud, continuous enrollment is approximated by patterns of encounters. Services recorded in the EMR or billed for and included in the claims data are included, however observed HCRU likely underestimates total HCRU as services paid for out-of-pocket or otherwise are not captured in the OM1 claims or EMR data.

Conclusion

In this observational RWE study over a post-operative period of 18 months, patients undergoing sinus surgery with steroid-eluting sinus implants had reduced HCRU compared to patients undergoing sinus surgery without implants, particularly with respect to otolaryngologist visits. These findings suggest use of steroid-eluting sinus implants after sinus surgery may reduce HCRU and improve economic outcomes.

Note

i. PROPEL family of sinus implants (PROPEL, PROPEL Mini and PROPEL Contour), Intersect ENT, Inc., Menlo Park, CA, USA.

Transparency

Declaration of funding

Intersect ENT, Inc. engaged and provided funding to OM1, Inc to conduct this study.

Declaration of financial/other relationships

VH, KMM, KM, IT and RG are employees of OM1, Inc. JEK is a paid consultant to Intersect ENT, Inc. Peer reviewers on this manuscript have no relevant financial or other relationships to disclose.

Author contributions

Conception/design of the study: KMM, RG; Acquisition/analysis of the data: KMM, VH, IT, KM; Interpretation of the data: All authors; Drafting of the paper or revising it critically for intellectual content: All authors; Final approval of the version to be published: All authors. All authors agree to be accountable for all aspects of the work.

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Previous presentation

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