

Claims-based surveillance for reintervention after endovascular aneurysm repair among non-Medicare patients



Jesse A. Columbo, MD, MS,^{a,b} Art Sedrakyan, MD, PhD,^c Jialin Mao, MD, MS,^c Andrew W. Hoel, MD,^d Spencer W. Trooboff, MD, MBA,^b Ravinder Kang, MD, MS,^b Jeremiah R. Brown, PhD,^b and Philip P. Goodney, MD, MS,^{a,b} Lebanon, NH; New York, NY; and Chicago, Ill

ABSTRACT

Objective: Many patients who undergo endovascular aortic aneurysm repair (EVR) also undergo repeat procedures, or reinterventions, to address suboptimal device performance and prevent aneurysm rupture. Quality improvement initiatives measuring reintervention after EVR has focused on fee-for-service Medicare patients. However, because patients aged less than 65 years and those with Medicare Advantage represent an important growing subgroup, we used a novel approach leveraging a state data source that captures patients of all ages and with all types of insurance.

Methods: We identified patients who underwent EVR (2011-2015) within the Vascular Quality Initiative registry and were also listed in the Statewide Planning and Research Cooperative System all-payer claims database of New York. We linked patients in the Vascular Quality Initiative to their Statewide Planning and Research Cooperative System claims file at the patient level with a 96% match rate. We compared outcomes between fee-for-service Medicare eligible, defined as age 65 or older or on dialysis, versus ineligible patients, defined as those younger than 65 and not on dialysis. Our primary outcome was reintervention. We used Cox proportional hazards regression and propensity score matching for risk adjustment.

Results: We studied 1285 patients with a median follow-up of 16 months (range, 1-57 months). The mean age was 74 years, 79% were male, and 84% of procedures were elective. Nearly one in six patients were not Medicare eligible (14%), and the remainder (86%) were Medicare eligible. Medicare-eligible patients were less likely to be male (77% vs 91%; $P < .001$), have a history of smoking (79% vs 93%; $P < .001$), and have a nonelective procedure (15% vs 23%; $P = .013$). The 3-year Kaplan-Meier rate of reintervention was 21%. We found similar rates of reintervention between Medicare-eligible patients and those who were not (19% vs 20%, log-rank $P = .199$; unadjusted hazard ratio [HR], 0.75; 95% confidence interval [CI], 0.49-1.16). This finding persisted in both the adjusted and propensity-matched analyses (adjusted HR, 0.82; 95% CI, 0.50-1.34; propensity-matched HR, 0.70; 95% CI, 0.36-1.37).

Conclusions: Reintervention can be monitored using administrative claims from both Medicare and non-Medicare payers, and serve as an important outcome metric after EVR in patients of all ages. The rate of reintervention seems to be similar between older, Medicare-eligible individuals, and those who are not yet eligible. (J Vasc Surg 2019;70:741-7.)

Keywords: Reintervention after EVR; All-payer claims; Device performance measurement

More than 50,000 Americans undergo endovascular aortic aneurysm repair (EVR) each year.^{1,2} Studies suggest that up to 30% of patients who undergo EVR may require additional procedures, termed reinterventions, to address suboptimal device performance, type II endoleak, or other procedure-related problems to ensure their aneurysm remains free from rupture over time.³⁻⁸ The rate at

which reinterventions occur represents an important quality indicator for these implanted devices, the monitoring of which is endorsed by both the Food and Drug Administration and the Society for Vascular Surgery.^{9,10}

Despite these recommendations, accurately measuring reintervention in contemporary practice is difficult. In real-world settings, patients often receive postoperative

From the Section of Vascular Surgery, Dartmouth-Hitchcock Medical Center,^a and The Dartmouth Institute for Health Policy and Clinical Practice,^b Lebanon; the Department of Surgery, Weill-Cornell Medical School, New York^c; and the Division of Vascular Surgery, Northwestern University, Chicago.^d

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Correspondence: Jesse A. Columbo, MD, MS, Section of Vascular Surgery, 3V, Dartmouth-Hitchcock Medical Center, 1 Medical Center Dr, Lebanon, NH 03766 (e-mail: jesse.a.columbo@dartmouth.edu).

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care at institutions other than the hospital where the operation was performed.^{11,12} In addition, compliance with manual entry of patient follow-up into quality improvement registries is variable.¹² These two factors in aggregate make assessing the true rate of reintervention after EVR problematic and likely leads to an incomplete assessment of postoperative outcomes. Therefore, developing a mechanism to accurately assess the rate of reintervention after EVR in the real-world setting is integral to the objective measurement of device performance.

To address this problem, prior investigators have used Medicare claims data to improve follow-up for patients undergoing EVR.^{3,11,13} Linking Medicare claims to existing clinical registries such as the Vascular Quality Initiative (VQI) has allowed an accurate assessment of the rate of reintervention after EVR.¹⁴ However, because these studies are limited to Medicare fee-for-service patients, they fail to capture individuals who are under 65 years of age and have not yet reached Medicare eligibility, and those who subscribe to Medicare Advantage plans. Whether such a method of reintervention assessment is possible for this important and growing subgroup of patients is unknown.

Therefore, the objective of this study was to create a combined registry-claims system capable of capturing patients of all ages and insurance types and then to assess the rate of reintervention after EVR for both Medicare eligible patients (>65 years and/or dialysis dependent) and younger patients who had not yet reached Medicare eligibility. Our hypothesis was that reintervention could be assessed for all patients using this method and that reintervention rates would be similar across the groups.

METHODS

Data sources and cohort creation. We used data from the VQI to identify patients who underwent EVR in New York.^{15,16} Patients were eligible for inclusion if they had undergone EVR at a VQI participating center in New York between January 2011 and September 2015. Patients who underwent more than one aortic procedure in the same day were assigned according to the first procedure (open repair or EVR) they underwent. We then obtained corresponding discharge records from the New York Statewide Planning and Research Cooperative System (SPARCS) all-payer claims database. The SPARCS system captures discharge data from all in-hospital and emergency department encounters for New York.¹⁶ Next, we linked patients in the VQI with their respective SPARCS claims file. A validated sequential linkage algorithm was used for indirect linkage.¹⁷ Indirect identifiers were the facility identification number and patients' year and month of birth, sex, and procedure date. All variables and exact procedure dates were used in the first step. In later steps, flexibility was allowed by omitting patients' sex or month of birth and having a 3-day window before or after the procedure date. At each step, flexibility in

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective analysis of prospectively collected data from the Vascular Quality Initiative and an all-payer claims database from the state of New York
- **Key Findings:** Endovascular aortic aneurysm repair in 1285 patients resulted in a 3-year reintervention rate of 21%, similar between Medicare-eligible and -ineligible patients.
- **Take Home Message:** Reinterventions after endovascular aortic aneurysm repair is an important quality measure and can be determined by claims based databases.

only one of these aspects was permitted while matching to VQI data. This algorithm has been validated internally to have greater than 90% sensitivity and greater than 99% accuracy.¹⁷ We obtained a successful match in 96% of patients (1285/1336). The most common reason for nonmatching was that VQI patients could not be identified in SPARCS. This occurred at random. This combined VQI-SPARCS database formed our cohort for analysis. SPARCS data was available from January 2011 to September 2015. SPARCS data after October 1, 2015, were not analyzed because at that time billing encounters transitioned from the *International Classification of Diseases Ninth Revision* (ICD-9) to the *tenth revision* (ICD-10) and therefore coding algorithms used to identify clinical events in ICD-9 could no longer be used. VQI follow-up information was available through December 2017.

Primary exposure, outcomes, and definitions. Our primary exposure was Medicare eligibility. Medicare eligibility was defined at the time of the patients index operation as those aged 65 years or older or on dialysis.¹⁸ To examine the utility of all-payer claims datasets in evaluating reintervention in non-Medicare-eligible patients, we performed an analysis on patients who were Medicare eligible versus those who were not.

Our primary outcome of interest was reintervention after EVR. We defined reintervention after EVR, consistent with prior work, as any repeat procedure related to the aneurysm or for the aneurysm repair after discharge from the index hospitalization.¹⁴ We examined reintervention from both the VQI and SPARCS data. Reinterventions found in both sources were counted only once. We measured reintervention events in the SPARCS database with ICD-9 codes using a validated algorithm used in our research as part of longitudinal work examining outcomes after EVR.^{2,3,14} Patients were censored at death or at the end of their known VQI-SPARCS follow-up. Vital status was determined using the Social Security Death Index. All SPARCS data before September 2015 consisted of ICD-9 billing encounters. Therefore, no ICD-10 codes were used.

Statistical analysis. Patient characteristics were compared between those who were Medicare eligible at the time of the index EVR procedure and those who were not Medicare eligible. We report absolute numbers and percentages where appropriate. Continuous variables are represented as means with standard deviations or medians with interquartile ranges, and categorical variables are listed as percentages. We used Student's *t*-test to compare continuous variables and χ^2 analysis to compare categorical variables.

We first examined the rate of reintervention after EVR using Kaplan-Meier survival estimation. We used the log-rank test to compare survival curves stratified by Medicare eligibility. We next compared the unadjusted hazard ratio (HR) of reintervention between patients who were Medicare eligible at the time of their index operation versus those who were not using Cox proportional hazards regression. The difference between the unadjusted HR and the Kaplan-Meier analysis is that the Cox model enforces the proportional hazards assumption.¹⁹

Two different methods were used to account for differences in patient characteristics between the groups. We first used a multivariable Cox model to adjust for confounding variables, including patients sex, race, clinical characteristics, preoperative medication, and operative characteristics. Because age and dialysis are closely related to Medicare eligibility, we created two Cox regression models, one including age and dialysis, and one without. We noted no meaningful difference between the two models and report the model that does not include age and dialysis.

We next created a nearest neighbor propensity-matched cohort balanced in baseline covariates, similar to previous work.²⁰ We used the known clinical and procedure characteristics in the [Table](#) to create a logistic regression model where the dependent variable was Medicare eligibility. We calculated the probability of Medicare eligibility (propensity score) for each patient.²¹ We matched patients who were not Medicare eligible with similar patients who were. Patients were not matched on age or dialysis because these characteristics determine Medicare eligibility.¹⁸ We then calculated the HR of reintervention between the two groups using Cox regression with robust variance estimation to account for censoring.

We performed all statistical analyses using Stata version 12 software (College Station, Tex).

Human subjects protection. VQI data are collected under the auspices of an Agency for Healthcare Research and Quality designated Patient Safety Organization. This study was approved by the Center for the Protection of Human Subjects at Dartmouth and the Weill Cornell Institutional Review Board. All patient personal health information was protected, records and outcomes were deidentified, and no testing or procedures were required

for this study in accordance with SPARCS data use agreements. Thus, a Health Insurance Portability and Accountability Act waiver and a waiver of consent were obtained.

RESULTS

Cohort characteristics. We studied 1285 patients who underwent EVR during the study period ([Table](#)). The median follow-up was 16 months (range, 1-57 months). Patients who were not eligible for Medicare at the time of their index operation made up 13.6% of the cohort (175/1285). Patients who were not Medicare eligible were younger (mean age, 59.7 years versus mean age, 76.6 years; $P < .001$) and more likely to be male (90.9% versus 76.5%; $P < .001$).

Patients who were not Medicare eligible were similar to Medicare-eligible patients in most clinical characteristics with the exception of chronic obstructive pulmonary disease (not Medicare eligible, 21.4% versus Medicare eligible, 31.7%; $P = .006$), hypertension (not Medicare eligible, 81.0% versus Medicare eligible, 87.0%; $P = .033$) or having a body mass index of less than 35 (not Medicare eligible, 18.9% versus Medicare eligible, 8.4%; $P < .001$). There were important differences in operative characteristics between the two groups. Those who were not Medicare eligible were more likely to have an urgent or emergent procedure (not Medicare eligible, 22.9% versus Medicare eligible, 15.2%; $P = .013$), or have an iliac artery aneurysm (not Medicare eligible, 23.8% versus Medicare eligible, 17.6%; $P = .048$).

Given these differences, we created a propensity-matched cohort to better align baseline characteristics between Medicare-eligible and non-Medicare-eligible patients. Propensity matching yielded 167 matched pairs of patients. Although there was a trend toward more male patients in the group that was not Medicare eligible (not Medicare eligible, 90.4%, versus Medicare eligible, 95.8%; $P = .052$), the propensity matched cohort was well balanced in all other clinical and operative characteristics ([Table](#)).

Rates of reintervention. The Kaplan-Meier estimated rate of reintervention after EVR for the entire cohort increased over the 3-year follow-up period ([Fig 1](#)). At 1 year, the cumulative rate was 5%. This rate increased to 14% at 2 years and 20% at 3 years. The shape of the curves indicated that many reintervention events occurred during the initial postoperative period, and then again between 1 and 2 years postoperatively. Although fewer events occurred after 2 years, the rate did not seem to decrease in slope after two years.

We found no statistically significant difference in the Kaplan-Meier estimated rate of reintervention after EVR for patients who were Medicare eligible versus those who were not ([Fig 2](#)). The cumulative rate of reintervention for those who were Medicare eligible was 5% at

Table. Clinical and operative characteristics of the cohort

Variable	Entire cohort			Propensity-matched cohort		
	Medicare eligibility		P value	Medicare eligibility		P value
	No (n = 175)	Yes (n = 1110)		No (n = 167)	Yes (n = 167)	
Demographics						
Age mean (SD), years	59.7 (4.0)	76.6 (7.0)	<.001	59.7 (4.1)	75.9 (7.2)	<.001
Male, %	90.9	76.5	<.001	90.4	95.8	.052
White race	78.7	86.1	.095	80.2	82.6	.573
Clinical characteristics						
Coronary disease	27.4	28.0	.872	27.0	30.5	.468
Coronary revascularization	14.9	12.3	.327	14.6	13.2	.751
Heart failure	8.6	11.5	.265	7.2	10.2	.331
COPD	21.4	31.7	.006	21.1	28.3	.127
Smoking history	93.1	78.7	<.001	92.8	88.0	.137
Prior aortic surgery	2.3	2.8	.694	2.4	3.6	.521
Positive preoperative stress test	8.5	7.5	.807	8.4	4.8	.186
BMI >35	18.9	8.4	<.001	18	18.0	1
Hypertension	81.0	87.0	.033	80.8	84.4	.386
Diabetes	23.1	21.4	.607	22.3	22.8	.919
Chronic kidney disease ^a	8.6	8.2	.850	7.8	12.8	.137
Preoperative medications						
Aspirin	61.5	61.7	.959	61.7	63.5	.734
P2y12 inhibitor	15.5	19.0	.276	16.2	21.6	.208
Statin	59.2	66.4	.065	59.9	67.7	.139
Operative characteristics						
Urgency			.013			
Elective	77.1	84.8		79	78.4	.524
Urgent	14.3	11.0		14.4	12.0	
Emergent (ruptured)	8.6	4.2		6.6	9.6	
AAA diameter			.628			
<5.5 cm	49.7	47.1		50.9	47.5	.703
5.5-6.4 cm	28.6	32.2		28.7	28.4	
≥6.5 cm	21.7	20.7		20.4	24.1	
Iliac aneurysm	23.8	17.6	.048	22.8	24.6	.699
Conversion to open	0	0.1	.693	0	0.6	.324

AAA, Abdominal aortic aneurysm; BMI, body mass index (kg/m²); COPD, chronic obstructive pulmonary disease; SD, standard deviation.

^aCreatinine >1.7 mg/dL.

1 year and increased to 19% at 3 years. Among patients who were not Medicare eligible, the rate of reintervention was 4% at 1 year and 20% at 3 years (log-rank $P = .199$). The adjusted regression model revealed no statistically significant difference between the two groups, with an adjusted HR of 0.82 (95% confidence interval [CI], 0.50-1.34). The unadjusted HR was also not statistically significant (HR, 0.75; 95% CI, 0.49-1.16).

The propensity-matched model demonstrated similar findings (Fig 3). Among the propensity-matched cohort, the cumulative rate of reintervention at 1 and 3 years for patients who were not Medicare eligible was 4% and 21%, respectively. The cumulative rate for patients

who were Medicare eligible at the time of their index operation at 1 and 3 years was 7% and 23%, respectively (log-rank $P = .276$). However, because of the sample size, the standard error for the 3-year estimate of those who were Medicare eligible was 10.6%. The HR for reintervention for the propensity-matched cohort was similar to the unadjusted and adjusted models with a propensity-matched HR of 0.70 (95% CI, 0.36-1.37).

Predictors of reintervention. Our Cox proportional hazards regression model revealed additional factors that were significantly associated with reintervention after EVR. Patients with a history of any type of aortic

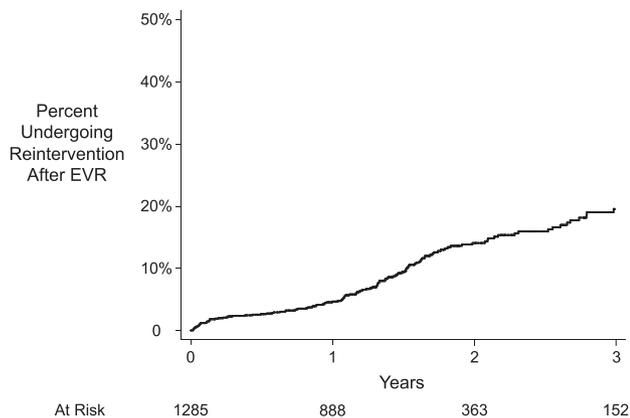
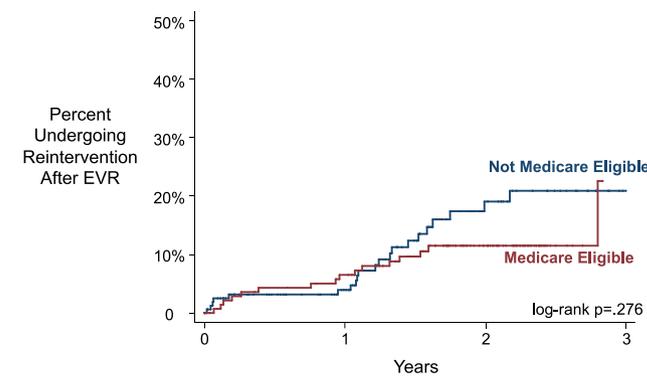
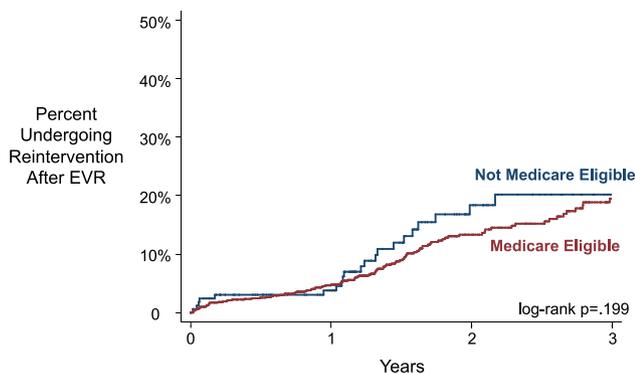


Fig 1. Kaplan-Meier estimated cumulative incidence of reintervention after endovascular aneurysm repair (EVR) among participating centers in New York. The standard error is less than 10%.



At Risk	0	1	2	3
Not Medicare Eligible	167	124	50	25
Medicare Eligible	167	127	64	<11

Fig 3. Kaplan-Meier estimated cumulative incidence of reintervention after endovascular aneurysm repair (EVR) among participating centers in New York, propensity-matched cohort. Data are censored where the standard error is greater than 10%.



At Risk	0	1	2	3
Not Medicare Eligible	175	129	53	25
Medicare Eligible	1110	760	311	127

Fig 2. Kaplan-Meier estimated cumulative incidence of reintervention after endovascular aneurysm repair (EVR) among participating centers in New York, stratified by Medicare eligibility. The standard error is less than 10%.

surgery before their index EVR demonstrated a nearly 3.5-fold higher risk of reintervention (HR, 3.47; 95% CI, 1.71-7.04; $P < .001$). Patients who underwent their index EVR for a ruptured aortic aneurysm had a HR of reintervention of 3.43 (95% CI, 1.57-7.50; $P = .002$). The year in which the operation was performed seemed to correlate with the rate of reintervention, with an increase in the HR of reintervention for each year. When compared with patients who had their operations performed in 2011, those who underwent EVR in 2012 had a HR of reintervention of 0.97 (range, 0.36-2.59), those in 2013 had a HR of 1.61 (range, 0.56-4.58), those in 2014 had a HR of 2.76 (range, 1.01-7.55), and those undergoing surgery in 2015 had a HR of 4.28 (range, 1.51-12.14). Comorbidities, including heart failure, coronary artery disease, chronic obstructive pulmonary disease, diabetes, and chronic kidney disease, did not demonstrate a statistically

significant association. In addition, the size of the aortic aneurysm at the index operation was not significantly associated with the likelihood of reintervention, nor was the presence of an iliac artery aneurysm. In multivariable modeling, Medicare eligibility (age ≥ 65 years or on dialysis) was not associated with reintervention (HR, 0.82; 95% CI, 0.50-1.33; $P = .427$).

DISCUSSION

In this study, we successfully linked clinical registry data from the VQI with all-payer claims data from the SPARCS system of New York at the patient level. Using this novel combined data source, we found that approximately one in five patients underwent reintervention after within the first 3 years after EVR. Although other investigators have used claims data to assess the rate of reintervention after EVR, these analyses are limited to fee-for-service Medicare patients.^{11,13} By using all-payer claims data, our study was able to capture patients of all age groups and insurance types.

Patients who are not yet eligible for Medicare make up a growing and important subgroup of individuals who undergo EVR, representing nearly one in six patients in our cohort. Interestingly, we found that patients who were Medicare eligible underwent reintervention at a similar rate to those who were not Medicare eligible. Although our power is limited to detect smaller differences between these groups, our finding of no difference is important, because it indicates that once patients have undergone EVR they are treated with reintervention at the similar rate, regardless of whether they are eligible for Medicare coverage.

Our study highlights the need for diligent surveillance after EVR. We found that younger patients—those under the age of 65 at the time of their initial EVR—can expect an approximately 20% chance of undergoing

reintervention within the first 3 years after their procedure, and this risk does not seem to diminish over the first 3 years. Our findings demonstrate that a novel approach that leverages both clinical registry data and all-payer claims can be used to monitor important quality metrics after EVR in patients of all age groups and insurance types.

Surveillance after EVR is challenging in clinical practice. Adherence to follow-up is important, because up to 30% of patients can expect to undergo reintervention within the first 5 years after EVR, a finding supported by our observational analysis described herein and by others.^{5,11,13,14} Despite recommendations for regular surveillance by the U.S. Food and Drug Administration, the Society for Vascular Surgery, and other professional cardiovascular organizations, many clinical practices have difficulty with longitudinal patient follow-up after EVR.^{9-12,22,23} This concern is not without merit, because reports have described that nearly one-half of patients have not had the annual surveillance recommended by the Society for Vascular Surgery by 3 years after their initial procedure.¹¹ As the proportion of EVR procedures out of the total aortic repairs continues to increase over time, these challenges are likely to worsen.²

Linked registry-claims data sources may provide an efficient option for monitoring reintervention after EVR. Using linkages between clinical registries and administrative data sources for outcome assessment has been successful for a number of clinical specialties, including the American College of Cardiology, the Organ Procurement and Transplantation Network, and the Surveillance Epidemiology and End Results cancer registry.²⁴⁻²⁶ The VQI has also been linked to fee-for-service Medicare claims, and allowed ascertainment of reintervention EVR at 3 years with 92% sensitivity and 96% specificity.^{3,14} Our work described herein demonstrates the same strategy can also be used for younger patients who are not Medicare eligible and those on Medicare Advantage plans by leveraging all-payer claims data. Finally, we found rates of reintervention similar to prior validation studies, indicating that the VQI-SPARCS registry-claims system likely accurately reflects the rate of reintervention at VQI participating centers in New York.¹⁴

Our study has limitations. This study was limited to the state of New York. All-payer claims systems exist in other states but are often difficult to obtain. The collection and dissemination of claims information for the purpose of surveillance would represent a step forward for clinical research and quality measurement, should stakeholders begin to analyze these data for quality improvement and comparative effectiveness research. The SPARCS database captures in hospital and emergency department encounters within the state of New York, we cannot comment on patients who have moved to another state or have traveled outside of the state for treatment, or patients who were seen in the outpatient clinic. However,

because most reintervention procedures happen in a hospital setting, we feel that it is unlikely that this factor would meaningfully affect our results. Furthermore, because this analysis is limited to New York patients, our statistical power is limited to detect small differences between groups and lack of differences in some cases may represent a type 2 error. However, our reported rates of reintervention are consistent with prior validation efforts, indicating this system likely provides an accurate representation of reinterventions following EVR. We considered patients Medicare eligible if they were over 65 or on dialysis. Other factors that may also lead to Medicare eligibility such as a spouse on Medicare, or being on social security disability income, were not captured by our analysis. Not all reinterventions are of equal magnitude. A more granular characterization of reintervention events is an area of active investigation for our research group. The SPARCS claims system does not include data on care performed at Veteran's Association hospitals. Therefore, patients who undergo reintervention at those institutions are not captured. In addition, we did not have data available on surveillance or imaging compliance after EVR. Examining the association between recommended surveillance and reintervention is an area of active investigation for our group. This study was retrospective in nature, and the decision to perform a reintervention was ultimately at the discretion of the operating surgeon.

CONCLUSIONS

Among a cohort of patients who underwent EVR in New York, we successfully linked registry data in the VQI to the SPARCS all-payer claims data system at the patient level. We found that approximately one in five patients can expect to undergo reintervention after EVR and that this rate does not differ between older, Medicare-eligible individuals, and those who have not yet reached eligibility. Our findings demonstrate that reintervention can be monitored using claims from both Medicare and non-Medicare payers. This combined registry-claims data system may offer solutions to some of the challenges posed by post-EVR surveillance by monitoring key outcomes in a way that is less labor intensive than current methods.

AUTHOR CONTRIBUTIONS

Conception and design: JC, AS, JM, PG
Analysis and interpretation: JC, AS, JM, AH, ST, RK, JB, PG
Data collection: JC, AS, JM, PG
Writing the article: JC, PG
Critical revision of the article: JC, AS, JM, AH, ST, RK, JB, PG
Final approval of the article: JC, AS, JM, AH, ST, RK, JB, PG
Statistical analysis: JC, JM
Obtained funding: AS, PG
Overall responsibility: JC

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