Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Preliminary analysis of coronavirus disease 2019 variable insertion into Vascular Quality Initiative registries

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The Society for Vascular Surgery (SVS) Vascular Quality Initiative (VQI) reported a dramatic reduction in vascular registry activity at the start of the coronavirus 2019 (COVID-19) pandemic following the President's order for a national lockdown in March 2020.[1,2] Although the pandemic's effect was global, variations in registry activity were noted between the VQI and Vascunet (a collaboration of international vascular registries administered by the European Society for Vascular Surgery) registries, with some countries maintaining a more normal workload during the first half of 2020. By August 2020, both the VQI and the Vascunet registries had achieved nearly 85% of their prepandemic volumes.[3] Recognizing the need to better understand the pandemic's effects on procedural volumes and outcomes, the VQI added COVID-19 variables to all procedure-based registries in September 2020. In the present study, we sought to determine the mortality effects of COVID-19 infection on the VQI registries. The VQI is uniquely suited to examining the relationship of overall periprocedural mortality for patients who have tested positive for COVID-19 because most registries had included a mortality variable on procedure discharge.

METHODS

The SVS VQI registry data from September 2020 to February 2021 were queried for COVID-19 variables and procedure mortality. Procedures without discharge information, such as the varicose vein registry, were included for the procedure volume but excluded from the mortality analysis. The COVID-19 variables included COVID-19 testing, procedure delay attributed to COVID-19 infection, and whether the procedure delay had affected the outcome. Details of the COVID-19 variables and help text are listed in Table I. For comparison, the registry activity from 2018 and 2019 served as historical (before COVID-19) controls and was reviewed for procedure complications and comorbidities. Urgency status variables (ie, urgent, symptomatic, emergent) were used to determine the comparative nonelective ratios for each registry with those from before the COVID-19 era. The procedure complications used to determine the postoperative event rates included myocardial infarction, congestive heart failure, dysrhythmia, pulmonary complications, dialysis, and stroke, in addition to mortality. These rates were then compared with the historical control data among the disease categories. The procedure complication rates for the registries were grouped into disease category: carotid endarterectomy (CEA), which included carotid artery stenting for carotid artery and aortic aneurysm endograft repair (endovascular aortic aneurysm repair [EVAR]) and open repair for aortic aneurysms, and individually for peripheral artery disease lower extremity bypass, amputation, peripheral vascular intervention (PVI), and thoracic EVAR. The ratios of the COVID-19 event rate to the historical event rate were calculated, with a value greater than one indicating an increased rate from before to after COVID-19. Unadjusted odds ratios and the associated 95% confidence intervals were calculated to evaluate differences in mortality among the groups of COVID-19 test status and symptoms. Differences in mortality and all other outcomes were determined using the χ^2 test for independence of categorical variables. A two-tailed P value of $<.05$ was considered statistically significant. Statistical analysis was performed using R statistical software, version 4.0.2 (R Foundation for Statistical Computing, Vienna, Austria).[4] Data for the present study were obtained from the SVS VQI, an Agency for Healthcare Research and Quality–approved Patient Safety Organization. The data were aggregated and fully de-identified and, thus, were exempt from institutional review board review and the need for patient consent.

RESULTS

From September 2020 through February 2021, 50,586 procedures with added COVID-19 variables were included in the initial analysis. The COVID-19 variable responses, completeness, volumes, and respective mortality rates are outlined in Table II. The nonelective rates, COVID-19 status, and treatment delay rates stratified by

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Author conflict of interest: none.

Additional material for this article may be found online at www.jvascsurg.org.

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The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

J Vasc Surg 2022;76:1383-7

0741-5214

https://doi.org/10.1016/j.jvs.2022.06.009

Table I. Coronavirus disease 2019 (COVID-19) procedure variables

Variable	Level	Help text
COVID-19 status at procedure		
	0, Unknown, not tested	Patient had no symptoms and no test performed before procedure
	1, Negative test result preoperatively	Negative COVID-19 test result within 1 week before procedure
	2, Positive test result preoperatively	Positive COVID-19 test result within 1 week before procedure
	3, Negative test result preoperatively but positive postoperatively	Negative COVID-19 test result immediately before procedure but positive test result before discharge
	Positive COVID-19 test result	Any laboratory test confirming infection, including nasal polymerase chain reaction or serologic positive result, including antibody- and/or antigen-positive tests
Treatment delay by pandemic		How long was the procedure delayed due to COVID-19 pandemic determined by symptoms and/or hospital policy? Typical scheduling delays (ie, if the case would have typically been scheduled within 3 weeks and was not scheduled until 8 weeks, the answer should be "delayed 2-6 weeks") should not be included
	0	None
	1	Delayed <2 weeks
	2	Delayed 2-6 weeks
	3	Delayed >6 weeks
	4	Uncertain
Effect of treatment delay (if delayed)		
	0, No, no effect on treatment	Decision to delay procedure did not affect procedure outcome
	1, Yes, treatment affected	Decision to delay procedure did affect procedure outcome according to increased length of stay, change in urgency, disease progression; physician should be consulted
	2, Indeterminate	Unable to assess whether outcome was affected or physician unwilling or unable provide answer

registry are presented in Supplementary Table I (online only). COVID-19 testing status was recorded for 97.3% of the cases, with 72.9% (n = 36,871) testing negative, 1.2% (n = 626) testing positive, and 23.1% recorded as unknown or not tested. No treatment delay was recorded for 89.5% of cases (n = 45,276), with a delay in treatment documented for 1.3% (n = 653) and an uncertain delay for 5.4%. For only 0.1% of cases (n = 36) was it reported that a COVID-19–related delay in treatment had resulted in an adverse outcome. Also, overall mortality was negatively associated with a positive COVID-19 test. Patients with a negative COVID-19 test exhibited an overall mortality of 1.5%, which was comparable to the 4-year average across all VQI registries of 1.4% (Fig 1). Those patients with a positive test had had an overall mortality of 7.3%. The overall mortality across registries stratified by test status is listed in Supplementary Table II (online only). The test status influence on mortality rates across time is shown in Fig 2. A COVID-19–related decision to delay a procedure (Table II) did not adversely affect overall mortality (range, 0%-1.5%), although a treatment delay could not be determined for 9.2% (uncertain for 5.4% and missing for 3.8%). Mortality plotted for asymptomatic CEA and elective EVAR showed minimal variations across the regional groups (Supplementary Fig, online only).

The ratios of the event rates for complications demonstrated variations between the historical controls and the COVID-19 data (Table III). Although an overall trend toward increased mortality rates in the COVID-19 period was observed, the difference was only statistically

Table II. Coronavirus disease 2019 (COVID-19) variable distribution (total cases, n = 50,586)

Variable	Cases, No. (%)	Periprocedural mortality rate,[a] %
COVID-19 status		
Unknown/not tested	11,707 (23.1)	1.5
Negative test result	36,871 (72.9)	1.5
Positive test result	626 (1.2)	7.3
Missing	1382 (2.7)	NA
COVID-19–related treatment delay		
None	45,276 (89.5)	1.5
<2 Weeks	94 (0.2)	1.1
2-6 Weeks	214 (0.4)	0.0
>6 Weeks	345 (0.7)	0.3
Uncertain	2713 (5.4)	0.9
Missing	1944 (3.8)	NA
COVID-19 treatment delay effect		
No	509 (1.0)	NA
Yes	36 (0.1)	NA
Indeterminate	105 (0.2)	NA
Missing/NA[b]	49,936 (98.7)	NA

NA, Not applicable.
[a]Defined as mortality recorded at discharge.
[b]Included cases for which a delay was present but field not completed (missing) and cases for which no delay was present (NA).

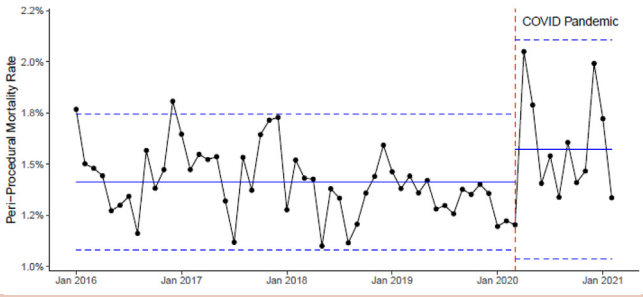


Fig 1. Periprocedural mortality over time. Coronavirus disease 2019 (COVID-19) pandemic defined as March 2020 to February 2021. *Horizontal solid line* represents mean mortality across time; and *horizontal dashed lines*, two standard deviations from the mean.

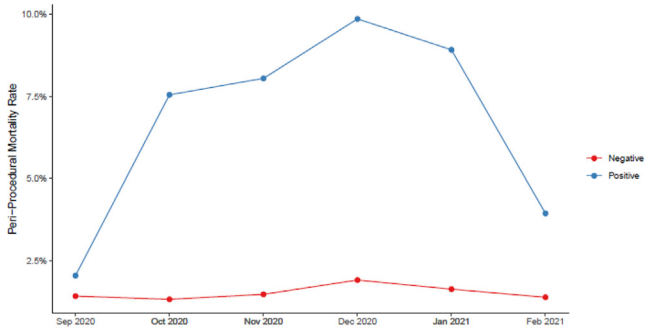


Fig 2. Periprocedural morality over time stratified by coronavirus disease 2019 (COVID-19) status. *Negative* indicates negative COVID-19 test result at the time of the procedure; and *positive*, as positive COVID-19 test results at the time of the procedure.

significant for the carotid artery and PVI disease categories. No consistent trend across disease categories was noted within the COVID-19 era for the complications listed.

DISCUSSION

In the present analysis, we have continued the investigation of the effects of COVID-19 on vascular surgery practice as documented in the VQI. At the time of the variable insertion, vaccination status was unknown because the availability and distribution of the vaccine did not receive Food and Drug Administration emergency use authorization approval until late December 2020. Thus, the SVS Patient Safety Organization added vaccination and booster information to all registries on December 16, 2021.

Our initial analysis had revealed several noteworthy findings.[1,2] First, only 1.7% of the patients had tested positive for COVID-19 at the time of their procedure (626 of 37,497 with a recorded test result). The background community infection rates during this period had varied from 5% to 18%.[5] Although this likely reflected a restrictive pattern by surgeons and hospitals, a component of patient reluctance to seek vascular surgery attention to avoid COVID-19 (exposure or infection) could have been present. Although the restriction of practice for elective procedures could have contributed to this low positive COVID-19 test incidence, it was not reflected in our

Table III. Adverse outcome event rate ratios stratified by before[a] versus during[b] coronavirus disease 2019 (COVID-19)

Variable	MI	CHF	Dysrhythmia	Pulmonary complications	Dialysis	Stroke	Periprocedural mortality
Amputation	1.05	0.96	0.86	0.93	1.03	NA	1.14
Aortic	1.23	1.23	0.99	1.05	1.06	0.83	0.97
Carotid	0.77	0.78	0.98	NA	NA	0.98	**1.42**
PAD	1.14	**0.69**	0.84	0.96	**0.61**	1.00	1.06
PVI[c]	1.12	1.12	1.12	NA	**1.39**	NA	**1.43**
TEVAR	1.00	**1.72**	1.03	1.06	0.83	NA	1.17
Overall	1.02	1.04	0.98	1.02	**1.15**	0.99	**1.18**

CHF, Congestive heart failure; *MI,* myocardial infarction; *NA,* not applicable; *PAD,* peripheral artery disease; *PVI,* percutaneous vascular intervention; *TEVAR,* thoracic endovascular aortic aneurysm repair.
Boldface values were statistically significant ($P < .05$).
[a]From January 2018 to December 2019.
[b]From September 2020 to February 2021.
[c]PVI definitions differed from those of other registries; CHF and/or dysrhythmia both contained a single outcome (a cardiac complication); and dialysis also included changes in renal function (outcome: renal complication).

data. We have previously reported that the practice volumes had reached and, at times, exceeded the prepandemic levels by fall 2020.[3] In the present analysis, the nonelective rates (used to determine the percentage of elective vs nonelective procedures) were not significantly different from the historical values: PVI before COVID-19, 15.8%; PVI during COVID-19, 19.4%; EVAR before COVID-19, 15.6%; EVAR during COVID-19, 15.6%; CEA before COVID-19, 13.3%; and CEA during COVID-19, 15.1%. These data suggest that the practice patterns had resumed with a similar elective/nonelective case mix ratio during the COVID-19 period and, thus, showing little restriction in the performance of elective procedures.

Second, mortality was associated with a positive COVID-19 test. The presence of a positive COVID-19 test had elevated overall mortality from 1.5% to 7.3% (odds ratio, 5.1; 95% confidence interval, 3.7-7.1), most likely related to the clinical urgency of the procedure.

Third, we did not observe an increase in mortality risk for patients who had experienced a delay in their procedure because of the pandemic. Whether due to a logistical scheduling delay or a delay because of prior COVID-19 exposure, no notable trend in mortality was identified for either elective or nonelective procedures. It is unclear whether a procedural delay might have altered the procedural outcome or procedure type. However, further analysis from these VQI data might be unable to answer that question, because the procedure delay was only captured for those patients undergoing vascular procedures. The VQI cannot determine those who had had a procedure delayed and had experienced a devastating or lethal event that negated the need for a procedure (eg, aneurysm progressing to rupture and death, disabling stroke event of carotid artery disease). Coordinating this VQI information with the VASCC (Vascular surgery COVID-19 collaborative), which was created to answer that question, might help determine this.[6]

Finally, procedural complications, including stroke, were not uniformly different from the pre–COVID-19 historical data (Table III). Mortality for carotid artery and PVI procedures was significantly increased compared with the pre–COVID-19 historical data. Information on whether bypass graft thrombosis, reoperation, or limb salvage was affected by COVID-19 might benefit from further analysis.

The present analysis had several limitations. The COVID-19 variable definitions and help text were created early on as the pandemic evolved, and much has been learned since. In addition, limiting a COVID-19 test variable definition to 1 week before the procedure date cannot account for the limited accuracy or methods used with the various COVID-19 testing kits. Also, vaccination status was not collected during the present analysis, and discussions about COVID-19 colonization vs infection in a patient's test response could not be determined.[7] Because most patients treated during the present study period were unvaccinated (only 10% of U.S. population have been vaccinated by February 10, 2021), both the infection rates and the mortality effects of COVID-19 might be favorably altered by increased vaccination rates compared with the present data. Our determination of whether a treatment delay had affected care was arbitrary and limited by interpretation by the data managers' review of the patients records and outcomes. A COVID-19 variable determination of the treatment effect frequency of 0.1% (n = 36) suggests that the accuracy of this variable might be unreliable. The true effects of a delay in surgery could not be completely measured using a procedural registry. Thus, if the treatment of a patient with high-grade carotid artery stenosis was delayed and the patient had sustained a stroke or a large abdominal aortic aneurysm subsequently ruptured and the patient had died, those patients might never be included in a VQI procedural registry. As such, we could not fully appreciate the true effects of treatment delays from a VQI analysis.

Further information from other databases focusing on COVID-19 infection, such as the VASCC, might be better able to address the effects of treatment delay.

Although procedure urgency status was used in the present analysis for the comparisons over time, we did not use this variable for the outcomes analysis. Not all registries capture urgency (eg, inferior vena cava filter, hemodialysis). The help text definitions for urgency as a variable are not uniform across the registry platforms (under revision) and have demonstrated insufficient accuracy in select registries owing to misinterpretation of the variable definitions. We, therefore, thought it would be inadequate for the outcomes assessment.

Despite the large cohort of patients (n = 50,586), the overall mortality data reported included all registries requiring a discharge and, thus, might not be reflective of ambulatory procedure outcomes or 30-day mortality. Although the individual registry mortality rates varied compared with those for the historical controls, the data were aggregated across all registries to calculate the unadjusted odds ratios. Thus, the results will not necessarily be reflective of the individual registry outcomes. Furthermore, important, registry-specific confounders (eg, facility participation) could have been present that were unaccounted for in the unadjusted, aggregated analysis. Similarly, our observed trend toward increased mortality in the COVID-19 period (Fig 1) might indicate an influence from COVID-19 infection on the patient cohorts that would be important to consider in future registry-specific analyses. We also could not distinguish mortality between patients with colonized COVID-19 vs those infected with COVID-19 and those testing positive for COVID-19.

CONCLUSIONS

Our analysis of the COVID-19–related variables in the VQI demonstrated a significant increase in mortality across multiple registries when stratified by COVID-19 test status. Carotid artery intervention and PVI demonstrated statistically significant mortality when analyzed stratified by adverse outcomes. Patients undergoing a vascular surgery procedure from September 2020 through February 2021 exhibited a lower baseline COVID-19 infection rate than that found in most communities during the same interval. The evolving use of vaccination could affect the ongoing analysis of the influence of COVID-19 on procedure outcomes. The VQI remains committed to understanding the magnitude of the effects of COVID-19 on vascular surgery outcomes through continued registry analysis.

AUTHOR CONTRIBUTIONS

Conception and design: KS, KH, JEJ, GL
Analysis and interpretation: KS, LM, KH, JEJ, GL
Data collection: KS, KH, GL
Writing the article: KS, JEJ, GL
Critical revision of the article: KS, JEJ, GL
Final approval of the article: KS, LM, KH, JEJ, GL
Statistical analysis: KS, KH
Obtained funding: Not applicable
Overall responsibility: GL

REFERENCES

1. Natarajan JP, Mahenthiran AK, Bertges DJ, Huffman KM, Eldrup-Jorgensen J, Lemmon GW. Impact of COVID-19 on the Society for Vascular Surgery Vascular Quality Initiative arterial procedure registry. J Vasc Surg 2021;34:28-36.
2. Mahenthiran AK, Natarajan JP, Bertges DJ, Huffman KM, Eldrup-Jorgensen J, Lemmon GW. Impact of COVID-19 on the Society for Vascular Surgery Vascular Quality Initiative venous procedure registries (varicose vein and inferior vena cava filter). J Vasc Surg Venous Lymphat Disord 2021;9:1093-8.
3. Aziz F, Behrendt CA, Sullivan K, Beck AW, Beiles CB, Boyle JR, et al. The impact of COVID-19 pandemic on vascular registries and clinical trials. Semin Vasc Surg 2021;34:28-36.
4. R Core Team. R: a language and environment for statistical computing. Vienna, Austria: R Foundation for Statistical Computing; 2020.
5. Centers for Disease Control and Prevention. COVID Data Tracker. Available at: https://covid.cdc.gov/covid-data-tracker/#datatracker-home. Accessed November 15, 2021.
6. Mouawad NJ, Cuff RF, Hultgren R, Chuen J, Galeazzi E, Wohlauer M. The vascular surgery COVID-19 collaborative (VASCC). J Vasc Surg 2020;72:379-80.
7. Coffey KC, Diekema MD, Morgan DJ. Interpreting SARS-CoV-2 test results. JAMA 2021;326:1528-9.

Submitted Feb 16, 2022; accepted Jun 11, 2022.

Additional material for this article may be found online at www.jvascsurg.org.

Supplementary Table I (online only). Coronavirus disease 2019 (COVID-19) capture stratified by registry data

Registry data	Cases, No.	Nonelective,[a] %	Inpatient,[b] %	COVID-19 status entered, %	Positivity,[c] %	COVID-19 delay recorded, %	Delayed,[d] %
AMP	1374	35.6	100.0	98.6	3.6	98.6	0.4
CAS	5947	20.7	97.2	96.9	1.4	95.7	1.6
CEA	7942	15.1	100.0	99.3	1.1	98.3	1.4
EVAR	3324	15.6	100.0	97.5	1.1	96.9	2.0
HEMO	3146	0.0	18.0	99.6	0.6	100.0	1.0
INFRA	3385	20.7	100.0	98.2	1.3	97.1	1.5
IVC	773	NA	NA	98.7	6.5	98.7	0.3
OPEN	627	28.1	100.0	99.5	1.6	99.5	3.0
PVI	18,869	19.4	48.6	95.2	1.1	93.5	0.8
SUPRA	871	20.8	100.0	99.2	1.1	99.2	3.2
TEVAR	1371	33.3	100.0	97.8	1.8	94.5	1.5
VV	2957	0.0	0.3	99.8	0.1	99.8	2.5
Total	50,586	17.0	68.0	97.3	1.2	96.2	1.3

AMP, Amputation; *CAS,* carotid artery stent; *CEA,* carotid endarterectomy; *EVAR,* endovascular aortic aneurysm repair; *HEMO,* hemodialysis; *INFRA,* lower extremity bypass; *IVC,* inferior vena cava (filter); *NA,* not applicable; *OPEN,* open aneurysm repair; *PVI,* peripheral vascular intervention; *SUPRA,* suprainguinal bypass; *TEVAR,* thoracic endovascular aortic aneurysm repair and complex aortic aneurysm repair, including aortic dissection; *VV,* varicose vein.

[a]Percentage of cases with urgency status of urgent, emergent, symptomatic, or ruptured, with HEMO and VV assumed to be exclusively elective procedures (IVC filter placement was not captured).

[b]Percentage of cases recorded as inpatient; AMP, CEA, EVAR, INFRA, OPEN, SUPRA, and TEVAR were assumed to be exclusively inpatient procedures (IVC filter placement was not captured).

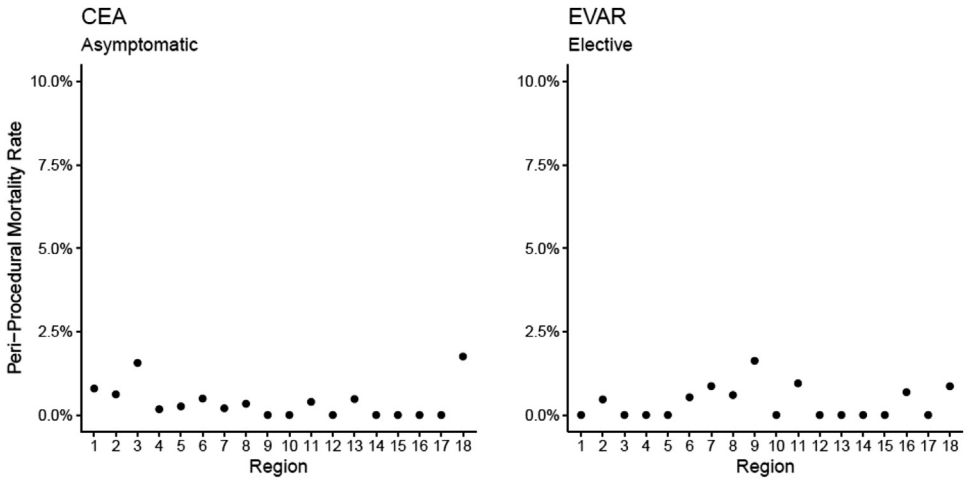
[c]Percentage of cases with positive COVID-19 status.

[d]Percentage of cases with COVID-19 treatment delay recorded.

Supplementary Table II (online only). Periprocedural mortality stratified by registry data

		Mortality and COVID-19, %	
Registry data	Cases, No.	Negative status[a]	Positive status[b]
AMP	1374	4.6	6.1
CAS	5947	1.1	4.7
CEA	7942	0.4	2.3
EVAR	3324	1.3	8.1
HEMO	3146	0.6	5.6
INFRA	3385	1.6	2.3
IVC	773	4.5	22.0
OPEN	627	7.2	40.0
PVI	18,869	1.4	6.7
SUPRA	871	2.4	0.0
TEVAR	1371	5.4	8.0
VV[c]	2957	NA	NA
Total	50,586	1.5	7.2

AMP, Amputation; *CAS,* carotid artery stent; *CEA,* carotid endarterectomy; *EVAR,* endovascular aortic aneurysm repair; *HEMO,* hemodialysis; *INFRA,* lower extremity bypass; *IVC,* inferior vena cava (filter); *NA,* not applicable; *OPEN,* open aneurysm repair; *PVI,* peripheral vascular intervention; *SUPRA,* suprainguinal bypass; *TEVAR,* thoracic endovascular aortic aneurysm repair and complex aortic aneurysm repair, including aortic dissection; *VV,* varicose vein.
[a]Discharge status of dead and COVID-19 status of negative.
[b]Discharge status of dead and COVID-19 status of positive.
[c]Discharge status not captured for VV.



Supplementary Fig (online only). Periprocedural mortality across regions. *CEA Asymptomatic,* Carotid endarterectomy with asymptomatic status for which prior neurologic status was listed as "no"; *EVAR Elective,* endovascular aortic aneurysm repair for which urgency status was listed as "elective"; *Region,* assigned number of Vascular Quality Initiative (VQI) regional study group.