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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 pre-pandemic 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 peri-procedural 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 χ2 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 ratios, COVID-19 status, and treatment delay rates stratified by
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 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 | 0 None                     | 1 Delayed <2 weeks                                         |
|                             | 1 Delayed 2-6 weeks         | 2 Delayed >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 |
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. 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%. 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

| Variable                                      | Cases, No. (%) | Periprocedural mortality rate, % |
|-----------------------------------------------|----------------|----------------------------------|
| 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                                    | 49,936 (98.7)  | NA                               |

NA, Not applicable.

*Defined as mortality recorded at discharge.

†Included cases for which a delay was present but field not completed (missing) and cases for which no delay was present (NA).
data. We have previously reported that the practice volumes had reached and, at times, exceeded the preponderance levels by fall 2020. 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 after COVID-19 exposure, with no notable trend in mortality when 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.

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.

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.

### Table III. Adverse outcome event rate ratios stratified by before versus during 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     | 114                      |
| 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            | 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).

*From January 2018 to December 2019.
*From September 2020 to February 2021.
*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).
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

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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           | 775        | 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, supravascular bypass; TEVAR, thoracic endovascular aortic aneurysm repair and complex aortic aneurysm repair, including aortic dissection. VV, varicose vein.

aPercentage 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).
bPercentage 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).
cPercentage of cases with positive COVID-19 status.
dPercentage of cases with COVID-19 treatment delay recorded.
### Supplementary Table II (online only). Periprocedural mortality stratified by registry data

| Registry data | Cases, No. | Mortality and COVID-19, % | Negative status | Positive status |
|---------------|------------|---------------------------|-----------------|-----------------|
| 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             |
| VVc           | 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.