Outcomes of Vascular and Endovascular Interventions Performed During the Coronavirus Disease 2019 (COVID-19) Pandemic

The Vascular and Endovascular Research Network (VERN) COVID-19 Vascular Service (COVER) Tier 2 Study

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Objective: The aim of the COVER Study is to identify global outcomes and decision making for vascular procedures during the pandemic.

Background Data: During its initial peak, there were many reports of delays to vital surgery and the release of several guidelines advising later thresholds for vascular surgical intervention for key conditions.

Methods: An international multi-center observational study of outcomes after open and endovascular interventions.

Results: In an analysis of 1103 vascular intervention (57 centers in 19 countries), 71.6% were elective or scheduled procedures. Mean age was 67 ± 14 years (75.6% male). Suspected or confirmed COVID-19 infection was documented in 4.0%. Overall, in-hospital mortality was 11.0% [aortic interventions mortality 15.2% (23/151), amputations 12.1% (28/232), carotid interventions 10.7% (11/103), lower limb revascularisations 9.8% (51/521)]. Chronic obstructive pulmonary disease [odds ratio (OR) 2.02, 95% confidence interval (CI) 1.30–3.15] and active lower respiratory tract infection due to any cause (OR 24.94, 95% CI 12.57–241.70) ware associated with mortality, whereas elective or scheduled cases were lower risk (OR 0.4, 95% CI 0.22–0.73 and 0.60, 95% CI 0.45–0.98, respectively. After adjustment, antiplatelet (OR 0.503, 95% CI: 0.273–0.928) and oral anticoagulation (OR 0.411, 95% CI: 0.205–0.824) were linked to reduced risk of in-hospital mortality.

Conclusions: Mortality after vascular interventions during this period was unexpectedly high. Suspected or confirmed COVID-19 cases were uncommon. Therefore an alternative cause, for example, recommendations for delayed surgery, should be considered. The vascular community must anticipate longer term implications for survival.

Keywords: abdominal aortic aneurysm, carotid endarterectomy, COVID-19, peripheral arterial disease, vascular surgery

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The coronavirus disease 2019 (COVID-19) pandemic has impacted vascular services in unprecedented ways.[1] Some national and international surgical bodies had initially recommended limiting surgery to only the most severe or late-stage presentations of certain vascular conditions, such as crescendo transient ischaemic attacks, ischaemic limbs with tissue loss or rest-pain, and abdominal aortic aneurysms (AAA) larger than the global standard treatment thresholds of 5.5 cm (that is 6.5–7 cm for asymptomatic AAA).[2–4] The reduction in hospitals' capacity to treat non-COVID-19 pathologies, coupled with staff shortages and resource limitations, have led to considerable deviations from the established gold standards of vascular surgical care.[5–7]

In addition to an estimated overall mortality rate of up to 15% for those with a severe COVID-19 infection and a surgical pathology, it is now recognized that there are significant increases in "excess deaths" due to the pandemic for patients without COVID-19, that is, delayed treatments for cancer, or delayed presentation of patients with cardiovascular disease.[8,9] Many specialities have reported vastly reduced or delayed presentation for serious pathologies such as myocardial infarctions.[10] A number of international studies are currently investigating surgical interventions and clinical outcomes specifically in patients diagnosed with COVID-19,[11] however, little is known about the outcomes of any patients undergoing cardiovascular surgery during the pandemic, irrelevant of COVID-19 diagnosis.

The prospective Vascular and Endovascular Research Network (VERN) COVID-19 Vascular SERvice (COVER) Study was therefore developed to prospectively document outcomes for all vascular procedures performed during the pandemic, in COVID-19 positive and negative patients worldwide. COVER is a 3-tier global collaborative research project supported by multiple international vascular organizations.[12,13] The primary aim of this analysis was to report in-hospital outcomes during the first months of the COVID-19 pandemic worldwide. The secondary aims were to compare in-hospital mortality to pre-pandemic rates and to establish the impact of changes to vascular care demonstrated in the tier 1 COVER report.

METHODS

Study Design

The VERN COVER Study is a prospective observational cohort study (ISRCTN registration reference number: 80453162). The full protocol is available online.[12] The study was performed and is reported in accordance with the STROBE guidelines.[14]

Any institution performing vascular procedures was eligible to participate. Invitations to participate were circulated via social media, national and multinational vascular society mailing lists, and personal communications worldwide. Appropriate sites underwent virtual site initiation via email and video conferencing with the lead investigators.

Study Approvals

UK National Health Service (NHS) Research Ethics Committee and Health Research Authority (HRA) approvals were granted before commencing recruitment (20/NW/0196 Liverpool Central) in March 2020. International centers obtained institutional review board approval before participation as per local and national guidance/law. Study sponsorship was provided by the research and development department, University hospitals Coventry and Warwickshire, Coventry, United Kingdom. The study is being conducted in line with the Declaration of Helsinki.

Participants

All consecutive patients with a vascular pathology undergoing any vascular or endovascular procedure over a period of 12 weeks from the study opening at each site were prospectively recorded, after providing written informed consent. All study forms were translated by the site investigators/collaborators, where necessary.

Study Objectives

The primary aim was to capture procedural information on all vascular and endovascular interventions being undertaken during the COVID-19 pandemic and for a period of twelve weeks. Outcomes were in-hospital morbidity (all complications) and mortality. This included unplanned admission(s) to critical care and suspected or confirmed COVID-19 infection(s). Testing for Severe Acute Respiratory Syndrome CoronaVirus 2 (SARS-CoV-2) infection was performed and documented (prospectively) as per local hospital policy. Centers were asked to document if patients were suspected to have COVID-19 based on a clinical diagnosis with highly suspicious symptoms consistent with SARS-CoV-2 infection including cough, fever, loss of taste or smell, and myalgia.[15] This definition and approach were used, based on criteria used in similar cohort studies relating to COVID-19 in other clinical areas.[11]

Baseline data recorded prospectively included: demographics, type/nature of procedure, co-existing health conditions, medications being taken before the procedure (on admission or started acutely), American Society of Anaesthesiologists physical status classification, and clinical frailty scale.[16] Peri-procedural data collected included the time from presentation to intervention, mode of anesthesia, type of operation, and postoperative care environment. Post-procedural data included unplanned admission to critical care, in-hospital mortality, total length of hospital stay, COVID-19 pneumonia (using center's own practice standards), and postoperative complications. All information were recorded prospectively be each site's investigators/collaborators using a remote purpose-built case report form. Training was provided to all investigators/collaborators as required, before opening each site to recruitment. Missing data were prospectively queried with the site investigators/collaborators.

Alteration to Routine Practice

For every case, the surgical team were asked to document if there had been any significant change in practice compared to their own standard care pre-pandemic. This was asked, to link results for in-hospital mortality to the prevalence of altered practice by surgical condition. The decision on whether management of the patient constituted a change in practice was left to each center's discretion.

Data Management

De-identified data were transferred to a UK NHS server (based at the University of Birmingham) as per HRA and NHS principles. Data sharing agreements were used for all participating institutions. Each center was required to record local identifiers on a secure, local, General Data Protection Regulation compliant database to allow longitudinal data capture and linkage, overseen by the study Sponsor.

Data Handling and Analysis

The first patient was recruited and data were entered on the April 10th, 2020. A data lock was applied on the June 16th, 2020 to permit an interim analysis, reported here. Individual dates for surgery were not collected, to maintain de-identified datasets as per HRA rules. Data were not analyzed by center for the same reason. The data are presented as a global dataset, reflecting the picture of local/regional peaks of patient COVID-19 caseloads and impacts on vascular services even amongst countries with documented high rates of per-head infection.

Data are presented for all procedures performed during April, May, and June 2020 with completed records for their inpatient stay as of the 16th June. Normally distributed data are presented as mean ($\pm$ standard deviation) and non-normally distributed data are presented as median (range) values. Binary logistic regression was used to assess risk factors for in hospital mortality, with confounder adjusted analysis performed using multivariate logistic regression. Those risk factors found to be statistically significant at the 95% confidence level in the univariate binary logistic regression analysis were taken forward to multivariate logistic regression. These included, ethnicity, co-morbidities (including COVID status), medications, American Society of Anaesthesiologists grade, frailty score, and urgency of surgery. Statistical analysis was performed using SPSS version 26 (SPSS, IBM, Chicago, IL). The analyses were led by a qualified medical statistician using a pre-determined analysis plan.

Role of the Funding Source

Funding sources and the study sponsor had no role in study design, collection, analysis, or interpretation of the data.

RESULTS

At the time of analysis (June 16th, 2020), records for 1257 individual patients had been entered. Of those patients, 1103 patients had completed records reporting in-hospital death or survival to discharge, and the results from this smaller cohort is reported here. Data were entered from 57 individual vascular units in 19 countries (Supplemental Data 1, http://links.lww.com/SLA/C861). Table 1 contains baseline characteristics of the cohort.

In Hospital Mortality

The overall in hospital mortality was 11.0% (121/1103 patients). Men accounted for 80.2% of deaths. More comprehensive details of post-procedural outcomes are recorded in the Supplementary Material (Supplemental Table 2, http://links.lww.com/SLA/C862), including missing data.

Aortic Surgery

Aortic interventions had a combined (open and endovascular procedures) all-cause mortality of 15.2%. Elective aortic surgery had lower mortality compared to non-elective surgery (7.4%, 5 of 68 vs 23.7%, 18 of 76, respectively). Combined elective and emergency endovascular aneurysm repairs had a mortality of 15% (14 of 93). The highest mortality rate was seen in symptomatic unruptured AAA (38.5%, 10 of 26), followed by ruptured aneurysms (28.6%, 4 of 14), acute aortic syndromes (type B aortic dissection, aortic ulcer or transmural hematoma) (23%, 3 of 13), aneurysms meeting center size threshold for repair (7.4%, 5 of 68), and rapid aneurysm growth (4.5%, 1 of 22).

Carotid Surgery

In-hospital mortality for any carotid intervention overall was 10.7%, with a combined stroke or death rate of 13.6% (14 of 103). A third (36.9%; 38 patients) of the carotid interventions were performed for asymptomatic carotid stenosis with a 7.9% (3 patients)

TABLE 1. Baseline Characteristics for All Patients Included in Analysis (n = 1103)

		In Hospital Mortality	Odds Ratio	95% CI
Age				
Mean	66.9 +/− 13.9	119 (10.8%)	1.01	0.99–1.02
Median	69.0 (1–104)			
Missing: 4				
Male				
Missing: 2	832 (75.6%)	97 (11.7%)	0.74	0.46–1.19
Ethnicity				
White Missing: 52	816 (77.6%)	98 (12.0%)	0.82	0.98–6.87
Comorbidity				
Diabetes 1 or 2	522 (47.3%)	54 (10.4%)	0.89	0.61–1.30
Hypertension	733 (66.5%)	85 (11.6%)	1.22	0.81–1.84
Chronic lung disease	174 (15.8%)	31 (17.8%)	2.02	1.30–3.15
Atrial fibrillation (missing: 14)	85 (7.8%)	13 (15.3%)	1.51	0.81–2.82
Myocardial infarction	253 (22.9%)	32 (12.7%)	1.24	0.81–1.91
Chronic kidney disease	193 (17.5%)	23 (11.9%)	1.12	0.69–1.82
Stroke/transient ischaemic attack	146 (13.2%)	17 (11.6%)	1.08	0.63–1.86
Current smoker	206 (18.7%)	20 (9.7%)	0.85	0.51–1.41
Cancer	78 (7.1%)	9 (11.5%)	1.06	0.52–2.19
Dementia	27 (2.4%)	2 (7.4%)	0.64	0.15–2.75
Peripheral arterial disease	424 (38.4%)	41 (9.7%)	0.80	0.54–1.19
Current respiratory infection (any pathogen)	4 (0.4%)	3 (75.0%)	24.94	2.574–241.704
Renal replacement therapy/dialysis	95 (8.6%)	9 (9.5%)	0.84	0.41–1.71
Confirmed COVID 19	15 (1.4%)	2 (13.3%)	1.25	0.28–5.62
Suspected COVID 19	29 (2.6%)	7 (24.1%)	2.68	1.12–6.41
ASA Grade 1–2	235 (21.58%)	19 (8.1%)	0.66	0.39–1.10
ASA Grade 3–5 Missing: 14	854 (78.42%)	101 (11.8%)	1.53	0.91–2.55
Frailty Score 4–9 Missing: 19	546 (50.37%)	66 (12.1%)	1.23	0.84–1.80
Urgency of surgery				
Elective	238 (22.3%)	13 (5.5%)	0.40	0.22–0.73
Scheduled	526 (49.3%)	47 (8.9%)	0.66	0.45–0.98
Urgent	244 (22.9%)	48 (20.7%)	2.68	1.79–3.99
Immediate	59 (5.5%)	9 (15.3%)	1.50	0.72–3.14
Missing: 36				

ASA indicates American Society of Anaesthesiologists.

all-cause mortality. Symptomatic carotid interventions were associated with a 12.3% (8 of 68) all-cause mortality. The mean time from index neurological event to intervention was 26.3 ± 41.1 days. Unadjusted in hospital mortality for local anesthetic procedures was 13.0% versus 10.0% for those performed under general anaesthetic.

Lower Limb Interventions

Mortality in lower limb arterial revascularization was 9.8% overall (51/521). Open and endovascular procedures are presented as a combined group and breakdowns of these into hybrid, endovascular, and open vascular surgery can be found in Supplementary Table 2, http://links.lww.com/SLA/C862. The indication for lower limb revascularization was chronic limb threatening ischemia or tissue loss in 61.8% (310 patients), with a reported in hospital mortality of 5.6% and 8.1% respectively. Acute limb ischemia was seen in 18.5% (93 patients) of presentations for lower limb, with a documented mortality of 20.4%. In those undergoing revascularization for claudication, reported in hospital mortality was 8.9%.

Amputation

The overall in-hospital mortality rate after amputation at any level was 12.1% (28 of 232). The most common level of amputation was trans-femoral in 27.4% of patients (62/232), followed by trans-tibial amputation in 22.1% (50/232). In hospital mortality after "major" amputation (including knee disarticulations), was 14.3% (17/119).

Postoperative Events

The median length of stay was 5 (0–100) days. Seventy-three patients (6.6%) had an unplanned return to theatre. Wound infection was the most frequently recorded in-hospital complication, identified in 4.3% (46 patients), followed by limb ischemia (3.8%, 42 patients), respiratory complications (3.4%, 38 patients), cardiac events (3.2%, 35 patients), and bleeding (2.7%, 30 patients).

Alteration to Routine Practice

Table 2 shows the frequency of surgical procedures that were considered a change from normal practice due to the COVID-19 pandemic for each category of major arterial intervention. Surgical procedures were recorded as a deviation in normal practice in 7.1% of procedures. The largest proportional change in practice related to type of surgical procedure performed for specific clinical presentation. In cases of amputations a change in practice occurred in 2/232 cases (9%). Procedure choice differed from normal practice in 34 lower limb interventions (8.1%, 521 patients undergoing open and/or endovascular intervention). COVID-related alterations to the anesthetic plan for any case occurred in 21 (2.0%) surgical procedures. A change in the choice of postoperative destination was made in 22 (2.0%) cases.

TABLE 2. Changes Due to COVID 19 Pandemic

	Carotid (n = 103)*	Lower Limb (n = 521)†	Amputation (n = 232)‡	Aortic (n = 151)§
Choice of procedure a deviation from normal practice due to COVID pandemic?	5 (4.9%)	34 (8.1%)	20 (9%)	7 (4.8%)
Confirmed COVID Positive Patients	2 (1.9%)	7 (1.3%)	3 (1.3)	0 (0%)
Suspected COVID Positive Patients	2 (1.9%)	6 (1.2%)	13 (5.6%)	4 (2.7%)
Postoperative destination				
Ward	67 (65%)	364 (71.9%)	198 (87.6%)	70 (47.3%)
Stepdown ward from critical care unit	5 (4.9%)	44 (8.7%)	5 (2.2%)	9 (6.1%)
Level 2/High dependency unit	20 (19.4%)	47 (9.3%)	12 (5.3%)	30 (20.3%)
Level 3/Critical care	11 (10.7%)	34 (6.7%)	5 (2.2%)	36 (24.3%)
Died in theatre	0 (0%)	0 (0%)	0 (0%)	3 (2.0%)
Day case	0 (0%)	17 (3.4%)	6 (2.7%)	0 (0%)
Destination after surgery a change in practice due to COVID pandemic?	3 (2.9%)	8 (1.6%)	7 (3.1%)	3 (2.1%)
Mode of anesthesia				
Local anesthesia	23 (22.3%)	221 (43.8%)	23 (10.2%)	33 (22.6)
Spinal/Epidural	0 (0%)	58 (11.5%)	56 (24.9%)	11 (7.5%)
Peripheral Nerve Block	0 (0%)	3 (0.6%)	54 (24.0%)	0 (0%)
General Anesthesia	80 (77.7%)	222 (44.0%)	92 (40.9%)	102 (69.9%)
Mode of anesthesia a change in practice due to COVID pandemic	0 (0%)	3 (0.6%)	13 (5.8%)	2 (1.4%)

*Carotid; Change in mode of anesthesia: missing 1 data point (n 102).

†Lower limb revascularisation; Procedure: missing 103 data points (n 418) Mode of anesthesia: missing 17 data points (n 504) Change in mode of anesthesia: missing 16 data points (n 505) Post-operative destination: missing 15 data points (n 506) Change in postoperative destination: missing 15 (n 506).

‡Amputation; Procedure missing 10 data points (n 222) Mode of anesthesia: missing 7 data points (n 225) Change in mode of anesthesia: missing 6 data points (n 226) Postoperative destination: missing 6 data points (n 226) Change in postoperative destination: missing 6 (n 226).

§Aortic; Procedure missing 6 data points (n 145) Mode of anesthesia: missing 5 data points (n 146) Change in mode of anesthesia: missing 5 data points (n 146) Postoperative destination: missing 3 data points (n 148) Change in postoperative destination: missing 5 (n 146).

Adjusted Risk Prediction for In-hospital Mortality

The results of the adjusted risk modeling are shown in Figure 1. After adjustment for confounders, urgent or emergency patients, risk of in-hospital mortality was greater in patients with a history of chronic obstructive pulmonary disease, those with a current chest infection (not COVID-19), and patients of Caucasian ethnicity. Patients treated with antithrombotic medication (antiplatelet or anticoagulant therapy) were at lower risk of postoperative in-hospital mortality.

DISCUSSION

This global prospective cohort study reports an overall in-hospital mortality of 11% for 1,103 vascular operations/interventions performed across 19 countries during the COVID-19 pandemic. The mortality rate is remarkably consistent across all procedural categories. This is despite the majority of patients having no evidence of SARS-CoV-2 infection.

Other teams have reported excessive mortality rates after surgery in SARS-CoV-2 infected patients of 23.8%. However, given the low rate of suspected or detected rate of SARS-CoV-2 infection among the cohort reported here, these results would suggest that high postoperative mortality rates in vascular patients during the pandemic are not limited to those with confirmed SARS-CoV-2 infection. The data presented cannot confirm the true rate of infection; only that based on clinical suspicion swabs performed due to suspected infection. At the time of data collection, several studies documented that it was not routine practice to swab all patients admitted, only those with suspected infection.[1,11]

In-hospital mortality after vascular interventions in the COVER study cohort is considerably higher than pre-pandemic reports from national registry data (Table 3). For example, contemporary carotid artery interventions are associated with 30-day mortality rates of 1%.[17] All-cause mortality after lower limb revascularization have been reported as between 1% and 5% (depending on the intervention and urgency).[18] Elective aneurysm procedures in this cohort have an in-patient mortality double that of pre-pandemic reported mortality of 3.0% for open surgery and 0.5% for endovascular aneurysm repairs, including complex repairs.[19] One explanation for this was the publications of national guidelines recommending increasing threshold for aneurysm treatment to ≥6.5 cm during the peak of cases (compared to 5.5 cm in ‘‘normal’’ practice).[2–4] Observational data suggest larger aneurysms, especially those over 6.5 cm in diameter, are associated with greater 30-day postoperative mortality, even in the elective setting.[20] Hence, the justification for delaying repair of aneurysms until they reach a maximal diameter of 6.5 cm has been balanced against the risk of mortality now associated with postoperative COVID-19 associated respiratory complications, reported to be as high as 23.8% at 30-days, for a variety of surgical procedures.[11] Therefore, if not due to COVID-19 infection, it is possible to hypothesize that alterations in established pathways of care, changes to team structures, and other structural or infrastructural changes made as a consequence of the pandemic have led to worse outcomes; as a consequence of guidelines suggesting delayed treatment in response to the extreme challenges of operating within such altered practice frameworks.

The outcome of confounder adjusted predictors in this study suggest that Caucasian patients were twice as likely to die. COVID-19 infection is well documented to have worse outcomes in Black and ethnic minority populations.[21] We do not have a clear explanation for these findings other than in this study, the majority of patients were documented as being Caucasian, risking type 1 error. Other variables are consistent with what is known about vascular pathologies; patients with chronic obstructive pulmonary disease, active

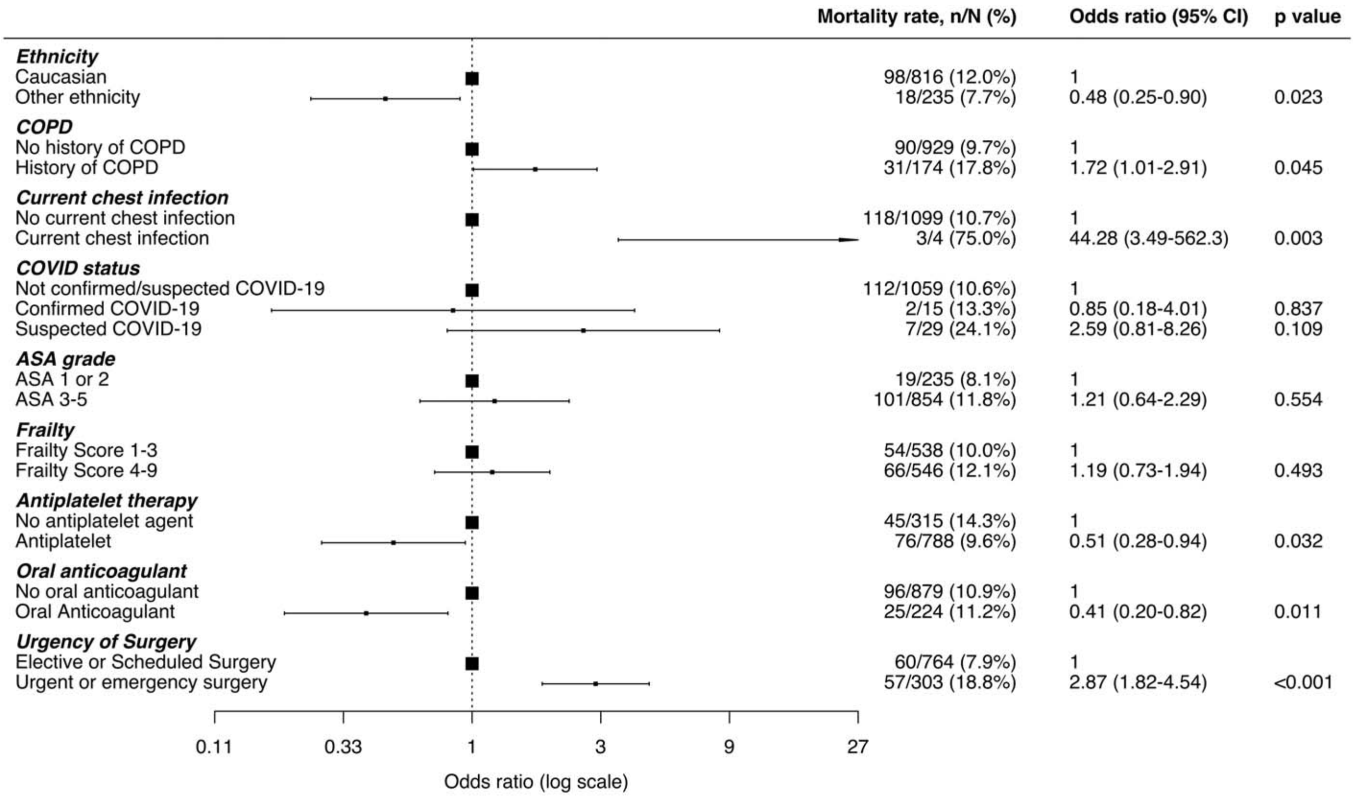

FIGURE 1. Adjusted model of predictors for in-hospital mortality including data from the 1103 patients with completed in-hospital recorded outcomes. As expected, urgency of surgery and active chest infection correlated strongly with reduced likelihood of survival to discharge. ASA indicates American Society of Anaesthesiologists; COPD, chronic obstructive pulmonary disease.

pneumonia, and undergoing urgent or emergency surgery had higher mortality rates, whilst antiplatelet and anticoagulant medication were protective, even in the short term.[22]

Vascular pathology is associated with increasing age, male sex, and multiple comorbidities such as smoking and systemic cardiovascular disease, all of which can be optimized with adequate resources and support.[23] On the other hand, resource limitations and closure of services to reduce spread has reduced access to support systems, and guidance to delay surgery until more emergent clinical presentations may be reducing surgeons' ability to optimize their patients before surgery. This places vascular cohorts at increased risk of suffering serious surgical complications, and placing them in the highest risk cohort if they were to contract COVID-19 while in hospital, with reduced eligibility for admission to intensive care units in a resource-rationed setting.[24]

Limitations

Participating centers were often working in challenging contexts with relative limitations in resources (including staff absence and redeployment), consequently there are likely to have been some missed patient enrolments, confounded by the need for informed consent which may have been unachievable in emergency situations especially those with a fatal outcome. This may lead to an underestimate of the mortality rate. However, patients were screened, recruited, and consented at all centers by VERN investigators, that is, surgical trainees or consultants who are present at each site 24/7,

TABLE 3. Comparison of Pre-pandemic In-hospital Mortality From Observational or Registry Data, and Rates Identified in the COVER Tier 2 Cohort. To Ensure Equivalent Comparisons, the Figure for Open Emergency Repair Excludes 4 Patients Who Underwent Open Emergency Revision Surgery, All of Whom Survived to Discharge. For the Same Reason, the Figures for EVAR Exclude 11 Patients Who Underwent Complex EVAR Either Electively or as an Emergency. Of Those, the 9 Elective Cases Survived to Discharge, As Did the 2 Cases Performed Nonelectively

	Pre-pandemic Reported In Hospital Mortality	COVER Reported In Hospital Mortality
Carotid intervention	1% (17)	10.7%
Lower limb Revascularisation	1–5% (18)	9.8%
Amputation	7.70% (18)	12.1%
Aortic intervention	Elective: 3% (19) Emergency: 40.9% (18)	Elective: 10.5% Emergency: 33.3%
EVAR	Elective: 0.5% (19) Emergency: 22.6% (18)	Elective: 9.8% Emergency: 24.4%

ensuring that as many emergencies and elective cases were captured as possible. During this study period, only 44 patients (4%) had documented confirmed or suspected COVID-19 status. It was not clear how many of the remaining patients were tested or not due to low suspicion. This limits the ability of the study to comment on rates of postoperative respiratory infections due to COVID-19. Anecdotally many regions globally, and their local hospitals have moved to testing all inpatients within the past few months. However this was not the case at the time of the analysis, therefore, suspected cases were also included. Accurate reports of regional incidence of infection for vascular patients along is not currently available for comparison. Analysis has also not included comparison with local population COVID-19 rates. The vast majority of data presented here was captured in countries experiencing significant constraints on services due to the COVID-19 pandemic, closely representing vascular surgery in the pandemic era.

CONCLUSIONS

The presented data reflect contemporary overall in-hospital mortality for patients undergoing urgent vascular procedures in centers affected by the early stages of the COVID-19 pandemic. The vast majority of the patients in the present study did not have confirmed COVID-19 infection; results emphasize the second-order mortality effects of healthcare within a pandemic.

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