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## **Impact of COVID-19 on Vascular Patients Worldwide – Analysis of the COVIDSurg Data**

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## **Abstract**

### *Background*

The COVIDSurg collaborative was an international multicentre prospective analysis of peri-operative data from 235 hospitals in 24 countries. It found that peri-operative COVID-19 infection was associated with a mortality rate of 24%. At the same time, the COVER study demonstrated similarly high peri-operative mortality rates in vascular surgical patients undergoing vascular interventions even without COVID-19, likely associated with the high burden of co-morbidity associated with vascular patients. This is a vascular subgroup analysis of the COVIDSurg cohort.

### *Methods*

All patients with a suspected or confirmed diagnosis of COVID-19 in the 7 days prior to, or in the 30 days following a vascular procedure were included. The primary outcome was 30-day mortality. Secondary outcomes were pulmonary complications (adult respiratory distress syndrome, pulmonary embolism, pneumonia and respiratory failure). Logistic regression was undertaken for dichotomous outcomes.

### *Results*

602 patients were included in this subgroup analysis, of which 88.4% were emergencies. The most common operations performed were for vascular-related dialysis access procedures (20.1%, 121). The combined 30-day mortality rate was 27.2%. Composite secondary pulmonary outcomes occurred in half of the vascular patients (275, 45.7%).

### *Conclusion*

Mortality following vascular surgery in COVID positive patients was significantly higher than levels reported pre-pandemic, and similar to that seen in other specialties in the COVIDSurg cohort. Initiatives and surgical pathways that ensure vascular patients are protected from exposure to COVID-19 in the peri-operative period are vital to protect against excess mortality.

## **Background**

The coronavirus-19 (COVID-19) pandemic has had a profound impact on patients with vascular disorders. Due to concerns and uncertainty about the risk COVID-19 infection on vascular patients, who are known to have a high burden of comorbidity, several national guidelines for the management of vascular conditions were released with recommendations for major reductions in elective and urgent activity. These changes included increasing the threshold for abdominal aortic aneurysm repair, a shift to endovascular revascularisation or primary amputation for critical limb threatening ischaemia rather than surgical bypass, and advising carotid endarterectomy for only those with crescendo transient ischaemic attack (1, 2). These recommendations were largely followed by vascular centres globally(3).

The original COVIDSurg collaborative landmark paper highlighted the high global 30-day mortality rate of 38.0% in patients undergoing any type of operation with a concomitant (confirmed or suspected) diagnosis of COVID-19 (4). The Vascular and Endovascular Research Network (VERN) collaborative COVER study further identified that any vascular patient, regardless of COVID-19 infection status, had a much higher in-hospital mortality rate (11.0%) during the pandemic compared to an equivalent procedure performed in the pre-pandemic era (5).

Patients with vascular conditions represent a population with a high burden of associated comorbidity including cardiac disease, chronic lung disorders and systemic frailty, all linked to peri-operative risk. Therefore it is hypothesised that patients undergoing vascular surgery in the COVIDSurg cohort would be at greater risk of mortality than those undergoing other types of operations. The aim of this subgroup analysis is to further examine the outcomes of the vascular subgroup during the first major COVID-19 pandemic peak and to explore whether certain patient characteristics were associated with worse outcomes.

## **Methods**

### *Recruitment*

This is a subgroup analysis of the international multi-centre cohort study by the COVIDSurg collaborative using data from 1677 hospitals in 122 countries. The full methodological details are published in the Lancet (4). The study was registered as a clinical audit in the United Kingdom. In other countries the study was granted appropriate approval from ethical regulatory bodies as required by the individual country's regulations.

### *Inclusion*

Patients who were diagnosed with, or tested positive for, COVID-19 in the 7 days prior to surgery or in the 30 days following surgery were included. For those undergoing multiple operations the surgery closest to the diagnosis of COVID-19 was considered the index procedure. Patients were prospectively recruited by clinicians at each centre. Retrospective data was allowed in centres where the initial peak has already passed. COVID-19 diagnosis was made with a positive PCR test from nasal or bronchial swab samples, clinical diagnosis from a senior clinician or radiological diagnosis from

a CT thorax in line with local hospital reporting protocols. If a patient with a positive clinical or radiological diagnosis went on to have a PCR test which was negative, they were excluded from the study. Anonymised record IDs with aortic pathology, lower limb pathology, carotid pathology, venous pathology or vascular support services were identified from the database and extracted.

### *Outcomes*

The primary outcome in this analysis was 30-day mortality. The secondary outcome was a composite of pulmonary complications including adult respiratory distress syndrome (ARDS), pulmonary embolism (PE), pneumonia and respiratory failure at 30 days.

### *Data collection & analysis*

Data was collected on the Research Electronic Data Capture (REDCap) online application. For centres without reliable internet collection, data was also collected onto paper case report forms and subsequently uploaded onto REDCap. Patient demographics, physiological parameters, operative details and diagnosis were collected. Data related to the vascular cases were extracted from the REDCap COVIDSurg database. Data analysis was undertaken using the language and statistical computing software R (6) utilising additional software libraries. Simple statistics was undertaken for baseline characteristics.

Independent variables (type of procedure, diagnosis) were treated as nominal factors. Numerical data (age, baseline observations, haemoglobin, white blood cell count, c-reactive protein) were treated as continuous data to maintain power. Primary and secondary outcomes were treated as dichotomous variables. After performing simple statistics on baseline characteristics, completeness of data was interrogated with a threshold of 90% for participants and 70% for dependent variables. Logistic regression was undertaken for the primary outcome. Univariate analysis was performed on all independent variables as a prerequisite for inclusion in the multivariate analysis, a threshold of  $p < 0.1$  was set. The referencing for independent variables was deemed as the closest to physiological e.g. Grade 1 in the American Society of Anesthesiologists (ASA) grade. Multivariate analysis for 30-day mortality, including all eligible independent variables was undertaken and odds ratios calculated using the subsequent coefficients.

## **Results**

### *Patient characteristics*

Demographics are shown in table 1. Data was collected prospectively between 01/01/2020 and 30/09/2020. A total of 602 patients from 1677 centres in 122 countries were included. The modal age category was 70 - 79 years of age, with the majority of patients 50 to 79 years of age. The healthy weight range (BMI 18.5 - 24.9) was the modal BMI category, however over half of participants had a BMI over 25. Only 72 (12%) of patients were documented as being current smokers. ASA grade was 3 or greater in 523 (86.9%) of patients. The preoperative patient characteristics are shown in Table 2.

### *Diagnoses & preoperative investigations*

The commonest diagnosis was critical limb threatening ischaemia (173, 28.9%), followed by acute limb ischaemia (110, 18.3%), renal failure requiring vascular access (118, 19.6%) and diabetic foot disease (87, 14.5%). Surgery for aortic pathologies made up 4.9% of procedures (n=29) and carotid interventions 1.5% (n=9). Frequency distribution of presenting diagnoses are illustrated in Table 3. Emergency admission predominated (532, 88.4%) with few elective admissions (70, 11.6%). Vital observations were normally distributed around the physiological normal range of each variable. The mean c-reactive protein (CRP) was raised preoperatively (95.5mg/L). Just under a third of patients had a preoperative oxygen requirement (182, 30.2%) with 12.6% (76) requiring ventilation (mechanical or non-invasive).

The most common procedure type performed was vascular access related operations for dialysis (20.1%, 121). The most common revascularisation procedure was lower limb thromboembolism (11.0%, 66). Mean length of stay was 15.9 days (SD 12.7).

### *30-day mortality:*

The overall 30-day mortality rate for all vascular patients was 26.2%. Mortality for a diagnosis related to aortic aneurysm was 25% (5/20) and for aortic dissection was 11.1% (1/9). Mortality related to lower limb pathology was 27.2% (47/173) for critical limb ischaemia, 40.9% (45/110) for acute limb ischaemia and 26.4% (23/87) for diabetic foot associated disease (infection). Mortality related to a carotid pathology was 44.4% (4/9) and 20.7% (19/92) for vascular support services. The mortality for each diagnosis is shown in Table 3.

The overall 30-day mortality rate following a vascular procedure was 27.2%. The highest mortality was following fasciotomy (100%, 1/1), arterial catheter directed thrombolysis (50%, 3/6) and upper limb amputation (50%, 1/2). The mortality for each procedure is shown in Table 4.

### *Composite outcome:*

The composite outcome (mortality, pneumonia, ARDS, respiratory failure and pulmonary embolism) occurred in nearly half of the included patients (45.7%, 275).

### *Respiratory complications:*

A peri-operative diagnosis of pneumonia was documented in 32.1% (193) of vascular patients, 14.1% (85) of whom went on to develop ARDS. Respiratory failure occurred in 20.3% (122), and pulmonary embolism was diagnosed in 2.0% of patients (12).

### *Outcome associations*

Following a univariate analysis for 30-day mortality, the following independent variables had a p-value <0.1 and met criteria for inclusion in the multivariate analysis: age, ARDS, ASA, baseline comorbidities, chest X-ray status, CRP, diagnosis, dialysis status, haemoglobin, preoperative ventilatory requirements, preoperative respiratory disease, treatment status and white cell count. CRP level was at threshold for completeness of data (70%). To alleviate concerns regarding the subsequent removal of participants with inclusion of CRP, the multivariate analysis was performed with and without this factor. The outcome did not differ and hence CRP was included in the

multivariate analysis due to its clinical significance and associated p-value in the univariate analysis.

Multivariate analysis revealed ARDS, CRP and need for dialysis was associated with 30-day mortality (Table 5). The remaining included factors failed to reach significance. Development of ARDS had an associated odds ratio of 8.52 for mortality (95% CI 1.40-14.5,  $p < 0.001$ ). Need for dialysis (but not at 30-days), with no dialysis as the reference level, was associated with an odds ratio of 3.66 (95% CI 1.40-9.87,  $p < 0.01$ ). Conversely, for per incremental day length of stay, there was an associated odds ratio of 0.95 (95% CI 0.89-0.96,  $p < 0.001$ ). Procedure type was not significantly associated with mortality.

## Discussion

This subgroup analysis of vascular procedures from the COVIDSurg collaborative study showed vascular patients who go on to develop a confirmed or suspected diagnosis of COVID-19 perioperatively have a high 30-day mortality rate. This study supports the current knowledge that pulmonary complications, on a background of having a diagnosis of COVID-19 are associated with a higher mortality (4).

Older age, male sex, and the presence of comorbidities such as cardiovascular disease, diabetes, and smoking are all risk factors for vascular disease, as well as being identified as significant risk factors for inpatient mortality in patients diagnosed with COVID-19 (4). Therefore it could be hypothesised that vascular patients undergoing vascular surgery with a concomitant diagnosis of COVID-19 would be at greater risk of death than those undergoing other types of surgery. However this was not found to be the case.

### *Contrasting with normal practice*

Within the United Kingdom, contemporary estimates from the National Vascular Registry suggest that the 30-day mortality rate of carotid endarterectomy to be as low as 0.3% (7). This is scales different to the mortality rate of 44.4% reported in this cohort, even when considering the relatively small number of included procedures. Furthermore, the National Vascular Registry reported that in-hospital mortality rates for abdominal aortic aneurysm repair and peripheral arterial vascular procedures performed during the coronavirus-19 pandemic was as high as 42.6% for patients with COVID-19 and a coinciding respiratory complication (8). This is not dissimilar to the 42.4% 30-day mortality for those undergoing lower limb thromboembolism in this cohort. These findings are over double the mortality rate reported in COVER study which found an all-cause mortality of 15.2% for aortic surgery and 20.4% of lower limb revascularisation for acute limb ischaemia (5). For those with COVID-19 requiring hospitalisation and surgery, outcomes in vascular surgery appear to be consistently poor, but in line with the outcomes reported for all surgery patients reported from the COVIDSurg cohort.

Meta-analysis data for rates of in-hospital mortality for any patient with coronavirus disease has been reported at 15% (95% CI: 13 to 17), with an eight fold risk increase for those who went on to develop ARDS (9). Our study found almost double the mortality rate, potentially relating to a higher risk and more comorbid patient

population. The risk of mortality in those with ARDS was very similar. In the cohort reported here, the significant factors in this cohort can be related to severity of clinical condition due to COVID-19, as well as their vascular presentation: ARDS and need for dialysis (with exception of length of stay). This suggests that indicators of mortality were also indicators of severe COVID-19.

This subgroup analysis suggests that for those vascular inpatients with COVID-19 undergoing any kind of procedure, the outcomes are poor. Given that operative mortality was similar across all genres of procedures, a vascular access-related procedure taking some 45 minutes was no different to that of an infrainguinal bypass, it may well have not been the vascular operation that results in poor outcomes. International guidance released by several vascular societies recommended delays to non-essential surgery, with global vascular data confirming a significant drop in vascular activity during the initial peak (3). Therefore it can be assumed that only patients presenting with the most severe vascular disease, requiring urgent intervention that couldn't be delayed, were operated on and therefore included in this cohort.

Evidence continues to suggest that diagnosis of COVID-19 is linked to an increased risk of systemic thrombotic complications, and an associated rise in the need for vascular intervention(10). Admission to intensive care unit (ICU) with COVID-19 and a subsequent thrombotic complication has been associated with mortality rates as high as 59.8% (9, 11).

#### *Should we intervene?*

The poor outcomes reported in this prospective cohort raises the question of risk versus benefit for surgical intervention, and whether intervening in this patient group worsens their clinical condition. However, as is discussed, there is little evidence to suggest that vascular procedures themselves are casual in these outcomes. The clinical decision to undertake a procedure will have been based on the risk of surgery and concomitant COVID-19 diagnosis, against the risk to life and/or limb associated with conservative management.

#### *Limitations*

This is an observational study that attempts to describe the observed outcomes, however, is unable to establish causality. Additionally, there is a considerable selection bias as all those included in this cohort underwent a vascular procedure - the decision making process that led to operative management tends to exclude those who are deemed too high-risk to offer an intervention. This likely falsely improved some of the reported outcomes which may have been worse if all those with a diagnosed vascular pathology (unoperated) were included. Data relating to patients who were not operated on will be available from future COVER study reports. Within this cohort, there is a large skew towards lower limb procedures - hence all conclusions should weigh towards this patient group. There were very few patients included with aortic pathologies. Furthermore, data was incomplete for some independent variable (<70% completeness) precluding their inclusion in the multivariate analysis.

#### **Conclusion**

A concomitant diagnosis of COVID-19 in patients undergoing a vascular surgical procedure had poor postoperative outcomes, with high 30-day mortality. It is unclear the impact of performing procedures on patient outcomes. It must be considered that these outcomes could be related to the need for intervention in the context of being hospitalised with COVID-19, rather than the extent of the intervention itself.

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#### Conflicts of interest

The authors have no conflicts of interest to declare.

The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author and analysis group had full access to all the data in the study and the corresponding author and the writing committee had final responsibility for the decision to submit for publication.

**Table 1: Demographic data of coronavirus disease 2019 (COVID-19)-positive patients undergoing vascular surgery**



<b>Sex</b>	<b>n</b>	<b>%</b>
Female	181	30.1
Male	421	69.9
<b>Age</b>	<b>n</b>	<b>%</b>
1-9 years	1	0.2
10-19 years	3	0.5
20-29 years	10	1.7
30-39 years	21	3.5
40-49 years	56	9.3
50-59 years	114	18.9
60-69 years	142	23.6
70-79 years	164	27.2
80-89 years	77	12.8
90+ years	14	2.3
<b>Body mass index</b>	<b>n</b>	<b>%</b>
BMI < 18.5	29	4.8
BMI 18.5-24.9	189	31.4
BMI 25-29.9	172	28.6
BMI 30-34.9	93	15.4
BMI 35-39.9	38	6.3
BMI ≥40	16	2.7
Not stated	65	10.8
<b>Pre-existing respiratory risk factors</b>	<b>n</b>	<b>%</b>
Smoker	72	12.0
Pre-existing respiratory disease	94	15.6

BMI: Body Mass index

**Table 2: Preoperative participant characteristics**

<b>Baseline observations</b>	<b>Mean</b>	<b>SD</b>
Respiratory rate	18.8	5.5
Heart rate	85.7	18.4
Systolic blood pressure (mmHg)	133.0	25.1
Diastolic blood pressure (mmHg)	72.7	15.5
<b>Baseline blood parameters</b>	<b>Mean</b>	<b>SD</b>
Haemoglobin	106.0	24.5
White cell count	11.4	6.3
C-reactive protein (units)	97.5	101.4
<b>Operative urgency</b>	<b>n</b>	<b>%</b>
Elective	70	11.6
Emergency	532	88.4
<b>Preoperative oxygen / ventilatory requirement</b>	<b>n</b>	<b>%</b>
No support	342	56.8
Oxygen	182	30.2
Ventilated	76	12.6
Not stated	2	0.3

**Table 3: Summary of diagnoses and associated mortality**

<b>Diagnosis</b>	<b>Total n</b>	<b>Mortality n</b>	<b>Mortality %</b>
<b>Aortic pathologies</b>			
Abdominal aortic aneurysm $\geq$ 5.5cm in maximal diameter, asymptomatic or non-urgent	0	0	0.0
Aortic aneurysm urgent (e.g. ruptured or patient presenting with pain)	10	3	30.0
Aortic aneurysm of undetermined urgency	10	2	20.0
Type A aortic dissection	2	0	0.0
Type B aortic dissection or thoracoabdominal aneurysm or acute aortic syndrome or traumatic aortic injury	7	1	14.3
<b>Lower limb pathologies</b>			
Severe claudication or chronic limb-threatening ischaemia	173	47	27.2
Acute limb ischaemia	110	45	40.9
Compartment syndrome	1	1	100.0
Diabetic foot infection or ulceration	87	23	26.4
<b>Carotid pathologies</b>			
Symptomatic carotid artery disease (atherosclerotic)	5	1	20.0
Carotid artery disease (atherosclerotic) (symptomology not stated)	4	3	75.0
<b>Venous pathologies</b>			
Deep vein thrombosis	4	0	0.0
Venous leg ulceration	3	0	0.0
<b>Vascular support services</b>			
Trauma (inc iatrogenic line injuries)	21	6	26.6
Vascular access	118	24	20.3

Others / Not stated	45	8	18.2
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**Table 4: Summary of operations performed and associated mortality**

<b>Operations performed</b>	<b>Total n</b>	<b>Mortality n</b>	<b>Mortality (%)</b>
Above knee amputation (including through knee)	44	14	32.6
Arterial catheter directed thrombolysis	6	3	50.0
Below knee amputation	41	11	26.8
Carotid endarterectomy	9	4	44.4
Diagnostic angiogram	1	0	0.0
EVAR	10	2	20.0
Exploration for trauma	20	6	30.0
Fasciotomy	1	1	100.0
Forefoot amputation	9	0	0.0
Hybrid TEVAR	3	1	33.3
Infra-inguinal angioplasty	20	6	30.0
Infra-inguinal bypass	36	11	30.6
Infra-inguinal endarterectomy +/- patch	14	3	21.4
Lower limb thromboembolectomy	66	28	42.4
Major lower limb amputation (not specified)	57	18	31.6
Minor amputation of digit / toe(s)	50	13	27.1
Open infrarenal aneurysm repair	6	1	16.7
Repair of pseudoaneurysm	9	1	11.1
TEVAR	5	1	20.0
Total arch replacement	2	0	0.0
Upper limb amputation	2	1	50.0
Upper limb thromboembolectomy	20	7	35.0
Vascular access-related procedure	121	23	19.0

Venous catheter directed thrombolysis / perc thrombectomy	1	0	0.0
Wound debridement and washout	36	8	22.2
Other, Vascular	13	1	7.7

**Table 5: significant independent variables in the multivariate analysis for 30-day mortality**

<b>Independent variable</b>	<b>Odds ratio</b>	<b>p-value</b>
ARDS	8.52 (CI: 1.40 - 14.5)	<0.001
Need for dialysis, but not at 30 days	3.66 (CI: 1.40 - 9.87)	<0.01
Length of stay	0.95 (CI: 0.89 - 0.96)	<0.001

ARDS: adult respiratory distress syndrome

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## Appendix 1: Authorship\*

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