



Observations Regarding the Effect of COVID-19 on Amputations and Lower Extremity Interventions in a Tertiary Referral Health System

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Abstract

OBJECTIVE: In response to the COVID-19 pandemic, our tertiary referral center implemented guidelines to triage procedures and shift toward telehealth encounters. The aim of this analysis is to evaluate the impact of this alteration in practice pattern on amputation rate and vascular procedural experience for similar time intervals before and during the initial pandemic.

MATERIALS AND METHODS: The institutional Vascular Quality Initiative database was queried to compare amputations and contemporaneous vascular procedures performed on patients with chronic limb-threatening ischemia in the 6 months following the pandemic-related healthcare changes (April-September 2020) to a 6-month period immediately prior to this interval (July-December 2019). All lower extremity interventions performed by a single vascular surgery practice across 5 hospitals of a major healthcare system were included.

RESULTS: The total number of amputations increased by 52%, with 42 (16.8% of procedures) performed during the pre-pandemic interval and 64 (27.5% of procedures) during the COVID-19 period ($P=.005$). The increase in amputations was predominantly an 88% increase in minor amputations, from 17 (6.8%) to 32 (13.7%) ($P=.011$). There was a corresponding 23% decrease in revascularization procedures including bypass and endovascular interventions ($P=.005$). The amputation-to-revascularization ratio increased significantly, doubling during the COVID-19 study period ($P=.004$).

CONCLUSIONS: A rise in the total number of amputations and a corresponding decrease in revascularization procedures was observed during the initial COVID-19 pandemic. Further investigation is warranted to identify the underlying etiology of this impact: case reprioritization, delayed care, infection, or the result of COVID-related complications. Future emphasis on the appropriate delivery of care to prevent amputation and optimize outcomes for vulnerable patients during a pandemic is indicated.

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Key words: COVID-19, chronic limb-threatening ischemia, amputation

In December 2019, a pneumonia outbreak was reported in Wuhan, China, and was soon after identified as a novel strain of coronavirus—severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2, COVID-19).^{1,2} By January 2020, 9976 novel coronavirus cases were confirmed worldwide in 21 countries, including the first U.S. case on January 20, 2020, and community transmission ensued.³ Rapid international spread was well underway and on March, 11, 2020, the World Health Organization had declared a global pandemic, with 118,319 cases and 4292 deaths worldwide.⁴ Although respiratory compromise characterizes the typical presentation of

COVID-19, multiorgan system complications have been well recognized.^{5,6} Most notable is the hypercoagulable state of the disease, leading to worse prognosis and predisposition for arterial and venous thromboembolic events, which raised particular concern for vascular surgery patients.⁷⁻¹⁰

In preparation for a surge in critically ill patients in the United States, and in an effort to decrease disease transmission and conserve resources, the country adopted widespread measures in March 2020 that drastically changed healthcare delivery. The Centers for Medicare & Medicaid Services (CMS) announced on March 18, 2020 that “all elective surgeries,

TABLE 1. OVERVIEW OF PROCEDURES PERFORMED DURING STUDY PERIODS.

	2019 (Jul-Dec)	2020 (Apr-Sep)	P-value
Total number of procedures	250	233	
Total amputations, number (%)	42 (16.8)	64 (27.5)	.005
Total amputations, mean (SD)	7 (1.9)	10.7 (2.9)	.028
Minor amputations, number (%)	17 (6.8)	32 (13.7)	.011
Minor amputations, mean (SD)	2.8 (1.7)	5.3 (1.2)	.016
Major amputations, number (%)	25 (10)	32 (13.7)	.203
Major amputations, mean (SD)	4.2 (0.8)	5.3 (2.1)	.223
Bypass, number (%)	84 (33.6)	67 (28.8)	.251
Bypass, mean (SD)	14 (4)	11.2 (3.9)	.241
PVI, number (%)	124 (49.6)	102 (43.8)	.401
PVI, mean (SD)	20.7 (2.4)	17 (6.7)	.373
Bypass + PVI, number (%)	208 (83.2)	169 (72.5)	.005
Bypass + PVI, mean (SD)	34.7 (4)	28.2 (10.2)	.195
Ratio total number of amputations: bypass	0.5	1	.011
Ratio total number of amputations: PVI	0.3	0.6	.009
Ratio total number of amputations: bypass + PVI	0.2	0.4	.004

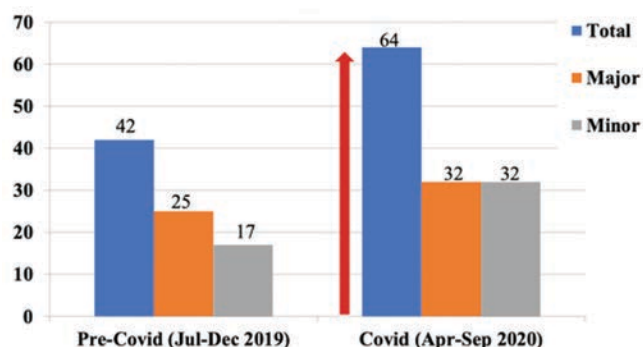
Percentages listed are percent of total number of procedures. SD = standard deviation; PVI = peripheral vascular intervention.

nonessential medical, surgical and dental procedures should be delayed during the COVID-19 outbreak.”¹¹ The American College of Surgeons (ACS) released subspecialty-specific triage guidelines, further encouraging the consideration of nonoperative management when feasible.¹² The Inova Health System Department of surgery, along with surgical practices nationwide, underwent major restructuring in response to pandemic guidelines in an effort to decrease virus transmission and conserve resources.

To evaluate the potential impact of institutional pandemic-related changes on the vulnerable vascular patient population, we reviewed the procedures performed for chronic limb-threatening ischemia (CLTI) before and after March 2020 when the Inova Department of Surgery cancelled elective cases based on guidelines from CMS, the Surgeon General, and ACS.

Methods

The Inova Health System Institutional Review Board approved this study under title #U20-11-4313. A full waiver of HIPAA Research Authorization was granted as no direct patient contact or harm resulted from the study. The institutional Vascular

**FIGURE 1.** Amputations during study periods.

Quality Initiative database was retrospectively queried to identify all adult patients (>18 years) who underwent lower extremity intervention for ischemia between July 1, 2019 and September 30, 2020. Operations performed in the 6 months following the pandemic-related changes (April 1 to September 30, 2020) were compared with a 6-month period immediately prior to this interval (July 1 to December 30, 2019). Procedures that occurred in March 2020 were excluded from the analysis to account for the dynamic practice variation that occurred during this time, as we were adapting to the unstable nature of initial resource allocation across hospitals. By April 2020, there was systemwide compliance in the triage process for vascular surgical cases at our institution, and most outpatient referrals and follow-ups were conducted via telehealth whenever possible. Prior to March 2020, elective operative cases and routine in-person outpatient encounters were proceeding in usual “pre-pandemic” routine.

All lower extremity interventions on patients with CLTI performed by a single vascular surgery practice across 5 hospitals of a major healthcare system were included. Amputations from the pelvis to the transmetatarsal level were included, with major amputations defined as pelvis to transtibial and minor amputations involving the toes or forefoot. Exclusion criteria included procedures performed not due to underlying critical ischemia (ie, claudication, trauma, acute compartment syndrome, infection without ischemia, etc.).

The study population was stratified into 2 groups based on 6-month study periods, such as July to December 2019 (2019) and April to September 2020 (2020), before and after changes due to the pandemic. The results of descriptive statistics were presented as frequencies and percentages for categorical variables and means and standard deviation (SD) for continuous variables. Differences between groups were assessed for statistical significance with Pearson's chi-square test for categorical data and t test for continuous data. All results were considered statistically significant if $P \leq .05$. All statistical analyses were performed using SPSS Statistics (Windows Version 26).

Results

Institutional Pandemic Experience and Protocols

The nonprofit Inova Health System is a tertiary referral center with a robust catchment area serving the Washington, DC area, including northern Virginia and southern Maryland. The Division of Vascular Surgery is comprised of 10 attending surgeons across 5 Inova Hospital locations in the geographical area. The main Inova Fairfax Medical Campus includes an academic vascular service comprised of 3 to 4 general surgery residents, 2 vascular surgery fellows, 3 advanced practice providers, and medical students.

In accordance with CMS and ACS guidelines, the Inova Health System department of surgery cancelled elective operative cases on March 19, 2020. Uniform compliance with pandemic triage guidelines was adopted by all Inova hospitals. In accordance with surgical subspecialty guidance provided by ACS, vascular procedures for CLTI, thrombolysis, and deep debridement of wound infection/necrosis were classified as Tier 2b—postpone as possible. Cases given priority to proceed were acute aortic presentations and those with septic and immediately limb-threatening conditions. Additionally, all patients exhibiting fever or generalized respiratory symptoms, and those anticipated to need blood products, discharge to inpatient rehab or skilled nursing, or postop ICU admission were postponed if possible. All potential operating room patients had COVID-19 testing, and if found to be COVID-positive, their case was postponed unless in immediately limb- or life-threatening cases. Interventions for claudication were classified as Tier 1—postpone all. Additionally, efforts were made for most outpatient evaluations to occur via telemedicine wherever possible.

Amputations

A total of 250 procedures were performed in July to December 2019 and 233 procedures in April to September 2020. The breakdown of overall total, major, and minor amputations is presented in **Figure 1**. The total number of amputations increased by 52%, from 42 (16.8%) in the 2019 pre-pandemic interval to 64 (27.5%) during the 2020 pandemic ($P=.005$). Minor amputations increased by 88% with 17 (6.8%) in 2019 to 32 (13.7%) in 2020 ($P=.011$). Although the number of major amputations increased from 25 (10%) in 2019 to 32 (13.7%) in 2020, it was not statistically significant ($P=.203$) (**Table 1**).

Revascularization Procedures

The total number of revascularization procedures including open bypass and endovascular peripheral vascular interventions (PVI) decreased by 23% from 208 (83.2%) in 2019 to 169 (72.5%) in 2020 during the COVID study period ($P=.005$). There was a decline in the number of bypasses from 84 (33.6%) in 2019 to 67 (28.8%) in 2020 ($P=.251$) and PVIs from 124 (49.6%) to 102 (43.8%) ($P=.401$), which did not reach statistical significance.

The amputation-to-revascularization ratio significantly doubled during the COVID study period ($P=.004$).

Discussion

Vascular practices across the country engaged in care prioritization in response to the COVID-19 pandemic. In anticipation of a strain on healthcare resources, our tertiary referral center implemented guidelines to tier procedures by type and urgency while incorporating a shift toward telehealth encounters in the practice. Patients' tendencies to seek medical attention were notably altered due to social distancing, local shelter-in-place guidelines, and the transition to telehealth visits vs in-person exams for routine care. While the importance of public health adaptations to curtail the impact of COVID-19 should not be ignored, this led to an unprecedented cancellation and delay in surgical practices and interruption of routine care, with many hospitals only performing emergency operations during peak virus outbreaks.¹³ This poses specific concern in the vascular surgical community where patients with peripheral arterial disease may not only be more vulnerable to direct sequelae of COVID-19, but also because their outcomes depend on direct examination, prompt recognition, and surgical intervention.¹⁴

Post-pandemic literature regarding vascular surgery has recognized more advanced ischemia on presentation, higher clot burden and revascularization failure, and higher rates of complications, amputations, and death.¹⁵⁻¹⁸ Our study sought to evaluate the immediate impact of these issues on systems-level changes that occurred over a short time period in a single health system, especially on amputation rates and vascular procedures. We did observe a statistically significant increase in the number of amputations performed. The increase was driven by minor amputation, which may reflect delayed care with intervening infection and a lack of continued wound care. There was also a relative increase in amputation compared with surgical bypass and endovascular revascularization procedures. Again, this may reflect an increase in soft tissue impact prior to revascularization being able to be performed.

This observational study adds to the growing body of literature demonstrating the profound reach of this virus beyond its direct physiological effects, through its global and population health-related practice changes on high-risk vascular surgery patients. When routine care processes are interrupted, we must recognize the inevitable sequelae on tenuous populations who are highly dependent on structured surveillance and prompt interventions to prevent life-threatening complications of their disease, aka progressive ischemia, infection, and amputation. Without specific contingency plans in place in anticipation of a pandemic, we observed significant increases in amputations at our institution.

This study does not directly address nor compare baseline differences in clinical presentations between groups that could

potentially impact outcomes; rather, it is an observational report on practice variation in response to the pandemic, thus conclusions cannot be drawn outside of this. Specifically, the study design does not distinguish between COVID-related thrombosis and non-COVID cases who experienced delays in care; therefore, the direct etiology of observed outcomes during the pandemic cannot be determined. Additionally, it is limited in that it is a single institution retrospective report with limited follow-up and does not evaluate the practice change in relation to mortality or other longer-term outcomes. Nonetheless, recognition of this statistically significant change in practice as it relates to amputation in vascular surgery is highly relevant to guide future quality initiatives and emergency preparedness.

Conclusions

A rise in the total number of amputations, predominantly minor, and a corresponding decrease in revascularization procedures was observed during the initial COVID-19 pandemic. Further investigation is warranted to identify the underlying etiology of this impact: decreased revascularization performed, delayed care, infection, or the result of case prioritization. Future emphasis on the appropriate delivery of care to prevent amputation and optimize outcomes during a pandemic is indicated.

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