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Impact of the coronavirus disease 2019 pandemic on an academic vascular practice and a multidisciplinary limb preservation program

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ABSTRACT

With the aggressive resource conservation necessary to face the coronavirus disease 2019 pandemic, vascular surgeons have faced unique challenges in managing the health of their high-risk patients. An early analysis of patient outcomes after pandemic-related practice changes suggested that patients with chronic limb threatening ischemia have been presenting with more severe foot infections and are more likely to require major limb amputation compared with 6 months previously. As our society and health care system adapt to the new changes required in the post–coronavirus disease 2019 era, it is critical that we pay special attention to the most vulnerable subsets of patients with vascular disease, particularly those with chronic limb threatening ischemia and limited access to care. (J Vasc Surg 2020;72:1850-5.)

Key words: Chronic limb threatening ischemia; COVID-19; Decision support; Medical decision making; Triage

The outbreak of a novel strain of coronavirus, severe acute respiratory syndrome coronavirus 2, in December 2019 resulted in a restructuring of the delivery of health care in the United States, both to preserve resources for the anticipated large volumes of patients critically ill with coronavirus disease 2019 (COVID-19) and to mitigate disease spread.[1,2] Thus, patient care classified as nonurgent at the outset of the pandemic was deferred and in-person outpatient–physician interaction was largely replaced. These changes pose particular challenges to the care of patients with chronic limb threatening ischemia (CLTI) because of the risk of clinical deterioration, the importance of the physical examination in patient assessment, and the need for hemodynamic and imaging studies to direct treatment.

To assess the effects of COVID-19–induced health care system changes on patients in the University of California, San Francisco (UCSF), Limb Preservation Program and the Diabetic Foot, we reviewed the clinical profile and outcomes of patients with CLTI treated during the COVID-19 pandemic compared with patients treated during a similar period before the pandemic.

UCSF DIVISION OF VASCULAR SURGERY STRUCTURE

The UCSF Division of Vascular Surgery, Department of Surgery, includes nine full-time faculty, three clinical fellows, and five advanced practice providers, with six general/vascular surgery residents and two to six medical students rotating on service at any time. The faculty, fellows, and residents provide care for vascular patients at the main UCSF campus and at two partner hospitals (San Francisco Veteran Affairs [SFVA] Medical Center and Zuckerberg San Francisco General Hospital [a safety net/community hospital]). In addition, the UCSF Center for Limb Preservation and the Diabetic Foot, established in 2011 at the main campus, provides interdisciplinary care for patients with threatened limbs, through partnership by vascular surgeons, three podiatric surgeons, one limb preservation podiatry fellow, and one to two rotating podiatry residents.

SURGICAL CASE VOLUME

In accordance with the Centers for Medicare and Medicaid Services guidelines regarding cancellation of elective cases, the UCSF Department of Surgery provided instructions for cancelling all "elective" cases starting March 16, 2020.[3] Although the Department of Surgery offered broad guidelines for prioritizing cases according

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to the anticipated outcomes of delaying surgery, options for alternative nonsurgical treatment, and anticipated resource usage (ie, personal protective equipment, blood supply, ventilators, intensive care unit beds, hospital beds), subspecialty triage systems were developed using the expertise of individual divisions and sections. Modifying the surgical case prioritization template provided by the Centers for Medicare and Medicaid Services, the UCSF Division of Vascular Surgery developed its own diagnosis-based categorizations for procedural urgency (Table I). Patients with CLTI with gangrene, major tissue loss, advanced ischemia or infection (Wound, Ischemia, foot Infection [WIfI] stage 4) were categorized as tier 3 (most urgent cases) and given scheduling priority. Patients with pain at rest or a minor ulcer were included in tier 2B and scheduled, pending operating room availability. Patients in tiers 1 and 2A were deferred until adequate resources had been secured and in accordance with local public health guidelines.

Using this triage system, the overall case volume within the Division of Vascular Surgery had decreased by 46% from baseline in the first week and by 74% from baseline in the next 2 weeks. Since April 22, 2020, when nonurgent cases (including tier 2A and some tier 1 cases) were allowed to be selectively added back to the surgical schedule, the case volume increased to ~80% of baseline at our main hospital (Fig, *A*). At the main university hospital, the proportion of cases performed for lower extremity revascularization (lower extremity bypass or endovascular interventions) had increased from 31% of the total operative volume at baseline to 42% of the operative volume from March 15 to May 16, 2020. However, the absolute number of limb revascularization cases was similar between the two intervals.

Although all our hospitals (UCSF, SFVA Medical Center, and Zuckerberg San Francisco General Hospital) were swift and effective in reducing the case volumes initially, each had a different experience in resuming nonurgent surgical care. At the SFVA Medical Center, case scheduling protocols have been guided by regional and national leadership teams, rather than institutional leadership, such as occurred at UCSF. This led to a much slower resumption of operative cases at the SFVA Medical Center (Fig, *A*).

CLINIC FUNCTION/MANAGEMENT

With the institution of local shelter in place orders on March 16, 2020, providers were instructed to cancel or convert to telehealth all appointments that did not absolutely require an inpatient visit. In addition, public health messaging instructed citizens to delay "nonessential" medical visits during the high-risk period. Providers prioritized in-person clinic visits for patients with advanced lower extremity peripheral artery disease (PAD) with concern for CLTI (eg, new tissue loss), because physical examinations and vascular studies are essential for evaluation. Patients requiring dialysis access, especially those with previous failed access, also were seen in person, as were postoperative patients requiring a physical examination. Patients with foot wounds requiring ongoing wound care were still seen by the podiatry team in our Limb Preservation Clinic. Those with aneurysmal and carotid disease, especially when asymptomatic, were encouraged to undergo the necessary imaging studies locally and were seen virtually to obtain a focused history. All routine surveillance visits were otherwise deferred for 3 months. Family members were not allowed to accompany patients to clinic visits unless deemed medically necessary and with special clearance.

Compared with the standard clinic patient volumes, in-person visits across all three care sites had been decreased by 84% within 2 weeks, and 70% of visits had been conducted by telephone or video. The vascular laboratory volume had also decreased, in parallel, by 75% across all three sites (Fig, *B*). Since the beginning of the shelter in place orders, the proportion of lower extremity arterial duplex ultrasound and toe/ankle pressure examinations performed by the vascular laboratory has remained relatively stable. However, 61% of the studies performed during this period were in the inpatient setting compared with only 34% before the pandemic. Because assessing wounds through a video stream is challenging, if not impossible, we have had a persistent rate of in-person clinic visits for patients in the Limb Preservation Program, although still decreased by >40% from baseline (Fig, *C*). The decrease had resulted from a combination of the decline in new referrals and established patients not showing, cancelling, or rescheduling their follow-up visits.

Similar to many specialties, we have continued to work to find the best methods to resume outpatient care—balancing the needs for in-person patient visits and patient–provider safety. We have implemented social distancing policies in our clinic and have continued to operate at a reduced capacity to ensure these policies can be enforced. At present, our visits remain at ~30% to 50% virtual and 50% to 70% of our normal prepandemic volume.

RISKS OF DELAYED CARE ON LIMB PRESERVATION

To evaluate the early effects of the pandemic on patients with CLTI, we compared the WIfI stage for all patients with CLTI admitted to our main university hospital from March 15, 2020 through May 15, 2020 to that of a baseline cohort from 6 months before the pandemic (September 1, 2019 through October 31, 2019). Additionally, we determined the overall number of amputations performed at our main university hospital and the SFVA Medical Center for the same periods. The UCSF institutional review board approved the present study.

Table I. Surgical case triage algorithm

Tier 1	Tier 2A	Tier 2B	Tier 3
Low priority/ elective	Intermediate priority; should be scheduled within 3 months	High priority; possible adverse consequences with delay of >1 month	Urgent; possible adverse consequences with delay of >7 days
Claudication	Asymptomatic, stable aneurysms that meet size guidelines	Asymptomatic, stable, larger aneurysms (>6 cm or 6.5 cm)	Symptomatic/rapidly enlarging or very large/unstable aneurysms
Venous interventions	Asymptomatic carotid stenosis	High grade/critical asymptomatic carotid stenosis (>80%)	Complicated type B aortic dissection
	Renal artery disease with HTN indications	Chronic or subacute limb threatening ischemia with rest pain/minor ulcer	Acute limb or visceral ischemia
	Dialysis access creation	Chronic mesenteric insufficiency with severe, episodic symptoms	Symptomatic carotid stenosis
			Chronic limb threatening ischemia with gangrene/major ulcer (WIfI stage 4)
			Suspected graft infection/mycotic process, any location
			Threatened bypass graft (impending failure)
			Severe renal artery disease with pulmonary edema or malignant HTN

HTN, Hypertension; *WIfI,* Wound, Ischemia, foot Infection.

The overall number of inpatient vascular surgery admissions and consultations decreased by 34% since our local shelter in place orders went into effect on March 16, 2020. Although the number of patients admitted with CLTI has remained relatively stable compared with 6 months before the pandemic, our patients appeared to be presenting with a more severe limb threat (Table II). In our patient population, we have seen a significant increase in the foot infection component of the WIfI score for patients admitted because of CLTI, with an average score of 1.38 during the pandemic (March 15 through May 15) compared with 0.79 for the 6 months before ($P = .01$). Also, a notable, significant increase has occurred in the major to minor amputation ratio, from 0.3 to 0.7 ($P = .003$), with the number of major amputations nearly tripling compared with the prepandemic levels. We found no significant changes in the distribution of race, gender, or average age among the patients who had undergone a major amputation before vs during the pandemic.

DISCUSSION

As the pandemic has persisted and evolved, vascular specialists have seen the effects of the drastic changes in patient care patterns and policies on clinical events. The results from our early analysis of outcomes for patients with CLTI support the initial concerns that these changes, although likely necessary, had negative consequences for some high-risk patients. Furthermore, we have become concerned that these deleterious trends could persist for an extended period. The CLTI population is characterized by advanced age and a high prevalence of comorbidities, such as diabetes and cardiac and renal disease, known to increase the risk of severe COVID-19 infections among those exposed. Thus, it was not surprising that many such patients chose to maintain their sheltering in place and potentially minimize the significance of advanced signs and symptoms in the leg or foot. Many vascular surgery patients, especially those with PAD, will have issues with poor compliance. Studies have shown that intensified center-based care provided by a vascular medicine group can improve outcomes.[4] In addition to the deleterious effects from delaying diagnoses and/or operations, it is possible that deferring clinic visits could affect patient compliance with important medical therapies and lifestyle interventions, leading to compromised outcomes. We are concerned that this could be especially true for patients with CLTI who require regular in-person evaluations and frequent interventions to prevent adverse outcomes such as a major limb amputation.[5-7]

Our results align with those from other early studies demonstrating increased amputation rates and PAD severity in the setting of the COVID-19 pandemic.[8,9]

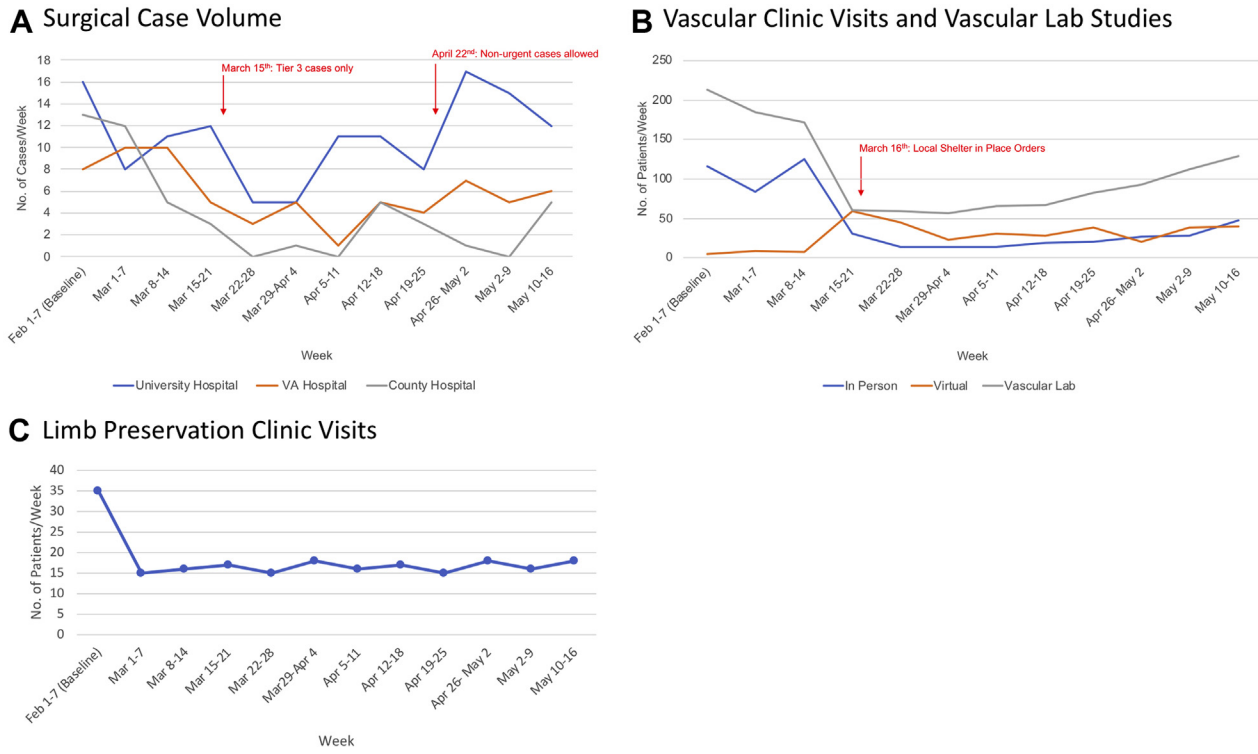

Fig. A-C, Changes in patient volume in response to coronavirus disease 2019 (COVID-19). *VA*, Veterans Affairs.

Recent reports outside of vascular surgery have suggested we are not alone in our observation of negative pandemic-related effects. A recent study reported that the weekly rates of hospitalization for acute myocardial infarction had decreased by 48% during the pandemic, suggesting that emergent patient needs were likely not being addressed.[10] In addition, numerous studies have found an increase in diabetic foot wounds and complications since the onset of the pandemic.[11,12]

We hypothesized that the observed increase in major amputation resulted from delayed presentations and changes in the regular surveillance mechanisms caused by both limited hospital capacity and patient reluctance to travel and interact with the health care system. We did not experience an inability to admit patients with CLTI requiring hospital-level care during this period, nor was access to the operating room restricted for high priority limb revascularization procedures. The vascular laboratory studies performed for evaluation of limb perfusion had decreased proportionally with the overall volume of studies, possibly leading to delays in the diagnosis and treatment of threatened limbs. Additionally, most vascular surgery patients are elderly and could have trouble using the technology needed for successful virtual visits, when appropriate. This has been especially relevant during this time of social distancing, when support from family and friends could be limited. Furthermore, providing successful virtual visits in the County Hospital, where patients often have limited resources, has been nearly impossible.

Although further research is needed to understand the root causes of these differential outcomes and to identify the optimal methods to address them, it is clear that more attention (and outreach) must be given to patients with severe PAD. Virtual clinic appointments and telehealth remain an effective care option for a subset of our patients, in particular, those with aortic aneurysms or carotid artery stenosis. However, the role for virtual appointments is more limited in the Limb Preservation Clinic and for patients with limited technology resources. Attempting to maintain care for some of our most vulnerable patients, the Limb Preservation podiatry fellow has been assessing patient-sent digital images of wounds to triage and provide guidance on when patients should be seen in clinic or evaluated urgently. In addition, UCSF Health has been taking proactive measures to encourage patients with high-risk conditions to seek care when appropriate and needed. These measures have included reassurance about the safety measures, telephone and video follow-up targeting high-risk patients, and direct communication with referring providers regarding the reopening of services. Finally, the adaptations made during the pandemic have presented an opportunity to improve care delivery and resource usage in CLTI that could be accelerated. Adaptation and implementation of recently developed remote limb monitoring tools such as biosensors[13] and "Smart Socks"[14] represent methods for providing safe and effective care for patient with CLTI amidst the drastic changes in

Table II. Effects of coronavirus disease 2019 (*COVID-19*) on key limb preservation program metrics

Variable	Before COVID-19 (September 1 to October 31, 2019)	After shelter in place order (March 15 to May 15, 2020)
Total vascular OR cases	139	94
Total LE revascularization cases	42	40
Total vascular admissions/consultations	153	101
Admissions/consultations for CLTI	43	32
Mean limb preservation clinic visits weekly	26	12
WIfI stage at admission	3.3 ± 1.1	3.6 ± 0.9
Wound score	1.9 ± 0.8	2.0 ± 0.9
Ischemia score	1.6 ± 1.2	1.6 ± 1.2
Foot infection score	0.8 ± 1.0[a]	1.4 ± 1.0[a]
Total amputations, No.	25	36
Above knee amputation	1	4
Below knee amputation	4	10
Transmetatarsal amputation	10	7
Other minor amputation	10	13
Major/minor amputation ratio	0.3[a]	0.7[a]

CLTI, Chronic limb threatening ischemia; *LE,* lower extremity; *OR,* operating room; *WIfI,* Wound, Ischemia, foot Infection.
Data presented as number or mean ± standard deviation.
[a]Statistically significant difference from before to during COVID-19 ($P < .05$).

health care necessitated by the COVID-19 pandemic. The field would benefit by testing and improving specific remote monitoring and telehealth tools applicable to patients with limited access to care and those at risk of limb loss.

CONCLUSIONS

Despite the challenges unique to the vascular surgery patient population, coordinated efforts based on the best available evidence have allowed for rapid modification of the care pathways across a tertiary care, multihospital academic vascular surgery practice during a pandemic. As our society and health care system adapt to the new changes required in the COVID-19 era, it is critical that we give special attention to the many vulnerable subsets of the vascular surgery population, especially those with CLTI and limited access to care. The recent acute increase in major amputations we have witnessed is a concerning trend that requires a strategic response from each practice, health system, and public health sector. Further study is needed to understand the underlying causes and the most effective methods to mitigate the negative outcomes now and prevent them in the future.

AUTHOR CONTRIBUTIONS

Conception and design: EL, BW, JI, AO, WG, SV, EW, JH, CE, EL, AR, LR, JS, MC
Analysis and interpretation: EL, AO, WG
Data collection: EL, BW, AO, WG, EW
Writing the article: EL, MC
Critical revision of the article: EL, BW, JI, AO, WG, SV, EW, JH, CE, EL, AR, LR, JS, MC
Final approval of the article: EL, BW, JI, AO, WG, SV, EW, JH, CE, EL, AR, LR, JS, MC
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