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Influence of the COVID-19 pandemic on the management of chronic limb-threatening ischemia

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The COVID-19 pandemic negatively impacted patients with conditions that are associated with significant morbidity, but might not be immediately life-threatening. Patients with chronic limb-threatening ischemia (CLTI) were affected by delays in care, potentially increasing major limb amputations. This study sought to review strategies employed, and limb salvage outcomes reported, during the COVID-19 pandemic. We performed a literature review of the electronic database PubMed from December 2019 to December 2020. Articles subjected to analysis must have had a specific CLTI group before the pandemic to compare to the pandemic group. Case reports, case series, and non–CLTI comparisons were excluded. The literature search yielded 55 articles for review, of which 6 articles met criteria for analysis. The main classifications used for disease stratification included Rutherford, Fontaine, and SVS WIF (Wound, Ischemia, Foot Infection). Overall, a decrease in vascular clinical volume was reported, ranging from 29% to 54%. A higher major limb amputation rate (2.6% to 32.2%) during the pandemic surge was reported in 5 of 6 publications. Four of 6 studies also reported minor amputations; 3 of these demonstrated an increase in minor amputations (7% to 17.7%). The CLTI population is vulnerable and it appears that both minor and major amputation rates increased in this population during the pandemic. The limited data available in CLTI patients during the COVID-19 pandemic and use of different stratifications schemes in areas impacted to variable extents prevent recommendations for the best treatment strategy. Further data are required to improve strategies for treating this population to minimize negative outcomes.

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1. Introduction

The novel coronavirus disease 2019 (COVID-19) originated in Wuhan, China and spread rapidly across the globe [1,2]. With devastating numbers of cases across the world and an increasing death toll, health care systems have been challenged in multiple ways to diagnose, manage, and treat non–COVID-related illness. COVID-19 has affected the availability of hospital beds and resources, such as ventilators, personal protective equipment, and health care staff [3]. In order to mitigate the spread, several governments have implemented lockdowns and rapid vaccination development programs [4,5].

Owing to surges of hospitalized patients infected with COVID-19, usual treatment of many nonemergent disorders required periodic postponement. Patients with chronic limb-threatening ischemia (CLTI) are a good example of a population for whom optimal treatment has been deferred by the pandemic. CLTI, although not emergent, poses a major risk for limb loss and death if left untreated [6,7]. Vascular surgeons in many settings were forced to implement triage strategies...
to improve selection of CLTI patients for admission and treatment [8,9]. The goal of these strategies was to safely and judiciously defer patients when deemed safe and to admit only those in need of urgent intervention or revascularization to prevent limb loss [8,9].

Since the onset of the pandemic, which often occurred in waves, hospitals across the world have periodically become oversaturated and unable to provide usual and timely care for all patients. Some have employed deferment strategies for patients with CLTI. Collectively, this patient population is likely to have been impacted negatively by this pandemic. The primary objective of this review was to identify the main outcomes in limb salvage and amputations in the CLTI population across the available publications to date during the COVID-19 pandemic.

2. Methods

A literature search was performed in the electronic database PubMed from December 2019 to December 2020 [10]. The following terms were used CLTI COVID 19, Amputations COVID 19, and limb preservation COVID 19. All references found with the terms used were reviewed despite language or age group.

2.1. Inclusion and exclusion criteria

Articles that were included required 2 time period comparison groups, before COVID-19 pandemic and during the initial COVID-19 pandemic surge. Included articles had a specific CLTI comparator group with limb outcomes and amputation rates. All age groups and regions across the world were included. We excluded case reports, case series, articles reporting only cases of acute limb ischemia and articles reporting only data from the pandemic with no prepandemic comparison group.

According to recent Global Vascular Guidelines, CLTI is defined as ischemic rest pain or tissue loss in the presence of hemodynamic compromise for at least 2 weeks [11]. Multiple classification systems have been created to stratify CLTI, including the Fontaine, Rutherford, and WIfI (Wound, Ischemia, Foot Infection) threatened limb classifications [12–14]. Each of these classifications was used in various studies to stratify severity of disease and included in this review.

2.2. Outcome

The main goal of this review was to understand how COVID-19 has impacted treatment and outcomes of the CLTI population, specifically, amputation and limb salvage rates. Secondarily, we want to explore the implications of COVID-19 for institutions and the adaptive changes invoked to treat this vulnerable population.

3. Results

The literature search provided a total of 55 articles published from 2019 to 2020. After thorough review of the abstracts and articles, 49 were excluded from this study. Six articles met our inclusion criteria, as shown in Figure 1.

Among the 6 studies reviewed, 2 were from the United States, 1 was from the United Kingdom, 1 was from the Netherlands, and 2 were from Italy. The 2 studies from the United States originated from San Francisco, CA, and Houston, TX. The 2 studies from Italy were from Campania and Northern Italy (Veneto and Lombardy regions). These regions were impacted differently by COVID-19 and different measures were taken in order to minimize hospital staff exposure and efficiently utilize supplies and personal protective equipment, while providing optimal care to those most in need. To contextualize the differential impact of the pandemic in these regions, the peak number of confirmed COVID-19 cases per million inhabitants at the time of each study is shown in Tables 1 to 3 [15]. In general, CLTI was stratified by disease severity using existing classification grading systems (Fontaine, Rutherford, and SVS WIfI). Those in the most severe categories met indication for intervention, and CLTI patients in the mild to moderate categories were most often deferred and followed as outpatients. The duration and severity of lockdown periods varied in different regions. In some areas, only truly emergent, lifesaving procedures were possible. Conversely, in other settings, urgent, as opposed to truly emergent, procedures were possible for most of the pandemic.

Lancaster et al. [16] (United States) used the WIfI classification scheme to dictate urgency of care. Their indications for treatment were gangrene, major tissue loss, and advanced ischemia or infection (WIfI stage 4). Miranda et al. [17] (United States) also used the WIfI classification; indications for inpatient treatment were a WIfI clinical stage 4 limb, a WIfI foot infection grade $\geq 2$, or disabling and unrelenting rest pain. Stabile et al. [18] (Italy) used the Fontaine classification, with indications for intervention being Fontaine class 3 with disabling rest pain or a Fontaine class 4 with gangrene or tissue loss. Piazza et al. [19] (Italy) used the Rutherford classification. Any patient with a Rutherford class 5 limb with rapidly wors-
Table 1 – Reduction in clinical volume and severity of chronic limb-threatening ischemia disease.

| Study first author | Location | Confirmed cases per million [15] | Overall decrease in volume, n (%) | CLTI classification | Prepandemic | Pandemic, n (%) |
|--------------------|----------|----------------------------------|-----------------------------------|---------------------|-------------|-----------------|
| Piazza [19]        | Padua, Italy | 2,313.0                          | 52 (54.2)                        | Rutherford         | 16 (53.3)   | 6 (42.9)        |
|                    |          |                                  |                                   | Stage 4/5          | 11 (36.7)   | 8 (57.1)        |
|                    |          |                                  |                                   | Stage 6            |             |                 |
| Lancaster [16]     | San Francisco, CA, United States | 2,285.8                          | 45 (32.4)                        | WIfI               |             |                 |
|                    |          |                                  |                                   | Overall mean       | 3.3 ± 1.1  | 3.6 ± 0.9       |
|                    |          |                                  |                                   | Wound score        | 1.9 ± 0.8  | 2.0 ± 0.9       |
|                    |          |                                  |                                   | Ischaemia score    | 1.6 ± 1.2  | 1.6 ± 1.2       |
|                    |          |                                  |                                   | Foot infection score | 0.8 ± 1.0 | 1.4 ± 1.0       |
| Schuivens [20]     | Breda, The Netherlands | 2,017.28                          | 16 (29.6)                        | Rutherford         |             |                 |
|                    |          |                                  |                                   | Stage 1            | 1 (3)       | 0 (0)           |
|                    |          |                                  |                                   | Stage 2            | 6 (19)      | 0 (0)           |
|                    |          |                                  |                                   | Stage 3            | 1 (3)       | 1 (5)           |
|                    |          |                                  |                                   | Stage 4            | 8 (26)      | 1 (5)           |
|                    |          |                                  |                                   | Stage 5/6          | 15 (48)     | 17 (90)         |
| Stabile [18]       | Campania, Italy | 646.2                            | 221 (65.6)                       | Fontaine           |             |                 |
|                    |          |                                  |                                   | Stage 3            | 145 (43)    | 32 (27.6)       |
|                    |          |                                  |                                   | Stage 4            | 192 (57)    | 84 (72.4)       |
| Musajee [21]       | London, United Kingdom | 3,472.3                          | 44 (31.7)                        | Rutherford         |             |                 |
|                    |          |                                  |                                   | Stage 4            | 30 (27)     | 28 (38)         |
|                    |          |                                  |                                   | Stage 5            | 41 (36)     | 24 (32)         |
|                    |          |                                  |                                   | Stage 6            | 46 (49)     | 21 (29)         |
| Miranda [17]       | Houston, TX, United States | 1,166.9                          | 45 (47.4)                        | WIfI               |             |                 |
|                    |          |                                  |                                   | Stage 1            | 2 (5.1)     | 1 (3.3)         |
|                    |          |                                  |                                   | Stage 2            | 24 (61.5)   | 7 (23.3)        |
|                    |          |                                  |                                   | Stage 3            | 8 (20.5)    | 8 (26.7)        |
|                    |          |                                  |                                   | Stage 4            | 5 (12.8)    | 14 (46.7)       |

Abbreviations: CLTI, chronic limb-threatening ischemia; WIfI, Wound, Ischemia, Foot Infection.

a Represents fall in clinical volume from 2019 to 2020.
b Values are n (%).
c Values are mean ± standard deviation.
d Represents fall in clinical volume from 2018 to 2020.

Regarding the classification scheme used for CLTI stratification, most groups reported an increase in severity and a drop in overall patient and procedural volume. Lancaster et al [16] (United States) reported a mean increase in WIfI clinical stage from 3.3 to 3.6. The main drivers for increased severity were increases in wound and foot infection grades. They also experienced a 32.4% fall in vascular case volume. Miranda et al [17] (United States) reported a 47.4% drop in clinical volume with a higher frequency of patients with WIfI stage 3 and 4 limbs treated during the lockdown period. Stabile et al [18] (Italy) noted a decrease of 65.6% in clinical volume and reported a higher frequency of Fontaine stage 4 during the lockdown period. Piazza et al [19] (Italy) reported a 54.2% reduction in clinical volume and also reported higher disease severity with an increased frequency of Rutherford stage 6. Schuivens et al [20] (The Netherlands) experienced an increase in clinical volume of 23.7% from 2019 to 2020, but a decrease of 29.5% from 2018. This group also noted an increased frequency of Rutherford stage 5 and 6 patients. Lastly, Musajee et al [21] (United Kingdom) experienced a decrease of 31.7% in clinical volume and observed an increase of Rutherford stage 4, but a decrease of Rutherford stages 5 and 6 during the pandemic surge, as is shown in Table 1.

Limb preservation and amputation rates were impacted during the pandemic lockdown period, shown in Figure 2. Lancaster et al [16] (United States) reported an overall increase in minor and major amputations during the lockdown period (23.3% and 11.6% v 40.6% and 43.8%, respectively). Miranda et al [17] (United States) also demonstrated an increase in both minor and major amputations during the pandemic (8% and 0% v 23.7% and 2.6%, respectively), although not statistically significant. Stabile et al [18] (Italy) also demonstrated a 15.9% increase in amputation rates, which was statistically significant; however, the analysis failed to differentiate minor from major amputations. Piazza et al [19] (Italy) also observed a greater number of major amputations during lockdown (4% to 8% and 10% to 15%, respectively), but minor amputations were not reported. Schuivens et al [20] (The Netherlands) reported a decrease in minor amputations 0% during lockdown, but a significant increase in major limb amputations (42% v 18%
Table 2 – Indication for intervention during the pandemic and amputation rate.

| Study first author | Location | Confirmed cases per million, n [15] | Time period (1: prepandemic; 2: pandemic) | CLTI indication for intervention-pandemic | No. of CLTI patients | Major amputation rates, % |
|--------------------|----------|--------------------------------------|------------------------------------------|-------------------------------------------|----------------------|--------------------------|
|                    |          |                                      |                                          |                                           | Pre/Post             | Pre/Post                  |
| Piazza [19]        | Padua, Italy | 2,313.0                              | 1: Feb 2–Mar 8, 2020 2: Mar 9–Apr 5, 2020 | Rutherford class 5 and 6                  | 27/14               | 4–8/10–15                 |
| Lancaster [16]     | San Francisco, CA, United States | 2,285.8                              | 1: Sept 1–Oct 31, 2019 2: Mar 15–May 15, 2020 | WIfI stage 4                              | 43/32               | 11.6/43.8                |
| Musajee [21]       | London, United Kingdom             | 3,472.3                               | 1: Mar 3–May 31, 2019 2: Mar 3–May 31, 2020 | Rutherford class 4, 5 and 6               | 76/47               | 7/5                      |
| Stabile [18]       | Campania, Italy                    | 646.2                                 | 1: Feb 3–Mar 8, 2020 2: Mar 9–Apr 13, 2020 | Fontaine stage 3 and 4                    | 337/116             | 13.4/29.3                |
| Schuivens [20]     | Breda, The Netherlands              | 2,017.28                              | 1a: Mar 16–Apr 30, 2018 1b: Mar 16–Apr 30, 2019 2: Mar 16–Apr 30, 2020 | Rutherford class 4, 5 and 6               | 1a: 31/1b: 19       | 1a: 15/1b: 42            |
| Miranda [17]       | Houston, TX, United States         | 1,166.9                               | 1: Mar 25–Apr 25, 2019 2: Mar 25–Apr 25, 2020 | WIfI stage 4                              | 50/38               | 0/2.6                    |

Abbreviations: CLTI, chronic limb-threatening ischemia; WIfI, Wound, Ischemia, Foot Infection.

a Major amputation defined as any above the ankle amputation for the described time period (within 30 days).

Fig. 2 – Amputation rates by era (prepandemic v pandemic).

a Reflects the highest amputations rates reported in the study by Piazza et al. [19].

b Reflects amputation data from 2019 in the study by Schuivens et al. [20].
and 15% in the 2 years prior). Finally, Musajee et al. [21] (United Kingdom) reported a 7% increase in minor amputations and a 2% decrease in major amputations, but neither difference was statistically significant (Tables 2 and 3).

4. Discussion

The current times are unprecedented; the pandemic has profoundly influenced the management of many chronic diseases, especially limb preservation care in the CLTI population. This review delineates the initial changes implemented by institutions across the world and, in general, the strategies were similar; to treat the most advanced disease in the CLTI spectrum and observe those in the earlier stages of the disease. The main outcome of note during the pandemic surge was an observed increase in major and minor amputations. Furthermore, all of the institutions reported a decrease in overall clinical volume in order to maintain available resources for those affected by COVID-19.

One of the challenges posed to vascular surgeons is which patient should undergo operation during the lockdown period. This becomes a difficult decision in large academic institutions, as most patients are already complex cases and have been referred for that reason [22]. Nonetheless, different criteria based on existing CLTI classification systems were created to select the most severe for intervention. The main driver for this approach was to preserve hospital beds and resources and to treat only those at highest risk. Although these schemes of patient deferment have not been validated, it is noteworthy that the increase in major amputations in some institutions was generally less severe than expected. Nonetheless, this observation could systematically underestimate true clinical rates because nonsalvageable limbs could have been amputated by other services or a limb salvage mindset abandoned due to an overwhelmed health care system secondary to the pandemic. Furthermore, 3 of the 6 studies reported an increase in minor amputations, which might indicate the importance of a multidisciplinary team approach for limb salvage composed of a vascular surgeon, podiatrist, medicine diabetes specialist, and infectious disease specialist [23].

The management of CLTI has grown to adopt an endovascular first approach in many patients, but multiple studies in this review observed an equal or higher number of open interventions [24].

This observation can most likely be attributed to greater disease burden, however, these studies were not designed for this specific outcome and should be considered when interpreting these findings. Ideally, minimally invasive procedures with rapid recoveries would be favored during the pandemic to limit ventilator and intensive care unit use but achieving this can be difficult with high disease severity and limitations on resources. The generally observed increase in CLTI severity during the lockdown period could be attributable to several causes. First, patients may have avoided emergency departments and potential hospitalization for fear of contracting COVID-19. Second, many institutions lacked the capacity to admit patients for operation, postoperative care, and recovery. Lastly, the deferment of these patients likely affected adherence. Although telehealth capacity increased, in many areas, outpatient surveillance programs might have been problematic or impossible to implement in other settings. In addition, the limited adoption of the technology needed for telehealth visits in a more elderly and potentially socially isolated patient population might have contributed to adverse outcomes [25].

The CLTI population is often elderly, frail, and characterized by multiple comorbidities, including diabetes and renal failure. These factors also place them at a higher risk of contracting COVID-19. This review demonstrates that limb salvage can be adversely impacted without appropriate means of surveillance and stimulation of patient adherence. Most institutions reported a higher number of major limb amputations in patients with greater CLTI severity compared to historical controls before lockdown. In a recent review of the Vascular Quality Initiative, Ho et al. [26] reported that during the initial pandemic surge in the United States, there was a significant increase in urgent and emergent lower extremity interventions in patients with more severe comorbidities. The potential inciting factors leading to these outcomes include patient deferment, poor surveillance, poor adherence, or lack of access to care due to the pandemic. The true factors remain unknown and further research is warranted to elucidate them. However, we hypothesize that regular supervision programs with nursing assistance, such as using virtual appointments, telephone hotlines, evaluation of digital images from foot wounds, or telemedicine for patients in the CLTI spectrum, might improve outcomes. Furthermore, a generalized systematic approach for disease stratification is warranted for validation and widespread use.
Perhaps the most significant impact COVID-19 has had on academic institutions was decreased surgical volume. In this review, we saw a drop in overall vascular case volume of 29% to 54%. This drop in surgical cases also might have had a negative impact on vascular surgery trainees [27]. Institutions have coped with this problem in multiple ways, such as by having online, virtual conferences, didactics, and grand rounds; changes to the call schedule to minimize exposure; and some have created “simulation kits” to address procedural knowledge decay [28,29]. The long-term effects in reduction of surgical volume remain unknown. However, the development of innovative ways to improve surgical education should be continued to address training gaps caused by this pandemic. Finally, innovative partnering with industry can enhance options for delivering care [30].

Despite generally similar trends noted in most studies, this review has several limitations. Most of the included studies are retrospective and single-center, with small sample sizes. These studies also measured and stratified CLTI using differing classifications, making it difficult to determine whether adverse outcomes were truly related to the impact of the COVID-19 surge versus inappropriate deferral of a patient with truly severe CLTI. In addition, none of the methods used to designate which patient should receive more urgent intervention have been validated. Lastly, the regions in which these studies were published were impacted unevenly and experienced different lockdown measures. Therefore, adaptations of different institutions might not be generalizable to other geographic locations. Regardless of these limitations, the uncontrolled outbreak of this disease led to expedited changes in an attempt to maintain surgical care and further adaptations are needed to improve outcomes. The tools gained through these difficult times will remain applicable if there is another COVID-19 resurgence, natural disaster, or future pandemic.

5. Conclusions

The vascular surgeon has faced many challenges during this pandemic and multiple strategies have been used to provide care to those most in need, while directing often scarce resources to those critically ill with COVID-19. The CLTI population is vulnerable and requires special attention during this pandemic, as we appear to have identified an increase in amputations. As we continue to investigate the underlying causes for these outcomes, we must further adapt to minimize negative outcomes and seek changes at local, state, federal and international levels.

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