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Clinical Research

The effects of COVID-19 pandemic on patients with lower extremity peripheral arterial disease: A near miss disaster

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Background: The COVID-19 pandemic has led to widespread postponement and cancellation of elective vascular surgeries in Switzerland. The consequences of these decisions are poorly understood.

Patients and methods: In this observational, retrospective, single-center cohort study, we describe the impact of COVID-19 pandemic containment strategies on patients with lower extremity peripheral arterial disease (PAD) referred during the period March 11, to May 11, 2020, compared to the same time frames in 2018 to 2019. Patients admitted for acute limb ischemia (ALI) or chronic PAD and undergoing urgent or elective vascular surgery or primary amputation were included. Patients' characteristics, indications for admission, and surgical features were analyzed. The occurrence of 30 day outcomes was assessed, including length of stay, rates of major adverse cardiovascular events (MACE) and major adverse limb events (MALE), and procedural and hemodynamic success.

Results: Overall, 166 patients were included. Fewer subjects per 10 day period were operated in 2020 compared to, 2018 to 2019 (6.7 vs. 10.5, respectively; $P < 0.001$). The former had higher rates of chronic obstructive pulmonary disease (COPD) (25% vs. 11.1%; $P = 0.029$), and ASA score (3.13 vs. 2.90; $P = 0.015$). The percentage of patients with ALI in 2020 was about double that of the same period in 2018 to 2019 (47.5% vs. 24.6%; $P = 0.006$). Overall, the types of surgery were similar between 2020 and 2018 to 2019, while palliative care and primary amputations occurred only in 2020 (5 out of 40 cases). The rate of post-operative MACE was significantly higher in 2020 (10% vs. 2.4%; $P = 0.037$).

Conclusions: During the first state of emergency for COVID-19 pandemic in 2020, less regular medical follow-up and hindered hospital access could have resulted in more acute and advanced clinical presentations of patients with PAD undergoing surgery. Guidelines are needed to provide appropriate care to this vulnerable population and avoid a large-scale disaster.

No potential conflicts of interest to declare.

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INTRODUCTION

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) is responsible for a clinical condition called Coronavirus Disease 2019 (COVID-19), first reported in Wuhan, China, in December 2019 and rapidly spread around the world in early 2020, causing global public health emergency.¹ Since the World Health Organization declared the COVID-19 outbreak a pandemic on March 11, 2020, governments worldwide have been prompted to adopt restrictive measures to control the exponential diffusion of the virus,² including lockdown, quarantine, and social distancing.^{3,4} In Switzerland, a state of emergency was declared, the population was semi-confined, schools were closed, and the borders shut. In hospitals, elective surgical and outpatient activities were halted. Such strategies were implemented on March 16 and lasted until May 11, 2020.⁵

Whilst effective in containing the first wave of the pandemic, these measures have led to several serious consequences, deeply affecting hospital functioning and health of chronic patients. On the one hand, restrictions on surgical indications were introduced both to divert hospital resources to COVID-19 patients and minimize unnecessary exposure of subjects to a potentially infectious environment. In our Angiology and Vascular Surgery Divisions, non-urgent vascular consultations and treatments were postponed. On the other hand, since the general population was encouraged to stay home, many patients suffering from peripheral artery disease (PAD) faced not only an interruption of an otherwise regular outpatient care program, but also a disruption of those lifestyle habits that are essential part of their treatment. This is particularly the case of subjects with chronic PAD. For these patients walking exercise is a first-line therapy.⁶ This environment, together with patients' reluctance to attend the hospital for fear of being exposed to the virus, led to a worsening of vascular disease in several PAD patients.⁷

Another notable concern during the first COVID-19 wave consisted in drug adherence. PAD is frequently associated with comorbidities like type 2 diabetes, dyslipidemia, hypertension, and other forms of cardiovascular disease.⁸ Such conditions are also highly prevalent among patients with COVID-19, and are associated with poorer outcomes.⁹ Initial reports even mentioned a possible increased susceptibility to the virus in subjects receiving inhibitors of the renin-angiotensin-aldosterone system in the setting of the above diseases, since ACE2 receptor has been proposed

as one of the main mechanism of entry of SARS-CoV2 in human cells.¹⁰ Although current data do not confirm this concern,^{11,12} a number of PAD patients may have discontinued their medications during the first wave of the pandemic, which may have contributed to a worsening of their cardiovascular status.

In light of these aspects, aim of our study was to retrospectively analyze staging of clinical presentation and management of PAD patients referred for vascular management in our Swiss tertiary care center during the first wave of COVID-19 pandemic in 2020, as compared to PAD patients referred in the same time frame in 2018 and 2019.

MATERIALS AND METHODS

Study design

This is an observational, retrospective, single-center cohort study of patients with PAD admitted and treated at the Angiology and Vascular Surgery Divisions of the Lausanne University Hospital (CHUV). They underwent vascular surgery, primary amputation, and/or palliative care without any intervention, during the period March 11, to May 11, 2020 (which corresponds to the first state of emergency imposed by the Swiss Federal Authorities as a result of the COVID-19 pandemic). Clinical characteristics, surgical treatments and outcomes of these subjects were compared to those of patients referred to our Institution during the same time frame in 2019 and 2018. The study was conducted according to the principles of the Declaration of Helsinki and approved by the local Ethic Committee (Project-ID 2020-01106). All patients signed the informed consent form for data collection and analysis provided by the CHUV.

Patients

All patients referred to the Angiology and/or Vascular Surgery Divisions and undergoing urgent or elective vascular surgery or primary amputation for PAD, including acute limb ischemia (ALI) Rutherford I to III and chronic PAD Fontaine stages I to IV during the period March 11, to May 11, of 2018, 2019 and 2020, were included in the study. In 2020, all included patients underwent testing of nasopharyngeal swab specimens by quantitative reverse-transcriptase polymerase chain reaction (RT-qPCR) at admission to detect SARS-CoV-2 infection. Exclusion criteria were patient's explicit refusal to be included in the study.

Definitions

Chronic PAD was defined as the presence of partial or complete obstruction of one or more lower limb arteries associated with an ankle-brachial index (ABI) ≤ 0.9 , or a toe-brachial index (TBI) ≤ 0.7 in case of a high ABI (≥ 1.40) related to medial calcification, according to the European Society of Cardiology and European Society for Vascular Surgery and European Society for Vascular Medicine guidelines.^{6,13} Chronic PAD severity was stratified according to the Fontaine classification.¹⁴ Acute limb ischemia (ALI) was defined as an abrupt decrease in limb arterial perfusion with consequent limb viability threatening. ALI severity was stratified according to the Rutherford classification.¹⁵ Pre-operative drug treatment was recorded at time of hospital admission. Treatments were classified as open surgery, endovascular surgery, hybrid surgery, primary lower limb amputation, and palliative care. Procedural success was defined as technical success and completion of the procedure without complications. Hemodynamic success was defined as a post-operative increase of > 0.15 of ABI, or > 0.1 of TBI, and patency of treated segment.¹⁶ Post-operative course was defined as the 30 days period after the intervention or the hospital admission if no intervention was performed. Major adverse limb events (MALE) included either secondary major amputation of the revascularized limb or reintervention on the revascularized segment. Major adverse cardiovascular events (MACE) was defined as cerebrovascular accident, myocardial infarction, or cardiovascular death.

Objectives

The primary objective of the study was to describe patients' clinical staging of PAD at referral, and indications for hospital admission (ALI, chronic PAD Fontaine stages I-II or III-IV). For all patients, surgical features (type of treatment, duration of intervention, procedural success, and intra-operative death) were collected as well as patients' characteristics: gender, age, body mass index (BMI), presence of comorbidities (arterial hypertension, type 2 diabetes, dyslipidemia, chronic kidney disease, chronic obstructive pulmonary disease (COPD), heart disease, and cerebrovascular disease), smoking habit, baseline medical treatment at hospital admission, American Society of Anesthesiologists (ASA) score, and presence of a positive test for COVID-19 at hospital admission. Data were compared to those of patients admitted during the same time frame in 2018 and 2019. Secondary objectives were 30 day rates

of overall death, major adverse cardiovascular events (MACE), and major adverse limb events (MALE), as well as immediate procedural, 30 day hemodynamic success and length of stay (LOS).

Statistical analysis

Categorical variables are expressed as frequencies and percentages. Continuous variables are expressed as mean values with standard deviations. In order to avoid reporting measures without standard deviation, some data was aggregated in 10 day or 30 day periods. This also allowed correction for weekday (fewer admissions on weekends) and accurate description of absolute numbers of records. Patients admitted in 2018 and 2019 were grouped and compared to patients admitted in 2020. Differences between groups were tested using the Chi-square test for categorical variables, and the Student's *t*-test for continuous variables. All tests were two tailed, and $P \leq 0.05$ was considered to be statistically significant. Statistic computations were performed with R software version 3.5.1.¹⁷

RESULTS

Patients' characteristics

Patients' characteristics are shown in [Table I](#). A total of 166 subjects were included (40 patients in 2020, and 126 in 2018 to 2019). The number of admissions per 10 day period was significantly lower in 2020 compared to 2018 to 2019 (6.7 ± 3.5 vs. 10.5 ± 4.6 , respectively; $P < 0.001$). Patients admitted in 2020 had a significantly lower BMI (kg/m^2) (24.4 ± 4.4 vs. 26.3 ± 5.2 ; $P = 0.026$) and a significantly higher prevalence of COPD upon admission (25% vs. 11.1%; $P = 0.029$). The ASA score was significantly higher in 2020 (3.13 ± 0.52 vs. 2.90 ± 0.47 ; $P = 0.015$). As for baseline treatment, preoperative anticoagulation was significantly more frequent among patients admitted in 2020 (42.5% vs. 24.6%; $P = 0.029$), while the use of statins (45% vs. 62.7%; $P = 0.048$) and anti-hypertensive drugs (52.5% vs. 72.2%; $P = 0.020$) was less frequently reported in this group. A trend towards higher prevalence of heart disease amongst patients admitted in 2020 was observed. In 2020, 3 out of 40 patients were tested positive for COVID-19 at hospital admission. None of the patients had prior documented COVID-19 infection.

Indications for hospital admission

Indications for admissions are summarized in [Table II](#). The percentage of patients admitted for ALI

Table I. Patients' characteristics

	2020	2019-2018	P value
Total number of patients	40	126	
Number of patients per 10-day period (\pm SD)	6.7 (3.5)	10.5 (4.6)	< 0.001*
Male gender	26 (65%)	88 (69.8%)	0.57
Age (years) (\pm SD)	70.7 (15.0)	69.0 (12.2)	0.52
Body mass index (kg/m ²) (\pm SD)	24.4 (4.4)	26.3 (5.2)	0.026*
Hypertension	30 (75%)	103 (81.7%)	0.87
Tobacco use	32 (80%)	97 (77.0%)	0.69
<i>Current</i>	20 (50%)	65 (51.6%)	0.86
<i>Former</i>	12 (30%)	32 (25.4%)	0.57
<i>Never</i>	8 (20%)	29 (23%)	0.69
Diabetes	12 (30%)	50 (39.7%)	0.27
Dyslipidemia	23 (57.5%)	80 (63.5%)	0.50
Chronic renal disease	4 (10%)	20 (15.9%)	0.36
COPD	10 (25%)	14 (11.1%)	0.029*
Cardiac disease	26 (65%)	62 (49.2%)	0.081
<i>Coronary artery disease</i>	18 (45%)	47 (37.3%)	0.38
<i>Heart valve disease</i>	5 (12.5%)	15 (11.9%)	0.92
<i>Arrhythmia</i>	11 (27.5%)	30 (23.8%)	0.64
Cerebrovascular disease	7 (17.5%)	27 (21.4%)	0.59
Treatment at admission			
<i>Anticoagulation</i>	17 (42.5%)	31 (24.6%)	0.029*
<i>Antiplatelet therapy</i>	31 (77.5%)	102 (80.9%)	0.63
<i>Statin</i>	18 (45%)	79 (62.7%)	0.048*
<i>Antihypertensive drugs</i>	21 (52.5%)	91 (72.2%)	0.020*
ASA Score (\pm SD)	3.13 (0.52)	2.90 (0.47)	0.015*
COVID-19 test positive at admission	3 (7.5%)	NA	NA

ASA, American Society of Anesthesia; COPD, chronic obstructive pulmonary disease; SD, standard deviation.

Table II. Indications for hospital admission

	2020 (n = 40)	2019-2018 (n = 126)	P value
Acute limb ischemia	19 (47.5%)	31 (24.6%)	0.006*
<i>Acute limb ischemia 30-day period (\pm SD)</i>	9.5 (0.7)	7.8 (2.6)	< 0.001*
<i>Rutherford I</i>	8/19 (42.1%)	11/31 (35.5%)	0.051
<i>Rutherford IIa</i>	5/19 (26.3%)	9/31 (29.0%)	0.29
<i>Rutherford IIb</i>	4/19 (21%)	11/31 (35.5%)	0.81
<i>Rutherford III</i>	2/19 (10.5%)	0/31 (0%)	NA
Chronic PAD	21 (52.5%)	95 (75.4%)	0.006*
<i>Fontaine I-II</i>	7/21 (33.3%)	50/95 (52.7%)	0.010*
<i>Fontaine III - IV</i>	14/21 (66.7%)	45/95 (47.3%)	0.93
<i>Fontaine I-II per 30-day period (\pm SD)</i>	3.5 (0.7)	12.5 (6.4)	< 0.001*
<i>Fontaine III-IV per 30-day period (\pm SD)</i>	7.0 (1.4)	11.3 (3.4)	< 0.001*

PAD, peripheral arterial disease; SD, standard deviation.

in 2020 was nearly doubled that of the same period in 2018 to 2019 (47.5% vs. 24.6%, respectively; $P = 0.006$). The absolute number of patients with ALI per 30 day period admitted in 2020 was also significantly higher than in 2018 to 2019 (9.5 ± 0.7 vs. 7.8 ± 2.6 ; $P < 0.001$). There was no significant difference in terms of Rutherford staging between groups although a trend towards higher

rate of Rutherford stage III among patients with ALI admitted in 2020 (10.5% vs. none) was observed.

Overall, the percentage of patients admitted for chronic PAD was significantly lower in 2020 compared to, 2018 to 2019 (52.5% vs. 75.4%, respectively; $P = 0.006$). Data show a trend towards higher percentage of patients admitted for chronic PAD Fontaine stages III-IV in 2020 (66.7% vs.

Table III. Treatment features

Type of Treatment	2020 (n = 40)	2019-2018 (n = 126)	P value
<i>Hybrid</i>	12 (30%)	30 (23.8%)	0.43
<i>Endovascular</i>	13 (32.5%)	49 (38.9%)	0.47
<i>Open</i>	10 (25%)	47 (37.3%)	0.15
<i>Palliative care</i>	3 (7.5%)	0 (0%)	NA
<i>Primary amputation</i>	2 (5%)	0 (0%)	NA
Duration of intervention (min) (\pm SD)	128 (69)	125 (66)	0.81
Procedural success	34 (85%)	117 (92.9%)	0.13
Intra-operative death	0	0	NA

SD, standard deviation.

47.3%; $P = 0.11$), however absolute number of such patients per 30 day period was significantly lower than in 2018 to 2019 (7 ± 1.4 vs. 11.3 ± 3.4 ; $P < 0.001$). Not surprisingly, patients with chronic PAD Fontaine stages I-II were significantly underrepresented in 2020, both in relative (33.3% vs. 52.7%; $P = 0.010$) and absolute numbers per 30 day period (3.5 ± 0.7 vs. 12.5 ± 6.4 ; $P < 0.001$).

Treatments and procedural outcomes

All treatment features are listed in Table III. Overall, types of surgeries were similar between 2020 and 2018 to 2019. A trend towards less open surgery was observed in 2020. Palliative care and primary amputations occurred only in 2020. A total of 5 patients (12.5%) were managed with palliative care (3 patients) or primary amputation (2 patients). During the COVID period, 43% of the patients were operated in emergency, while 57% could be managed in a semi-elective manner. There was no intra-operative death and procedural success was similar between 2020 and 2018 to 2019 (85% vs. 93%, respectively; $P = 0.13$).

Post-operative 30 day course

A trend towards lower rates of primary hemodynamic success and higher rates of post-operative overall death was observed in 2020 compared to 2018 to 2019, but neither reached statistical significance. The rate of post-operative MACE was significantly higher in 2020 (10% vs. 2.4%; $P = 0.037$), while the rate of post-operative MALE and the duration of hospital stay were similar between groups (Table IV).

DISCUSSION

Present study showed significantly decreased overall PAD patient admission in 2020. Among PAD admitted patients, majority had ALI. Chronic

PAD stages I-II were less frequently reported as indication for surgery in the latter period, since many non-urgent operations had been deliberately postponed, as observed in other Vascular Centers.^{7,18-22} Intriguingly, despite a trend towards a higher percentage of chronic PAD stages III-IV in 2020, absolute number per 30 day period was significantly lower than in 2018 to 2019. This suggests that even this group of patients may have had reduced medical attention during the first wave of COVID-19. Overall, patients admitted in 2020 were sicker. In particular, they presented higher rates of COPD and ASA score. Moreover, despite similar prevalence of hypertension, diabetes, and cardiovascular disease, they were less frequently on statin and anti-hypertensive medications upon admission, thus raising the suspicion that initial controversies relayed in the press on the potentially negative impact of several cardiovascular medications on COVID-19 may have led to their discontinuation in several cases. Of note, rates of COVID-19 positive tests were low among PAD patients in this period. Therefore, the direct consequences of COVID-19 on this vulnerable population cannot be assessed in our study. Overall, types of surgical procedures, as well as rates of intra-operative death and procedural success were similar between 2020 and the previous two years, while palliative management and primary amputations occurred only in 2020. At 30 days after surgery, rates of MACE were significantly higher in 2020 as compared to previous years. Although not statistically significant, a trend toward higher rates of post-operative death was reported as well in this group of patients.

The present study improves understanding of the impact of COVID-19 pandemic on patients with PAD, shedding light on the effects of restrictive population-level containment strategies on this vulnerable population. Importantly, a significant

Table IV. Post-operative 30 days course

	2020 (n = 40)	2019-2018 (n = 126)	P value
Hemodynamic success	29 (72.5%)	107 (84.9%)	0.075
LOS (\pm SD)	11.5 (11.8)	8.8 (7.5)	0.18
Post-operative death	4 (10%)	4 (3.2%)	0.079
MACE	4 (10%)	3 (2.4%)	0.037*
<i>Cardiovascular death</i>	1 (2.5%)	3 (100%)	NA
MI	3 (75%)	0	NA
MALE	11 (27.5%)	29 (23.0%)	0.56

LOS, length of hospital stay; MACE, major adverse cardiovascular events (cardiovascular death, myocardial infarction, stroke, and heart failure); MALE, major adverse limb events (amputation, worsening in Fontaine stage, reintervention, occlusion of revascularized segment); SD, standard deviation.

relative and absolute over-representation of patients with ALI was observed in 2020, corroborating previous findings by colleagues in Northern Italy.²³ This aspect could be explained by suboptimal routine care, decreased daily exercise, and concomitantly delayed health care access. Another potential explanation is that follow-up visits of patients with chronic PAD stages I and II were halted during the first wave of COVID-19, and their access to surgical treatment and appropriate management was limited. Similar hypothesis may be raised for chronic PAD patients stages III-IV, who were significantly underrepresented in 2020, though they accounted for two-thirds of patients admitted for PAD during this period. It may be hypothesized that some of these patients faced massive deterioration of their vascular state leading to ALI. The relevance of early management of PAD patients is emphasized by the fact that 5 out of 40 patients in 2020 were deemed unsuitable for revascularization and underwent palliative care and/or primary amputations. This was not the case in the previous two years, when no patient was referred to our department with similar clinical status.

Even if absolute numbers are substantially low in our study, they could translate into a catastrophic scenario if extended on a large scale. Consistently, the COVER project, analyzing the impact of COVID-19 pandemic on provision, practice, and outcomes of vascular surgery, has reported changes in the management of PAD patients during the pandemic, with a majority of participating units performing a higher proportion of major amputation or palliative care rather than attempting revascularization for chronic limb threatening ischemia.²⁴ In our study, this dramatic situation was partially mitigated by the organization of our center, which allowed us to maintain some semi-elective surgical activity twice a week in addition to the emergency rooms. Indeed,

more than half of the patients were treated with this strategy in 2020.

The 2020 lockdown not only impacted access to surgery but also the type of surgery performed. In fact, 60% of vascular units in the COVER project documented a shift towards an endovascular-first treatment strategy, especially in chronic PAD Fontaine stages III and IV.²⁴ In our study, the proportion of open, endovascular, and hybrid procedures were not significantly different between 2020 and 2018 to 2019. Nevertheless, the endovascular approach accounted for more than two-thirds of patients in both periods of the study. A possible explanation is that our vascular surgery division, well-experienced in both open and endovascular techniques, already has a large proportion of patients treated by hybrid or endovascular techniques in its daily practice. As this strategy was maintained during the COVID period, it resulted in good outcomes despite a high proportion of ALI, patients' vulnerability, and delayed clinical presentation. Indeed, no differences were observed regarding procedural and hemodynamic success, LOS, as well as rates of MALE, and overall death. The only significant difference observed in the post-operative period in 2020 concerned MACE rates, which were 4-fold those reported in 2018 to 2019. This may be attributable to patients' comorbidities and clinical status, as well as to suboptimal medical treatment upon surgery.

Our study offers a lesson for the future. In particular, it underlies the importance of establishing guidelines for PAD patients during the COVID-19 pandemic, and particularly in case of lockdown or other population-level containment strategies. First, we showed that limited access to routine outpatient care and elective surgery can lead to potentially dramatic consequences. Moreover, our findings suggest that patients with PAD were probably less likely to seek medical

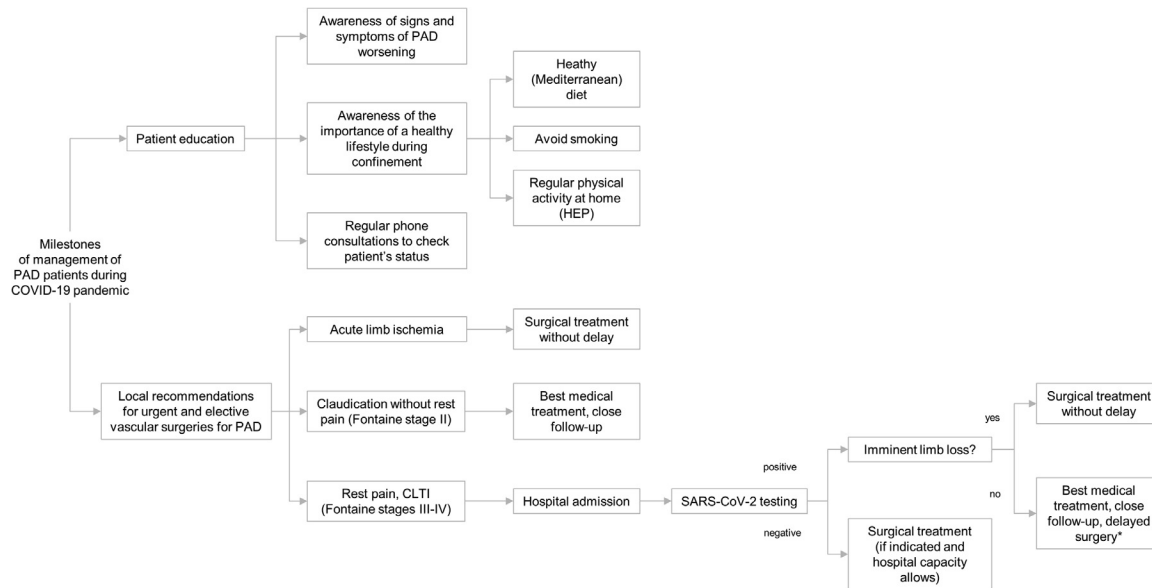


Fig. 1. Algorithm for the management of patients with lower extremity peripheral arterial disease in case of future COVID-19 pandemic containment strategies. *Delay surgery until 14 days after positive SARS-CoV-2 test with 3 days of being afebrile (if not on antipyretics) and significant resolution of symptoms. CLTI: critical limb threatening ischemia; HEP: Home exercise program.

contact and tended to manage pharmacological treatment independently. These aspects are in line with previous reports and studies both in the setting of vascular surgery,^{24,25} and other specialties.²⁶⁻²⁸ These results highlight a need to maintain the expertise and resources to provide appropriate and safe care of PAD patients, during a pandemics as also suggested by other colleagues.²⁹ A potential algorithm for the management of patients with PAD in case of future COVID-19 pandemic containment strategies is provided in Figure 1.

Our study has several limitations worth noting. First, the low sample size strongly limits any firm conclusions. Moreover, because of the monocentric and retrospective design of the study, our results are difficult to generalize, although in line with previous reports from other centers.^{27,28} Another limitation is the lack of information of levels and types of physical activities, as well as other life habits during the study periods, which may have influenced the clinical presentation and outcomes of patients. Finally, long-term outcomes beyond 30 days after surgery were not evaluated.

In conclusion, during the first wave of the COVID-19 pandemic, fewer patients with PAD but with a more severe clinical presentation were admitted for surgery, as compared to the same time frame in the previous two years, resulting in palliative care and primary amputations in some cases. Therefore, tailored guidelines are warranted

in the next future to provide appropriate care to this vulnerable population and avoid a large-scale disaster.

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