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Peripheral arterial occlusive disease prevalence in COVID-19 infection

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Abstract

Introduction: COVID-19 is a disease with many diverse manifestations, ranging from asymptomatic disease to mild symptoms, and more severely, thrombotic events, acute respiratory syndrome, and death. As our understanding for the disease evolved, it has become evident that widespread vascular coagulopathy and infection-triggered inflammatory escalations may be mechanisms that explain adverse outcomes such as respiratory failure and mortality.

Objective: To assess the peripheral arterial occlusive disease prevalence in covid-19 infection.

Methods: This is an observational, retrospective, single-center cohort study of patients with PAD admitted and treated at the Vascular and Surgery Department of Sher-E-Bangla Medical College Hospital, Barisal, Bangladesh June 2021 to 30 May 2023. Sixty (60) patients included in our study. Clinical characteristics, surgical treatments and outcomes of these subjects were compared to those of patients referred to our Institution during the same time. All patients signed the informed consent form for data collection and analysis. 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: A total of 60 subjects were included. Among covid-19 30(50%) and non-covid-19 30(50%). The number of admissions per 10-day period was significantly lower in compared to negative (6.7 ± 3.5 vs. 10.5 ± 4.6 , respectively; $P < 0.001$). Patients admitted in positive had a significantly lower BMI (kg/m²) (24.4 ± 4.4 vs. 26.3 ± 5.2 ; $P = 0.026$) and a significantly higher prevalence of COPD upon admission (26.7% vs. 10.0%; $P = 0.029$). A trend towards lower rates of primary hemodynamic success and higher rates of post-operative overall death was observed in positive compared to negative, but neither reached statistical significance. The rate of post-operative MACE was significantly higher in positive (10.0% vs. 3.3%; $P = 0.037$), while the rate of post-operative MALE and the duration of hospital stay were similar between groups. Show that covid-19 recovery rate 90% and death 10%.

Conclusion: During the first state of emergency for COVID-19 pandemic, 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.

Keywords: COVID-19, Undergoing Surgery, MACE.

Introduction

COVID-19 is a disease with many diverse manifestations, ranging from asymptomatic disease to mild symptoms, and more severely, thrombotic events, acute respiratory syndrome, and death. As our understanding for the disease evolved, it has become evident that widespread vascular coagulopathy and infection-triggered inflammatory escalations may be mechanisms that explain adverse outcomes such as respiratory failure and mortality. 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].

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Reports have suggested an increased incidence of acute extremity large vessel arterial occlusions with COVID-19 [6], which could result in limb loss. This led our team to investigate this phenomenon to assess common risk factors that could potentially lead to early screening for high-risk 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. This is particularly the case of subjects with chronic PAD. For these patients walking exercise is a first-line therapy [7]. 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 [8]. 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 [9]. Such conditions are also highly prevalent among patients with COVID-19, and are associated with poorer outcomes [10]. 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 [11]. We identified 9 patients who presented to our healthcare system emergency rooms between February and April of 2020 with lower or upper extremity large vessel arterial occlusion in the setting of COVID-19. Although current data do not confirm this concern [12, 13], 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.

Materials and Methods

This is an observational, retrospective, single-center cohort study of patients with PAD admitted and treated at the Vascular and Surgery Department of Sher-E-Bangla Medical College Hospital, Barisal, Bangladesh June 2021 to 30 May 2023. Sixty (60) patients included in our study. Clinical characteristics, surgical treatments and outcomes of these subjects were compared to those of patients referred to our Institution during the same time. All patients signed the informed consent form for data collection and analysis. 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. 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. 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 treatments were 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 courses were 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 re-vascularized limb or re-intervention on the re-vascularized segment. Major adverse cardiovascular events (MACE) were defined as cerebrovascular accident, myocardial infarction, or cardiovascular death.

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. 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. 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<0.05 was considered to be statistically significant. Statistic computations were performed with SPSS software version 20.

Results

A total of 60 subjects were included. Among covid-19 30(50%) and non-covid-19 30(50%). The number of admissions per 10-day period was significantly lower in compared to negative (6.7 ± 3.5 vs. 10.5 ± 4.6 , respectively; $P < 0.001$). Patients admitted in positive 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 (26.7% vs. 10.0%; $P = 0.029$). The ASA score was significantly higher in positive (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 positive patients (43.3% vs. 23.3%; $P = 0.029$), while the use of statins (46.7% vs. 63.3%; $P = 0.048$) and anti-hypertensive drugs (53.3% vs. 73.3%; $P = 0.020$) was less frequently reported in this group.

Table 1: Distribution of Covid and non-covid-19 patients (N=60)

	Upper limb (30)	lower limb (30)
	N (%)	N (%)
Covid-19	13(43.3%)	17(56.7%)
Non-Covid-19	9(30.0%)	21(70.0%)

Table 2: Patients' characteristics (N=60)

	Covid-19	Non-Covid-19	Total	p-value
	N (%)	N (%)	N (%)	
Total number of patients	30	30	60	
Number of patients per 10-day period (\pm SD)	6.7 (3.5)	10.5 (4.6)		< 0.001*
Male gender	20(66.7%)	21(70.0%)	41(68.3%)	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	23(76.7%)	24(80.0%)	47(78.3%)	0.87
Tobacco use	24(80.0%)	23(76.7%)	47(78.3%)	0.69
Current	15(50.0%)	16(53.3%)	31(51.7%)	0.86
Former	9(30.0%)	8(26.7%)	17(28.3%)	0.57
Never	6(20.0%)	7(23.3%)	13(21.7%)	0.69
Diabetes	9(30.0%)	12(40.0%)	21(35.0%)	0.27
Dyslipidemia	17(56.7%)	19(63.3%)	36(60.0%)	0.50
Chronic renal disease	3(10.0%)	5(16.7%)	8(13.3%)	0.36
COPD	8(26.7%)	3(10.0%)	11(18.3%)	0.029*
Cardiac disease	20(66.7%)	15(50.0%)	35(58.3%)	0.081
Coronary artery disease	14(46.7%)	11(36.7%)	25(41.7%)	0.38
Heart valve disease	4(13.3%)	3(10.0%)	7(11.7%)	0.92
Arrhythmia	8(26.7%)	7(23.3%)	15(25.0%)	0.64
Cerebrovascular disease	5(16.7%)	6(20.0%)	11(18.3%)	0.59
Treatment at admission				
Anticoagulation	13(43.3%)	7(23.3%)	20(33.3%)	0.029*
Antiplatelet therapy	23(76.7%)	24(80.0%)	47(78.3%)	0.63
Statin	14(46.7%)	19(63.3%)	59(55.0%)	0.048*
Antihypertensive drugs	16(53.3%)	22(73.3%)	38(63.3%)	0.020*
ASA Score (\pm SD)	3.13 (0.52)	2.90 (0.47)		0.015*
COVID-19 test positive at admission	2(6.7%)	NA	02 (3.3%)	NA

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

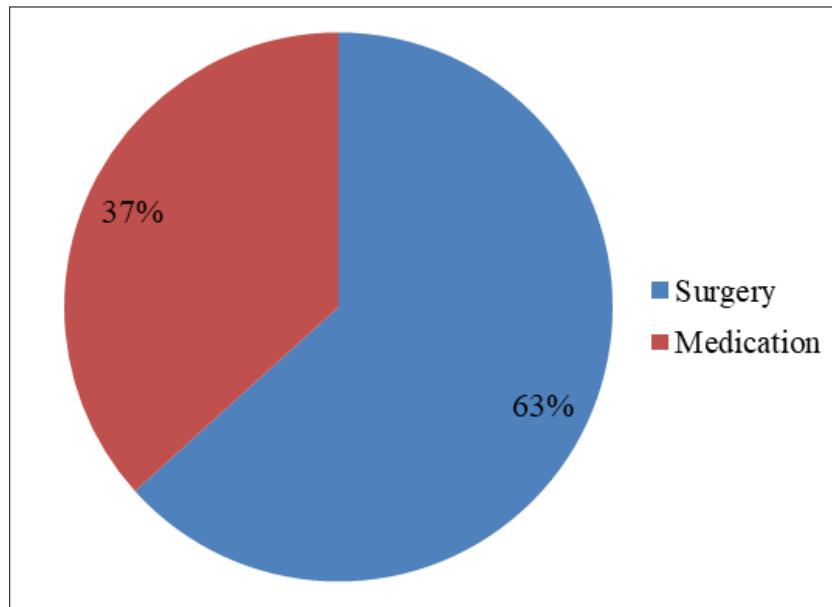
Table 3: Indications for hospital admission (N=30)

	Covid-19 Positive (30)	Covid-19 Negative (30)	p-value
Acute limb ischemia	14 (46.7%)	8 (26.7%)	0.006*
Acute limb ischemia 30-day period (\pm SD)	9.5 (0.7)	7.8 (2.6)	<0.001*
Rutherford I	6/14 (42.9%)	3/8 (37.5%)	0.051
Rutherford II a	4/14 (28.6%)	2/8 (25.0%)	0.29
Rutherford II b	3/14 (21.4%)	3/8 (37.5%)	0.81
Rutherford III	1/14 (7.1%)	0/8 (0%)	NA
Chronic PAD	16 (53.3%)	23 (76.7%)	0.006*
Fontaine I-II	5/16 (31.3%)	12/23 (52.2%)	0.010*
Fontaine III-IV	11/16 (68.8%)	11/23 (47.8%)	0.93
Fontaine I-II per 30-day period (\pm SD)	3.5 (0.7)	12.5 (6.4)	<0.001*
Fontaine III-IV per 30-day period (\pm SD)	7.0 (1.)	11.3 (3.4)	< 0.001*

PAD, peripheral arterial disease; SD, standard deviation.

In positive was nearly doubled that of the same period in negative (46.7% vs. 26.7%, respectively; P=0.006). The absolute number of patients with ALI per 30-day period admitted in positive was also significantly higher than in negative (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 positive (7.1% vs. none) was observed.

Overall, the percentage of patients admitted for chronic PAD was significantly lower in positive compared to negative (73.3% vs. 76.7%, respectively; P=0.006). Data show a trend towards higher percentage of patients admitted for chronic PAD Fontaine stages III-IV in positive (68.8% vs. 47.8%; P=0.11), however absolute number of such patients per 30-day period was significantly lower than in negative (7 ± 1.4 vs. 11.3 ± 3.4 ; P<0.001). Figure-1 show medication 37% and surgery 63%.

**Table 4:** Treatment features (N=60)

	Covid-19 Positive (30)	Covid-19 Negative (30)	p-value
Hybrid	9(30.0%)	7(23.3%)	0.43
Endovascular	10(33.3%)	12(40.0)	0.47
Open	8(26.7%)	11(36.7)	0.15
Palliative care	2(6.7%)	0(0%)	NA
Primary amputation	1(3.3)	0(0%)	NA
Duration of intervention (min) (\pm SD)	128 (69)	125 (66)	0.81
Procedural success	26(86.7%)	28(93.3%)	0.13
Intra-operative death	0	0	

SD, standard deviation.

Overall, types of surgeries were similar between positive and negative. A trend towards less open surgery was observed in positive patients. A total of 4 patients (13.3%) were managed with palliative care (2 patients) or primary amputation (1 patient). 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 positive and negative (86.7% vs. 93.3%, respectively; P = 0.13).

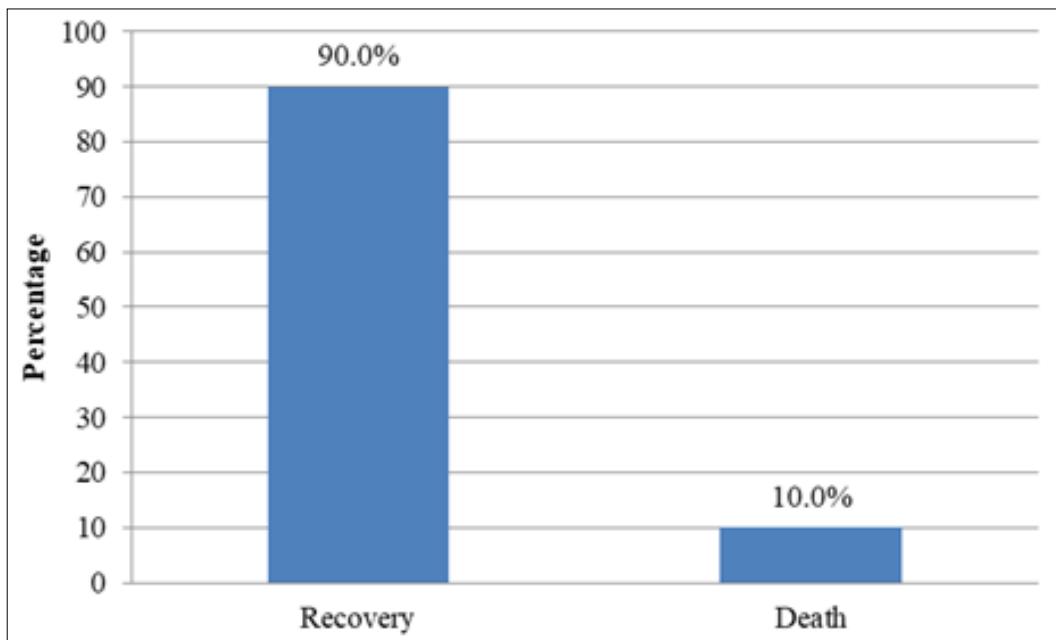
Table 5: Post-operative 30 days course (N=60)

	Covid-19 Positive (30)	Covid-19 Negative (30)	p-value
Hemodynamic success	22(73.3%)	25(83.3%)	0.075
LOS (\pm SD)	11.5 (11.8)	8.8 (7.5)	0.18
Post-operative death	3(10.0%)	1(3.3%)	0.079
MACE	3(10.0%)	1(3.3%)	0.037*
Cardiovascular death	1(3.3%)	1(3.3%)	NA
MI	2(6.7%)	0	NA
MALE	8(26.7%)	7(23.3%)	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, re-intervention, occlusion of re-vascularized segment); SD, standard deviation.

A trend towards lower rates of primary hemodynamic success

and higher rates of post-operative overall death was observed in positive compared to negative, but neither reached statistical significance. The rate of post-operative MACE was significantly higher in positive (10.0% vs. 3.3%; P 0.037), while the rate of post-operative MALE and the duration of hospital stay were similar between groups (Table-5). Figure-2 show that covid-19 recovery rate 90% and death 10%.

**Fig 2:** Distribution of recovery and death.

Discussion

The majority of our patients had associated comorbidities with hypertension and obesity being the most common. Most patients also had typical pulmonary findings of COVID pneumonia in the visualized lung bases. The length of arterial occlusion did not correlate with the severity of pneumonia. All patients with lower extremity arterial occlusions had at least one occlusive segment longer than 10 cm which was readily apparent on all multiplanar reformats as well as volume rendered imaging. A total of 60 subjects were included. Among covid-19 30(50%) and non-covid-19 30(50%). The number of admissions per 10-day period was significantly lower in compared to negative (6.7 ± 3.5 vs. 10.5 ± 4.6 , respectively; $P < 0.001$). Patients admitted in positive had a significantly lower BMI (kg/m²) (24.4 ± 4.4 vs. 26.3 ± 5.2 ; $P = 0.026$) and a significantly higher prevalence of COPD upon admission (26.7% vs. 10.0%; $P = 0.029$). The ASA score was significantly higher in positive (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 positive patients (43.3% vs. 23.3%; $P = 0.029$), while the use of statins (46.7% vs. 63.3%; $P = 0.048$) and anti-hypertensive drugs (53.3% vs. 73.3%; $P = 0.020$) was less frequently reported in this group. We found that pre-existing calcific atherosclerotic disease is not a necessary factor in the development of COVID related arterial occlusion. Present study showed significantly decreased overall PAD patient admission in positive patients. 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 [8, 17-21]. A trend towards lower rates of primary hemodynamic success and higher rates of post-operative overall death was observed in positive compared to negative, but neither reached statistical significance. The rate of post-operative MACE was significantly higher in positive (10.0% vs. 3.3%; $P = 0.037$), while the rate of post-operative MALE and the duration of hospital stay were similar between groups. In our study, covid-19 recovery rate 90% and death 10%. 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. A trend towards lower rates of primary hemodynamic success and higher rates of post-operative overall death was observed in positive compared to negative, but neither reached statistical significance. The rate of post-operative MACE was significantly higher in positive (10.0% vs. 3.3%; $P = 0.037$), while the rate of post-operative MALE and the duration of hospital stay were similar between groups. Figure show that covid-19 recovery rate 90% and death 10%. Although not statistically significant, a trend toward higher rates of post-operative death were 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 relative and absolute over-representation of patients with ALI was observed in positive, corroborating previous findings by colleagues in Northern Italy [22]. 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 patient's stages III-IV, who were significantly underrepresented in positive patients, 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. This was not the case in the previous two years, when no patient was referred to our department with similar clinical status. 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. 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. This may be attributable to patients' comorbidities and clinical status, as well as to suboptimal medical treatment upon surgery. These aspects are in line with previous reports and studies both in the setting of vascular surgery [23, 24], and other specialties [25-27]. In the next future to provide appropriate care to this vulnerable population and avoid a large-scale disaster. 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 [28]. 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 [26, 27]. 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.

Conclusion

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

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