

# Optimizing Peripandemic Care for Veteran Major Non-Traumatic Lower Extremity Amputees: A Proposal Informed by a National Retrospective Descriptive Analysis of COVID-19 Risk Factor Prevalence

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## ABSTRACT

### Introduction

In response to the Coronavirus 2019 (COVID-19) pandemic, vascular surgeons in the Veteran Affairs Health Care System have been undertaking only essential cases, such as advanced critical limb ischemia. Surgical risk assessment in these patients is often complex, considers all factors known to impact short- and long-term outcomes, and the additional risk that COVID-19 infection could convey in this patient population is unknown. The European Centre for Disease Prevention and Control (ECDC) published risk factors (ECDC-RF) implicated in increased COVID-19 hospitalization and case-fatality which have been further evidenced by initial reports from the United States Centers for Disease Control and Prevention. CDC reports additionally indicate that African American (AA) patients have incurred disparate infection outcomes in the United States. We set forth to survey the Veterans Affairs Surgical Quality Improvement Program (VASQIP) database over a nearly 20 year span to inform ongoing risk assessment with an estimation of the prevalence of ECDC-RF in our veteran critical limb ischemia population and investigate whether an increased COVID-19 comorbidity burden exists for AA veterans presenting for major non-traumatic amputation.

### Materials and Methods

The VASQIP database was queried for all above knee amputation (AKA) and below knee amputation (BKA) completed 1999–2018 after IRB approval (MIRB:#02507). Patient race and ECDC-RF including male gender, age > 60 years, smoking status, hypertension, diabetes, chronic obstructive pulmonary disease, cancer, and cardiovascular disease were recorded from preoperative patient history. AKA and BKA cohorts were compared via  $\chi^2$ -test with Yates correction or unpaired *t*-test and a subgroup analysis was conducted between AA and all other race patients for COVID-19 comorbidities in each cohort.

### Results

VASQIP query returned 50,083 total entries. Average age was  $65.1 \pm 10.4$  years and  $68.2 \pm 10.5$  years for BKA and AKA cohorts, respectively, ( $P < .0001$ ) and nearly all patients were male (99%). At least one ECDC-RF comorbidity was present in 25,526 (88.7%) of BKA and 17,558 (82.4%) of AKA patients ( $P < .0001$ ). AA BKA patients were significantly more likely than non-AA BKA patients to present with at least one ECDC-RF comorbidity ( $P = .01$ ).

### Conclusions

According to a large national Veterans Affairs database, there are high rates of ECDC-RF in veteran amputees. During the present crisis, management of these patients should incorporate telehealth, expedient discharge, and ongoing COVID-19 transmission precautions.

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## INTRODUCTION

Around 2.2 million amputees live in the United States today, 64.2%, or 1.4 million, with a lower limb amputation.<sup>1</sup> Annu-

ally >150,000 non-traumatic lower extremity amputations are performed, over a third of which are major below knee amputation (BKA) or above knee amputation (AKA).<sup>2</sup> Vascular surgeons are among those primarily responsible for the perioperative care and long-term recovery of these patients.

Optimum perioperative care for these patients becomes more complex in the setting of a national healthcare emergency as embodied by the current Coronavirus 2019 (COVID-19) pandemic. Surgical triage guidelines released by the American College of Surgeons have made it clear that emergent amputation, whether necessitated due to infection, necrosis, or non-salvageable lower extremity disease, is among the procedures that should never be postponed.<sup>3</sup> Vascular surgeons commonly undertake complex perioperative risk assessment in patients undergoing non-

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traumatic amputations due to associated comorbid conditions. As the COVID-19 crisis will continue to impact healthcare facilities for some time to come, the formation of a consensus regarding recommended perioperative interdisciplinary care, discharge, and rehabilitation for these patients in the context of this crisis should be considered. Ideally, these considerations should reflect the prevalence of risk factors for COVID-19 progression in this unique patient population.

The first major analysis of risk factors for severe COVID-19 outcomes was conducted during the virus' initial spread, in a cohort of >40,000 confirmed cases, in Wuhan, China.<sup>4</sup> After the virus spread through Europe, the European Centre for Disease Prevention and Control (ECDC) confirmed these risk factors (ECDC-RF) by reviewing cases across 14 countries, including Germany, Italy, and Spain. Significant increases in hospitalization and case-fatality rates were found for patients with certain comorbidities and demographics including older patient age (starting at age 60 years), male gender, and presence of comorbid hypertension, diabetes, cancer, cardiovascular, or respiratory disease. Smoking status was noted as a potential risk factor with more limited evidence.<sup>5</sup> A report from the United States Centers for Disease Control confirmed that 94% of initial COVID-19 related deaths in the United States had occurred in patients with at least one underlying health condition or risk factor.<sup>6</sup>

In the United States, race may be an additional risk factor for adverse COVID-19 infection outcomes. In a recent survey of hospitalizations across 14 states, African American (AA) patients comprised 33% of COVID-19 hospitalizations despite only making up 18% of the study population.<sup>7</sup> Analysis to date suggests that disparities in both socioeconomic factors and the prevalence of high risk comorbidities may play a role in the disparate death rates of AA patients.<sup>8</sup> It has not been ascertained whether the prevalence of COVID-19 high risk comorbidities differ significantly by race in the veteran amputee population.

In our experience, many of the risk factors now understood to confer high risk for COVID-19 progression with infection are common comorbidities in patients undergoing non-traumatic lower extremity amputation in the Veteran Affairs Health Care System. Determining the prevalence of COVID-19 risk factors in veterans undergoing non-traumatic amputation due to critical limb ischemia can inform current triage efforts to balance prevention of viral transmission in the setting of maintaining appropriate standard of care. Descriptive retrospective analyses can be specifically and expediently conducted for vulnerable surgical populations utilizing large surgical quality improvement databases while more definitive outcomes-based studies are pursued. The Veterans Affairs Surgical Quality Improvement Program (VASQIP) database was developed as a nationwide effort to ensure quality surgical care for veterans, containing entries representing a nationwide sampling of surgical cases at Veterans Affairs Medical Centers. Cases abstracted on an 8-day cycle act as a representative sample of the cases performed at each hospital, with trained medical personnel recording case

data for >200 variables including the preoperative conditions and demographics that have been published to date as severe COVID-19 progression risk factors.<sup>9,10</sup>

We set forth to survey preoperative history for all BKA and AKA procedures in the VASQIP database over a nearly 20-year period to generate a reliable estimate of COVID-19 risk factor prevalence in this potentially vulnerable veteran patient population and investigate whether AA veterans undergoing major non-traumatic lower extremity amputation may be presenting with disparate COVID-19 comorbidity burdens.

## METHODS

### *Data Sources and Sample Population*

After obtaining institutional review board approval from the Central Virginia Veterans Affairs Health Care System (#02507), the VASQIP database was queried for all below (BKA; CPT codes 27880, 27881, 27882, 27884, 27886) and above knee amputations (AKA; Current Procedural Technology (CPT) codes 27590, 27591, 27592, 27594, 27596) at all veteran healthcare centers from 1999 to 2018. Data received were de-identified, with each entry representing a unique procedure rather than a unique patient. All variables were obtained from the national database warehouse and downloaded per institutional guidelines for analysis.

## MEASURES

All ECDC-RF were investigated from routinely listed VASQIP preoperative variables. Male gender, age >60 years, and preoperative smoking history were noted for each procedure. Abstracted data are defined as follows: hypertension included all patients with chronic hypertension as well as patients with hypertension reported within 30 days of amputation; chronic obstructive pulmonary disease (COPD) was singularly reported and recorded to reflect comorbid chronic respiratory disease; diabetes was inclusive of patients with diabetes managed with oral medication or insulin; cancer included patients who had been treated with chemotherapy within 30 days of surgery or who had disseminated cancer diagnosis documented prior to or during surgery; and cardiovascular disease included patients with preoperative history of congestive heart failure, angina, and/or myocardial infarction. Patient race, self-selected by patients using options defined by the VASQIP database (AA versus all other race categories), was additionally recorded for use in a descriptive subgroup analysis.

## ANALYSIS

Procedural entries were separated into cohorts by amputation level (BKA versus AKA) and descriptive statistics were used to characterize these cohorts respectively. Subgroup analysis of patients by race was also performed, comparing AA patients (AA) to patients of all other races combined.  $\chi^2$ -

**TABLE 1.** Prevalence of COVID-19 Progression Risk Factors in Presenting Veteran Major Lower Extremity Amputation Patients

COVID-19 progression risk factors as recorded in preoperative history	BKAs 1999–2018 n = 28,768		AKAs 1999–2018 n = 21,315		P-value
	Patient count	Not reported	Patient count	Not reported	
Male	28,470 (99%)	0	21,050 (98.8%)	0	.0329
Age 60+	20,115 (7.0%)	0	<b>16,819 (78.9%)</b>	0	<.0001
Smoker (current or past)	12,630 (44.0%)	66	<b>11,019 (51.9%)</b>	93	<.0001
Presence of any COVID-19 comorbidity	<b>25,526 (88.7%)</b>	0	17,558 (82.4%)	0	<.0001
Diabetes	<b>20,498 (71.4%)</b>	73	10,817 (51.0%)	89	<.0001
Cardiovascular disease	4,423 (15.4%)	1	3,385 (15.9%)	1	.1257
Hypertension	<b>16,372 (56.9%)</b>	606	11,164 (52.4%)	834	<.0001
COPD	4,802 (16.7%)	1	<b>4,966 (23.3%)</b>	2	<.0001
Cancer	312 (1.1%)	0	<b>380 (1.8%)</b>	3	<.0001

A comparison of COVID-19 risk factor prevalence between all presenting non-traumatic AKA and BKA recorded in the VASQIP database from 1999 to 2018. Bold text indicates a significant difference and the respective highest value between cohorts.

**TABLE 2.** Comparison of COVID-19 Progression Risk Factors In Presenting Veteran BKA Patients by Race

COVID-19 risk factor	AA BKA n = 7,237	Non-AA BKA n = 21,531	P-value
Hypertension	<b>4,259 (58.9%)</b>	12,113 (56.2%)	<b>.0001</b>
Diabetes	5,203 (71.9%)	15,295 (71.0%)	.1679
COPD	854 (11.8%)	<b>3,948 (18.3%)</b>	<b>.0001</b>
Cancer	81 (1.1%)	231 (1.1%)	.7918
Cardiovascular disease	1,055 (14.6%)	<b>3,368 (15.6%)</b>	<b>.0313</b>
Presence of any comorbidity	<b>6,479 (89.5%)</b>	19,047 (88.5%)	<b>.0142</b>

All patients presenting for non-traumatic BKA recorded in the VASQIP database from 1999 to 2018 were divided into two groups—AA versus all other races (non-AA). The prevalence of published risk factors for COVID-19 progression as recorded in preoperative history were compared between these two groups to investigate whether AA patients in the BKA population may face disparate risks to COVID-19 based on comorbidity burden alone.

Bold text indicates a significant difference and the respective highest value between cohorts.

test with Yates correction was utilized to assess differences of categorical data between cohorts and average cohort age was compared using an unpaired *t*-test (QuickCalcs v2018, GraphPad Software, San Diego, CA, USA).

**RESULTS**

A total of 50,083 lower extremity amputations were identified in the VASQIP database from 1999 to 2018 at 86 Veteran Affairs Health Care Centers, representing 28,768 BKA and 21,315 AKA procedures, respectively. Average sample age was 65.1 ± 10.4 years versus 68.2 ± 10.5 years for the BKA and AKA cohorts, respectively (*P* < .001). Prevalence of ECDC-RF was examined in both cohorts (Table 1). BKAs were more likely to present as emergent with 2,879 emergent cases (10%) as compared to 1,893 emergent AKA procedures (8.9%), *P* < .001.

AA patients represented 25.2% (n = 7,237) of BKAs and 26.0% (n = 5,547) of AKAs, respectively (*P* = .03). In patients that underwent BKA, AA patients (n = 6,479, 89.5%) were more likely to have one or more ECDC-RF compared to non-AA patients (n = 19,047, 88.5%), *P* = .014, as shown in Table 2. This trend was reversed in the AKA cohort (Table 3).

**DISCUSSION**

In a retrospective cohort study using nationwide data from a Veterans Affairs Surgical Quality Improvement database, a significant proportion of veterans requiring non-traumatic lower extremity amputations were found to have one or more comorbidities that have been definitively associated with elevated rates of COVID-19 hospitalization and case fatality.

Between 40 and 50% of presenting lower extremity amputation patients reported positive current or past smoking status, well beyond the prevalence of smoking in the general United States population.<sup>11</sup> While smoking is itself a risk factor for many of the comorbidities linked to COVID-19, no independent correlation between smoking status and COVID-19 infection severity has been definitively established to date.<sup>12,13</sup> Regardless of whether smoking status is definitively linked to COVID-19 progression, such a high prevalence of smoking history in this population underscores the importance of counseling these patients regarding smoking cessation to positively influence postoperative outcomes and the trajectory of chronic comorbidities.

A quarter of the veterans who presented for amputation from 1999 to 2018 were AA. This is much greater than the proportion of AA patients in the national male veteran pop-

**TABLE 3.** Comparison of COVID-19 Progression Risk Factors In Presenting Veteran AKA Patients by Race

COVID-19 risk factor	AA AKA n = 5,547	non-AA AKA n = 15,768	P-value
Hypertension	<b>2,976 (53.7%)</b>	8,188 (51.9%)	<b>.0282</b>
Diabetes	2,716 (49.0%)	8,101 (51.4%)	.1302
COPD	947 (17.1%)	<b>4,019 (25.5%)</b>	<b>.0001</b>
Cancer	104 (1.9%)	276 (1.8%)	0.5866
Cardiovascular disease	847 (15.3%)	2,538 (16.1%)	0.1536
Presence of any comorbidity	4,470 (80.6%)	<b>13,088 (83.0%)</b>	<b>.0001</b>

All patients presenting for non-traumatic AKA recorded in the VASQIP database from 1999 to 2018 were divided into two groups—AA versus all other races (non-AA). The prevalence of published risk factors for COVID-19 progression as recorded in preoperative history were compared between these two groups to investigate whether AA patients in the BKA population may face disparate risks to COVID-19 based on comorbidity burden alone.

Bold text indicates a significant difference and the respective highest value between cohorts.

ulation treated at Veterans Affairs facilities overall, recently estimated at 10.7%, making race as a potential COVID-19 progression factor in the veteran critical limb ischemia population especially concerning.<sup>14</sup> Hypertension and diabetes were the two most prevalent comorbidities in all cohorts regardless of race. In both BKA and AKA cohorts, AA veterans showed elevated prevalence of hypertension and decreased prevalence of COPD when compared to veterans of all other races combined. While veteran AA patients were found to have a significantly higher prevalence of one or more ECDC-RF comorbidities in the BKA cohort, the opposite was found to be true in the AKA cohort. While these differences were statistically significant, they reflect only slight differences in prevalence and most likely confer no differential clinical significance. Accordingly, the recommendations suggested by these authors for peripandemic care are universal to all veteran amputees without regard to race. As disparities in outcomes relate to more factors than comorbidities alone, peripandemic outcomes in veteran amputees should nonetheless be monitored for potential racial disparities as data becomes available.

### Implications for Emergent Amputation

Consideration of comorbid respiratory disease, cardiovascular disease, diabetes, hypertension, and cancer have long been part of the risk assessment conducted as standard of care in emergent amputations.<sup>15</sup> These comorbidities should be assumed to convey additional risk during risk assessment for presenting patients who may be infected with COVID-19. In the context of the current pandemic, screening for COVID-19 has been recommended in all patients prior to surgery and all staff members are required to wear appropriate protective equipment during any aerosol generating procedures.<sup>16</sup> Additional precautions must be taken for known COVID-19 positive patients requiring surgery.<sup>17</sup> During the national response to COVID-19, preoperative testing may not be a feasible and well applied standard, making risk assessment in the setting of a pandemic even more crucial for surgeons undertaking lower extremity amputations in this high-risk population. In emergent amputation, if there is insufficient time to receive test results, surgery and recovery should

proceed under the same precautions as if the patient were positive for COVID-19.

Based on the high prevalence of COVID-19 hospitalization and case-fatality risk factors in this population, expedient discharge should also be prioritized in any amputation patients to both minimize the opportunity for these patients to contract COVID-19 during their hospital stay and maintain bed capacity. Reverse triage, a model developed in emergency medicine for increasing hospital capacity during times of crisis, discharges patients who have not required any critical intervention for 4 days. This model has been used to prioritize patients that should remain in the hospital when beds are limited.<sup>18</sup> Development of a modified reverse triage approach for amputation patients is not the solution, but should be considered as an effective measure for the vascular surgeon to advocate for disposition of this at risk population.

### Implications for Postsurgical Care and Rehabilitation

Efforts to limit nosocomial spread of COVID-19 will be ongoing in hospitals, rehabilitation centers, and assisted living facilities for some time, including aggressive restrictions on patients, visitors, and health professionals with even mild symptoms of respiratory infection.<sup>19,20,21</sup> Regardless of the status of state-level stay at home orders, based on our data on COVID-19 risk factors in the veteran amputee population, we believe veteran amputees are at a much higher risk for complications and negative outcomes if infected with COVID-19 than the general population. Efforts to eliminate unnecessary hospital visits should be undertaken until the risk of viral transmission is considered minimal. When hospital visits cannot be reasonably circumvented to provide appropriate care, front desk screening protocols for COVID-19 reflecting universal precautions and procedures should be utilized to ensure patient safety.<sup>22</sup>

Postsurgical follow-up should continue to be accomplished through telehealth when possible during this crisis to limit the possibility of these patients contracting COVID-19. The Veterans Affairs Administration has extensive experience and expertise in medical telehealth services and has employed

telehealth in previous times of crisis for vulnerable patient populations.<sup>23,24,25</sup> Due to their high risk, all amputees should be counseled on proper sanitation, the importance of social distancing, and monitored for sudden changes or advancement of existing respiratory disease. During postsurgical follow-up it will also be imperative to monitor for possible COVID-19 symptoms as an addition to the standard of care.

Current clinical practice guidelines for amputation rehabilitation specify that rehabilitation should be undertaken in an inpatient rehabilitation facility unless a skilled nursing facility is required for patient safety.<sup>26</sup> Amputation patients carry a potential and significant risk for vectoring COVID-19 into the home and rehabilitation environment due to the need to aggressive convalesce these patients. The effect of extending COVID-19 into these additional para-healthcare facilities could potentially cause unforeseen extension into the community to potential other patients who have similar vulnerable risk factors for adverse outcomes. While reports of Coronavirus spread in nursing homes in the United States are only starting to become published in medical literature, news reports suggest that nursing home deaths account for a large proportion of the total COVID-19 death toll in the United States and may be grossly underestimated worldwide.<sup>27,28</sup> In order to minimize risk to patients, Veterans Affairs facilities are currently placing patients only at internally operated rehabilitation facilities and nursing homes. It is our recommendation that these particularly at risk patients should be among those prioritized for relocation should an outbreak occur at any of these facilities and receive regular routine testing for COVID-19 status even when asymptomatic.

Surgeons should also be ready to counsel patients on how the current COVID-19 crisis may delay the ability for patients to receive prosthetics and undergo physical rehabilitation. There are already some international reports that balancing COVID-19 precautions with ending non-emergent hospital visits has impacted prosthetic fittings.<sup>29</sup> In the United States, prosthetic and orthotic facilities are considered essential healthcare services and the face-to-face requirements usually required for the replacement of prosthetics have been waived for Medicare recipients.<sup>30,31</sup> In Veterans Affairs facilities, outpatient services and care coordination by vendors and contractors are locally determined by VA facility directors. Should prosthetics delivery be delayed, patients should be given exercises that have been shown to improve long-term functional outcomes.<sup>32</sup>

Rehabilitation of mobility after amputation has long been recognized as one of the most important components of optimizing quality of life for amputees.<sup>33</sup> Social integration relates to regaining function in these patients as well.<sup>34</sup> Social distancing requirements may negatively impact both rehabilitation and the mental well-being of recovering amputees, making the environment these patients return to a crucial consideration of their overall transdisciplinary plan. In contrast to following, a universal strategy where economic factors tend to guide early and aggressive patient placement, early placement in rehabilitation facilities should be prioritized for

patients confirmed free of COVID-19 infection as a mortality reduction measure. While patients who are COVID-19 positive should not be discharged into the rehabilitation environment until they are both asymptomatic and test-negative, rehabilitation efforts that include resumption of virtual social contacts should be initiated in the hospital environment until these patients can be safely discharged.

### **Study Limitations**

The present study was conducted retrospectively in the national veteran population for the purposes of informing perioperative care for patients at Veterans Affairs and Department of Defense facilities. As the general demographics and prevalence of comorbidities are known to differ between the veteran and general populations, our findings should not be taken to apply to the general population.<sup>35</sup> A similar accounting of COVID-19 risk factor prevalence could be conducted in other large surgical quality improvement databases to characterize special surgical populations in general population and inform proposals for peripandemic care for these patients specifically. Since the veteran population is predominantly male, and male gender has been linked to higher rates of COVID-19 progression, the veteran amputee community may be more vulnerable than the amputee community in the general population.

This survey of VASQIP data offers a snapshot that is representative of the average age and risk factor burden of all patients at the time of presentation for amputation. While re-amputation within 30 days is recorded in entries as 30 day operating room return, re-amputation beyond 30 days could conceivably result in a separate VASQIP entry. It should be noted that data from the VASQIP database provides a representative sample rather than representing all cases performed. While as many as a quarter of patients would be expected to present for re-amputation based on previously published rates of lower limb re-amputation in veterans and Medicare beneficiaries, because VASQIP entries arise from a random sampling of all surgical cases performed at a particular facility the odds that any patient would be selected multiple times for inclusion in the database is minimal.<sup>36,37</sup> Nonetheless, lacking access to unique patient identifiers which could be used to bar inclusion of re-amputation entries altogether is a major limitation of this study. The VASQIP database does not include patients from the same population who received their amputations outside Veterans Affairs facilities.

### **Potential Applicability of Frailty Scores**

While risk assessment has always been conducted in all surgical fields, the recent development of standardized frailty indicators may be particularly relevant in a pandemic that primarily impacts elderly patients with health comorbidities. The risk factors for COVID-19 assessed in the present study bear similarity to many of the factors assessed in surgical frailty scores including the Risk Assessment Index and NSQIP risk calculator.<sup>38,39</sup> Future studies should be conducted to determine whether scoring systems that have been predictive

of postsurgical outcomes have additional predictive value in predicting the severity of infectious disease in vulnerable patient populations including those with critical lower limb ischemia.

## CONCLUSIONS

According to a survey of preoperative history in the national VASQIP database, risk factors for COVID-19 hospitalization and case-fatality are highly prevalent across the veteran non-traumatic amputee population. The predominance toward advanced age in this patient population puts these patients at especially high risk should they contract the virus. Until the pandemic is abated, telehealth should be utilized for routine follow-ups following amputation and postoperative care should include screening for upper respiratory symptoms. Expedient postamputation discharge is recommended to protect these patients. Surgeons should also keep in mind how rehabilitation of these patients may be impacted by the current crisis.

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