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ORIGINAL ARTICLE

Early Outcomes in Major Amputations of Patients with Peripheral Arterial Disease of Lower Limbs: A Study in a Referral Hospital in Medellín, Colombia

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ABSTRACT

Introduction: Major amputation is a significant intervention in advanced stages of peripheral arterial disease (PAD) and has important morbidity and mortality rates. Despite being a frequently performed procedure in Colombia, local statistics on its frequency and outcomes are not available.

Objectives: To analyze the morbidity and mortality in patients with lower limb PAD during the 30 days following major amputation or during the index hospitalization. To identify factors related to the outcome and characterize the population.

Methods: A retrospective study of patients with lower limb PAD who underwent major amputation for acute ischemia (AI) or chronic limb-threatening ischemia (CLTI) between March 2011 and December 2019 at Hospital Universitario San Vicente Fundación in Medellín, Colombia (HUSVF). Variables related to the underlying disease and perioperative morbidity were calculated in a general analysis and by groups, according to the level of amputation.

Results: A total of 558 major amputations were performed, 83.5% for CLTI. The overall mortality rate was 14.7%, with 32.6% in AI and 11.2% in CLTI. The most frequent complication was delirium (28.8%). After multivariate analysis, no influential factors were identified for fatal outcomes, except for cardiovascular complications in AI.

Conclusions: In this study, the only variable related to early mortality was cardiovascular complications in patients with AI. The percentages of heart disease are lower compared to those reported in studies from other countries. The most common complication was delirium.

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ARTÍCULO ORIGINAL

Desenlaces tempranos en amputación mayor de pacientes con enfermedad arterial periférica de miembros inferiores. Estudio en un hospital de referencia en Medellín, Colombia

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RESUMEN

Introducción: la amputación mayor es una herramienta relevante en grados avanzados de la enfermedad arterial periférica (EAP) y tiene tasas importantes de morbimortalidad. Aun siendo un procedimiento que se realiza frecuentemente en Colombia, no se dispone de estadísticas locales sobre su frecuencia y resultados.

Objetivos: analizar la morbimortalidad en los pacientes con EAP de miembros inferiores durante los 30 días siguientes a la amputación mayor o durante la hospitalización índice. Determinar los factores relacionados con el desenlace y caracterizar la población.

Métodos: estudio retrospectivo de pacientes con EAP de miembros inferiores que fueron llevados a amputación mayor por isquemia aguda (IA) o isquemia crónica que amenaza la extremidad (ICAE), entre marzo del 2011 y diciembre del 2019 en el Hospital Universitario San Vicente Fundación de Medellín, Colombia (HUSVF). Se calcularon las variables relacionadas con la enfermedad de base y morbilidad perioperatoria en un análisis general y por grupos, de acuerdo con el nivel de amputación.

Resultados: se realizaron 558 amputaciones mayores, 83,5% por ICAE. La mortalidad global fue del 14,7%, del 32,6% en la IA y del 11,2% en la ICAE. La complicación más frecuente fue el *delirium* (28,8%). Tras el análisis multivariado no hubo factores influyentes en el desenlace fatal, salvo las complicaciones cardiovasculares en la IA.

Conclusiones: en este estudio la única variable relacionada con la mortalidad temprana fueron las complicaciones cardiovasculares en pacientes con IA. Los porcentajes de cardiopatía son menores respecto a los reportados en estudios de otros países. La complicación más frecuente fue el *delirium*.

INTRODUCTION

Peripheral Arterial Disease (PAD) is defined by the presence of single or multiple stenoses or occlusions, leading to a reduction or cessation of anterograde flow in the principal arteries (1). The clinical manifestation can be either acute or chronic, depending on whether the duration of symptoms is shorter or longer than two weeks (2). Within chronic PAD, chronic limb-threatening ischemia (CLTI) represents the most severe form and accounts for 11% of cases (3). Although there are multiple causes, embolism in acute PAD and atherosclerosis in chronic PAD explain the majority of cases (4).

Globally, it is estimated that there are 202 million people with chronic PAD of the lower limbs. These patients exhibit twice as many coronary events compared to the general population, along with high rates of mortality in the short, medium, and long term (5-7).

Despite the availability of medical and revascularization treatments for managing PAD in the lower limbs, major amputation (performed above the ankle) remains a commonly used therapeutic option in advanced stages of the disease. In the United States, this procedure is conducted in 6.8% of hospitalized PAD patients, and this proportion increases to between 15% and 20% for those diagnosed with CLTI. There are high rates of perioperative complications and a 40.4% mortality rate within one year (4,8-9).

In terms of factors associated with early mortality, the literature describes a broad variety. These include hypoalbuminemia, cerebrovascular disease (CVD), chronic kidney disease (CKD), and chronic obstructive pulmonary disease (COPD) (5,10-12).

Considering the aforementioned points and the lack of reported data in Colombia on the clinical behavior of PAD patients in the lower limbs who have undergone major amputation, we conducted this study as a preliminary approach to the subject.

PATIENTS AND METHODS

A retrospective study was conducted on a cohort of patients with PAD of the lower limbs who underwent major amputation performed by the vascular surgery team between March 2011 and December 2019 at the HUSVF in Medellín, Colombia.

Patients who underwent this procedure during the specified time frame were identified from the institutional coded database. Only those diagnosed with PAD by a vascular surgeon and who had indications for surgery corresponding to advanced stages of the disease were included. Patients with unclear or incomplete preoperative data, or those with indications for amputation other than PAD, were excluded.

For the analysis, patients were classified based on whether their clinical presentation was acute or chronic PAD at admission, either acute or chronic PAD . Each of these groups was further subdivided based on whether the level of amputation was above or below the knee. In line with previous studies, complications were categorized into renal (renal failure), cardiovascular (acute myocardial infarction, pulmonary thromboembolism, arrhythmias, cerebrovascular disease, heart failure), pulmonary (pneumonia, pleural effusion), surgical site infection, wound dehiscence, and delirium.

The primary outcome evaluated was mortality within 30 days following the amputation or index hospitalization. Secondary outcomes included complication rates, re-amputation, and an increase in the level of amputation.

Early mortality was defined as that which occurred during the index hospitalization or within 30 days postoperatively. Patient follow-up was conducted through a review of electronic medical

records registered at the institution, making it challenging to control for information bias from patients who sought follow-up care at other institutions.

Statistical processing and analysis were performed using SPSS V.25®. The selection of clinical variables was based on data from similar studies. The influence of factors on mortality was determined through univariate and multivariate analysis. The chi-square test was used for categorical variables and the WALD test for numerical variables in univariate analysis. Multivariate analysis was conducted using COX regression, and for inconclusive factors, additional logistic regression analysis was performed based on significant factors in the univariate analysis.

The study was approved by the HUSVF Research Ethics Committee. In accordance with Resolution 008430 of 1993 from the Ministry of Health of Colombia, the research posed no risk to patients as it was a retrospective review of de-identified medical records. Therefore, informed consent was not required.

RESULTS

During the study period, 1,165 records of major amputations were documented. Of these, 607 were excluded as they neither met the inclusion nor exclusion criteria. It is noteworthy that in this institution, since the establishment of the vascular surgery service in 1995, amputations for PAD are performed by the vascular surgery team.

Out of the 558 individuals with PAD who underwent a major amputation either above or below the knee level—classified as supracondylar (SCA) and infracondylar (ICA)—466 (83.5%) were cases with chronic limb-threatening ischemia (CLTI), and 92 (16.4%) were cases of acute PAD. According to institutional protocols and evidence-based clinical guidelines, these patients were not suitable candidates for revascularization for various reasons, such as severe comorbidities, bedridden status, extensive tissue loss, and failure of previous revascularization attempts, among others.

Acute Lower Limb PAD

A total of 92 patients required a major amputation due to acute PAD. Hypertension was the most prevalent comorbidity. Above-the-knee amputations accounted for 94.6% of the cases. Perioperative delirium emerged as the most frequent complication, followed by cardiovascular, renal, and pulmonary conditions (See Table 1).

Table 1. Characteristics of Patients with Acute Ischemia (N=92)

Variable	Number (%)
Average Age	74.3 years
Gender: Male vs. Female	62 (67.4%) vs. 30 (32.6%)
Medical History	
Hypertension	71 (77%)
Smoking	55 (59.8%)
Diabetes Mellitus	34 (37%)
Atrial Fibrillation	23 (25%)
Chronic Obstructive Pulmonary Disease (COPD)	22 (23.9%)
Chronic Kidney Disease (CKD)	20 (21.7%)
Peripheral Arterial Disease (PAD)	19 (20.7%)
Cerebrovascular Disease	16 (17.4%)
Heart Failure	15 (16.3%)
Coronary Artery Disease	8 (8.7%)
Procedure	N (%)
Prior Intervention to Index Hospitalization	8 (8.7%)
Limb Salvage Therapy During Index Hospitalization	16 (17.4%)
Supracondylar (SCA) vs. Infracondylar (ICA) Amputation	87 (94.6%) vs. 5 (5.4%)
Reamputation	4 (4.3%)
Complications	
Delirium	29 (31.5)
Cardiovascular	20 (21.7)
Renal	16 (17.4)
Pulmonary	15 (16.3)
Surgical Site Infection	14 (15.2)
Wound Dehiscence	2 (2.2)
Mortality	N (%)
Overall Mortality	30 (32.6)
Mortality in Reamputation	1 (1.1)
Mortality in Supracondylar Amputation (SCA)	30 (32.6)
Mortality in Infracondylar Amputation (ICA)	0 (0)
Pre-surgical Laboratory Tests	Mean (SD):
Creatinine	1.5 (1.4)
Hemoglobin	12.1 (2.9)
C-reactive Protein	16.1 (11)
Glycated Hemoglobin	7.7 (3.3)
Albumin	3 (0.8)

Source: Own elaboration

The overall mortality rate among the patients was 32.6%. In the univariate analysis, atrial fibrillation (as a comorbidity), history of PAD management (as a precedent), and cardiovascular or pulmonary complications were found to be associated with mortality. However, in the multivariate analysis, only cardiovascular complications emerged as statistically significant risk factors for death.

Chronic Limb-Threatening Ischemia (CLTI)

A total of 466 patients required a major amputation due to CLTI. Hypertension was the most prevalent comorbidity. Over half of the patients had a PAD diagnosis prior to institutional admission, and a third underwent some form of limb salvage therapy during the index hospitalization. The most frequently performed type of amputation was supracondylar (SCA), with a ratio of 7:3 compared to infracondylar (ICA) amputations. Mortality rates in both groups were 12.4% and 8.1%, respectively, without a statistically significant difference (OR 0.62; 95% CI 0.3-1.2; P=0.17). Smokers were observed to have a higher risk of undergoing SCA (OR 1.63, 95% CI 1.09-2.43; P < 0.001), as were patients with low albumin levels. ICA was predominantly performed on male patients, diabetics, or those with chronic kidney disease (CKD). Perioperative delirium was the most common complication, followed by cardiovascular, pulmonary, and renal diseases (See Table 2).

Table 2. Characteristics of Patients with Chronic Limb-Threatening Ischemia (CLTI) (N=466)

Variable	Number (%)
Average Age	72.7 años
Gender: Male vs. Female	267 (57.3%) vs. 199 (42.7%)
Medical History:	N (%)
Hypertension	387 (83%)
Peripheral Arterial Disease (PAD)	267 (57.3%)
Diabetes Mellitus	261 (56%)
Smoking	256 (54.9%)
Chronic Kidney Disease (CKD)	133 (28.5%)
Heart Failure	105 (22.5%)
Chronic Obstructive Pulmonary Disease (COPD)	93 (20%)
Coronary Artery Disease	65 (13.9%)
Cerebrovascular Disease	57 (12.2%)
Atrial Fibrillation	39 (8.4%)
Procedure:	N (%)
Prior Intervention to Index Hospitalization	144 (30.9%)
Limb Salvage Therapy During Index Hospitalization	166 (35.6%)
Supracondylar vs. Infracondylar Amputation	330 (70.8%) vs. 136 (29.2%)
Reamputation	15 (3.2%)
Complications:	N (%)
Delirium	134 (28.8%)
Cardiovascular	54 (11.6%)
Pulmonary	49 (10.5%)
Renal	44 (9.4%)
Surgical Site Infection	34 (7.3%)
Wound Dehiscence	9 (1.9%)
Mortality:	N (%)
Overall Mortality	52 (11.2%)
Mortality in Reamputation	3 (23.1%)
Mortality in Supracondylar Amputation (SCA)	41 (12.4%)
Mortality in Infracondylar Amputation (ICA)	11 (8.1%)
Pre-surgical Laboratory Tests	Mean (SD):
Creatinine	1.6 (3.2)
Hemoglobin	10.4 (2.4)
C-reactive Protein	14.2 (10)
Glycated Hemoglobin	7.8 (3.1)
Albumin	2.9 (0.6)

Source: Own elaboration

Mortality and Associated Factors

The univariate analysis revealed that mortality was associated with a history of heart failure or chronic kidney disease (CKD) with all complications except for surgical site infection. Patients with normal albumin levels and a diagnosis of PAD prior to the index hospitalization exhibited a reduction in mortality (Hazard Ratio [HR]: 0.553). The multivariate analysis did not reveal a statistically significant association between any of the previously described factors and mortality.

In the multivariate analysis, factors significantly associated with the presence of pulmonary complications included atrial fibrillation (HR 3.008 [1.055-8.573]), chronic obstructive pulmonary disease (COPD) (HR 2.45 [1.061-5.675]), smoking (HR 2.493 [1.052-5.908]), and elevated levels of C-reactive protein (HR 1.097 [1.019-1.097]). Factors associated with surgical site infection were limb salvage therapy (Odds Ratio [OR] 2.981, 1.101-8.071) and bilateral amputation (OR 11.424, 1.431-91.199). For renal complications, the associated factor was dyslipidemia (HR 5.851 [1.640-20.874]).

The rate of re-amputation was 37.7 times more frequent in patients who underwent infracondylar amputation (ICA) (95% CI 4.9-290; P<0.001). Higher levels of albumin were associated with a 3.5-fold reduction in the re-amputation rate (95% CI 1.18-10.6, P: 0.02). The univariate analysis did not identify other variables that were significantly related to the outcomes statistically.

DISCUSSION

In the present study, we evaluated the morbidity and mortality rates and the factors associated with them in a large cohort of PAD patients who underwent either supracondylar (SCA) or infracondylar (ICA) amputations over a nine-year period at HUSVF, a regional and national reference center for the management of these conditions.

Acute Peripheral Arterial Disease

In this group, although sharing several characteristics with chronic ischemia, the history of atrial fibrillation was higher, and the diagnosis of PAD prior to hospital admission was much lower, outcomes that are expected given its etiology. The majority of patients (94.7%) with acute PAD underwent SCA, and of these, only 17% had a history of some form of intervention prior to amputation. This is related to the severe limb involvement these patients arrive with , which in turn limits more distal amputation levels. The rate of studied complications in this group was higher than in the CLTI group, with a mortality rate of 32.6%. These data align with previous studies, which also show that these patients are at higher risk of death and re-intervention, with cardiovascular complications as the only factor significantly associated with mortality rates (17-19).

Chronic Limb-Threatening Ischemia (CLTI)

The overall mortality in our study was similar to that reported in previous works (7.2%, 22%, and 14%) (2,5,8). Although the multivariate analysis did not show a relationship between the studied variables of our cohort and increased mortality, previous studies have reported associations, such as the relationship between decreased albumin levels and early mortality (HR 3.87 [1.12-16.3 CI]; P: 0.03) as per Morisaki et al. (5), or increased mortality due to heart failure, bilateral amputation, or guillotine amputation reported by other authors (13,14).

In our population, the gender distribution was equitable, and the type of comorbidities did not differ significantly from those reported in the literature (12); however, some reports show a strong tendency towards males (5,10,11,13). The proportion of coronary artery disease in our cohort was

lower compared to that described by Jones et al. (61.3%) (12), Fard et al. (26%) (13), and Morisaki et al. (36.8%) (5). This could be due to underdiagnosis in our population, as the studied individuals were at an advanced stage of vascular disease and many did not undergo additional studies beyond electrocardiography and echocardiography.

The prevalence of smoking in our cohort was below that reported in Dutch studies, such as Fortington et al., where it was 60% (11), and Fard et al., 76% (13). However, we do not have regional data that would allow us a better understanding of our reality.

In our study, there is a trend towards performing proximal amputations, similar to that reported in others, such as Morisaki et al. (SCA 66.9%) (5). This is due to the need to ensure adequate stump perfusion and because many patients had conditions (bedridden status, advanced age, etc.) that make rehabilitation with an infracondylar prosthesis unfeasible. Other series show a more balanced distribution in terms of the selected amputation level, for example, Fortington et al. (11) and Fard et al. (13), who reported performing SCA on almost 50% of patients.

Among people subjected to limb salvage therapies, a higher rate of wound dehiscence, stump infection, and the need for re-amputation at a higher level were evident. This may be related to the instrumentation and the longer time elapsed until the index amputation. Although delirium was the most frequent complication, the factors that influenced its development could not be determined based on the evaluated variables.

Diabetic patients show greater involvement of smaller-caliber vessels, which is related to a higher rate of distal amputation, as evidenced in our cohort. Studies such as those by Yamada et al. and Pourghaderi et al. associate diabetes with an increase in the number of cardiac complications, an association not observed in our study.

Some works show a rate of re-amputation after one year of follow-up of 25.6% in ICA cases and 9.7% in SCA cases, with an overall re-amputation rate of 34% (14,15) and conversion rates from ICA to SCA of 12.9% (16). These data are not comparable to those seen in our cohort due to the difference in follow-up time.

LIMITATIONS

This was a retrospective study conducted at a single center with an information bias owing to the use of electronic medical records and a clinical follow-up bias due to the possible loss of patients who consulted at other centers.

CONCLUSIONS

The series presented here shows mortality and morbidity rates similar to those reported elsewhere although it does not clearly identify the factors involved in the occurrence of perioperative complications. The only factor associated with the risk of early mortality was cardiovascular complications in the group of patients amputated for acute PAD. Despite the similarity between the variables studied in our cohort and those described in other studies, ours showed a much lower percentage of a history of heart disease, which could be due to underdiagnosis in our population.

Approximately one-third of the patients developed perioperative delirium, thus it is important to be vigilant for this diagnosis in the postoperative period and consider conducting studies to determine its triggers. Further research is needed on patients with PAD undergoing major amputation, preferably prospective and multicenter studies, to establish associations and obtain findings of greater magnitude and impact.

CONFLICT OF INTERESTS

None of the authors reported conflicts of interest.

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