

Endovascular Revascularization in Chronic Limb-Threatening Ischemia

Revascularización endovascular en isquemia crítica de miembros inferiores

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ABSTRACT

Background: Management of chronic limb-threatening ischemia (CLTI) is based on surgical or endovascular arterial revascularization. Over the past two decades, the widespread adoption of endovascular treatments has increased their application in patients with CLTI.

Objective: The aim of this study was to describe the results of infrainguinal endovascular revascularization of patients with CLTI due to chronic obstructive arteriopathy.

Methods: We conducted a retrospective analysis of a prospectively followed cohort of 211 patients with CLTI undergoing endovascular treatment between January 2015 and December 2020.

Results: Of the total angioplasty procedures performed, 100 were below the knee (47.4%), 63 were above the knee (29.9%) and 48 were combined (22.7%) procedures. A total of 167 patients (79.2%) underwent primary balloon angioplasty procedures, and stents were placed in 44 (20.8%) cases. Mortality at 30 days was 0.95%. Survival rate at 1.3 and 5 years was 87%, 65% and 51%, respectively. Lower limb salvage was 78% at 1 year, 72% at 3 years and 68% at 5 years. At least one surgical or endovascular reintervention was required in 65.8% of the patients and 63.7% required at least one readmission. Wound healing was achieved in 121 patients, 118 were able to ambulate and 59 had independent ambulatory ability. Only 57 patients (29%) presented ideal results, which means that they achieved limb salvage, wound healing, elimination of ischemic pain and the attainment of independent ambulatory ability during follow-up.

Conclusions: Infrainguinal endovascular revascularization in CLTI proved to be safe and achieved favorable salvage rates. However, the results include a low rate of full functional recovery due to poor independent ambulatory ability and wound healing and high need for reinterventions during follow-up.

Keywords: Chronic limb-threatening ischemia - Peripheral artery disease - Endovascular - Hospital readmissions

RESUMEN

Introducción: El tratamiento de la isquemia crítica de miembros inferiores (ICM) se basa en la revascularización arterial quirúrgica o endovascular. En las últimas décadas, la generalización y perfeccionamiento de las técnicas endovasculares ha incrementado su indicación en pacientes con ICM.

Objetivo: Describir los resultados de la revascularización endovascular infrainguinal de pacientes con ICM por arteriopatía obstructiva crónica.

Material y métodos: Análisis retrospectivo de una cohorte seguida prospectivamente de 211 pacientes con ICM y tratamiento endovascular, entre enero de 2015 y diciembre de 2020.

Resultados: Se realizaron 100 angioplastias infrapatelares (47,4%), 63 suprapatelares (29,9%) y 48 combinadas (22,7 %). En 167 casos (79,2 %) se trató de angioplastias primarias con balón, y en 44 (20,8 %) de angioplastias con colocación de stent. La mortalidad a los 30 días fue de 0,95 %. La supervivencia fue del 87% al año, 65 % a los 3 años y 51% a los 5 años. El salvataje de miembro inferior fue del 78% al año, 72 % a los 3 y 68 % a los 5 años. El 65,8 % de los pacientes requirió al menos una reintervención quirúrgica o endovascular y el 63,7 % una reintervención. Curaron las lesiones tróficas 121 pacientes, 118 deambularon, y 59 en forma independiente. Solo 57 pacientes (29%) presentaron resultados ideales, es decir salvaron el miembro inferior, curaron las lesiones o lograron la desaparición del dolor isquémico y deambularon en forma independiente.

Conclusiones: La revascularización endovascular infrainguinal en ICM fue segura y presentó buenas tasas de salvataje; sin embargo, entre los resultados resaltan una baja tasa de recuperación funcional completa por la escasa deambulación independiente; baja tasa de curación de lesiones, y elevada necesidad de reintervenciones en el seguimiento.

Palabras clave: Isquemia crítica de miembro inferior - Enfermedad arterial periférica - Endovascular - Readmisión hospitalaria

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INTRODUCTION

Chronic peripheral artery disease (PAD) is primarily due to atherosclerotic obstruction of the arteries of the lower limbs. Chronic limb-threatening ischemia (CLTI) is the most advanced stage, affecting 11% of patients with PAD and is defined as ischemic rest pain and/or wounds with tissue loss (ulceration or gangrene) in the lower extremities. (1-3) It is associated not only with high risk of lower limb loss, impaired functional status and adverse effects on quality of life, but also with high probability of cardiovascular events such as ischemic heart disease or stroke and death. (4,5)

In the absence of arterial revascularization, the annual incidence of major lower extremity amputation is 25% with mortality rates of 20-30% at 2 years in patients with CLTI. (6,7) The objective of arterial revascularization (either by open bypass surgery or endovascular revascularization with balloon angioplasty with or without stent implant) in CLTI is to improve distal perfusion of the stenotic area or arterial occlusion to eliminate rest pain and achieve wound healing and lower limb salvage and reduce mortality. (8-10)

Over the past two decades, the widespread adoption of endovascular treatments has increased their application in patients with CLTI. This is due to advancements in the technique and the introduction of new technologies which have resulted in reduction in the morbidity rate. (11-13)

The objective of our study is to report the traditional aspects of treatment, including lower limb salvage, morbidity and mortality, wound healing, ambulatory status and functional recovery, as well as the need for hospitalization and reinterventions. Furthermore, the study aims to contribute to the understanding of the outcome of patients who underwent endovascular treatment for CLTI.

METHODS

We conducted a retrospective analysis of a prospectively followed cohort of 211 patients with CLTI due to chronic obstructive peripheral artery disease who underwent endovascular treatment by percutaneous balloon angioplasty, with or without stenting, between January 1, 2015, and December 31, 2020. Patients with a diagnosis of arterial injuries, aneurysmal disease, and acute lower limb ischemia were excluded.

The information was obtained from the database of the Operating Room Department of our hospital and from the medical records. Follow-up information was retrieved from the most recent assessment of patients who were still alive and who had visited the outpatient clinic or by contacting the patients and/or their families by telephone. Seven patients (3.3%) were lost to follow-up.

Demographic variables, cardiovascular risk factors, length of hospital stay, site of endovascular treatment, stent placement, lower limb salvage, complications, reinterventions, hospital readmission, intraoperative mortality, in-hospital and 30-day mortality, and overall survival were analyzed. The postoperative functional recovery was also evaluated based on the ability to walk independently or with assistance, as well as wound healing or elimination of ischemic pain.

All the patients underwent angiography and the revascularization procedures were classified as above and below-the-knee angioplasties, depending on whether the intervention was performed above or below the joint line of the knee. Combined angioplasty was considered when revascularization was performed above and below the knee.

All the statistical calculations were performed using STATA and RStudio software packages. Qualitative variables are presented as frequency and percentage and quantitative variables are expressed as mean and standard deviation or median and interquartile range (IQR). Survival was analyzed with Kaplan-Meier actuarial curves. Univariate and multivariate analyses were performed to define independent predictors of events. The significance level accepted was an alpha error of 0.05. Population projections were also calculated with their 95% confidence intervals (95% CI).

RESULTS

Of the 211 patients analyzed, 143 (67.8%) were men. Mean age was 67.9 ± 11 years. The most common risk factors were diabetes mellitus and hypertension (Table 1).

Within the diagnosis of CLTI, 198 patients (93.8%) had in limb wounds (ulcer or gangrene) and 13 (6.1%) had pain at rest. Of the total angioplasty procedures performed, 100 were below-the-knee procedures (47.4%), 63 were above-the-knee-procedures (29.9%) and 48 were combined (22.7%) procedures. One hundred and sixty-seven (79.2%) were primary balloon angioplasties, and a stent was implanted in 44 (20.8%) with stent placement (in cases of occlusions, residual stenosis or arterial dissection with no flow restoration after angioplasty). Angioplasty was performed on a single vessel in 56.4% of the cases, and on 2 or more vessels in the remaining cases. The femoral artery was treated in 85 cases (40.2%), the popliteal artery in 50 (23.7%), the anterior tibial artery in 80 (37.9%), the posterior tibial artery in 59 (27.9%), the fibular artery in 38 (18%) and the tibiofibular trunk in only 24 patients (11.3%). Double antiplatelet therapy with acetylsalicylic acid and clopidogrel was indicated in the postoperative period. Median length of hospital stay following surgery was 7 days (IQR 2-19). After hospital discharge, median follow-up was 42 months (IQR 20 - 58 months) in 196 patients (excluding the 8 deaths during hospitalization and the 7 patients lost to follow-up).

Table 1. Demographic data and comorbidities (n = 211)

Age	67.9 ± 11 years
Male sex	147 (67.8%)
Diabetes mellitus	174 (82.5%)
Hypertension	171 (81%)
Current smoking	122 (57.8%)
Dyslipidemia	101 (47.9%)
Coronary artery disease	49 (23.2%)
Stroke	24 (11.4%)

Lower limb salvage

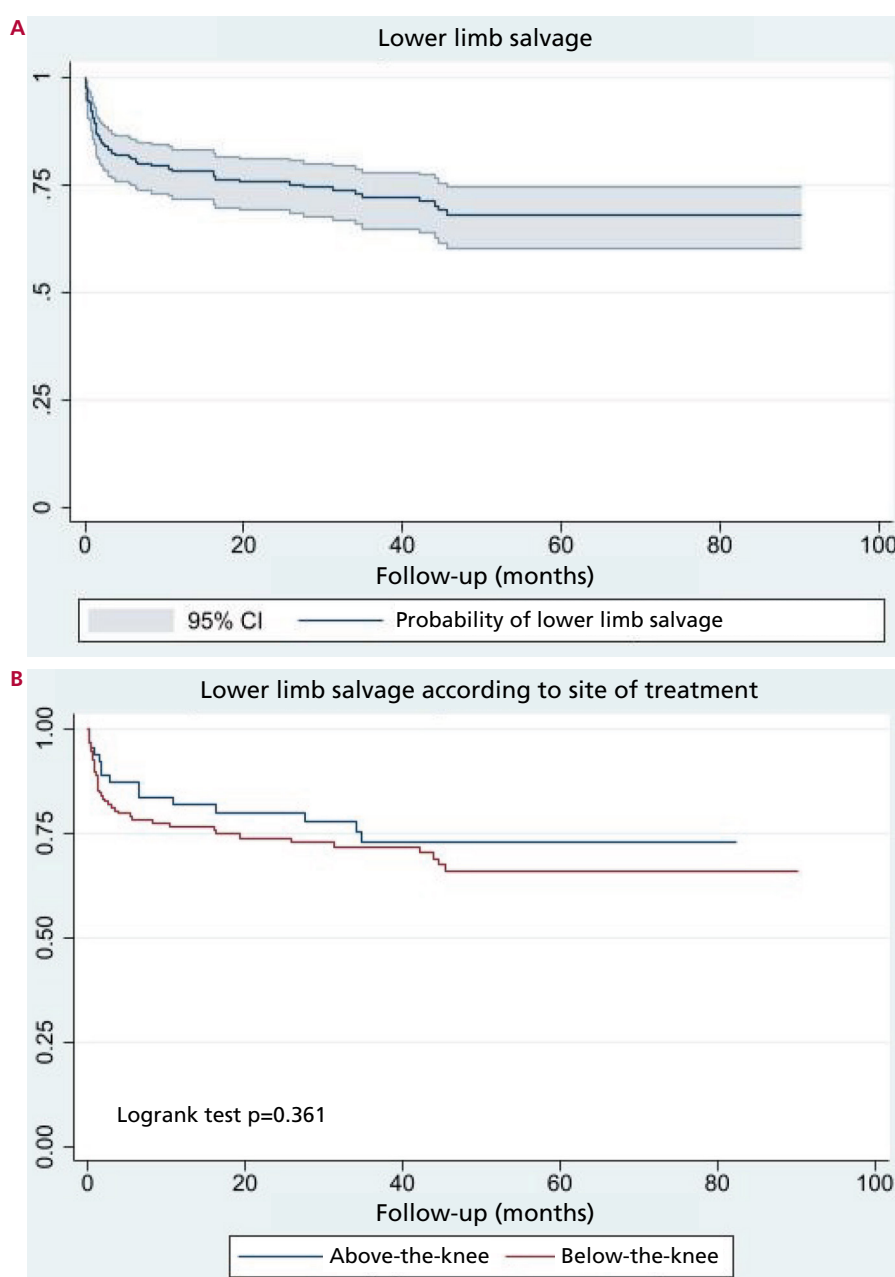
Overall salvage rate was 73%; the probability of lower limb salvage at 1, 3 and 5 years was 0.78 (95% CI 0.72-0.83), 0.72 (95% CI 0.65-0.78) and 0.68 (95% CI 0.60-0.75), respectively (Fig. 1A). The probability of salvage was analyzed according to the anatomic location of the angioplasty procedure. In above-the-knee angioplasty procedures, the probability of salvage at 12 months was 0.82 (95% CI 0.69-0.89) and 0.73 (95% CI 0.58-0.83) at 3 and 5 years. In below-the-knee angioplasty procedures, the probability of salvage at 12 months was 0.76 (95% CI 0.69-0.83), 0.72 (95% CI

0.63-0.79) at 3 years and 0.66 (95% CI 0.56-0.74), with no significant differences at 5 years ($p=0.361$) (Fig. 1B).

Complications

The most common complications were thrombosis of the treated vessel in 21 patients (9.9%), cardiovascular events in 11 (5.2%), and sepsis related to the revascularized limb in 9 (4.2%). Two patients (0.9%) presented retroperitoneal hematoma, and one of them required surgery due to active bleeding. Of the 11 patients with cardiovascular events, 10 presented an

Fig. 1A. Kaplan-Meier curve for lower limb salvage. **1B.** Kaplan -Meier curve for lower limb salvage according to above-the-knee or below-the-knee treatment.



acute coronary syndrome and 1 had decompensated heart failure. Among these patients, 90.9% died within 4 years of follow-up.

Reinterventions

A total of 350 reinterventions were required following endovascular treatment of the lower limb in 211 patients with CLTI. These included reoperations of the treated lower limb, revascularization of the contralateral limb, coronary artery revascularization, valve replacement, and carotid artery or aortic surgery.

The mean number of reinterventions was 2.5 ± 1.7 (median 2). Between one to seven reinterventions (surgical and/or endovascular) were documented during follow-up in 139 of the 211 patients (65.8%) (Table 2).

A total of 37.9% of patients (80 cases) required

at least one cardiovascular surgical reintervention (endovascular or conventional) within 30 days after treatment. Of these, 88.7% (7 cases) were related to the revascularized lower limb. During the first year after treatment, there were 122 cases (57.8%) with cardiovascular surgical reinterventions (endovascular or conventional), related to the treated lower limb in more than 90% of cases (111 patients).

Survival

There was no operative mortality. Mortality at 30 days was 0.95% (2 patients, 1 due to pre-existing cancer). In-hospital mortality was 3.8% (8 patients, in 7 cases due to sepsis related to soft tissue or bone infection in the operated lower limb).

In the overall survival analysis after endovascular revascularization of the 211 cases, the probability of survival at 1, 3 and 5 years was 0.87 (95% CI 0.82-0.91), 0.65 (95% CI 0.58-0.72), and 0.51 (95% CI 0.43-0.58), respectively (Fig. 2). The most common causes of death during follow-up were sepsis related to the revascularized lower limb (34.4%), cardiovascular events (25.2%) and COVID-19 (10.4%).

On univariate analysis, the factors significantly associated with long-term mortality were stroke (HR 2.02; 95% CI 1.19-3.42; $p=0.009$), age > 65 years (HR 1.61; 95% CI 1.05-2.46; $p=0.028$) and coronary artery disease (HR 1.79; 95%CI 1.16-2.76; $p=0.008$). Multivariate analysis showed a significant association of the same factors with mortality: stroke (HR 1.78; 95% CI 1.04-3.05; $p=0.034$), age > 65 years (HR 1.56; 95% CI 1.01-2.39; $p=0.041$) and coronary artery disease (HR 1.63; 95% CI 1.04-3.05; $p=0.031$) (Table 3).

Table 2. Surgical and/or endovascular reinterventions for CLTI (n = 139).

Reinterventions	Frequency	Percentage
1	58	41.7%
2	25	17.9%
3	20	14.4%
4	14	10%
5	13	9.3%
6	2	1.4%
7	7	5%

CLTI: Chronic limb-threatening ischemia

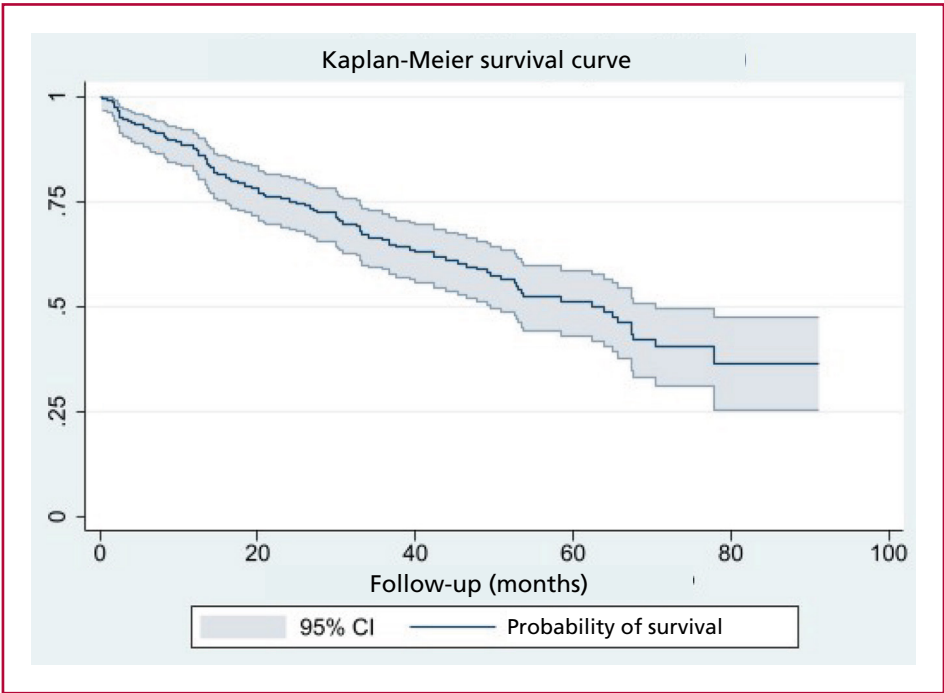


Fig. 2. Kaplan-Meier survival curve.

A total of 196 patients followed-up after discharge were considered for the analysis of readmissions, wound healing and ambulatory status after revascularization. The 8 in-hospital deaths and the 7 patients lost to follow-up (3.3%) were excluded.

Readmissions

Between 1 and 6 readmissions occurred during follow-up in 125 of the 196 patients (63.7%) analyzed (Table 4). A total of 23 patients (11.7%) were readmitted at least once within 30 days of discharge due to an adverse event in the revascularized limb. Sixty patients (30.5%) required readmissions related to the revascularized limb within the first year.

Wound healing

Wound healing or resolution of ischemic rest pain occurred in 121 patients (61.7%) during follow-up; 95 (48.4%) were also able to ambulate and 57 (29%) were independently ambulatory. In the logistic regression analysis, wound healing had a clearly positive impact with an OR of 8.26 (95% CI 4.29–15.98), indicating a more than eightfold increased likelihood of ambulation.

Ambulation

Ambulatory status was evaluated during the last follow-up control after hospital discharge. For the analysis, we considered whether the patients required assistance for ambulation (cane, crutches, walker,

prosthesis or help from other persons) or achieved independent ambulatory ability.

A total of 118 patients (60.2%) ambulated, 59 (30.1%) were fully independent and 59 required some type of assistance. We defined ideal results in patients with a diagnosis of CLTI who underwent endovascular treatment and achieved full functional recovery during outpatient follow-up visits. These results include limb salvage associated with wound healing or resolution of rest pain and independent ambulatory ability and were observed in 57 patients (29%).

DISCUSSION

Chronic limb-threatening ischemia is the most severe manifestation of PAD due to atherosclerotic disease of the lower extremities. Treatment of CLTI includes medical therapy to reduce cardiovascular risk factors, revascularization to improve arterial perfusion of the lower extremity, and management of infections and wound healing with local care.

The optimal modality of revascularization in CLTI remains controversial and is the focus of the most recent randomized controlled trials. The BEST-CLI trial reported that in patients with CLTI who were suitable candidates for surgical or endovascular interventions, revascularization with a single segment of great saphenous vein was superior to endovascular therapy to reduce major adverse limb events or death. The results were similar when a great saphenous vein conduit was not available. (14) The BASIL-2 trial showed

Table 3. Univariate and multivariate analysis of factors associated with long-term mortality (n=211).

Risk Factors	HR	Univariate analysis	
		95% CI	p
Age > 65 years	1.61	1.05 - 2.46	0.028
Male sex	0.96	0.62 - 1.47	0.860
Diabetes Mellitus	1.22	0.70 - 2.12	0.477
Current smoking	0.77	0.52 - 1.16	0.223
Coronary artery disease	1.79	1.16 - 2.76	0.008
Stroke	2.02	1.19 - 3.42	0.009
Risk Factors	HR	Multivariate analysis	
		95% CI	p
Age > 65 years	1.56	1.01 - 2.39	0.041
Coronary artery disease	1.63	1.04 - 2.54	0.031
Stroke	1.78	1.04 - 3.05	0.034

Table 4. Readmissions after endovascular treatment for CLTI (n = 125)

Readmissions	Frequency	Percentage
1	75	60%
2	27	21.6%
3	8	6.4%
4	5	4%
5	6	4.8%
6	4	3.2%

CLTI: Chronic limb-threatening ischemia

that vein bypass first revascularization strategy was associated with a 35% increased risk of major amputation or death in patients with CLTI. (15) In a meta-analysis of randomized controlled trials comparing both techniques, Mufarrih et al. concluded that there is no difference in clinical outcomes between endovascular surgery and conventional surgery as the first revascularization strategy in CLTI. (16)

Kodama et al. assessed the impact of revascularization on ambulation in patients with CLTI and infrainguinal revascularization (surgical and endovascular) and found that the proportion who ambulated at baseline decreased to 40% at 3 years. Advanced age, reduced mobility at the time of revascularization, and being on dialysis were associated with ambulation loss during follow-up. (17) Taylor et al. analyzed more than 800 patients with CLTI and surgical or endovascular revascularization and described that 70.6% of patients were able to maintain ambulation at 5 years. The independent predictors of poor functional outcome were impaired ambulatory status at presentation, dementia, and diabetes mellitus. (18)

Historically, studies on revascularized CLTI patients considered the absence of major amputation as a successful clinical outcome. However, limb salvage rate does not always indicate a successful outcome because patients may survive for an extended period without undergoing a major amputation but with ischemic wounds, rest pain or die before symptoms are relieved. Therefore, we consider that wound healing is an important goal after revascularization for CLTI.

Okazaki et. al. reported that endovascular revascularization was associated with longer wound healing time and lower wound healing rate (60% at 1 year) compared to surgical revascularization. Among other risk factors, a history of coronary artery disease, congestive heart failure, and dialysis requirement were associated with a significantly shorter wound-free period. (19) Browder et. al. found that, except in patients with CLI and an ankle-brachial index <0.4 , revascularization was not associated with better wound healing time and wound-free period. (20) Sano et. al. showed that a non-ambulatory status was an independent risk factor for impaired wound healing after revascularization, and delayed healing time. (21)

In our series, wound healing after revascularization had a favorable impact on patients' ability to ambulate during follow-up.

The need for hospital readmission and reinterventions in the outcome of patients revascularized for CLTI is well known. (14,15) Hospital readmissions are mainly due to cardiovascular causes. (22) In the case of endovascular and/or surgical reinterventions, they are generally necessary to achieve complete wound healing in the treated lower limb. In a review of 59 714 patients revascularized for CLTI, Martínez et al. reported readmission rates at 30 days and 1 year of 19.2% and 40.3%, respectively. (23) Ochoa Chaar et al. analyzed 1410 cases with endovascular revasculariza-

tion for CLTI. They found that 49% had at least one hospital readmission per year and the most common reasons were related to tissue wounds or infection of the revascularized limb. (24) In the BASIL-2 trial, the reintervention rate was 19% in patients with below-the-knee revascularization in the endovascular group, while in the BEST-CLI the rate of major and minor reinterventions was 23.5% and 33%, respectively, in the endovascular group, cohort 1 (compared with single greater saphenous vein bypass). (14,15) In Argentina, Jozami et al. evaluated patients with CLTI who underwent endovascular treatment and reported reintervention and amputation rates of 21.4% and 14.3%, respectively, at one year. (11)

In our series, we recorded a high rate of reinterventions and hospital readmissions mainly due to the revascularized lower limb. However, the population analysis revealed that patients had significant distal artery involvement, (tibial and fibular arteries), reflected in the high proportion of below-the-knee or combined treatments, and that most patients had diabetes. In patients revascularized for PAD, diabetes is an independent risk factor for hospital readmission and high rates of major adverse events in the lower limb, such as major amputation of the revascularized limb and/or reintervention in the revascularized segment. (25)

In our experience, endovascular treatment was safe with low 30-day mortality ($<1\%$). The 5-year mortality rate is consistent with that reported for patients revascularized for CLTI. (14,15,22) In terms of functional recovery, more than half of our population ambulated (with or without assistance) and achieved wound healing. On the other hand, only one third of patients presented ideal results, which means that they achieved full functional recovery, limb salvage associated with wound healing and independent ambulatory ability during follow-up.

Patients with CLTI constitute a heterogeneous group so it is difficult to standardize treatments in advanced stages of the disease considering the systemic cardiovascular risk (comorbidities), the anatomical complexity of the atherosclerotic arterial obstruction (severity and number of vessels affected), and the extent of tissue injured in the limb. In our opinion, an initial technical success in endovascular revascularization does not necessarily guarantee an optimal clinical response. The outcome of patients with CLTI requires close monitoring and consideration of reinterventions (open and/or endovascular) and hospital readmission if necessary.

Our study has some limitations. We made a retrospective analysis of a prospectively followed cohort from a single center. The choice of endovascular revascularization treatment was not randomized. Ischemic wounds were not stratified by their location and extent. Finally, the ambulatory status was not evaluated before revascularization.

CONCLUSION

Infrainguinal endovascular revascularization in CLTI proved to be safe with good limb salvage rates. However, the results indicate that the rate of full functional recovery was low because independent ambulatory ability and wound healing rates were low and there was high need for reinterventions during follow-up.

Ethical considerations

Clinical research protocol, Approved on 3/27/23 by the Ethics Committee of the Hospital de Clínicas “José de San Martín” U.B.A.

Conflicts of interest

None declared.

(See authors' conflict of interests forms on the web).

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