



PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY OF LIMB WITH CRITICAL ISCHEMIA

Angioplastia de salvamento de extremidad con
isquemia crítica infrapoplítea



Key words (MeSH)

Angioplasty
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Palabras clave (DeCS)

Angioplastia
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Summary

Objective: To evaluate and describe the clinical results of percutaneous transluminal angioplasty of critical limb ischemia in a level IV care center. **Materials and methods:** Observational analytical ambispective cohort study. **Results:** An infra-popliteal angioplasty was performed in the Radiology service of FOSCAL and FOSCAL International between the months of September 2013 and April 2016 to 65 patients. Prior to the procedure, 89% of the patients presented claudication and pain, 88% coldness of the limb, 81% of the patients presented ulceration and 64% infection, noting that 63% of the population had 3 associated symptoms. The patients were divided into two groups; the first, those who had undergone angioplasty in a single vessel and the second group who had undergone angioplasty in two or more vessels. We found that the amputation-free time was greater in the group one compared to group two, with a statistically significant P value. **Conclusion:** Angioplasty of infrapopliteal vessels in patients with peripheral arterial disease (PAD) and critical lower limb ischemia reduces pain, claudication and infection in patients. There is a low rate of major amputations after therapy as a measure of salvage of the limb. The probability of survival of the limb at 573 days is 50%.

Resumen

Objetivo: Evaluar y describir los resultados clínicos de la técnica Angioplastia de rescate en pacientes con isquemia crítica de miembros inferiores con enfermedad arterial infrapoplítea en un centro de atención nivel IV. **Materiales y métodos:** Estudio de cohorte ambispectivo analítico observacional. **Resultados:** Se realizaron angioplastias infrapoplíteas en el Servicio de Radiología de FOSCAL y FOSCAL Internacional entre septiembre de 2013 y abril de 2016, a 65 pacientes. Previo al procedimiento, en el 89 % de los pacientes se observó claudicación y dolor; en el 88 %, frialdad de la extremidad; en el 81 %, úlcera y en el 64 %, infección. En el 63 % de la población se encontraron tres síntomas asociados. Se dividieron los pacientes en dos grupos: el primero, aquellos a quienes se les había realizado

angioplastia en un solo vaso y el segundo, a quienes se les había realizado angioplastia en dos o más vasos. Se encontró que el tiempo libre de amputación fue mayor en el grupo uno, comparado con el dos, con valor de P estadísticamente significativo. **Conclusión:** La angioplastia de vasos infrapoplíteos en pacientes con enfermedad arterial periférica (EAP) e isquemia crítica de miembros inferiores disminuye el dolor, la claudicación y la infección en los pacientes. Favorece una tasa baja de amputaciones mayores posteriores a la terapia como medida de salvamento de la extremidad. La probabilidad de supervivencia de la extremidad a los 573 días es del 50 %.

1. Introduction

Peripheral arterial disease (PAD) is a chronic atherosclerotic process that decreases the peripheral arterial lumen and causes a set of acute or chronic syndromic conditions due to insufficient blood flow in the lower extremities. It is a multifactorial pathology that affects a large number of people in the world, with a prevalence of 3-10%, with an increase of 15-20% in people over 70 years old (1). Endovascular therapy, which has been considered as a treatment option in patients with arterial disease at a critical ischemic stage, was first applied four decades ago by Dotter and Judkins, but various inputs, such as balloons and stents, have been developed, as well as techniques for its implementation.

There are controversies regarding the indications, patient selection and long and medium term results (2). Critical lower limb ischemia is a manifestation of peripheral arterial disease, which is defined as ischemic pain at rest with or without ischemic skin lesions -such as ulcers that do not scar- or gangrene of associated tissues, which is considered the final stage of chronic arterial disease with low blood supply to the lower limb (3, 4). Due to the dismal outcome of this pathology, it is necessary to revascularize in order to save the limb, for which there are various techniques: open or conventional surgery versus an endovascular technique. At present, the survival and rescue rate of the limb at 1 year is greater than 25% with the application of the technique; without revascularization, the amputation rate is up to 95% (3).

Limb salvage after revascularisation is defined as the preservation of the foot or some of the toes. A waiting time of up to three days is considered for establishing perfusion and determining the demarcation or amputation zone (5).

It is important to note that these patients have high mortality, up to 70% at five years, generally attributed to associated cardiovascular events. Endovascularization techniques include: balloon angioplasty (PTA), stenting, coated stents and plaque resection procedures. Balloon angioplasty is the most commonly used because it offers the advantages of ease of use and the short time required for the procedure (4). The most commonly accepted indication for endovascular revascularization is critical lower limb ischemia defined in Fontaine classifications III or IV, Rutherford 4, 5 or 6, and Wagner 2 or 4 (tables 1 to 3).

The rate of limb salvage with endovascular therapy ranges from 73-91%, in the short term (6). The objective of this work is to evaluate and describe the clinical results of the application of the rescue angioplasty technique in patients with critical lower limb ischemia with infra-popliteal arterial disease, in a level IV care center.

Table 1. Fontaine's clinical classification

Grade	Classification
Grade I	Asymptomatic. Detectable by ankle-brachial index < 0.9
Grade IIa Grade IIb	Non-limiting intermittent claudication for the patient's lifestyle Limiting intermittent claudication for the patient
Grade III	Pain or paresthesia at rest
Grade IV	Gangrene established. Trophic lesions

Source: Taken from Hardman et al (7).

Table 2. Rutherford's classification

Grade	Category	Classification
0	0	Asymptomatic
I	1	Mild claudication
I	2	Moderate claudication
I	3	Severe claudication
III	4	Ischemic pain at rest
III	5	Minor tissue loss
IV	6	Ulceration and gangrene

Source: Taken from Hardman et al (7).

Table 3. Wagner's classification

Grade	Injury	Features
0	None, risk foot	Thick corns, metatarsal heads, claw toes, bone deformities
I	Superficial ulcers	Destruction of the total thickness of the skin
II	Deep ulcers	Penetrates oily skin, ligaments, but does not affect bone, infected
III	Deep ulcer plus abscess (osteomyelitis)	Extensive and deep, secretion, bad smell
IV	Limited Gangrene	Necrosis of a part of the foot or toes, heel or sole
V	Extensive gangrene	Whole foot affected, systemic effects

Source: Taken from Armstrong and collaborators (8).

2. Materials and methods

- **Type of study:** Ambispective (retro- and prospective) analytical observational cohort study.
- **Reference population:** Patients using the radiology and peripheral vascular surgery service of the FOSCAL and FOSCAL International Clinics.
- **Eligible population:** Patients diagnosed with critical lower limb ischemia who were candidates for infra-popliteal angioplasty as a rescue therapy.
- **Inclusion criteria:**
 - Patients over 18 years of age.
 - Patients with a diagnosis of critical lower limb ischemia.

Critical ischemia was defined according to symptoms, pain at rest or tissue loss such as ulcers and necrosis with a Rutherford classification of 3, 4, 5 or 6 or a Fontaine IIb to IV classification.

- **Exclusion criteria:**
 - Patient who does not allow monitoring and follow-up.
- **Description of the technique:** By puncture of the contralateral common femoral artery, under Doppler ultrasound vision and on a hydrophilic guide, a pigtail catheter is passed through a 5 FR introducer into the aorta to perform an aortogram and lower limb arteriography in order to evaluate the findings. When severe stenosis of the infrapopliteal arteries is confirmed, different catheters are inserted into the common iliac artery of the involved limb and a long support introducer is positioned in the common or superficial femoral artery. An intermediate catheter is passed to the superficial femoral or popliteal artery and then, with a microcatheter and microguide system, the lesions are repermeabilized and crossed to perform the angioplasty, with medicated or non-medicated balloons, of the diseased arteries. When it is not possible to cross the lesions by antegrade route, the ultrasound-guided pedal access technique is used in the anterior tibial and posterior tibial arteries with micro-puncture equipment. Once the access is made,

a microcatheter-mounted pedal introducer system is introduced and the lesions are crossed, either intraluminal or subintimal, to make the connection with the antegrade access. This connection is made in two ways: one, introducing the microguide from the retrograde pathway to the microcatheter located by the antegrade pathway, and two, using a two-millimeter loop from the antegrade pathway to capture the guide coming from the retrograde pathway and create a through and through system, in order to perform the respective predilatations and dilations. Before the angioplasty, the patient is given anticoagulant, 80 IU/kg of unfractionated heparin, and the result is confirmed with an intraprocedural Activated Coagulation Time, which should be above 170 seconds.

The inflow and outflow of the tibialis anterior, tibialis posterior and peroneal arteries and the plantar arch are evaluated. At the end of the procedure, the systems are removed and the arterial access is closed with manual compression or a percutaneous closure system (Figures 1 to 4).

- **Data processing and analysis:** The data were recorded in an Excel database in duplicate and then checked and refined into a single database for final analysis in Stata 14.
 - The clinical characteristics of the patients were described using means and ratios with their respective 95% confidence intervals. Measures of frequency, association, and impact were defined and a logistic regression analysis was performed to evaluate factors associated with the success or failure of the procedure.
 - The Student T test and the Fischer exact test, with their significance at 0.05, were used to evaluate differences between dichotomous and continuous variables, respectively.
 - We estimated the Hazard Ratio and its 95% CI of amputation survival, which measured the success of the technique.
 - Univariate, bivariate and logistic regression analyses were performed, the latter in order to assess the independent effects of possible clinical risk factors for amputation.
 - A value of $p < 0.05$ was considered significant.



Figure 1. a) Occlusion of the superficial femoral artery is observed in its middle and lower third. b) Balloon angioplasty. c) Stent position, which is permeable throughout its path.

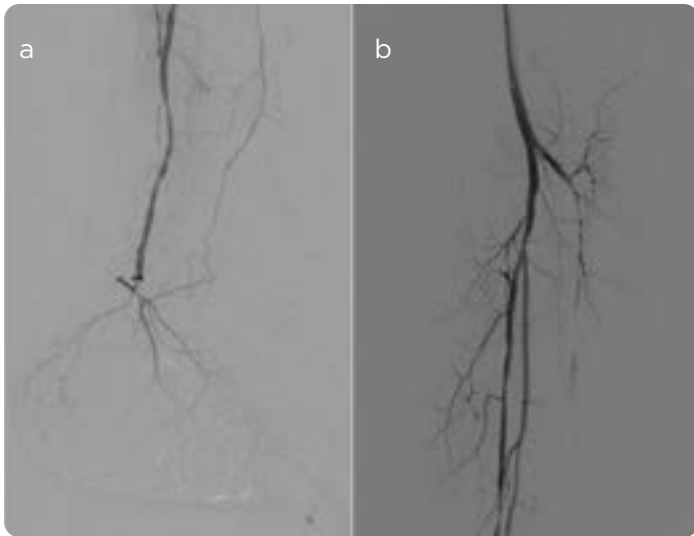


Figure 2. a) Occlusion of the distal third of the posterior tibial artery and the plantar arch. b) Occlusion of the anterior tibial artery in the proximal middle third and distal third.



Figure 3. a) Ball angioplasty of the posterior tibial artery. b) Ball angioplasty of the plantar arch. c) Ball angioplasty of the anterior tibial artery.

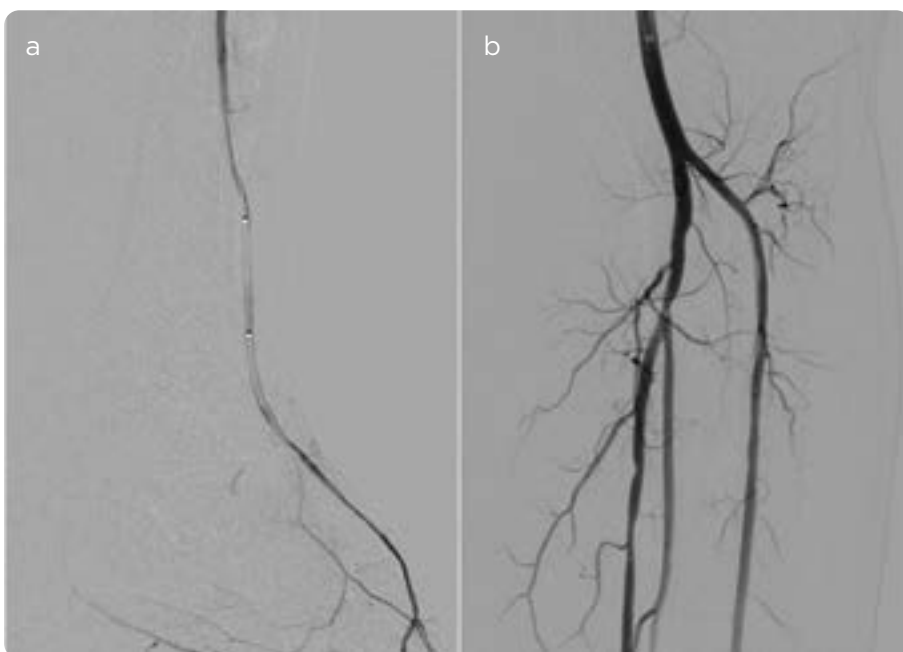


Figure 4. a) Opening of the plantar arch and anterior tibial artery in the middle and distal third. b) Opening of the anterior tibial artery in the proximal third.

3. Results

3.1 Individual analysis of variables

Infra-popliteal angioplasty was performed as a limb salvage with critical ischemia, in the radiology service of FOSCAL and FOSCAL International between September 2013 and April 2016, on 65 patients, 59% of whom were male and 41% female.

The average age of the patients included in the study was 71 years, with a minimum of 51 and a maximum of 90 years.

High blood pressure (HBP) was the most common associated comorbidity (88% of patients), followed by diabetes (74%); more than 31% of patients had two or more associated comorbidities.

Twelve percent of the population had a history of amputation: 3.5% of the patients were at supra- and infra-delta height and 7.5% had a history of angioplasty, which was found in 10% of the patients (Table 4).

Table 4. Individual analysis of variables

Sex	n	% (Fr)
Male	38	59
Female	27	41
Age		Years
Average		71
Minimum		51
Maximum		90
Comorbidities	n	% (Fr)
None	0	0
HBP	58	87.8
Diabetes mellitus	49	74.24
Heart Disease	16	24.24
CRF	30	45.45
Pneumopathy	14	21.21
Two comorbidities	19	31.82
Three comorbidities	12	19.70
Four comorbidities	13	19.70
Previous amputation	n	(Fr)
No	57	87
Yes	8	12

Fr: frequency; HBP: high blood pressure; CRF: chronic renal failure.

Source: Own elaboration.

3.2 Clinical findings

Pain, claudication, coldness, infection and ulceration were documented before the procedure. Claudication and pain were reported in 89% of the patients, 88% of the patients showed coldness of the limb, and 63% of the population found three associated symptoms.

In terms of clinical classification, taking into account the Fontaine, Rutherford and Wagner scales, 81% of patients were classified as Fontaine IV; 38% and 43% were classified as Rutherford 5 and 6, respectively; 30% were classified as Wagner grade 2 and 30% as Wagner grade 4 (Table 5).

Table 5. Clinical findings

Scale	Frequency	Percentage
Fontaine		
IIa	0	0
IIb	4	6.1
III	8	12.3
IV	53	81.54
Total	65	100
Rutherford		
I	0	0
II	3	4.6
III	1	1.54
IV	8	12.31
V	25	38.46
VI	28	43.08
Total	65	100
Wagner		
0	2	4.08
1	5	10.20
2	15	30.61
3	6	12.24
4	15	30.61
5	6	12.24
Total	49	100

Source: Own elaboration.

3.3 Intervention

The most frequently performed interventions (angioplasty), with a frequency of 53%, 44% and 44%, were those of the anterior tibial artery, posterior tibial artery and peroneal artery, respectively. Simultaneous angioplasty was performed on 74.2% of the population (Tables 6 and 7).

Table 6. Angioplasty according to the vessel affected

Angioplasty	Frequency	Percentage
Tibialis anterior	35	53.03
Peronea	29	43.94
Tibialis posterior	29	43.94
Superficial femoral	21	31.82
Poplitea	12	18.18
Tibiaperoneal trunk	9	13.64
Pedia	2	3.03
Distal beds	1	1.52

Source: Own elaboration.

Table 7. Simultaneous angioplasties

Number of simultaneous angioplasties	Frequency	Percentage
1	17	25.76
2	28	43.94
3	16	24.24
4	4	6.06
Total	65	100.00

Source: Own elaboration.

3.4 Clinical results

To evaluate the clinical results it was directly compared with the respective control.

- **Pain:** This was the predominant clinical symptom referred by all patients at study entry (89%). At the time of evaluation and follow-up, its incidence decreased significantly to 43.7%, although with a p value that does not show statistical significance, probably in relation to the number of patients.
- **Claudication:** This symptom, as well as pain, was prevalent (89%), with a decrease to 43.7%
- **Amputation:** 33% of the population required post-procedure amputation, of which 10,6% had a major amputation and 22,7% a minor amputation; however, it is important to note that the degrees of amputation were divided into: toes, forefoot, foot and supracondylar region, with a frequency of 21,2%, 1,5%, 1,5% and 9%, respectively (Tables 8 and 9).
- **Reintervention:** The need for reintervention angioplasty was 7.46%.
- **Infection:** It appeared in 64.6% of the population, but after the intervention this symptom decreased in 47.4%.
- **Ulcer:** It appeared in 81.53% of patients. In the control it was observed that 26,5% had partial healing and 42,9% total healing.

Table 8. Clinical results

Symptom	Patients	Absolute risk (CI 95 %)	p-value
Basal pain	65		0.69
Basal pain	59	89.39 % (81.8-97.2)	
Pain control	31	51.7 % (38.6-64.7)	
Claudication	59		0.265
Basal claudication	59	86.1 % (74-98)	
Claudication control	29	48.43 % (35.9-61)	
Previous amputation	8	12 %	0.58
Supracondilea	3	3.5 %	
Infracondilea	5	7.5 %	
Amputation control	22	33.3 %	
Major amputation	7	10.6 % (0.3-21)	
Minor amputation	15	22.7 % (0.4-26)	
Re-intervention	5	7.46 %	
Basal infection			0.58
Basal infection	42	64.6 % (52.6-76.6)	
Infection control	11	17.2 % (7.7-26.7)	

Source: Own elaboration.

Table 9. Degree of amputation

Grade	Frequency	% (Fr)
None	43	66.08
Fingers	14	21.22
Forefoot	1	1.51
Foot	1	1.51
Supracondilea	6	9.09
Total	65	100.00

Source: Own elaboration.

- **Functional classification:** Functional classification of the limb was evaluated according to the Rutherford, Fontaine and Wagner scales. It was very striking that 81% of the patients presented a Rutherford basal classification between 5 and 6 and in control only 3% of the patients remained in these classifications, likewise it is observed with the Fontaine classification that, 81% initially were in the classification 4 and only 10% of the population remained in this category in the control; Finally, the Wagner classification was used for the diabetic patients, of which 54% were distributed in categories III to V in the initial evaluation and of these, 17% remained in these categories, which evidences an important clinical improvement; however, it was not statistically significant (table 10).

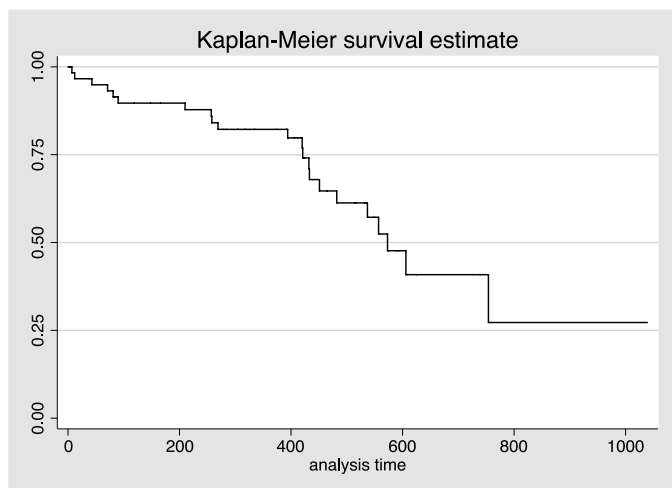


Figure 5. Limb survival graph

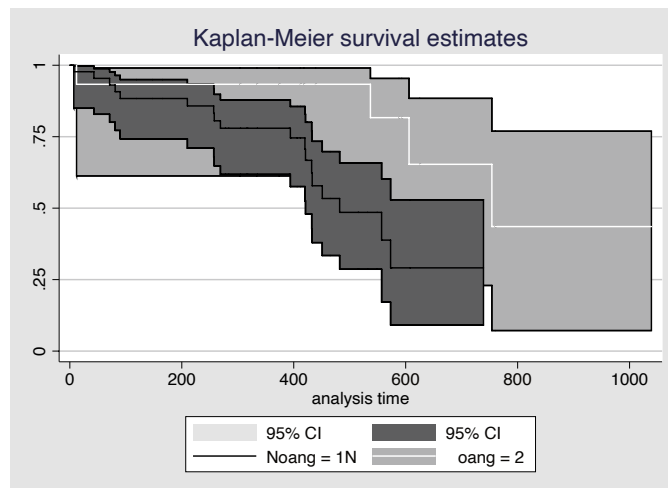


Figure 6. Limb survival graph taking into account the number of angioplasties performed.

Table 10. Functional classification

Rutherford*			Fontaine**			Wagner***		
	Basal %	Control %		Basal %	Control %		Basal	Control
O	0	27.1	O	0	5	O	4.08	13.6
I	0	20.3	I	0	20	I	10.20	43.1
II	4.6	8.11	Ila	0	20	II	30.61	25
III	1.54	23.7	Ilb	6.1	15	III	12.24	4.5
IV	12.31	13.6	III	12.31	30	IV	30.61	6.8
V	38.46	3.3	IV	81.54	10	V	12.24	6.8
VI	43.08	3.89						

*p = 0,666 ** p = 0,637 ***, Only patients with diabetes p = 0.505.

Source: Own elaboration.

- Mortality: Of the 65 patients who underwent angioplasty, 10 (15.38%) died. The main cause was cardiovascular in 40 % (table 11).

Table 11. Mortality

Mortality	% (Frequency)
Global	15,38 (10)
Cause	
Sepsis	30 (3)
Cardiovascular	40 (4)
Unknown	30 (3)
Total	100.00

Source: Own elaboration.

3.5 Limb Survival

The minimum follow-up time was two days and maximum 1039, with an average of 373 days, the incidence of amputations was 33%, of which 10.6% were major amputations and 22.7% minor amputations.

Two methods were analyzed for limb survival analysis: one, the Kaplan-Meier estimator, and the other, the actuarial method, which showed that the 50 % probability of survival is very similar between 557-573 days for Kaplan-Meier and 540-573 with the actuarial method (Figure 5).

The survival of the limb was considered taking into account the number of angioplasties performed, which is why two groups were obtained: group 1, consisting of patients who underwent angioplasty in a single vessel, and group 2, who underwent angioplasty in two or more vessels. It was observed that in group 1, 50% of the amputations occurred at 750 days, while in group 2, 50% of the amputations occurred at 500 days, with a statistically significant p value of 0.025 (Figure 6).

4. Discussion

Peripheral arterial disease is a pathology of multifactorial origin. In this work it was shown that 87 and 74 % of the patients have HBP and diabetes as comorbidity, findings that coincide with those reported in the literature, in which diabetes, HBP, smoking and dyslipidemia are implicated in 80-90 % of the patients (9, 10).

The average age of affected patients was 71 years, similar to that described in the literature, in which 15-20 % of patients over 70 years of age have PAD (1, 2).

Surgical treatment for critical lower limb ischemia is a procedure accompanied by perioperative morbimortality, which ranges from 1.8 % to 6 %, values that are very relevant when talking about the rate of complications (11, 12). In a study by Agarwal and collaborators (13) compared surgical revascularization vs. endovascular revascularization, with a result of reduced hospital mortality with endovascular therapy (2.34 % vs. 2.73 %, $p < 0.001$), despite similar major amputation rates (6.5 % vs. 5.7 %, $p = 0.75$).

Endovascular treatment is a minimally invasive revascularization technique, with the possibility of an antegrade or retrograde approach, due to the continuous development of small diameter and longer balloons (14, 15). In this work we presented an operative mortality rate at 30 days of 0 %, the rate of major amputation (defined as supramalleolar amputation) was 10.6 % and the rate of minor amputation was 22.7 %, results that were lower than those described by Spreen and collaborators (16), who described a higher amputation rate after 1 year of 11.4% (95% CI, 4.0% -18.8%) in the drug-eluting stents (DES) group and 20.5% (95% CI, 10.5% -30.5%) in the percutaneous transluminal angioplasty group.

On the other hand, for patients with critical lower limb ischemia, the traditional surgical treatment offered was primary amputation; however, with the advent of endovascular revascularization it was observed that patients undergoing this procedure have a longer survival and better quality of life, compared to amputees (17). We hope to be able to improve the follow-up process for a longer time and measure quality of life.

The typical distribution of atherosclerotic disease in patients with critical limb ischemia comprises various areas of stenosis and occlusions that may include from the femoral artery to the vessels of the plantar arch (18). However, in 25% of patients with critical ischemia, the lesions are confined to the infra-popliteal territory (19, 20). In this study the anterior tibial artery followed by the posterior tibial and peroneal arteries were the most intervened, 53 and 44% respectively, and more than 44% of all angioplasties were performed on two or more vessels.

The patients were divided into two groups: the first, those who had undergone angioplasty in a single vessel, and the second, those who had undergone angioplasty in two or more vessels, and it could be seen that the amputation-free time was greater in the first group: 50% at 750 days compared to 50% at 500 days in the second group, with a statistically significant p value. This can be explained by the lower degree of disease in patients treated with a single angioplasty.

The probability of limb survival in the present study is 50% at 573 days of follow-up, taking into account that even with endovascular infra-popliteal treatment, amputation cannot be avoided; however, it favours a lower degree of amputation.

With this technique, an improvement in the perfusion of the treated limb was observed, which is evidenced by better clinical outcomes of

the disease, such as pain and claudication, which were the predominant clinical symptoms referred by the patients upon admission to the study (89%). In the evaluation and follow-up, the incidence decreased significantly to 43.7%; likewise, the absolute risk of infection decreased (47.4%), from 64.6% to 17.2%; however, it was not statistically significant ($p = 0.5$). This last parameter was not comparable, since in the review of the available literature this variable is not found as an evaluated parameter. Nevertheless, these values allow us to infer that the technique is effective in terms of clinical response.

The functional classification of the limb according to the Rutherford, Fontaine and Wagner scales was also taken into account. It is noteworthy that the percentage of patients in the clinical stage increased in the lower scales and in the upper scales (5 and 6 for Rutherford, 4 for Fontaine and III to V for Wagner), there was a decrease, clinically relevant, as 81% of patients classified Rutherford 5 and 6, after rescue angioplasty, in clinical follow-up, 3% continued in category 5; in the Fontaine classification, 81% were in category 4 and in the control 10% of the population continued in the same category and in the Wagner classification, 54% of the patients were distributed in classifications III to V and only 16% continued in these categories.

The differences that were presented in the functional classifications for both Rutherford, Fontaine and Wagner, considering that the improvement of the ulcerative lesions are of long evolution and despite having follow ups longer than 1 year, are due to a subjective component that could explain the variability in the lower categories, but with little margin of error in the upper ones, where the lesions are their main characteristic, subjectivity that can be explained by the improvement of the pain. Another factor could be the natural evolution of the disease, in which the atherosclerotic process and ischemia are progressive, and endovascular therapy could be the best alternative to delay ulceration and maintain a better quality of life. The results obtained with our treatment and with the different techniques informed for this pathology, will never be successful if there is not multidisciplinary management and adequate adherence to the treatment of its comorbidities.

5. Limitations of the study

The sample size and the short follow-up of patients in this study limited the achievement of stronger and more generalizable results. However, there is no evidence from recent studies in our environment or in Latin America, which encourages the different groups to highlight the benefits of the results of this type of endovascular treatment through studies with a better level of evidence and degree of recommendation.

Control and monitoring of peripheral arterial disease (PAD) risk factors (diabetes, hypertension, dyslipidemia and smoking) were not evaluated.

It is likely that, due to the characteristics of our health system, patients undergoing this procedure do not have a multidisciplinary approach, which indirectly alters the results of the study.

6. Conclusions

Angioplasty of infra-popliteal vessels in patients with PAD and critical lower limb ischemia is a safe technique, as there was no perioperative mortality in this study.

Angioplasty of infrapopliteal vessels in patients with PAD and critical lower limb ischemia reduces pain, claudication and infection in patients.

The rate of major amputations after therapy as a limb-salvage measure is decreased.

The probability of limb survival at 573 days is 50%.

There are no significant differences with the use of medicated vs. unmedicated balloon. Better disease outcomes are observed with endovascular therapy, as evidenced by Rutherford, Fontaine and Wagner's classifications.

The lower the degree of disease, the longer the survival time of the limb.

Rescue angioplasty can be considered as first-line treatment in patients with critical ischemia, even if amputation is unavoidable, it can ensure lower degrees of amputation.

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