Journal of the Society for Cardiovascular Angiography & Interventions 3 (2024) 101931

JSCAI

The official journal of the Society for Cardiovascular Angiography & Interventions

Original Research

Rationale and Design of the Latin-American Registry of Peripheral Interventions: Insights From SOLACI Peripheral

Luis R. Virgen-Carrillo, MD, PhD [a,b,*], Larry Díaz-Sandoval, MD, PhD [c], Maximiliano Rossi, MD [d], Gustavo O. Pedernera, MD [e], Ernesto R. Duarte, MD [f], Julio A. Pascua, MD [g], Leslie M. Lugo-Gavidia, MD, MSc, PhD [h,i], Pablo Lamelas, MD [j]

[a] *Department of Interventional Cardiology, Virgen Cardiovascular Research, Guadalajara, Mexico;* [b] *Department of Interventional Cardiology, Universidad Autonóma de Guadalajara, Guadalajara, Mexico;* [c] *Department of Interventional Cardiology, Ascension Borgess Hospital, Kalamazoo, Michigan;* [d] *Department of Interventional Cardiology, Instituto Cardiovascular Rosario, Santa Fe, Argentina;* [e] *Department of Interventional Cardiology, ICBA Instituto Cardiovascular, Buenos Aires, Argentina;* [f] *Department of Interventional Cardiology, Hospital Escuela de Agudos Dr Madariaga, Posadas Misiones, Argentina;* [g] *Department of Interventional Cardiology, Hospital Italiano La Plata, Buenos Aires, Argentina;* [h] *Dobney Hypertension Centre, Medical School, University of Western Australia, Perth, Australia;* [i] *Mexican Academic Consortium for Clinical Data Acquisition, Culican, Sinalos, Mexico;* [j] *Instituto de Cardiologia y Cirugia Cardiovascular Hospital Universitario Fundacion Favaloro, Buenos Aires, Argentina*

ABSTRACT

Background: Chronic limb-threatening ischemia (CLTI) represents the most advanced stage of lower extremity peripheral artery disease (PAD). The aim of this manuscript is to provide an overview of the demographic and clinical characteristics of patients with lower-limb peripheral artery disease, as well as the procedural and technical aspects of peripheral endovascular interventions in Latin-America.

Methods: The SOLACI peripheral registry is a prospective, multi-center, observational, and hospital-based registry of patients with lower-limb PAD, who are treated with endovascular interventions across Latin American countries.

Results: A total of 1057 independent procedures (997 patients) were analyzed in this report. The most common clinical presentation was CLTI (61.2%): Advanced stage of the disease was common, and the symptomatic classification was predominately Rutherford V (minor tissue loss) in 37.6%. Index endovascular procedures mainly treated femoral-popliteal and infrapopliteal regions. Disease extending across multiple vascular territories was common and 27.6% of patients underwent angioplasty of multiple regions during the same procedure. There was a high prevalence of cardiovascular risk factors and concomitant comorbidities: hypertension (84.5%), dyslipidemia 67.4%), diabetes mellitus (64.7%), myocardial infarction (17%) and stroke (8.4%). Major adverse events during hospitalization included death from any cause (1.3%), cardiovascular death (0.7 %), myocardial infarction (0.4%), stroke (0.1%) and bleeding (0.8%).

Conclusions: Real-world data on lower limb-PAD in Latin American countries will help us identify unmet needs and generate evidence-based recommendations to facilitate the development of more effective preventive and treatment strategies according to each country's necessities and resources.

Introduction

Chronic limb-threatening ischemia (CLTI) represents the most advanced stage of lower extremity peripheral artery disease (PAD) and is a major global health concern with escalating prevalence and significant health care costs.[1] In the last 20 years, there has been a continuous technological evolution paired with ever-advancing endovascular operator skills and technique development resulting in rapidly advancing and improving revascularization strategies, which have successfully reduced the number of patients who were previously deemed untreatable. Over the past 2 decades, endovascular treatment has emerged as the therapy of choice for patients with symptomatic lower-limb peripheral artery disease (LL-PAD).[2–4] Angioplasty has shown similar long-term outcomes compared with bypass surgery in this scenario with the benefit of minimal invasiveness, shorter hospitalization time, and reduced periprocedural complications.[2,4,5] Improvements in patient assessment, operators' experience, and new-generation techniques have certainly contributed to an increase

Abbreviations: CLTI, chronic limb-threatening ischemia; COMPASS, Cardiovascular Outcomes for People Using Anticoagulation Strategies; LL-PAD, lower-limb peripheral artery disease; MALE, major adverse limb events; MI, myocardial infarction; SOLACI, Latin-American Society of Interventional Cardiology.

Keywords: endovascular; Latin America; lower-limb peripheral artery disease.

* Corresponding author: drvirgen@cardiovascular.mx (L.R. Virgen-Carrillo).

https://doi.org/10.1016/j.jscai.2024.101931
Received 29 November 2023; Received in revised form 8 February 2024; Accepted 6 March 2024
Available online 4 April 2024

in the efficacy and safety of the procedure over the years. However, endovascular interventions have some challenges (eg, long lesions, small caliber arteries, calcification, need for longer devices) and they are not exempt from complications (including the inherent risk of revascularization failure); hence, exhaustive revascularization surveillance is required in these patients.[6]

Given the recently observed increase in the number of LL-PAD interventions, it is of utmost relevance to understand the clinical presentation and treatment patterns to accurately assess acute, intermediate, and long-term outcomes in this setting. Although most of the initial evidence is derived from randomized controlled clinical trials,[5,7] these studies commonly include selected populations and are thus limited in their reflection of real-world clinical practice. In recent years, there has been special interest in using registries to provide a better understanding of different areas of cardiovascular disease. It is important to note that most of the LL-PAD registries currently available are derived from the US or European populations. Little is known about the presentation of PAD and its endovascular approach and management in Latin America.

In order to address this issue, the Latin-American Society of Interventional Cardiology (SOLACI) initiated the SOLACI peripheral registry to provide a detailed overview of peripheral endovascular interventions and their characteristics in this previously understudied group. This manuscript aims to describe the design and implementation of the SOLACI Peripheral registry and presents a comprehensive description of the baseline characteristics of the first 1057 independent procedures included.

Materials and Methods

Study design

The SOLACI peripheral registry is a prospective, multicenter, observational, and hospital-based registry of peripheral endovascular interventions performed in LL-PAD patients aged >21 years. The registry is currently collecting data from 44 sites across 10 countries (the complete list of countries and sites can be found in Supplemental Table S1). The major exclusion criteria were acute limb-threatening ischemia and acute onset of symptoms (defined as the beginning of symptoms within 15 days of the index procedure).

Patients were approached for participation during their index admission at the interventional cardiology units from the participating centers. Written informed consent for confidential data management was obtained from each patient before they were included in the registry. The study complied with the Declaration of Helsinki and received approval from the local ethics committees in adherence with each center's regulations.

All patients were treated as per standard clinical practice and the selection of the revascularization strategy (eg, access type, lesion crossing strategy, balloon/stent type/dimensions—among others) was at the discretion of the attending physician.

Core data elements and time points

Every single procedure was entered as an independent record. Data were collected from medical records using anonymized electronic case report forms and captured in the Research Electronic Data Capture system (a secure web-based tool hosted at SOLACI Research offices in Buenos Aires, Argentina).

The core data elements that were included were demographic characteristics, risk factors, previous limb interventions, medical therapy instituted at the moment of inclusion, clinical presentation, lesion characteristics, procedural information, periprocedural complications, both major adverse cardiovascular and cerebrovascular events (MACCE) and major adverse limb events (MALEs). Major adverse cardiovascular and cerebrovascular events collected included death from any cause, cardiovascular death, myocardial infarction (MI), stroke, and major bleeding (Bleeding Academic Research Consortium >3a or clinically relevant). MALE included minor or major amputations and clinically driven revascularization of the target lesion.

Clinical follow-up after the index procedure was divided into early (≤45 days) and long-term follow-up (>45 days). The data collected during follow-up time points included Rutherford classification, pharmacologic therapy adherence, MACCE, and MALE.

Study end points

The SOLACI peripheral registry aims to collect and analyze data pertaining to the clinical features of Latin-American patients with LL-PAD, the vascular procedure approaches (ie, arterial access, crossing strategies, therapeutic algorithms, adjunctive device utilization, balloons, drug-coated balloons, stents, and drug-eluting stents), angiographic severity of the lesions (severe lesions were defined as >70% stenosis by visual estimate reported by the attending physician), angiographic success, medical therapy at the time of the interventions, procedure-related complications, and the occurrence of major cardiovascular and limb events in order to assess short and long-term outcomes in different health care scenarios and populations.

The primary end points included in-hospital occurrence of all-cause death, fatal and nonfatal MI, stroke, vessel (or stent) thrombosis, access complications, bleeding, and emergency reinterventions (defined as nonplanned reinterventions performed during the same admission as the index procedure). Secondary end points included all-cause death, fatal and nonfatal MI, stroke, repeated limb revascularization, and major and minor amputations.

The clinical follow-up is currently ongoing. The data used in this report correspond to the patient status at the time of inclusion in the registry and reflect the baseline characteristics during the index hospitalization.

Statistical analysis

All the analyses presented in this report are descriptive. Categorical variables were expressed as frequencies and percentages. Continuous variables were reported as mean and SD for normally distributed data and as median and 25th and 75th percentiles (Q1 and Q3, respectively) for data with a skewed distribution. Strict quality controls with data processing were applied to cross-check and ensure the quality of the data. Values falling out of the upper and lower boundary (Q1 − 3IQR and Q3 + 3IQR) were defined as extreme outliers and were excluded. Only cases with complete demographic characteristics data were considered for the present analysis. Data processing was performed using R 4.0.3 software.

Results

Demographic characteristics, risk factors, and medical therapy

A total of 1057 interventions performed on 997 patients were included in this report. The baseline characteristics of the study cohort are summarized in Table 1.

The mean age was 68.9 ± 10.5 years. Gender distribution revealed that 65.4% of patients (652) were men whereas 34.6% (345) were women. There was a high prevalence of hypertension (84.5%), dyslipidemia 67.4%), and diabetes mellitus (DM, 64.7%, mostly insulin-dependent). Overall, 17% had a previous history of MI, and 8.4% had

Table 1. Baseline characteristics.

	Overall (N = 997)
Age, y	68.9 ± 10.5
Male sex	652 (65.4%)
Body mass index, kg/m^2	27.1 ± 4.27
Active smoking	184 (18.5%)
Ex-smoker	396 (39.7%)
Diabetes (not insulin-dependent)	298 (29.9%)
Diabetes (insulin-dependent)	347 (34.8%)
Hypertension	842 (84.5%)
Dyslipidemia	672 (67.4%)
Previous myocardial infarction	169 (17.0%)
Previous PCI/CABG	216 (21.7%)
Stroke/TIA	84 (8.4%)
Heart failure	99 (9.9%)
Creatinine, mg/dL	1.005 (0.82-1.3)
Dialysis	55 (5.5%)
Peripheral disease (other vascular beds)	212 (21.3%)
Previous endovascular revascularization	221 (22.2%)
Previous surgical revascularization	59 (5.9%)
Previous amputation	148 (14.8%)

Data are shown as mean ± SD or median (IQR) for continuous variables and frequency and percentage for categorical variables.
CABG, coronary artery bypass graft; PCI, percutaneous coronary intervention; TIA, transient ischemic attack.

a previous stroke or transient ischemic attack. The median creatinine level was 1.005 mg/dL (IQR, 0.82-1.3), 133 (13%) patients presented a creatinine level >1.5 mg/dL and 55 (5.5%) were on dialysis. Interestingly, more than a fifth (21.3%) of the population had documented peripheral disease in other vascular bed (eg, carotid and aortic) and 32.9% had 1 or more treatments on the lower limbs before the index procedure (either amputation and/or limb revascularization). Previous endovascular angioplasty was present in 22.2% whereas previous surgical approach was used in 5.9%.

The medical therapy that the patient was on at the time of the intervention was collected for each procedure (Table 2). Most of the patients were already taking aspirin and statins (85.7% and 78.6%, respectively). The additional antiplatelet strategies included clopidogrel in almost half of the population (49.8%), cilostazol (35%), and 17.1% were under some anticoagulant strategy (rivaroxaban 2.5 mg was used in 4.4%).

Clinical presentation

Most patients (61.2%) presented with CLTI (defined as ischemic rest pain and/or tissue loss present for at least 2 weeks, accompanied by objective evidence of LL-PAD). The most common presentations by Rutherford categories corresponded to Rutherford 5 (37.6%) and 3 (30.9%). For patients presenting with CLTI (Rutherford 4-6), the Wound, Ischemia, foot Infection assessment was applied (Table 3). The angiographic findings are summarized in Table 3. Overall, the most affected arteries were the superficial femoral artery (severe disease 28.3%; occluded 21.1%); anterior tibial (severe disease 19.8%; occluded 30%), and posterior tibial (severe disease 14.7%; occluded 29.3%).

Table 2. Pharmacotherapy at the time of intervention.

	Overall (N = 1057)
Aspirin	906 (85.7%)
Statins	831 (78.6%)
Clopidogrel	526 (49.8%)
Cilostazol	370 (35.0%)
Anticoagulation[a]	134 (12.7%)
Rivaroxaban	47 (4.4%)

Data are shown as frequency and percentage.
[a] Any anticoagulation therapy except rivaroxaban 2.5 mg.

Vascular territories were divided into the iliac and common femoral region, femoral-popliteal region, and infrapatellar region. Most of the procedures treated 1 vascular region; however, more than 1 territory was treated in 27.6% of the procedures. The most frequently targeted territory was the femoral-popliteal region (N = 595), followed by the infrapatellar region (N = 554). The target lesion details were collected for each vascular region (Figure 1). Lesion segments range from 2.5 mm up to 450 mm. On average, longer lesions were seen below the knee (144 ± 88.4 mm). In all the regions, the presence of thrombus was <2%. Moderate calcification was predominant in the femoral-popliteal region (58.0%); this was also the region where atherectomy was more frequently used (4.4%). Severe calcification was present in 28.8% in the iliac and femoral region, 23.7% in the femoral-popliteal region, and 28.2% in the infrapatellar region. The use of stents was more frequent in the iliac and common femoral region (86%) whereas in the infrapatellar region, there was a predominant use of balloon angioplasty with stenting only used in rare occasions (47 interventions [8.4%] of which 22 were indicated as rescue stenting or bail-out).

Overall, the most frequent intraprocedural complication was thrombosis presenting in 1.9% (n = 20), followed by hematoma in the access site (1.5%). Major adverse events during hospitalization included death from any cause (1.3%), cardiovascular death (0.7 %), MI (0.4%), stroke (0.1%), and Bleeding Academic Research Consortium ≥3a bleeding (0.8%). Intrahospital events occurred mostly in procedures treating multiple territories (Figure 2).

Discussion

Lower-limb peripheral artery disease is a growing epidemic. Epidemiologic data show a continuous increase in the number of disability-adjusted life-years caused by LL-PAD, which highlights the importance of implementing early and effective treatments, such as endovascular procedures, especially in low and middle-income countries where access to these therapies is limited due to socioeconomic conditions.[8,9] Other studies have also documented disparities in PAD management and outcomes according to race and socioeconomic status.[10,11] Our cohort consisted predominantly of CLTI rather than intermittent claudication, representing an advanced stage of the disease. Additionally, more than one-third of the population had interventions in the lower limb (amputation and/or revascularization) before the index procedures. This also relates to the increased presence of concomitant comorbidities, such as the affection of other vascular beds (which has been reported to be associated with worse outcomes).[6,12,13] Multiple studies have shown the detrimental long-term impact of worse symptom status.[6,14–18] In the Cardiovascular Outcomes for People Using Anticoagulation Strategies trial, higher rates of MALE events were detected in patients with a more severe presentation at baseline.[15,19] The VOYAGER trial also showed a difference in the outcome rates according to the severity of baseline presentation.[17,20] Our findings concur with those of a recently published subanalysis of the EUCLID trial, which demonstrated differences in the clinical presentation among global regions (Europe, Asia, Central/South America, and North America). In this study, Central/South America presented at baseline with higher rates of amputations than other regions.[8] Additionally, worse limb symptoms were present in higher proportions among Central/South American patients (29.2% severe claudication, 2.9% ischemic rest pain, 2.5% minor tissue loss, and 0.6% major tissue loss). Interestingly, our registry population presented with higher rates of ischemic rest pain (15.9%), minor (37.6%), and major tissue loss (7.8%) than those reported for the Central/South America region in the aforementioned study.[8] Although other risk factors were similar to the rates reported for Central/South America in this trial, our cohort had

Table 3. Clinical presentation.

	Right (n = 533)	Left (n = 524)	Overall (N = 1057)
Clinical presentation			
Intermittent claudication	221 (41.5%)	184 (35.1%)	405 (38.3%)
Chronic limb-threatening ischemia	309 (58.0%)	338 (64.5%)	647 (61.2%)
Rutherford classification			
Asymptomatic	2 (0.4%)	1 (0.2%)	3 (0.3%)
Mild/moderate claudication	43 (8.1%)	35 (6.7%)	78 (7.4%)
Severe claudication	178 (33.4%)	149 (28.4%)	327 (30.9%)
Ischemic rest pain	85 (15.9%)	83 (15.8%)	168 (15.9%)
Minor tissue loss	192 (36.0%)	205 (39.1%)	397 (37.6%)
Major tissue loss	32 (6.0%)	50 (9.5%)	82 (7.8%)
ABI	0.701 ± 0.188	0.720 ± 0.219	0.710 ± 0.203
WIFI classification[a]			
Wound (W)			
No ulcer or gangrene (ischemic pain at rest)	60 (11.3%)	63 (12.0%)	123 (11.6%)
Small or superficial ulcer on leg or foot, without gangrene (SDA or SC)	138 (25.9%)	140 (26.7%)	278 (26.3%)
Deep ulcer with exposed bone, joint, or tendon ± gangrene limited to digits (MAD or standard TMA ± SC)	94 (17.6%)	117 (22.3%)	211 (20.0%)
Deep, extensive ulcer involving forefoot and/or midfoot ± calcaneal involvement ± extensive gangrene (CR of the foot or nontraditional TMA)	14 (2.6%)	15 (2.9%)	29 (2.7%)
Ischemia (I)			
ABI >0.8/SBP of the ankle >100 mm Hg/TP, $TCPO_2$ >60	49 (9.2%)	57 (10.9%)	106 (10.0%)
ABI 0.6-0.79/SBP of the ankle 70-100 mm Hg/TP, $TCPO_2$ 40-59	63 (11.8%)	74 (14.1%)	137 (13.0%)
ABI 0.4-0.59/SBP of the ankle 50-70 mm Hg/TP, $TCPO_2$ 30-39	77 (14.4%)	86 (16.4%)	163 (15.4%)
ABI <0.39/SBP of the ankle <50 mm Hg/TP, $TCPO_2$ <30	32 (6.0%)	45 (8.6%)	77 (7.3%)
Foot infection (FI)			
Uninfected	115 (21.6%)	108 (20.6%)	223 (21.1%)
Mild local infection, involving only the skin and subcutaneous tissue, erythema >0.5 to 2 cm	99 (18.6%)	119 (22.7%)	218 (20.6%)
Moderate local infection, with erythema >2 cm or involving deeper structures	71 (13.3%)	87 (16.6%)	158 (14.9%)
Severe local infection with signs of SIRS	2 (0.4%)	6 (1.1%)	8 (0.8%)
Angiographic findings			
Iliac and common femoral region			
Common iliac artery			
Severe	53 (9.9%)	35 (6.7%)	88 (8.3%)
Occluded	8 (1.5%)	14 (2.7%)	22 (2.1%)
External iliac artery			
Severe	30 (5.6%)	26 (5.0%)	56 (5.3%)
Occluded	8 (1.5%)	7 (1.3%)	15 (1.4%)
Internal iliac artery			
Severe	5 (0.9%)	5 (1.0%)	10 (0.9%)
Occluded	3 (0.6%)	2 (0.4%)	5 (0.5%)
Common femoral artery			
Severe	18 (3.4%)	23 (4.4%)	41 (3.9%)
Occluded	11 (2.1%)	4 (0.8%)	15 (1.4%)
Femoral-popliteal region			
Superficial femoral artery			
Severe	147 (27.6%)	152 (29.0%)	299 (28.3%)
Occluded	121 (22.7%)	102 (19.5%)	223 (21.1%)
Deep femoral artery			
Severe	7 (1.3%)	5 (1.0%)	12 (1.1%)
Occluded	3 (0.6%)	2 (0.4%)	5 (0.5%)
Popliteal artery			
Severe	94 (17.6%)	104 (19.8%)	198 (18.7%)
Occluded	51 (9.6%)	59 (11.3%)	110 (10.4%)
Infrapatellar region			
Tibioperoneal trunk			
Severe	70 (13.1%)	95 (18.1%)	165 (15.6%)
Occluded	22 (4.1%)	34 (6.5%)	56 (5.3%)
Anterior tibial artery			
Severe	102 (19.1%)	107 (20.4%)	209 (19.8%)
Occluded	136 (25.5%)	181 (34.5%)	317 (30.0%)
Posterior tibial artery			
Severe	75 (14.1%)	80 (15.3%)	155 (14.7%)
Occluded	143 (26.8%)	167 (31.9%)	310 (29.3%)
Peroneal artery			
Severe	78 (14.6%)	88 (16.8%)	166 (15.7%)
Occluded	52 (9.8%)	77 (14.7%)	129 (12.2%)
Dorsalis pedis artery			
Severe	17 (3.2%)	18 (3.4%)	35 (3.3%)
Occluded	11 (2.1%)	11 (2.1%)	22 (2.1%)

Data are shown as mean ± SD for continuous variables and frequency and percentage for categorical variables.
ABI, ankle-brachial index; CR, complex reconstruction; MDA, multiple digital amputations; SBP, systolic blood pressure; SC, skin coverage; SDA, simple digital amputation; SIRS, systemic inflammatory response syndrome; $TCPO_2$, transcutaneous oxygen pressure; TMA, transmetatarsal amputation; TP, toe pressure (SBP of toe); WIfI, Wound, Ischemia, and foot Infection.

[a] Applicable for patients with chronic limb-threatening ischemia Rutherford >3.

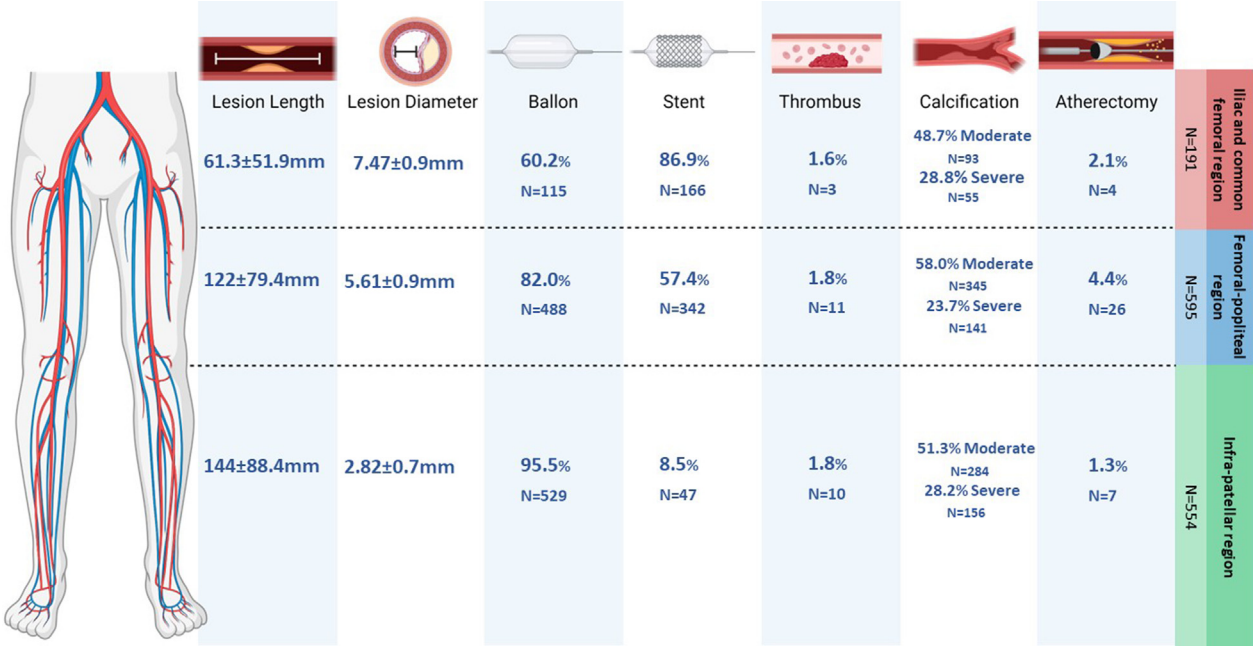


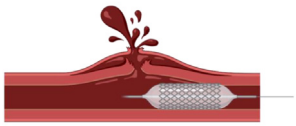
Figure 1.
Target lesion details by vascular region. Data are shown as mean ± SD for continuous variable. Percentages were calculated based on the total number of lesions treated for the corresponding region.

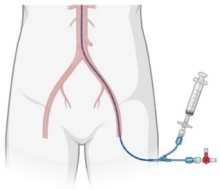
higher proportions of DM and hypertension. The high proportion of DM (64.7%) is of special interest, as other regions ranged between 32.6% and 43%. Furthermore, high proportions of DM and worse presentation were also notable when comparing our population with a larger registry exploring low-extremity endovascular procedures (n = 45,316) conducted in the United States.[21] These differences might be related to the selection criteria in controlled trials, which highlights the need for real-world data in this scenario but could also be representative of the impact that geographic location, dietary habits, cultural factors, and socioeconomic conditions may have on the presentation of PAD, underlining the importance of obtaining local information, rather than assuming that the disease presents in the same fashion everywhere in the world (Central Illustration). These results also call for earlier identification, prompt diagnosis, and earlier institution of guideline-directed medical therapy and risk factor modification strategies (smoking cessation, appropriate management of diabetes, hypertension, and hyperlipidemia), as well as adequate surveillance in our population.

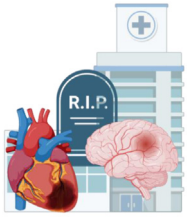
Regarding the medical therapy established before the intervention, aspirin was the preferred antithrombotic agent followed by clopidogrel. Although the American Heart Association/American College of Cardiology and the European Society of Cardiology guidelines have some discrepancies regarding the use of antithrombotic therapy in asymptomatic patients with PAD, for symptomatic PAD, both guidelines recommend the use of single antiplatelet therapy with aspirin or clopidogrel for MACCE prevention (recommendation IA). Interestingly, the use of a low dose of rivaroxaban was only documented in <5%, despite the evidence of its benefit to reduce MALE reported in the COMPASS trial.[15,19] The use of other direct oral anticoagulants in this context is still under investigation. The lesser use of anticoagulation strategy is probably due to the "relatively recent" data supporting this approach (published after the American Heart Association/American College of Cardiology and European Society of Cardiology guidelines release). This can also be related to the cost associated with the use of these agents in Latin-American countries. Surprisingly, regardless of the well-established recommendation for the use of statins, >20% of the population did not have an established statin therapy.[6,22]

A comprehensive description of the anatomy and disease location is extremely important as a wide spectrum of anatomic lesion distribution can be found. Consistent with other reports, the most affected regions in our population were the femoropopliteal and infrapopliteal regions.[6,23] Different risk factors have been previously related to the anatomic lesion presentation. Diehm et al[24] showed that although the tibio-pedal disease was primarily associated with older age and diabetes (relative risk ratio, 1.68; 95% CI, 1.47-1.92), the aorto-iliac region seems to especially relate to active smoking (relative risk ratio, 2.02; 95% CI, 1.68-2.42).[6] Our population not only had a high prevalence of diabetes, but also more than one-third were on insulin therapy, which may explain the distribution of the lesions and the presence of polyvascular disease. The anatomic distribution needs to be taken into account when planning the best revascularization strategy, as each region has its own technical complexity and poses diverse challenges for endovascular management. In general, aorto-iliac interventions have a high-success rate and long-term patency, both of which progressively decrease in direct proportion to the decrease in vessel diameter as we go into the femoro-popliteal and the infrapopliteal segments. Stent deployment was most commonly employed in the aorto-iliac segment, whereas its use was nearly absent in the infrapatellar segment. In this context, it is known that endovascular treatment for lesions below the knee is very challenging (long lesions, calcification, and small caliber) and has poor long-term patency.[6] Although a wide spectrum of endovascular approaches is currently under investigation,[3,25] the best long-term therapeutical approach for infrapopliteal disease is still a matter of debate. Infrapopliteal lesions were common in our population, with patients presenting longer lesions (144 ± 88.4 mm) compared with the ones reported in other studies investigating these strategies (mean lesion lengths of 43.8-82.73 mm).[3,25]

Procedural complications were more prominent when the iliac femoral region was treated. Intrahospital major events were more frequent in procedures addressing multiple territories, as they are generally more complex. In our population, nearly 30% required treatment in multiple territories, which added to the risk factor distribution making our population especially challenging.





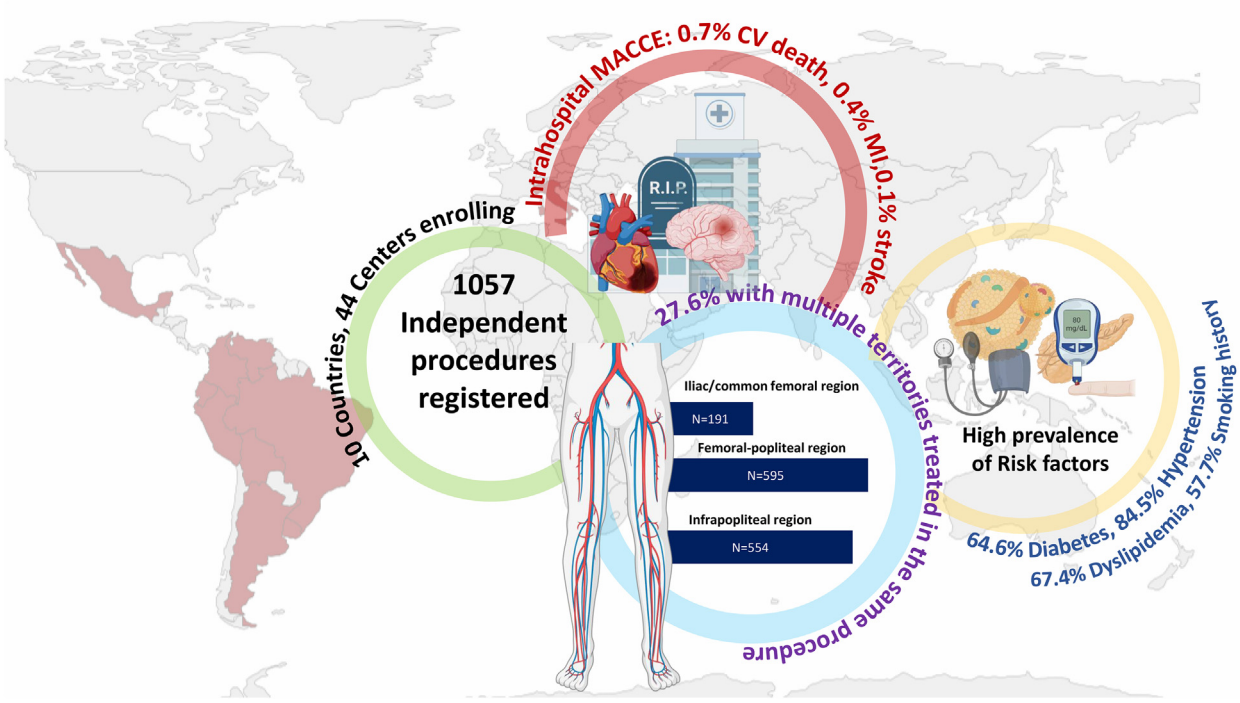


		Iliac-femoral (N=137)	Femoral-popliteal (N=309)	Infrapopliteal (N=304)	Multiple territories (N=291)
Intraprocedural Complications	Embolism	3(2.2%)	4(1.3%)	1(0.3%)	6(2.1%)
	Thrombosis	4(2.9%)	5(1.6%)	5(1.6%)	6(2.1%)
	Perforation	3(2.2%)	6(1.9%)	2(0.7%)	1(0.3%)
Vascular access Complications	Fistula	0(0%)	4(1.3%)	0(0%)	0(0%)
	Aneurism	1(0.7%)	2(0.6%)	0(0%)	3(1.0%)
	Hematoma	5(3.6%)	4(1.3%)	4(1.3%)	3(1.0%)
	Retroperitoneal Bleed	3(2.2%)	1(0.3%)	0(0%)	2(0.7%)
	Compartmental Sx	0(0%)	1(0.3%)	0(0%)	0(0%)
	Reintervention	4(2.9%)	2(0.6%)	4(1.3%)	2(0.7%)
Intrahospital Major Events	Intrahospital Death	2(1.5%)	2(0.6%)	3(1.0%)	7(2.4%)
	Cardiovascular	2(1.5%)	0(0%)	0(0%)	5(1.7%)
	Myocardial Infraction	0(0%)	1(0.3%)	0(0%)	3(1.0%)
	Stroke/TIA	0(0%)	0(0%)	0(0%)	1(0.3%)
	Bleeding	4(2.9%)	1(0.3%)	1(0.3%)	2(0.7%)

Figure 2.
Complications and intrahospital events details by treated region. Percentages were calculated based on the total number of procedures for the corresponding region. *16 procedures were not reported due to missing data. TIA, transient ischemic attack

Compared with other interventional procedures (such as percutaneous coronary interventions, transcatheter aortic valve replacement, etc) there is limited published data regarding LL-PAD interventions. Most of the current information is derived from clinical trials, which include selected populations, mainly from the United States and Europe.[4,12,17,19,26–30] There is still a shortage of real-world evidence of the benefits of percutaneous revascularization in LL-PAD, especially in low and middle-income countries.

Our study has limitations that need to be acknowledged. Given the registry-based nature of the study, from the total number of patients included, a proportion of patients had insufficient/inadequate data available for evaluation resulting in a reduction in the sample size. Of



Central Illustration.
Overview of baseline characteristics—Latin-American Society of Interventional Cardiology peripheral registry. CV, cardiovascular; MACCE, major adverse cardiovascular and cerebrovascular events; MI, myocardial infarction.

note, the overall sample size of our cohort compares favorably to several other reports exploring peripheral endovascular procedures. As with all registries, the sites that agreed to participate may represent a specific health practice type (ie, private vs public) resulting in a convenience sampling bias and could exclude some other particular populations. Nevertheless, this study included several previously underreported populations. To our knowledge, this is the largest multicenter, international report on LL-PAD with peripheral interventions in Latin America. Finally, the patients were included in this registry after the choice for endovascular revascularization strategy was made. The data provided correspond to patients presenting with already advanced LL-PAD. Therefore, the details from the beginning of exposure to risk factors, the appearance of symptoms, presentation to adequately-trained medical personnel, time to diagnosis and treatment, as well as the type of previous treatments, compliance and/or discontinuation of therapy, were not analyzed in the study. Consequently, our results are limited to reflect the clinical progression of LL-PAD, which is highly influenced by all the aforementioned factors.

Conclusion

Real-world data provided by national surveys and longitudinal registries are essential for understanding the sociodemographic, medical, and health care barriers according to country-specific settings. This information can help facilitate and improve evidence-based strategies for revascularization. There is a clear need to improve diagnosis, management, and continuous surveillance postendovascular procedures. This is particularly relevant in Latin-American countries where the cultural, social, and economic situation limits access to some therapies. The long-term results, including the patient-reported and hard outcomes from SOLACI peripheral registry will provide valuable insights into the prognosis of peripheral endovascular procedures and the unmet needs in Latin America.

Acknowledgments

All images in the paper are original and created with BioRender.com.

Declaration of competing interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding sources

This work was not supported by funding agencies in the public, commercial, or not-for-profit sectors.

Ethics statement and patient consent

Written informed consent for confidential data management was obtained from each patient before they were included in the registry. The study complied with the Declaration of Helsinki and received approval from the local ethics committees in adherence with each center's regulations.

Supplementary material

To access the supplementary material accompanying this article, visit the online version of the *Journal of the Society for Cardiovascular Angiography & Interventions* at 10.1016/j.jscai.2024.101931.

References

1. Fowkes FG, Rudan D, Rudan I, et al. Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis. *Lancet*. 2013;382(9901):1329–1340. https://doi.org/10.1016/S0140-6736(13)61249-0
2. Hong MS, Beck AW, Nelson PR. Emerging national trends in the management and outcomes of lower extremity peripheral arterial disease. *Ann Vasc Surg*. 2011;25(1):44–54. https://doi.org/10.1016/j.avsg.2010.08.006
3. Khalili H, Jeon-Slaughter H, Armstrong EJ, et al. Atherectomy in below-the-knee endovascular interventions: one-year outcomes from the XLPAD registry. *Catheter Cardiovasc Interv*. 2019;93(3):488–493. https://doi.org/10.1002/ccd.27897
4. Weissler EH, Wang Y, Gales JM, et al. Cardiovascular and limb events following endovascular revascularization among patients ≥65 years old: an American College of Cardiology PVI registry analysis. *J Am Heart Assoc*. 2022;11(12):e024279. https://doi.org/10.1161/JAHA.121.024279
5. Wu RMD, Yao CMDP, Wang SMD, et al. Percutaneous transluminal angioplasty versus primary stenting in infrapopliteal arterial disease: a meta-analysis of randomized trials. *J Vasc Surg*. 2014;59(6):1711–1720. https://doi.org/10.1016/j.jvs.2014.03.012
6. Beckman JA, Schneider PA, Conte MS. Advances in revascularization for peripheral artery disease: revascularization in PAD. *Circ Res*. 2021;128(12):1885–1912. https://doi.org/10.1161/CIRCRESAHA.121.318261
7. Ambler GK, Radwan R, Hayes PD, Twine CP. Atherectomy for peripheral arterial disease. *Cochrane Database Syst Rev*. 2014;3(3):CD006680. https://doi.org/10.1002/14651858.CD006680.pub2
8. Norgren L, North R, Baumgartner I, et al. World regional differences in outcomes for patients with peripheral artery disease: insights from the Euclid trial. *Vasc Med*. 2022;27(1):21–29. https://doi.org/10.1177/1358863X211038620
9. GBD 2013 DALYs and HALE Collaborators, Murray CJ, Barber RM, et al. Global, regional, and national disability-adjusted life years (DALYs) for 306 diseases and injuries and healthy life expectancy (HALE) for 188 countries, 1990-2013: quantifying the epidemiological transition. *Lancet*. 2015;386(10009):2145–2191. https://doi.org/10.1016/S0140-6736(15)61340-X
10. Arya S, Binney Z, Khakharia A, et al. Race and socioeconomic status independently affect risk of major amputation in peripheral artery disease. *J Am Heart Assoc*. 2018;7(2). https://doi.org/10.1161/JAHA.117.007425
11. Newhall K, Spangler E, Dzebisashvili N, Goodman DC, Goodney P. Amputation rates for patients with diabetes and peripheral arterial disease: the effects of race and region. *Ann Vasc Surg*. 2016;30:292–298.e1. https://doi.org/10.1016/j.avsg.2015.07.040
12. Gutierrez JA, Mulder H, Jones WS, et al. Polyvascular disease and risk of major adverse cardiovascular events in peripheral artery disease: a secondary analysis of the Euclid trial. *JAMA Netw Open*. 2018;1(7):e185239. https://doi.org/10.1001/jamanetworkopen.2018.5239
13. Bonaca MP, Gutierrez JA, Cannon C, et al. Polyvascular disease, type 2 diabetes, and long-term vascular risk: a secondary analysis of the IMPROVE-IT trial. *Lancet Diabetes Endocrinol*. 2018;6(12):934–943. https://doi.org/10.1016/S2213-8587(18)30290-0
14. getABI Study group. getABI: German epidemiological trial on ankle brachial index for elderly patients in family practice to dedect peripheral arterial disease, significant marker for high mortality. *Vasa*. 2002;31(4):241–248. https://doi.org/10.1024/0301-1526.31.4.241
15. Eikelboom JW, Connolly SJ, Bosch J, et al. Rivaroxaban with or without aspirin in stable cardiovascular disease. *N Engl J Med*. 2017;377(14):1319–1330. https://doi.org/10.1056/NEJMoa1709118
16. Jones WS, Baumgartner I, Hiatt WR, et al. Ticagrelor compared with clopidogrel in patients with prior lower extremity revascularization for peripheral artery disease. *Circulation*. January 17 2017;135(3):241–250. https://doi.org/10.1161/CIRCULATIONAHA.116.025880
17. Bonaca MP, Bauersachs RM, Anand SS, et al. Rivaroxaban in peripheral artery disease after revascularization. *N Engl J Med*. 2020;382(21):1994–2004. https://doi.org/10.1056/NEJMoa2000052
18. Debus ES, Nehler MR, Govsyeyev N, et al. Effect of rivaroxaban and aspirin in patients with peripheral artery disease undergoing surgical revascularization: insights from the VOYAGER PAD trial. *Circulation*. 2021;144(14):1104–1116. https://doi.org/10.1161/CIRCULATIONAHA.121.054835
19. Steffel J, Eikelboom JW, Anand SS, Shestakovska O, Yusuf S, Fox KAA. The COMPASS trial: net clinical benefit of low-dose rivaroxaban plus aspirin as compared with aspirin in patients with chronic vascular disease. *Circulation*. 2020;142(1):40–48. https://doi.org/10.1161/CIRCULATIONAHA.120.046048
20. Hiatt WR, Bonaca MP, Patel MR, et al. Rivaroxaban and aspirin in peripheral artery disease lower extremity revascularization: impact of concomitant clopidogrel on efficacy and safety. *Circulation*. 2020;142(23):2219–2230. https://doi.org/10.1161/CIRCULATIONAHA.120.050465
21. Jones WS, Kennedy KF, Hawkins BM, et al. Expanding opportunities to understand quality and outcomes of peripheral vascular interventions: the ACC NCDR PVI Registry. *Am Heart J*. 2019;216:74–81. https://doi.org/10.1016/j.ahj.2019.07.007
22. Gerhard-Herman MD, Gornik HL, Barrett C, et al. 2016 AHA/ACC guideline on the management of patients with lower extremity peripheral artery disease: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice guidelines. *Circulation*. 2017;135(12):e686–e725. https://doi.org/10.1161/CIR.0000000000000470

23. Rueda CA, Nehler MR, Perry DJ, et al. Patterns of artery disease in 450 patients undergoing revascularization for critical limb ischemia: implications for clinical trial design. *J Vasc Surg*. 2008;47(5):995–999. https://doi.org/10.1016/j.jvs.2007.11.055
24. Diehm N, Shang A, Silvestro A, et al. Association of cardiovascular risk factors with pattern of lower limb atherosclerosis in 2659 patients undergoing angioplasty. *Eur J Vasc Endovasc Surg*. 2006;31(1):59–63. https://doi.org/10.1016/j.ejvs.2005.09.006
25. Varcoe RL, DeRubertis BG, Kolluri R, et al. Drug-eluting resorbable scaffold versus angioplasty for infrapopliteal artery disease. *N Engl J Med*. 2024;390(1):9–19. https://doi.org/10.1056/NEJMoa2305637
26. Farber A, Menard MT, Conte MS, et al. Surgery or endovascular therapy for chronic limb-threatening ischemia. *N Engl J Med*. 2022;387(25):2305–2316. https://doi.org/10.1056/NEJMoa2207899
27. Bradbury AW, Moakes CA, Popplewell M, et al. A vein bypass first versus a best endovascular treatment first revascularisation strategy for patients with chronic limb threatening ischaemia who required an infra-popliteal, with or without an additional more proximal infra-inguinal revascularisation procedure to restore limb perfusion (BASIL-2): an open-label, randomised, multicentre, phase 3 trial. *Lancet*. 2023;401(10390):1798–1809. https://doi.org/10.1016/S0140-6736(23)00462-2
28. Banerjee S, Sarode K, Mohammad A, et al. Femoropopliteal artery stent thrombosis: report from the excellence in peripheral artery disease registry. *Circ Cardiovasc Interv*. 2016;9(2):e002730. https://doi.org/10.1161/CIRCINTERVENTIONS.115.002730
29. Söderström MI, Arvela EM, Korhonen M, et al. Infrapopliteal percutaneous transluminal angioplasty versus bypass surgery as first-line strategies in critical leg ischemia: a propensity score analysis. *Ann Surg*. 2010;252(5):765–773. https://doi.org/10.1097/SLA.0b013e3181fc3c73
30. Spreen MI, Martens JM, Knippenberg B, et al. Long-term follow-up of the PADI trial: percutaneous transluminal angioplasty versus drug-eluting stents for infrapopliteal lesions in critical limb ischemia. *J Am Heart Assoc*. 2017;6(4):e004877. https://doi.org/10.1161/JAHA.116.004877