ULTRASOUND-GUIDED ENDOVASCULAR THROMBECTOMY AS AN ALTERNATIVE FOR THE MANAGEMENT OF PERIPHERAL ARTERY DISEASE. REPORT OF TWO CASES

Keywords: Thrombectomy; Ultrasonography, Doppler; Peripheral Artery Disease; Renal Insufficiency, Chronic.

Palabras clave: Trombectomía; Ultrasonografía doppler; Enfermedad Arterial periférica; Insuficiencia renal crónica.

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RESUMEN

Introducción. Usualmente el tratamiento de la enfermedad arterial periférica (EAP) es quirúrgico convencional o endovascular guiado mediante angiografía o ultrasonido. Existen reportes del uso del sistema de aterectomía y trombectomía mecánica Rotarex® y/o del ultrasonido dúplex (UD) como guías para trombectomías de forma separada; sin embargo, la combinación de ambos dispositivos representa una gran ventaja al convertirse en una opción con buena tasa de éxito que podría emplearse en el manejo de diferentes tipos de patologías.

Presentación de los casos. Se presentan dos casos de pacientes con antecedente de colocación de stent infrapoplíteo, quienes asistieron al servicio de urgencias de un hospital universitario de Bucaramanga (Colombia) por claudicación intermitente, discromía y dificultad en la marcha (índice tobillo-brazo en examen físico de 0.3 y 0.6). En ambos pacientes se evidenció trombosis del stent mediante dúplex arterial, por lo que se les realizó angioplastia con sistema Rotarex® guiada por UD, logrando resultados clínicos y hemodinámicos satisfactorios en el postoperatorio. Los pacientes fueron dados de alta a los 4 y 6 días después del procedimiento y en ninguno de los dos casos hubo seguimiento posterior al egreso.

Conclusiones. La trombectomía con sistema Rotarex® guiada por UD se plantea como una alternativa viable, real y costo–efectiva en pacientes con EAP. Se recomienda implementar este tipo de estrategias con el fin de realizar trabajos con mayor poder estadístico para el análisis de los resultados y que permitan obtener conclusiones reproducibles sobre tasas de éxito, permeabilidad y salvamento de la extremidad.

ABSTRACT

Introduction: Peripheral artery disease (PAD) is usually treated with conventional or endovascular surgery guided by angiography or endovascular ultrasound. Although there are reports on the use of the Rotarex® atherectomy and mechanical thrombectomy systems and/or duplex ultrasound (DU) as separate guides for thrombectomies, the combination of both devices offers a greater advantage as this option has a good success rate and could be used in the management of different types of conditions.

Case presentation: Two cases of patients with a history of infrapopliteal stent are reported. They visited the emergency department of a university hospital in Bucaramanga (Colombia) due to intermittent claudication, dyschromia, and gait disturbance (ankle–brachial index on physical examination of 0.3 and 0.6). Both patients presented with stent thrombosis detected by means of arterial duplex and underwent angioplasty using the Rotarex® system combined with DU, achieving satisfactory clinical and hemodynamic outcomes in the postoperative period. The patients were discharged 4 and 6 days after the procedure, and there was no post–discharge follow–up in either case.
Conclusions. This combined procedure is a viable, real, and cost-effective alternative in comorbid patients at high risk of PAD. The implementation by different surgical groups of this type of strategy is recommended to carry out studies with greater statistical power for the analysis of results and to obtain reproducible conclusions on success rates, patency, and limb salvage.

INTRODUCTION

Peripheral artery disease (PAD) is a circulatory condition in which the blood supply to the limbs (mostly lower limbs) is reduced due to the narrowing of the blood vessels. It affects more than 200 million people worldwide and has a prevalence that increases with age, reaching up to 56% in people over 25 years of age. Mortality is difficult to estimate because it is an underdiagnosed disease (1–5).

PAD is a multifactorial condition that is related to tobacco use, diabetes mellitus (DM), arterial hypertension (AHT), advanced age, among others. Most patients are initially asymptomatic, then develop leg pain that occurs during walking (intermittent claudication), and finally present critical limb ischemia (CLI) (21%) or sometimes acute limb ischemia (ALI) (1.7%) (1–7).

CLI is a severe form of PAD characterized by lower limb pain at rest that lasts for more than 2 weeks and wounds that develop gangrene or do not heal. It has a prevalence of 1.3% in patients older than 40 years and is considered one of the most challenging conditions for medical–surgical management because it contributes to an increased risk of death (95% within 10 years of the initial presentation of the disease), cardiovascular events, and limb loss (up to 40%) (8,9). On the other hand, ALI results in limb amputation in 10–15% of cases and has a 30-day mortality rate of 15–25% (9,10).

The management of PAD is based on non–pharmacological, pharmacological, and surgical therapy. The first is focused on physical activity, ambulation, and lifestyle changes (7,8); the second involves anticoagulant therapy, antiplatelet therapy, statins, antihypertensives, and other drugs; and the third is the last resort when patients do not improve clinically with the established treatment or develop CLI or ALI. Preoperative assessment is performed using duplex ultrasound (DU) or cross-sectional imaging (magnetic resonance imaging and/or computed tomography angiography) (3,8–10).

The surgical management of PAD can be endovascular, which has lower rates of morbidity and mortality and hospital stay, and/or conventional open surgery (3,6). Choosing the best method depends on the characteristics of the arterial condition of each patient, which are assessed by means of multiple instruments such as the GLASS system (Global Limb Anatomic Staging System) or the WIFI (Wound, Ischemia and Foot Infection) classification (3,6,11).

Endovascular management strategies include balloon angioplasty (conventional or medicated), stenting (conventional or medicated), and atherectomy
(directional, orbital, laser and rotational), which can be angiography- or intravascular ultrasound-guided (12-14). Likewise, mechanical arterial thrombectomy has also emerged as a strategy with high success rates for less invasive procedures in patients with comorbidities (13-17). In turn, DU is a cost-effective option that reduces radiation exposure, decreases the use of nephrotoxic agents, and provides high-quality images with reliable hemodynamic parameters that allow for an immediate evaluation of postoperative results (12-17).

The following are two cases of patients with PAD and previous stent thrombosis, who were successfully treated with rotational atherectomy guided by the Rotarex® atherectomy and mechanical thrombectomy system.

**CASE PRESENTATION**

**Case 1**

A 68-year-old man attended the emergency department of the Hospital Universitario de Santander in Bucaramanga, Colombia, because he had been experiencing pain in the right lower limb (RLL) and difficulty in ambulation secondary to mild distal coldness and cyanosis for the last 3 days. The patient had the following medical history: atrial fibrillation, Chagas heart disease, hypertension, chronic obstructive pulmonary disease, chronic kidney disease (CKD) and PAD that required left above-the-knee amputation and angioplasty plus endovascular stenting of the femoral popliteal artery (Lifestent) in the right lower limb (RLL) 4 months prior to admission. In addition, he had poor adherence to anticoagulant therapy (vitamin K antagonists).

On physical examination, the following findings were reported: absence of popliteal pulse and infrapatellar pulses, visual analog scale (VAS) score of 8/10, and ankle-brachial index (ABI) of 0.6; no ischemic ulcers were observed. Considering these findings and history, the patient was admitted to the inpatient service.

Admission laboratory tests showed a serum creatinine level of 1.4 mg/dL for a glomerular filtration rate (GFR) of 51 mL/min/1.73m² (CKD stage 3a) according to the CKD-EPI creatinine equation (18). In view of this kidney involvement, a venous duplex (VD) of the RLL was performed after admission, with negative findings for deep vein thrombosis, as well as an arterial duplex (AD) that revealed a 5mm stent surrounded by hyperechoic material in its entirety. Consequently, it was considered that the patient had subacute stent thrombosis in a segment of the popliteal femoral artery with distal recanalization by collateral circulation to compensate for the obstruction in the tibiofibular trunk (Figure 1).
Based on the physical examination findings, laboratory and imaging test results, and multiple comorbidities, and in order to reduce exposure to nephrotoxic drugs as much as possible, it was decided that the patient was a candidate for stent for permeabilization by means of DU-guided endovascular mechanical thrombectomy plus angioplasty (Rotarex® system) under local anesthesia. The procedure was scheduled to be performed two days later.

However, on the second day of hospitalization, symptoms worsened, with increased RLL pain (VAS: 9/10), paresthesia, dysesthesia, progression of cyanosis, decreased ABI (0.3), and absence of distal pulses. Therefore, DU + angioplasty (Rotarex® system) was performed (Figure 2).
The following is a description of the procedure performed on the patient (DU-guided endovascular mechanical thrombectomy + angioplasty with Rotarex® stent system in a segment of the right femoral popliteal artery):

1. An initial assessment was performed in the hemodynamics room using ultrasound to identify and select the arterial segments to be treated.
2. Local anesthesia (lidocaine 1% 10cm³, without epinephrine) was injected in the puncture area of the right common femoral artery.
3. An 8Fr sheath was inserted under ultrasound guidance and following the Seldinger technique.
4. Ultrasound guided advance and navigation (0.035x260mm hydrophilic guidewire) were achieved, partially flanking the stent up to the second segment of the popliteal artery.
5. Under ultrasound-guided navigation and using a vertebral catheter to improve the support of the hydrophilic guidewire, the blocked segment of the stent was completely crossed, verifying the location of the hydrophilic guidewire in the tibiofibular trunk and the posterior tibial artery.
6. Heparin was administered systemically (unfractionated heparin at a dose of 100 IU/kg).
7. Mechanical thrombectomy was performed using the Rotarex® 6Fr system under sequential ultrasound guidance following the recommendations of the manufacturer.
8. Biphasic wave DU for stent control and ultrasound-guided conventional balloon angioplasty (Invatec Admiral Xtreme 5x120mm) were performed.
9. A follow-up AD was performed, revealing triphasic flow in the stent, the tibiofibular trunk, and the distal posterior tibial artery.
10. The hydrophilic guidewire was removed under ultrasound guidance and antiplatelet therapy was initiated with acetylsalicylic acid and clopidogrel (loading dose of 300mg each).
11. Finally, 4 hours after administration of unfractionated heparin, the sheath was removed.

After the surgical procedure, the patient showed clinical improvement (Table 1).

<table>
<thead>
<tr>
<th>Case 1</th>
<th>Preoperative</th>
<th>Postoperative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anatomical structure</td>
<td>PSV</td>
<td>Flow</td>
</tr>
<tr>
<td>External iliac artery</td>
<td>69</td>
<td>Triphasic</td>
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<td>Biphase</td>
</tr>
<tr>
<td>P1 segment of the popliteal artery</td>
<td>* Occlusion/floatung thrombus</td>
<td>61</td>
</tr>
<tr>
<td>P2 segment of the popliteal artery</td>
<td>* Occlusion</td>
<td>84</td>
</tr>
<tr>
<td>P3 segment of the popliteal artery</td>
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</tr>
<tr>
<td>Tibiofibular trunk</td>
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<td>-</td>
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<td>* Occlusion</td>
<td>-</td>
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<td>* Occlusion</td>
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<tr>
<td>Distal peroneal artery</td>
<td>* Occlusion</td>
<td>10</td>
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</tbody>
</table>

PSV: peak systolic velocity.  
* No flow-occlusion  
Source: Own elaboration.
After confirming the presence of popliteal pulses and observing a reduction in pain (VAS: 2/10), improvement in the perfusion of the RLL, and a decrease in paresthesia, 48 hours after surgery, a follow-up AD was performed, which showed stent patency in its entirety with triphasic flow (normal morphology of the arterial flow curve), acceptable infrapatellar flows (Figure 3), and pseudoaneurysm with a hematoma of 2.7x4mm at the puncture site, with no evidence of flow inside (color Doppler) that was treated with compression bandage for anticoagulation. Four days after surgery, the patient was discharged with an indication for outpatient physical therapy and anticoagulation with warfarin 4 mg/day indefinitely, with monitoring of the international normalized index.

![Figure 3. Follow-up duplex ultrasound 48 hours after ultrasound-guided mechanical thrombectomy, A) popliteal femoral artery stent patency, triphasic flow with no residual stenosis; B) distal peroneal artery run-off with evidence of triphasic flow. Source: Image obtained while conducting the study.](image)

At the time of writing this report, there was no follow-up of the case due to a lack of adherence by the patient.

**Case 2**

A 75-year-old woman attended the emergency department of the Hospital Universitario de Santander after presenting symptoms of pain in the right foot secondary to necrosis of the proximal phalanx of the hallux for 5 months. The patient had a history of DM, AHT and PAD resulting in amputation of the distal phalanx of the third toe of the right foot 2 years prior to admission and angioplasty plus endovascular stenting of the popliteal artery in RLL performed to avoid limb amputation.

On physical examination, the following findings were reported: bilateral femoral pulse and left popliteal pulse, absence of bilateral right popliteal and dorsalis pedis pulse, and ABI of 0.6. Admission laboratory tests showed a serum creatinine level of 1.3 mg/dL for a GFR of 40.1 mL/min/1.73m² according to the CKD-EPI creatinine equation (CKD stage 3a) (18).
In view of these findings, the patient was admitted to the inpatient service. An AD of the RLL was performed, which showed PAD with suprapatellar and infrapatellar involvement, stent occlusion in the right popliteal artery (segments 1 and 2) with recanalization of the tibiofibular trunk due to collaterality, occlusion of the anterior tibial artery in the middle third and posterior tibial artery, as well as occlusion of the left posterior tibial artery along its entire course (Figure 4). Therefore, the patient was rated as a PAD patient with Rutherford 5 classification for the RLL.

Figure 4. Duplex ultrasound of right lower limb on admission. A) proximal segment of distal popliteal femoral artery stent blocked by hypoechogetic material; B) collateral circulation near the stent in the second segment of the popliteal artery, monophasic flow; C) duplex with biphasic flow in collateral circulation coming from peroneal artery; D) duplex with biphasic flow at the tibiofibular trunk level.
Source: Image obtained while conducting the study.

Considering the results of laboratory and imaging tests and her multiple comorbidities, and in order to reduce exposure to nephrotoxic drugs as much as possible, the patient underwent stent permeabilization by ultrasound-guided endovascular mechanical thrombectomy plus angioplasty (Rotarex® system) on the second day of admission. This procedure was performed without complications following the same steps described in case 1 (Figure 5).
Figure 5. Ultrasound-guided endovascular mechanical thrombectomy and postoperative management. A) passage of mechanical thrombectomy system over support guidewire through the blocked stent; B) and C) 2D and color duplex with confirmation of previously occluded stent permeabilization; D) color duplex showing adequate stent patency and second segment of the popliteal artery in the immediate postoperative period.
Source: Image obtained while conducting the study.

Following the surgical procedure, the patient presented pain reduction (VAS: 2/10) and clinical improvement and better perfusion in the RLL. In the follow-up AD performed postoperatively on the same day of the procedure, a permeable femoral shaft, permeable stent in segments 1 and 2 of the popliteal artery, adequate run-off (infra patellar flow target artery up to the foot) through peroneal artery with biphasic flow, and absence of pseudoaneurysm were observed. Table 2 shows the evolution of the patient after surgery. On the sixth postoperative day, the patient was discharged with follow-up by vascular surgery and internal medicine.
Table 2. Comparison of preoperative and postoperative arterial duplex in case 2.

<table>
<thead>
<tr>
<th>CASE 2</th>
<th>Preoperative</th>
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<td>Flow</td>
<td>PSV</td>
<td>Flow</td>
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<td>Triphasic</td>
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<td>Distal posterior tibial artery</td>
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<tr>
<td>Hunter’s canal</td>
<td>180</td>
<td>Triphasic</td>
<td></td>
<td></td>
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</tbody>
</table>

PSV: peak systolic velocity.
* No flow - occlusion

Source: Own elaboration.

At the time of writing this report, no follow-up of the case was recorded due to the patient’s lack of adherence.

Discussion

PAD mainly affects people over 60 years of age, as in the cases presented, and has a prevalence that increases with age, being 4.4% in the general population in Colombia. This is also a condition of great public health relevance as patients with this condition have a 1–3% risk of amputation 5 years after diagnosis (3,6,8,19,20).

The risk factors for PAD are AHT, DM, CKD, obesity, hyperlipidemia, and smoking. In case 1 reported in the present study, PAD and its complications appeared early because the patient had more than 3 risk factors, which represents...
an increased risk of developing PAD of almost 13.2 times compared to case 2, in which the patient had only 2 risk factors (3,6,8,19,20).

During the clinical course and follow-up of patients with PAD, emphasis should be placed on vascular examination, since it allows for the detection of alterations that depend on the degree of arterial involvement, such as decreased pulses, abnormal gait, intermittent claudication, among others (6).

The use of the ABI as a screening and diagnostic method for PAD has a sensitivity of 94–97%, with abnormal values <0.9. However, when patients present with CKD and DM there may be arterial stiffness, which results in an ABI>1.3. In these cases, it is recommended to use the digit-brachial index as a complementary diagnostic method (6). In the cases reported above, the patients had an ABI<0.9 on admission, which was used to define the surgical approach to be used (6).

CLI increases the risk of death and cardiovascular events, and also involves an increased risk of loss of the affected limb, as evidenced in case 1. It has been established that the amputation rate in patients with CLI is 10–40% and the mortality rate is 20% at one year, 40–70% at 5 years, and 80–95% at 10 years. Therefore, it is important to offer different strategies aimed at trying to save the limb, thus improving the prognosis of this population (6,8–10). American and European guidelines for the management of CLI agree that outcomes are similar between endovascular and surgical approaches (21), although they favor the endovascular approach in patients with ominous comorbidities or without adequate autologous vein for arterial bypass (8,22).

On the other hand, ALI requires an emergency approach, and the revascularization strategy in these patients should be individualized on a case-by-case basis taking into account the available resources, the experience of the treating group of professionals, and the clinical presentation of the condition. Thus, the technique that leads to rapid restoration of arterial flow with the least possible risk to the patient should be selected (8). Endovascular procedures for the management of ALI and CLI are indicated as primary therapy because of their lower morbidity and mortality (23).

In the present study, taking into account that current guidelines recommend catheter-guided thrombolysis (CGT) as an effective treatment for ALI and percutaneous mechanical thrombectomy as a complement to it (22–24), in the cases presented, DU-guided mechanical thrombectomy was proposed as the initial surgical strategy due to the lack of authorization for the use of systemic thrombolytics at the peripheral arterial level, the specific characteristics of the patients (CKD, DM, AHT), and the presence of subacute and chronic thrombosis.

Endovascular mechanical thrombectomy offers multiple advantages over conventional procedures for the management of arterial thrombosis since it is
a less invasive procedure where vessel recanalization is faster and there is less bleeding (25). In the case of lower limb ALI, it has been established that the clinical success rate with the Rotarex® system is between 91.4% and 97%, while the success rate for thrombolysis is between 46% and 67.9% and for surgery is 74.3%. Regarding limb salvage at one year, the Rotarex® system remains superior, with rates between 93.7% and 100%, compared to CGT (65–87%) and conventional surgery (69.9–89.6%) (25).

Mechanical thrombectomy, as well as any invasive procedure, poses risks and complications such as rethrombosis (8.1%), vascular dissection (4.1%), vascular perforation (1.4%), distal embolism (5.5%), myocardial infarction (7%), stroke (1.6%), and kidney failure (2.3%) (25). Among the cases described in this report, there was only one pseudoaneurysm at the puncture site, which was treated with medical management.

So far there are no studies that analyze the cost-benefit of the Rotarex® system, but it is clear that although its use leads to an increase in the cost of the revascularization procedure, this is outweighed by the fact that it is minimally invasive, requires less hospital stay, and does not imply the need for admission to the intensive care unit (25).

For its part, AD has great advantages as an alternative to angiography, particularly in patients with DM or CKD, since these conditions predispose them to a higher risk of developing contrast-induced acute kidney injury (AKI) (26,27). In addition, AD eliminates radiation exposure with low complication rates and allows for the dynamic and immediate assessment of post-surgical results, thus quantitatively diagnosing the presence or absence of residual stenosis suitable for further management (27) (Table 3).

Table 3. Advantages and disadvantages of the Rotarex® system and ultrasound.

<table>
<thead>
<tr>
<th>System</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rotarex®</td>
<td>• Minimally invasive&lt;br&gt;• Easy to use&lt;br&gt;• Short operative time&lt;br&gt;• Reduced thrombus size&lt;br&gt;• Suitable for all types of supracondylar vessels&lt;br&gt;• Low complication rates&lt;br&gt;• No endothelial damage&lt;br&gt;• High revascularization success rates&lt;br&gt;• Unmasks underlying injuries&lt;br&gt;• No need for thrombolytic medication or vessel preparation&lt;br&gt;• Short hospital stay required&lt;br&gt;• No admission to the ICU&lt;br&gt;• Affordable</td>
<td>• Inefficient in angulated bifurcations and sclerotic bifurcations&lt;br&gt;• Aortic dissection due to fissure of the intima and perforation in highly calcified vessels&lt;br&gt;• Expensive catheter required&lt;br&gt;• Distal embolization is required with indication of thrombectomy or lytic therapy&lt;br&gt;• Not suitable for infracondylar vessels&lt;br&gt;• Minimum vessel lumen of 4mm is required</td>
</tr>
</tbody>
</table>
### Case Reports

**System**

<table>
<thead>
<tr>
<th>Benefits</th>
<th>Disadvantages</th>
</tr>
</thead>
</table>
| • Capacity to determine the diameter and length of the stenotic lesion  
• No need for contrast medium and its associated complications, especially in patients with renal failure  
• Capacity to perform a real-time hemodynamic evaluation of the treated arterial segment  
• Useful not only to identify the exact location and severity of occlusive disease, but also to accurately measure the extent of the lesion  
• Visualization of the artery, regardless of patency, and the arterial wall, in real time, regardless of limb motion, with objective measurements of flow direction and waveform  
• Image magnification up to 5 times and multiple projections provide accurate information for balloon and stent placement  
• Immediate and accurate identification of complications associated with balloon angioplasty, such as embolization or thrombosis using duplex ultrasound, which can also be successfully treated with duplex guidance alone | • Requires readiness to abandon this approach in favor of a standard technique because visualization of the segment to be treated may not be acceptable, such as in cases of very calcified arteries or in very obese patients in whom the arteries are >4 cm deep  
• Ultrasound-guided duplex procedures on infrapopliteal arteries should be attempted only in the presence of an experienced vascular technologist and an interventionalist who is also familiar with lower extremity arterial duplexing |

**ICU**: intensive care unit.

Source: Own elaboration based on Kithcart et al. (22), Aboyans et al. (23), Khan et al. (24), Loffroy et al. (25), Bolt et al. (26), and Ascher et al. (27).

Some studies have achieved technical success rates between 93% and 100% using DU as a guide for balloon angioplasty and stenting, with no statistically significant differences between primary and secondary occlusions. In turn, patency at one month and limb salvage rates between 95% and 100% have been reported, taking into account works mainly developed in segments of the superficial femoral artery and proximal popliteal arteries (28–30).

Consequently, ultrasound-guided therapeutic procedures have been considered as feasible, efficient and cost-effective options that allow achieving anatomical and hemodynamic improvement, regardless of the extent of the stenosis, with few limitations and with greater utility in patients allergic to the contrast medium or those with CKD or DM. In this way, the risk of renal function deterioration and the need for renal replacement therapies is reduced (31).

### Conclusion

ALI and CLI are entities that can jeopardize the viability of a limb. Mechanical thrombectomy using DU-guided Rotarex® system is a viable, real and cost-effective alternative in patients with PAD, showing good short-term results. It is recommended to implement this type of strategy in order to carry out work with greater...
statistical power for the analysis of results and to obtain reproducible conclusions on success rates, patency, and long-term limb salvage.

ETHICAL CONSIDERATIONS

Informed consent was obtained from the patients for the preparation of this case report, and the center’s protocols for the diagnosis and handling of patient data were followed for its publication.

CONFLICT OF INTEREST

None stated by the authors.

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