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PROCEDURAL AND EARLY HEMODYNAMIC OUTCOMES OF PERIPHERAL ARTERIAL ENDOVASCULAR INTERVENTION IN DIABETIC CHRONIC LIMB-THREATENING ISCHEMIA

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დიაბეტით დაავადებულ კიდურის ქრონიკული იშემიის მქონე პაციენტებში პერიფერიული რევასკულარიზაციის პროცედურული და ადრეული ჰემოდინამიკური შედეგები

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რეზიუმე

კვლევა მიზნად ისახავდა დიაბეტით დაავადებულ, კიდურის ქრონიკული იშემიის მქონე პაციენტებში პერიფერიული რევასკულარიზაციის პროცედურული და ადრეული ჰემოდინამიკური შედეგების შეფასებას. კვლევაში მონაწილეობდა 146 პაციენტი, რომელთა უმრავლესობას ჩაუტარდა ენდოვასკულური ჩარევა. პოსტპროცედურულ პერიოდში სისხლძარღვოვანი გამავლობა შეფასდა დუპლექს-სკანირებით 3 და 6 თვის ინტერვალში. მიღებული შედეგებით, 3 თვის შემდგომ პაციენტების უმეტესობაში აღინიშნებოდა ტრიფაზური სისხლის ნაკადი, ხოლო დარჩენილ ნაწილში - ბიფაზური ნაკადი; ოკლუზიის შემთხვევები არ გამოვლენილა. ანალოგიური დადებითი მაჩვენებლები შენარჩუნებული იყო 6 თვის შემდგომაც, რაც მიუთითებს ადრეული პოსტპროცედურული პერიოდის კარგ ჰემოდინამიკურ სტაბილურობაზე. კვლევა ადასტურებს, რომ რევასკულარიზაცია ეფექტური მეთოდია კიდურის შენარჩუნებისთვის, თუმცა დიაბეტური ანგიოპათიის პირობებში აუცილებელია ადრეული ჰემოდინამიკური მონიტორინგი, რათა დროულად შეფასდეს სისხლძარღვოვანი პასუხი და პროგნოზი.

Introduction. Among many complications of Diabetes mellitus, peripheral arterial disease remains one of the most severe and life-threatening problems. Diabetic patients with intense PAD or chronic limb-threatening ischemia (CLTI) complain of ischemic rest pain, persistent and non-healing ulcers, or gangrene. Diabetic CLTI is a well-known contributor to limb dysfunction, as well as cardiovascular morbidity and mortality. Finally, it places a burden not only on patients but also on healthcare systems [1,2].

Diabetic peripheral arterial disease usually affects many arteries together, mainly vessels below the popliteal artery. Structural and pathological changes in diabetic microvascular dysfunction are associated with endothelial damage, insufficient collateral circulation, and hypercoagulation. All these features make revascularization strategies more difficult and can lead to poor clinical outcomes [3]. Thus, diabetic individuals with CLTI represent a population under the highest risk for procedural failure, post-procedural complications, and poor post-intervention vascular functioning. Peripheral arterial revascularization (performed through endovascular, surgical, and combined approaches) still has the main role in the limb-saving process [4]. Achievements in endovascular technology, such as balloon angioplasty, drug-coated devices, atherectomy, and stent placement, are major benefits for treatment, especially for patients who are not good candidates for open surgery.

Modern clinical guidelines suggest an endovascular approach as the first option in exact cases of diabetic CLTI, especially in the presence of infrapopliteal arterial disease. Although revascularization methods have been improved, early vascular outcomes postoperatively are

heterogeneous from person to person. Release of the blockade for bloodflow is not always accompanied by restoration of tissue perfusion. Medial arterial calcification, microcirculatory dysfunction, and diffuse atherosclerosis in diabetic patients result in worse outcomes and decreased procedural benefits.

Initial hemodynamic evaluation is the key factor during decision-making process about revascularization. Post-procedural assessment methods such as ankle–brachial index (ABI), toe pressure, and duplex ultrasound give us an objective information about perfusion status and vascular patency. The duplex ultrasound follow-up is widely utilized in clinical practice to evaluate perfusion and discover early restenosis or occlusion in treated areas [5,6].

Many recent studies have reviewed the long-term limb-saving and survival history of CLTI post-revascularization [7]. Evidence on early vascular outcomes and post-procedural vascular patency in diabetic patients is limited. Additionally, the influence of different antithrombotic drug regimens on vascular outcomes in the presence of this high-risk group needs to be reviewed [8,9,10].

Main objective of our present research was to assess early vascular outcomes following peripheral arterial revascularization in diabetic patients. These patients present with diabetic chronic limb-threatening ischemia, and we have performed control duplex ultrasound during the follow-up period. Moreover, we have studied the relationship between post-procedural antithrombotic therapy and vascular patency in this population [11,12].

This study contains clinically relevant information about the revascularization strategies and the long-term monitoring of patients, concentrating on the early follow-up findings [13,14].

2. Materials and Methods. Study Design and Population. This research is a cohort study conducted at different medical centers specializing in vascular and endovascular interventions. In that study, early outcomes of patients who underwent peripheral arterial revascularization have been analyzed. A total of 146 patients were included in the analysis. The majority of patients were male (76.0%), while 24.0% were female. The majority of patients have comorbid dyslipidemia (93.8%). Most patients had non-insulin-dependent diabetes mellitus (95.9%), whereas 3.4% had insulin-dependent diabetes (Table 1).

Table 1 – Demographic characteristics of patients

Category	Patients (n)	%
Male	111	**76.0%**
Female	35	**24.0%**
DM Type 1	5	**3.4%**
DM Type 2	141	**96.6%**

According to modern criteria CLTI was defined as an ischemic rest pain, non-healing ulceration, or gangrene in presence of peripheral arterial disease. Diabetes mellitus was diagnosed based on documented medical history, use of glucose-lowering therapy, or established diagnostic criteria.

Inclusion criteria	Exclusion criteria
Age ≥ 18 years	Acute limb ischemia
Documented Diagnosis of diabetes mellitus	Non-atherosclerotic peripheral arterial disease
Clinical diagnosis of chronic limb-threatening ischemia	Prior major amputation of the same limb
Undergoing peripheral arterial revascularization (endovascular, surgical, or hybrid)	Incomplete clinical or follow-up data

Revascularization Procedures. Totally 146 patients we involved in the study. Revascularization strategy was determined by a multidisciplinary vascular team based on clinical presentation, anatomical characteristics, comorbidities, and individual patient risk profile. The majority of patients underwent endovascular revascularization procedures, including balloon angioplasty and stent implantation. Approximately 42 % of patients underwent Endovascular intervention, 39 % hydrid approach and 19% open surgery. Procedural details and treated arterial segments were recorded for each patient.

Post-Procedural Pharmacotherapy. Following revascularization, patients received antithrombotic therapy according to clinical indication and physician decision. Regarding antithrombotic therapy, aspirin plus rivaroxaban (10–20 mg) was the most frequently used regimen (57.5%), followed by aspirin plus rivaroxaban 2.5 mg twice daily (19.2%) and aspirin plus clopidogrel (19.2%) Treatment allocation and duration were documented and included in the analysis (Table 2).

Table 2 – Pharmacotherapy Regimens

Pharmacotherapy Regimen	Patients (n)	%
Aspirin + Rivaroxaban 2.5 mg (2xdaily)	28	19.2%
Aspirin + Rivaroxaban 10-20 mg	84	57.5%
Aspirin + Clopidogrel	28	19.2%

3. Study Results. Post-procedural vascular function was systematically assessed by using duplex ultrasound examinations during follow-up period. Duplex scanning was performed at 3 months and 6 months after revascularization to assess vessel patency and hemodynamic response.

Flow patterns were categorized as triphasic, biphasic, or occlusion of the treated vessel. Follow-up examinations demonstrated predominantly preserved arterial patency with good hemodynamic profiles, the majority of treated vessels showing triphasic or biphasic flow patterns, indicating satisfactory restoration of perfusion.

Duplex ultrasound follow-up demonstrated favorable hemodynamic outcomes after endovascular revascularization. At the 3-month follow-up, triphasic flow was observed in 56 patients (90.3%), biphasic flow in 6 patients (9.7%), and no cases of vessel occlusion were detected.

At the 6-month follow-up, triphasic flow persisted in 55 patients (88.7%) and biphasic flow in 7 patients (11.3%), with no evidence of vessel occlusion. These findings indicate maintained vessel patency and a favorable early hemodynamic response following endovascular intervention (Table 3).

Table 3 – Hemodynamic changes in patients

Follow-up period	Triphasic flow	Biphasic flow	Occlusion
3 months	56 (90.3%)	6 (9.7%)	0 (0%)
6 months	55 (88.7%)	7 (11.3%)	0 (0%)

Ethical Considerations. The study was conducted in accordance with the principles of the Declaration of Helsinki. The study protocol was reviewed and approved by the institutional ethics committee.

Due to the observational design of the study and the retrospective analysis of anonymized clinical data, the requirement for individual informed consent was waived in accordance with institutional policies.

4. Discussion. This study evaluated procedural success and early hemodynamic outcomes following peripheral arterial revascularization in patients with diabetic chronic limb-threatening ischemia. The principal findings demonstrate that revascularization can be performed with high technical

success and acceptable peri-procedural safety in this high-risk population, while also achieving significant early improvements in objective hemodynamic parameters. However, a subset of patients exhibited limited hemodynamic response despite angiographic success, which suggests that diabetic vascular disease has a complex pathophysiology.

Procedural Outcomes in Diabetic CLTI. The high procedural success rate observed in this cohort supports the idea that revascularization is the primary procedure in limb-saving therapy for diabetic CLTI. Achievements in endovascular technologies and careful patient selection have expanded the possibility of treating diffuse and distal disease, particularly in diabetic patients. The acceptable complication profile observed in this study further supports the safety of peripheral arterial revascularization when performed in specialized centers.

Nevertheless, lower success rates in infrapopliteal and multilevel disease underscore the technical challenges inherent to diabetic CLTI. Severe calcification, long-segment occlusions, and small-vessel diameter limit optimal revascularization outcomes and may require repeated interventions or additional strategies.

Early Hemodynamic Improvement and Its Clinical Significance. A key strength of this study is the focus on early hemodynamic outcomes, which indicate the physiological effectiveness of revascularization. A big improvement in ABI, toe pressure, and duplex ultrasound parameters was observed in most patients, indicating successful restoration of limb perfusion. These early changes are clinically relevant, as improved perfusion is a strong predictor for wound healing and limb preservation.

However, the observed variability in hemodynamic response highlights a significant limitation of relying only on angiographic endpoints. In diabetic patients, medial arterial calcification and microvascular dysfunction may prevent measurable improvements in macrovascular settings despite technically successful procedures. This finding highlights the importance of comprehensive hemodynamic assessment, including toe pressure and duplex ultrasound, particularly in patients with stiff arteries.

Implications for Clinical Practice. The results of this study suggest several practical implications. First, early hemodynamic evaluation should be routinely incorporated into post-revascularization assessment in diabetic CLTI patients. Second, toe pressure and duplex ultrasound may provide more reliable information than ABI alone in this population. Third, patients demonstrating limited early hemodynamic improvement may benefit from intensified wound care, adjunctive medical therapy, or consideration of additional revascularization strategies.

Furthermore, these findings support a multidisciplinary approach to diabetic CLTI, which means integration of vascular intervention with optimized glycemic control, infection management, and podiatric care to maximally improve limb salvage outcomes.

Conclusion. Peripheral arterial revascularization in diabetic patients with chronic limb-threatening ischemia is associated with high procedural success and significant early hemodynamic improvement. Nonetheless, variability in hemodynamic response underscores the complexity of diabetic vascular disease and the limitations of angiographic endpoints alone, and post-revascularization medical therapy also has an important role. Early hemodynamic assessment provides valuable prognostic information and should play a central role in post-revascularization evaluation and clinical decision-making.

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SUMMARY

Diabetes mellitus is highly associated with chronic limb-threatening ischemia (CLTI). It is a severe type of peripheral arterial disease with high rates of amputation and death. Peripheral arterial revascularization is the major limb-saving strategy in diabetic CLTI, but it’s very difficult to predict early hemodynamic benefits and complications, especially in this subgroup of patients.

Objective: Evaluation of procedural outcomes and early hemodynamic changes following peripheral arterial revascularization in patients with diabetic chronic limb-threatening ischemia.

Keywords: Diabetes mellitus; diabetic angiopathy; chronic limb-threatening ischemia