



ORIGINAL ARTICLE

Outcomes and Predictors of Amputation After Endovascular Revascularization in Diabetic Foot Disease with Peripheral Artery Involvement

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ABSTRACT

Background: Peripheral arterial disease (PAD) is significantly more prevalent in diabetic populations and is a major contributor to non-traumatic lower limb amputations.

Aim: This study assesses outcomes of percutaneous revascularization in diabetic PAD patients, comparing clinical characteristics between those who underwent amputation and those who did not.

Study Design: A single center retrospective observational study.

Methods: The study was conducted on 100 diabetic PAD patients undergoing endovascular revascularization between March 2023 and April 2024. Clinical classifications and laboratory parameters [hemoglobin A1c (HbA1c), renal function, C-reactive protein, low-density lipoprotein] were analyzed at baseline and 6 months.

Results: Amputation occurred in 15 patients (15%). These patients had significantly higher HbA1c (10.5 vs. 8.8, $p<0.001$), creatinine (1.52 vs. 0.89, $p<0.001$), and lower estimated glomerular filtration rate (47 vs. 89, $p<0.001$). PAD severity scores (Rutherford, Fontaine, Wagner, Wifl, TASC II) were all significantly higher in the amputation group. Receiver operating characteristic (ROC) analysis showed Wagner classification had the best predictive value (area under the ROC curve 0.982).

Conclusion: Advanced PAD in diabetics correlates with worse metabolic control and renal dysfunction. Early diagnosis and revascularization are critical to avoid amputation.

Keywords: Peripheral artery disease, interventional cardiology, below-the-knee intervention, diabetic foot

INTRODUCTION

Individuals with diabetes mellitus (DM) have a substantially elevated lifetime risk—approximately tenfold—of developing cardiovascular disease compared to the general population.¹ Cardiovascular complications account for about 77% of diabetes-related hospitalizations in the United States.²

Peripheral artery disease (PAD), a form of atherosclerotic occlusion affecting the arteries of the lower extremities, is a common and serious complication among diabetic patients.³ Atherosclerosis obliterans is the leading cause of chronic arterial blockage in the lower limbs,

particularly in those over 35 years of age.⁴ Importantly, nearly half of diabetic patients with foot ulcers also have PAD,⁵ and non-healing foot ulcers are among the most frequent concerns in this group. The incidence of PAD is estimated to be two to four times higher in individuals with diabetes compared to those without,⁶ and diabetes is present in roughly 20-30% of patients diagnosed with PAD.⁷ An estimated 15% of diabetic individuals will develop a foot ulcer during their lifetime,⁶ and PAD is identified in up to 90% of diabetic patients who undergo major limb amputation.⁸ Diabetes is, in fact, the most common cause of non-traumatic lower limb amputations, with rates of major amputation being 5-10 times greater than those in non-diabetic individuals.⁹

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Cite as: Süleymanoğlu C, Kırık A, Kaya Z, Çamkırın V. Outcomes and predictors of amputation after endovascular revascularization in diabetic foot disease with peripheral artery involvement. *Inter Cardio Pers.* 2025;1(2):52-58

Received: 04.06.2025

Accepted: 21.07.2025

Publication Date: 11.08.2025

Vascular disease in diabetes is predominantly macrovascular in nature, resulting from atherosclerosis, rather than being caused by microvascular arteriolar obstruction.¹⁰ This distinction holds clinical importance, as macrovascular disease is often responsive to revascularization procedures. Nevertheless, diabetes also induces microvascular dysfunction through autonomic neuropathy (neuroischemia), which leads to capillary hypoperfusion and compromised collateral blood flow.¹¹ Furthermore, endothelial dysfunction and reduced nitric oxide-mediated vasodilation contribute to the worsening of ischemic injury.¹² In diabetic patients, PAD typically presents at a younger age, advances more quickly, and frequently affects long, distal segments of the arterial system.⁷

Multiple classification systems are used to assess the severity of PAD and guide treatment strategies. The Fontaine and Rutherford systems are commonly used for clinical staging.¹³ In the Fontaine classification, stage 1 corresponds to asymptomatic disease, stage 2a to claudication occurring beyond 100 m; stage 2b to claudication within 100 meters; stage 3 to rest pain; and stage 4 to ulceration or gangrene—stages 3 and 4 are categorized as critical limb ischemia (CLI). The Wagner classification is typically applied to grade the severity of diabetic foot ulcers,¹⁴ while the TASC II classification provides anatomical stratification of aortoiliac and femoropopliteal lesions.¹⁵

This study evaluated diabetic patients with PAD who underwent percutaneous revascularization. We compared those who eventually underwent limb amputation during follow-up with those who did not, emphasizing clinical parameters and potential predictors of limb salvage versus limb loss.

METHODS

This retrospective study was carried out in the Clinic of Cardiology at Osmaniye State Hospital over a 1-year period, from March 2023 to April 2024. The objective was to evaluate the outcomes of 100 endovascular revascularization procedures performed in patients with ischemic diabetic foot.

Patient Selection and Ethical Approval

Patients were referred from the diabetic foot clinic as confirmed cases of DM, diagnosed based on the criteria established by the American Diabetes Association, and presented with ischemic foot lesions. Informed consent was obtained from all participants after a thorough explanation of the procedure and possible complications. The study received ethical approval from the Osmaniye State Hospital Ethical Committee (decision number: 254426875, date: 19.09.2024).

Diagnostic Evaluation

All patients underwent Doppler ultrasonography to localize, visualize, and assess the hemodynamic characteristics of arterial lesions. Evaluations included gray-scale imaging, color Doppler mapping, power Doppler, and pulsed-wave Doppler to assess blood flow.

Conventional angiography was performed in all cases. Percutaneous transluminal angioplasty was carried out on one or more infrapopliteal arteries—preferably targeting the artery supplying the ulcer—when critical stenosis or occlusion was identified. For patients with associated

superficial femoral artery (SFA) involvement, SFA angioplasty was performed during the same session.

Medical Management

All patients received comprehensive medical treatment for cardiovascular risk factors. Perioperative management included the following:

- Surgical debridement of necrotic tissue,
- Glycemic control using insulin therapy,
- Administration of broad-spectrum antibiotics,
- Antiplatelet therapy with aspirin (100 mg/day) and/or clopidogrel (75 mg/day).

For patients with elevated creatinine levels (>1.1 mg/dL), a renal protection strategy was implemented, which included intravenous hydration and oral N-acetylcysteine (600 mg twice daily) starting the day before the procedure. Metformin was discontinued 2 days prior to angiography and resumed afterward. Dialysis was initiated in patients who developed renal failure following the procedure. Blood urea nitrogen and serum creatinine were routinely assessed prior to angioplasty.

Interventional Procedure

All procedures were conducted under local anesthesia. The primary approach involved an antegrade puncture of the ipsilateral common femoral artery (CFA) using a 6F introducer sheath. In select cases, a contralateral CFA puncture with a crossover technique was employed. Angiographic evaluation utilized a nonionic contrast agent (iodixanol), digital subtraction angiography, and multiple oblique and lateral views of the foot to ensure optimal visualization.

Lesions were traversed using 0.014", 0.018", or 0.035" guidewires. For total occlusions, true lumen recanalization was the first-line approach, using dedicated coronary or peripheral guidewires. If this was unsuccessful, a subintimal technique was used.

Balloon angioplasty commenced with predilation using low-profile balloons, followed by inflation of peripheral balloons selected according to a 1:1 artery-to-balloon diameter and ratio and the length of the lesion, with inflation maintained for 3 minutes. No stents were deployed in any of the interventions. Intravenous heparin (70 IU/kg) was administered following guidewire advancement. In cases of vessel spasm, a bolus of 0.1-0.2 mg intra-arterial nitroglycerin was administered. Hemostasis at the puncture site was achieved with manual compression.

Statistical Analysis

All statistical analyses were conducted using IBM Statistical Package for the Social Sciences statistics for Windows, version 25.0 (IBM Corp., Armonk, NY, USA). The distribution of continuous variables was assessed visually through histograms and Q-Q plots. Descriptive statistics are reported as mean \pm standard deviation for variables with normal distribution, median (interquartile range, 25th-75th percentile) for variables without normal distribution, and frequency (percentage) for categorical variables.

Group comparisons were made using the Student's t-test for normally distributed continuous variables and the Mann-Whitney U test for those not normally distributed. Categorical variables were analyzed using the chi-squared test, Fisher's exact test, or the Fisher-Freeman-Halton test, depending on the context.

Receiver operating characteristic (ROC) curve analysis was used to assess the predictive value of clinical and laboratory variables for amputation. Optimal cut-off points were identified by maximizing Youden's index. A two-sided p value of <0.05 was considered statistically significant.

RESULTS

The study included 100 patients, consisting of 62 males and 38 females, with a mean age of 60.46 ± 9.43 years (range, 40-80 years). Major lower extremity amputation was performed in 15 patients (15.0%). No in-hospital deaths were recorded.

There were no statistically significant differences in age or sex between the amputation and non-amputation groups.

Clinical Classifications and Disease Severity

Patients who underwent amputation had significantly more severe disease, as indicated by the following:

Rutherford classification: Grade 3/category 5 and grade 3/category 6 were significantly more prevalent in the amputation group ($p < 0.001$).

Fontaine classification: Grade 4 occurred significantly more often in the amputation group ($p < 0.001$).

Wagner classification: Grade 4 was significantly more frequent among patients who underwent amputation ($p < 0.001$).

WIFI (Wound, Ischemia, and foot Infection) classification: Grade 3 was significantly more common in the amputation group ($p < 0.001$).

TASC II classification: Type D lesions were significantly more prevalent in the amputation group ($p < 0.001$).

Diabetes-related and Baseline Characteristics

The duration of DM was significantly longer in the amputation group ($p = 0.011$), and a previous history of amputation was also significantly more frequent in this group ($p < 0.001$).

There were no statistically significant differences between the groups in terms of smoking status, hypertension, or history of coronary artery disease.

Procedural Characteristics

Combined below- and above-knee interventions were significantly more common in patients who underwent amputation ($p < 0.001$). Additionally, the amount of contrast agent used was significantly greater in this group ($p < 0.001$). Balloon diameter and inflation time (3 minutes in all cases) did not differ significantly between the groups.

Renal Function and Contrast-induced Nephropathy

Baseline serum creatinine levels were significantly higher ($p < 0.001$), and estimated glomerular filtration rate (eGFR) was significantly

lower ($p < 0.001$) in the amputation group. An increase in creatinine levels occurred in six patients (6.0%), and two patients (2.0%) required temporary hemodialysis. Although the frequency of creatinine elevation was significantly greater in the amputation group ($p < 0.001$), the requirement for hemodialysis did not significantly differ between the groups.

Metabolic and Inflammatory Markers

Patients in the amputation group exhibited significantly poorer glycemic and lipid control:

- Baseline hemoglobin A1c (HbA1c) ($p = 0.001$) and 6-month HbA1c ($p = 0.002$) levels were elevated.

- Baseline low-density lipoprotein (LDL) ($p < 0.001$) and 6-month LDL ($p = 0.002$) levels were also higher.

- Baseline C-reactive protein (CRP) ($p < 0.001$) and 6-month CRP ($p < 0.001$) levels were significantly increased.

No significant differences were found between the groups regarding baseline or 6-month hemoglobin levels (Table 1).

Predictive Value of the Clinical Classification Systems

All five classification systems—Rutherford, Fontaine, Wagner, WIFI, and TASC II—were statistically significant predictors of amputation (each with $p < 0.001$).

Among these:

- Rutherford, Fontaine, and Wagner classifications demonstrated the highest sensitivity (100.0%) and negative predictive value (NPV) (100.0%), indicating strong reliability in excluding amputation risk in lower-grade cases.

- Wagner classification showed the highest specificity (96.47%), accuracy (97.0%), and positive predictive value (PPV) (83.33%), making it the most effective tool for predicting limb loss in this cohort.

- Wagner classification also achieved the highest area under the ROC curve (AUC) [AUC=0.982, 95% confidence interval (CI): 0.959-1.000], indicating excellent diagnostic accuracy (Table 2).

Predictive Value of the Baseline Laboratory Parameters

Baseline levels of creatinine ($p < 0.001$), eGFR ($p < 0.001$), HbA1c ($p = 0.001$), LDL ($p < 0.001$), and CRP ($p < 0.001$) were all statistically significant predictors of major limb amputation.

Among these markers:

- HbA1c and CRP showed the highest sensitivity (100.0%) and NPV (100.0%), indicating strong utility in ruling out amputation risk when values are within normal limits.

- eGFR demonstrated the highest specificity (92.94%), accuracy (91.0%), and PPV (66.67%), supporting its usefulness in identifying patients at higher risk.

- CRP achieved the largest (AUC=0.944, 95% CI: 0.897-0.990), reflecting excellent discriminative power for predicting limb loss (Figures 1, 2 and, Table 3).

Table 1. Summary of variables by amputation status

	Amputation			p
	Total (n=100)	No (n=85)	Yes (n=15)	
Age	60.46±9.43	60.82±9.22	58.40±10.61	0.361 [†]
Sex				
Male	62 (62.00%)	54 (63.53%)	8 (53.33%)	0.644 [#]
Female	38 (38.00%)	31 (36.47%)	7 (46.67%)	
Rutherford classification				
Grade 1/category 3	22 (22.00%)	22 (25.88%)	0 (0.00%)	<0.001 [†]
Grade 2/category 4	34 (34.00%)	34 (40.00%)	0 (0.00%)	
Grade 3/category 5	25 (25.00%)	18 (21.18%)	7 (46.67%)	
Grade 4/category 6	19 (19.00%)	11 (12.94%)	8 (53.33%)	
Fontaine classification				
Grade 2b	22 (22.00%)	22 (25.88%)	0 (0.00%)	<0.001 [#]
Grade 3	34 (34.00%)	34 (40.00%)	0 (0.00%)	
Grade 4	44 (44.00%)	29 (34.12%)	15 (100.00%)	
Wagner classification				
Grade 0	20 (20.00%)	20 (23.53%)	0 (0.00%)	<0.001 [†]
Grade 1	26 (26.00%)	26 (30.59%)	0 (0.00%)	
Grade 2	21 (21.00%)	21 (24.71%)	0 (0.00%)	
Grade 3	15 (15.00%)	15 (17.65%)	0 (0.00%)	
Grade 4	18 (18.00%)	3 (3.53%)	15 (100.00%)	
Grade 5	0 (0.00%)	0 (0.00%)	0 (0.00%)	
WIFI classification system				
Grade 0	0 (0.00%)	0 (0.00%)	0 (0.00%)	<0.001 [#]
Grade 1	41 (41.00%)	41 (48.24%)	0 (0.00%)	
Grade 2	34 (34.00%)	31 (36.47%)	3 (20.00%)	
Grade 3	25 (25.00%)	13 (15.29%)	12 (80.00%)	
TASC II classification				
Type A	24 (24.00%)	24 (28.24%)	0 (0.00%)	<0.001 [†]
Type B	24 (24.00%)	24 (28.24%)	0 (0.00%)	
Type C	28 (28.00%)	24 (28.24%)	4 (26.67%)	
Type D	24 (24.00%)	13 (15.29%)	11 (73.33%)	
Smoking	72 (72.00%)	59 (69.41%)	13 (86.67%)	0.222 [§]
Duration of diabetes, years	8 (7-9)	8 (6-9)	9 (8-9)	0.011 [‡]
Comorbidity				
Hypertension	28 (28.00%)	26 (30.59%)	2 (13.33%)	0.293 [§]
Coronary artery disease	48 (48.00%)	38 (44.71%)	10 (66.67%)	
Both	24 (24.00%)	21 (24.71%)	3 (20.00%)	
Prior amputation	23 (23.00%)	10 (11.76%)	13 (86.67%)	<0.001 [§]
Location of the intervention				
Below knee	65 (65.00%)	63 (74.12%)	2 (13.33%)	<0.001 [#]
Below and above the knee	35 (35.00%)	22 (25.88%)	13 (86.67%)	
Amount of contrast substance, cc	26 (24-28)	24 (24-28)	28 (28-30)	<0.001 [‡]

Table 1. Continued

	Total (n=100)	Amputation		p
		No (n=85)	Yes (n=15)	
Size of the balloon				
2.0 mm	44 (44.00%)	38 (44.71%)	6 (40.00%)	0.325 [‡]
2.5 mm	31 (31.00%)	24 (28.24%)	7 (46.67%)	
3.0 mm	25 (25.00%)	23 (27.06%)	2 (13.33%)	
Balloon inflation time per lesion				
3 min	100 (100.00%)	85 (100.00%)	15 (100.00%)	N/A
Creatinine	0.93 (0.74-1.14)	0.89 (0.72-1.00)	1.52 (1.21-1.64)	<0.001 [‡]
eGFR	87.5 (67-97)	89 (79-97)	47 (42-53)	<0.001 [‡]
Increase in the creatinine	6 (6.00%)	1 (1.18%)	5 (33.33%)	<0.001 [§]
Hemodialysis	2 (2.00%)	1 (1.18%)	1 (6.67%)	0.279 [§]
HbA1c				
Baseline	9.25 (8.15-10.55)	8.8 (8.1-10.5)	10.5 (9.8-11.7)	0.001 [‡]
6 th month	8.35 (7.55-9.2)	8.0 (7.4-9.1)	9.2 (8.7-10.0)	0.002 [‡]
LDL				
Baseline	124.5 (104-144)	121 (102-139)	157 (143-162)	<0.001 [‡]
6 th month	89 (79.5-93.5)	88 (79-93)	92 (89-101)	0.002 [‡]
CRP, mg/L				
Baseline	7 (4-18)	7 (4-10)	27 (24-31)	<0.001 [‡]
6 th month	4 (2-5.5)	4 (2-5)	7 (5-8)	<0.001 [‡]
Hemoglobin, g/dL				
Baseline	13.07±0.85	13.04±0.81	13.18±1.05	0.572 [‡]
6 th month	12.74±0.88	12.71±0.90	12.89±0.78	0.484 [‡]

Descriptive statistics are expressed as mean±standard deviation for continuous variables with normal distribution, median (25th-75th percentile) for non-normally distributed continuous variables, and frequency (percentage) for categorical variables.

[‡]Student's t-test, [§]Mann-Whitney U test, [#]chi-squared test, [§]Fisher's exact test, [‡]Fisher-Freeman-Halton test, N/A: Not applicable, eGFR: Estimated glomerular filtration rate, HbA1c: Hemoglobin A1c, LDL: Low-density lipoprotein, CRP: C-reactive protein

Table 2. Predictive performance of clinical classification systems and ROC curve analysis for amputation

Classification	Rutherford	Fontaine	Wagner's	WIFI	TASC II
Cut-off	Grade 3	Grade 4	Grade 4	Grade 3	Type D
Sensitivity	100.00%	100.00%	100.00%	80.00%	73.33%
Specificity	65.88%	65.88%	96.47%	84.71%	84.71%
Accuracy	71.00%	71.00%	97.00%	84.00%	83.00%
PPV	34.09%	34.09%	83.33%	48.00%	45.83%
NPV	100.00%	100.00%	100.00%	96.00%	94.74%
AUC (95% CI)	0.856 (0.780-0.931)	0.829 (0.749-0.910)	0.982 (0.959-1.000)	0.872 (0.793-0.950)	0.865 (0.789-0.942)
p	<0.001	<0.001	<0.001	<0.001	<0.001

ROC: Receiver operating characteristic, PPV: Positive predictive value, NPV: Negative predictive value, AUC: Area under the ROC curve, CI: Confidence interval

Table 3. Predictive performance of baseline laboratory parameters and ROC curve analysis for amputation

Measurement, baseline	Creatinine	eGFR	HbA1c	LDL	CRP
Cut-off	>1.20	≤55	>9.4	>133	>11
Sensitivity	80.00%	80.00%	100.00%	93.33%	100.00%
Specificity	88.24%	92.94%	60.00%	69.41%	78.82%
Accuracy	87.00%	91.00%	66.00%	73.00%	82.00%
PPV	54.55%	66.67%	30.61%	35.00%	45.45%
NPV	96.15%	96.34%	100.00%	98.33%	100.00%
AUC (95% CI)	0.887 (0.798-0.975)	0.896 (0.807-0.985)	0.771 (0.674-0.869)	0.864 (0.787-0.941)	0.944 (0.897-0.990)
p	<0.001	<0.001	0.001	<0.001	<0.001

ROC: Receiver operating characteristic, PPV: Positive predictive value, NPV: Negative predictive value, AUC: Area under the ROC curve, CI: Confidence interval, eGFR: Estimated glomerular filtration rate, HbA1c: Hemoglobin A1c, LDL: Low-density lipoprotein, CRP: C-reactive protein

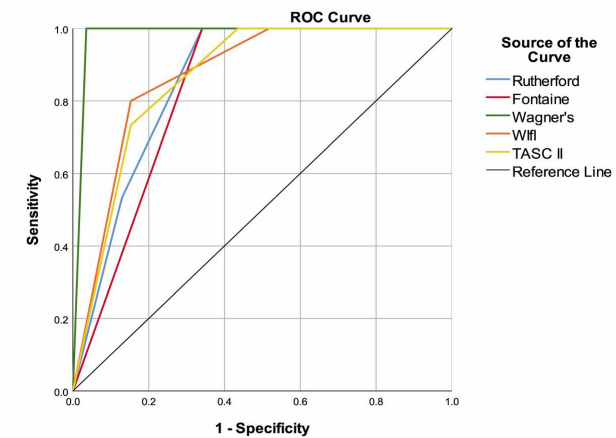


Figure 1. ROC curves for clinical classification systems. ROC curves illustrating the predictive accuracy of the Wagner, Rutherford, Fontaine, Wiffl, and TASC II classifications for amputation in patients with diabetic peripheral artery disease

ROC: Receiver operating characteristic

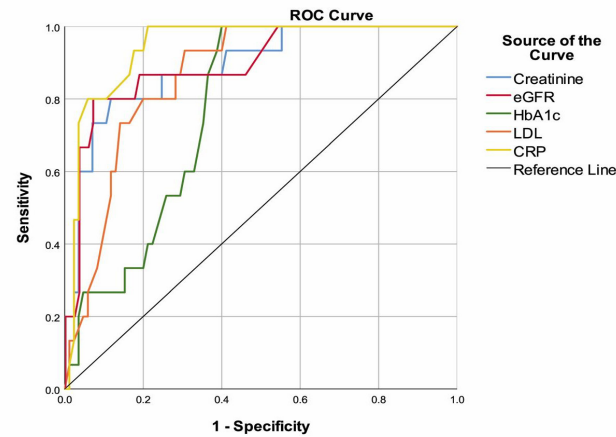


Figure 2. ROC curves for baseline laboratory parameters. ROC curves depicting the predictive performance of baseline laboratory values (HbA1c, creatinine, eGFR, CRP, LDL) for amputation in patients with diabetic peripheral artery disease

ROC: Receiver operating characteristic, eGFR: Estimated glomerular filtration rate, HbA1c: Hemoglobin A1c, LDL: Low-density lipoprotein, CRP: C-reactive protein

DISCUSSION

This study evaluated 100 patients with diabetic PAD who underwent percutaneous revascularization, among whom 15 required major amputation during follow-up. Demographic characteristics and comorbid conditions were comparable between the amputation and non-amputation groups, with the exception of diabetes duration, which was significantly longer in those who underwent amputation.

Inadequate glycemic control, as indicated by elevated baseline and 6-month HbA1c levels, was also significantly linked to a higher risk of amputation. This observation is consistent with earlier studies showing that poor diabetes control and prolonged disease duration are associated with a greater incidence and severity of diabetes-related complications, including PAD.^{16,17} These findings emphasize the essential role of maintaining tight glycemic control to reduce the risk of limb-threatening ischemia.

Renal dysfunction was significantly more pronounced in the amputation group, as indicated by higher baseline creatinine levels and lower eGFR. This finding suggests that PAD severity may reflect broader systemic target organ damage, including renal impairment. The greater volume of contrast agent used during revascularization procedures in this group likely corresponds to more extensive and complex arterial disease, which may contribute to additional kidney injury. As a result, this group exhibited a higher rate of contrast-induced nephropathy, demonstrated by a significant postprocedural increase in creatinine and a greater, though not statistically significant, requirement for hemodialysis.

The study also demonstrated that clinical and anatomical severity scores—specifically the Rutherford, Fontaine, Wagner, Wiffl, and TASC II classifications—were significantly higher in patients who underwent amputation. These scoring systems proved to be valuable predictors of amputation risk, highlighting the critical importance of early diagnosis and prompt treatment of PAD to prevent progression to CLI and eventual limb loss.

Collectively, these findings underscore PAD as a serious complication of DM, closely linked to both the duration and severity of the disease, as well as to damage in other target organs. The relationship among poor glycemic control, advanced vascular disease, and declining renal

function highlights the need for integrated management approaches that address all contributing factors.

Finally, the results indicate that patients with advanced PAD should be closely monitored for renal function, particularly when undergoing contrast-enhanced endovascular interventions, to minimize the risk of additional kidney injury and enhance overall clinical outcomes.

Study Limitations

This study has several limitations. First, its retrospective nature may introduce selection bias and restrict the ability to draw causal inferences. Although the sample size was sufficient, it was relatively small and sourced from a single center, which may limit the broader applicability of the results. Furthermore, follow-up was limited to 6 months, and extended observation would be beneficial to assess the long-term durability of revascularization and outcomes such as recurrent ischemia or mortality.

Future research should include prospective, multicenter studies with larger patient populations and longer follow-up periods to confirm these findings. Further investigation into the role of emerging endovascular techniques, adjunct pharmacologic therapies, and integrated multidisciplinary care models in reducing amputation rates among patients with diabetic PAD may help refine treatment approaches.

CONCLUSION

This study shows that diabetic patients with PAD undergoing endovascular revascularization remain at considerable risk for limb amputation, especially those with prolonged diabetes duration, poor glycemic control, advanced PAD classification scores, and compromised renal function. Early detection, effective diabetes management, and close monitoring of kidney function are essential to enhance limb salvage and overall outcomes. These findings highlight the importance of a multidisciplinary approach in the management of diabetic PAD to prevent progression to critical ischemia and the need for amputation.

Ethics Committee Approval: The study received ethical approval from the Osmaniye State Hospital Ethical Committee (decision number: 254426875, date: 19.09.2024).

Informed Consent: Informed consent was obtained from all participants after a thorough explanation of the procedure and possible complications.

Authorship Contributions: Concept: C.S., Design: C.S., Data Collection or Processing: C.S., A.K., Analysis or Interpretation: V.Ç., Literature Search: Z.K., Writing: C.S., Z.K.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study received no financial support.

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