

Rotational Atherectomy-Assisted Balloon Angioplasty versus Plain Balloon Angioplasty for Infrapopliteal Lesions in Chronic Limb-Threatening Ischemia: A Retrospective Observational Study

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Abstract

Objective: This study aimed to compare procedural and mid-term clinical outcomes between rotational atherectomy-assisted balloon angioplasty (RA+POBA) and POBA alone for infrapopliteal (IP) lesions in patients with chronic limb-threatening ischemia (CLTI).

Methods: This retrospective study included 71 consecutive patients with CLTI who underwent endovascular intervention for IP peripheral arterial disease between January 2020 and January 2025 and had at least 6 months of follow-up. A total of 78 limbs were analyzed and categorized into RA+POBA and POBA groups. The primary outcome was target lesion revascularization (TLR) during follow-up. Limb-level outcomes were analyzed accounting for within-patient clustering.

Results: Patient-level analysis included 35 patients in the RA+POBA group and 36 patients in the POBA group. Follow-up duration was similar between groups (18.0 [12–63] vs. 21.0 [12–82] months; $p=0.919$). TLR occurred in 6 limbs in both groups (15.4% vs. 15.4%; risk ratio [RR] 1.15, 95% confidence interval [CI] 0.23–5.66; $p=0.866$). Major amputation occurred in 1 limb in the RA+POBA group and 9 limbs in the POBA group (2.6% vs. 23.1%; RR 0.12, 95% CI 0.02–0.81; $p=0.030$). No significant differences were observed in minor amputation or all-cause mortality.

Conclusion: In this retrospective cohort, RA+POBA was associated with a lower major amputation rate. However, this secondary, unadjusted finding was based on a limited number of events and should be considered hypothesis-generating. Furthermore, the absence of differences in TLR and mortality suggests that these findings should not be interpreted as evidence of superior patency, durability, or survival benefit.

Keywords: Angioplasty; balloon atherectomy; chronic limb-threatening ischemia; endovascular procedures; peripheral arterial disease.

Kronik Ekstremitayı Tehdit Eden İskemide İnfrapopliteal Lezyonlarda Rotasyonel Aterektomi Destekli Balon Anjiyoplasti ile Balon Anjiyoplastinin Karşılaştırılması: Retrospektif Gözlemsel Çalışma

Özet

Amaç: Bu çalışmada, kronik ekstremitayı tehdit eden iskemide (KETİ) hastalarında infrapopliteal (IP) lezyonlar için rotasyonel aterektomi destekli balon anjiyoplasti (RA+POBA) ile balon anjiyoplasti (POBA) arasında prosedürel başarı ve orta dönem klinik sonuçların karşılaştırılması amaçlandı.

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Yöntem: Bu retrospektif gözlemsel çalışmaya, Ocak 2020 ile Ocak 2025 tarihleri arasında IP periferik arter hastalığı nedeniyle endovasküler girişim uygulanan ve en az 6 aylık takip süresi bulunan 71 KETİ hastası dahil edildi. Toplam 78 ekstremitte analiz edildi ve RA+POBA ile POBA gruplarına ayrıldı. Primer sonlanım, takip süresince hedef lezyon revaskülarizasyonu (HLR) olarak belirlendi. Ekstremitte bazı sonuçların analizinde hasta içi kümelenme dikkate alındı.

Bulgular: Hasta bazı analizde RA+POBA grubunda 35 hasta, POBA grubunda 36 hasta yer aldı. Ekstremitte bazı analizde her iki grupta 39 ekstremitte bulunuyordu. Takip süresi RA+POBA ve POBA grupları arasında benzerdi (18.0 [12–63] vs. 21.0 [12–82] ay; $p=0.919$). HLR her grupta 6 ekstremitte görüldü (%15,4 vs. %15,4; risk oranı [RR]=1,15; %95 güven aralığı [GA]=0.23–5.66; $p=0.866$). Majör amputasyon, RA+POBA grubunda 1 ekstremitte, POBA grubunda ise 9 ekstremitte görüldü (%2,6 vs. %23,1; RR=0,12; %95 GA=0.02–0,81; $p=0.030$). Minör amputasyon veya tüm nedenlere bağlı mortalite açısından anlamlı fark gözlenmedi.

Sonuç: Bu retrospektif kohortta RA+POBA, daha düşük majör amputasyon oranıyla ilişkiliydi. Ancak sınırlı sayıda olaya dayanan bu ikincil ve düzeltilmemiş bulgu, hipotez oluşturuca nitelikte değerlendirilmelidir. HLR veya tüm nedenlere bağlı mortalite açısından fark gözlenmemiş olup üstün açıklık, dayanıklılık veya sağkalım konusunda bir sonuca varılamaz.

Anahtar sözcükler: Aterektomi; balon anjiyoplasti; kronik ekstremitteyi tehdit eden iskemi; endovasküler işlemler; periferik arter hastalığı.

Introduction

Peripheral arterial disease (PAD) in patients with diabetes mellitus (DM) frequently involves infrapopliteal (IP) segments.^[1] In patients with distal arterial involvement, chronic limb-threatening ischemia (CLTI) represents the most severe form of PAD and is associated with poor prognosis due to high amputation and mortality rates.^[2–4] Current PAD guidelines emphasize that the selection of a treatment modality should be individualized, accounting for patient-specific clinical presentation, anatomical disease severity, expected benefits, procedural risks, and long-term durability.^[5,6] Plain old balloon angioplasty (POBA) forms the basis of endovascular treatment.^[7] Factors such as small vessel diameter, plaque complexity, and diffuse disease may compromise the procedural success and durability of POBA in IP lesions.^[8] Complications after balloon angioplasty, including flow-limiting dissection, restenosis, and reocclusion, may limit procedural success and durability, particularly in heavily calcified lesions.^[9,10] The higher calcific burden of IP arteries compared with femoral or iliac arteries provides a rationale for vessel preparation strategies before balloon angioplasty.^[11] Atherectomy may provide technical advantages by debulking calcified plaque, improving lesion compliance, and facilitating more favorable subsequent balloon angioplasty expansion.^[12] There are no consistent results in the literature regarding the contribution of atherectomy to clinical outcomes. While some studies have reported higher patency rates and lower rates of reintervention and amputation,^[13] others have shown similar clinical outcomes with higher reintervention or local complication rates in the atherectomy group.^[14] Therefore, the contribution of atherectomy to procedural and clinical outcomes in IP lesions remains unclear.

In this study, we aimed to compare procedural and mid-term follow-up outcomes between patients undergoing POBA alone and those undergoing rotational atherectomy (RA) + POBA for IP lesions.

Materials and Methods

Study Design

This retrospective single-center study evaluated all 71 consecutive eligible patients who underwent endovascular treatment

for IP PAD between January 2020 and January 2025 in our institution. The primary outcome was target lesion revascularization (TLR) during follow-up. Secondary outcome measures comprised major and minor amputation, all-cause mortality, and procedure-related complications. Baseline clinical data and procedural information were extracted from medical records and the hospital electronic database.

Ethics Committee Approval

This study was approved by the University of Health Sciences, Sancaktepe Martyr Prof. Dr. İlhan Varank Research and Training Hospital Scientific Research Ethics Committee (Date: 10.06.2026, Decision no: 2026/311). All study procedures were carried out in accordance with the Declaration of Helsinki. Written informed consent was secured from all patients for the procedure.

Patient Population

Patients were considered to have IP PAD when compatible clinical findings were supported by vascular imaging. Out of 113 patients (125 limbs) who were diagnosed with IP PAD and underwent endovascular intervention, 71 CLTI patients (78 limbs) with at least 6 months of follow-up were selected for inclusion. Patients with concomitant inflow vessel disease (iliac, femoral, or popliteal) were included. Exclusion criteria included patients with intermittent claudication (Rutherford class ≤ 3), acute limb ischemia, visible thrombus within the target lesion, non-atherosclerotic arterial disease (such as vasculitis, Buerger disease), hybrid procedures, prior vascular surgical intervention (vascular bypass surgery, endarterectomy, or embolectomy), aborted procedures without endovascular treatment, incomplete clinical or procedural data, and loss to follow-up. Patient selection and group allocation are summarized in Figure 1.

Preprocedural Evaluation

All patients underwent detailed clinical and radiological evaluation before the procedure. The decision for endovascular intervention was made based on a combined assessment of clinical findings, imaging findings, and distal circulation characteristics. Endovascular intervention was planned in patients with rest pain, non-healing foot ulcers, or tissue loss. All patients under-

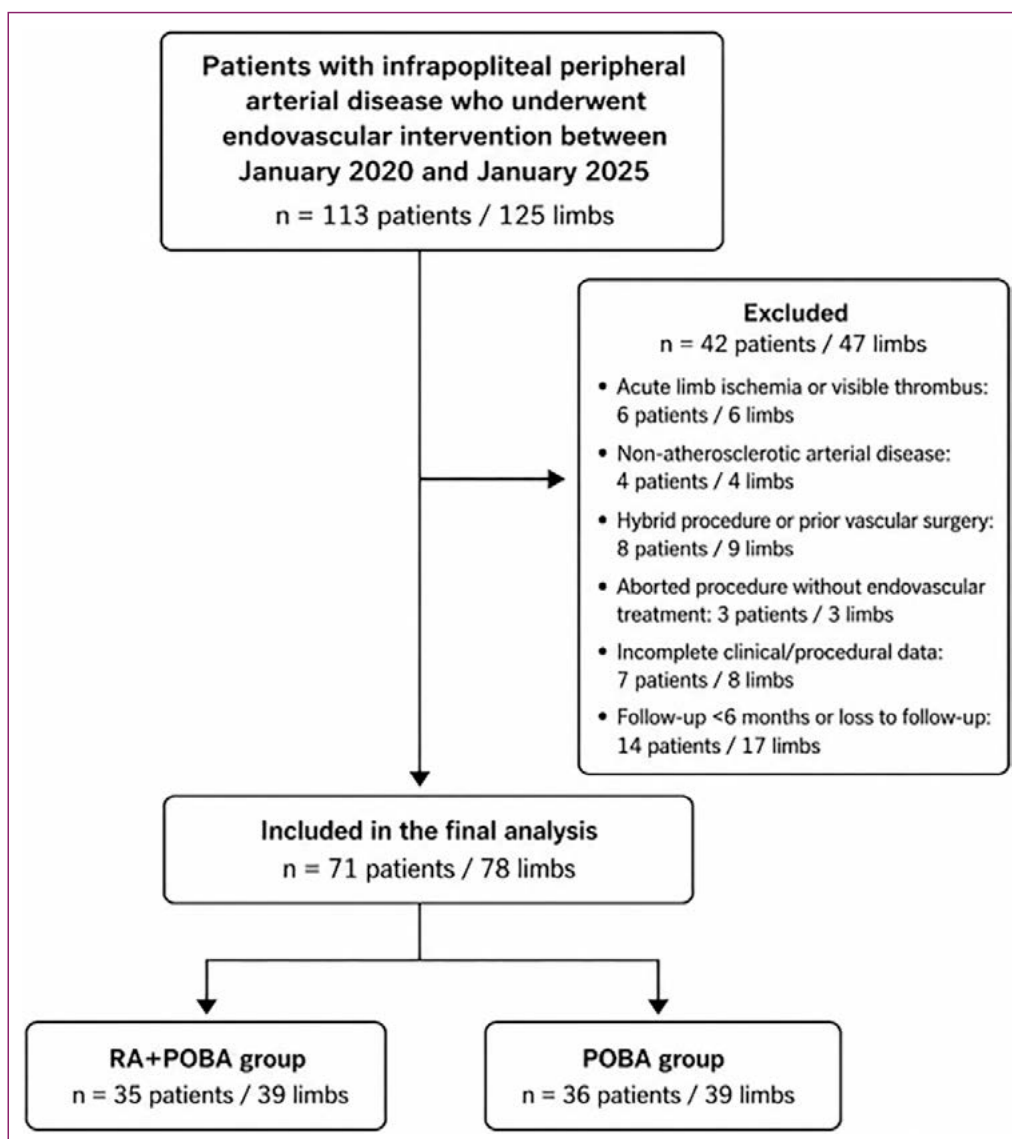


Figure 1. Patient selection flow diagram.

RA+POBA: Rotational atherectomy-assisted balloon angioplasty; POBA: Plain old balloon angioplasty.

went arterial Doppler ultrasonography and computed tomography angiography (CTA) pre-procedure. The location and morphological characteristics of lesions across all vascular segments were evaluated and recorded based on imaging findings. Anatomical complexity was retrospectively assessed using the global limb anatomic staging system (GLASS), which incorporates lesion length, stenosis or occlusion pattern, and severe calcification along the target artery path. Each limb was categorized as stage I, II, or III. In addition to IP lesions, any hemodynamically significant lesions detected in the inflow vessels were treated simultaneously, thereby ensuring adequate proximal arterial flow before IP revascularization.

Treatment Protocol

All procedures were performed by the same vascular surgery team in the angiography suite. Under local anesthesia, vascular access was obtained through the ipsilateral/contralateral femo-

ral artery using a 6F introducer (Terumo, Tokyo, Japan). Pedal access was used in cases where antegrade penetration to the lesion could not be achieved. Diagnostic imaging was performed following systemic heparinization at 10,000 IU. Before IP revascularization, when present, intervention was performed on all hemodynamically significant lesions, >70% stenosis or chronic total occlusion (CTO), in the inflow vessels. Subsequently, runoff vessels and the pedal arch were evaluated in detail to determine the appropriate treatment. A 0.018-inch diameter guidewire (Boston Scientific V18, Marlborough, MA) and 5F catheters were used to target relevant vascular structures. In cases requiring pedal arch reconstruction, 0.014-inch diameter guidewire (Boston Scientific V14, Marlborough, MA) was used due to its greater flexibility compared to the V18.

The treatment strategy was selected according to lesion morphology, arterial anatomy, and availability of the required devices. RA (TemREN, Invamed, Ankara, Türkiye) was preferred

for focal, eccentric, and heavily calcified lesions, especially in proximal tibial segments. Conversely, POBA (Minerva™ PTA Balloon Dilatation Catheter, BrosMed Medical Co., Ltd., Dongguan, China) was favored for long CTOs, tandem, or distal lesions. Predilation was not routinely performed before RA to allow effective plaque debulking. In the RA+POBA group, adjunctive balloon angioplasty was subsequently performed to optimize luminal gain and reduce residual stenosis. In the POBA group, predilation was performed routinely to facilitate adequate balloon expansion and luminal restoration. The balloon size was determined based on the diameter of the target artery and the length of the lesion.

After completion of the procedure, control arteriography was performed in all patients to confirm procedural success and detect acute complications, such as rupture, flow-limiting dissection, thrombosis, and distal embolization. Technical success was defined as <30% residual stenosis of the target vessel and restoration of distal flow. In cases of rupture or flow-limiting dissection, prolonged angioplasty was performed (3–5 min). Intra-arterial nitroglycerin was used in case of vasospasm. Following the completion of the procedure, aspirin 100 mg/day, clopidogrel 75 mg/day, and statins were administered to all patients as medical treatment for 12 months. Following the 12-month period, clopidogrel was discontinued, and aspirin and statin therapy were continued.

Follow-Up

Patients were scheduled for outpatient follow-up at 3, 6, 12, 18, and 24-month post-procedure and annually thereafter. At follow-up visits, symptom status, procedure-related adverse events, and newly developed complaints were reviewed. When clinical deterioration, persistent ischemic symptoms, or suspicion of restenosis/reocclusion was present, further evaluation was performed using arterial Doppler ultrasonography or CTA. Recurrence was defined as the reoccurrence or worsening of symptoms during follow-up that prompted further diagnostic evaluation. TLR was defined as any repeat endovascular or surgical revascularization of the previously treated IP lesion due to clinically driven restenosis or reocclusion. Amputations above the ankle were classified as major, whereas those below the ankle were classified as minor. No additional medications were administered during follow-up.

Statistical Analysis

Data analysis was conducted with IBM Statistical Package for the Social Sciences Statistics for Windows, version 25.0 (IBM Corp., Armonk, NY, USA). Categorical variables were summarized as n (%) and continuous variables as median (min-max). Distribution of continuous data was checked with the Kolmogorov–Smirnov test. Because the variables were not normally distributed, intergroup comparisons were made using the Mann–Whitney U test. For categorical variables, Pearson's Chi-square test or Fisher's exact test was used according to data distribution. Demographic and comorbidity variables, as well as mortality, were analyzed on a patient basis, whereas

lesion characteristics, procedural variables, TLR, and amputation outcomes were analyzed on a limb basis. Because seven patients contributed bilateral limbs, analyses of limb-level outcomes accounted for within-patient correlation by specifying the patient identifier as the clustering variable. For binary limb-level outcomes, modified Poisson generalized estimating equation (GEE) models with robust standard errors were used to estimate risk ratios (RRs). Absolute risk differences (RDs) and 95% confidence intervals (CIs) for both RDs and RRs were obtained using patient-level cluster bootstrap resampling (2,000 bootstrap samples; random seed=20260804). RDs were defined as Risk (RA+POBA)–Risk (POBA) and RRs as Risk (RA+POBA)/Risk (POBA). For patient-level all-cause mortality, crude group comparisons were performed using Fisher's exact test. Absolute RDs with 95% CIs were calculated using the Newcombe–Wilson method, whereas 95% CIs for RRs were estimated using patient-level bootstrap resampling. Overall survival (OS) was estimated using the Kaplan–Meier method, with follow-up duration as the time scale and all-cause mortality as the event of interest. Survival distributions were compared using the log-rank test, and treatment effects were quantified using univariable Cox proportional hazards regression, reported as hazard ratios (HRs) with 95% CIs. All statistical tests were two-sided, and a $p < 0.05$ was considered statistically significant. Given the limited number of primary outcome events, multivariable outcome modeling was not performed because of the risk of overfitting and unstable estimates. Propensity-based adjustment was also not performed because of the limited cohort size and the absence of standardized data on important potential confounders, including wound severity and infection status.

Sample Size Justification

A sensitivity power analysis was performed using G*Power for the comparison of two independent proportions. With 39 limbs in each treatment group, a two-sided α level of 0.05, 80% power, and an allocation ratio of 1:1, the minimum detectable standardized effect size was Cohen's $h = 0.634$. Accordingly, the available sample provided 80% power to detect a Cohen's h of 0.634 or greater, whereas smaller effects may not have been detected.

Results

The demographic and clinical features of the patients are given in Table 1. Of the 71 patients, 64 contributed a single limb and seven contributed bilateral limbs. Among the bilateral cases, three patients underwent RA+POBA in both limbs, one underwent POBA in both limbs, and three underwent RA+POBA in one limb and POBA in the contralateral limb. The RA+POBA and POBA groups were comparable in terms of age, gender distribution, hypertension, hyperlipidemia, smoking, coronary artery disease, dialysis, stroke history, and DM. DM was the most frequent comorbidity in both groups (Table 1).

The lesion and limb characteristics of the treated limbs are given in Table 2. Rutherford class distribution, lesion side, number

Table 1. Baseline characteristics

Variable	RA+POBA (n=35)	POBA (n=36)	p
Age			
Median (min-max)	62 (40–80)	63 (39–85)	0.872 ^a
Male gender	25 (71.4)	29 (80.6)	0.368 ^b
DM	30 (85.7)	31 (86.1)	0.962 ^b
HT	25 (71.4)	23 (63.9)	0.497 ^b
Hyperlipidemia	13 (37.1)	17 (47.2)	0.390 ^b
Smoking	13 (37.1)	11 (30.6)	0.557 ^b
CAD	16 (45.7)	19 (52.8)	0.552 ^b
Dialysis	3 (8.6)	5 (13.9)	0.710 ^c
Stroke history	2 (5.7)	6 (16.7)	0.260 ^c

^a: Mann–Whitney U test; ^b: Pearson's Chi-square test; ^c: Fisher's exact test. Values are presented as n (%) unless otherwise indicated. p<0.05 was considered statistically significant. DM: Diabetes mellitus; HT: Hypertension; CAD: Coronary artery disease.

Table 2. Lesion and limb characteristics

Variable	RA+POBA (n=39)	POBA (n=39)	p	Cluster-adjusted/global p
Lesion side				
Right	21 (53.8)	20 (51.3)	1.000 ^b	
Left	18 (46.2)	19 (48.7)		-
Rutherford class				
4	2 (5.1)	1 (2.5)	0.731 ^c	0.711
5	17 (43.6)	20 (51.3)		
6	20 (51.3)	18 (46.2)		
Target vessel				
1	21 (53.8)	22 (56.4)	0.891 ^b	0.857
2	15 (38.5)	13 (33.3)		
3	3 (7.7)	4 (10.3)		
Number of CTO vessels				
0	1 (2.6)	3 (7.7)	0.519 ^c	0.502
1	12 (30.8)	8 (20.5)		
2	19 (48.7)	18 (46.2)		
3	7 (17.9)	10 (25.6)		
Number of stenotic vessels				
0	18 (46.2)	18 (46.2)	0.475 ^c	0.475
1	18 (46.2)	14 (35.9)		
2	3 (7.7)	6 (15.4)		
3	0 (0)	1 (2.6)		
Runoff vessels				
0	7 (17.9)	10 (25.6)	0.519 ^c	0.502
1	19 (48.7)	18 (46.2)		
2	12 (30.8)	8 (20.5)		
3	1 (2.6)	3 (7.7)		
GLASS stage				
1	2 (5.1)	5 (12.8)	0.622 ^c	0.493
2	15 (38.5)	14 (35.9)		
3	22 (56.4)	20 (51.3)		
Pedal arch status				
No filling	8 (20.5)	6 (15.4)	0.365 ^c	0.365
Partial filling	11 (28.2)	17 (43.6)		
Complete filling	20 (51.3)	16 (41)		

^b: Pearson's Chi-square test; ^c: Fisher's exact test. Values are presented as n (%) unless otherwise indicated. p<0.05 is statistically significant. CTO: Chronic total occlusion.

Table 3. Procedural characteristics

Variable	RA+POBA (n=39)	POBA (n=39)	RR (95% CI)	p
Access type				
Antegrade	6 (15.4)	17 (43.6)		0.023 ^c
Pedal	1 (2.6)	1 (2.6)	-	
Crossover femoral	32 (82.1)	21 (53.8)		
Predilation	15 (38.5)	32 (82.1)	0.43 (0.26–0.72)	<0.001 ^b
Inflow lesion treatment	21 (53.8)	16 (41.0)	1.49 (0.73–3.05)	0.364 ^b
Technical success	35 (89.7)	38 (97.4)	0.92 (0.81–1.02)	0.358 ^c
Rupture	0 (0)	3 (7.7)	NE	0.239 ^c

^b: Pearson's Chi-square test; ^c: Fisher's exact test. Values are presented as n (%) unless otherwise indicated. p<0.05 was considered statistically significant. RRs and 95% confidence intervals were estimated using modified Poisson GEE models with robust standard errors, with patient identifier specified as the clustering variable. Overall comparisons for multicategory variables were performed using cluster-adjusted models whenever estimable; otherwise, Pearson's Chi-square test or Fisher's exact test was used, as appropriate. Effect estimates are reported as not estimable for variables with zero events in one or both groups because reliable estimation was not possible. RA: Rotational atherectomy; POBA: Plain old balloon angioplasty; RR: Risk ratio; CI: Confidence interval; GEE: Generalized estimating equation; NE: Not estimable.

of target vessels, number of CTO and stenotic vessels, runoff vessels, and pedal arch status were similar between the groups. The distribution of GLASS stages I, II, and III did not differ significantly between the RA+POBA and POBA groups (5.1%, 38.5%, and 56.4% vs. 12.8%, 35.9%, and 51.3%, respectively; p=0.493) (Table 2).

The procedural characteristics of the treated limbs are given in Table 3. Access type differed significantly between the groups (p=0.023), and crossover femoral access was more frequently used in the RA+POBA group. Predilation was performed less frequently in the RA+POBA group than in the POBA group (15 vs. 32 limbs, p<0.001). Inflow lesion treatment, technical success, and rupture rates were similar between the groups. No distal embolization, flow-limiting dissection, bailout stent requirement, or access site complication was observed (Table 3).

The follow-up outcomes are given in Table 4. Follow-up duration was similar between the RA+POBA and POBA groups (18.0 [12–63] vs. 21.0 [12–82] months, p=0.919). TLR occurred in 6 of 39 limbs (15.4%) in each group, corresponding to an RD of 0.0% points (95% CI –14.4–16.1) and an RR of 1.15 (95% CI 0.23–5.66; p=0.866). Major amputation occurred in 1 limb (2.6%) in the RA+POBA group and 9 limbs (23.1%) in the POBA group, corresponding to an RD of –20.5% points (95% CI –34.9–6.6) and an RR of 0.12 (95% CI 0.02–0.81; p=0.030). Minor amputation and all-cause mortality did not differ significantly. Overall, 8 deaths occurred during follow-up, including 4 due to sepsis, 2 due to myocardial infarction, and 2 due to malignancy-related causes (Table 4).

The available clinical characteristics of the ten limbs that underwent major amputation are presented in Table 5.

The Kaplan–Meier survival analysis is presented in Figure 2. Kaplan–Meier analysis showed no significant difference in OS between the RA+POBA and POBA groups (HR=1.59, 95% CI 0.34–7.38; log-rank p=0.550) (Fig. 2).

Table 4. Clinical outcomes

Variable	RA+POBA	POBA	RD (95% CI)	RR (95%CI)	p
Limb-based outcomes	n=39	n=39			
Follow-up duration					0.919 ^a
Median (min-max)	18.0 (12–63)	21.0 (12–82)			
TLR	6 (15.4)	6 (15.4)	0.0 (-14.4–16.1)	1.15 (0.23–5.66)	0.866 ^b
Major amputation	1 (2.6)	9 (23.1)	-20.5 (-34.9– -6.6)	0.12 (0.02–0.81)	0.030 ^b
Minor amputation	8 (20.5)	5 (12.8)	7.7 (-10.1–25.4)	2.49 (0.70–8.89)	0.159 ^b
Patient-based outcome	n=35	n=36			
All-cause mortality	5 (14.3)	3 (8.3)	5.3 (-10.5–21.1)	1.62 (0.31–6.56)	0.710 ^b

^a: Mann–Whitney U test; ^b: Pearson's Chi-square test. Data are presented as n (%). RD was defined as risk (RA+POBA)-Risk (POBA) and is expressed in percentage points. Risk ratio (RR) was defined as Risk (RA+POBA)/Risk (POBA), with POBA as the reference group. For limb-level outcomes, RRs and p-values were estimated using modified Poisson generalized estimating equation (GEE) models with robust standard errors, with patient identifier specified as the clustering variable. The 95% confidence intervals (CIs) for RDs and RRs were obtained using patient-level cluster bootstrap resampling (2,000 samples). For patient-level all-cause mortality, the p-value was obtained using Fisher's exact test. The 95% CI for RD was calculated using the Newcombe-Wilson method, whereas the 95% CI for RR was estimated using patient-level bootstrap resampling. CI: Confidence interval; GEE: Generalized estimating equation; POBA: Plain old balloon angioplasty; RA: Rotational atherectomy; RD: Risk difference; RR: Risk ratio; TLR: Target lesion revascularization.

Table 5. Clinical characteristics of limbs undergoing major amputation

Case	Treatment group	Dialysis	Preprocedural IP runoff vessels, n	Indication for major amputation
1	RA+POBA	No	2	Progressive ischemic tissue loss
2	POBA	No	1	Progressive ischemic tissue loss with infection
3	POBA	No	0	Progressive ischemic tissue loss with infection
4	POBA	No	1	Progressive ischemic tissue loss with infection
5	POBA	Yes	1	Revascularization failure
6	POBA	No	1	Progressive ischemic tissue loss with infection
7	POBA	No	1	Progressive ischemic tissue loss with infection
8	POBA	No	1	Progressive ischemic tissue loss
9	POBA	No	1	Progressive ischemic tissue loss with infection
10	POBA	Yes	0	Progressive ischemic tissue loss with infection

IP: Infrapopliteal; POBA: Plain old balloon angioplasty; RA: Rotational atherectomy.

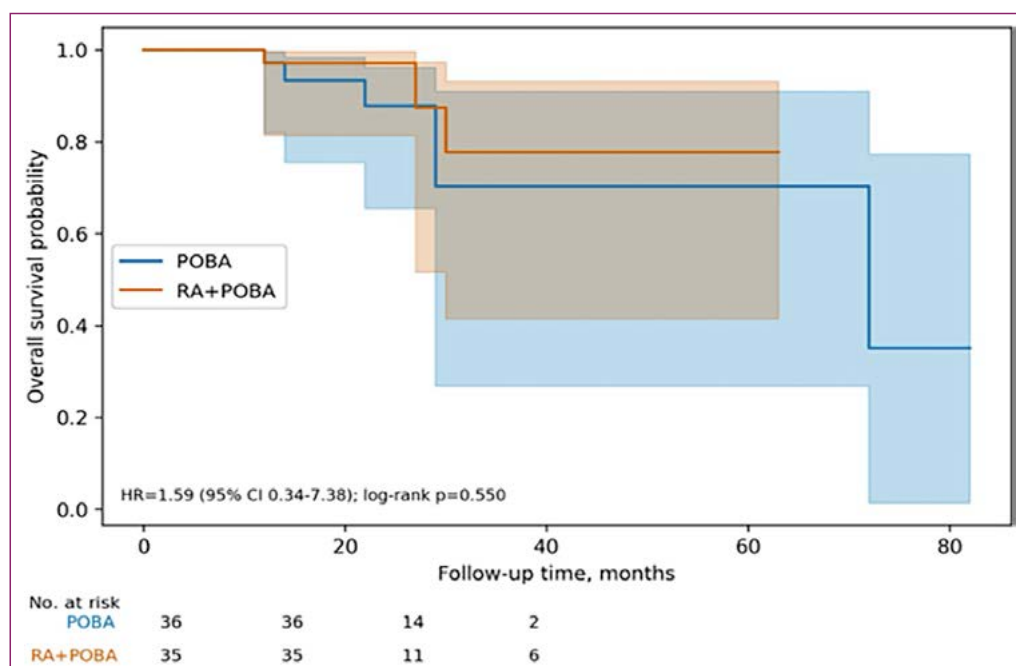


Figure 2. Kaplan–Meier curves for overall survival in the RA+POBA and POBA groups. Shaded areas represent 95% confidence intervals. Numbers at risk are presented below the curves.

CI: Confidence interval, POBA: Plain old balloon angioplasty, RA: Rotational atherectomy.

Discussion

The literature on RA+POBA in IP lesions remains heterogeneous, partly because studies differ in the atherectomy devices, lesion characteristics, and adjunctive treatment strategies evaluated, making device-specific interpretation difficult. Comparative clinical data on TemREN are particularly limited. This retrospective observational study addresses this gap by providing mid-term comparative data on TemREN RA+POBA versus POBA alone in patients with CLTI. Moreover, the inclusion of patients undergoing concomitant inflow treatment, rather than limiting the cohort to isolated IP disease, more closely reflects the multilevel arterial disease commonly encountered in routine CLTI practice. The primary outcome, TLR, occurred in 15.4% of limbs in each group. After accounting for within-patient clustering, no between-group difference was observed (RR 1.15, 95% CI 0.23–5.66; $p=0.866$). Major amputation was less frequent in the RA+POBA group (2.6% vs. 23.1%; RR 0.12, 95% CI 0.02–0.81; $p=0.030$). Minor amputation did not differ significantly, and Kaplan–Meier analysis showed no statistically significant difference in survival (HR=1.59, 95% CI 0.34–7.38; log-rank $p=0.550$). Treatment allocation was non-random, and no multivariable or propensity-based adjustment was performed. These results should therefore be regarded as an exploratory association rather than evidence of a causal limb-salvage benefit.

Amputation outcomes constituted the most clinically important limb-related finding of the present study. Major amputation is a particularly relevant endpoint in CLTI because it reflects failure to preserve a functional limb and also serves as a marker of poor overall prognosis, impaired survival, mobility loss, and reduced quality of life.^[15,16] Pitoulis et al.^[17] similarly reported higher limb salvage after RA+POBA compared with POBA alone, although without statistical significance (97.8% vs. 94.0%, $p=0.35$). Previous studies have demonstrated high mortality and reduced mobility after major amputation in patients with CLTI, highlighting the clinical significance of even small differences in amputation rates.^[18] In addition, broader vessel preparation literature suggests that atherectomy and other plaque-modification strategies may provide technical benefit in selected calcified below-the-knee lesions, although available data remain heterogeneous across device types and adjunctive therapies.^[19,20] The divergence between major and minor amputation rates in our cohort warrants clinical consideration. In CLTI, minor amputation may occur as part of planned local tissue control after revascularization, whereas major amputation represents failure to preserve a functional limb. Therefore, the higher numerical rate of minor amputation in the RA+POBA group should not necessarily be interpreted as an unfavorable signal, particularly in the presence of a markedly lower major amputation rate. These findings do not establish RA+POBA as a uniformly superior strategy. Any potential benefit in CLTI may be better reflected by limb-salvage outcomes than by total amputation rates alone. Future studies should assess major amputation-free survival, wound healing, time to wound closure, and functional limb preservation.

In the present cohort, TLR was similar between the RA+POBA and POBA groups (RR 1.15, 95% CI 0.23–5.66; $p=0.866$). The

absence of a difference in TLR should be interpreted cautiously. TLR is a clinically driven endpoint and may be influenced by symptom recurrence, wound progression, surveillance intensity, and the threshold for repeat intervention rather than restenosis alone. In CLTI trials, TLR is frequently reported, but wound-related outcomes and functional endpoints are less consistently assessed, which may limit direct interpretation of reintervention rates as a surrogate for limb salvage.^[21] A recent study reported a numerically lower TLR rate after RA+POBA than after POBA alone (2.1% vs. 24%, $p=0.057$).^[17] Similarly, another study reported lower 12-month TLR after RA combined with adjunctive balloon angioplasty compared with balloon angioplasty alone (6.1% vs. 17.4%, $p=0.001$), while mortality remained comparable between groups.^[22] Thus, unlike previous reports, our data did not demonstrate a TLR advantage with RA+POBA. This discordance may indicate that, in CLTI, repeat revascularization and limb preservation do not necessarily move in parallel. Restoration of clinically meaningful perfusion to the wound-related angiosome or ischemic territory may influence wound healing and limb salvage, even when repeat revascularization rates remain unchanged.^[23] In our cohort, all-cause mortality was also similar between the groups. This result is consistent with the systemic nature of CLTI, in which mortality is often driven by comorbid cardiovascular disease, infection, renal dysfunction, inflammation, and frailty rather than by the local revascularization method alone. In a recent cohort of CLTI patients with ischemic foot ulcers, 5-year all-cause mortality reached 60.5%, and mortality was associated with factors such as creatinine, fibrinogen, and treatment in multiple anatomical regions.^[24] Accordingly, the mortality results should not be interpreted as directly parallel to limb-related outcomes in this high-risk CLTI population.

Regarding procedural outcomes, RA+POBA appeared technically feasible in selected IP lesions. Technical success rates in isolated IP lesions are generally reported to be high in the literature. Similarly, a recent study comparing RA+POBA with POBA in isolated IP lesions found similar technical success rates between the groups (88% in the POBA group, 95.7% in the RA+POBA group).^[17] Our cohort did not consist solely of isolated IP lesions. Our technical success rates were favorable (97.4% in the POBA group, 89.7% in the RA+POBA group), although a substantial proportion of limbs underwent simultaneous inflow lesion treatment (53.8% in the RA+POBA group and 41.0% in the POBA group). The higher crossover rate in the RA+POBA group may be explained by a higher frequency of concomitant inflow treatment, as crossover access allows iliofemoral and IP lesions to be treated through the same access route. Crossover access may also have been favored when ipsilateral antegrade puncture was technically challenging because of common femoral artery calcification, high femoral bifurcation, or obesity. The lower predilation rate in the RA+POBA group is to be expected, since RA was the primary vessel preparation method. Predilation in the RA+POBA group was used in selected cases where vessel diameter was relatively small and device passage was difficult. Safety outcomes regarding the use of the TemREN device in IP lesions are also lacking in the literature. Procedural safety in IP interventions should be interpreted in the context

of lesion complexity, small vessel diameter, calcification burden, access strategy, and the need for adjunctive balloon angioplasty. In this regard, the absence of distal embolization, flow-limiting dissection, bailout stent requirement, and access site complications in our cohort is clinically relevant. However, these findings should be viewed as supportive safety observations rather than definitive evidence of a device-related protective effect. The low number of procedural complications also limits any direct comparison between treatment strategies. Therefore, our procedural results suggest that TemREN RA can be applied in selected IP lesions without an apparent increase in acute procedural complications. Pitoulas et al.^[17] reported no significant difference in intraprocedural complication rates between the RA+POBA and POBA groups, with rates of 12% and 8%, respectively. In our cohort, procedural complications were limited to rupture, which occurred only in the POBA group (7.7%). The primary limitations of this study include its relatively small sample size, single-center setting, and retrospective design. This retrospective approach introduces the risk of selection bias, as treatment strategies and the utilization of RA were determined by clinical and imaging findings rather than by randomization. The limited number of outcome events did not permit reliable multivariable or propensity-based adjustment. The study may also have been underpowered to detect smaller between-group differences, and the limited number of events across multiple secondary outcome comparisons requires the observed major amputation finding to be interpreted as hypothesis-generating. Follow-up periods were not standardized among patients, and long-term outcomes could not be evaluated. Standardized pre- and postprocedural pressure measurements, such as ankle-brachial index, were not systematically available, limiting the objective comparison of hemodynamic changes between the treatment groups. Standard imaging-based data on patency, restenosis, and reocclusion were not available. Although anatomical complexity was assessed using GLASS, standardized wound, ischemia and foot infection staging and detailed wound, tissue-loss, and infection data were unavailable because these variables were incompletely and non-standardly documented in the retrospective records. Because the exact event times for TLR and major amputation were not completely available, competing-risk analyses accounting for death and standardized time-point estimates for these outcomes could not be reliably performed. Lesion calcification was not classified using an objective scoring system. Finally, differences in access type and predilation practices between groups created procedural heterogeneity.

Conclusion

In this retrospective cohort, RA+POBA was associated with a lower major amputation rate in patients with CLTI undergoing treatment of IP lesions. This secondary, unadjusted finding was based on a limited number of events and should therefore be considered hypothesis-generating. No difference was observed in TLR or all-cause mortality, and no conclusion regarding superior patency, durability, or survival can be drawn. Larger prospective multicenter studies evaluating limb-salvage, wound-healing, and functional outcomes are needed.

Disclosures

Ethics Committee Approval: The study was approved by the University of Health Sciences, Sancaktepe Martyr Prof. Dr. İlhan Varank Research and Training Hospital Scientific Research Ethics Committee (no: 2026/311, date: 10/06/2026).

Informed Consent: Informed consent was obtained from all subjects involved in the study.

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