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Results of endovascular interventions for peripheral arterial diseases on the targeted arterial segments

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Abstract. – OBJECTIVE: Endovascular interventions (EVIs) are an effective and minimally invasive therapeutic option for peripheral arterial diseases (PADs). This study aimed to evaluate the results of EVIs for PADs on the targeted arterial segments (TASs).

PATIENTS AND METHODS: One hundred and sixteen (116) participants with PADs were included in this cohort study. The diagnosis of PAD in this study was based on the ankle-brachial index (ABI) and Rutherford classification, confirmed by Duplex ultrasound and computed tomography angiography (CTA). The targeted arterial segments (TASs) were treated using either balloon angioplasty or endovascular stenting. At the end of each EVI, a post-procedure angiography was performed to evaluate the EVIs' results (i.e., balloon angioplasty and endovascular stenting) for PADs on the TASs. The results of EVIs were classified as either satisfactory or unsatisfactory. Satisfactory if the TASs were recanalized or had <30% stenosis after the EVIs. Unsatisfactory if the TASs were still occluded or had >30% stenosis after the EVIs.

RESULTS: The mean participants' age was 54.42±7.74 years; 35.3% of them were diabetic, 36.2% were hypertensive, and 28.5% had multiple medical disorders. Based on Rutherford classification, 44.83% of the participants had grade I, category 2 chronic ischemia, 23.28% had grade I, category 3 chronic ischemia, 12.93% had grade II, category 4 chronic ischemia, and 18.96% had grade III, category 5 chronic ischemia. About 87.1% of the participants' PADs were managed using balloon angioplasty. The affected arteries were the superficial femoral arteries in 47.5%, popliteal arteries in 18.8%, posterior tibial arteries in 18.8%, and anterior tibial arteries in 14.9%.

About 12.9% of the participants' PADs were managed using endovascular stenting and the affected arteries were the common iliac arteries in 60%, and external iliac arteries in 40%. The results of EVIs were satisfactory in 98.28% of the participants, while it was unsatisfactory in 1.72% of them.

CONCLUSIONS: Endovascular interventions in this study were an effective and minimally invasive therapeutic option for PADs, with satisfactory results in 98.28%. Further studies, including the long-term and clinical outcomes after EVIs for PADs, are required.

Key Words:
Endovascular interventions, EVIs, Peripheral arterial diseases, PADs.

Abbreviations

6-MWT: 6-Minute walk test. ABI: Ankle-brachial index. BMI: Body mass index. CTA: Computed tomography angiography. DCB: Drug coated balloon. ECG: Electrocardiogram. EPS: Embolic prevention system. EVIs: Endovascular interventions. FDA: Food and Drug Administration. IC: Intermittent claudication. PADs: Peripheral arterial diseases. PTA: Percutaneous transluminal angioplasty. QoL: Quality of life. TASs: Targeted arterial segments. SES: Self-expanding stents.

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Introduction

Peripheral arterial diseases (PADs) are chronic obliterating arterial diseases of the lower extremities, and it is a manifestation of progressive stenotic or occlusive arterial lesions[1].

PADs affect approximately 202 million adults worldwide[2]. The prevalence of PADs increases with age and with other risk factors such as diabetes mellitus, smoking, hypertension, and dyslipidemia[3].

Impaired blood supply to the lower extremities in PADs can be asymptomatic or can be presented with intermittent claudication (IC) during physical exercises or walking[1].

The current epidemiological data indicate that PADs are a significant economic burden on healthcare systems[4].

Endovascular interventions (EVIs) (i.e., balloon angioplasty or endovascular stenting) are an effective, safe, and minimally invasive therapeutic option for PADs[5,6].

Based on the hypothesis that EVIs are an effective and minimally invasive therapeutic option for PADs, this cohort study was designed to evaluate the results of EVIs (i.e., balloon angioplasty and endovascular stenting) for PADs on the targeted arterial segments (TASs).

Patients and Methods

One hundred and sixteen (116) participants with PADs were included in this cohort study, which was conducted during the year 2023 in the National Scientific Oncology Center of Astana after the West Kazakhstan Marat Ospanov Medical University (WKMU) ethical committee approval (No. 10; dated 28 December 2022) to evaluate the results of EVIs (i.e., balloon angioplasty and endovascular stenting) for PADs on the TASs.

Inclusion criteria include >20 and <70 years old participants with PADs [ankle-brachial index (ABI) <0.80[7], and Rutherford classification grade I-III] and failed medical treatment to control their PADs.

The ankle-brachial index (ABI) measures the ankle's systolic pressure to the arm's systolic pressure ratio (ABI <0.80 is sensitive and specific for diagnosing PADs)[8]. ABI <0.80 means grade 0 ischemia, ABI 0.6-0.79 ischemia grade I, ABI 0.4-0.59 ischemia grade II, and ABI ≤0.39 ischemia grade III[8].

Failed medical treatment means failed glycemic, cholesterol, and blood pressure controls, antiplatelets and anticoagulants to treat and/or control the participants' PADs.

The diagnosis of PADs in this study was based on the ABI index, Rutherford classification of chronic ischemia[9] (Table I), confirmed by Duplex ultrasound (100% sensitive for detecting the TASs for EVIs), and computed tomography angiography (CTA), (provides high-quality images with 91-100% sensitivity and 93-96% specificity for diagnosing the TASs for EVIs)[10].

Exclusion criteria include participants with thrombotic PADs, PADs with infected chronic ulcers, congestive heart failure (III-IV New York Heart Association[11]), abnormal renal function

Table I. Rutherford classification for chronic limb ischemia.

Grade	Category	Clinical description	Objective criteria
0	0	Asymptomatic (no hemodynamically significant occlusive disease)	Normal treadmill or reactive hyperaemia test
	1	Mild claudication	Completes treadmill exercise. Ankle pressure after exercise >50 mmHg but at least 20 mmHg lower than resting value
I	2	Moderate claudication	Between categories 1 and 3
	3	Severe claudication	Cannot complete standard treadmill exercise, and ankle pressure after exercise <50 mmHg
II	4	Ischemic rest pain	Resting ankle pressure <40 mmHg, flat or barely pulsatile ankle or metatarsal pulse volume recording, toe pressure <30 mmHg
III	5	Minor tissue loss (non-healing ulcer, focal gangrene with diffuse pedal ischemia)	Resting ankle pressure <60 mmHg, flat or barely pulsatile ankle or metatarsal pulse volume recording, toe pressure <40 mmHg
	6	Major tissue loss (extending above trans-metatarsal level, functional foot no longer salvageable)	Resting ankle pressure <60 mmHg, flat or barely pulsatile ankle or metatarsal pulse volume recording, toe pressure <40 mmHg

tests (elevated creatinine and blood urea), allergy to radio-opaque dye, pregnant or breastfeeding, previous major cardiac surgeries, previous EVI for PAD, history of acute myocardial infarction, acute cerebrovascular accident, pulmonary embolism, refused to participate, unable to communicate and/or to give consent.

The participants' PADs in this study were treated according to the Republic of Kazakhstan protocol for diagnosis and treatment of lower limb angiopathy.

After a thorough history and general examination, the studied participants were hospitalized for glycemic, cholesterol, and blood pressure controls and to manage their antiplatelets and anticoagulants when indicated according to the hospital's protocol.

Before EVIs, participants were subjected to routine laboratory investigations according to the hospital's protocol, including electrocardiogram (ECG), renal and liver function tests, lipid profile (i.e., cholesterol and triglyceride), coagulation profile, fibrinogen, blood sugar, hepatitis, and HIV screening. Participants were then subjected to radiological evaluation, including chest X-ray, abdominal ultrasound (SonoScape S6, Guangzhou Yueshen Co., China), arterial Duplex ultrasound (Vivid 5, GE Health Care Co., Chicago, IL, USA), and CTA.

The targeted ischemic zones were thoroughly examined to detect the ischemic skin, and muscles changes, volume of femoral, popliteal, ankle and metatarsal pulses.

The EVIs in this study aimed to re-establish blood flow through the TASs[7]. Under complete aseptic technique, local anesthesia (20 mL lidocaine 0.5%), and imaging screen (GE Innova 3100 IQ, GE Health Care Co., Chicago, IL, USA) using the retrograde access technique, the common femoral artery was catheterized[12]. The sites of the vascular occlusion (TASs) were assessed under the imaging screen and after intra-arterial instillation of the radiopaque dye. All EVIs were done in the angiography room under an imaging screen, and at least two vascular surgeons (>10 years' experience in endovascular surgeries) and two interventional radiologists (>10 years' experience in angiography and interventional radiology) should attend each EVI according to the hospital's protocol. The decision to perform either balloon angioplasty or vascular stenting for the TASs was based on the diameter of the TASs and the decision of the operating team.

The percutaneous transluminal balloon angioplasty (PTA) in this study was done using a 3-10 mm diameter Passeo-35 (BIOTRONIK Inc., New York, NY, USA) angioplasty balloon with variable up to 200 mm length. The delivery of the angioplasty balloon to the TASs was followed by balloon angioplasty. The CGuard™ embolic prevention system (EPS) (InspireMD, OBELIS S.A., Belgium) was inserted to re-canalize the TASs if the TASs did not respond to the balloon angioplasty.

One arterial segment was treated at each EVI session. Participants with multiple arterial segments occlusion or stenosis were treated in multiple EVI sessions according to the hospital's protocol.

At the end of each EVI, a post-procedure angiography was performed to assess the results of EVIs on the TASs, followed by manual compression (20 min. over the femoral puncture site), aseptic pressure bandage for 12 hrs., and bed rest. The results of EVIs were classified as either satisfactory or unsatisfactory. It was deemed satisfactory if the TASs were recanalized or had <30% stenosis after the EVIs. Unsatisfactory if the TASs were still occluded or had >30% stenosis after the EVIs[13].

The participants' data, including age, sex, smoking, body mass index (BMI), chronic medical disorders (e.g., diabetes, hypertension, renal, and/or cardiac), Rutherford classification, EVI's type and site, and its result (satisfactory or unsatisfactory), were collected to evaluate the results of EVIs (e.g., balloon angioplasty, and endovascular stenting) for PADs on the TASs.

Statistical Analysis

The G Power software[14,15] (Düsseldorf, Germany) with 0.95% power and 0.25 sample size was used to calculate the sample size for this study. A sample size of ≥100 participants was needed to produce an acceptable figure. The Chi-square (χ^2) and *t*-tests were used to analyze the categorical and continuous variables of the balloon angioplasty and endovascular stenting groups. The logistic regression analysis was also used to detect the association between the participants' variables and EVIs outcome. $p<0.05$ was considered significant.

Results

One hundred and sixteen (116) participants with PADs were included in this cohort study, which was conducted during the year 2023 in the National Scientific Oncology Center of Astana. to evaluate the results of EVIs (i.e., balloon angioplasty and endovascular stenting) for PADs on the TASs.

Table II. Characteristics of the studied participants, EVI's type, site, and results.

Variables	Studied participants (Number=116)
Age (Years) Mean ± SD	54.42±7.74
Sex (Number and %) -Males -Females	 82/116 (70.69%) 34/116 (29.31%)
BMI (Kg/m^2) Mean ± SD	27.52±2.07
Smoking (Number and %)	33/116 (28.5%)
Medical disorders (Number and %) - Diabetes - Hypertension **Multiple medical disorders** -Diabetic + renal disorders -Hypertensive + renal disorders -Hypertensive + diabetic -Hypertensive + cardiac diseases -Diabetic and hypertensive + renal ± cardiac diseases	 41/116 (35.3%) 42/116 (36.2%) **33/116 (28.5%)** 8/116 (6.9%) 5/116 (4.3%) 3/116 (2.6%) 3/116 (2.6%) 14/116 (12.1%)
Rutherford classification (Number and %) -Grade I, category 2 -Grade I, category 3 -Grade II, category 4 -Grade III, category 5	 52/116 (44.83%) 27/116 (23.28%) 15/116 (12.93%) 22/116 (18.96%)
EVI's type (Number and %) - Balloon angioplasty - Endovascular stenting	 101/116 (87.1%) 15/116 (12.9%)
Site of balloon angioplasty (Number and %) -Right -Left -Superficial femoral -Popliteal -Posterior tibial -Anterior tibial **Site of endovascular stenting** (Number and %) -Right -Left -Common iliac -External iliac	**101/116 (87.1%)** 54/101 (53.5%) 47/101 (46.5%) 48/101 (47.5%) 19/101 (18.8%) 19/101 (18.8%) 15/101 (14.9%) **15/116 (12.9%)** 10/15 (66.67%) 5/15 (33.33%) 9/15 (60%) 6/15 (40%)
Results of EVIs on TASs (Number and %) -Satisfactory* -Unsatisfactory**	 114/116 (98.28%) 2/116 (1.72%)

**Unsatisfactory EVI's result means the TAS was still occluded or >30% stenosed after the EVI. *Satisfactory EVI's result means the TAS was recanalized or had <30% stenosed after the EVI. BMI: body mass index (Kg/m^2). Data presented as mean ± standard deviation (SD) and number and percentage (%). EVIs: endovascular interventions. TASs: targeted arterial segments.

The mean participants' age was 54.42±7.74 years; 70.69% (82/116) were males, while 29.31% (34/116) were females. The mean participants' BMI was 27.52±2.07 Kg/m^2, and 28.5% (33/116) were smokers. About 35.3% (41/116) of the participants were diabetic, 36.2% (42/116) were hypertensive, and 28.5% (33/116) had multiple medical disorders (Table II).

The number of female and diabetic participants was significantly higher in balloon angioplasty [33.7% (34/101) and 40.6% (41/101), respectively] compared to the endovascular stenting group [0% (0/15) and 0% (0/15), respectively], (p=0.004 and 0.001, respectively) (Table III).

Based on the Rutherford classification, 44.83% (52/116) of the participants had grade I, category 2 chronic ischemia, 23.28% (27/116) had grade I, category 3 chronic ischemia, 12.93% (15/116) had grade II, category 4 chronic ischemia, and 18.96% (22/116) had grade III, category 5 chronic ischemia (Table II).

Number of participants with Rutherford classification grade I, category 2, grade I, category 3, and grade II, category 4 was significantly higher in balloon angioplasty [51.5% (52/101), 26.7% (27/101) and 14.9% (15/101), respectively] compared to endovascular stenting group [0% (0/15), 0% (0/15) and 0% (0/15), respectively], (p=0.0005, 0.009, 0.04, respectively) (Table III).

EVI's type and site, 87.1% (101/116) of the participants' PADs were managed using balloon angioplasty [53.5% (54/101) right-sided, and 46.5% (47/101) left-sided], and were affecting the super-

Table III. Characteristics of balloon angioplasty group *vs*. endovascular stenting group.

Variables	Balloon angioplasty (Number=101)	Endovascular stenting (Number=15)	p-value (95% CI)
Age (Years) Mean ± SD	54.2±6.26	56.1±13.99	p=1 (-9.8, 6.0)
Sex (Number and %) -Males -Females	67/101 (66.3%) 34/101 (33.7%)	15/15 (100%) 0/15 (0%)	p=0.3 p=0.004$^+$
BMI (Kg/m^2) Mean ± SD	27.34 ± 2.02	28.7 ± 1.99	p=0.5 (-2.5, -0.18)
Smoking (Number and %)	30/101 (29.7%)	3/15 (20%)	p=0.55
Medical disorders (Number and %) - Diabetes - Hypertension **Multiple medical disorders** -Diabetic + renal disorders -Hypertensive + renal disorders -Hypertensive + diabetic -Hypertensive + cardiac diseases -Diabetic and hypertensive + renal ± cardiac diseases	 41/101 (40.6%) 33/101 (32.7%) **27/101 (26.7%)** 8/27 (29.6%) 5/27 (18.5%) 1/27 (3.7%) 3/27 (11.1%) 10/27 (37.1%)	 0/15 (0%) 9/15 (60%) **6/15 (40%)** 0/15 (0%) 0/15 (0%) 2/6 (33.3%) 0/15 (0%) 4/6 (66.7%)	 p=0.001$^+$ p=0.2 **p=0.44** p=0.09 p=0.17 p=0.08 p=0.3 p=0.4
Rutherford classification (Number and %) -Grade I, category 2 -Grade I, category 3 -Grade II, category 4 -Grade III, category 5	 52/101 (51.5%) 27/101 (26.7%) 15/101 (14.9%) 7/101 (6.9%)	 0/15 (0%) 0/15 (0%) 0/15 (0%) 15/15 (100%)	 p=0.0005$^+$ p=0.009$^+$ p=0.04$^+$ p=0
Site of EVI (Number and %) -Right -Left -Superficial femoral -Popliteal -Posterior tibial -Anterior tibial -Common iliac -External iliac	 54/101 (53.5%) 47/101 (46.5%) 48/101 (47.5%) 19/101 (18.8%) 19/101 (18.8%) 15/101 (14.9%) 0/101 (0%) 0/101 (0%)	 10/15 (66.67%) 5/15 (33.33%) 0/15 (0%) 0/15 (0%) 0/15 (0%) 0/15 (0%) 9/15 (60%) 6/15 (40%)	 p=0.6 p=0.5 p=0.0008$^+$ p=0.02$^+$ p=0.02$^+$ p=0.04$^+$ p=0 p=0
Results of EVIs on TASs (Number and %) -Satisfactory* -Unsatisfactory**	 99/101 (98.02%) 0/101 (0%)	 15/15 (100%) 0/15 (0%)	 p=1 p=1

**Unsatisfactory EVI's result means the TAS was still occluded or >30% stenosed after the EVI. *Satisfactory EVI's result means the TAS was recanalized or had <30% stenosed after the EVI. $^+$: Significant difference. BMI: Body mass index (Kg/m^2). The chi-square (χ^2) test was used for statistical analysis when data was presented as number and %, and the t-test was used for statistical analysis when data was presented as mean ± SD. CI: confidence interval. Data presented as mean ± standard deviation (SD) and number and percentage (%). EVIs: endovascular interventions. TASs: targeted arterial segments.

ficial femoral arteries in 47.5% (48/101), popliteal arteries in 18.8% (19/101), posterior tibial arteries in 18.8% (19/101), and anterior tibial arteries in 14.9% (15/101). About 12.9% (15/116) of the participants' PADs were managed using endovascular stenting [66.67% (10/15) right-sided, and 33.33% (5/15) left-sided] and were affecting the common iliac arteries in 60% (9/15), and external iliac arteries in 40% (6/15) (Table II).

The percentage of PADs affecting the superficial femoral, popliteal, posterior tibial and anterior tibial arteries and targeted with balloon angioplasty was significantly higher in balloon angioplasty (47.5%, 18.8%, 18.8%, and 14.9%, respectively) compared to endovascular stenting group (0%, 0%, 0% and 0%, respectively), (p=0.0008, 0.02, 0.02, and 0.04, respectively) (Table III).

Results of EVIs on the TASs were satisfactory in 98.28% (114/116) of the studied participants (i.e., TASs were re-canalized or had <30% stenosis after the EVIs), while the results were unsatisfactory in 1.72% (2/116) of the studied participants (i.e., TASs were still occluded or >30% stenosis after the EVIs) (Table II).

The unsatisfactory results of EVIs were recorded in two diabetic and heavy smoker males [one of them had obesity grade 1 (BMI 31.2 Kg/m^2)], following posterior tibial arteries balloon angioplasty for grade I, category 3 chronic ischemia. The posterior tibial arteries were totally occluded and stenotic with failed balloon angioplasty. The follow-up of those two cases showed a progressive, ischemic PAD course, which ended with ankle amputation 12 months after the failed balloon angioplasty.

Logistic regression analysis in this study showed that the participants' variables, including age, gender, BMI, smoking, medical disorders, Rutherford classification, and EVI's site, did not affect the outcome of EVIs (Table IV).

Discussion

The EVIs are used to re-establish blood flow to the targeted ischemic zone and diminish the risk of limb loss[7]. EVIs is currently an effective alternative to conventional open endovascular surgeries used to treat PADs[13]. The success of EVIs depends on the experience of the operating team and the use of EVIs for proximal ischemic lesions with good arterial networks distal to the TASs[13].

Based on the hypothesis that EVIs are an effective and minimally invasive therapeutic option for PADs[5,6], one hundred sixteen (116) participants with PADs were included in this cohort study, which was conducted during the year 2023 in the National Scientific Oncology Center of Astana to evaluate the results of EVIs (i.e., balloon angioplasty and endovascular stenting) for PADs on the TASs.

The diagnosis of PAD in this study was based on the ABI[7], Rutherford classification[9], confirmed by Duplex ultrasound, and CTA[10]. The TASs were treated using either balloon angioplasty or endovascular stenting.

At the end of each EVI, a post-procedure angiography was performed and the results of EVIs were classified as either satisfactory or unsatisfactory[13]. The participants' data were collected to evaluate the results of EVIs for PADs on the TASs.

The mean participants' age was 54.42±7.74 years (70.69% males and 29.31% females). The mean participants' BMI was 27.52±2.07 Kg/m^2, and 28.5% of them were smokers. About 35.3% of the participants were diabetic, 36.2% were hy-

Table IV. Logistic regression analysis for the participants' variables versus EVIs outcome.

Variables	Coefficient	Standard Error (SE)	p-value	Odds ratio	95% (CI)
Age	0.025	0.07	0.72	1.03	0.89-1.18
Sex	18.88	8257.9	0.99	61983.8	0.0000
BMI	-0.24	0.31	0.43	0.79	0.4-1.44
Smoking	20.8	8713.98	0.99	85015.6	0.0000
Diabetes	20.59	9166.95	0.99	59818.1	0.0000
Hypertension	-18.97	7519.98	0.99	0.0000	0.0000
Multiple medical disorders	-17.65	7805.4	0.99	0.0000	0.0000
Rutherford classification	0.053	0.63	0.93	1.06	0.3-3.6
EVI's site	-0.498	0.41	0.23	0.6	0.3-1.4

BMI: body mass index, CI: confidence interval, EVI: endovascular intervention.

pertensive, and 28.5% had multiple medical disorders. Based on the Rutherford classification, 44.83% of the participants had grade I, category 2 chronic ischemia, 23.28% had grade I, category 3 chronic ischemia, 12.93% had grade II, category 4 chronic ischemia, and 18.96% had grade III, category 5 chronic ischemia.

EVI's type and site, 87.1% of the participants' PADs were managed using balloon angioplasty (53.5% right-sided, and 46.5% left-sided), and were affecting the superficial femoral arteries in 47.5%, popliteal arteries in 18.8%, posterior tibial arteries in 18.8%, and anterior tibial arteries in 14.9%. About 12.9% of the participants' PADs were managed using endovascular stenting (66.67% right-sided and 33.33% left-sided) and were affecting the common iliac arteries in 60% and external iliac arteries in 40%. The percentage of PADs affecting the superficial femoral, popliteal, posterior tibial and anterior tibial arteries and targeted with balloon angioplasty was significantly higher in balloon angioplasty (47.5%, 18.8%, 18.8%, and 14.9%, respectively) compared to endovascular stenting group (0%, 0%, 0% and 0%, respectively), (p=0.0008, 0.02, 0.02, and 0.04, respectively).

The results of EVIs on the TASs, the results of EVI were satisfactory in 98.28% (114/116) of the studied participants, while the results were unsatisfactory in 1.72% (2/116) of them.

The unsatisfactory results of EVIs were recorded in two diabetic and heavy smoker males following posterior tibial arteries balloon angioplasty. The posterior tibial arteries were totally occluded and stenotic with failed balloon angioplasty. The follow-up of those two cases showed a progressive, ischemic PAD course, which ended with ankle amputation 12 months after the failed balloon angioplasty. Logistic regression analysis in this study showed that the participants' variables, including age, sex, BMI, smoking, medical disorders, Rutherford classification, and EVI's site, did not affect the outcome of EVIs.

The PTA was established as the standard EVI in 2005. The PTA includes a balloon inflation in the target vessel to compress the atheroma into and against the vessel wall[16].

A review of EVIs records of patients who underwent EVIs between 2016 and 2019 showed 48 limbs with a mean age of 75 years were treated. About 93% of the studied patients had hypertension, 88% had diabetes, and 30% had chronic kidney disease. The EVIs were done using the conventional PTA and drug-coated balloons (DCBs) in 65 and 31% of EVIs, with no significant difference, and 90% of the participants had 12-month amputation-free intervals after the EVIs[13].

Schmidt et al[17], reported a 95.6% limb salvage at 12 months following balloon angioplasty for complicated infra-popliteal PADs (length 184 mm with 64.9% occlusion).

Krankenberg et al[18], post-hoc analysis when comparing Nitinol stents *vs.* PTA, suggests that in short, superficial femoral lesions, the outcomes after balloon angioplasty alone were similar to self-expanding stents (SES).

The BASIL randomized trial[19] showed similar rates of amputation-free interval at 12 months (71% *vs*. 68%, respectively) and 36 months (52% *vs*. 57%, respectively) for endovascular surgeries *vs*. balloon angioplasty. A meta-analysis reported reasonable rates of limb salvage with angioplasty alone in severe tibial vascular diseases with poor distal run-off[20].

A Cochrane review[21] reported insufficient evidence to make conclusions regarding the effects of PTA *vs.* primary endovascular stenting for stenotic and occlusive iliac vascular lesions and only one study reported lower distal embolization rates following primary stenting in iliac arteries occlusion.

Occlusive infra-popliteal PADs are often complex and calcified, with a high grade of stenosis. Successive balloon inflations to treat lengthy PADs increase the risks of dissection and perforation, which may be decreased by specifically designed long balloons[7].

The paclitaxel-DCBs showed 12-month rates of target lesion revascularization (17.3%) and limb salvage (95.6%) when used to treat long infra-popliteal lesions[22].

DCBs showed fewer adverse events with significant improvement of ABI at 12 months in patients with claudication due to femoropopliteal and infra-popliteal PADs compared to PTA[23]. Werk et al[24], found that the paclitaxel-DCBs were superior to PTA in the treatment of femoral restenosis.

The DCBs followed by stenting for the superficial femoral artery showed similar outcomes at 12 months compared to PTA followed by stenting[25].

A significant difference was reported in TAS patency when the paclitaxel-DCBs were compared to PTA in the THUNDER trial[26]. The THUNDER trial findings were supported by the PACIFIER[24], LEVANT-II[27], BIOLUX P-I[28], AcoArt-I[29], IN. PACT[30], and ILLUMENATE trials[31].

DCBs provide homogenous anti-proliferative drug delivery to the TASs when compared to the

conventional PTA and offer an innovative alternative to treat common femoral, superficial femoral artery, popliteal, and tibial PADs[32]. DCBs have potential benefits when used to treat PADs because they avoid endovascular stenting risks, including stent thrombosis, fracture, and prolonged antiplatelet therapy[33].

DCBs were recently approved by the FDA[34]. Although DCBs offer an attractive therapeutic advantage, further studies, including the long-term outcomes after DCBs-angioplasty, are required[35].

This study was the first cohort study conducted in the Republic of Kazakhstan to evaluate the results of EVIs (i.e., balloon angioplasty and endovascular stenting) for PADs on the TASs.

This study's limitations included the lack of clinical outcomes after EVIs for PADs, including QoL and a walking distance test. Further studies, including the clinical outcomes [i.e., walking distance, 6-Minute walk test (6-MWT), and QoL] after EVIs for PADs, are required.

Conclusions

Endovascular interventions in this study were an effective, and minimally invasive therapeutic option for PADs with satisfactory results in 98.28%. Further studies including the long-term and clinical outcomes after EVIs for PADs are required.

Conflict of Interest
The authors declare that they have no conflict of interest.

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Authors' Contributions
AC, SS, BZ, GC, DK, and LA are responsible for the study concept and design, data collection, literature review, and final revision before submission for publication.
IA, AD, AA, SSh, ZA, and ZK are responsible for statistical analysis, editing, literature review, and final revision before submission for publication.
All authors have read and agreed with the manuscript version submitted for publication.

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Ethics Approval
Participants were included in this study after obtaining the West Kazakhstan Marat Ospanov Medical University (WKMU) Ethical Committee approval No. 10 and dated 28 December 2022.

Informed Consent
Informed consents were obtained from all the participants involved in the study.

Data Availability
The datasets generated and/or analyzed during the current study are available from the corresponding author upon reasonable request.

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We hereby certify that no AI tools or automated writing systems were used in the creation of this research paper. All content, including the text, analysis, conclusions, and tables, were generated by the authors through traditional research and writing methods.

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