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Predictors for Better Blood-Flow Restoration of Long-Segmental Below-the-Knee Chronic Total Occlusions after Endovascular Therapy in Diabetic Patients

Xiao-Li Song, MD[1], Yue-Qi Zhu, MD[2], Hai-Tao Lu, MD[2], Fang Liu, MD[3], Li-Ming Wei, MD[2],
Heoung Keun Kang, MD[1], Jun-Gong Zhao, MD[2]

[1]Department of Radiology, Chonnam National University Medical School, Gwangju 501757, Korea; Departments of [2]Radiology and [3]Endocrinology, Shanghai Jiao Tong University Affiliated Sixth People's Hospital, Shanghai 200233, China

Objective: To prospectively investigate predictors for good restoration of blood flow of below-the-knee (BTK) chronic total occlusions (CTOs) after endovascular therapy in diabetes mellitus (DM) patients.

Materials and Methods: A total of 120 long-segmental (≥ 5 cm) BTK, CTOs in 81 patients who underwent recanalization were included in this study. After angioplasty, blood-flow restoration was assessed using modified thrombolysis in myocardial ischemia grades and classified as good flow (grade 3) and poor flow (grade 1/2). One hundred and six CTOs with successful recanalization were divided into a good flow group (GFG; n = 68) and poor flow group (PFG; n = 38). Multivariate logistic regression analyses were undertaken to determine independent predictors of blood-flow restoration. Receiver operating characteristic curves were constructed to determine the best cutoff value. The prevalence of target-lesion restenosis during follow-up was compared between two groups.

Results: Univariate analyses suggested that CTOs in GFG were characterized by lighter limb ischemia ($p = 0.03$), shorter course of ischemic symptoms ($p < 0.01$) and lesion length ($p = 0.04$), more frequent use of intraluminal angioplasty ($p = 0.03$), and higher runoff score ($p < 0.01$) than those in PFG. Multivariate regression analyses suggested that distal runoffs ($p = 0.001$; odds ratio [OR], 10.32; 95% confidence interval [CI]: 4.082–26.071) and lesion length ($p < 0.001$; OR, 1.26; 95% CI: 1.091–1.449) were independent predictors for good flow restoration. Kaplan-Meier analyses at 12 months showed a higher prevalence of non-restenosis in GFG ($p < 0.01$).

Conclusion: Distal runoffs and lesion length are independent predictors for good flow restoration for long-segmental BTK, CTOs in DM patients who receive endovascular therapy.

Keywords: *Chronic total occlusion; Extremity; Below the knee; Endovascular treatment; Blood flow restoration; Diabetes mellitus; DM*

INTRODUCTION

Below-the-knee (BTK) chronic total occlusions (CTOs) in subjects with diabetes mellitus (DM) are often characterized by multilevel and long segmental arterial involvement (1-3). Endovascular treatment is used to restore blood flow in the affected vessels in elderly DM patients with critical limb ischemia (CLI) (4-8). However, endovascular recanalization of the tibial vessels or arteries in the feet remains a challenge. Despite many recent studies on success rate of different recanalization techniques,

blood flow restoration is more important to improve limb ischemic symptoms. However, many factors such as clinic, angiographic or technical variables are likely to affect blood flow restoration; and multivariate analysis of various factors could predict the success of blood-flow restoration of BTK CTOs (9, 10). Therefore, we prospectively investigated predictors for good restoration of blood flow for BTK CTOs after endovascular recanalization in a group of DM subjects with chronic CLI. Furthermore, the prevalence of long-term patency of lesions and limb salvage were compared between patients with good and poor restoration of blood flow.

MATERIALS AND METHODS

Ethical Approval of the Study Protocol

The study was conducted in accordance with the recommendations of the Declaration of Helsinki, and was approved by the ethics committees of the participating hospitals. All patients gave written informed consent to participate in the study.

Patients

The inclusion criteria for the prospective study were: 1) a history of DM of > 5 years; 2) symptoms of CLI of grade III–IV according to the Fontaine classification; 3) subjects with planned digital subtraction angiography (DSA) and endovascular recanalization; 4) BTK CTO length ≥ 5 cm.

Exclusion criteria were: 1) stroke or myocardial infarction within the last 6 weeks; 2) severe impairment of renal function (glomerular filtration rate ≤ 30 mL/min; 3) life expectancy < 12 months; and 4) technique failed cases that did not receive CTO recanalization and subsequent angioplasty.

Recruitment for the study began in May 2012 and ended in September 2013; follow-up of patients continued until April 2014. A total of 106 CTOs in 70 patients (32 males; mean age, 71.3 ± 7.8 years) who met the inclusion and exclusion criteria and underwent BTK CTO recanalization were enrolled in the analyses of primary outcome (Fig. 1). Ninety-one target CTOs and 81 limbs in 61 patients undergoing regular angiographic and clinical follow-up (≥ 3 months) were enrolled in the analyses of secondary outcome.

Blood-flow restoration of CTOs after recanalization was divided into a good flow group (GFG; modified thrombolysis in myocardial ischemia [mTIMI] grade 3; n = 68) and poor flow group (PFG; mTIMI grade 1 and 2; n = 38).

Intra-Arterial Angiogram

Intra-arterial DSA prior to endovascular recanalization was performed by experienced angiographers. The procedure was performed under local anesthesia, and the target vessels were approached via antegrade access to the superficial femoral artery. A 4-Fr vertebral catheter (Cook,
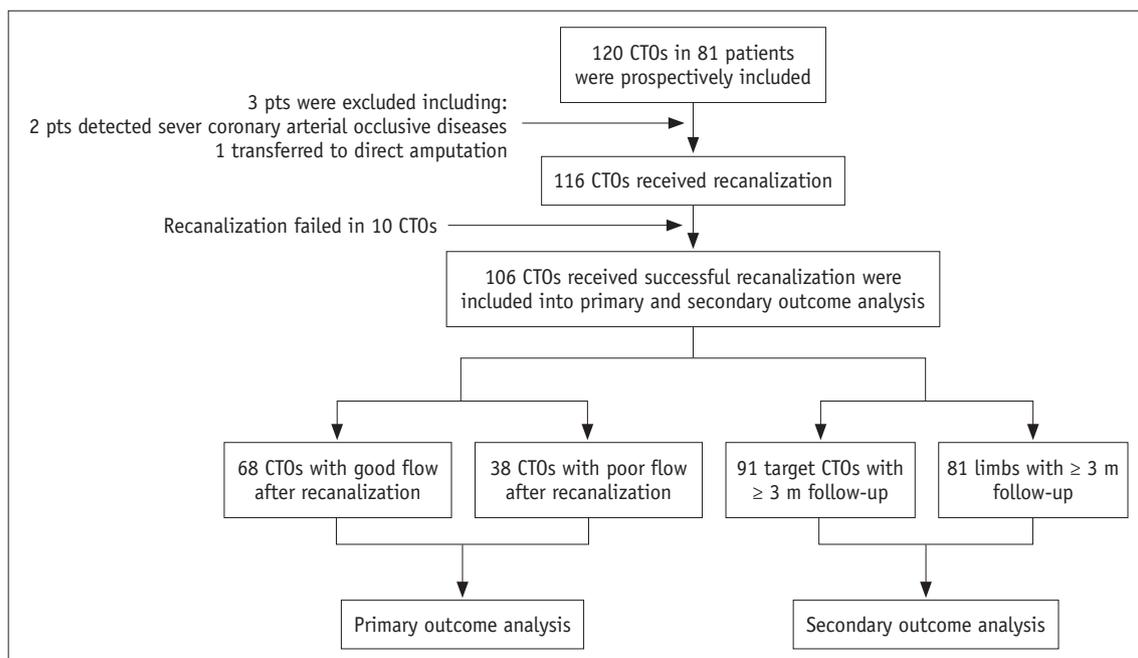

Fig. 1. Flow chart of present study. CTOs = chronic total occlusions

Bloomington, IN, USA) was introduced through a 5-Fr introducer. For angiogram of arteries below the knee, we routinely selected the catheter to popliteal artery below the knee lever, and the injection parameters were volume 7–8 mL and flow rate 3–4 mL/sec using an automatic high pressure injector. To identify the runoff vessels precisely, image collection time was often delayed to 24 seconds until complete disappearance of the visibility of all distal arteries. The artery was examined in posterior-anterior projections, and when necessary, additional lateral projections of a vascular region were obtained.

Distal runoffs of the target lesion were detected and classified based on intra-arterial DSA (referred as golden standard) images. Runoff scores were calculated according to the Society for Vascular Surgery/International Society for Cardiovascular Surgery scoring system proposed by Sacks et al. (11). A score of 0 to 2 indicated poor distal runoff, while a score of > 2 indicated good distal runoff (Table 1). Distal runoff was included into calculation of the score only if the vessel lumen had no stenosis or the stenosis was < 50% of the lumen of the normal adjacent artery. Analyses of runoff (calculation of runoff score; prediction of blood-flow restoration; prevalence of long-term patency of lesions and limb salvage) were specific to the target lesion; runoffs for untreated lesions were not included. Lesion length was defined as the total length of CTOs. CTOs involving orifice or bifurcation were defined as involvement of another tibial or peroneal artery. Lateral branch occupying ≥ 25% of the diameter of the adjacent main artery was included in the calculation.

Recanalization Procedures

Target lesion selection and treatment planning were based on the "angiosome concept" (12), when limb ischemia was classified as Fontaine grade IV. Treatment of other lesions classified as grade III was based on the conception that

at least one anterior or posterior tibial artery with < 30% residual stenosis should be recanalized to the malleolar or dorsal foot.

Intraluminal angioplasty was firstly attempted if the CTO was < 10 cm in length. However, intraluminal angioplasty was also carried out for longer CTOs if the guidewire could be advanced smoothly and moved forward without resistance, and good distal runoffs were noted.

Subintimal angioplasty was carried out if intraluminal angioplasty failed. For subintimal recanalization, a steerable guidewire (PT2 or V18; Boston Scientific, Natick, MA, USA) was used to enter the subintimal space and a catheter (TrailBlazer™ Support Catheter; ev3, Plymouth, MN, USA; Diver, Medtronic, Minneapolis, MN, USA or Cook, Bloomington, IN, USA) or a balloon catheter (Amphirion Deep, Medtronic, Minneapolis, MN, USA) was advanced into the subintimal space. A loop was created in the leading portion of the guidewire and advanced distally, until re-entry into the true lumen beyond the occlusion. If lesions involved below-the-ankle vessels, the guidewire loop was straightened to re-enter the true lumen or continue recanalization. After recanalization, an over-the-wire balloon catheter (diameter, 2–3 mm; length, 40–150 mm) was advanced through the diseased segment. Balloon dilation at 4–10 atmospheres for 1–3 minutes (depending on the degree of plaque calcification) was then carried out in the subintimal space to create an extraluminal channel to the distal lumen. In direct retrograde puncture, transpedal-plantar angioplasty, plantar-pedal loop angioplasty or angioplasty via collateral arteries was used; the decision to use intraluminal or subintimal methods was made by experienced interventional radiologists. Success was defined as recanalization of target CTOs using intraluminal or subintimal angioplasty in antegrade or retrograde directions.

Outcomes

The primary outcome was blood-flow restoration of recanalized CTOs on immediate DSA. Classification was based on the mTIMI grade: 0 (no perfusion) indicated absence of antegrade flow beyond the occlusion; 1 (penetration without perfusion), faint antegrade flow beyond the occlusion, with incomplete filling of the distal foot bed; 2 (partial reperfusion), delayed or sluggish antegrade flow with complete filling of the distal territory; 3 (complete perfusion), normal flow that completely fills the distal foot bed. A grade of 1 or 2 indicated poor blood flow, while a

Table 1. Weighting of Distal Runoff Arteries

Site of Intervention	Weighting of Runoffs Assigned		
	3	2	1
AT	Distal tibial	DPA	Pedal arch
PT	Distal tibial	LPA	Pedal arch
PER		DPA or LPA	Collaterals to AT and PT
DPA	Pedal arch		
LPA	Pedal arch		

AT = anterior tibial artery, DPA = dorsalis pedis artery, LPA = lateral plantar artery, PER = peroneal artery, PT = posterior tibial artery

grade of 3 indicated good blood flow. Angiograms from each patient were reviewed in consensus by three radiologists blinded to the study protocol. Angiographic- and procedure-related factors (e.g., lesion characteristics, distal runoffs, recanalization method) were compared between CTOs with good and poor blood flow after recanalization. Improvement in the ankle-brachial index (ABI) was also compared before and after the procedure.

The main secondary outcomes were the prevalence of patency of the target lesion and limb salvage during follow-up. Restenosis was defined as loss of luminal diameter of > 50% compared with the adjacent normal artery. Using

duplex scanning, the degree of stenosis in the studied segment was classified based on the peak systolic velocity ratio (PSVR). The PSVR was calculated by dividing the peak systolic velocity in the stenotic segment by the peak systolic velocity in the preceding normal segment or in the adjacent distal segment. A PSVR > 2.4 indicated > 50% stenosis (13). With follow-up computed tomography angiography (CTA) or magnetic resonance angiography (MRA), the stenosis was calculated from the ratio of the linear luminal diameter of the narrowest segment of the diseased portion of the artery to the diameter of the normal artery beyond the diseased lesion. Limb salvage was
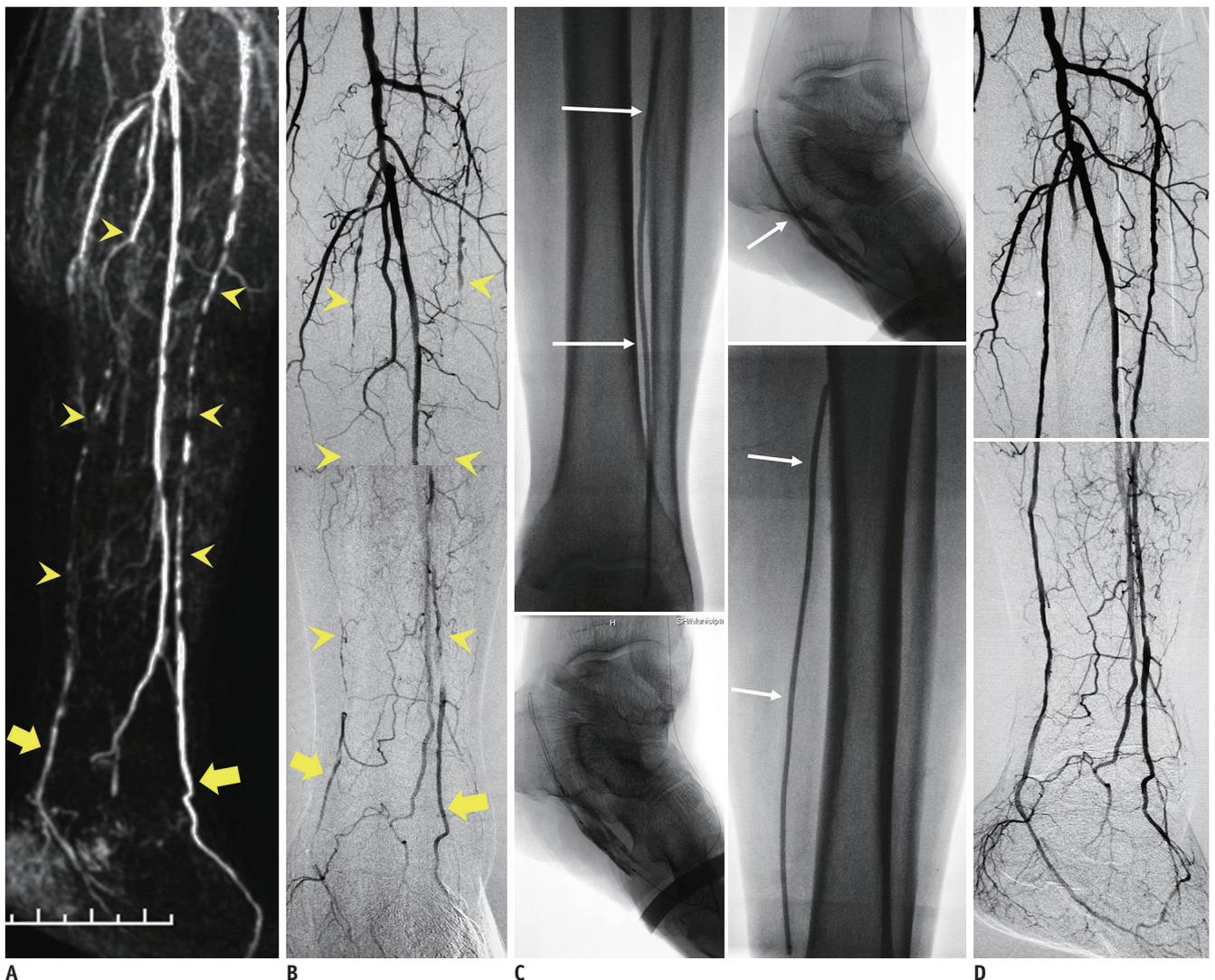

Fig. 2. Images of 71-year-old male patient who had experienced rest pain in left leg for 15 months.
CE-MRA revealed long CTOs of anterior and posterior tibial arteries (yellow arrowheads) in left lower limb. Good distal runoffs of CTOs were detected with CE-MRA (yellow wide arrows) **(A)**, which showed similar sensitivity to DSA **(B)**. Anterior tibial artery received intraluminal angioplasty treatment (white arrows). Retrograde intraluminal angioplasty of posterior tibial artery (white arrows) via pedal arch was performed when integrate subintimal recanalization failed **(C)**. Immediate DSA revealed good blood flow restoration of recanalized tibial arteries and distal tissue reperfusion **(D)**. CE-MRA = contrast-enhanced magnetic resonance angiography, CTOs = chronic total occlusions, DSA = digital subtraction angiography

considered if the plantar stand was maintained (even if achieved by tarsal-metatarsal amputation); any above-ankle amputation was considered a failure. Other improvements in secondary outcome included relief of rest pain (i.e., decrease in a visual analog scale of > 2 cm) and wound healing (decrease of > 50% in ulceration size at the end of follow-up).

Statistical Analyses

GraphPad Prism v5.0 (GraphPad Software, San Diego, CA, USA), and SPSS v12.0 (SPSS, Chicago, IL, USA) were used for statistical analyses. Patient characteristics for both groups and overall changes in the ABI before and after treatment were compared using the Student's t test. Fisher's exact test was used to compare nonparametric data. Multivariate logistic regression analyses were undertaken to determine independent predictors of blood-flow restoration. Univariate predictors of blood-flow restoration with $p < 0.05$ were entered into a multivariate logistic model. The following covariates were considered in the model: 1) clinical variables: CTO duration and limb ischemia; 2) angiographic variables: lesion length, distal runoff, lesions involve orifice or bifurcation and lateral branches; 3) procedural variables: intra-luminal or subintimal recanalization. The Kaplan-Meier method was used to calculate the prevalence of non-restenosis and limb salvage over time in both groups, and inter-group differences determined using the log-rank test. Continuous variables were the mean ± SD. Categorical variables were reported as numbers or percentages. $P < 0.05$ (two-sided) was considered significant.

RESULTS

Procedure

Total angioplasty was carried out successfully in 91.4% (106/116) of BTK CTOs (Fig. 2). The reasons for failure were vessel perforation in 2 CTOs, failure of re-entry into the true lumen in 6, and thrombosis in 2. Nine of the 10 failed CTOs had poor distal runoff for percutaneous transluminal angioplasty. Bailout BTK stent placement was done in 1 case owing to isolated dissection. No procedure-related death occurred. Intraluminal angioplasty was applied in 48 (45.3%) CTOs. ABI values showed a significant improvement from 0.40 ± 0.12 before to 0.78 ± 0.15 after recanalization ($p < 0.001$).

Primary Outcomes and Univariate Analysis

In the GFG, 58 CTOs had good distal runoffs with a runoff score ≥ 3, but only 4 CTOs had good runoff in the PFG ($p < 0.01$). CTOs in the PFG were characterized by longer CTO duration (10.82 ± 5.51 vs. 8.69 ± 4.87 months in the GFG; $p = 0.042$) and lesion length (24.32 ± 7.43 cm vs. 20.72 ± 8.96 cm in the GFG; $p = 0.038$), and more frequent involvement of the orifice or arterial bifurcation of the diseased artery (23.7% vs. 8.8% in the GFG; $p = 0.045$). Intraluminal angioplasty was used more often in the GFG (54.9% vs. 31.6% in the PFG; $p = 0.042$), in which 87.5% CTOs had good distal runoff (Table 2).

Multivariate Logistic Regression Analyses

Multivariate logistic regression analyses suggested that CTO length ($p = 0.001$; odds ratio [OR], 1.258; 95% confidence interval [CI], 1.091–1.449) and distal runoff ($p < 0.001$; OR, 10.316; 95% CI, 4.082–26.071) were independent predictors for immediate, good restoration of blood flow after endovascular recanalization.

Secondary Outcomes

Altogether, 59 CTOs in the GFG and 32 CTOs in the PFG underwent duplex sonography or CTA/MRA follow-up for > 3 months. At the end of follow-up (mean, 10.14 ± 4.13 months), restenosis or re-occlusion occurred in 14 (23.7%) CTOs in the GFG and 24 (75%) CTOs in the PFG ($p < 0.01$). Kaplan-Meier analyses revealed that total patency at 12 months was 60% for patients who underwent successful

Table 2. Characteristics for Target CTOs with Good and Poor Flow after Recanalization

Characteristics	GFG (n = 68)	PFG (n = 38)	P
CTO duration, years	8.69 ± 4.87	10.82 ± 5.51	0.042
Lesions causes severe limb ischemia (Fontaine stage IV)	10 (14.7%)	13 (34.2%)	0.027
Lesion length (cm)	20.72 ± 8.96	24.32 ± 7.43	0.038
Lesions with good distal runoff	60 (88.2%)	4 (10.5%)	< 0.001
Intra-luminal recanalization	36 (52.9%)	12 (31.6%)	0.042
Lesions involve orifice or bifurcation	6 (8.8%)	9 (23.7%)	0.045
Lesions with lateral branches	21 (30.9%)	19 (50%)	0.062

Data are numbers, data in parentheses are percentages. CTO = chronic total occlusions, GFG = good flow group, PFG = poor flow group

recanalization of the target lesion. However, further investigation based on restoration of blood flow revealed that lesion patency was much higher in the GFG at 12 months (72.1% vs. 43.1% in the PFG; log-rank test $p < 0.001$). During follow-up (mean, 10.67 ± 3.99 months), amputation was undertaken in 1 limb (1.9%) in the GFG and 5 limbs (17.9%) in the PFG ($p = 0.02$). Kaplan-Meier analyses at 12 months revealed the prevalence of total limb salvage as 89.3%, and higher in the GFG (96.0%), as compared with PFG (79.1%; log-rank test, $p = 0.02$) (Fig. 3).

Pain relief and/or ulcer healing was noted in 92.5% (49/53) and 71.4% (20/28) of patients in the GFG and PFG, respectively ($p = 0.02$). Re-intervention was required in 7 CTOs of 8 limbs in the GFG and 4 CTOs of 4 limbs in the PFG, because of symptom recurrence during follow-up. The remaining cases of restenosis or reocclusion were not treated because the patients did not complain of ischemic symptoms.

DISCUSSION

This prospective study revealed 4 main findings. Firstly, intraluminal angioplasty was used more commonly than subintimal angioplasty to achieve good blood flow for BTK CTOs. Secondly, univariate and multivariate analyses showed distal runoff and lesion length as independent predictors

of good blood flow restoration for BTK CTOs in DM patients with CLI. Thirdly, the optimal cutoff value of distal runoff score that best predicted good restoration of blood flow was 2.5 with sensitivity and specificity of ≤ 88.2% and ≤ 89.5%, respectively. Finally, Kaplan-Meier analyses revealed a greater prevalence of non-restenosis and limb salvage for CTOs with good restoration of blood flow.

Besides the recanalization method-based effects, ischemic symptoms and lesion imaging characteristics may influence immediate blood-flow restoration after recanalization. In the present study, univariate analyses showed that CTO duration, symptoms of limb ischemia, recanalization methods, lesion length, distal runoff, lesions involving orifices or bifurcations influenced the blood-flow restoration of CTOs with successful recanalization. However, multivariate analyses revealed only the lesion length and distal runoff as independent predictors of immediate good restoration of blood flow after endovascular recanalization. The lesion length was an independent predictor probably because: 1) a longer lesion often increases the risk of arterial dissection during recanalization, which directly affects blood flow and consequently, immediate or late thrombosis; 2) longer lesions suggest more severe disease and long-term disease course, so recoil of arterial walls after dilation is likely and sometimes the calcification can be so severe that dilation is not possible.
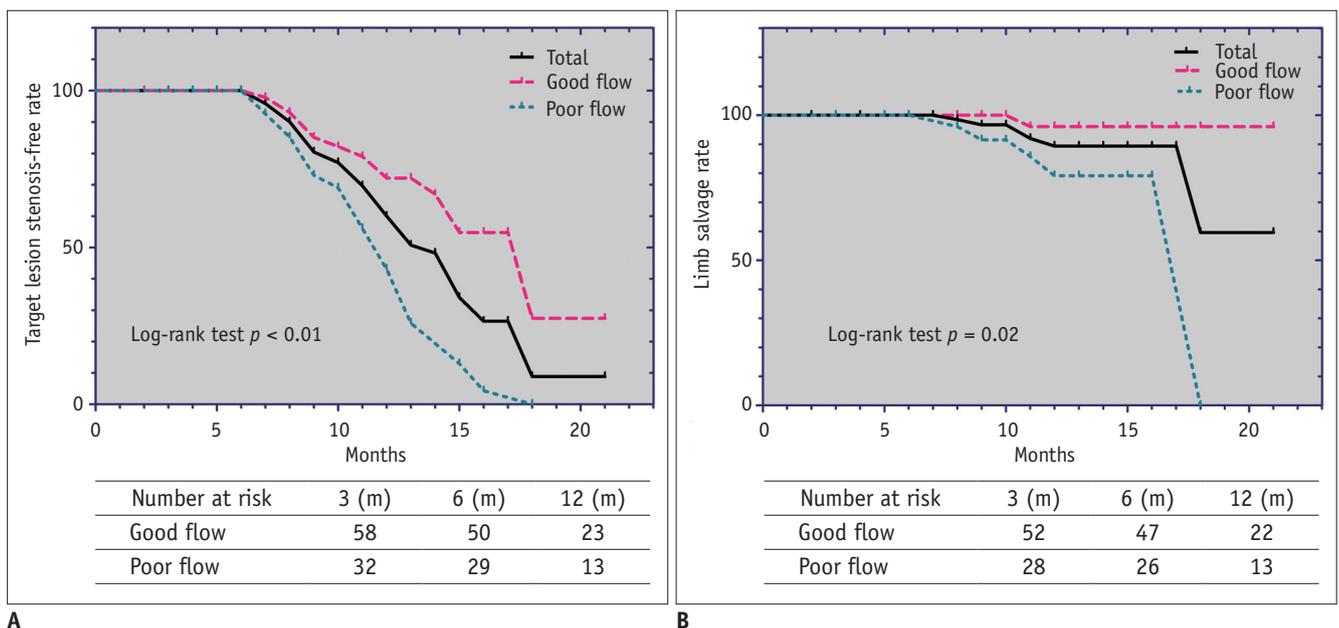

Fig. 3. Kaplan-Meier estimates for prevalence of non-restenosis (A) and limb salvage (B) and comparison between GFG and PFG.
Differences between groups were compared using log-rank test. Horizontal ticks along survival curve indicate censored times. Number of patients at risk of failure or remaining in at-risk set against corresponding times is indicated in table below graph. GFG = good flow group, PFG = poor flow group

Clear display of distal runoffs is extremely important for endovascular recanalization of BTK CTOs. Recently, Hiramori et al. (14) reported using infrapopliteal runoff score for treatment outcomes of femoropopliteal lesion recanalization, which was a good predictor for long term recanalization patency. Compared to previous reports, our runoff classification was based on the Society for Vascular Surgery/International Society for Cardiovascular Surgery scoring system (11), which is mainly used for predicting technique success and blood flow restoration for the treatment of infrapopliteal lesions; therefore, runoff vessels below the knee were further divided and assigned a weight. In addition, infrapopliteal arterial lesions mostly involved multi-vessel; hence, we only selected 1 or 2 vessels for the treatment. Consequently, all calculated runoff scores in the present study were target lesion based. Studies have reported occlusive lesions without good runoffs as negative predictors of lesion recanalization (15, 16), possibly since distal runoffs often indicate shorter lesions, less atherosclerosis, or less calcification of the diseased arterial wall, and can determine the course of the occlusive segment during intraluminal or subintimal angioplasty to reduce arterial perforation. Distal runoff may also increase the chances of the guidewire re-entering the true lumen during subintimal recanalization. More importantly, a sufficient length of the distal runoff allows for the application of retrograde recanalization via direct puncture of distal runoffs vessels or via pedal arch (17-19). Potential reasons for distal runoff as an independent predictor of good blood flow restoration include the following: 1) lack of distal runoffs despite good dilation of CTOs may restrict the volume and speed of blood outflow, making resumption of smooth blood flow difficult; 2) severely diseased runoffs may affect blood flow perfusion of distal tissue; 3) severely diseased runoffs are likely to increase the chances of minor arteriovenous fistulae at higher vessel level or bypass of flow via branches to hamper reperfusion of distal tissue (20).

For most tibial arterial CTOs, patency of the distal tibial artery and/or the dorsal pedal artery or lateral plantar artery and/or the foot arch can best predict good flow after endovascular recanalization. Studies have suggested that the chances of long-term patency of lesions or limb salvage can be predicted based on procedural success (21-23). However, good restoration of blood flow after recanalization may be a better predictor than the success of the procedure, for lesion patency or limb salvage in the long term. In the present study, the mean prevalence of lesion patency 12

months after successful recanalization was 60%, which is close to the previously reported 58–59.1% (21, 22). However, further layering analyses based on blood flow suggested that patency at 12 months in the GFG was 72.1%, as compared with only 43.1% in the PFG. Similarly, the prevalence of limb salvage in the GFG was 96.00%, which was much higher than the 79.1% observed in the PFG. However, analyses were based mainly on the Kaplan-Meier method, and the influences of ischemic symptoms or lesion characteristics based on imaging were not included. Hence, multivariate regression analyses is required to determine whether good restoration of blood flow is an independent predictor of better lesion patency or limb salvage in the long-term.

In present study, technique failed cases were excluded from final analysis, resulting in dual effects. Considering that recanalization failure could be affected by several factors, this exclusion criteria helped determine whether blood flow restoration was affected by distal runoff; however, as mostly failed CTOs were mainly those with poor distal runoff vessels, the exclusion criteria tended to exaggerate the influence of distal runoff.

In conclusion, our findings suggested that good distal runoff and lesion length are predictors for restoration of good blood flow after recanalization of BTK CTOs in DM patients with CLI. Moreover, CTOs with restoration of good blood flow can achieve higher prevalence of lesion patency and limb salvage in long-term follow-up. Therefore, imaging methods that depict runoffs precisely should be employed before recanalization is undertaken.

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