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Endovascular Revascularization for Patients with Critical Limb Ischemia: Impact on Wound Healing and Long Term Clinical Results in 189 Limbs

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Objective: To evaluate the impact on wound healing and long-term clinical outcomes of endovascular revascularization in patients with critical limb ischemia (CLI).
Materials and Methods: This is a retrospective study on 189 limbs with CLI treated with endovascular revascularization between 2008 and 2010 and followed for a mean 21 months. Angiographic outcome was graded to technical success (TS), partial failure (PF) and complete technical failure. The impact on wound healing of revascularization was assessed with univariate analysis and multivariate logistic regression models. Analysis of long-term event-free limb survival, and limb salvage rate (LSR) was performed by Kaplan-Meier method.
Results: TS was achieved in 89% of treated limbs, whereas PF and CF were achieved in 9% and 2% of the limbs, respectively. Major complications occurred in 6% of treated limbs. The 30-day mortality was 2%. Wound healing was successful in 85% and failed in 15%. Impact of angiographic outcome on wound healing was statistically significant. The event-free limb survival was 79.3% and 69.5% at 1- and 3-years, respectively. The LSR was 94.8% and 92.0% at 1- and 3-years, respectively.
Conclusion: Endovascular revascularization improve wound healing rate and provide good long-term LSRs in CLI.
Index terms: Critical limb ischemia; Infrapopliteal angioplasty; Diabetic foot

INTRODUCTION

Chronic critical limb ischemia (CLI) occurs when arterial blood flow to the part or entire foot, is markedly reduced, in most cases as a result of progressive obstructive atherosclerosis. According to Trans-Atlantic Inter-Society Consensus (TASC) (1), there will be approximately 500 to

1000 new cases of CLI every year in a European or North American population of 1 million. Prevalence of CLI seems to increase with the increasing prevalence of diabetes mellitus (2). CLI is difficult to summarize because treatment very much depends on the countries and the institutions to which the patient is referred. However, studies suggest that about 25% of the patients with CLI undergo primary foot amputation even in developed countries (1), and amputation seems to be the common first-line therapy in developing countries, where there is lack of specialized podiatry program (3).

Advances in techniques and devices have led to more widespread use of endovascular revascularization procedures for the restoration of blood flow in CLI, and evidence regarding safety and clinical effectiveness support its application (4-9). Clinical effectiveness of endovascular revascularization has been frequently judged by vessel

patency and limb salvage (6-8), but there is paucity of reports on outcomes of the wound. The goal of this study was to evaluate the impact on wound healing as well as long-term clinical outcomes of endovascular revascularization in a large single-center population of patients with CLI.

MATERIALS AND METHODS

Patients

The local Institutional Review Board of the hospital approved this retrospective study and waived the requirements for informed consent and research subject authorization. All patients with CLI (Rutherford category 4-6 [10]) who underwent endovascular revascularization between May 2008 and June 2010 were identified. During this period, 205 limbs of 167 patients were treated for chronic CLI. The decision to use endovascular revascularization as first line therapy was based upon the clinical examination, anatomic evaluation and judgment in a multidisciplinary meeting of vascular surgeons, orthopedic surgeons and interventional radiologists. Of them, 7 patients who were lost to follow-up and 9 functionally unsalvageable limbs were excluded. Endovascular revascularization of a functionally unsalvageable limb was done to facilitate healing of below the knee amputation (BKA) wound on a decision by attending orthopedic surgeons. Individual limbs were counted separately so that patients undergoing staged, bilateral procedures were recorded and evaluated as two entries. Thus, 189 limbs of 152 patients (age range 41-91, mean 67 year-old) were included in the study. Demographic and clinical factors are summarized in Table 1. The indication for endovascular revascularization was rest pain (category 4) in 45 (24%) limbs and non-healing wound (category 5, 6) in 144 (76%) limbs. Chronic renal failure (CRF) was defined as a pre-procedure serum creatinine > 1.7 mg/dL. Histories of coronary arterial obstructive disease, hypertension, and stroke were collected from full medical record review.

Lesions

All lesions were retrospectively analyzed based on the pre-procedure angiography and computed tomography (CT). The distribution of the arterial lesions in a limb was recorded. Femoropopliteal lesion was classified according to the TASC II system (1). Infrapopliteal lesions were classified based on the number of patent tibial (anterior

and posterior) or peroneal artery, because most cases with long segmental occlusion or total occlusion are classified to class D on TASC system. Peroneal artery continuing to the dorsalis pedis artery (n = 3) as an anatomical variation was classed to the anterior tibial artery. Distribution and characteristics of lesion are summarized in the Table 2.

Procedure

All patients were given 300 mg of clopidogrel (Handok Pharmaceutical, Seoul, Korea) and 324 mg of aspirin (Boryung Pharmaceutical, Seoul, Korea) as a loading dose a day before the procedure. Patients with preoperative renal insufficiency were given oral N-acetylcystine prior to procedure. Sedation and analgesia was achieved with an intravenous continuous infusion of remifentanil and local

Table 1. Patient Characteristics

Parameter	No. of Patients (n = 152)
Men	121 (80%)
Women	31 (20%)
Diabetes	138 (91%)
Hypertension	80 (53%)
Chronic renal failure	54 (36%)
Coronary artery disease	41 (27%)
Stroke history	21 (14%)
Indication	No. of Limbs (n = 189)
Resting pain (Rutherford 4)	45 (24%)
Tissue damage (Rutherford 5 and 6)	144 (76%)

Table 2. Lesion Characteristics

Variables	Number (%)
Lesion distribution (189 limbs)	
IL + FP	2 (1)
IL + IP	2 (1)
IL + FP + IP	27 (14)
FP	6 (3)
FP + IP	115 (61)
IP	37 (20)
FP lesions (150 limbs)	
TASC II A	100 (67)
TASC II B	10 (7)
TASC II C	31 (21)
TASC II D	9 (6)
IP lesions (181 limbs)	
Two patent tibial arteries	36 (20)
One patent tibial artery	62 (34)
Peroneal runoff only	57 (31)
No patent crural artery	34 (19)

Note.— IL = iliac, FP = femoropopliteal, IP = infrapopliteal, TASC = Trans-Atlantic Inter-Society Consensus

anesthesia of the groin. An intravenous heparin bolus (80 IU/kg) was administrated during the procedure. If arterial spasm occurred, 0.1-0.2 mg of nitroglycerin was infused as an intra-arterial in bolus. After the procedure, patients were given a 75 mg clopidogrel daily dose for at least 30 days, along with 81 mg aspirin indefinitely.

All lesions of one limb were treated through 6-7 Fr sheaths in the same session. For an iliac artery lesion (n = 31), a contralateral retrograde common femoral artery (CFA) access was made exclusively to spare the ipsilateral CFA for another possible access. Femoropopliteal artery lesions (n = 144) were treated through an ipsilateral antegrade CFA access in 110 (78%) or a contralateral CFA access in 34 cases (22%). We approached infrapopliteal artery lesions (n = 182) through an ipsilateral antegrade CFA access in 179 (98%) except for 3 cases (2%) with obesity and a high CFA bifurcation. No brachial or popliteal punctures were made. A distal retrograde access of the tibial artery was added to cross the tibial occlusive lesions in 10 cases.

Iliac and femoropopliteal arterial lesions were crossed preferentially with 0.035 inch hydrophilic guide wires (Radifocus, Terumo, Tokyo, Japan). Infrapopliteal arterial lesions were crossed preferentially with hydrophilic 0.018 inch (V18, Boston Scientific, Natick, MA, USA) or 0.016 inch wires (GT, Terumo, Tokyo, Japan). Subintimal crossing was used for complete occlusions that could not be crossed intraluminally.

Percutaneous angioplasty was performed with balloon catheters. Diameters of balloon catheters were decided to match the non-diseased segment adjacent to the lesion on CT or angiography. Non-compliant 6 to 8 mm diameter (Rider, Leventon, Barcelona, Spain) for iliac artery, 4 to 7 mm diameter (Savvy or Powerflex; Cordis, Miami Lakes, FL, USA) for femoropopliteal artery, and 2 to 4 mm (Savvy, Cordis; Miami Lakes, FL, USA) for infrapopliteal arterial lesions were preferred. Long angioplasty balloons were routinely used for the infrapopliteal arteries to cover all multiple or long segmental lesions. Balloon inflation pressures ranged from 4 to 14 atmospheres and were held for at least 60 seconds. Stents were placed for flow-limiting dissections or suboptimal angioplasty results (residual stenosis > 30%) in the iliac or femoropopliteal arteries. Stents were not placed in the infrapopliteal arteries considering high risk of thrombosis in low-flow vessels. Hemostasis was routinely performed with manual compression 3-6 hours after the procedure. A closure device was not used.

Complications

Complications were defined as minor and major, according to the definitions of the Society of Interventional Radiology (11). Puncture site hematomas were not considered a significant complication unless requiring intervention or blood transfusion. However, any event that prolonged hospital stay during the procedure or required specific medical or surgical treatment immediately after the procedure was recorded as a major complication.

Follow-Up

All patients were routinely prescribed oral aspirin (81 mg) and oral clopidogrel (75 mg) once daily for 3 months if no contraindications to either medication were present. The patients were examined every 1 or 2 weeks after discharge until wound healing, and instructed to visit the physician with irregular intervals thereafter. Checking the status of the wound, pain at rest, and the general condition of the patient were determined from the medical records. For 42 patients whose most recent follow-up data was incomplete, additional information was obtained from telephone calls to the patients and the patient's family members. Indications for reintervention during the follow-up included recurrence of symptoms, i.e., resting pain, or new wound of the foot.

Definitions and End Points

Angiographic outcomes were graded to technical success (TS), partial failure (PF) and complete technical failure (TF), defined in Table 3. A typical case of TS is shown in Figure 1.

For the limbs with non-healing wound, we investigate fate of wound. Healing success was defined when complete healing of initial wound was obtained or when no further amputation was required after planned minimal amputation.

Table 3. Grading of Angiographic Outcomes

| Variables	Angiographic Finding
Technical success	All inflow lesions with a residual stenosis < 30% and a straight line flow through at least one tibial artery which have intact flow to the pedal arch was achieved
Partial failure	The only iliac and/or femoropopliteal segment were successfully treated but no straight line flow to the foot
	All inflow lesions with a residual stenosis < 30% and a straight line flow through the peroneal artery was achieved
Complete technical failure	No apparent improvement in arterial inflow compared with pre-procedure angiography
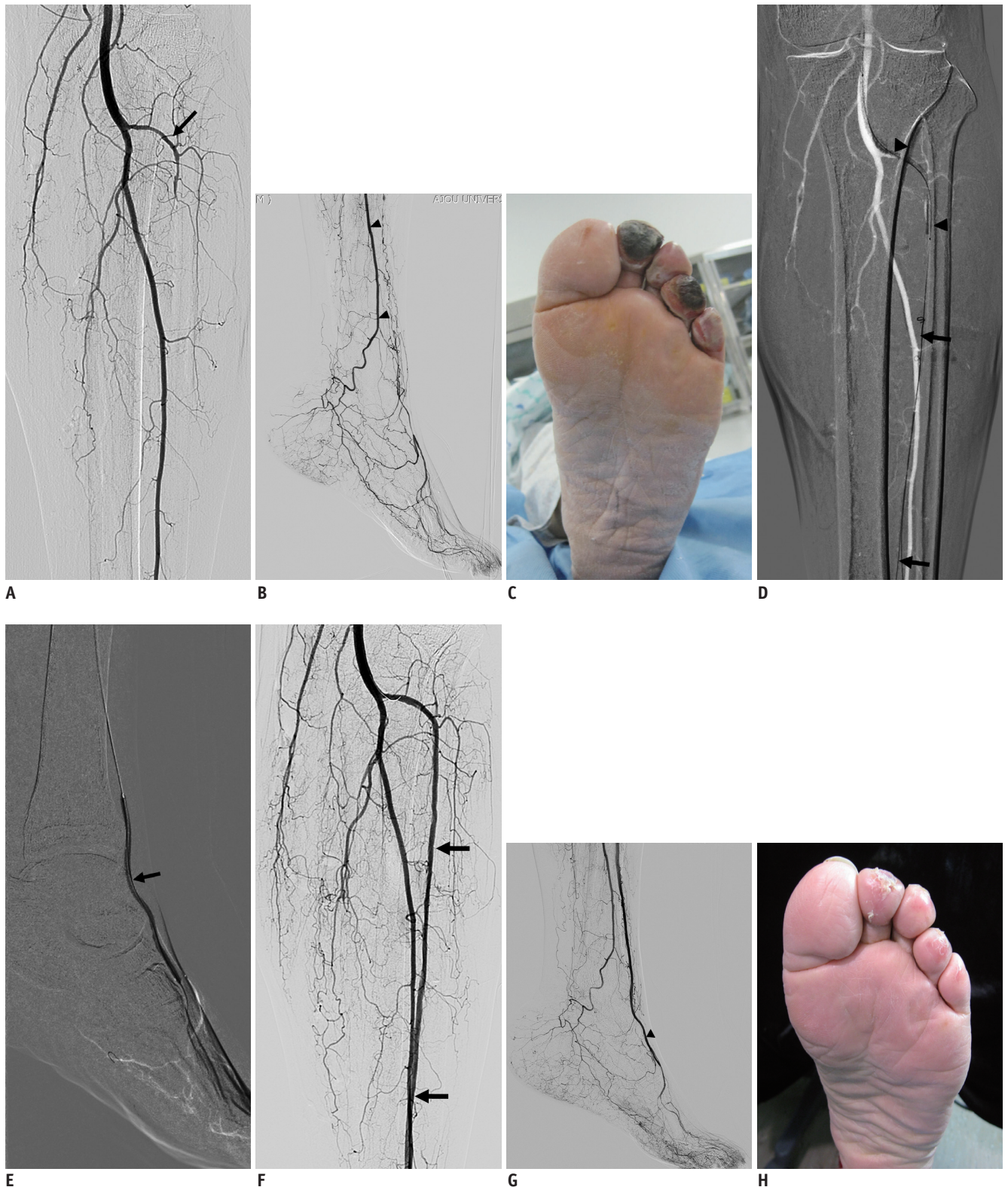
Fig. 1. Technical success was obtained in 60-year-old male with Rutherford category 5 critical limb ischemia.
A, B. Pre-procedural arteriography of infrapopliteal arteries. Origin of anterior tibial artery (ATA) (arrow) is seen. Posterior tibial artery is not seen. Peroneal artery (arrowheads) is patent. **C.** Non-healing wounds were gangrenes of 2nd and 4th toes of left foot. **D.** ATA was recanalized subintimally using 0.016 inch hydrophilic guide wire (arrows) with support of balloon catheter (arrowheads). **E.** After subintimally crossed wire reentered in distal dorsalis pedis artery (DPA). ATA was dilated with 2 mm and 2.5 mm balloon catheter (arrow). **F, G.** Recanalized ATA (arrows) and DPA (arrowhead) is evident. **H.** 2nd and 4th toe gangrenes healed completely 1 month after combined local wound care.

If the wounds persist even after local wound care at the last follow-up, if the patients died before wound could heal, or if progressed to further amputation, outcome was considered to be a healing failure.

During the follow-up, clinical recurrence, new ulceration, new major amputation or re-amputation were taken into account as events as well as the time and cause of death. Our measure of long-term clinical outcome was functional limb salvage. We considered functional limb salvage successful when the plantar stand was maintained, even when achieved by tarsal-metatarsal amputation (12). Any above-the ankle amputation was considered a failure of limb salvage.

Our definition of event-free limb survival was preservation of functional limb without event. Limb salvage was defined as salvage of a functional limb regardless of subsequent reintervention (6-8).

Statistics

Relationship between angiographic outcome and wound healing was examined by univariate analysis (Fisher's exact test) and multivariate analysis (multiple logistic regressions). Analysis of the long term effectiveness in limb salvage over time was performed using Kaplan-Meier model and comparisons were made with the log-rank test. Censored cases are those that did not experience the event of interest, i.e., amputation for a limb salvage analysis or death for a survival analysis, during the study period. The analyses were computed using Statistical Package for the Social Sciences (SPSS) version 18.0 (IBM SPSS, Chicago, IL, USA). Null hypotheses of no difference were rejected if p-values were less than 0.05.

RESULTS

Angiographic Results

The main lesions in iliac arteries were stenoses in 8 and occlusions in 23 limbs (mean length 7.1 ± 3.2 cm). Iliac lesions were treated successfully in all (100%) with stent placement in 18 limbs (58%). The main lesions in femoropopliteal arteries were stenoses in 100 and occlusions in 50 limbs (mean length 10.6 ± 6.2 cm). The femoropopliteal arterial stenoses were crossed intraluminally and successfully dilated in all. The total occlusions of the femoropopliteal artery were recanalized in 47 limbs (94%); intraluminally in 15 (32%) and subintimally in 32 (68%), with stent placement in 38 limbs (76%). Of 458 diseased

infrapopliteal arteries in 189 limbs, 330 infrapopliteal arteries were treated endovascularly (average 1.75 arteries per procedure). The main lesions of these arteries were stenoses in 125 and occlusions (mean length 15 ± 6 cm) in 215. The infrapopliteal arterial stenoses were intraluminally crossed and dilated successfully in all (100%). Crossing and dilatation of the infrapopliteal arterial occlusions were successful in 129 arteries (60%); intraluminally in 32 (28%) and subintimally in 97 (72%). Angiographic success was obtained in 169 limbs (89%). PF and complete failure occurred in 16 limbs (9%) and 4 limbs (2%) respectively. No limbs with partial or complete revascularization failure were suitable for distal bypass surgery.

Complications

Thirteen (7%) minor complications and twelve (6%) major complications were occurred. The 30-day mortality occurred in 4 patients (2%). Acute cardiac attacks including myocardial infarction, although it is unknown whether these were associated with the procedures, occurred during the hospital stay in 6 patients who all expired within 3 months (Table 4).

Follow-Up

Of 144 limbs with non-healing wound, 132 limbs were followed up excluding 12 limbs of 10 patients who expired due to aggravation of comorbidities within 3 months. Healing succeeded in 112 limbs (85%). Initial wounds healed without amputation in 48 limbs (36%). Planned minimal amputation was performed in 75 limbs; toe amputation in 52 limbs and trans-metatarsal (TM) amputation in 23 limbs. The planned amputation wound healed in 64 (49%) and failed in 20 limbs (15%). Wounds persisted at the moment of investigation (n = 5) or at their death (n = 4). Further amputations after planned amputation were required in 11 limbs; TM amputation (n = 1), Lisfranc amputation (n = 2), BKA (n = 8). Relationship between wound healing and angiographic outcome was summarized in Table 5. The healing success rate for PF group was statistically lower than that of TS group but statistically higher than that of CF group. The differences were statistically significant by univariate analysis (p = 0.003) and multivariate analysis adjusted for age, gender, diabetes, arterial hypertension, CRF, and Rutherford category (p = 0.002).

The mean follow-up period was 21 months (range 0-45 months). During the follow-up period, there were BKA in 12 limbs (6%). Recurrences of symptoms occurred in a total

of 53 limbs (28%), of which 50 limbs were managed with repeated endovascular intervention and 3 underwent BKA. No surgical revascularization was performed in any patient. Of 50 limbs underwent repeated intervention, 7 limbs (14%) progressed to BKA and 12 patients expired during the follow-up.

The cumulative event-free limb survival rate was 79.3% and 69.5% at 1- and 3-years respectively (Fig. 2). The

cumulative limb salvage rate (LSR) was 94.8% and 92.0% at 1- and 3-years retrospectively. The LSR for PF group was statistically lower than that for TS group, but statistically

Table 4. Complications within 1 Month after Procedure

| Complications	Number (%)
Minor (n = 13)	
Coil embolization for arterial perforation	6
Puncture site hematoma/pseudoaneurysm	4
Distal embolization	3
Major (n = 11)	
Cardiac function deterioration including myocardial infarction	6
Upper gastrointestinal hemorrhages required interventions	3
Puncture site bleeding required embolization	1
Aspiration pneumonia	1
Gastrointestinal perforation with sepsis	1
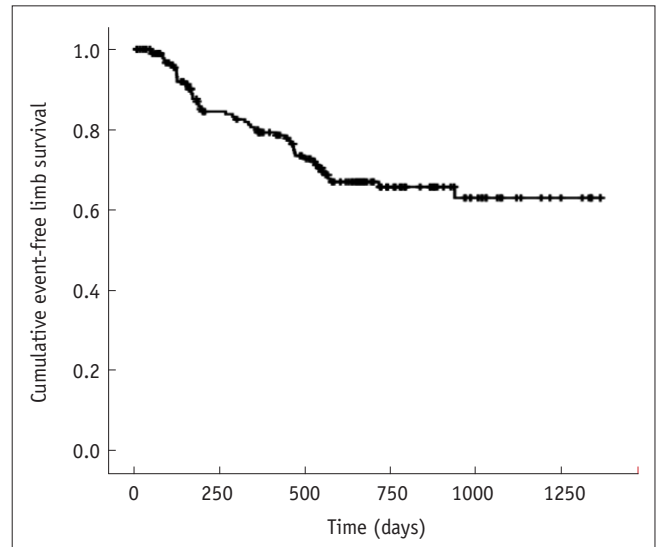
Fig. 2. Kaplan-Meier curve shows event-free survival of limbs after endovascular revascularization for critical limb ischemia. Probabilities of event free limb survival at 1 year and 3 years are 79.3% and 69.5%.

Table 5. Factors Affecting Healing of Wounds (n = 132)

	Univariate Analysis*		Multivariate Analysis†	
	P	Healing Success (%)	P	Odds Ratio (95% Confidence Interval)
Angiographic outcomes	0.003		0.002	4.7 (1.8-12.3)
Technical success (n = 114)		101 (89)		
Partial failure (n = 14)		10 (71)		
Technical failure (n = 4)		1 (25)		
Rutherford category	0.04		0.22	
Category 5 (n = 118)		103 (87)		
Category 6 (n = 14)		9 (64)		
Age	0.33		0.06	
< 65 (n = 56)		50 (89)		
> 65 (n = 76)		62 (82)		
Gender	0.47		0.65	
Male (n = 104)		89 (86)		
Female (n = 28)		23 (82)		
Diabetes	0.71		0.65	
Yes (n = 122)		103 (84)		
No (n = 10)		9 (90)		
Arterial hypertension	1.0		0.62	
Yes (n = 59)		50 (85)		
No (n = 73)		62 (86)		
Chronic renal failure	0.62		0.14	
Yes (n = 50)		41 (82)		
No (n = 82)		71 (60)		

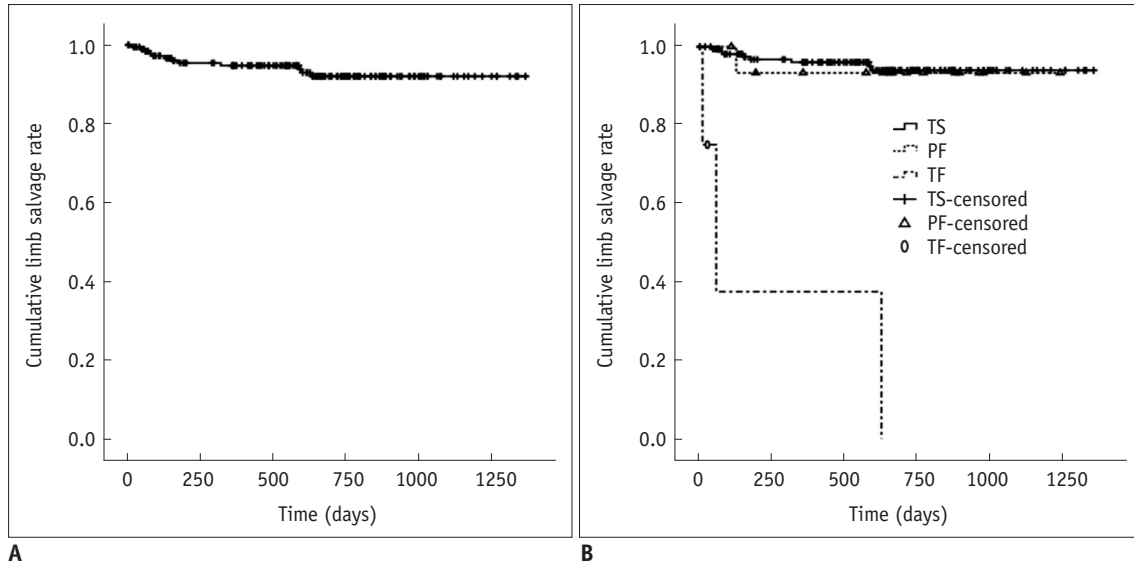**Note.**— *Analysis by Fisher's exact test, †Analysis by multiple logistic regression

Fig. 3. Kaplan-Meier curves showing limb salvage rate (LSR) after endovascular revascularization (A) overall LSRs at 1 year and 3 years are 94.8% and 92% respectively. (B) Differences of LSR were statistically significant between technical success and technical failure group ($p < 0.001$), and between partial failure and technical failure groups ($p < 0.001$). TS = technical success, PF = partial failure, TF = technical failure

higher than that for TF group ($p < 0.001$) (Fig. 3).

DISCUSSION

As the prevalence of diabetes increases and endovascular techniques advance, treatment of patients with CLI, most of whom have a non-healing diabetic foot wound with severe peripheral arterial disease (PAD) is a matter of concern. PAD is an important prognostic factor of the diabetic foot. PAD is a part of about 56% of diabetic foot ulcers (DFU), major amputation is more common in DFU limbs with PAD, and the revascularization group of DFU had lower major limb amputation rate (13-15).

This study is a large single-center experience of the effectiveness of endovascular treatment CLI. The mean follow-up of 21 months is comparable to other recent single-center reports (6-9).

Diabetic foot (91%) was the most common cause of CLI. Rates of comorbidities in the patient population and lesion distribution, characterized by the majority (96%) of the limbs having poor infrapopliteal arteries, are consistent with other studies (3, 7, 16-18).

Rate of subintimal crossing of the occluded femoropopliteal (68%) or infrapopliteal artery (72%) was high compared with other reports (7, 17, 19-21). The higher subintimal crossing rate is thought to be attributed to operator's preference of hydrophilic guide wire rather than chronic total occlusion wire, limitation of devices

due to restriction of reimbursement by the national health insurance, and no application of distal artery access until the late phase of the study period.

For the CLI patient with a wound, we wanted to focus on the impact of revascularization on wound healing itself, because avoidance of major amputation alone does not mean the wound is healed. A limb with a superficial toe ulcer can aggravate and turn out to TM amputation, even it is not major amputation, if the pedal arteries are jeopardized by the procedure and a limb with a deep plantar wound can be healed with wound care even after revascularization of the tibial artery fail. In our study, wounds did not heal in 11% even when revascularization of at least one tibial artery was successful, and wound healing in 71% or 25% after revascularization failed partially or completely. This result suggests that just revascularization of one tibial artery is not sufficient to heal a wound if it does not initially improve direct arterial flow to the wound, and stresses the importance of combined local management of wound. Differences of wound healing rate from other studies, in which Giles et al. (9) reported a 57% healing rate and Conrad et al. (6) reported a 57% healing rate, also reflect complexity of pathogenesis, patient's population and strategies of wound care in CLI.

The healing success rate of CF, PF and TS group gradually increased and the differences between the groups were statistically significant in our results. This means even partially successful revascularization through the peroneal

artery or treatment of inflow only can significantly improve clinical outcomes. This is partially supported by the study of Faglia et al. (5). They had seven (7%) major amputations in 104 limbs of only peroneal artery revascularization. These data may suggest that quantitative scoring of angiographic outcome rather than dichotomous grading from inflow artery to the wound related artery would be needed to predict short-term and long-term result.

We could not calculate patency rate because many patients received the procedure before establishment of institutional surveillance protocol of revascularized vessel. The event rate of free limb survival appears similar to other studies. Söder et al. (22) showed that 63% (45 of 72) of the limbs did not require further invasive treatment. Peregrin et al. (7) reported that the primary LSR, defined as functional limb salvage after the first revascularization with no subsequent intervention, of 76.1% after 1 year of follow-up in a large retrospective study. Our results of LSRs support the prior studies, which have found that despite an inferior primary patency, an endovascular revascularization leads to good LSRs that range from 80% to 95% at 1 to 3 years (4, 6-8, 17, 23).

Rate for major complication (6%) and 30-day mortality (2%) suggest that endovascular revascularization can be performed with lower peri-procedural morbidity and mortality even in high-risk patients (6, 7, 16). Higher upper gastrointestinal bleeding rate (1.6%) than other reported result (0.2%) (15) was thought to be caused by a high prevalence of peptic ulcer in the general population of the area where the study was performed (24).

The limitations of this study were that data were the retrospective design, changes in endovascular techniques and use of the devices during the study period, and the single center nature of the study, possibly biasing indication criteria or strategy. In addition, angiographic outcome and its relationship with wound healing were not analyzed based on the concept of angiosome and wound related artery (25, 26). Also, transcutaneous oxygen measurement as an objective indicator of revascularization was not possible due to lack of facility.

In conclusion, endovascular revascularization is effective to facilitate healing of wounds in CLI and can be performed without significant complications. Although recurrence rate is high, good LSRs are possible. Considering the high prevalence of comorbidities, endovascular revascularization should be chosen as first-line therapy in patients with CLI.

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