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Clinical Implications of Additional Pedal Artery Angioplasty in Critical Limb Ischemia Patients With Infrapopliteal and Pedal Artery Disease

Tatsuya Nakama, MD[1], Nozomi Watanabe, MD, PhD[1], Toshiyuki Kimura, MD[1], Kenji Ogata, MD[1], Shun Nishino, MD[1], Makoto Furugen, MD, PhD[1], Hiroshi Koiwaya, MD, PhD[1], Koji Furukawa, MD[2], Eisaku Nakamura, MD, PhD[2], Mitsuhiro Yano, MD, PhD[2], Takehiro Daian, MD, PhD[3], Nehiro Kuriyama, MD, PhD[1], and Yoshisato Shibata, MD[1]

Abstract

Purpose: To evaluate the clinical implications of additional pedal artery angioplasty (PAA) for patients with critical limb ischemia (CLI). **Methods:** Twenty-nine patients (mean age 77.8±8.6 years; 21 men) with CLI (32 limbs) presenting with de novo infrapopliteal and pedal artery (Kawarada type 2/3) disease were reviewed. The need for PAA was based on the existence of sufficient wound blush (WB) around the target wounds after conventional above-the-ankle revascularization. Fourteen patients with insufficient WB in 14 limbs received additional PAA, while 15 patients with sufficient WB in 18 limbs did not. The groups were compared for overall survival, limb salvage, and amputation-free survival within 1 year after the procedure. The wound healing rate, time to wound healing, and freedom from reintervention rate were also evaluated. **Result:** The success rate of additional PAA was 93% (13/14). All limbs with successful PAA achieved sufficient WB (13/13). Despite insufficient WB before the additional PAA, overall survival (86% vs 73%, p=0.350), limb salvage (93% vs 83%, p=0.400), amputation-free survival (79% vs 53%, p=0.102), and freedom from reintervention (64% vs 73%, p=0.668) rates were similar in both groups. Furthermore, the wound healing rate (93% vs 60%, p=0.05) was higher and time to wound healing (86.0±18.7 vs 152.0±60.2 days, p=0.05) was shorter in the patients who received PAA. **Conclusion:** Additional PAA might improve the WB and clinical outcomes (especially speed and extent of wound healing) in patients with CLI attributed to infrapopliteal and pedal artery disease.

Keywords

angiosome, balloon angioplasty, below-the-ankle intervention, critical limb ischemia, infrapopliteal disease, limb salvage, occlusion, pedal artery, percutaneous transluminal angioplasty, peripheral artery disease, wound healing

Introduction

Approximately 73% to 95% of patients with critical limb ischemia (CLI) lose their limbs within 1 year after conservative treatment.[1] Arterial revascularization is an effective treatment for saving limbs,[2] which can improve a patient's quality of life. While bypass graft surgery is a standard strategy for arterial revascularization, CLI patients are generally frail or otherwise unsuitable for invasive surgical treatment due to concomitant diseases. Less invasive endovascular therapy (EVT), on the other hand, can be a first-line treatment in these high-risk populations,[3,4] thanks to the recent development of dedicated devices and novel techniques and the amassed clinical experience in treating CLI.

The existence of below-the-ankle pedal artery disease is an important clinical problem in CLI patients because of its

[1]Department of Cardiology, Cardiovascular Center, Miyazaki Medical Association Hospital, Miyazaki, Japan
[2]Department of Cardiovascular Surgery, Cardiovascular Center, Miyazaki Medical Association Hospital, Miyazaki, Japan
[3]Department of Plastic and Reconstructive Surgery, Miyazaki Konan Hospital, Miyazaki, Japan

Corresponding Author:
Tatsuya Nakama, Department of Cardiology, Cardiovascular Center, Miyazaki Medical Association Hospital, Funato 738-1, Shinbeppu-tyo, Miyazaki, 880-0834 Japan.
Email: tatsuya_nakama@med.miyazaki-u.ac.jp

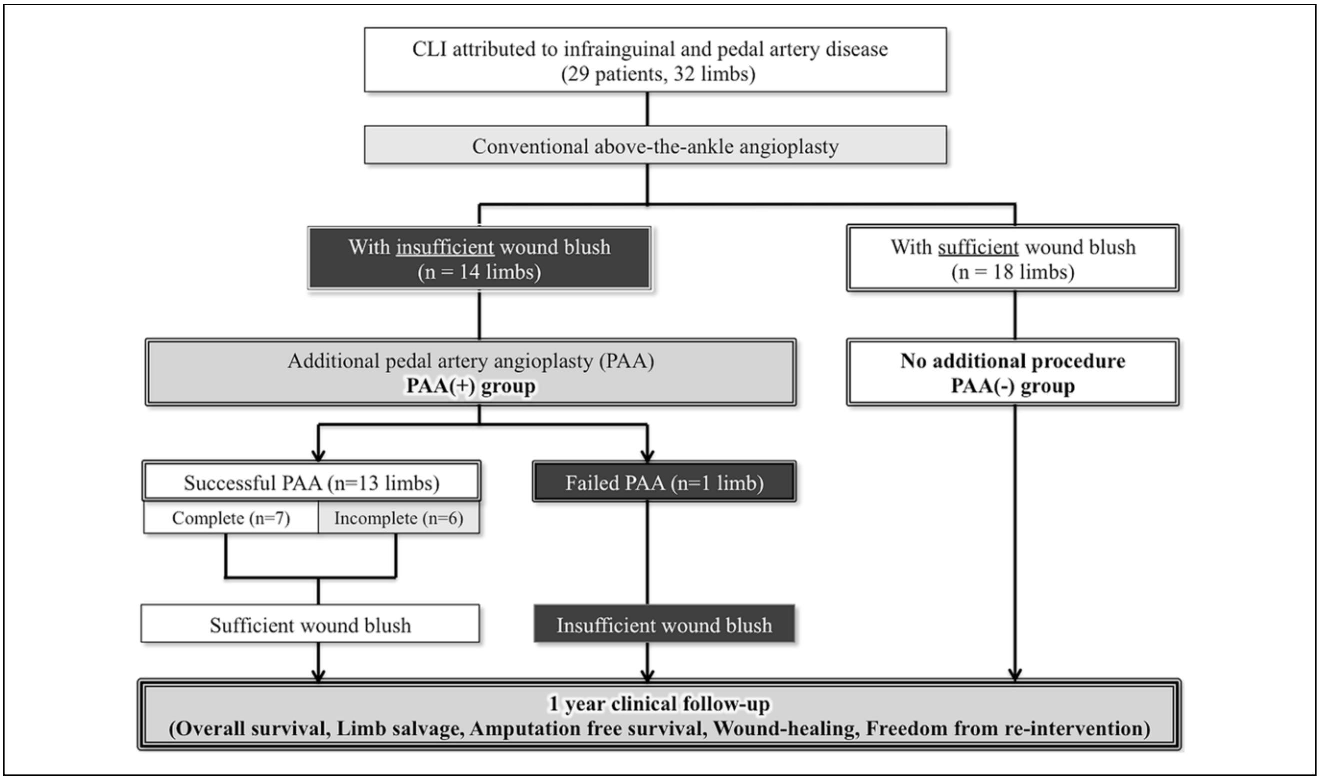


Figure 1. Patient flow. CLI, critical limb ischemia.

association with poorer amputation-free survival,[5] greater need for reintervention,[6] and delayed wound healing.[7,8] Successful pedal artery revascularization may improve clinical outcomes of CLI patients, as some reported cases of adjunctive pedal artery angioplasty (PAA) have shown.[9,10] However, the actual clinical implication of additional PAA still remains unclear.

Utsunomiya et al[11] showed the importance of wound blush (WB), contrast opacification of the vessels around the wound immediately after EVT, for patients with CLI. The prognosis of patients with insufficient WB is unfavorable.[11] Additional revascularization of the occluded pedal artery for patients with insufficient WB should enhance WB and improve limb salvage, wound healing, and overall prognosis. In the present study, we investigated the clinical impact of additional PAA in patients with CLI attributed to pedal artery occlusion with insufficient WB after conventional above-the-ankle percutaneous revascularization.

Methods

Study Design, Patient Sample, and Initial Evaluation

This study was a retrospective analysis of CLI patients with de novo infrapopliteal and pedal artery disease who underwent EVT with or without supplementary PAA at the Cardiovascular Center, Miyazaki Medical Association Hospital, from January 2012 to December 2013. A search of the center's prospectively maintained database found 29 patients (mean age 77.8±8.6 years; 21 men) with CLI who met the criteria for this analysis (Figure 1). All patients had ischemic gangrene or ulcerations and were categorized as either Rutherford stage 5 (n=21) or stage 6 (n=8). The baseline patient and limb characteristics are given in Table 1.

In each patient, the baseline skin condition of the limbs was evaluated; photographs were taken of the dorsal and plantar sides of the foot in addition to close-up views of each ulceration or gangrenous area. In infective cases, a plastic surgeon evaluated the lesions and performed surgical debridement as required.

Pulses in the bilateral common femoral, popliteal, dorsal, and distal posterior tibial arteries were assessed. The ankle-brachial index (ABI) and skin perfusion pressure (SPP) were measured to assess the hemodynamic status of affected limbs, and duplex ultrasound examinations were routinely performed.

Diagnostic lower limb angiography with digital subtraction angiography was performed before the revascularization procedure. Pedal artery disease was categorized according to the Kawarada classification system[7] (Figure 2):

Table 1. Baseline Patient Characteristics and Limb Status.[a]

	Overall (n=29)	PAA(+) (n=14)	PAA(–) (n=15)	p
Patient characteristics				
Age, y	77.8±8.6	77.0±9.2	78.7±8.1	0.970
Men	21 (72)	11	10	0.383
Nonambulatory	15 (52)	6	9	0.291
Body mass index, kg/m^2	21.1±2.8	21.3±2.4	20.9±3.1	0.329
Hypertension	22 (76)	11	11	0.542
Dyslipidemia	8 (28)	5	3	0.298
Diabetes mellitus	20 (69)	10	10	0.550
Smoking history	13 (45)	6	7	0.607
ESRD on HD	11 (38)	5	6	0.558
History of CAD	14 (48)	6	8	0.424
History of CVD	8 (28)	3	5	0.383
Albumin level, g/dL	3.41±0.50	3.49±0.47	3.34±0.53	0.681
LDL cholesterol, mg/dL	88.2±20.6	93.3±22.2	82.8±18.0	0.496
HDL cholesterol, mg/dL	41.7±10.4	43.1±9.6	40.2±11.4	0.791
Hemoglobin A1c, %	6.1±0.9	5.9±0.7	6.4±1.0	0.401
LVEF, %	64.0±10.1	65.7±10.8	61.0±9.6	0.277
Atrial fibrillation	4 (14)	2	2	0.674
Limb characteristics				
Rutherford class 6	8 (27)	3	5	0.504
Wound infection	10 (31)	4	6	0.541
Surgical debridement	14 (44)	6	8	0.607
CRP level, mg/dL	1.69±2.63	1.10±1.84	2.14±3.08	0.109
ABI before EVT	0.63±0.44	0.74±0.39	0.52±0.46	0.330
ABI after EVT	0.90±0.27	0.94±0.24	0.86±0.30	0.814
SPP (dorsal) before EVT	22.7±17.2	22.6±12.9	22.8±22.9	0.990
SPP (plantar) before EVT	23.2±16.4	19.6±12.9	28.1±20.2	0.318
SPP (dorsal) after EVT	56.3±15.1	60.7±16.7	49.8±10.3	0.144
SPP (plantar) after EVT	52.2±17.7	60.2±18.3	40.2±6.9	0.025
Pure infrapopliteal lesion	16 (50)	10	6	0.037
Runoff vessels before EVT	0.63±0.66	0.64±0.75	0.61±0.61	0.330
Runoff vessels after EVT	1.53±0.62	1.64±0.63	1.44±0.62	0.760
Pedal artery type 2/3 before EVT	15/17	3/11	12/6	0.038
Pedal artery type 1/2/3 after EVT		7/6/1		
Time to wound healing,[b] d	121.0 [26.1] (66.0–233.0)	86.0 [18.7] (63.0–155.0)	152.0 [60.2] (80.0–365.0)	0.050

Abbreviations: ABI, ankle-brachial index; CAD, coronary artery disease; CRP, C-reactive protein; CVD, cerebrovascular disease; ESRD, end-stage renal disease; EVT, endovascular therapy; HD, hemodialysis; HDL, high-density lipoprotein; LDL, low-density lipoprotein; LVEF, left ventricular ejection fraction; PAA, pedal artery angioplasty; SPP, skin perfusion pressure.

[a]Continuous data are presented as the means ± standard deviation unless noted otherwise; categorical data are given as the counts (percentage).

[b]Median [standard error] (interquartile range).

type 1 indicated patent dorsal and lateral plantar arteries, type 2 had either the dorsal (type 2A) or lateral plantar (type 2B) artery patent, and type 3 indicated that both dorsal and lateral plantar arteries were occluded. Patients with type 1 pedal artery disease were not included in this study. A group of vascular specialists, including vascular surgeons and cardiologists, judged whether EVT was indicated for each patient and identified the target lesion(s).

The study protocol was developed in accordance with the Declaration of Helsinki and approved by the hospital's ethics committee. All patients gave informed consent before treatment.

Endovascular Therapy Procedure

Dual antiplatelet therapy [aspirin (100 mg/d) and clopidogrel (75 mg/d) or cilostazol (200 mg/d)] was routinely started before EVT and continued for as long as possible. Antibiotics were routinely administered in the setting of infection.

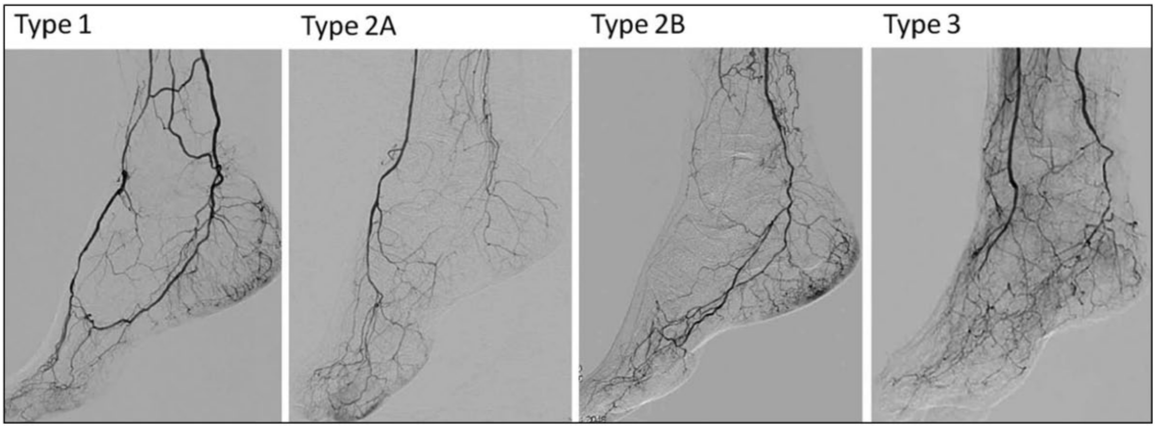


Figure 2. Definition of pedal artery disease was based on the Kawarada classification system.[7] Type 1—both dorsal and lateral plantar arteries were patent; type 2—either the dorsal (2A) or lateral plantar (2B) artery was opened; type 3—both the dorsal and lateral plantar arteries were occluded. Of these, types 2 and 3 were defined as pedal artery disease for purposes of the study.

All procedures were conducted under local anesthesia by interventional cardiologists who were knowledgeable and skilled in performing EVT in CLI patients. The most common access site was the ipsilateral common femoral artery. After sheath (4-F to 6-F) insertion, 5000 units of unfractionated heparin were routinely injected from the side arm of the sheath. If there were femoropopliteal lesions, they were addressed first with conventional angioplasty, followed by the infrapopliteal revascularization procedure on the target artery identified in the vascular conference.

A stenotic infrapopliteal lesion was treated with a 0.014-inch guidewire and a conventional balloon catheter using standard techniques.[12] The anterior tibial artery and posterior tibial artery were dilated with a 2.5 or 3.0-mm balloon, while a 2.0 or 2.5-mm-long balloon was used for the peroneal artery; each dilation was performed for at least 3 minutes at nominal pressure (6–8 atm).

When the 0.014-inch guidewire could not cross through an occlusion, subintimal angioplasty with a looped 0.014-inch hydrophilic guidewire was attempted. If that failed, retrograde access techniques (distal tibial/peroneal puncture[12,13] or a transcollateral approach[12,14]) were employed, and a bidirectional approach was established using the kissing wire, CART (controlled antegrade and retrograde subintimal tracking),[15–17] double balloon,[12,18] or wire rendezvous[12,19,20] technique. The occlusive lesion was dilated with a conventional balloon (sizes given above) for at least 3 minutes. No atherectomy devices or drug-coated balloons were used because these devices were not available in Japan.

The indication for PAA was based on angiographic evidence of insufficient WB toward the target wounds after conventional above-the-ankle revascularization. If there was sufficient WB around the target wounds, the procedure was terminated. If sufficient WB was not seen, additional pedal artery revascularization was conducted.

A 0.014-inch hydrophilic guidewire was advanced into the occluded pedal artery with the support of a microcatheter. When the guidewire could not cross the occlusion, a bidirectional wire access from both tibial arteries was established. If needed, special retrograde access techniques such as metatarsal artery puncture[21–23] or a transcollateral retrograde approach were used for an occluded pedal artery.[10]

After guidewire crossing, the occluded pedal artery was dilated with a 2.0-mm-long balloon for at least 3 minutes. If the 2.0-mm balloon could not be navigated through the lesion, low-profile balloons ≤1.5 mm in diameter were used. When no balloon could be crossed through the lesion or could not be fully dilated, the "PIERCE" technique[24] was sometimes used for lesion modification. A representative case of additional PAA is shown in Figure 3.

Follow-up Protocol

All patients were followed at 1 and 2 weeks; 1, 2, and 3 months; and then every 3 months up to 12 months after the procedure with duplex ultrasound scans and ABI and SPP measurements. If the patient did not return to the hospital, phone calls were made to check the limbs and general status. Plastic surgeons individually followed patients with open ulcers, evaluating the status of wound healing based on the TIME concept (T = tissue; I = infection or inflammation; M = moisture imbalance; E = edge of wound).

Definitions

Coronary artery disease was defined as the presence of angina pectoris, myocardial infarction, or previous history

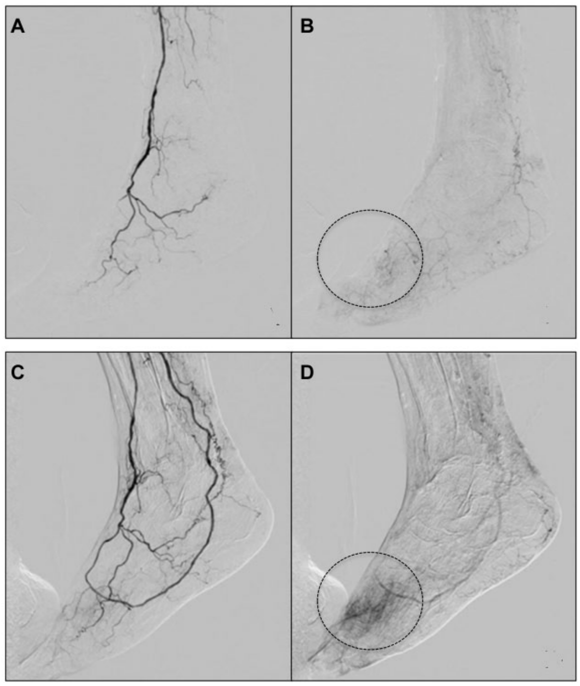


Figure 3. Successful complete pedal artery angioplasty. (A) After anterior tibial artery revascularization, digital subtraction angiography disclosed occluded distal dorsal and lateral plantar arteries indicative of type 3 pedal artery disease. (B) Wound blush was insufficient (circle), so additional pedal artery angioplasty (PAA) was performed. (C) After PAA, both the dorsal and lateral plantar arteries were revascularized, and (D) sufficient wound blush (circle) was observed.

of percutaneous coronary intervention or coronary bypass graft surgery. Cerebrovascular disease was defined as a history of any stroke (cerebral infarction and hemorrhage), transient ischemia attack, or carotid artery revascularization. Nonambulatory status was defined as daily wheelchair use or bedridden status. Infrapopliteal runoff was evaluated by determining the number of patent vessels (0–3).

Pedal artery angioplasty was successful if at least one (either dorsal or lateral plantar) artery was recanalized and complete if both dorsal and lateral plantar arteries were patent after treatment. Reintervention included any EVT or bypass surgery. Wound healing was defined as complete epithelialization of the target wounds. In patients who died before wound healing, the date of death was defined as the cutoff date. Limb salvage was defined as freedom from major amputation (above-the-ankle). In patients who underwent major amputation, the healing time was considered to be infinite.

Study Outcomes and Statistical Analysis

The outcome measures were rates of overall survival, limb salvage, and amputation-free survival at 1 year after the procedure. The wound healing rate, time to wound healing, and freedom from reintervention rate were also evaluated.

Statistical analysis was performed on an intention-to-treat basis. Continuous variables are given as the means ± standard deviations or median [standard error] and (interquartile range) for time to wound healing. Categorical variables are presented as counts. The unpaired *t* test was used to compare continuous variables, while the chi-square or Fisher's exact test was employed for categorical variables as appropriate. Survival analyses using the Kaplan-Meier method were applied to the primary and secondary outcomes; the groups were compared with the log-rank test. Statistical significance was defined as $p<0.05$. All statistical analyses were performed using SPSS software (version 19; IBM Corporation, Somers, NY, USA).

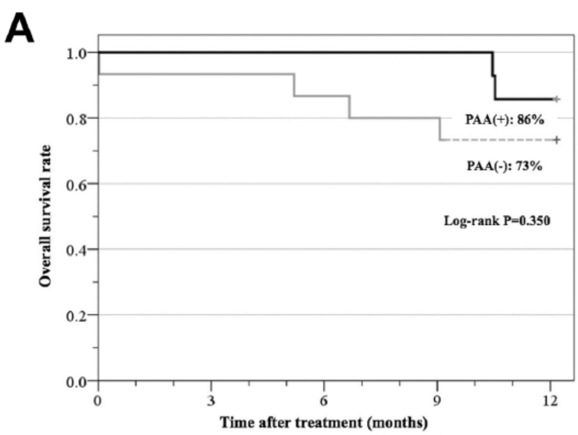
Results

In this cohort, 14 patients had additional PAA [PAA(+)] and 15 did not [PAA(–)]. Of the 3 patients with bilateral CLI limbs, 2 of them (4 limbs) had sufficient WB after initial above-the-ankle recanalization and were classified into the PAA(–) group. The remaining patient had one limb in either group. In the per-limb analyses (limb status, limb salvage, and wound healing), each limb was classified in its group. However, in the per-patient analyses (patient characteristics, amputation-free survival, and freedom from reintervention), this patient was classified in the PAA(+) group, which was considered to be the more severe condition.

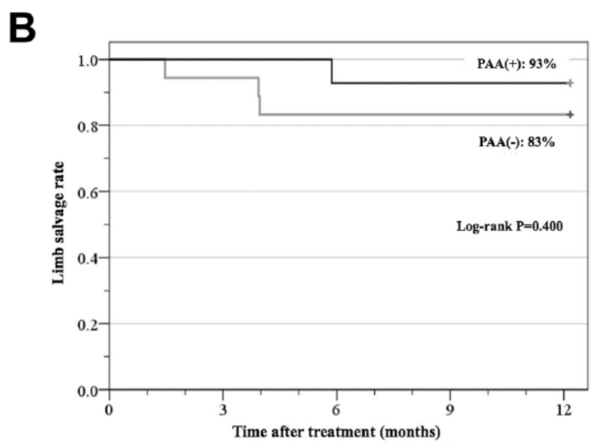
There were no significant differences in patient characteristics between groups, including the number of Rutherford 6 patients, infective wounds, and surgical debridement. ABI and SPP levels before EVT were also similar. Among the baseline angiographic characteristics, the PAA(+) group contained a higher number of pure infrapopliteal lesions than the PAA(–) group (10 vs 6, respectively; p=0.037); there was no significant difference in the number of infrapopliteal runoff vessels. However, pedal artery status before EVT differed significantly. The PAA(+) group had a greater number of type 3 (dorsal and plantar arteries occluded) pedal disease than the PAA(–) group (11 vs 6, respectively; p=0.038).

Additional PAA was successful in revascularizing at least the dorsal or lateral plantar artery in 13 of 14 cases, as indicated by sufficient WB. Of these, 7 cases had complete pedal artery revascularization (both dorsal and lateral plantar arteries). One limb with failed PAA did not display sufficient WB. There were no PAA-related complications.

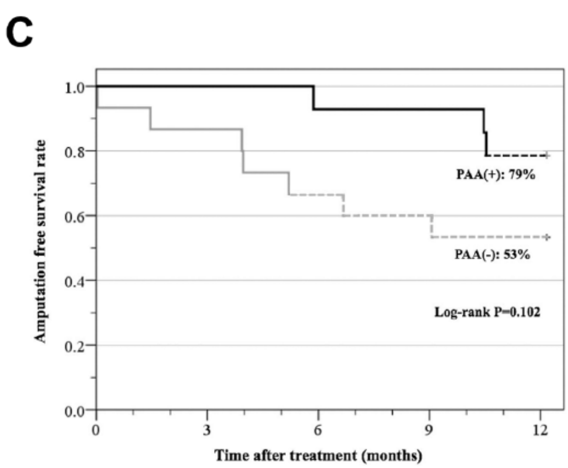
Overall survival (86% vs 73%, p=0.350; Figure 4A), limb salvage (93% vs 83%, p=0.400; Figure 4B), and amputation-free survival (79% vs 53%, p=0.102; Figure 4C) were similar between the two groups. Freedom from reintervention was also similar (64% vs 73%, p=0.734; Figure 4D), with 5 clinically driven reinterventions in the



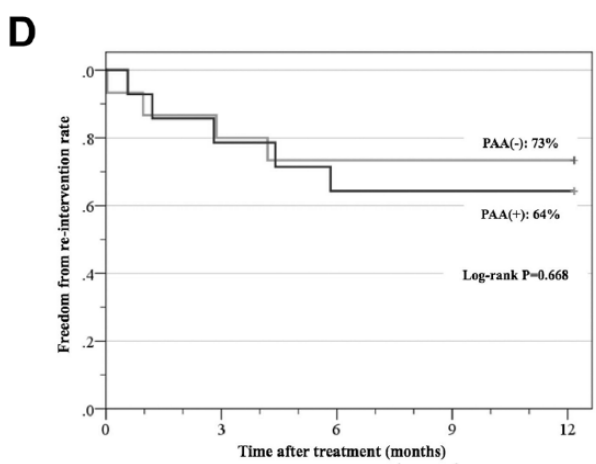
		0	3 months	6 months	9 months	12 months
PAA(+)	No. at risk	14	14	14	14	12
	%	100	100	100	100	86
	SE, %	0	0	0	0	9
PAA(-)	No. at risk	15	14	13	12	11
	%	100	93	87	80	73
	SE, %	0	6	9	10	11



		0	3 months	6 months	9 months	12 months
PAA(+)	No. at risk	14	14	13	13	13
	%	100	100	93	93	93
	SE, %	0	0	7	7	7
PAA(-)	No. at risk	18	17	15	15	15
	%	100	94	83	83	83
	SE, %	0	5	9	9	9



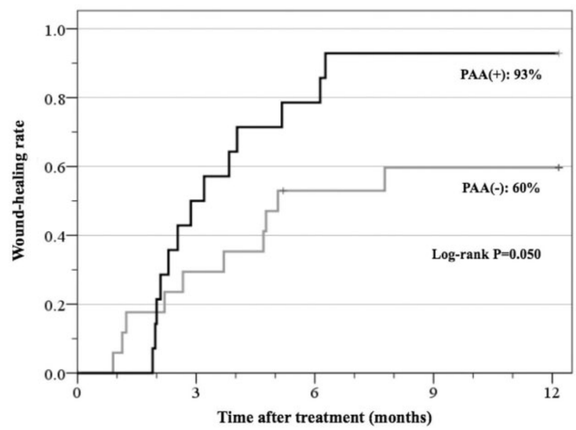
		0	3 months	6 months	9 months	12 months
PAA(+)	No. at risk	14	14	13	13	11
	%	100	100	93	93	79
	SE, %	0	0	7	7	11
PAA(-)	No. at risk	15	13	10	9	7
	%	100	87	67	60	53
	SE, %	0	9	12	13	13



		0	3 months	6 months	9 months	12 months
PAA(+)	No. at risk	14	10	9	9	9
	%	100	79	64	64	64
	SE, %	0	9	8	8	8
PAA(-)	No. at risk	15	12	11	11	11
	%	100	80	73	73	73
	SE, %	0	9	3	3	3

Figure 4. There was no significant difference in (A) overall survival, (B) limb salvage, (C) amputation-free survival, or (D) freedom from reintervention. PAA, pedal artery angioplasty; SE, standard error.

PAA(+) group and 4 in the PAA(–) group during 1-year follow-up. Furthermore, the wound healing rate was higher (93% vs 60%, p=0.050; Figure 5) and the time to wound healing was shorter (86.0±18.7 vs 152.0±60.2 days, p=0.050; Table 1) in the PAA(+) group than that of the PAA(–) group, respectively.



		0	3 months	6 months	9 months	12 months
PAA(+)	No. at risk	14	7	3	1	1
	%	0	50	79	93	93
	SE, %	0	5	2	7	7
PAA(-)	No. at risk	18	12	7	6	6
	%	0	29	53	60	60
	SE, %	0	6	3	3	3

Figure 5. The pedal artery angioplasty group [PAA(+)] showed a higher wound healing rate and shorter time to wound healing than limbs that did not have PAA [PAA(−)]. SE, standard error.

Discussion

To the best of our knowledge, the clinical implication of additional PAA for CLI patients undergoing infrapopliteal lesion treatment has not been demonstrated until now. Despite the absence of sufficient WB after conventional above-the-ankle revascularization in the PAA(+) group, limb salvage, amputation-free survival, and freedom from reintervention were similar to the PAA(–) group. Furthermore, the PAA(+) group had a higher wound healing rate and quicker wound healing than the PAA(–) group. Although these results were not statistically significant, likely due to the small samples, they suggest a beneficial effect of additional PAA.

Generally, it has been considered that the blood supply through a percutaneously revascularized infrapopliteal artery is poorer and more limited than after bypass surgery.[25] Several treatment strategies have been proposed to overcome the limited blood supply after EVT. For example, multivessel infrapopliteal arterial recanalization seemed to be a reasonable strategy, but interestingly, many retrospective studies showed its lack of efficacy.[7,26–28]

Recently, establishing a "direct" blood supply toward the wound(s) has come to be more important than the number of opened infrapopliteal arteries.[27,28] Based on Taylor and Palmer's[29] description of the angiosome concept, an arterial perfusion map of the foot, angiosome-oriented direct revascularization has become a strategy for utilizing the limited blood supply after EVT. Iida et al[27,30] reported the first assessment of angiosome-oriented revascularization from their relatively large retrospective study, concluding that the technique was superior to indirect revascularization in terms of limb salvage (86% vs 69%, respectively; p=0.029) at 1 year.

Angiosome-oriented direct revascularization has become popular because the strategy is simple and easy to understand. However, in patients with pedal artery disease, the blood supply to the target wound depends on the patency of the original artery-to-artery connections and newly developed collateral channels. Thus, pedal artery revascularization is necessary to re-establish "direct" blood supply to the target wounds. WB, an angiographic endpoint that is easily evaluated in the clinical setting, is one technique for judging the adequacy of PAA. Utsunomiya et al[11] showed in their study that the WB-positive group had superior limb salvage and amputation-free survival (82.1%, 73.2%, and 69.6% vs 56.8%, 45.9%, and 37.3%, respectively, at 1, 2, and 3 years; p=0.002, 0.001, and 0.001, respectively) vs the WB-negative group. Another qualitative technique is the use of indigo carmine angiography to visualize perfusion to ulcerated tissue fed by the reconstituted arteries.[31]

In our analysis, we hypothesized that an additional PAA may have the potential to improve clinical outcomes (limb salvage, amputation-free survival, freedom from reintervention, complete wound healing) of patients with insufficient WB after conventional above-the-ankle revascularization. As we expected, all patients with successful PAA demonstrated sufficient WB indicative of direct flow toward the wounds. Furthermore, the wounds healed better and quicker. Thus, additional PAA should be considered for patients with pedal artery disease when they do not show sufficient WB after conventional above-the-ankle revascularization.

On the other hand, even with sufficient WB after the conventional above-the-ankle angioplasty in the PAA(–) group, the clinical outcomes of these patients were not satisfactory. Although it is difficult to clearly interpret, we have to consider that infected wounds tend to get "contrast opacification" around them though it does not always mean sufficient blood flow for wound healing. It might be a result of inflammation, which can be considered a "WB-like finding." In our study, over 30% of the patients were suffering from wound infection. We cannot deny the possibility that some patients with "WB-like finding" due to infective inflammation were classified in the PAA(–) group. Nonetheless, we want to emphasize the paramount importance of additional PAA, which contributed to clinical outcomes in the limbs without WB that were at least on the same level as those limbs originally showing WB.

Limitations

First, this was a small retrospective analysis from a single-center database, which makes type 2 statistical errors more likely. Therefore, a larger multicenter randomized trial is required to confirm the results of our study.

Second, 9 patients (10 limbs) treated in 2012 did not have SPP values measured because our hospital did not perform SPP measurements until 2013.

Third, there is the question of selection bias. The indication of additional PAA was based on the existence of sufficient WB judged by agreement of at least two endovascular interventionists. However, WB is a subjective, qualitative parameter, and patient selection bias cannot be ruled out. Furthermore, WB-oriented additional PAA is controversial, especially in patients with ischemic gangrene or infective wounds. Additional PAA based on microcirculation assessment (SPP or transcutaneous oxygen values) should be considered in a future study.

Fourth, PAA has some technical difficulties. Complete pedal artery revascularization was obtained in only half the patients. Better interventional techniques and development of dedicated devices are required for standardization of occluded pedal artery revascularization.

Fifth, in this study, long-term patency of recanalized pedal arteries was not evaluated. Two angiographic follow-up studies disclosed a low patency rate for infrapopliteal arteries that had undergone EVT.[32,33] Because the vessel size of the pedal artery is smaller than the infrapopliteal artery, poorer durability may be expected in recanalized pedal arteries. Angiographic evaluation should be required to confirm the actual clinical impact of additional PAA.

Finally, in this study, each wound was evaluated based only on the Rutherford classification. For a more thorough assessment of wound severity, wound location and depth must be evaluated. In future studies, detailed assessment for each wound should be required.

Conclusion

Additional PAA may improve the clinical outcomes (especially wound healing rate and time to wound healing) in CLI patients with pedal artery disease being treated for infrapopliteal disease. This aggressive strategy may be a salvage procedure for patients with CLI.

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Declaration of Conflicting Interests

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