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Anatomical Predictors of Major Adverse Limb Events after Infrapopliteal Angioplasty for Patients with Critical Limb Ischaemia due to Pure Isolated Infrapopliteal Lesions

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WHAT THIS PAPER ADDS

- Despite widespread use of endovascular therapy (EVT) for infrapopliteal lesions in patients with critical limb ischaemia (CLI), morphological classification of infrapopliteal lesions has not been updated since the TASC 2000 guideline to reflect revascularisation modality selection. Also, anatomical features of infrapopliteal lesions associated with major adverse limb events (MALEs) remain unclear. We therefore sought to define a morphological classification based on anatomical factors associated with MALE in this setting. From this results, vessel diameter <2.5 mm, lesion calcification and below-the-ankle disease were associated with MALE after infrapopliteal angioplasty. This risk stratification based on these predictors allows us to estimate future incidence of MALE in CLI patients involving pure isolated infrapopliteal lesions.

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ABSTRACT

Objective: To identify anatomical factors associated with major adverse limb events (MALE) after angioplasty as the basis for a novel morphology-driven classification of infrapopliteal lesions.
Design: Retrospective-multicenter study.
Materials and methods: Between March 2004 and October 2010, 1057 limbs from 884 patients with CLI due to isolated infrapopliteal lesions were studied. Freedom-from MALE, defined as major amputation or any reintervention, was assessed out to 2 years by the Kaplan–Meier methods. Anatomical predictors and risk stratification for MALE were analyzed by multivariate analysis.
Results: Freedom-from MALE was 47 ± 1% at 2 years. Lesion calcification, target vessel diameter<3.0 mm, lesion length>300 mm and no below-the-ankle (BA) run-off were positively associated with MALE by multivariate-analysis. The total number of risk factors was used to calculate the risk score for each limbs for subsequent categorization into 3 groups with 0 or 1 (low-risk), 2 (moderate-risk) and 3 or 4 (high-risk) factors. Freedom-from MALE at 2 year-rates was 59% in low-risk, 46% in moderate-risk, and 29% in high-risk, respectively.
Conclusion: Target vessel diameter <3.0 mm, lesion calcification, lesion length > 300 mm and no-BA run-off were associated with MALE after infrapopliteal angioplasty. Risk stratification based on these predictors allows estimation of future incidence of MALE in CLI with isolated infrapopliteal lesions.

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Revascularisation of infrapopliteal lesions is indicated only for patients with critical limb ischaemia (CLI),[1,2] and The Inter-Society Consensus for Management of PAD (TASC) classification guides choice of revascularisation strategy. Patients with CLI, especially those with diabetes mellitus (DM) and end-stage renal disease (ESRD) on dialysis, generally have long, calcified, diffuse arteriosclerotic lesions in the infrapopliteal region;[3,4] this morphology is still considered best treated with saphenous vein graft bypass surgery as first-line therapy.[2] For instance, the commonly encountered occlusions longer than 2 cm or diffuse disease in the tibial and peroneal arteries are defined as TASC D which indicates for bypass surgery (BSX) according to the TASC guideline,[1] and few patients with CLI therefore are clinically indicated for angioplasty based on anatomical morphology. However, endovascular therapy (EVT) with traditional angioplasty currently is most widely used in the infrapopliteal region because it achieves technical and clinical success rate of up to 90% and 70%, respectively, and acceptable and in some cases slightly higher rates of limb salvage and amputation-free survival (AFS) when compared to BSX.[5,6] Moreover, patients are commonly not suitable surgical candidates secondary to comorbidities and advanced age.[2]

Based on the aforementioned considerations, the TASC-based morphological classification of infrapopliteal lesions does not determine revascularisation modality selection in current clinical practice. In revascularisation for coronary artery disease (CAD), on the other hand, the SYNTAX score which is based on anatomical features is used to predict future occurrence of major adverse cardiac events (MACEs) and to decide indication for coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI) with drug-eluting stents (DESs).[7,8] We therefore sought to define anatomical predictors of major adverse limb event (MALE) in patients with CLI due to pure isolated infrapopliteal lesions treated with EVT.

Methods

Enrollment

We retrospectively analysed our prospectively maintained database, including data on 2519 limbs in 2141 consecutive CLI patients, who underwent EVT from April 2004 to June 2011 and who consented to a follow-up at each of the participating 11 cardiovascular and vascular centres. To classify the severity of infrapopliteal lesions, this study included patients with CLI due to pure isolated infrapoliteal lesion who underwent EVT, and the infrapopliteal anatomical predictors of MALEs in these patients were identified and stratified as the basis for a novel anatomical classification. We excluded patients with involved suprapopliteal revascularisation. During this period, patients with CLI due to infrapopliteal lesions combined with either femoropopliteal (FP) lesions (47%, 1198 limbs in 1025 patients) or aorto-iliac (AI)-FP lesions (10%, 263 limbs in 232 patients) were excluded from this study. We also excluded from this analysis 170 patients considered to be poor candidates for both forms of revascularisation due to severe comorbidities as well as those who refused revascularisation, or who presented with acute limb ischaemia requiring emergent revascularisation or functionally unsalvageable limbs. Finally, 1058 limbs from 884 consecutive CLI patients suffering from intractable rest pain due to ischaemia (Rutherford 4), or life-threatening non-healing ulceration/gangrene (Rutherford 5 or 6) due to isolated infrapopliteal lesions were included. A total of 44% of limbs ($n = 465$) with isolated infrapopliteal lesions overlapped with those included in a previous study.[6] During the study period, 375 CLI patients were treated with crural bypass therapy by a vascular surgeon. The study protocol was developed in accordance with the Declaration of Helsinki, and approved by the ethics committee of each hospital. This study was registered in the University Hospital Medical Information Network Clinical Trial Registry (UMIN-CTR), which was approved by the International Committee of Medical Journal Editors (no. UMIN000007016, J-BEAT II registry: Japanese BElow-the-knee Artery Treatment registry II). All patients gave written informed consent prior to revascularisation.

Protocols

Our study protocol was reported previously.[6] Briefly, each arterial pulsation was evaluated and tissue loss was recorded as part of the preoperative vascular assessment. Lower limb severity was haemodynamically assessed by the ankle-brachial index (ABI) and skin perfusion pressure (SPP). Lower limb arteries were routinely evaluated by duplex ultrasound and digital subtraction angiography (DSA) before revascularisation. A group of vascular specialists including vascular surgeons judged whether EVT was indicated for each patient. All endovascular procedures were conducted under local anaesthesia by a cardiologist, radiologist or vascular surgeon depending on the institute. EVT was indicated when the lesion showed >50% diameter stenosis on duplex ultrasound and/or diagnostic angiography and haemodynamically underlying symptoms. Selection of EVT approach was left to the operator's discretion. An antegrade approach with a 3 or 4 Fr sheath from the ipsilateral common femoral artery was commonly selected. After inserting the sheath, unfractionated heparin (5000 U) was routinely injected into the artery. A 0.014-inch guide wire was advanced into the culprit lesion and an optimally sized balloon catheter was introduced. An appropriate balloon diameter was chosen to match that of the non-diseased artery adjacent to the lesion. Vessel diameter and lesion length were visually assessed using preprocedural duplex and the balloon catheter as reference. Decision of target lesion was based on lesion and limb severity. Target lesion was decided by the angiosome concept in patients with tissue loss, and easily treatable lesions were commonly selected in patients with rest pain. Dual antiplatelet therapy was started at least 1 week prior to EVT and continued lifelong. Antibiotics were routinely administered if the ulcer was complicated with limb threatening severe infection; in this case, the ulcer also was evaluated and managed by a plastic surgeon using the TIME concept.

Definitions

The definition of lower limb severity and the diagnosis of atherosclerosis risk factors has been reported previously.[6] Critical ischaemic limb was defined in accordance with TASC as tissue loss associated with an ankle pressure <70 mmHg or a toe pressure <50 mm and rest pain associated with an ankle pressure <50 mmHg or a toe pressure <30 mm. When these measurements could not be obtained due to intractable rest pain or a non-compressible artery secondary to severe calcification, the SPP was measured; an SPP less than 40 mmHg was defined as indicating a critical ischaemic limb. CAD and cerebrovascular disease (CVD) were defined as the presence of symptom or past history of infarction or history of any revascularisation. Lesion calcification was defined by angiography as readily visible densities noted within the apparent vascular wall. Below-the-ankle (BA) disease was defined as greater than 50% stenosis systemically affecting wound healing and indicated for revascularisation at both of BA arteries. When more than one vessel was treated by angioplasty, target lesion in this analysis was decided based on the perfusion area by final angiogram. Treated lesion was chosen as the lesion affecting the widest perfusion area in the limb. Procedural success was

defined as obtaining one straight-line flow to the ulcer or gangrene region. Reintervention including repeat angioplasty or bypass graft procedures were indicated for limbs with recurrent symptoms accompanied by recurrent stenosis greater than 50% as measured by duplex ultrasound or DSA. MALE was defined as major amputation or any reintervention, including surgical reconstruction or repeat angioplasty. Major amputation was defined as surgical excision of the limb above the ankle. Any amputation at or distal to the Lisfranc level was not considered a limb salvage failure. Amputation data were obtained through outpatient clinic follow-up contact.

Study outcomes

Study outcome was freedom from MALE at 2 years; this outcome is in accordance with the objective performance goals for evaluating catheter-based therapies in CLI recommended by the Society of Vascular Surgery (SVS).[9] Also, anatomical-independent predictors and risk stratification for MALE were analysed. Risk stratification of AFS was also evaluated based on anatomical factor of MALE.

Statistical analysis

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) (SPSS Inc., Chicago, IL, USA). Data are shown as mean ± standard deviation or error. An unpaired *t*-test was used to compare continuous variables between groups, and a chi-square test was used to compare proportions between groups; the statistical significance level was set at $p < 0.05$. Independent outcome determinants were identified by Cox proportional hazard ratio (HR) in multivariable analysis including all variables from univariable analysis with a p value of <0.1. We conducted risk stratification analysis for MALE and AFS using a simple score based on the number of variables independently associated with MALE in multivariable analysis. Freedom from MALE and AFS rate according to risk factor was estimated using the Kaplan–Meier method and compared using the log-rank test.

Results

Baseline patient and limb characteristics before angioplasty

Table 1 shows baseline patient and limb characteristics. Notable baseline characteristics included patient age (71 ± 10 years), DM (71%, 627/884) and ESRD on dialysis (62%, 546/884). Regarding limb status, 74% (781/1057) of limbs were complicated with tissue loss. Mean follow-up time was 18 ± 15 months and death was occurred in 31% (277/884) of patients.

Table 1
Baseline patient and limb characteristics.

Variables	
Patients status	
Age	71 ± 10
Male	69% (612)
BMI (body mass index)	22 ± 3
Risk factors	
Hypertension	73% (647)
Hyperlipidemia	31% (276)
Diabetes mellitus	71% (627)
Current smoking	36% (318)
End stage renal disease on dialysis	62% (546)
Cardiovascular disease	
CAD (Coronary Artery Disease)	51% (454)
CVD (Cerebrovascular disease)	24% (216)
COPD (Chronic obstructive pulmonary disease)	8% (68)
Limb status	
Rutherford classification	4.9 ± 0.7
Tissue loss	74% (781)
ABPI before angioplasty	0.81 ± 0.25

Baseline lesion characteristics before angioplasty

Baseline lesion characteristics are shown in Table 2. A total of 3486 infrapopliteal lesions in 1058 limbs were analysed. Average target lesion length was 190 ± 96 mm and reference vessel diameter (RVD) was 2.5 ± 0.5 mm. Presence of TASC D lesion was observed in 89% of cases. Calcification was present in 65% of lesions. RVD of peroneal artery was smaller than that of other tibial arteries. BA lesions were located in the dorsalis pedis and plantar arteries in approximately 40% of cases. In this study, procedural success was obtained in 96% (1010/1058) of the limbs.

Overall MALE

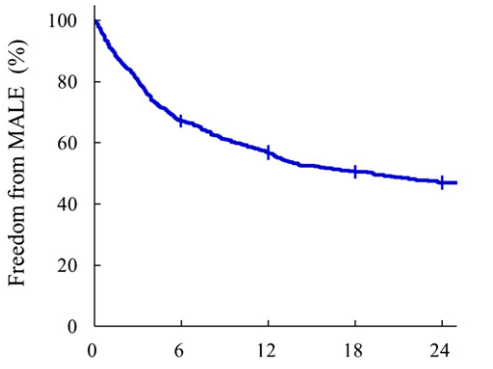
Two-year freedom from MALE rate is shown in Fig. 1; it was 57% and 47% at 1and 2 years, respectively.

Univariable and multivariable analysis for MALE

Comparison of lesion characteristics before angioplasty in MALE (+) and MALE (−) groups is shown in Table 3. There were no significant differences in baseline lesion characteristics including TASC classification and number of BTK run-off. RVD of target lesion was smaller and lesion length was longer in the MALE (+) than in the MALE (−) group. Lesion calcification and no-BA run-off, which was defined as presence of lesion at both of dorsalis pedis and plantar artery, were more frequently observed in the MALE (+) group. During the study phase, MALE was observed in 43% (455/1058) of limbs. After multivariable Cox proportional hazard regression analysis of MALE, lesion calcification (HR, 1.38; 95% confidence interval (CI),

Table 2
Baseline lesion characteristics before below-the-knee angioplasty.

Variables	Overall, $n = 1057$
TASC 2000 classification (A/B/C), (%)	3%/1%/7%
TASC 2000 D	89% (945)
Lesion calcification	65% (682)
Target lesion length (mm)	190 ± 96
Lesion length >100 mm	81% (855)
Target lesion % diameter stenosis before angioplasty	98 ± 5
Below-the-knee Chronic total occlusion	62% (651)
Below-the-ankle Chronic total occlusion	62% (659)
Target lesion reference vessel diameter (mm)	2.5 ± 0.5
Anterior tibial artery (ATA)	
Vessel diameter (mm)	2.5 ± 0.4
Intact/diseased	8% (85)/92% (972)
Occlusion	70% (737)
Posterior tibial artery	
Vessel diameter (mm)	2.4 ± 0.4
Intact/diseased	9% (98)/91% (959)
Occlusion	72% (760)
Peroneal artery	
Vessel diameter (mm)	2.2 ± 0.4
Intact/diseased	32% (340)/68% (717)
Occlusion	43% (457)
Number of below the knee run-offs	0.50 ± 0.68
Three-vessel disease	60% (634)
Dorsalis pedis artery	
Intact/diseased	62% (659)/38% (398)
Plantar artery	
Intact/diseased	58% (617)/42% (440)
Presence of below-the-ankle disease	59% (627)
Number of below-the-ankle (BA) run-offs	1.2 ± 0.8



Months	0	6	12	18	24
at risk	1057	538	362	263	183
%	100	67.2	56.6	50.5	47.0

Figure 1. Freedom from major adverse limb events (MALE) for 1057critical ischemic limbs due to pure isolated infrapopliteal lesions after angioplasty. Overall freedom from MALE was 57 and 47% at 1 and 2 years, respectively.

1.12–1.69, $p < 0.01$), target lesion in vessel with diameter <3 mm (HR, 1.26; 95% CI, 1.01–1.58, $p < 0.05$), lesion length ≥300 mm (HR, 1.47; 95% CI, 1.18–1.82, $p < 0.05$) and no-BA run-off (HR, 1.75; 95% CI, 1.36–2.25, $p < 0.01$) were positively associated with MALE.

MALE according to each predictor

Fig. 2(a–d) describe freedom from MALE for each predictor according to multivariable logistic analysis. Freedom from MALE rate in the target lesion in vessels with RVD <3 mm, target lesions length ≥300 mm, lesions with calcification and no-BA run-off was lower than in those with RVD ≥3 mm, target lesions length <300 mm, lesions without calcification and without no-BA run-off.

Risk stratification for MALE

Fig. 3 shows stratification of MALE by number of risk factors after multivariable logistic analysis. The total number of risk factors was then used to calculate the risk score for each patient for subsequent categorisation into three groups with zero or one (low-risk), two (moderate-risk) and three or four (high-risk) risk factors; patients were followed for up to 2 years. Freedom from MALE was significantly lower in higher-risk groups (2-year rates: low-risk, 59%; intermediate-risk, 46% and high-risk, 29%, respectively; low vs. moderate: $p = 0.0003$, low vs. high: $p < 0.0001$, moderate vs. high: $p < 0.0001$).

Table 3
Uni and multivariable analysis for MALE.

Lesion characteristics	Unadjusted HR [95% CI]	Adjusted HR [95% CI]
TASC 2000 class D	1.16 [0.84, 1.60]	1.03 [0.71, 1.50]
Lesion calcification	1.42 [1.16, 1.73]**	1.38 [1.12, 1.69]**
Target lesion length ≥300 mm	1.47 [1.20, 1.81]**	1.47 [1.18, 1.82]**
Chronic total occlusion in BTK	1.28 [1.04, 1.58]*	1.22 [0.98, 1.53]
Lesion reference diameter <3 mm	1.37 [1.10, 1.71]**	1.26 [1.01, 1.58]*
Number of BTK run-offs (vs. 3 run-offs)	1.00 (Ref)	1.00 (Ref)
2 run-offs	0.94 [0.58, 1.53]	0.85 [0.52, 1.39]
1 run-off	0.90 [0.58, 1.40]	0.71 [0.45, 1.15]
No run-off	0.95 [0.62, 1.46]	0.65 [0.41, 1.05]
Number of BA run-offs (vs. 2 run-offs)	1.00 (Ref)	1.00 (Ref)
1 run-off	1.04 [0.84, 1.29]	1.15 [0.92, 1.44]
No run-off	1.62 [1.23, 2.05]**	1.75 [1.36, 2.25]**
Diseased calcaneal branch	0.98 [0.81, 1.18]	0.98 [0.80, 1.19]

*$p < 0.05$, **$p < 0.01$.
TASC: Trans-Atlantic Inter-Society Consensus.
BTK: below the knee, BA: below the ankle.

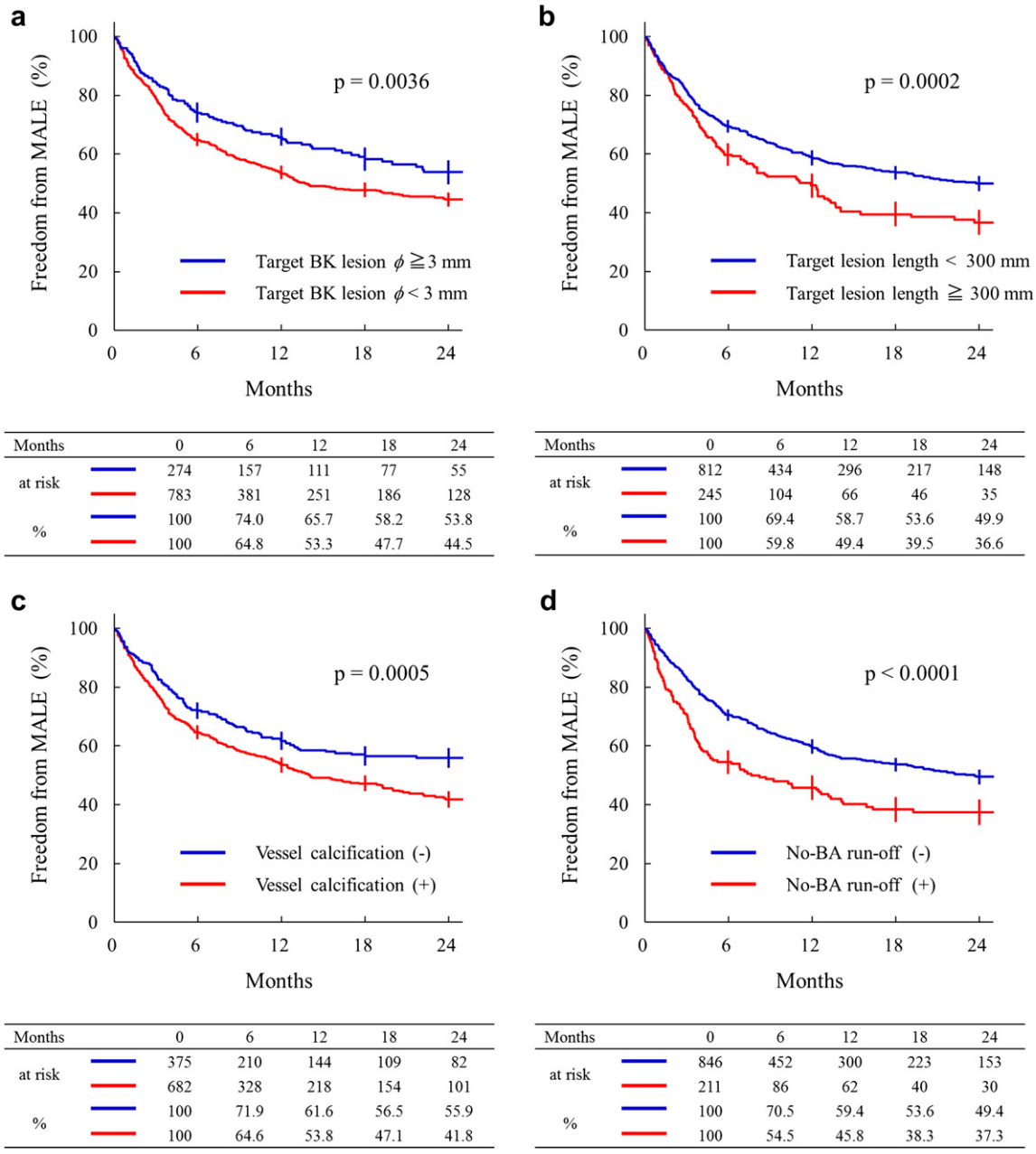
Risk stratification for AFS based on number of risk factors of MALE

Fig. 4 shows AFS rate according to number or risk factors of MALE. AFS rate was significantly lower in the higher-risk groups (2-year rates: low-risk, 72%; moderate-risk, 62% and high-risk, 54%, respectively; low vs. moderate: $p = 0.0012$, low vs. high: $p < 0.0001$, moderate vs. high: $p = 0.0076$).

Discussion

This multicentre study documents a 2-year freedom from MALE rate after infrapopliteal angioplasty was 47% and traditional TASC classification of infrapopliteal lesion not being associated with future occurrence of MALE. Lesion calcification, RVD <3 mm, lesion length ≥300 mm and no-BA run-off were independent anatomical predictors for future occurrence of MALE after multivariable analysis. After adjusting the hazards ratio after multivariable analysis based on risk score, freedom from MALE and AFS was lower in the higher score groups. These results indicate that risk stratification based on anatomical factors might be useful in clinical practice to estimate future occurrence of MALE and AFS.

Revascularisation outcomes commonly depend on anatomical features and those affecting patency include lesion severity in run-off arteries, stenosis/occlusion length and number of lesions treated.[1,2] While ilio-femoral TASC classification schemes have been modified from the original TASC 2000 guidelines to reflect inevitable technological advances, infrapopliteal classification has remained unchanged. However, approaches for the treatment of infrapopliteal arteries also have rapidly evolved yielding outcomes comparable to those of BSX.[10,11] The only trial attempting to compare BSX and EVT for limb salvage is BASIL (bypass vs. angioplasty in treatment of severe leg ischaemia) trial. In this trial, which examined CLI patients with infrainguinal arterial occlusive disease, similar results at 2 years but better AFS rates for BSX thereafter were observed; the choice of revascularisation technique (BSX or EVT) was consequently proposed based on the presence of useable vein and life expectancy.[12,13] However, no angiographic data were mentioned in the BASIL trial, and both FP and infrapopliteal lesions were included. Furthermore, the BASIL trial had low external validity, as only 6.8% of the patients undergoing infrapopliteal angioplasty were included. Recently, from the ESC guidelines on the diagnosis and treatment of peripheral artery diseases, primary percutaneous transluminal angioplasty (PTA) for infrapopliteal arterial lesions remains the standard of care, as it provides an acceptable clinical outcome at a low procedural cost compared to BSX; these guidelines recommended that with class IIa level an endovascular-first strategy should be considered when revascularisation in the infrapopliteal segment is indicated.[14] Also, a new recommendation published in the *European Journal of Vascular and Endovascular Surgery*, angioplasty as the first-line therapeutic modality for patients with CLI and infrapopliteal lesion is reasonable in the majority of cases, considering that the interventional procedure should not preclude future surgical intervention.[15] Despite the widespread use of primary PTA for the treatment of CLI with infrapopliteal lesions, morphological classification of infrapopliteal lesions in the TASC guideline has not been updated to



Months		0	6	12	18	24
at risk		274	157	111	77	55
		783	381	251	186	128
%		100	74.0	65.7	58.2	53.8
		100	64.8	53.3	47.7	44.5

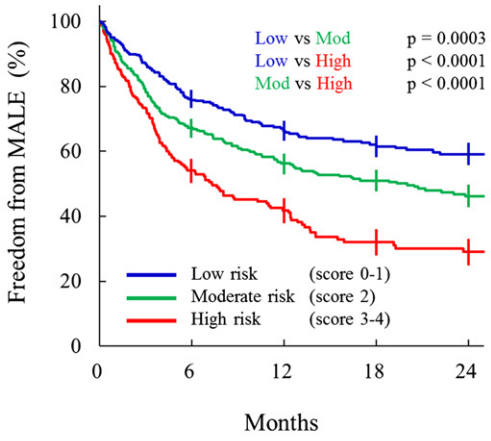
Months		0	6	12	18	24
at risk		812	434	296	217	148
		245	104	66	46	35
%		100	69.4	58.7	53.6	49.9
		100	59.8	49.4	39.5	36.6

Months		0	6	12	18	24
at risk		375	210	144	109	82
		682	328	218	154	101
%		100	71.9	61.6	56.5	55.9
		100	64.6	53.8	47.1	41.8

Months		0	6	12	18	24
at risk		846	452	300	223	153
		211	86	62	40	30
%		100	70.5	59.4	53.6	49.4
		100	54.5	45.8	38.3	37.3

Figure 2. a Comparison of freedom from MALE between target lesions with reference vessel diameter (RVD) < 3 mm and >= 3 mm Freedom from MALE rate in target lesions with RVD < 3 mm was lower than in those with RVD >= 3 mm (46% vs. 54% at 24 months, $p = 0.0036$). b Comparison of freedom from MALE between target lesions with length >= 300 mm and <300 mm Freedom from MALE rate in target lesions length >= 300 mm was lower than in those with <300 mm (37% vs. 50% at 24 months, $p = 0.0002$). c Comparison of freedom from MALE in lesions with and without calcification Freedom form MALE was lower in lesions with calcification than in lesion without calcification (42% vs. 56% at 24 months, $p = 0.0005$). d Comparison of freedom from MALE with and without below-the-ankle disease Freedom form MALE was lower in lesion with no-BA run-off than in lesion without no-BA run-off (37% vs. 49% at 36 months, $p < 0.0001$).

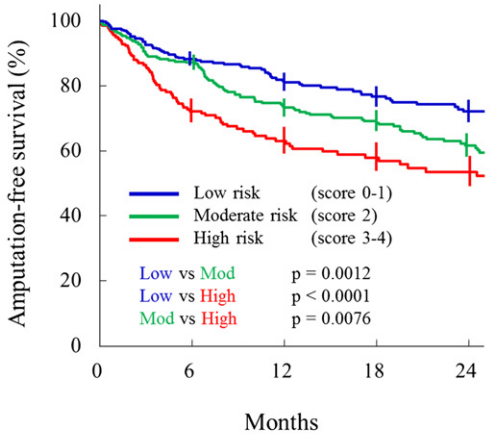
reflect revascularisation modality selection. Therefore, to help address this limitation, we investigated anatomical predictors of MALE after infrapopliteal angioplasty for patients with CLI due to pure isolated infrapopliteal lesions. To the best of our knowledge, this is the first attempt to identify novel anatomical predictors and to use them for risk stratification for future occurrence of MALE following angioplasty in patients with CLI due to isolated infrapopliteal lesions. Similar to the case with the ilio-femoral region, CLI patients, especially those with DM and ESRD on dialysis, commonly present with long, diffuse arteriosclerotic disease in the infrapopliteal region; lesion length consequently was an anatomical predictor for MALE. Comparison by Kaplan–Meier analysis showed a lower rate of freedom from MALE in lesions with RVD <3 mm compared to those with RVD ≥3 mm. This association of smaller RVD with worse outcomes after catheterisation treatment has been seen in other arterial lesions including coronary, renal, iliac and the other arteries.[16–18] Lesion calcification also negatively affected MALE after infrapopliteal angioplasty. Several prior studies have identified lesion calcification as an important determinant for coronary restenosis after both angioplasty and stent implantation.[19,20] Lesion calcification provokes insufficient balloon dilation and loss of acute gain due to elastic recoil after angioplasty which results in a high incidence of restenosis. Also, insufficient initial success in the presence of lesion calcification leads to poorer



Months		0	6	12	18	24
at risk		389	230	159	116	84
		404	211	143	112	73
		264	97	60	35	26
%		100	75.8	66.2	61.5	59.1
		100	67.1	56.3	51.0	46.2
		100	54.0	41.8	32.0	29.0

Figure 3. Risk stratification for MALE based on number of risk factors after multivariable logistic analysis Freedom from MALE rate was lower in the higher risk groups (2-year rates: low risk, 59%; moderate-risk, 46%; and high-risk, 29%, respectively; low vs. moderate: $P = 0.0003$, low vs. high: $P < 0.0001$, moderate vs. high: $P < 0.0001$).

arterial flow to the ischaemic wounds and delayed wound healing resulting in a greater likelihood of major amputation. Therefore, to address this challenge, lesion preparation would be helpful to modify the calcified lesions and consequently lead to a better rate of MALE. BA disease was also an independent predictor of MALE after multivariable analysis. Factors negatively affecting patency in



Months		0	6	12	18	24
at risk		341	243	176	131	99
		325	231	164	134	90
		209	115	80	58	44
%		100	88.2	81.0	76.7	72.1
		100	87.2	73.4	68.7	61.6
		100	72.2	63.0	57.9	53.6

Figure 4. Risk stratification for AFS (amputation-free survival) based on number of risk factors of MALE AFS rate was lower in the higher risk groups (2-year rates: low risk, 72%; moderate-risk, 62%; and high-risk, 54%, respectively; low vs. moderate: $P = 0.0012$, low vs. high: $P < 0.0001$, moderate vs. high: $P = 0.0076$).

AI and FP revascularisation include quality of BTK run-off vessels in TASC II.[2] Therefore, incidence of no-BA run-off as outflow vessel of BTK run-off accordingly plays an important role in affecting not only future occurrence of reintervention and surgical conversion but also incidence of major amputation after infrapopliteal angioplasty. Technique improvement and the availability of dedicated materials have resulted in improved clinical outcomes after endovascular treatment of patients with CLI due to isolated infrapopliteal lesions. However, classification of the infrapopliteal region has not yet been systematically updated and reconsidered in patients with CLI due to isolated infrapopliteal artery lesions. The results of this study should help inform selection of revascularisation strategy for patients with CLI due to isolated infrapopliteal lesions and this novel classification will be an attractive alternative to traditional infrapopliteal TASC classification.

Limitations

This was a retrospective and non-randomised study despite use of a prospectively maintained database with a very large number of CLI patients with isolated infrapopliteal lesions. Lack of complete follow-up to 2 years for all patients was presented in this study because of retrospective investigation. Patients considered unsuitable for revascularisation or treated with bypass therapy were not managed by the physicians involved in the study; therefore, data on these patients were not collected and analysed. Also, lesion characteristics before bypass therapy were not included in this study. Device use was limited to traditional balloon angioplasty, which was the only option available in Japan at the time of this study. However, infrapopliteal angioplasty has been widely used for treatment of CLI patients as is the case in our clinical practice. Newer classification in the era of next-generation devices for BTK intervention warrants further investigation against bypass results.

Conclusion

RVD, lesion length, calcification and no-BA run-off were associated with MALE after infrapopliteal angioplasty. Risk stratification based on these predictors plays an important role in estimating future incidence of MALE and AFS in CLI patients involving infrapopliteal lesions.

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Conflict of Interest

None.

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