Predictive scoring model of mortality after surgical or endovascular revascularization in patients with critical limb ischemia

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Objective: **The latest guideline points to life expectancy of <2 years as the main determinant in revascularization modality selection (bypass surgery [BSX] or endovascular therapy [EVT]) in patients with critical limb ischemia (CLI). This study examined predictors and a predictive scoring model of 2-year mortality after revascularization.**

Methods: **We performed Cox proportional hazards regression analysis of data in a retrospective database, the Bypass and Endovascular therapy Against Critical limb ischemia from Hyogo (BEACH) registry, of 459 consecutive CLI patients who underwent revascularization (396 EVT and 63 BSX cases between January 2007 and December 2011) to determine predictors of 2-year mortality. The predictive performance of the score was assessed with the area under the time-dependent receiver operating characteristic curve.**

Results: **Of 459 CLI patients (mean age, 72 ± 10 years; 64% male; 49% nonambulatory status, 68% diabetes mellitus, 47% on regular dialysis, and 18% rest pain and 82% tissue loss as treatment indication), 84 died within 2 years after revascularization. In a multivariate model, age >75 years (hazard ratio [HR], 1.77; 95% confidence interval [CI], 1.10-2.85), nonambulatory status (HR, 5.32; 95% CI, 2.96-9.56), regular dialysis (HR, 1.90; 95% CI, 1.10-3.26), and ejection fraction <50% (HR, 2.49; 95% CI, 1.48-4.20) were independent predictors of 2-year mortality. The area under the time-dependent receiver operating characteristic curve for the developed predictive BEACH score was 0.81 (95% CI, 0.76-0.86).**

Conclusions: **Predictors of 2-year mortality after EVT or BSX in CLI patients included age >75 years, nonambulatory status, regular dialysis, and ejection fraction <50%. The BEACH score derived from these predictors allows risk stratification of CLI patients undergoing revascularization. (J Vasc Surg 2014;60:383-9.)**

Revascularization is an optimal treatment for patients with critical limb ischemia (CLI).[1] In 2005, the BASIL (Bypass vs Angioplasty in Severe Ischaemia of the Leg) investigators reported similar 2-year main clinical outcomes (overall survival and amputation-free survival) after randomization to angioplasty-first or bypass-first revascularization strategies.[2] In 2010, they finally concluded that beyond 2 years after revascularization, there appeared to be a benefit for open bypass surgery (BSX).[3] However, the predictors of 2-year mortality after endovascular therapy (EVT) or BSX were not systematically examined.

Several predictive scoring models for outcomes in CLI patients have been reported.[4-6] The FINNVASC score evaluated 30-day amputation-free survival in CLI patients after infrainguinal surgical revascularization.[4] PREVENT III predicts 1-year amputation-free survival in CLI patients after infrainguinal bypass with autogenous vein.[5] The BASIL survival prediction model assessed death at 6, 12, and 24 months after EVT or BSX for severely ischemic limbs[6] and reported comparison of area under the receiver operating characteristic (ROC) curves for BASIL, FINNVASC, and PREVENT III scores.[7] At 2 years after revascularization, the area under the curve for BASIL, FINNVASC, and PREVENT III scores was 0.66, 0.53, and 0.62, respectively,[7] ie, clinically insufficient to estimate 2-year mortality after revascularization for CLI patients. Therefore, the current investigation was aimed at determining a precise and easy-to-use score to prognosticate 2-year survival in a population of CLI patients selected to undergo EVT or BSX.

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METHODS

Patients. Analysis in this study was based on data extracted from a two-center (Kansai Rosai Hospital and Shinsuma General Hospital) database, namely, the Bypass and Endovascular therapy Against Critical limb ischemia from Hyogo (BEACH) registry, including all 459 consecutive CLI patients (Rutherford class 4-6) who underwent revascularization between January 2007 and December 2011. One limb was included per enrolled patient. All data were entered at the time of first admission, and the registry was updated periodically with patient follow-up data up to

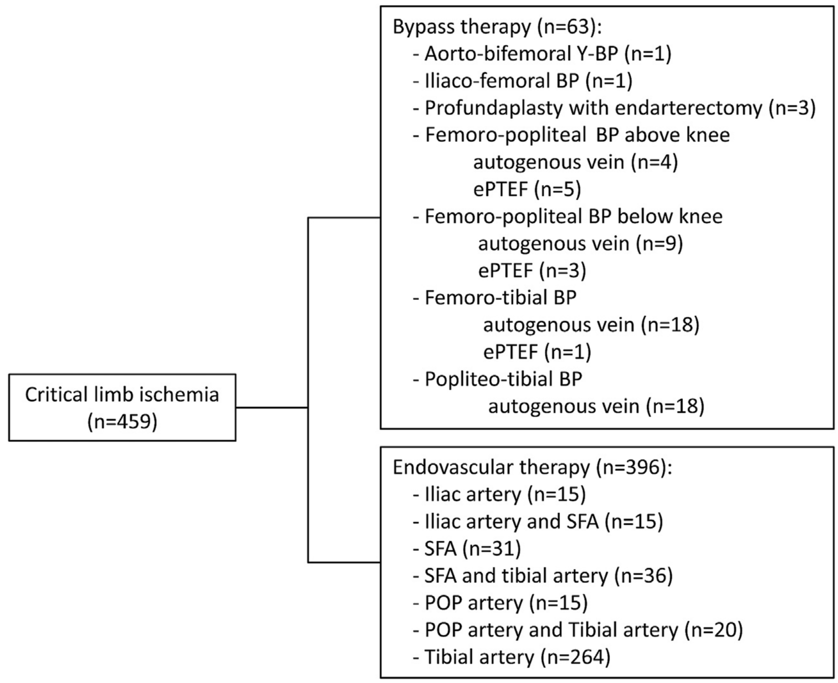


Fig 1. Initial treatment of patients with critical limb ischemia (CLI). Bypass surgery (BSX) was conducted in 13.7% (63 of 459) and endovascular therapy (EVT) in 86.3% (396 of 459). *BP,* Bypass; *ePTFE,* expanded polytetrafluoroethylene; *POP,* popliteal; *SFA,* superficial femoral artery.

24 months. Patients who were poor candidates for endovascular or surgical revascularization were defined as those with severe comorbidities and impairment at the functional (bedridden with intractable rest pain), cognitive (dementia not requiring institutionalization), or social (no family or professional career) level and those who refused revascularization. These patients were excluded from analysis before angiographic assessment because of the particular challenges they pose for follow-up and for assessment and interpretation of late consequences of treatment. The study protocol was developed in accordance with the Declaration of Helsinki and approved by the ethics committee of each participating hospital. All patients gave written informed consent before revascularization.

Study protocol. Briefly, ankle-brachial index (ABI) and skin perfusion pressure (SPP) were used to assess lower limb hemodynamics. A group of vascular specialists including vascular surgeons and radiologists judged whether EVT or BSX was indicated for each patient. According to the American Heart Association guidelines, it is reasonable to perform EVT as the initial procedure to improve distal blood flow in patients with limb-threatening lower extremity ischemia and an estimated life expectancy of 2 years or less when an autogenous vein conduit is not available. BSX is the reasonable choice when estimated life expectancy is more than 2 years and an autogenous vein conduit is available.[8] Life expectancy of more than 2 years was decided at the physician's discretion. After informed consent was obtained, the revascularization strategy was decided on the basis of the guidelines detailed before and the patient's preference. In EVT, a primary stenting strategy was used for aortoiliac lesions, whereas a provisional stenting strategy was used for femoropopliteal lesions. In femoropopliteal lesions, angioplasty was initially performed with an optimally sized balloon. If the result after balloon angioplasty was suboptimal, a nitinol stent (S.M.A.R.T.; Cordis J&J, Miami, Fla) was implanted. For infrapopliteal lesions, balloon angioplasty was repeatedly performed with an optimally sized balloon. A >200-mm-length balloon (Shiden, Kaneka Medix Corporation, Osaka, Japan; or Amphirion, Medtronic, Minneapolis, Minn) was commonly used, and balloon inflation was held at nominal pressure for at least 180 seconds to avoid flow-limiting dissection. Dual antiplatelet therapy (aspirin at 100 mg/d and ticlopidine at 200 mg/d or cilostazol at 200 mg/d) was started at least 1 week before EVT and continued lifelong. Medical treatment selection was left to the physician's discretion.

BSX was performed by standard bypass techniques, and autogenous vein graft was routinely used. Postprocedural medication prescription followed local clinical practice.

Follow-up protocol. Study participants were followed up in prospective visits at 1, 3, 6, 12, and 24 months after BSX or EVT. Each patient was routinely assessed for ischemic symptoms, ABI, SPP (SensiLase PAD 3000; Väsamed, Eden Prairie, Minn), and duplex ultrasound features as well as for wound condition. The indication for repeated revascularization was clinically driven by delayed wound healing or rest pain recurrence. Standard criteria for repeated revascularization in this study were

Table I. Baseline characteristics

	Overall (N = 459)	*BSX (n = 63)*	*EVT (n = 396)*	P
Patient status				
Age, years	72 ± 10	70 ± 8	72 ± 10	.14
Male gender	64.0% (294)	73.0% (46)	62.6% (248)	.11
BMI	21 ± 3	21 ± 3	21 ± 3	.72
BMI <18.5	22.4% (103)	22.2% (14)	22.4% (89)	.47
Nonambulatory status	49.6% (228)	36.5% (23)	51.8% (205)	.02
Diabetes mellitus	68.1% (313)	71.4% (45)	67.7% (268)	.55
Regular dialysis	46.8% (215)	33.3% (21)	49.0% (194)	.02
Coronary artery disease	41.1% (189)	44.4% (28)	40.7% (161)	.57
Ejection fraction, %	62 ± 12	64 ± 12	61 ± 12	.66
Ejection fraction <50%	15.6% (72)	12.6% (8)	16.1% (64)	.48
Cerebrovascular disease	22.2% (102)	31.7% (20)	20.7% (82)	.05
Limb status				
Tissue loss	81.6% (375)	82.5% (52)	81.6% (323)	.85
Isolated BTK artery disease	39.4% (181)	28.6% (18)	41.2% (163)	.06
Laboratory data				
Median CRP level, mg/dL	0.9	0.9	0.9	.65
Hematocrit, %	33 ± 5	34 ± 5	32 ± 5	.68
Hematocrit ≤30%	31.3% (144)	28.5% (18)	31.8% (126)	.19
Albumin level, g/dL	3.4 ± 0.6	3.3 ± 0.5	3.4 ± 0.6	.54
Medication				
Aspirin	85.6% (393)	76.2% (48)	88.2% (345)	<.01
Thienopyridine	27.6% (127)	17.5% (11)	42.5% (116)	<.01
Cilostazol	52.7% (242)	33.3% (21)	56.5% (221)	<.01
Warfarin	26.1% (120)	77.8% (49)	17.9% (71)	<.01
Statin	18.3% (84)	12.7% (8)	19.2% (76)	.05
ACE inhibitor/ARB	32.5% (149)	42.9% (27)	30.8% (122)	<.01
β Blocker	15.0% (69)	17.5% (11)	14.6% (58)	.52

ACE, Angiotensin-converting enzyme; *ARB,* angiotensin receptor blocker; *BMI,* body mass index; *BSX,* bypass surgery; *BTK,* below-the-knee; *CRP,* C-reactive protein; *EVT,* endovascular therapy.

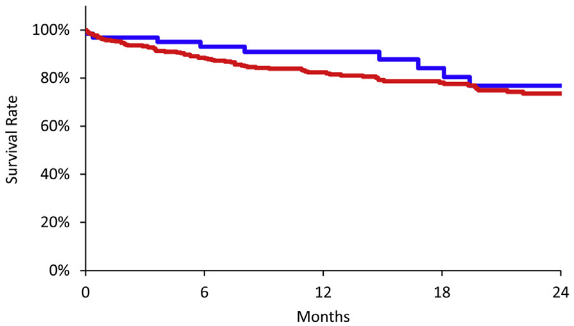
SPP <40 mm Hg and peak systolic velocity ratio >2.4 by duplex ultrasound imaging.

Definitions. A critically ischemic limb was defined according to the TransAtlantic Inter-Society Consensus II guideline. When definition-required measurements could not be obtained because of intractable rest pain or a noncompressible artery with severe calcification, SPP was measured instead of toe or ankle pressure; an SPP <40 mm Hg was defined as indicating a critically ischemic limb. Nonambulatory status was defined as wheelchair bound or bedridden. Coronary artery disease and cerebrovascular disease were defined as the presence of symptoms or past history of any intervention or infarction.

Statistical analysis. Data are expressed as mean and standard deviation for continuous variables or as percentage for dichotomous variables, unless otherwise mentioned. Prognostic outcomes were assessed with the Kaplan-Meier method and between-group differences with the log-rank test. Univariate and multivariate Cox proportional hazards regression models were used to investigate the unadjusted and adjusted association of preoperative characteristics with 2-year mortality, respectively. Hazard ratios (HRs) and 95% confidence intervals (CIs) are reported. The variables with statistical significance in the multivariate model were determined as the independent risk factors for the outcome. Risk stratification analysis was subsequently conducted by a simple score based on the number of the independent risk factors present. The predictive performance of the score was assessed by time-dependent ROC curve analyses.[9] A *P* value of < .05 was considered significant. Statistical analyses were performed with SPSS version 15.0J (SPSS Inc, Chicago, Ill), except for the time-dependent ROC curve analysis, which was performed by R.

RESULTS

The initial treatment strategy for the 459 CLI patients is summarized in Fig 1. BSX and EVT were conducted in 13.7% (63 of 459) and 86.3% (396 of 459) of patients, respectively. Baseline characteristics are shown in Table I. Mean age was 72 ± 10 years; 294 patients (64%) were male; and mean body mass index (BMI) was 21 ± 3, with 22.4% of patients being underweight (BMI <18.5). Notable comorbidities included diabetes mellitus (68.1%; 313 of 459), followed by regular dialysis dependence (46.8%; 215 of 459) and coronary artery disease (41.1%; 189 of 459). Regarding limb condition before revascularization, mean ABI and SPP were 0.65 ± 0.26 and 28 ± 16 mm Hg, respectively (not shown in table). The fact that almost half the patients studied were on dialysis, which is associated with calcification, may account for the falsely high ABI. Tissue loss was observed in 81.6% of patients (375 of 459), and 181 patients (39.4%) had isolated below-the-knee artery disease. Compared with the BSX group, the EVT group had a higher prevalence of nonambulatory status (36.5% vs 51.8%:



		0	6	12	18	24
BSX	at risk	63	47	33	23	16
	%±SE	100±0	93±3	91±4	80±7	77±7
EVT	at risk	396	281	200	134	97
	%±SE	100±0	88±2	82±2	78±2	74±3

Fig 2. Survival rate in bypass surgery (*BSX*) group (n = 63) and endovascular therapy (*EVT*) group (n = 396). The rates of survival after BSX (*blue line*, n = 63) and EVT (*red line*, n = 396) strategies did not differ significantly at 2 years (77% vs 74%; $P = .33$). *SE,* Standard error.

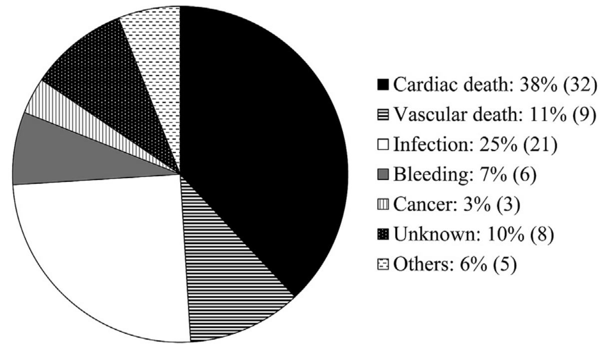


Fig 3. Cause of death within 2 years after revascularization (n = 84). The most prevalent cause was cardiac death (38%; 32 of 84), followed by infection (25%; 21 of 84). Almost half of the patients were dead because of cardiovascular events.

$P = .02$) and regular dialysis (33.3% vs 49.0%; $P = .02$). In laboratory testing, overall median C-reactive protein level, mean hematocrit, and mean albumin level were 0.9 mg/dL, 33% ± 5%, and 3.4 ± 0.6 g/dL, respectively, and levels were not significantly different between treatment modality groups. Antiplatelet therapy was prescribed more often for the EVT group than for the BSX group. On the other hand, warfarin was highly prescribed for patients treated with BSX compared with those in the EVT group. Statins were prescribed in 18.3% patients with CLI; however, they were prescribed to only 1.8% of patients in the BSX group. Angiotensin-converting enzyme inhibitors or angiotensin receptor blockers and β-blockers were prescribed to 32.5% and 15.0% of patients, respectively. Forty-two percent of patients (194 of 459) were followed up for 2 years, with 84 deaths during that period.

Prognosis of CLI patients after revascularization. Overall survival rate at 2 years after revascularization was 74%. Fig 2 shows that the 2-year survival rate was similar for BSX and EVT strategies (77% vs 74%; $P = .33$). Causes of death within 2 years after revascularization are shown in Fig 3. The most prevalent cause of death was cardiac (38%; 32 of 84), followed by infection (25%; 21 of 84). In terms of vascular death (11%; 9 of 84), five patients died secondary to bowel ischemia and four to stroke. Severe bleeding occurred in 7% (6 of 84) of those dying within 2 years after revascularization; upper gastrointestinal bleeding was observed in four cases, two of which were complicated by puncture bleeding. One death was associated with hemorrhagic shock secondary to trauma. Pneumonia accounted for the largest proportion (67%; 14 of 21) of deaths by infection in this study; sepsis of unknown etiology accounted for the remaining seven cases. Perioperative (<30 days) mortality after revascularization was 4% (18 cases). The causes of perioperative death were cardiovascular event (33%; 6 of 18), infection (22%; 4 of 18), gastrointestinal bleeding (11%; 2 of 18), bleeding related to revascularization (11%; 2 of 18), bowel ischemia (11%; 2 of 18), and stroke (11%; 2 of 18).

Predictors of survival within 2 years after EVT or BSX. As shown in Table II, univariate analysis revealed significant association with 2-year mortality for the following variables: age >75 years (HR, 1.63; 95% CI, 1.06-2.51; $P = .024$), nonambulatory status (HR, 7.08; 95% CI, 4.03-12.4; $P < .001$), BMI <18.5 (HR, 2.04; 95% CI, 1.31-3.20; $P = .001$), regular dialysis (HR, 2.58; 95% CI, 1.63-4.08; $P < .001$), and ejection fraction <50% (HR, 3.25; 95% CI, 2.05-5.15; $P < .001$). In multivariate analysis, age >75 years (HR, 1.77; 95% CI, 1.10-2.85; $P = .017$), nonambulatory status (HR, 5.32; 95% CI, 2.96-9.56; $P < .001$), regular dialysis (HR, 1.90; 95% CI, 1.10-3.26; $P = .019$), and ejection fraction <50% (HR, 2.49; 95% CI, 1.48-4.20; $P < .001$) were independent risk factors of 2-year mortality after revascularization.

Risk stratification by the number of independent predictors for 2-year mortality after revascularization. Stratification of patients based on the number of independent risk factors present yielded three significantly different estimates for 2-year survival rate for low-, intermediate-, and high-risk groups: 98%, 78%, and 29%, respectively ($P < .001$ for each comparison; Fig 4). As shown in Fig 5, the area under the time-dependent ROC curve was 0.81 (95% CI, 0.76-0.86).

DISCUSSION

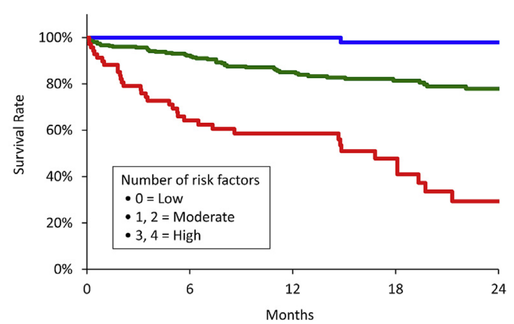
In this study, we developed a predictive scoring model using the BEACH registry database; predictive performance of the score was highly associated with 2-year mortality of CLI patients. The 2-year overall survival rate after revascularization for CLI was 74%. Age >75 years, nonambulatory status, regular dialysis, and ejection fraction <50% were the independent predictors of 2-year mortality after revascularization for CLI.

The BASIL investigators developed a model to predict death at 6, 12, and 24 months after EVT or BSX[6] on the

Table II. Univariate and multivariate analysis: Predictors of 2-year mortality after revascularization in CLI patients

	Univariate analysis		*Multivariate analysis (model 1)*		*Multivariate analysis (model 2)*	
Factors	*HR (95% CI)*	P	*HR (95% CI)*	P	*HR (95% CI)*	P
Age >75 years	1.63 (1.06-2.51)	.024	1.77 (1.10-2.85)	.017	1.80 (1.14-2.83)	.010
Male	1.01 (0.64-1.58)	.955	0.89 (0.56-1.44)	.658	–	
Tissue loss	1.76 (0.93-3.32)	.075	0.96 (0.49-1.91)	.927	–	
Isolated BTK disease	1.14 (0.73-1.75)	.552	1.33 (0.83-2.14)	.232	–	
Nonambulatory status	7.08 (4.03-12.4)	<.001	5.32 (2.96-9.56)	<.001	5.66 (3.21-10.0)	<.001
BMI <18.5	2.04 (1.31-3.20)	.001	1.35 (0.84-2.18)	.207	–	
Hematocrit ≤30%	1.52 (0.97-2.38)	.063	1.12 (0.69-1.80)	.638	–	
Regular dialysis	2.58 (1.63-4.08)	<.001	1.90 (1.10-3.26)	.019	2.15 (1.31-3.54)	.002
Diabetes mellitus	0.92 (0.59-1.44)	.732	0.87 (0.54-1.39)	.571	–	
Coronary artery disease	1.50 (0.97-2.30)	.062	1.09 (0.66-1.80)	.727	–	
Ejection fraction <50%	3.25 (2.05-5.15)	<.001	2.49 (1.48-4.20)	<.001	2.37 (1.47-3.83)	<.001
Cerebrovascular disease	1.24 (0.75-2.03)	.388	1.10 (0.65-1.84)	.718	–	

BMI, Body mass index; *BTK,* below-the-knee; *CI,* confidence interval; *HR*, hazard ratio.



			0	6	12	18	24
Low	at risk		70	64	52	36	31
	%±SE		100±0	100±0	100±0	98±2	98±2
Mod	at risk		317	229	154	108	77
	%±SE		100±0	92±2	85±2	81±3	78±3
High	at risk		72	36	28	15	7
	%±SE		100±0	64±6	59±6	41±8	29±8

Fig 4. Risk stratification by the number of risk factors after multivariate analysis. Stratification of the patients by the number of risk factors yielded three significantly different estimates for 2-year survival: low risk, 97% (*blue line*, n = 70); medium risk, 77% (*green line*, n = 317); and high risk, 29% (*red line*, n = 72) ($P < .001$ for each comparison). *SE*, Standard error.

basis of age, presence of tissue loss, serum creatinine concentration, number of ankle pressure measurements detectable, maximum ankle pressure measured, history of myocardial infarction or angina, history of stroke or transient ischemic attack, below-knee Bollinger angiogram score, BMI, and smoking status. Although the BASIL score requires many variables, predictive ability for 2-year mortality after revascularization was not high (area under the curve = 0.66 [0.59-0.74]).[7] Moreover, 2-year mortality cannot be estimated by the Bollinger angiogram score without angiography.

Data from the FINNVASC and PREVENT III registry have informed two risk-scoring models for amputation-free survival after BSX in CLI patients.[4,5] The FINNVASC registry demonstrated that diabetes mellitus, coronary artery disease, foot gangrene, and urgent operation were independent predictors of 30-day postoperative mortality or major amputation in patients undergoing infrainguinal surgical revascularization.[4] In the PREVENT registry, dialysis, presence of tissue loss, age >75 years, hematocrit <30, and advanced coronary artery disease were significant predictors for amputation-free survival in the multivariate model.[5] Calculation of a PREVENT III risk score was useful for clinical decision-making in the CLI population.[5] However, FINNVASC and PREVENT scoring models were not meant to assess 2-year mortality in CLI patients.[7]

We developed a predictive model for 2-year mortality based on the four independent mortality predictors identified in this study, and the result was consistent with that of previous reports.[4-6] On the other hand, several predictors known to be associated with amputation-free survival were not independently associated with 2-year mortality in this study.

Advanced age of the patient is a common concern because of the increasing number of comorbidities.[10] Octogenarians with CLI treated by surgical bypass had a fivefold higher 1-year mortality rate than that of nonoctogenarians.[11] Age >75 years also was an independent predictor for 2-year mortality in our study as it was in PREVENT III.

Hemodialysis patients with CLI have significantly poorer 5-year survival than nonhemodialysis ones do (24.3% vs 48.0%; $P < .001$).[12] Diabetes mellitus has been shown to be one of the chief atherosclerotic risk factors for CLI patients. In this study, regular dialysis was significantly associated with 2-year mortality, whereas diabetes mellitus was not.[13] Diabetes mellitus has been reported as a risk factor for amputation-free survival after BSX[4] but not for survival.[14] Diabetes might be relevant to amputation-free survival because of its impact on lower limb prognosis.

An active lifestyle reduces the risk of cardiovascular disease and consequently has a beneficial effect on mortality in a healthy elderly population.[15] Nonambulatory CLI patients could not perform sufficient exercise, leading to poorer outcomes compared with ambulatory CLI patients.

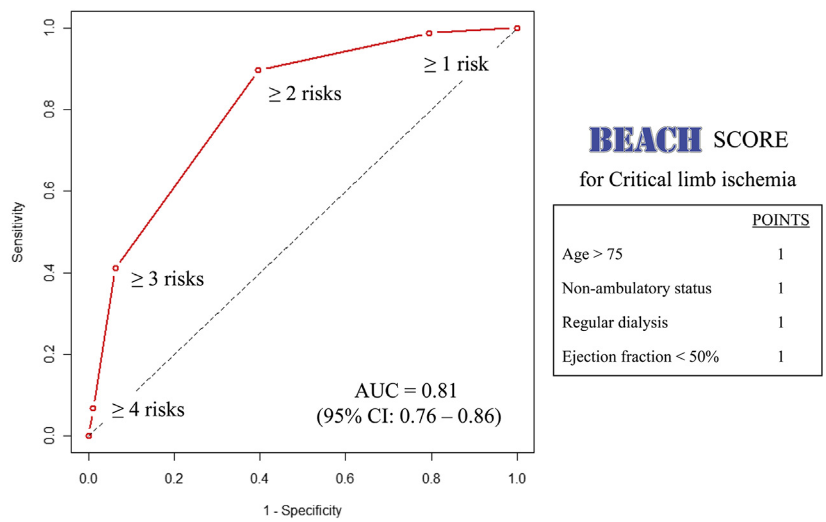


Fig 5. Time-dependent receiver operating characteristic (ROC) curve of the BEACH score. The BEACH score is defined as the sum of multivariable factors (0-4 points: age >75 years, nonambulatory status, regular dialysis, and ejection fraction <50%) associated with 2-year mortality. The area under the curve (*AUC*) was 0.81 (95% confidence interval [*CI*], 0.76-0.86).

In this study, nonambulatory status was the most significant factor associated with mortality (hazard ratio, 5.32).

Ejection fraction <50% from ultrasound examination was a strong independent predictor of 2-year mortality after revascularization. Cardiovascular events account for 50% of all causes of death after revascularization in CLI patients. The proportion of deaths secondary to acute coronary syndrome is lower than that of chronic heart failure and arrhythmia. Several reports have mentioned past history of coronary artery disease as one of the predictors in CLI patients.[4-6] Left ventricular dysfunction, however, was more strongly relevant to prognosis than was past history of coronary artery disease in our study.

FINNVASC and PREVENT III predictive methods suggested an association between presence of tissue loss and amputation-free survival. However, studies of midterm outcomes after EVT have reported an association between Rutherford criteria and amputation but not mortality.[14] Likewise in this study, tissue loss was not a multivariate independent predictor of 2-year mortality.

The area under the time-dependent ROC curve for the BEACH scoring model was as high as 0.81. A recent report evaluated the predictive power of the BASIL, FINNVASC, and PREVENT III models. The area under ROC curves with use of BASIL, FINNVASC, and PREVENT to predict 2- year mortality was only 0.66 (0.59-0.74), 0.53 (0.45-0.62), and 0.63 (0.54-0.71), respectively.[7] The developed predictive scoring model from the BEACH registry was highly associated, compared with previous models, with 2-year mortality in CLI patients after revascularization.

The characteristics of this developed predictive scoring model were simple. Accuracy of this model was estimated by area under the time-dependent ROC curve (0.81 [95% CI, 0.76-0.86]), which was not significantly different from those accounting for the relative strengths of the four risk factors' predictive power (0.82 [95% CI, 0.76-0.87]; $P = .499$). From this result, we adopted the simple scoring model; the ease of its calculation renders it clinically useful.

Limitations. This was a retrospective analysis of registry data. Only 42% of patients (194 of 459) were followed up for 2 years after revascularization. The data in this study were not separated into training and test data to develop and to assess, respectively, validity of predictive models. The current findings therefore should be externally validated in settings with similar sample characteristics. It remains to be determined if the developed model can be validated in the general population sampled independently of revascularization treatment use. Construction of a model in a random sample of the general population might be warranted; patients without revascularization were excluded, and the population of patients treated with primary amputation was not well examined. Only Japanese patients, characterized by a high proportion of dialysis dependence, were included in this study; therefore, it remains to be seen whether this predictive model would allow risk stratification of CLI patients in other countries. We did not collect information on the nature of tissue loss (ulcer and gangrene). Information on medical therapy was collected only after revascularization. We could not determine compliance, discontinuation, or other details of medication use during the 2-year follow-up after revascularization. The predictive power of the BEACH model was not evaluated directly against that of any other scoring model. Further evaluation of differences among prediction models in CLI patients is warranted.

CONCLUSIONS

Independent predictors of 2-year mortality after EVT or BSX for CLI include age >75 years, nonambulatory status, regular dialysis, and ejection fraction <50%. The predictive BEACH scoring model derived from these independent predictors allows postrevascularization mortality risk assessment in CLI patients.

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AUTHOR CONTRIBUTIONS

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Data collection: TS, OI, MT, SO, IK, YT
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Critical revision of the article: OI, MT, HT, MU
Final approval of the article: TS, OI, MT, SO, IK, YT, HT, MU
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REFERENCES

1. Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG, et al. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). Eur J Vasc Endovasc Surg 2007;33(Suppl 1):S1-75.
2. Adam DJ, Beard JD, Cleveland T, Bell J, Bradbury AW, Forbes JF, et al. Bypass versus angioplasty in severe ischemia of the leg (BASIL): multicentre, randomized controlled trial. Lancet 2005;366:1925-34.
3. Bradbury AW, Adam DJ, Bell J, Forbes JF, Fowkes FG, Gillespie I, et al. Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial: analysis of amputation free and overall survival by treatment received. J Vasc Surg 2010;51:18S-31S.
4. Biancari F, Salenius JP, Heillinen M, Luther M, Ylönen K, Lepäntalo M. Risk-scoring method for prediction of 30-day postoperative outcome after infrainguinal surgical revascularization for critical lower-limb ischemia: a Finnvasc registry study. World J Surg 2007;31:217-25.
5. Schanzer A, Mega J, Meadows J, Samson RH, Bandyk DF, Conte MS, et al. Risk stratification in critical limb ischemia: derivation and validation of a model to predict amputation-free survival using multicenter surgical outcomes data. J Vasc Surg 2008;48:1464-71.
6. Bradbury AW, Adam DJ, Bell J, Forbes JF, Fowkes FGR, Gillespie I, et al. Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial: a survival prediction model to facilitate clinical decision making. J Vasc Surg 2010;51:52S-68S.
7. Moxey PW, Brownrigg J, Kumar SS, Crate G, Holt PJ, Thompson MM, et al. The BASIL survival prediction model in patients with peripheral arterial disease undergoing revascularization in a university hospital setting and comparison with the FINNVASC and modified PREVENT scores. J Vasc Surg 2013;57:1-8.
8. Anderson JL, Halperin JL, Albert NM, Bozkurt B, Brindis RG, Curtis LH, et al. Management of patients with peripheral artery disease (compilation of 2005 and 2011 ACCF/AHA guideline recommendations): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation 2013;127:1425-43.
9. Heagerty PJ, Lumley T, Pepe MS. Time-dependent ROC curves for censored survival data and a diagnostic marker. Biometrics 2000;56:337-44.
10. Lange S, Trampisch H, Haberl R, Darius H, Pittrow D, Schuster A, et al. High prevalence of peripheral arterial disease and co-morbidity in 6880 primary care patients: cross-sectional study. Atherosclerosis 2004;172:95-105.
11. Brosi P, Dick F, Do DD, Schmidli J, Baumgartner I, Diehm N. Revascularization for chronic critical lower limb ischemia in octogenarians is worthwhile. J Vasc Surg 2007;46:1198-207.
12. Nakano M, Hirano K, Iida O, Soga Y, Kawasaki D, Suzuki K, et al. Prognosis of critical limb ischemia in hemodialysis patients after isolated infrapopliteal balloon angioplasty: results from the Japan below-the-knee artery treatment (J-BEAT) registry. J Endovasc Ther 2013;20:113-24.
13. Takahara M, Kaneto H, Iida O, Gorogawa S, Katakami N, Matsuoka TA, et al. The influence of glycemic control on the prognosis of Japanese patients undergoing percutaneous transluminal angioplasty for critical limb ischemia. Diabetes Care 2010;33:2538-42.
14. Iida O, Soga Y, Hirano K, Kawasaki D, Suzuki K, Mitashita Y, et al. Midterm outcomes and risk stratification after endovascular therapy for patients with critical limb ischemia due to isolated below-the-knee lesions. Eur J Vasc Endovasc Surg 2012;43:313-21.
15. Hakim AA, Petrovitch H, Burchfiel CM, Ross GW, Rodriguez BL, White LR, et al. Effects of walking on mortality among nonsmoking retired men. N Engl J Med 1998;338:94-9.

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