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PERIPHERAL

Two-Year Life Expectancy in Patients With Critical Limb Ischemia

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ABSTRACT

OBJECTIVES This study sought to estimate the 2-year life expectancy (2YLE) (estimated survival rate >50% at 2 years) in patients with critical limb ischemia (CLI) using the risk score based on predictors of all-cause mortality within 2 years.

BACKGROUND It has been reported that 2YLE is one of the important factors in the decision making of the revascularization strategy. However, little is known about the probability and the prognostic factors of a 2YLE.

METHOD This study was performed as a multicenter retrospective analysis. Between March 2004 and December 2011, 995 CLI patients with follow-up period >730 days undergoing endovascular therapy (EVT) were identified and analyzed.

RESULTS Within 2 years, 412 patients (41%) died, and a cardiovascular cause accounted for 47% of deaths. On multivariate analysis, the independent prognostic factors were age 65 to 79 years (odds ratio [OR]: 1.9), 80 years of age or older (OR: 3.7), body mass index (BMI) 18.0 to 19.9 kg/m^2 (OR: 1.5), BMI <18.0 kg/m^2 (OR: 2.9), nonambulatory status (OR: 2.4), hemodialysis (OR: 2.1), cerebrovascular disease (OR: 1.6), left ventricular ejection fraction (LVEF) of 40% to 49% (OR: 1.8), LVEF <40% (OR: 2.6), Rutherford class 5 (OR: 1.9), and Rutherford class 6 (OR: 3.4). The 2-year survival rate in each risk score was calculated based on each OR (full score: 15 points). After that, 2YLE was estimated based on the survival rate in each risk score, the probability of a 2YLE of ≥8 points indicated a <50% probability of 2-year survival.

CONCLUSIONS The independent prognostic factors for the 2YLE were age, BMI, nonambulatory status, hemodialysis, cerebrovascular disease, LVEF, and tissue loss. A 2YLE score of ≥8 points indicated a <50% probability of 2-year survival. This score seemed to be helpful for identifying CLI patients with a poor prognosis. (J Am Coll Cardiol Intv 2014;7:1444–9) © 2014 by the American College of Cardiology Foundation.

The results of the BASIL (Bypass versus Angioplasty in Severe Ischaemia of the Leg) trial (1) reported in 2005 demonstrated the equivalence of endovascular therapy (EVT) and bypass surgery as revascularization for critical limb ischemia (CLI) patients. In the subsequent BASIL 2007 trial, the 2-year life expectancy (2YLE) was greater with bypass surgery, which indicated that this approach was appropriate as first-line revascularization for CLI patients with durable veins and an expected life expectancy of ≥2 years (2). In light of these findings, the European Society of Cardiology guidelines (3) and the American College of Cardiology Foundation/American Heart Association 2005 updated guidelines

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(4) were revised to indicate that life expectancy of ≥2 years is an important factor in the selection of the initial revascularization procedure for CLI patients.

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This approach is limited because CLI is a disease with a poor prognosis, and it is difficult to predict life expectancy of ≥2 years before the revascularization procedure. There are no definitive guidelines to determine life expectancy in CLI patients, and this is judged subjectively in actual clinical settings. Therefore, the aim of this study was to identify prognostic factors of 2-year mortality in CLI patients and to estimate the 2YLE on the basis of the risk score calculated by these prognostic factors.

METHODS

DATA COLLECTION. This study was performed as a multicenter retrospective analysis of a prospectively maintained database enrolling at 17 Japanese cardiovascular centers. The registration was performed in accordance with the pre-specified criteria, and the analysis was performed by an independent analyst. The revascularization strategy was decided by each institution in consultation with the department of vascular or cardiovascular surgery. Between March 2004 and December 2011, 3,741 consecutive patients underwent primary EVT for chronic infrainguinal ischemia. With the exception of 1,868 claudicant patients, 497 patients with follow-up <730 days, and 381 patients with a lack of data, 995 patients were included in this analysis.

PROCEDURES AND FOLLOW-UP. All patients received dual-antiplatelet therapy (aspirin 100 mg/day + clopidogrel 75 mg/day) before the procedure. After insertion of a 4- or 6-F sheath, an intra-arterial bolus of 3,000 to 5,000 IU of heparin was injected, with additional heparin given intravenously during the procedure to maintain the activated clotting time at >200 s. For superficial femoral artery lesions, balloon angioplasty was performed with a reference vessel size. If a suboptimal result caused by flow-limiting dissection or residual stenosis of >30% was found for a femoropopliteal lesion, a stent was implanted. The lesion was basically covered by 2 types of bare metal nitinol stents: Luminexx (Bard, Murray Hill, New Jersey), and S.M.A.R.T. (Cordis J&J, Miami, Florida). The stent size was chosen to be 1 to 2 mm larger than the reference vessel diameter. For infrapopliteal lesions, after passage of the guidewire, the balloon angioplasty (not the drug-coated balloon), and the vessel was expanded for at least 60 s. When flow-limiting dissection, significant recoil or acute occlusion was found after balloon angioplasty, balloon angioplasty was repeatedly performed with low pressure, and a long inflation time. Bailout stenting for infrapopliteal lesion was not performed.

After the procedure, all patients were prescribed lifelong aspirin (100 mg/day) and prolonged (at least 1 month) clopidogrel 75 mg/day, ticlopidine 100 mg twice a day, or cilostazol 100 mg twice a day was recommended. Clinical information was obtained within 30 days and at least every 6 months thereafter. Cause of death was considered as cardiac in origin unless obvious noncardiac causes could be identified. Vascular death was defined as that related to cerebral, aortic, or peripheral vascular disease or renal disease. Myocardial infarction was defined as the detection of an increase in cardiac troponin and/or creatine phosphokinase and with at least 1 of the following: 1) symptoms of ischemia; 2) new or presumed new significant ST-segment T-wave changes; 3) development of pathological Q waves on the electrocardiogram; 4) imaging evidence of new loss of viable myocardium or new regional wall motion abnormality. Dyslipidemia was regarded as low-density lipoprotein cholesterol ≥140, triglyceride level ≥150, and high-density lipoprotein cholesterol <40 or a patient under medical treatment for dyslipidemia. Ambulatory status was defined as ambulatory (including crutch walking) without a walking aid in daily life before the onset of CLI. Patients requiring a walker or wheelchair or bedridden patients were classified as nonambulatory. A 2YLE was regarded as >50% probability of a 2-year survival rate. Coronary artery disease was defined as stable angina with documented coronary artery disease, a history of percutaneous coronary intervention or coronary artery bypass graft surgery, or previous myocardial infarction. Cerebrovascular disease was defined as a hospital or neurologist report of the diagnosis of transient ischemic attack or ischemic stroke.

OUTCOME MEASURES. The primary outcome measure was to estimate the 2YLE by using the risk score based on predictors of all-cause mortality within 2 years. The secondary outcome measures were causes of death and prognostic factors at 2 years.

STATISTICAL ANALYSIS. Values are reported as mean ± SD. Continuous variables were examined using an unpaired Student *t* test. Categorical variables were compared by using the chi-square test. Logistic regression analyses were performed to investigate the association of baseline characteristics with the outcome; the depend using variable was death within 2 years and the explanatory variables were the baseline characteristics. The independent prognostic factors

ABBREVIATIONS AND ACRONYMS

2YLE = 2-year life expectancy
BMI = body mass index
CI = confidence interval
CLI = critical limb ischemia
EVT = endovascular therapy
LVEF = Left ventricular ejection fraction
OR = odds ratio

TABLE 1 Patient Characteristics

	Overall (n = 995)	Nonsurvivors (n = 412)	Survivors (n = 583)	p Value
Age, yrs				
<65	220 (22)	66 (70)	154 (30)	<0.001
65–79	527 (53)	221 (58)	306 (42)	
≥80	248 (25)	125 (50)	123 (50)	
Female	335 (34)	140 (34)	195 (33)	0.86
BMI, kg/m^2				
≥20.0	647 (65)	221 (34)	426 (66)	<0.001
18.0–19.9	213 (21)	106 (50)	107 (50)	
<18.0	135 (14)	85 (63)	50 (37)	
Ambulatory	560 (56)	156 (38)	404 (69)	<0.001
Hypertension	745 (75)	304 (74)	441 (76)	0.51
Dyslipidemia	380 (38)	129 (31)	251 (43)	<0.001
Diabetes	695 (70)	279 (68)	416 (71)	0.22
Hemodialysis	587 (59)	282 (68)	305 (52)	<0.001
Current smoker	300 (30)	116 (28)	184 (32)	0.25
Cerebrovascular disease	272 (27)	140 (34)	132 (23)	<0.001
Coronary artery disease	541 (54)	230 (56)	311 (53)	0.44
LVEF, %				
≥50	739 (74)	263 (36)	476 (64)	<0.001
40–49	134 (13)	73 (54)	61 (46)	
<40	120 (12)	75 (63)	45 (38)	
Rutherford class				
4	245 (25)	58 (14)	187 (32)	<0.001
5	505 (51)	211 (51)	294 (50)	
6	245 (25)	143 (35)	102 (17)	
Tissue loss	750 (75)	354 (86)	396 (68)	<0.001
Medication				
Aspirin	784 (79)	334 (81)	450 (77)	0.14
Thienopyridine	385 (39)	151 (37)	234 (40)	0.27
Cilostazol	498 (50)	196 (48)	302 (52)	0.19
Statin	224 (23)	74 (18)	150 (26)	0.004
Beta-blocker	169 (20)	81 (22)	88 (18)	0.12
Anticoagulant agent	197 (20)	91 (22)	106 (18)	0.13

Values are n (%).
BMI = body mass index; LVEF = left ventricular ejection fraction.

were determined by the multivariate model in which all the baseline characteristics were entered. The predictive risk score for assessing the 2YLE was thereafter developed on the basis of another multivariate model the explanatory variables of which were limited to all the independent prognostic factors. In the development of the risk score, weighted points on the basis of the regression coefficients in this model were assigned to the prognostic factors. To develop such a simple score that could be easily calculated in clinical practice, the point of each prognostic factor was set between 1.0 and 3.0 points in 0.5-point units. The survival rates observed in the study population were plotted according to the developed risk scores. Error bars indicate their 95% confidence intervals (CIs) calculated by the Clopper-Pearson exact method. The 2YLE was estimated by the penalized cubic regression spline model. A p value <0.05 was considered to be significant, and 95% CIs were given when required. All statistical analyses were performed using SPSS Statistics Version 19 (SPSS Inc., Chicago, Illinois).

RESULTS

BASELINE CHARACTERISTICS. Of the 995 subjects enrolled in the study, 412 (41%) died within 2 years. The subjects in the nonsurvivor group were older than those in the 2-year survivor group (74 ± 10 vs. 71 ± 11 years of age, $p < 0.0001$). The rates of ambulatory status (38% vs. 69%, $p < 0.001$), hyperlipidemia (31% vs. 43%, $p < 0.001$), and use of a statin (38% vs 69%, $p < 0.001$) were lower in the nonsurvivor group, and those of hemodialysis (68% vs. 52%, $p < 0.001$), cerebrovascular disease (34% vs. 23%, $p < 0.001$), and Rutherford class ($p < 0.001$) were higher (Table 1).

CAUSES OF DEATH. The causes of death in the 412 subjects were cardiac in 121 (29%), vascular in 41 (10%), sudden death in 32 (8%), noncardiovascular in 191 (46%), and unknown in 27 (7%) (Table 2). Cardiovascular death, including sudden death, accounted for 47% (194 of 412) of all deaths. The most common cause of cardiac death in the nonsurvivor group was heart failure, followed by acute myocardial infarction and ventricular fibrillation, which suggests that management of heart failure and prevention of ischemic cardiac events are important in CLI patients. The noncardiovascular causes of death included sepsis, pneumonia, and malignant tumors. A total of 142 subjects (34%) died of infectious disease, which accounted for most of the noncardiovascular deaths.

2-YEAR LIFE EXPECTANCY. On multivariate analysis of 2-year mortality (Figure 1), the independent prognostic factors were 65 to 79 years of age (odds ratio [OR]: 1.9; $p < 0.001$), 80 years of age or older (OR: 3.7; $p < 0.001$), body mass index (BMI) 18.0 to 19.9 kg/m^2 (OR: 1.5; $p = 0.022$), BMI <18.0 kg/m^2 (OR: 2.9; $p < 0.001$); nonambulatory status (OR: 2.4; $p < 0.001$), hemodialysis (OR: 2.1; $p < 0.001$), cerebrovascular disease (OR: 1.6; $p = 0.004$), left ventricular ejection fraction (LVEF) 40% to 49% (OR: 1.8; $p = 0.005$), LVEF <40% (OR: 2.6; $p = 0.005$), Rutherford class 5 (OR: 1.9; $p = 0.001$), and Rutherford class 6 (OR: 3.4; $p < 0.001$) (Table 3). Clinical procedural failure did not affect the 2YLE (OR: 1.07; 95% CI: 0.60 to 1.91; $p = 0.83$). Furthermore, bypass conversion after EVT did not affect the 2YLE (OR: 1.14; 95% CI: 0.68 to 1.92; $p = 0.62$).

On the basis of the multivariate model, the risk score for a 2YLE was developed (2YLE score, full score: 15 points) (Table 4). Figure 1 shows the survival rate when the subjects were stratified on the basis of the scores specified for this study and the 2-year

TABLE 2 Causes of Death

Cardiac death (n = 121, 29%)	
Heart failure	45
Acute myocardial infarction	27
Ventricular fibrillation	12
Aortic stenosis	5
Cardiogenic shock	4
Infectious endocarditis	1
Unknown	27
Vascular death (n = 41, 10%)	
Stroke	21
Renal failure	13
Ischemic colitis	7
Sudden death (n = 32, 8%)	32
Noncardiovascular death (n = 191, 46%)	
Sepsis	72
Pneumonia	48
Other infection	22
Malignancy	21
Multiple organ failure	12
Intestinal bleeding	6
Unknown (n = 27, 7%)	27

Values are n.

survival rate, which was estimated on the basis of the scores specified for this study. Patients with a high score had a higher risk of mortality. This scale predicts that patients with a score ≥8 points will not likely survive for ≥2 years. Such patients accounted for 31% (312 of 995) in the current study.

DISCUSSION

This study on the 2YLE of CLI patients undergoing EVT revealed multiple mortality-related factors. This finding suggests that a comprehensive assessment of mortality risk, rather than assessment of a single factor, will provide a more accurate predicted life expectancy. Previous studies investigated prognostic factors of perioperative death and composite outcomes including mortality in CLI patients undergoing EVT. They reported that the prognostic factors include gangrene, renal failure, heart failure, BMI <18, nonambulatory status, and left ventricular dysfunction (5,6). These findings suggest that EVT seems to be appropriate as first-line therapy in CLI patients with a shorter life expectancy. Although the importance of this concept has been fully understood, it is actually difficult to carry out in daily practice. From these standpoints, it was considered that there are quite a few meanings of this study.

Cardiovascular death is the most common cause of death in patients with peripheral arterial disease (7), but causes of death in CLI patients have not been fully studied. Cardiac death and infectious diseases were the main causes of death in the current study. Infectious disease, including sepsis and pneumonia, occurred in 142 subjects (34%) and was the most common noncardiovascular cause of death.

With regard to oral medication, the efficacy of statins (8) and optimal medical therapy (9) for the prevention of cardiovascular events has been reported in clinical guidelines (7). In the current study, the univariate analysis showed that life expectancy was associated with oral administration of aspirin (OR: 1.5; p = 0.04), thienopyridine (OR: 0.9; p = 0.35), cilostazol (OR: 0.7; p = 0.047), anticoagulant agent (OR: 1.1; p = 0.65), statin (OR: 0.8; p = 0.39), and beta-blocker (OR: 1.4; p = 0.11), but none of these oral drugs emerged as independent predictors on multivariate analysis. The variable stepwise selection model also did not identify any of these drugs as important factors. One possible explanation might be that a longer observation period is needed for these therapies to provide beneficial effects on the prevention of cardiovascular events. Another explanation might be that the common causes of 2-year mortality were infectious diseases and sudden death, in addition to cardiovascular events; the impact of cardiovascular events on all-cause mortality might be relatively small in CLI patients. However, the influence of medical therapy on CLI remains unclear. To verify these findings, detailed data regarding medical therapy including follow-up are needed.

The 2YLE is an important factor in the selection of bypass surgery or EVT in CLI patients (2), but

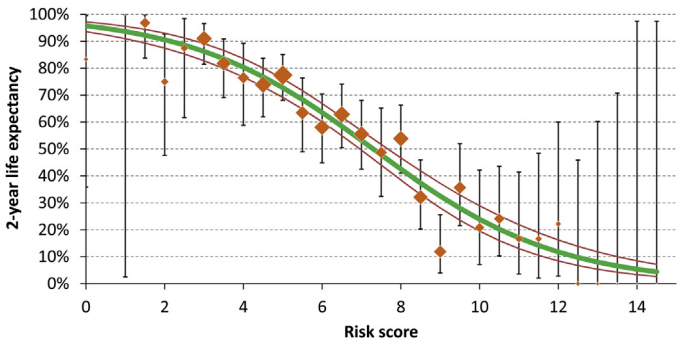

FIGURE 1 Two-Year Life Expectancy in Each Risk Score

The plotted **orange diamonds** represent the 2-year life expectancy observed in the study population when they were stratified according to the developed risk scores. Error bars indicate their 95% confidence intervals calculated by the Clopper-Pearson exact method. The **size of each diamond** represents the sample number, which ranged from 1 (risk score = 1, 14, and 14.5) to 102 (risk score = 5). The **bold green line** represents the 2-year life expectancy estimated by the penalized cubic regression spline model. The **thin lines** indicate the 95% confidence intervals.

TABLE 3 Predictors of Death

	Univariate Model Unadjusted OR (95% CI)	Multivariate Model 1 Adjusted OR (95% CI)	Multivariate Model 2 Adjusted OR (95% CI)
Male	1.0 (0.7–1.3), p = 0.861	0.8 (0.6–1.2) (p = 0.314)	
Age, yrs			
<65	1.0 (Ref.)	1.0 (Ref.)	1.0 (Ref.)
65–79	1.7 (1.2–2.4), p = 0.002	2.0 (1.3–2.9), p < 0.001	1.9 (1.3–2.8), p < 0.001
≥80	2.4 (1.6–3.5), p < 0.001	3.6 (2.2–5.7), p < 0.001	3.7 (2.3–5.8), p < 0.001
Body mass index (vs. ≥20.0 kg/m^2)	1.0 (Ref.)	1.0 (Ref.)	1.0 (Ref.)
18.0–19.9	1.9 (1.4–2.6), p < 0.001	1.5 (1.0–2.1), p = 0.039	1.5 (1.1–2.2), p = 0.022
<18.0	3.3 (2.2–4.8), p < 0.001	2.8 (1.8–4.3), p < 0.001	2.9 (1.9–4.5), p < 0.001
Nonambulatory status	3.7 (2.8–4.8), p < 0.001	2.4 (1.8–3.3), p < 0.001	2.4 (1.7–3.2), p < 0.001
Hypertension	0.9 (0.7–1.2), p = 0.506	1.1 (0.8–1.6), p = 0.507	
Hyperlipidemia	0.6 (0.5–0.8), p < 0.001	0.8 (0.6–1.1), p = 0.118	
Diabetes mellitus	0.8 (0.6–1.1), p = 0.218	0.8 (0.6–1.2), p = 0.315	
Smoking	0.8 (0.6–1.1), p = 0.249	1.2 (0.9–1.7), p = 0.234	
Hemodialysis	2.0 (1.5–2.6), p < 0.001	2.2 (1.6–3.0), p < 0.001	2.1 (1.6–2.9), p < 0.001
Cerebrovascular disease	1.8 (1.3–2.3), p < 0.001	1.6 (1.2–2.2), p = 0.004	1.6 (1.2–2.2), p = 0.004
Coronary artery disease	1.1 (0.9–1.4), p = 0.439	0.9 (0.7–1.3), p = 0.728	
Ejection fraction, % (vs. ≥50%)	1.0 (Ref.)	1.0 (Ref.)	1.0 (Ref.)
40–49	2.2 (1.5–3.1), p < 0.001	1.8 (1.2–2.8), p = 0.006	1.8 (1.2–2.8), p = 0.005
<40	3.0 (2.0–4.5), p < 0.001	2.7 (1.7–4.2), p < 0.001	2.6 (1.7–4.0), p < 0.001
Rutherford classification (vs. class 4)	0.0 (0.0–0.0), p < 0.001	0.0 (0.0–0.0), p < 0.001	0.0 (0.0–0.0), p < 0.001
Class 5	2.3 (1.6–3.3), p < 0.001	1.9 (1.3–2.8), p < 0.001	1.9 (1.3–2.7), p = 0.001
Class 6	4.5 (3.1–6.7), p < 0.001	3.4 (2.2–5.4), p < 0.001	3.4 (2.2–5.2), p < 0.001
Isolated infrapopliteal disease	1.0 (0.8–1.3), p = 0.900	1.0 (0.7–1.4), p = 0.953	

In multivariate model 1, all the baseline characteristics were entered. In the multivariate model 2, the variables that were significant in the multivariate model 1 were entered.
CI = confidence interval; OR = odds ratio; Ref. = reference.

this decision is not easy. In this study, we scored the predictors of the 2YLE, and stratified the risk to evaluate the 2YLE. Several studies predicted the prognosis using a single factor (10), prognostic factors (11,12), and scoring systems (13,14), but this is the first study to evaluate the 2YLE on the basis of multiple independent prognostic factors for 2-year mortality, including age, BMI, nonambulatory status, hemodialysis, cerebrovascular disease, LVEF, and tissue loss. Our results suggest that a scoring system on the basis of a combination of these factors can help to predict life expectancy and may make an important contribution to deciding on a treatment strategy for CLI patients. Patients with scores ≥8 points have a 2YLE <50%, which suggests that EVT is preferable for revascularization in these cases. Furthermore, because a graft of a diameter ≤3 mm is likely to be occluded (15) and severe ischemic heart disease and heart failure are at high risk with general anesthesia, EVT will be also favorable for patients without a good vein conduit and with these severe comorbidities, even if the patients had a score of <8 points (≥50% probability of 2-year survival). However, this study was performed with only patients undergoing EVT, not all CLI patients, because those who underwent bypass surgery were not included. Because the aim of this study was to aid the decision-making process about different procedures (EVT or bypass), it seemed to be a weak point that it does not include patients who underwent a bypass. However, in this study, it is difficult to compensate for the selection bias. Therefore, future work should include prospectively

TABLE 4 Two-Year Life Expectancy Score in CLI Patients

Variables	Score*
Nonambulatory status	2.0
Rutherford class	
5	1.5
6	3.0
Cerebrovascular disease	1.0
Hemodialysis	2.0
BMI, kg/m^2	
18.0–19.9	1.0
<18.0	2.0
Age, yrs	
65–79	1.5
≥80	3.0
Ejection fraction, %	
40–49	1.5
<40	2.0

*Full score = 15 points.
BMI = body mass index; CLI = critical limb ischemia.

assessing the ability of the score to predict life expectancy before the score is used clinically.

STUDY LIMITATIONS. First, the study was a retrospective analysis, despite the use of a large-scale prospectively maintained database. Second, selection bias could be present because the evaluation of 2YLE in CLI patients excluded 128 patients with missing data and 497 patients who were not known to be dead or alive and had a follow-up period <730 days. Exclusion of these patients could have caused the mortality to be overestimated. The validation in a separate sample should be performed. Also, this analysis does not include CLI patients who underwent bypass surgery. Therefore, the possibility of selection bias cannot be denied. Further investigation is needed to judge the validity of these findings in both treatments (EVT and bypass surgery), although it has been reported that the mortality up to 2 years between CLI patients who underwent revascularization was almost similar (1). Last, multiple factors that are considered to be historically important may influence the evaluation of the 2YLE, but this study focused on database items only. Therefore, other factors such as socioeconomic status and insurance status, which were not evaluated in this study, may be prognostic factors. Overall health status such as frailty (16,17) should be included in the prediction of life expectancy of CLI patients. Collection of more data is needed to examine the effects of frailty and other factors on life expectancy in these patients.

CONCLUSIONS

We evaluated the causes of death and the 2YLE in CLI patients. The most common causes of death were cardiovascular events and infections, and the independent prognostic factors for the 2YLE were age, BMI, ambulatory status, hemodialysis, cerebrovascular disease, LVEF, and tissue loss. A 2YLE score was calculated from the hazard ratios for these factors. A score of ≥8 points indicated a <50% probability of 2-year survival. We suggested that this score seemed to be helpful for identifying CLI patients with a poor prognosis who may be more suitably treated with EVT rather than bypass surgery.

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