Paramalleolar Arterial Bollinger Score in the Era of Diabetes and End-Stage Renal Disease
– Usefulness for Predicting Operative Outcome of Critical Limb Ischemia –

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Background: The aim of this study was to evaluate the usefulness of paramalleolar arterial Bollinger score (PBS) for predicting postoperative outcome of infra-popliteal bypass surgery for critical limb ischemia (CLI).

Methods and Results: A total of 104 consecutive patients (118 limbs) who underwent infra-popliteal (tibial or paramalleolar) arterial bypass surgery with an autologous vein conduit for the treatment of CLI (Rutherford 4–6) between January 2002 and December 2012 were classified according to PBS ≤45 or >45. Postoperative outcome was compared between these groups. Primary outcomes were major adverse limb events plus perioperative death, and amputation-free survival (AFS). The secondary outcomes were overall survival, limb salvage and secondary graft patency. More than 80% of patients had either diabetes mellitus (DM) or end-stage renal disease (ESRD) and 30 patients with 36 limbs had PBS >45. Compared with the PBS ≤45 group, the PBS >45 group had higher CVD and carotid stenosis rate, poor nutrition status and lower malignancy rate. On overall analysis, the PBS >45 group had worse outcome for AFS and survival but this was not statistically significant (P=0.12, NS). In DM or ESRD patients, the PBS >45 group had significantly worse outcome for both AFS (P=0.04, 0.02) and overall survival rate (P=0.04, 0.03).

Conclusions: PBS successfully classified CLI patients with DM or ESRD who had worse outcome after infra-popliteal bypass surgery. (Circ J 2016; 80: 235–242)

Key Words: Bollinger score; Critical limb ischemia; Diabetes mellitus; Distal bypass; End-stage renal disease

Peripheral artery disease (PAD) reflects the status of systemic atherosclerosis and has been found to have similarly bad prognosis to that of cancer. Critical limb ischemia (CLI) is the end result of PAD and approximately 40% of CLI patients require limb amputation within 1 year. As for treatment strategy, in addition to pharmacologic approach and lifestyle management including smoking cessation, autologous vein bypass for tibial or paramalleolar arteries is the main target of therapy to achieve total revascularization in the management of complicated infra-popliteal disease burden. Nowadays, a large proportion of CLI patients have diabetes mellitus (DM), along with severe comorbidities that directly affect postoperative outcome, especially atherosclerosis-related disease such as end-stage renal disease (ESRD), cerebrovascular disease (CVD) and ischemic heart disease (IHD). There are a number of clinical studies on postoperative outcome and risk factors in patients with CLI. Of these, the Bypass vs. Angioplasty in Severe Ischemia of the Leg (BASIL) trial used the Bollinger score system to analyze arterial condition and postoperative outcome in severe limb ischemia patients. In the BASIL trial, mean below-knee Bollinger angiography score was an independent risk factor for both time to death after operation and amputation-free survival (AFS). Although this trial has been recognized as one of the most significant studies in the field of vascular surgery, there have been few further studies on the Bollinger score system.

In the present study, we analyzed CLI patients who underwent infra-popliteal bypass surgery, from the point of view of anatomic disease, using the paramalleolar arterial Bollinger...
perioperative death (MALE+POD) and AFS. The secondary outcomes were overall survival, limb salvage and secondary graft patency. MALE was defined as above-ankle amputation of the index limb or major reintervention (new bypass graft, jump or interposition graft revision, thrombectomy or thrombolysis). POD was defined as death within 30 days after operation. AFS was defined as above-ankle amputation of the index limb or death (any cause). Limb salvage was defined as preservation of enough of the foot to allow ambulation and included feet requiring a toe, or ray (finger amputation), or transmetatarsal amputation after bypass surgery. Patients receiving Syme’s amputation, or below- or above-knee amputation were included in the limb loss criteria.

The study protocol was carried out according to the Declaration of Helsinki and the institutional ethics policies. All patients provided informed consent, and all procedures were performed in accordance with the standards of the institutional ethics committee.

**Indications for Surgery and Preoperative Assessment**

The exclusion criteria for distal bypass were as follows: poor condition (respiratory impairment, severe impairment of coronary function, non-ambulatory status with CVD); surgery under general anesthesia considered impossible; expected short life expectancy due to cancer or other diseases; infection or necrosis of the ischemic foot extending above heel level and unable to be controlled by medication; lack of appropriate autologous vein or anastomosis arterial site; non-ambulatory status caused by consciousness disorder or paralysis or contraction; and patient refusal of arterial reconstruction. In order to reduce postoperative mortality rate, all patients underwent systemic organ function assessment. In the case that severe stenosis of coronary arteries or valve stenosis was confirmed on coronary angiography, computed tomography angiography (CTA) or ultrasonic cardiography, cardiac surgery or percutaneous coronary intervention (PCI) was performed before infra-popliteal bypass surgery.

**Surgical Procedure**

The operative techniques have been previously described. Bypass target sites were selected based on preoperative imaging (CTA and IADSA). When several candidates were available for an anastomotic site, the angiosome concept was used to choose the optimal one. In the case of isolated popliteal lesion, sequential bypass was performed. In this study, paramalleolar bypass was performed in 48% of patients. Reversed autologous vein graft was used for 98% of patients and sequential bypass was performed in 22% of patients (Table S1). All patients regularly received oral antplatelet agents (aspirin, ticlopidine or clopidogrel) at the time of discharge and were followed at 1–3-month intervals. Graft revision operation was performed when severe stenosis or occlusion of vein graft or stenosis of anastomotic sites was seen on Doppler ultrasonography or CTA.

**Variables**

Demographic variables were collected and detailed vascular exam carried out prior to surgery as part of a comprehensive history and physical examination (Table 1). Data analysis also included hypertension (defined as systemic blood pressure >140 mmHg, diastolic blood pressure >90 mmHg, or both; or use of antihypertensive medications), DM (use of anti-diabetic treatment or documented presence), dyslipidemia (use of lipid-lowering therapy), smoking status (current or former), CVD, carotid stenosis, and ESRD. IHD was defined as history of myocardial infarction, acute coronary syndrome, or angina

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**Methods**

**Study Design**

Between January 2002 and December 2012, 106 consecutive patients (120 limbs) with PAD and CLI (rest pain, gangrene, non-healing ischemic ulcer; Rutherford classification 4–6) who underwent infra-popliteal (tibial or paramalleolar) arterial bypass at The University of Tokyo Hospital were enrolled in this study (Table 1). Of these, 2 patients were excluded from the study because of insufficient preoperative imaging (contrast media allergy and emergency operation). Intra-arterial digital subtraction angiography (IADSA) was done for all patients before bypass surgery and the Bollinger score of the paramalleolar region (distal half of anterior/posterior tibial artery, peroneal artery and plantar arch) was estimated. The patients were then classified according to PBS ≤45 or >45, and postoperative outcome was compared between these 2 groups.

Patient clinical data were based on hospital medical records. The primary outcomes were major adverse limb events plus perioperative death (MALE+POD) and AFS. The secondary outcomes were overall survival, limb salvage and secondary graft patency.

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**Table 1. Baseline Characteristics: Present Study vs. BASIL Trial**

| Patient characteristics (n=104) | BASIL trial† |
|-------------------------------|-------------|
| Age (years)                   | 69±10       |
| ≥80 years old                | 17 (17)     |
| Male gender                   | 79 (76)     |
| Hypertension                  | 88 (85)     |
| Dyslipidemia                  | 41 (39)     |
| DM                            | 80 (77)     |
| Smoking history               | 75 (72)     |
| IHD                           | 68 (65)     |
| Ejection fraction (%)         | 63±12       |
| CVD and carotid stenosis      | 36 (35)     |
| Respiratory disorder          | 15 (14)     |
| Malignancy                    | 15 (14)     |
| ESRD                          | 62 (60)     |
| Anti-platelet agents          | 90 (86)     |
| Limb and nutrition status (n=118) |            |
| ABI                           | 0.56±0.35   |
| Ankle pressure (mmHg)         | 80±52       |
| Skin perfusion pressure (mmHg)| 22±11       |
| Rutherford                    |             |
| 4                             | 9 (8)       |
| 5                             | 92 (78)     |
| 6                             | 17 (14)     |
| Infection of the ischemic foot| 40 (34)     |
| PBS 40±9                      |             |
| >45                           | 36 (31)     |
| Serum albumin (g/dl)          | 3.4±0.6     |
| Albumin <0.3.g/dl             | 23 (19)     |
| Hemoglobin <10.0.g/dl         | 39 (33)     |

Data given as mean±SD or n (%). †Baseline characteristics of bypass-first procedure group. ABI, ankle-brachial index; CVD, cerebrovascular disease; DM, diabetes mellitus; ESRD, end-stage renal disease; IHD, ischemic heart disease; PBS, paramalleolar Bollinger score.

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score (PBS), and assessed how PBS related to postoperative outcome.
PBS in the New Era

According to the original scoring method, PBS was defined as the sum of the scores for each of the 4 target arteries (maximum, 60; minimum, 0; Figure 1). PBS threshold for differentiating postoperative outcome was arbitrarily defined as >45, which is clinically equivalent to severe occlusive lesions in 4 of the 3 arteries of the paramalleolar segment, and stenosis or occlusion in the other artery.

Inter-Observer Reliability

The results for 50 patients were studied in order to assess inter-observer reliability of the scoring method between the 2 vascular surgeons. After this trial, cause of discrepancy was discussed and cut-off score defined, and the number of patients was increased to >100. As part of this procedure, IADSA for each patient was studied more than twice after a 1-year interval, and the reliability of each patient’s score confirmed.

Statistical Analysis

Statistical analysis was performed using JMP® pro ver.9 (SAS Institute, Cary, NC, USA). Data are given as mean±SD. Prognostic outcome was estimated using the Kaplan-Meier method, and statistical differences were estimated using log-rank test. Multivariate analysis was estimated using the Cox regression proportional hazards model. P<0.05 was defined as statistically significant.

Results

Approximately 80% of patients had DM and 60% had ESRD, pectoris and/or PCI, coronary artery bypass graft, or history of >70% stenosis of the coronary artery confirmed on coronary angiogram. CVD was defined as history of cerebrovascular accident. Carotid stenosis was defined as >70% stenosis of the internal carotid artery. ESRD was defined as requirement of hemodialysis. Other variables included nutritional assessment (albumin, hemoglobin), use of medication (antiplatelet agents) and the presence of cancer. Respiratory disorder was defined as forced expiratory volume in 1s/forced vital capacity <0.70.

Diagnosis of CLI was defined according to Trans Atlantic Inter-Society Consensus (TASC II) guidelines. For patients with ulcers or gangrene, the presence of CLI is confirmed on ankle pressure (AP) <70 mmHg, and for patients with ischemic rest pain it is defined as AP <50 mmHg. Skin perfusion pressure (SPP) was used to assist diagnosis when target AP was not properly measured. Ischemic lower extremity SPP <40 mmHg was diagnosed as CLI. Infection of the ischemic foot was defined as edema or induration, elevated C-reactive protein, and/or a positive germ culture of purulent discharge.

PBS

Digital subtraction angiography of each segment of artery (common iliac artery/common femoral artery/popliteal artery/anterior and posterior tibial artery/peroneal artery/plantar arch) was carried out routinely before distal bypass surgery. In this study, lateral view of angiogram of the foot was used to estimate each of the 4 feeding arteries (distal half of anterior/posterior tibial artery, peroneal artery and plantar arch) according to the original scoring method. PBS was defined as the sum of the scores for each of the 4 target arteries (maximum, 60; minimum, 0; Figure 1). PBS threshold for differentiating postoperative outcome was arbitrarily defined as >45, which is clinically equivalent to severe occlusive lesions in 4 of the 3 arteries of the paramalleolar segment, and stenosis or occlusion in the other artery.

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Results

Approximately 80% of patients had DM and 60% had ESRD,
Table 2. Baseline Characteristics vs. Bollinger Score (n=104)

| PBS          | ≤45 (n=74) | >45 (n=30) | P-value |
|--------------|-----------|-----------|---------|
| Age (years)  | 69±1      | 70±2      | 0.71†   |
| Age ≥80 years old | 11 (15) | 6 (20) | 0.52    |
| Male gender  | 55 (74)   | 24 (80)   | 0.54    |
| Hypertension | 63 (85)   | 25 (83)   | 0.82    |
| Dyslipidemia | 33 (45)   | 8 (27)    | 0.09    |
| DM           | 58 (78)   | 22 (73)   | 0.58    |
| Smoking history | 55 (74) | 20 (67) | 0.43    |
| IHD          | 47 (64)   | 21 (70)   | 0.53    |
| Ejection fraction (%) | 63±12    | 63±12     | 0.76†   |
| CVD and carotid stenosis | 21 (29) | 15 (45) | 0.04    |
| Respiratory disorder | 9 (12) | 6 (20) | 0.30    |
| Malignancy   | 15 (18)   | 0 (0)     | <0.01   |
| ESRD         | 45 (61)   | 17 (57)   | 0.70    |

Limb and nutrition status

| (n=82)      | (n=36)    |         |
|-------------|-----------|---------|
| Rutherford 6 | 12 (15)   | 5 (14)  | 0.98    |
| Preoperative ABI | 0.6±0.1 | 0.5±0.1 | 0.41†   |
| Ankle pressure (mmHg) | 83±7 | 73±11 | 0.47†   |
| Skin perfusion pressure (mmHg) | 21±2 | 24±2 | 0.33†   |
| Infection of the ischemic foot | 25 (30) | 15 (42) | 0.24    |
| Serum albumin (g/dl) | 3.5±0.1 | 3.1±0.1 | 0.01†   |
| Albumin <3.0 g/dl | 14 (17) | 9 (25) | 0.32    |
| Hemoglobin <10.0 g/dl | 23 (28) | 16 (44) | 0.08    |

Surgical procedure

| (n=82)      | (n=36)    |         |
|-------------|-----------|---------|
| Paramalleolar bypass | 30 (37) | 12 (33) | 0.73    |

Data given as mean±SD or n (%). †Student’s t-test. Abbreviations as in Table 1.

Table 3. DM Patient Characteristics vs. Bollinger Score

| PBS          | ≤45 (n=58) | >45 (n=22) | P-value |
|--------------|-----------|-----------|---------|
| Age (years)  | 68±1      | 68±2      | 0.89†   |
| Age ≥80 years old | 7 (12) | 3 (14) | 0.85    |
| Male gender  | 35 (60)   | 13 (59)   | 0.91    |
| Hypertension | 53 (91)   | 18 (82)   | 0.23    |
| Dyslipidemia | 27 (47)   | 7 (32)    | 0.23    |
| ESRD         | 41 (71)   | 14 (64)   | 0.54    |
| Smoking history | 44 (76) | 14 (64) | 0.27    |
| IHD          | 41 (71)   | 16 (73)   | 0.86    |
| Ejection fraction (%) | 62±13    | 62±12     | 0.90†   |
| CVD and carotid stenosis | 17 (29) | 10 (45) | 0.17    |
| Respiratory disorder | 6 (10) | 3 (14) | 0.68    |
| Malignancy   | 13 (22)   | 0 (0)     | <0.01   |

Limb and nutrition status

| (n=65)      | (n=28)    |         |
|-------------|-----------|---------|
| Rutherford 6 | 12 (19)   | 5 (18)  | 0.95    |
| Preoperative ABI | 0.7±0.1 | 0.5±0.1 | 0.13†   |
| Ankle pressure (mmHg) | 106±10  | 77±17   | 0.13†   |
| Skin perfusion pressure (mmHg) | 22±2  | 23±3    | 0.66†   |
| Infection of the ischemic foot | 21 (32) | 4 (14) | 0.11    |
| Serum albumin (g/dl) | 3.5±0.1 | 2.9±0.2 | <0.01†  |
| Albumin <3.0 g/dl | 12 (19) | 9 (32) | 0.15    |
| Hemoglobin <10.0 g/dl | 17 (26) | 14 (50) | 0.03    |

Data given as mean±SD or n (%). †Student’s t-test. Abbreviations as in Table 1.
Table 4. ESRD Patient Characteristics vs. Bollinger Score

| PBS      | ≤45 (n=45) | >45 (n=17) | P-value |
|----------|------------|------------|---------|
| Age (years) | 66±1       | 66±2       | 0.91†   |
| Age ≥80 years old | 3 (7)       | 0 (0)      | 0.28    |
| Male gender | 35 (60)     | 13 (59)    | 0.91    |
| Hypertension | 39 (87)     | 14 (82)    | 0.67    |
| Dyslipidemia | 21 (47)     | 5 (29)     | 0.22    |
| DM       | 36 (91)     | 16 (82)    | 0.33    |
| Smoking history | 32 (71)     | 11 (65)    | 0.63    |
| IHD      | 30 (67)     | 13 (76)    | 0.46    |
| Ejection fraction (%) | 61±14       | 59±14      | 0.65†   |
| CVD and carotid stenosis | 12 (27)     | 9 (53)     | 0.05    |
| Respiratory disorder | 1 (2)       | 1 (6)      | 0.47    |
| Malignancy | 11 (21)     | 0 (0)      | 0.02    |

| Limb and nutrition status | (n=50) | (n=22) |
|---------------------------|--------|--------|
| Rutherford 6 | 8 (16) | 5 (23) | 0.49   |
| Preoperative ABI | 0.7±0.1 | 0.5±0.1 | 0.07† |
| Ankle pressure (mmHg) | 104±7  | 71±14  | 0.07†  |
| Skin perfusion pressure (mmHg) | 22±2 | 25±3 | 0.34† |
| Infection of the ischemic foot | 16 (32) | 9 (41) | 0.50   |
| Serum albumin (g/dl) | 3.4±0.1 | 3.1±0.1 | 0.13† |
| Albumin <3.0 g/dl | 9 (18) | 6 (27) | 0.37   |
| Hemoglobin <10.0 g/dl | 19 (38) | 14 (64) | 0.04   |

Data given as mean±SD or n (%). †Student’s t-test. Abbreviations as in Table 1.

Figure 2. Comparison of postoperative outcome between paramalleolar arterial Bollinger score (PBS) >45 and ≤45 in the whole patient group. (A) Freedom from major adverse limb events plus perioperative death (MALE+POD) rate; (B) amputation-free survival (AFS) rate; (C) overall survival rate; (D) limb salvage rate; and (E) secondary graft patency rate.
Figure 3. Comparison of postoperative outcome between paramalleolar arterial Bollinger score (PBS) >45 and ≤45 in diabetes mellitus patients. (A) Freedom from major adverse limb events plus perioperative death (MALE+POD) rate; (B) amputation-free survival (AFS) rate; (C) overall survival rate; (D) limb salvage rate; and (E) secondary graft patency rate.

Figure 4. Comparison of postoperative outcome between paramalleolar arterial Bollinger score (PBS) >45 and ≤45 in end-stage renal disease patients. (A) Freedom from major adverse limb events plus perioperative death (MALE+POD) rate; (B) amputation-free survival (AFS) rate; (C) overall survival rate; (D) limb salvage rate; and (E) secondary graft patency rate.
and 50% of patients had both as baseline comorbidities. ESRD patients had markedly high AP and ankle-brachial index (ABI) due to severe calcification of arteries, and thus mean AP and ABI were higher than the defined cut-offs given in the previous section. A total of 65% of patients had poly-vascular disease (IHD or CVD or carotid stenosis). More than 90% of limbs were classified as Rutherford 5 or 6, and 33% of patients had poor nutrition (hemoglobin <10.0 g/dl or serum albumin <3.0 g/dl; Table 1).

As a result, 30 patients with 36 limbs had PBS >45. Compared with the PBS ≤45 group, the PBS >45 group had higher CVD and carotid stenosis rate and lower malignancy rate. The PBS >45 group also had poor nutrition status (lower serum albumin) compared with the PBS ≤45 group. Proportion of type of surgical procedure (tibial or paramalleolar bypass) was not different between these groups (Table 2). In the subanalysis of DM patients, the PBS >45 patients still had poor nutrition status and higher CVD and carotid stenosis rate (Table 3). This tendency was the same in the subanalysis of ESRD patients (Table 4). On multivariate analysis, CVD and carotid stenosis (HR, 2.43; 95% CI: 1.07–5.60; P=0.030) was an independent risk factor for PBS >45 (Table S2).

There were 13 major amputation events and 29 deaths in the observation period. Mean observation period was 41±27 months. Freedom from MALE+POD rate was 79%, 75%, and 68% at 1, 3, and 5 years, while AFS rate was 89%, 76%, and 60% at 1, 3, and 5 years, respectively. Overall survival rate was 93%, 81%, and 66% at 1, 3, and 5 years, respectively. Limb salvage rate was 91%, 90%, and 86% at 1, 3, and 5 years, while secondary graft patency rate was 91%, 89%, and 85% at 1, 3, and 5 years, respectively (Figure S1).

The PBS >45 group had poorer AFS and survival but this was not statistically significantly different (P=0.12). Freedom from MALE+POD was not different between these groups (P=0.22). The PBS >45 group had worse overall survival (P=0.18) and limb salvage rate (P=0.14) but this was not statistically significantly different. Secondary graft patency rate was not different between these groups (P=0.55; Figure 2). In the DM patients, both AFS rate (P=0.04) and overall survival rate (P=0.04) were significantly lower in the PBS >45 group. AFS rate was 82%, 62%, and 52% at 1, 2, and 5 years, while overall survival rate was 89%, 68%, and 57% at 1, 2, and 5 years, respectively. Freedom from MALE+POD rate (P=0.26), limb salvage rate (P=0.10) and secondary graft patency rate (P=0.50) were not statistically significantly different between PBS >45 group and PBS ≤45 group (Figure 3). With regard to ESRD patients, the PBS >45 group had the worst AFS (P=0.02) and overall survival rate (P=0.03). AFS rate was 72% and 51% at 1 and 2 years, while overall survival rate was 81% and 58% at 1 and 2 years, respectively. Freedom from MALE+POD was still not significantly different between these groups (P=0.67). The other outcomes were not different between the PBS ≤45 and PBS >45 groups (Figure 4). In the patients with DM and ESRD, both survival rate (P=0.05) and AFS rate (P=0.10) were lower in the PBS >45 group but this was not statistically significant. Freedom from MALE+POD rate (P=0.43), limb salvage rate (P=0.10) and secondary graft patency rate (P=0.32) were also not statistically significantly different in this patient group (data not shown).

Discussion

In this study, we used PBS to identify the CLI patients who had worse outcome of infra-popliteal bypass surgery. The Bollinger scoring system was originally proposed in 1981; it was used to divide lower extremity arteries into several segments, and analyze various patterns of occlusions and stenosis on angiography. This system was adopted as the method for postoperative assessment in the BASIL trial and was also adapted for nationwide registration of CLI patient data in Japan. In the BASIL trial, mean below-knee Bollinger angiography score was an independent risk factor for both time to death after operation and AFS. In the original paper by Bollinger et al, arterial segments were defined as ranging from the abdominal aorta to the anterior/posterior tibial arteries and peroneal artery, which did not include the foot region. Given that loss of pedal arch quality is the main culprit lesion in patients with DM and ESRD, and that it is directly related to postoperative outcome after bypass surgery, we consider that evaluation of the plantar arch is as important as of other arteries.

We extended the definition of arterial segments to a more peripheral level and defined the paramalleolar segment as the distal half of the anterior/posterior tibial artery, peroneal artery and plantar arch.

In order to use this system for postoperative assessment, however, several problems had to be resolved. First, we had to improve the utility of the system. From a technical viewpoint, scoring all segments of the lower extremity arteries and evaluating all of them were complicated tasks, with the risk of an unclear result. In order to resolve this problem, we decided to focus solely on the paramalleolar segment of the arteries to simplify the evaluation process.

Second, the threshold score was set according to the clinical point of view. Given that we had a limited number of cases, this was the most difficult process. In this study, PBS >45 was arbitrarily defined as critical ischemic vascular status of the foot. This value (45) is clinically equivalent to severe occlusive lesions in 3 paramalleolar arteries (15×3) and stenosis in 1 patent artery. From a surgical point of view, the presence of at least 1 patent paramalleolar artery is the minimum condition for distal bypass surgery. And we often find that the other 3 arteries are completely occluded or severely damaged in the case of limb salvage surgery. A total of 31% of the present patients had PBS >45, and this was considered acceptable for further statistical analysis (Table 1).

Notable PBS >45 patient characteristics consisted of high CVD and carotid stenosis rate and poor nutrition status (Table 2). These characteristics were prominent in the DM or ESRD groups (Tables 3, 4). Although the clinical significance of PBS in CLI patients has not yet been proved, it is possible that the combination of poor general condition and progression of systemic atherosclerosis may cause the worse outcome in the PBS >45 group with DM or ESRD (Figures 3, 4). Prevalence of DM and ESRD was not statistically significantly different between the PBS >45 and PBS ≤45 group, although this lack of statistical power may have been due to the relatively small number of patients in the analysis. Another notable finding was that freedom from MALE+POD, secondary graft patency and limb salvage rates were not affected by PBS even in the DM or ESRD groups (Figure 4). This implies that once hemodynamic success is achieved via infra-popliteal bypass, severity of arterial stenosis does not affect graft patency or limb salvage rate.

Finally, we should mention that CLI patients enrolled in this study had multiple comorbidities compared with participants of the BASIL trial bypass first procedure group (Table 1). In order to optimize postoperative outcome, we performed strict preoperative management such as treatment for IHD before bypass surgery (PCI or coronary artery bypass graft first strategy) and selected the most effective bypass site using...
preoperative imaging. As a result, we achieved better AFS rates than those reported in the BASIL trial bypass first model groups. Nevertheless, the DM or ESRD patients with PBS >45 still had significantly worse outcome than the others. We hope that the present finding is useful for clinicians engaged in the treatment of CLI patients.

**Study Limitations**

This was a single-center retrospective study, and the study group was limited to the CLI patients who were considered feasible for distal bypass surgery. As mentioned here, the PBS >45 threshold score was decided intentionally. Given that the total number of cases was limited, we were unable to investigate other threshold scores thoroughly due to lack of statistical power.

**Conclusions**

PBS successfully classified CLI patients with DM or ESRD who had worse outcome after infra-popliteal bypass surgery. An additional study is needed to confirm this finding.

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**Supplementary Files**

**Supplementary File 1**

Figure S1. Overall postoperative outcome.

Table S1. Surgical procedures (n=118)

Table S2. Independent risk factors for PBS >45

Please find supplementary file(s) at:

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