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Original Article

# Comparison of Clinical Outcomes after Surgical and Endovascular Revascularization in Hemodialysis Patients with Critical Limb Ischemia

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**_Aim_: The treatment strategy for hemodialysis (HD) patients with critical limb ischemia (CLI) has been clinically debatable. Here we compared clinical outcomes after bypass surgery (BSX) and after endovascular therapy (EVT) using propensity score matching.**
**_Methods_: A retrospective multicenter database of 246 (68 BSX and 178 EVT) consecutive HD patients with CLI (79% with tissue loss) who underwent infrainguinal revascularization from 2007 to 2009 was used to compare clinical outcomes, including overall survival (OS), major amputation (MA), major adverse limb event (MALE: repeat EVT, surgical reconstruction, or MA), and MALE-free survival after BSX vs. EVT using propensity score matching.**
**_Results_: The median (interquartile range) follow-up duration after revascularization was 21 (8−33) months. The analysis of the 63 propensity score-matched pairs revealed no significant difference in OS (53% vs. 52%, $P=0.96$), MA (25% vs. 14%, $P=0.71$), MALE (42% vs. 58%, $P=0.63$), and MALE-free survival (33% vs. 11%, $P=0.37$) at 3 year after BSX vs. EVT.**
**_Conclusions_: In HD patients with CLI who underwent infrainguinal revascularization, OS, MA, MALE, and MALE-free survival rates were not significantly different after EVT vs. BSX. The less invasive EVT should be considered as the first-choice therapeutic strategy for HD patients with CLI.**

**Key words:** Critical limb ischemia, Hemodialysis, Endovascular therapy, Bypass surgery



## Introduction

The number of patients on hemodialysis (HD) therapy with end-stage renal disease has been increasing worldwide[1]. Patients on HD generally have multiple systemic comorbidities, and their arteries are affected by severe calcification leading to lower extremity peripheral artery disease (LE-PAD)[2, 3]. Because the incidence of critical limb ischemia (CLI) is 16% at 5 years from HD initiation[4], it is important to choose the optimal treatment strategy for HD patients with CLI.

Either revascularization [bypass surgery (BSX) or endovascular therapy (EVT)] is recommended as the optimal treatment for patients with CLI[5]. A recent systematic review of patients with CLI regarding the

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**Table 1.** Revascularization characteristics before and after propensity score matching

| Factors | Before Matching (*n*=246) | After Matching (*n*=126) |
|---|---|---|
| Endovascular therapy | 72% (178) | 50% (63) |
| Femoropopliteal | 16% (40) | 10% (12) |
| Femoropopliteal and Tibial | 29% (72) | 16% (21) |
| Tibial artery | 27% (66) | 24% (30) |
| Bypass surgery | 28% (68) | 50% (63) |
| Femoropoptliteal BSX above knee | | |
| -autogenous vein | 1% (2) | 1.5% (2) |
| -ePTEF | 2% (5) | 1.5% (2) |
| Femoropopliteal BSX below knee | | |
| -autogenous vein | 1% (3) | 1.5% (2) |
| Femorotibial BSX | | |
| -autogenous vein | 8% (19) | 15% (19) |
| Popliteo (above knee)-tibial BSX | | |
| -autogenous vein | 7% (16) | 13% (16) |
| -ePTEF | 1% (3) | 2.5% (3) |
| Popliteo (below knee)-tibial BSX | | |
| -autogenous vein | 8% (20) | 15% (19) |

BSX, bypass; ePTEF, expanded polytetrafluoroethylene

effectiveness of BSX vs. EVT demonstrated that there was no statistically significant difference in the long-term clinical outcomes[6)]. However, a recent prospective observational study (CRITISCH registry), in which in-hospital outcomes after revascularization were analyzed, revealed that patients with CLI who received BSX were at a higher risk of in-hospital death and repeat intervention than those who received EVT[7)].

Patients with CLI and HD were notably associated with a higher incidence of death or limb loss after revascularization than those with CLI alone[8)]. Treatment for HD patients with CLI is the most challenging, and the optimal revascularization strategy for them is still debatable. The current study aimed to investigate clinical outcomes by comparing HD patients with CLI who underwent BSX vs. EVT using propensity score matching.

## Methods

### Participants

This study used a retrospective registry, involving eight institutions in Japan, to identify all consecutive HD patients with CLI due to infrainguinal arterial lesions who first underwent BSX or EVT from January 2007 to December 2009. In this study, one limb was included per enrolled patient. In patients with bilateral CLI, the first treated limbs were registered. A group of vascular specialists, including cardiologists, vascular surgeons, and radiologists, judged whether EVT or BSX was indicated for each patient based on each clinical setting. All baseline characteristics were entered during first admission, and the registry was periodically updated with patient follow-up data generally obtained at 1, 3, and 6 months, and thereafter, at every 3 months. If a patient did not return to the hospital, the patient's general condition and limb status were followed-up via a phone interview. Assessment procedures were performed in accordance with the principles of the Declaration of Helsinki and were approved by the ethics committee in Kansai Rosai Hospital (approval number: 150404).

### BSX Procedure

BSX was performed under general anesthesia using standard techniques with an autogenous vein graft. The vein was harvested, flushed with heparinized saline solution, and reversed. Prosthetic vascular grafts were used in cases lacking appropriate usable autogenous vein grafts. Post procedural medications were selected according to the local angioplasty that was initially performed. A nitinol stent was provisionally implanted if the post balloon result was suboptimal. For infrapopliteal lesions, only balloon angioplasty was performed. Dual antiplatelet therapy (aspirin at 100 mg/day and clopidogrel at 75 mg/day, ticlopidine at 200 mg/day, or cilostazol at 200 mg/day) was generally initiated at least 1 week prior to

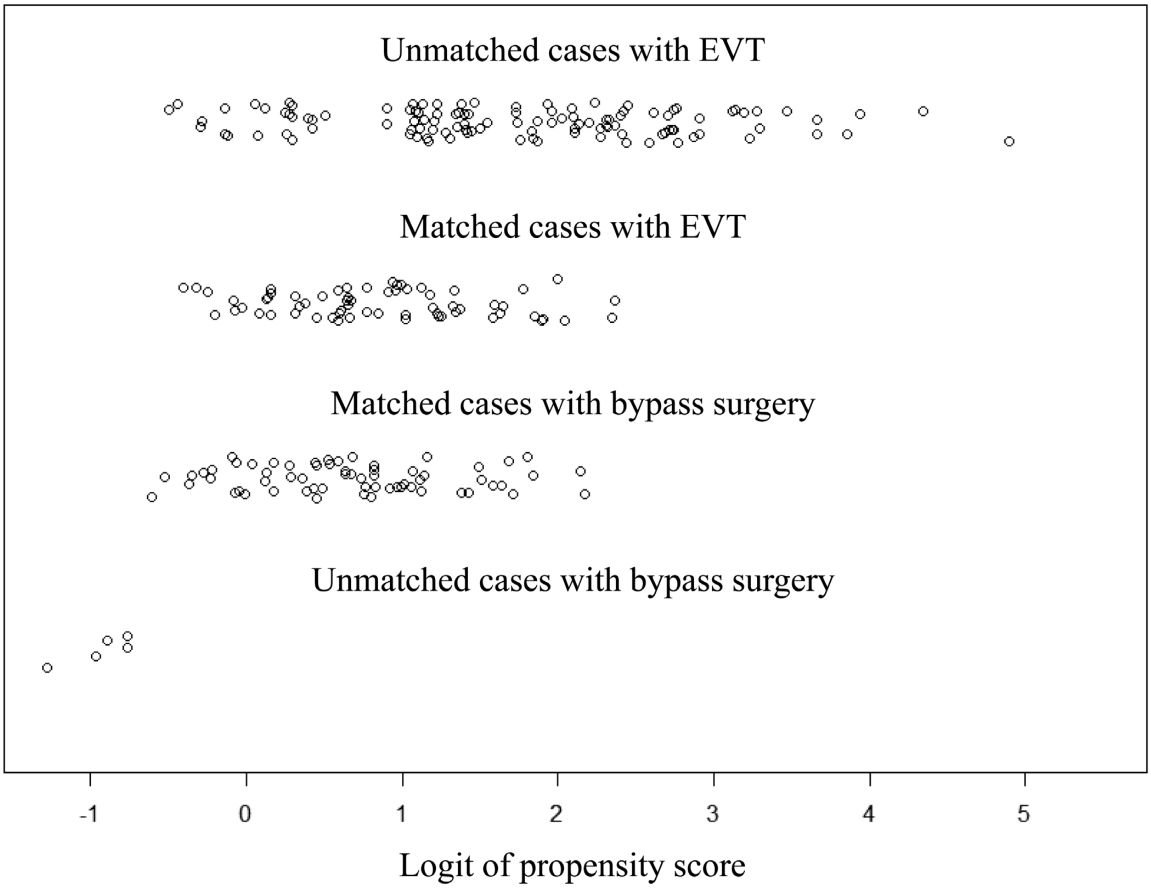



**Fig. 1.** Distribution of propensity scores in both matched and unmatched cases with EVT and BSX

EVT and continued lifelong. Medical treatment was left to the physician's discretion.

**Outcome Measures and Variables**

The outcome measures of this study were overall survival (OS), major amputation (MA), major adverse limb event (MALE: repeat EVT, surgical reconstruction, or major amputation), and MALE-free survival after revascularization.

**Definitions**

CLI was defined in accordance with the TransAtlantic Inter-Society Consensus (TASC) guideline as tissue loss or rest pain due to chronic ischemia associated with ankle pressure of <70 mmHg or toe pressure of <50 mmHg[5]. When these measurements could not be obtained, skin perfusion pressure (SPP) was measured at the dorsum and plantar side of the foot for evaluating ischemia. An ischemic limb was indicated by an SPP of <40 mmHg[9]. These non-invasive blood flow measurements were essentially conducted on non-dialysis day. MA was regarded as an amputation above the ankle. Repeat intervention, including surgical or endovascular revascularization, was conducted in the cases with recurrent rest pain or ischemic wounds.

Non-ambulatory status was regarded as requiring a wheelchair or being bedridden. Diabetes mellitus was based on the World Health Organization criteria or on the need for treatment with insulin and/or oral hypoglycemic agents. Coronary artery disease (CAD) was defined as stable angina with documented coronary arterial lesions, a history of percutaneous coronary intervention or coronary artery bypass graft surgery, or a previous myocardial infarction. Chronic heart failure (CHF) was defined as a past history of admission for treating heart failure or a left ventricular ejection fraction of <50%. The ejection fraction was evaluated by transthoracic echocardiography. Cerebrovascular disease was defined as the presence of symptoms or a past history of infarction. CLI severity was determined according to the Rutherford classification[10]. Isolated tibial disease was defined as a lesion located only in below-the-knee arteries. Lesion severity was classified according to the TASC II guideline after evaluation by aortography or computed tomog-

**Table 2.** Baseline characteristics of the study population before and after propensity score matching

| | Before Matching | | | After Matching | | |
|---|---|---|---|---|---|---|
| | EVT ($n$=178) | BSX ($n$=68) | $P$ | EVT ($n$=63) | BSX ($n$=63) | $P$ |
| Patients status | | | | | | |
| Age | 69±10 | 70±9 | 0.348 | 69±10 | 69±9 | 0.844 |
| Male | 70% (124) | 71% (48) | 0.887 | 76% (48) | 70% (44) | 0.503 |
| Body mass index | 21±3 | 21±3 | 0.349 | 21±3 | 20±4 | 0.858 |
| Non-ambulatory status | 45% (111) | 37% (25) | 0.103 | 46% (29) | 40% (25) | 0.571 |
| Hypertension | 83% (148) | 79% (54) | 0.467 | 81% (51) | 79% (50) | 1.000 |
| Dyslipidemia | 28% (49) | 25% (17) | 0.689 | 24% (15) | 25% (16) | 1.000 |
| Diabetes mellitus | 67% (120) | 74% (50) | 0.353 | 70% (44) | 71% (45) | 1.000 |
| Current smoking | 31% (55) | 16% (11) | 0.019 | 21% (13) | 17% (11) | 0.815 |
| Coronary artery disease | 59% (146) | 60% (41) | 0.852 | 60% (38) | 60% (38) | 1.000 |
| Chronic heart failure | 28% (49) | 24% (16) | 0.524 | 33% (21) | 25% (16) | 0.499 |
| Ejection fraction | 59±14 | 60±13 | 0.461 | 59±14 | 60±13 | 0.537 |
| Cerebrovascular disease | 22% (53) | 34% (23) | 0.180 | 32% (20) | 32% (20) | 1.000 |
| Hemoglobin (g/dL) | 10.6±1.7 | 10.5±1.7 | 0.625 | 10.3±1.5 | 10.6±1.7 | 0.413 |
| Albumin (g/dL) | 3.3±0.5 | 3.4±0.5 | 0.790 | 3.4±0.5 | 3.4±0.5 | 0.826 |
| CRP (mg/dL) | 0.7 (0.2-2.6) | 1.1 (0.4-3.4) | 0.730 | 1.0 (0.3-3.6) | 1.0 (0.4-3.0) | 0.459 |
| Limb status | | | | | | |
| Rutherford category | | | 0.011 | | | 0.782 |
| Ⅳ | 26% (46) | 9% (6) | | 10% (6) | 10% (6) | |
| Ⅴ | 63% (113) | 75% (51) | | 79% (50) | 75% (47) | |
| Ⅵ | 11% (19) | 16% (11) | | 11% (7) | 16% (10) | |
| Lesion status | | | | | | |
| Isolated tibial disease | 37% (66) | 41% (28) | 0.554 | 48% (30) | 44% (28) | 0.850 |
| TASC Ⅱ classification | | | | | | |
| Femoropopliteal lesions | | | | | | |
| A/B/C/D | 24/28/37/23 | 5/15/8/12 | 0.680 | 4/10/10/9 | 5/12/7/11 | 0.841 |
| Infrapopliteal lesions | | | | | | |
| A/B/C/D | 1/7/9/121 | 0/1/2/50 | 0.571 | 0/2/2/47 | 0/1/2/48 | 0.883 |

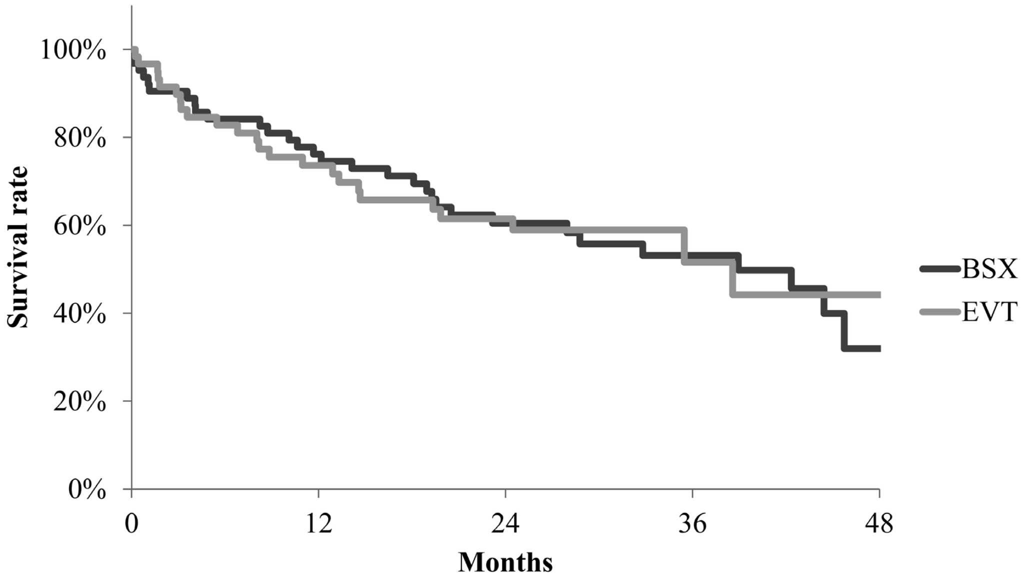
raphy angiography[5].

**Statistical Analysis**

Data are expressed as mean and standard deviation (SD), median (25th−75th, quartiles) for continuous variables, or percentage for dichotomous variables, unless otherwise mentioned. The propensity score was developed using a logistic regression model in which the following variables were entered: sex, age, ambulatory status, body mass index, hypertension, diabetes mellitus, dyslipidemia, current smoking, CAD, CHF, ejection fraction, cerebrovascular disease, hemoglobin, albumin, C-reactive protein, Rutherford category, TASC classification, and isolated tibial disease. Using Austin's recommendation[11], we matched the logit of the propensity score within the caliper of 0.2 SD of the value. Continuous variables were examined using the unpaired $t$ test before propensity score matching and the paired $t$ test or the Wilcoxon signed-rank test after propensity score matching. Categorical variables were compared using the chi-square test before propensity score matching and the McNemar and Wilcoxon signed-rank tests after propensity score matching. The outcome measures in the matched population were assessed using the Kaplan−Meier method, and curves were compared using the stratified log-rank test. A $P$ value of $<0.05$ was considered statistically significant. Propensity score matching was performed using R version 3.1.0 software (R Development Core Team, Vienna), whereas other statistical analyses were performed using SPSS version 21 (SPSS Inc., Chicago, Ill., USA).

## Results

The initial revascularization strategy is shown in



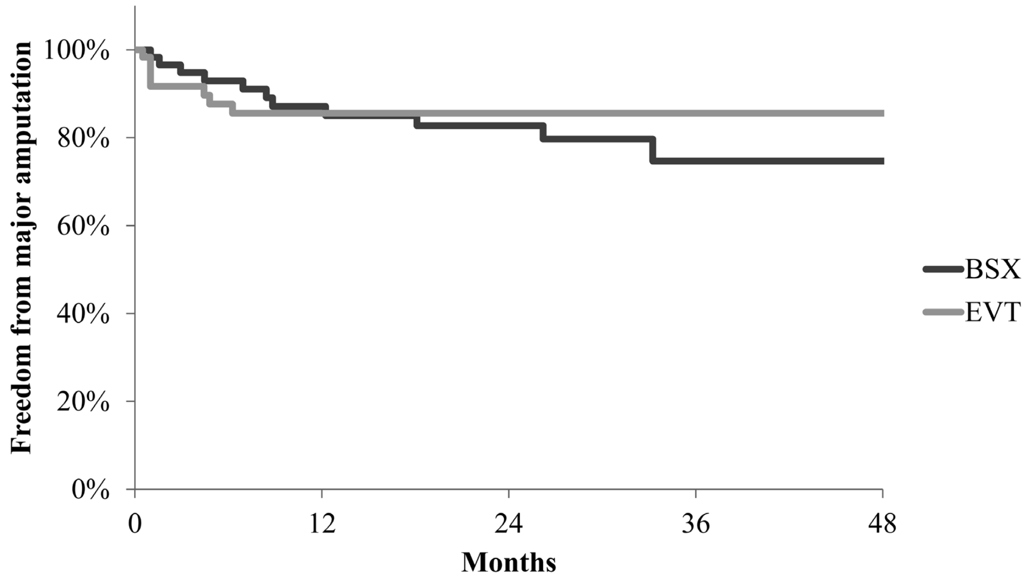

| | | 0 | 12 | 24 | 36 | 48 |
|---|---|---|---|---|---|---|
| BSX | No. at risk | 63 | 47 | 32 | 19 | 5 |
| | Rate±SE (%) | 100±0 | 75±6 | 60±6 | 53±7 | 32±10 |
| EVT | No. at risk | 63 | 39 | 26 | 8 | 4 |
| | Rate±SE (%) | 100±0 | 74±6 | 61±7 | 52±9 | 44±10 |

**Fig. 2.** OS for the propensity-matched pairs

**Table 1**. Surgical bypass and EVT were performed in 68 (28%) and 178 (72%) patients, respectively. Among those undergoing EVT, stents were implanted in 64% of the limbs (72/112) with femoropopliteal lesions. BSX with an autogenous vein graft was conducted in 88% of the limbs (60/68). Patients with a history of current smoking and with ischemic tissue loss were more frequently observed in the BSX group than in the EVT group (all $P<0.05$). Information on HD duration (the time from dialysis initiation to vascular intervention) was available in 44% (109/246) of the study patients. The median duration of HD was 5 (2−10) months.

The distribution of the propensity score in the study population is shown in **Fig. 1**. The propensity score matching extracted a total of 63 pairs. Technical failure after BSX, defined as the demand of revision surgery within 1 week, was 6% (4/68). Technical failure after EVT, defined as unsuccessful recanalization or over 75% residual stenosis of target lesion, was 2% (4/178). In the propensity analysis, three cases with technical failure after BSX and two cases with technical failure after EVT were included. After propensity score matching, there was no significant difference in the baseline characteristics (**Table 2**). In the matched population, the median follow-up period was 21 (8−33) months.

At 3 years after revascularization, the OS rates, as revealed by Kaplan−Meier analysis, were 53%±7% in the BSX group and 52%±9% in the EVT group (**Fig. 2**. $P=0.715$). The freedom from MA rates at 3 years was 75%±7% in the BSX group and 86%±5% in the EVT group (**Fig. 3**. $P=0.564$). The freedom from MALE at 3 years was 58%±7% in the BSX group and 42%±11% in the EVT group (**Fig. 4**. $P=0.577$). The MALE-free survival at 3 years was 33%±6% in the BSX group and 11%±9% in the EVT group (**Fig. 5**. $P=0.405$). Death within 30 days was observed in four patients (6%) in the BSX group and two patients (3%) in the EVT group ($P=0.687$). The causes of death within 30 days after BSX were infection ($n=2$), stroke ($n=1$), and bowel ischemia ($n=1$), whereas those death within 30 days after EVT was cardiac death ($n=1$) and gastrointestinal bleeding




| | | 0 | 12 | 24 | 36 | 48 |
|---|---|---|---|---|---|---|
| BSX | No. at risk | 63 | 43 | 29 | 15 | 5 |
| | Rate±SE (%) | 100±0 | 87±5 | 83±5 | 75±7 | 75±7 |
| EVT | No. at risk | 63 | 34 | 23 | 7 | 3 |
| | Rate±SE (%) | 100±0 | 86±5 | 86±5 | 86±5 | 86±5 |

**Fig. 3.** MA for the propensity-matched pairs

($n = 1$).

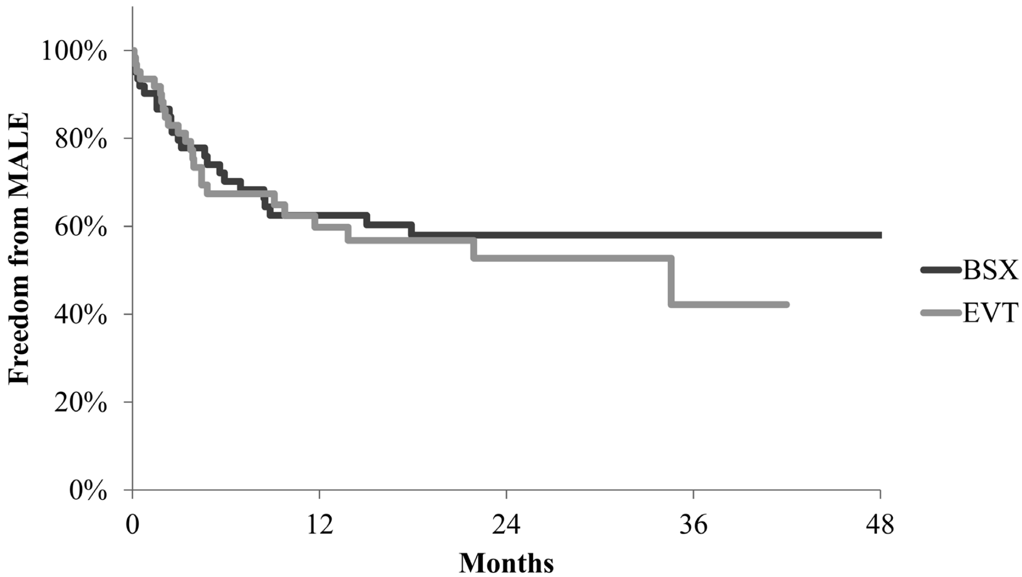
## Discussion

The current study using propensity score matching demonstrated that there was no statistically significant difference in clinical outcomes of HD patients with CLI after surgical or endovascular revascularization. Baseline patient and limb characteristics before matching were not significantly different except for a history of current smoking and prevalence of ischemic tissue loss. Patients with a more severe limb condition were selected for BSX; however, the baseline anatomical complexity defined by the TASC classification was not different between the groups. For precise investigation comparing BSX and EVT for HD patients with CLI, a propensity score adjustment was used in the current study.

Bernard *et al*. reported that compared with EVT, BSX for HD patients with LE-PAD was associated with both a higher all-cause mortality [hazard ratio (HR), 1.37; 95% confidence interval (CI), 1.10−1.70] and MA (HR, 4.00; 95% CI, 2.46−6.57) using multivariate Cox hazard model[12]. However, their study has several limitations; 1) patients with BSX had higher risk characteristics (high prevalence of smoking, coronary artery disease, and diabetes mellitus) than patients with EVT, and 2) lesion morphology and severity were not recorded[12].

Clinical outcomes for HD patients with CLI after surgical and endovascular revascularization have been reported[13-16]. In these patients, the mortality rates after BSX were 28% at 1 year and 59% at 3 years, whereas those after EVT were 24% at 1 year and 47% at 3 years. These previous results were similar to those of the current study.

We previously reported the comparison of clinical outcomes after BSX vs. EVT for Japanese patients with CLI[17]. From this registry, amputation-free survival was similar for BSX and EVT as the first revascularization in real-world practice. However, the frequency of repeat revascularization was significantly higher in the EVT group than in the BSX group[17]. Although BSX was generally expected to be a more permanent treatment, the incidence of clinically driven revascularization was not significantly different after




| | | 0 | 12 | 24 | 36 | 48 |
|---|---|---|---|---|---|---|
| BSX | No. at risk | 63 | 32 | 20 | 12 | 3 |
| | Rate±SE (%) | 100±0 | 62±7 | 58±7 | 58±7 | 58±7 |
| EVT | No. at risk | 63 | 24 | 13 | 2 | - |
| | Rate±SE (%) | 100±0 | 60±7 | 53±8 | 42±11 | - |

**Fig. 4.** Freedom from MALE (major amputation, repeat endovascular, or surgical reconstruction) for the propensity-matched pairs

BSX vs. EVT (33%±7% at 2 year in the BSX group and 40%±8% at 2 year in the EVT group; log-rank $P=0.637$) in the current study focusing on HD patients with CLI. BSX for HD patients with CLI was the most challenging due to severe vessel calcification and numerous comorbidities leading to a high risk of loss of patency. From the current results, we suggest that the less invasive EVT is the better first-line therapeutic strategy for HD patients with CLI.

This study had several limitations; 1) it was a retrospective analysis and included only Japanese patients; 2) sample size was not enough to investigate the predictors of clinical outcomes; and 3) detailed data on below-the-ankle information, lesion length, severity of vascular calcification, calcium-phosphate homeostasis, and medication was missing. However, this is the first report to compare the effectiveness of surgical and endovascular revascularization in HD patients with CLI.

## Conclusion

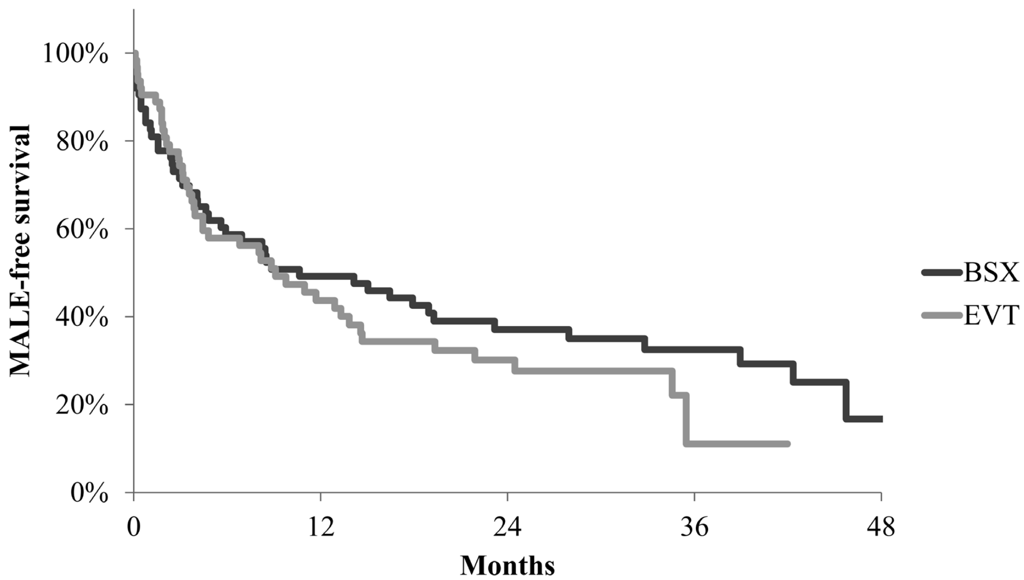
The current study using propensity score matching suggested that clinical outcomes after EVT and BSX were not significantly different in HD patients with CLI. The less invasive EVT should be considered as the first-line therapeutic strategy for HD patients with CLI.

## COI

There is no financial arrangement or other relationship that could be construed as a conflict of interest.

## Abbreviations

ABI: ankle−brachial index
BSX: bypass surgery
CI: confidence interval
CLI: critical limb ischemia
EVT: endovascular therapy




| | | 0 | 12 | 24 | 36 | 48 |
|---|---|---|---|---|---|---|
| BSX | No. at risk | 63 | 32 | 20 | 12 | 3 |
| | Rate±SE (%) | 100±0 | 49±6 | 37±6 | 33±6 | 17±8 |
| EVT | No. at risk | 63 | 25 | 14 | 2 | - |
| | Rate±SE (%) | 100±0 | 44±6 | 30±6 | 11±9 | - |

**Fig. 5.** MALE (major amputation, repeat endovascular, or surgical reconstruction)-free survival for the propensity-matched pairs

HD: hemodialysis
HR: hazard ratio
MA: major amputation
MALE: major adverse limb event
PAD: peripheral artery disease
POD: perioperative death
SPP: skin perfusion pressure
TASC: TransAtlantic Inter-Society Consensus

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