Five-year prognosis after endovascular therapy in claudicant patients with iliofemoral artery disease

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Brief title: Outcome of claudicant patients after endovascular therapy.

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Abstract

Purpose: To examine the prognosis of patients with intermittent claudication (IC) who received treatment with endovascular therapy (EVT).

Methods and Results: A multicenter, retrospective study was performed in 2,930 consecutive patients (mean age, 71.5±8.9 years old, 78.7% male) with IC treated by EVT for a de novo iliofemoral lesion. The primary endpoint was overall survival. The secondary endpoints were freedom from major adverse cardiovascular events (MACE; all-cause mortality, myocardial infarction and stroke) and from major adverse cardiovascular and limb events (MACLE; repeat revascularization in target limb and leg amputation, in addition to MACE). The overall survival rates were 97.2%, 90.8%, and 83.4% at 1, 3 and 5 years. The cause of death was cardiovascular in 42.8% of cases. Freedom from MACE was 96.7%, 88.6%, and 77.3% at 1, 3 and 5 years. Cox multivariate regression analysis identified age, dialysis, LV dysfunction, diabetes treated by insulin, complication of hematoma, coronary artery disease, and SFA plus iliac lesions as positive predictors of all-cause mortality. In risk stratification of all-cause mortality, the first five positive predictors above were scored as 2 points and the last two as 1 point each. Low-, moderate- and high-risk patients were classified as those with total scores of 0 to 2, 3 to 5, and ≧6 points, respectively. The overall 5-year survival rate was significantly lower in high-risk patients compared to the other groups (90.1% vs. 78.6% vs. 53.5%, P<0.0001).

Conclusions: The prognosis after EVT for patients with IC was relatively good, but that for high-risk patients with IC was extremely poor.

Key words: peripheral arterial disease, intermittent claudication, outcome, endovascular therapy

Introduction

Atherosclerotic disease is increasing worldwide due to aging of society and changes in lifestyle. The increase in the prevalence of peripheral arterial disease (PAD) is particularly significant with increasing age [1]. The incidence of cardiovascular events is high in patients with PAD [2] and outcomes in these patients differ between those with intermittent claudication (IC) and critical limb ischemia (CLI). The one-year mortality is 25% in the natural course of patients with CLI, whereas the 5-year mortality is 15% in that of patients with IC [2]. Therefore, some claudicant patients seem to have a relatively good prognosis, compare to the patients with CLI. However, several large-scale studies have found that the mortality rate of claudicant patients is 2.5 times higher than that of non-claudicant patients and that the risk of a fatal cardiovascular event is 3 to 6 times higher than that of non-claudicant patients [1,3,4].

In claudicant patients with limited exercise performance and walking capacity, revascularization procedures are the most effective way to improve symptoms. Both open repair/bypass surgery and endovascular therapy (EVT) can be used, and the Trans-Atlantic Intersociety Consensus (TASC) II guidelines recommend the choice of revascularization. Some recent reports have found that the patency rate of EVT is similar to that of surgery [5, 6], but little is known about the long-term prognosis of claudicant patients after EVT. Therefore, in the present study, we evaluated the long-term prognosis for limb and life in claudicant patients with iliofemoral artery disease who underwent EVT.

Methods

Study design

Between January 2005 and December 2009, 7177 consecutive patients underwent EVT for iliofemoral artery disease (iliac artery and superficial femoral artery (SFA), excluding those with common femoral artery disease) at 18 Japanese institutions that participated in the study.

Of these patients, 4045 were excluded because of a history of lower extremity bypass surgery or EVT (333 patients), restenotic lesions (1612 patients), critical limb ischemia (1499 patients), Rutherford class < 2 (312 patients), acute onset limb ischemia (162 patients), persistent sciatic artery (2 patients), popliteal artery entrapment syndrome (1 patient), post-amputation (1 patient), angioseal-related occlusion (1 patient), and inadequate data (120 patients). Of the remaining 3132 cases, 2930 patients (3802 limbs) with IC who underwent successful EVT for de novo IF disease were identified retrospectively and analyzed with regard to the primary and secondary outcomes (Figure 1). Baseline clinical characteristics and procedural data were collected from hospital medical records or databases. Follow-up data were obtained from hospital charts or by contacting patients, family members or referring physicians. The mean follow-up period was 958.5±628.4 days. The research protocol was approved by the hospital ethics committee or relevant review board in all 18 participating centers and the study was performed in accordance with the Declaration of Helsinki. Written informed consent was obtained from every patient.

Endpoints

The primary endpoint was overall survival. The secondary endpoints were freedom from major adverse cardiovascular events (MACE; all-cause death, myocardial infarction and stroke) and freedom from major adverse cardiovascular and limb events (MACLE; any repeat revascularization for limb and leg amputation, in addition to MACE).

Definitions

Successful EVT was defined as <30% residual stenosis without any procedural complication. Complications were defined as all-cause mortality, stroke, myocardial infarction (MI), intestinal bleeding, blood transfusion, prolongation of hospitalization due to hematoma, pseudoaneurysm of access site artery, distal embolization including cholesterol crystal embolization, worsened renal function, surgical repair, perforation or rupture, aortic dissection, stent thrombosis, or any other event requiring prolongation of hospitalization. Restenosis was defined as a peak systolic velocity ratio >2.4 on duplex, >50% stenosis on angiography or computed tomography, or a 0.2 decrease of the resting ankle-brachial index (ABI). MI was defined as creatine kinase (CK) or CK-MB above the upper limit of normal at each hospital or as development of significant Q waves in at least two contiguous leads of an electrocardiogram. Coronary artery disease (CAD) was defined as >50% stenosis in a coronary vessel on angiography, history of coronary artery bypass graft surgery, or previous MI. Stroke was defined as ischemic stroke that persisted for ≥24 h and was diagnosed by a neurologist. In each patient, clinical history and risk factors were assessed at the first visit. Heart failure (HF) was defined based on a previous diagnosis of HF, history of hospitalization for HF, or current treatment for HF. Diabetes was defined as HbA1c >6.5%, casual plasma glucose >200 mg/dl or treatment with oral hypoglycemic agents or insulin injection. Hypertension was defined as systolic BP ≥140 mmHg, diastolic BP ≥90 mmHg, or ongoing therapy for hypertension. Dyslipidemia was defined as a serum total cholesterol concentration ≥220 mg/dl, a low-density lipoprotein-cholesterol concentration ≥140 mg/dl, or current treatment with lipid-lowering therapy.

Chronic kidney disease (CKD) was defined to be present when serum creatinine was >1.5 mg/dl. Left ventricular ejection fraction (LVEF) was measured by echocardiography and LVEF <40% was regarded to indicate LV dysfunction. Elderly age was defined as >70 years old. Below-the-knee (BTK) artery disease was assessed on angiography before or after the procedure and was defined as ≥2 occlusions of the anterotibial artery, peroneal artery, or posterotibial artery. Stent fracture was defined as clear interruption of stent struts identified by x-ray from more than two projections at restenosis occurred.

Statistical Analysis

Continuous variables are reported as means ± SD. Vessel patency rates and event-free survival curves were estimated using the Kaplan-Meier method and compared by log-rank test. Cox multivariate regression analysis was used to determine predictors for all-cause mortality. Clinically prespecified predictors (age, male gender, diabetes, hypertension, statin administration, current smoker, stroke, CAD, hemodialysis, TASC II C/D, calcified lesion, ACEI/ARB administration, Ca-antagonist administration, and stent fracture) with $P < 0.05$ in Cox univariate analysis were used in the multivariate Cox regression model. A P value of <0.05 was considered to be statistically significant in all analyses.

Results

Baseline Demographics

The mean follow-up period was 958.5±628.4 days (range 1-1825). The mean age of the 2930 patients was 71.5±8.9 years old (range 37-98) and 2307 (78.7%) were male. The characteristics of the patients and lesions are shown in Tables 1 and 2. The 3802 lesions included 1352 in the iliac artery alone, 1616 in the SFA alone, and 834 in both. In the TASCII classification, 1560 (41.0%), 1037 (27.3%), 468 (12.3%), and 739 patients (19.4%) were in classes A, B, C and D, respectively.

Prognosis for Survival

The overall 1-, 3- and 5-year survival rates were 97.2%, 90.8%, and 83.4% (Figure 2). Freedom from MACE was 96.7%, 88.6%, and 77.3%, and freedom from MACLE was 84.5%, 68.1%, and 58.7% at 1, 3 and 5 years, respectively (Figure 2). There was no significant difference in the overall 5-year survival rate between patients with iliac and SFA lesions 8(91.3% vs. 92.1%, P=0.54). Similarly, the 5-year freedom from MACE did not differ between the two types of lesions (88.2% vs. 88.8%, P=0.33). However, there was a significant difference in the 5-year freedom from MACLE between iliac and SFA lesions (62.8% vs. 50.4%, P<0.0001). The overall 5-year survival rate was similar for Rutherford II and Rutherford III cases (83.9% vs. 83.2%, P=0.11). The 5-year freedom from MACE was also similar in these two groups (89.3% vs. 88.1%, P= 0.27), but the 5-year freedom from MACLE was significantly higher in Rutherford II cases (61.0% vs. 53.9%, P<0.0001). The overall 5-year survival rate was also similar for TASC II A/B and TASC II C/D (81.6% vs. 87.3%, P=0.27). The 5-year freedom from MACE was also similar between the patients with diabetes and those without (73.5% vs. 78.4%, P= 0.62), however the 5-year freedom from MACLE was significantly lower in the patients with diabetes (49.9% vs. 62.0%, P<0.0001).

There were 243 deaths during the follow-up period, including cardiac death in 73 patients (30.0%) (18 due to acute coronary syndrome, 16 to sudden death, and 19 to heart failure), vascular death in 31 patients (12.8%), and non-cardiovascular death in 139 patients (57.2%). Vascular death included stroke (10, 4.1%), ruptured aortic aneurysm (4, 1.6%), and renal failure (3, 1.2%). In total, cardiovascular death occurred in 104 patients (42.8%). Multivariate analysis performed using a Cox hazards model showed that elderly age, dialysis, LV dysfunction, insulin administration, complication of hematoma, CAD, and iliac + SFA lesions were positive independent predictors of all-cause mortality (Table 3). Administration of ACEIs/ARBs and of Ca-antagonists were negative independent predictors of all-cause mortality. Stent fracture was not an independent predictor of all-cause mortality.

Risk stratification of all-cause mortality was performed based on the seven positive predictors, with elderly age, dialysis, LV dysfunction, diabetes treated by insulin and complication of hematoma scored as 2 points each and CAD and iliac + SFA lesions as 1 point each. Low-, moderate- and high-risk patients were classified as those with total scores of 0 to 2, 3 to 5, and ≧6 points, respectively. The overall 5-year survival rate was significantly lower in high-risk patients than in the other two groups (90.1% vs. 78.6% vs. 53.5%, P<0.0001) (Figure 3A). Freedom from MACE at 5 years was also significantly lower in high-risk patients (87.0% vs. 72.3% vs. 52.4%, P<0.0001) (Figure 3B). Freedom from MACLE at 5 years was similarly significantly lower in high-risk patients (65.5% vs. 50.7% vs. 32.3%, P<0.0001).

Discussion

Prior reports have consistently documented an increased overall 5-year mortality of patients with claudication of approximately 15% to 30% [2,7]. Our results show that the prognosis for survival of claudicant patients at 5-years after EVT was close to that in the natural course. These data suggest that EVT for the patients with IC don`t worsen prognosis of them. The mortality was significantly higher in the natural course of patients with CLI than in that of patients with IC [2]. Therefore, some claudicant patients seem to have a relatively good prognosis, compare to the patients with CLI. The main cause of death of patients with PAD is cardiovascular, and the Reduction of Atherothrombosis for Continued Health (REACH) registry found that about 3 out of 5 patients with PAD had CAD or CVD [8]. Therefore, screening for polyvascular disease (CAD, CVD, renal artery stenosis (RAS), aortic disease) beyond the lower extremity artery should be performed in diagnosis and management of patients with PAD. Dormandy et al. found that 40-60% of deaths of PAD patients were associated with CAD, 10-20% with cerebrovascular disease, and 10% with other vascular diseases [9].

In the current study, the percentage of cardiac, cerebrovascular and other deaths were 30.0%, 6.2%, and 6.6%, respectively. These data also suggest that patients who undergo EVT should receive screening for polyvascular disease and subsequent treatment. However, we found no significant difference in all-cause mortality between patients with severe and mild claudication, in contrast to a previous finding that the outcomes of patients with CLI are poorer than those in claudicant patients [1]. Furthermore, we found no significant difference in all-cause mortality between patients with TASC II A/B and TASC II C/D in claudicant patients. However, patients at high risk for ischemic events existed among the claudicant patients. Therefore, we evaluated whether risk scores used to classify patients with PAD can predict the clinical outcome. The patients were classified using the seven positive independent predictors of all-cause mortality as low- (1,410, 48.1%), moderate- (1,406, 48.0%) and high- (114, 3.9%) risk cases, respectively. This risk stratification was useful for prediction of all-cause mortality and ischemic events.

The inclusion of complication of EVT among the seven positive independent predictors of all-cause mortality is an important result. These complications were distal embolization including cholesterol crystal embolization (HR=2.02, 95%CI=0.55–7.45, P=0.29), prolongation of hospitalization due to hematoma (HR=2.75, 95%CI=1.08–6.98, P=0.034), and worsening renal function (HR=2.11, 95%CI=0.39–11.33, P=0.38). Forty-two patients had complication of hematoma. Of them, 4 patients died within 60 days, all cause of death were related hematoma. Other 4 patients died later, 1 due to acute coronary syndrome, 1 to abdominal aortic aneurysm (AAA) rupture, 1 to stroke, and 1 to malignancy. In case of AAA rupture, AAA was not detected before EVT. The other independent predictors of all-cause mortality are difficult to change, but prevention of severe hematoma may be possible by careful performance of EVT. The main cause of hematoma was an access site complication, which indicates that puncture should be performed carefully and that the access site should be checked frequently during the procedure. In our study, access site were femoral artery in 7/8 cases of death. A femoral approach has a higher risk of vascular complication in patients with advanced atherosclerosis [10], and thus additional care is needed when performing EVT from the femoral artery.

We also found that treatment with ACEIs/ARBs and Ca-antagonists had an independent beneficial effect on prognosis. The efficacy of statins was also shown in univariate analysis. There is considerable evidence that ACEIs/ARBs and statins are effective in primary and secondary prevention of cardiac disease [11-14], which suggests that these drugs may improve the prognosis of PAD patients. Ca-antagonists have been reported to have similar effects to those of ACEI/ARBs [15].

The general purpose of EVT is extension of the absolute claudication distance (ACD) and reduction of leg pain during walking. Prior studies showed that successful revascularization of lower extremity arteries in claudicant cases improves functional status and quality of life, and is also associated with a reduction of major cardiovascular events [16,17]. This reduction of cardiovascular events by EVT is partly due to extension of the ACD [2,6,18] because increased walking ability after EVT is associated with improvements of blood pressure, lipid metabolism and carbohydrate metabolism through exercise [19, 20]. EVT also improves endothelial dysfunction [21], which plays a key role in the pathophysiology and natural history of atherosclerotic disease [22]. Patients with PAD typically have severe systemic atherosclerosis and poorer endothelial function compared to patients without PAD [23]. Among patients with PAD, poorer endothelial function is associated with higher rates of cardiovascular events [24]. A prior report also found that therapeutic exercise improves endothelial function [25].

Four points should be considered for improvement of the prognosis of patients after EVT: screening for polyvascular disease at the time of diagnosis of PAD; avoidance of complications of EVT, especially prolongation of hospitalization due to hematoma; therapeutic exercise for patients after EVT; and intensive therapy for hypertension and dyslipidemia using ACEIs/ARBs, Ca-antagonists and statins.

This study has several limitations, including its retrospective nature and the absence of data on medication at the end of the follow-up period and on improving functional status and quality of life. Duplex ultrasound for detection of hematoma or pseudoaneurysm was not done routinely post-intervention.

Conclusions

Within these limitations, we conclude that the prognosis after EVT is relatively good for most patients with IC, but extremely poor for high-risk patients with IC.

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N	2,930
Age(years)	71.5±8.9
Male (%)	2307 (78.7)
BMI	22.6±3.3
Hypertension (%)	2456 (83.8)
Dyslipidemia (%)	1504 (51.3)
Diabetes (%)	1631 (51.4)
Insulin (%)	481 (16.4)
Hemodialysis (%)	450 (15.4)
Current Smoker (%)	1003 (34.2)
Previous Smoker (%)	1110 (37.9)
Previous stroke (%)	553 (18.9)
CAD (%)	1479 (50.5)
Heart failure (%)	274 (9.4)
LV dysfunction (%)	193 (6.6)
Af	356 (12.1)
Rutherford class	
Ⅱ/Ⅲ	1,121/1,809
pre-procedual ABI	0.65±0.2
post-procedual ABI	0.91±0.17
Medication	
Aspirin	2,548 (87.0)
Thienopyridines	1,502 (51.3)
Cilostazol	1,271 (43.4)
Statins	1,197 (40.9)
ACEⅠ/ARBs	1,606 (54.8)
β-blockers	724 (24.7)
Ca-antagonist	1,361 (46.5)
Warfarin	340 (11.6)

Table.1

Data given as n (%) or mean ± SD. LV dysfunction was defined as <40% of LV ejection fraction. BMI, body mass index; ABI, ankle-brachial index; ACEI, angiotensin-converting enzyme inhibitors; ARBs, angiotensin receptor blockers; BMI, body mass index; CAD, coronary artery disease; LV, left ventricular.

Lesion Characteristics	
No.lesions	3,802
Use of stent (%)	3,267 (85.9)
Iliac artery (%)	1,896 (49.9)
Lesion length (mm)	53.1±39.3
Reference vessel diameter (mm)	8.2±2.5
Pre-diameter stenosis (%)	80±18.8
Post-diameter stenosis (%)	20.4±10.2
Chronic total occlusion (%)	457 (24.1)
Calcified lesion (%)	913 (48.2)
TASC Ⅱ class A/B/C/D	889/521/220/266
Use of stent (%)	1,896 (100)
Involving SFA lession (%)	544 (27.7)
SFA (%)	1,906 (50.1)
Lesion length (mm)	74.5±89.0
Reference vessel diameter (mm)	5.2±1.0
Pre-diameter stenosis (%)	91.0±11.5
Post-diameter stenosis (%)	11.5±13.7
Chronic total occlusion (%)	877 (46.0)
Calcified lesion (%)	1092 (57.3)
TASC Ⅱ class A/B/C/D	671/516/248/473
Use of stent (%)	1371 (71.9)
Involving iliac lesion (%)	290 (15.2%)

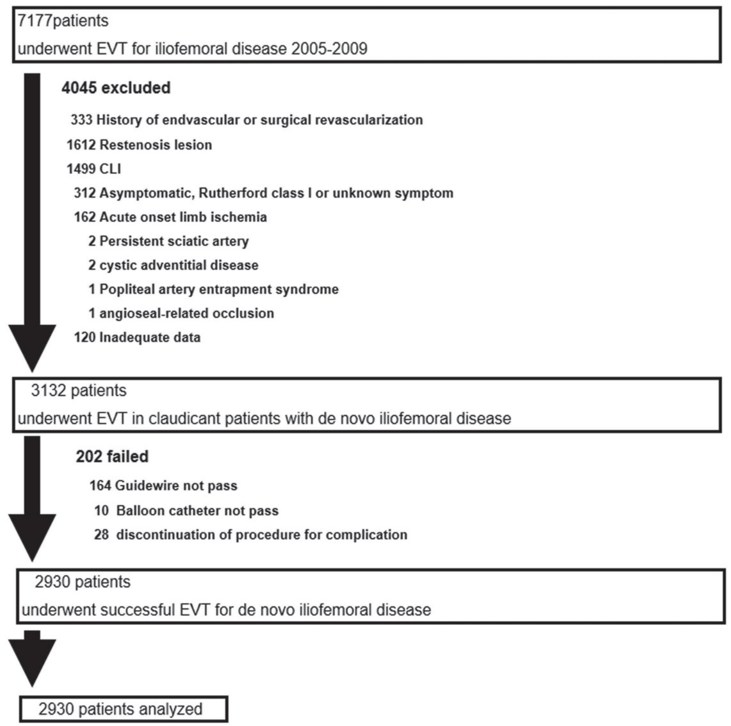
Table.2

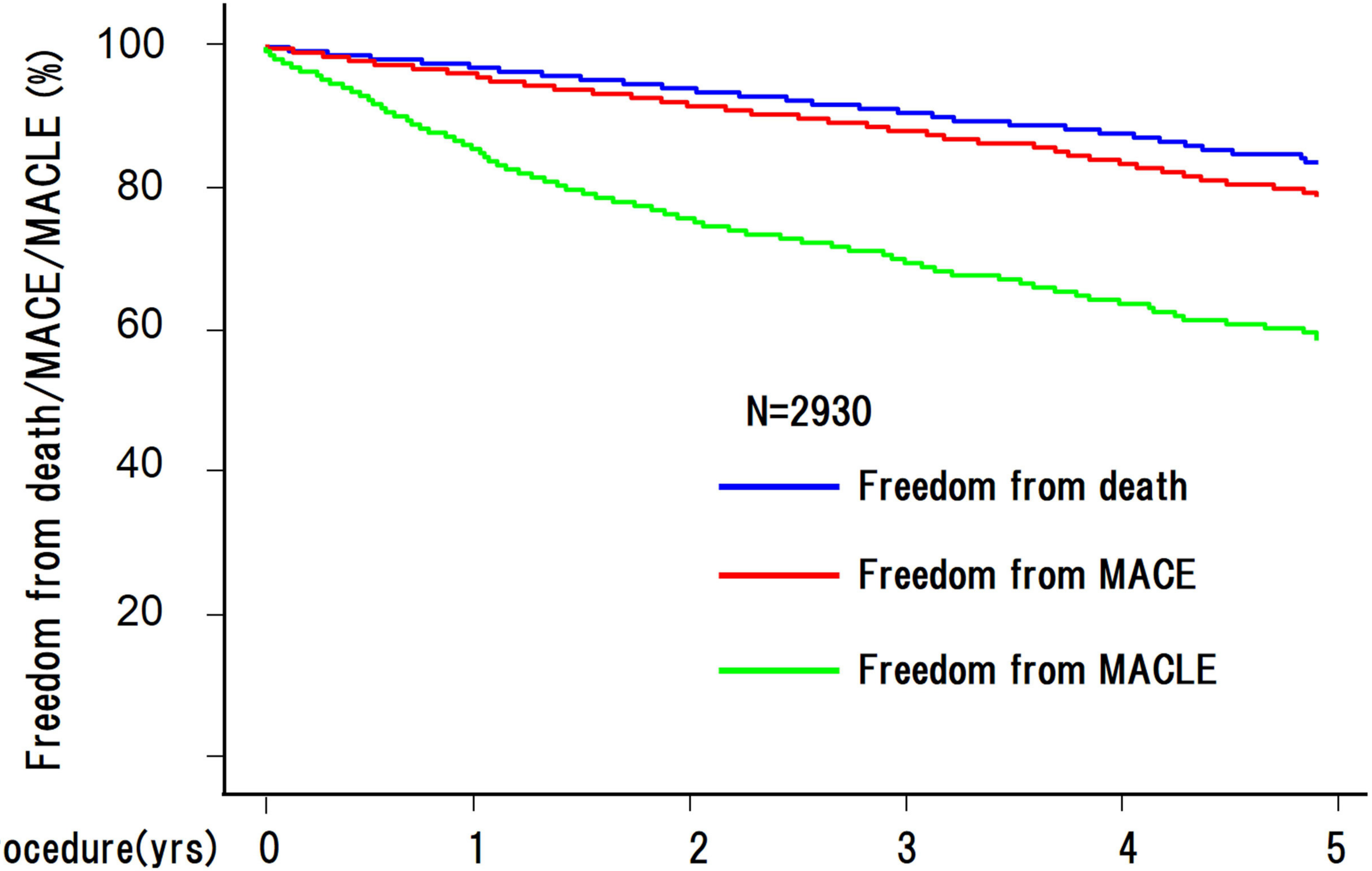
Data given as n (%) or mean ± SD. Calcified lesion defined as obvious densities noted within the apparent vascular wall in the angiogram. TASCII, Trans-Atrantic Inter-Society Consensus; SFA, superficial femoral artery.

Univariate and Multivariate Predictors of all cause death				
	Unajusted HR (95%CI)	P value	Adjusted HR (95%CI)	P value
Variables				
Complication of hematoma	2.68 (1.23–5.85)	0.014	2.75 (1.08–6.98)	0.034
LV dysfunction	3.16 (2.15–4.66)	<0.0001	2.70 (1.74–4.19)	<0.0001
Dialysis	2.91 (2.17–3.90)	<0.0001	2.54 (1.73–3.73)	<0.0001
Elderly	1.46 (1.10–1.95)	0.009	2.05 (1.43–2.92)	<0.0001
Diabetes treated by insulin	1.51 (1.09–2.08)	0.013	1.70 (1.14–2.55)	0.0095
CAD	1.54 (1.18–2.02)	0.0017	1.43 (1.03–2.01)	0.036
Iliac ＋SFA lesion	1.38 (1.02–1.87)	0.04	1.43 (1.01–2.01)	0.044
Ca-antagonist administration	0.65 (0.49–0.85)	0.0018	0.67 (0.48–0.93)	0.018
ACEI/ABRs administration	0.62 (0.47–0.80)	0.0004	0.61 (0.44–0.85)	0.0033
Statins administration	0.63 (0.47–0.83)	0.0013		

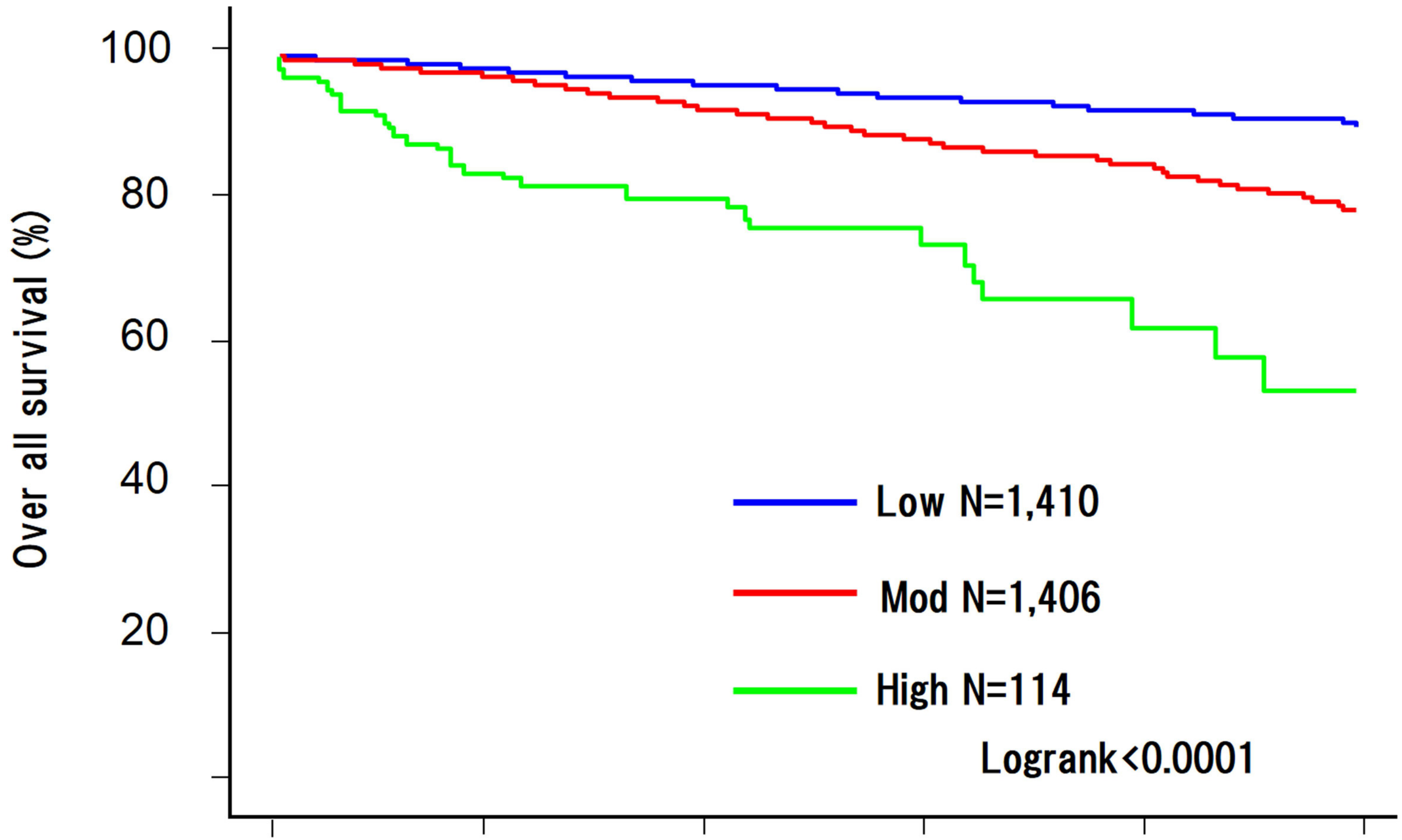
Table.3

LV dysfunction was defined as <40% of LV ejection fraction. Elderly age was defined as >70. CI, confidence interval; HR, hazard ratio; LV, left ventricular; CAD, coronary artery disease; SFA, superficial femoral artery; ACEI, angiotensin-converting enzyme inhibitors; ARBs, angiotensin receptor blockers

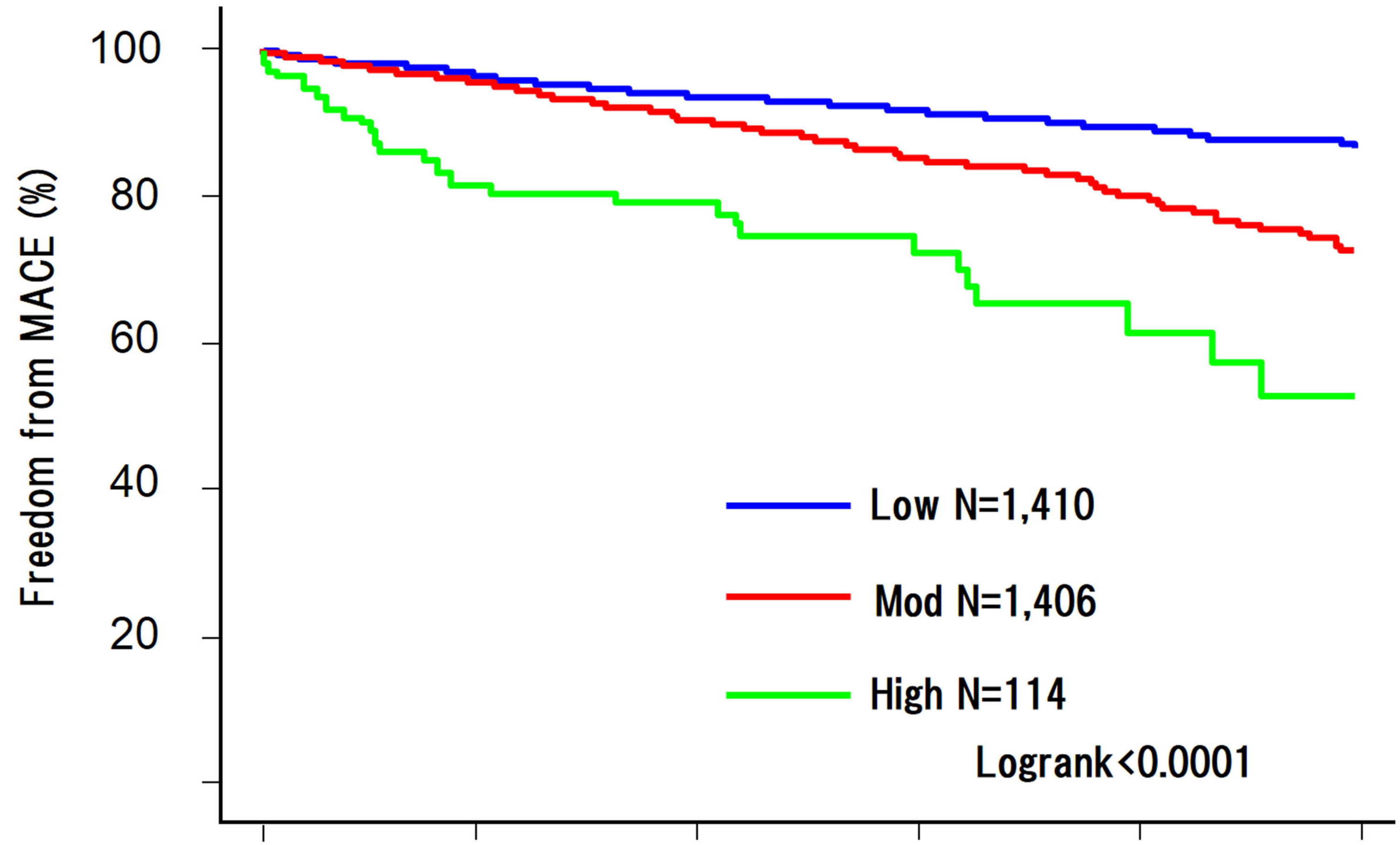

7177patients
underwent EVT for iliofemoral disease 2005-2009
4045 excluded
333 History of endvascular or surgical revascularization
1612 Restenosis lesion
1499 CLI
312 Asymptomatic, Rutherford class I or unknown symptom
162 Acute onset limb ischemia
2 Persistent sciatic artery
2 cystic adventitial disease
1 Popliteal artery entrapment syndrome
1 angioseal-related occlusion
120 Inadequate data
3132 patients
underwent EVT in claudicant patients with de novo iliofemoral disease
202 failed
164 Guidewire not pass
10 Balloon catheter not pass
28 discontinuation of procedure for complication
2930 patients
underwent successful EVT for de novo iliofemoral disease
2930 patients analyzed



	0	1	2	3	4	5
at risk	2930	2411	1687	1048	603	305
Freedom from death (%)		97.2	93.9	90.8	87.7	83.4
SE (%)		0.3	0.5	0.7	0.9	1.2
at risk	2930	2411	1686	1048	603	305
Freedom from MACE (%)		96.7	93.0	88.6	84.0	77.3
SE (%)		0.3	0.5	0.7	1.0	1.4
at risk	2930	2121	1381	834	447	218
Freedom from MACLE (%)		84.5	74.4	68.1	61.7	58.7
SE (%)		0.7	0.9	1.0	1.2	1.3



Time after Procedure(yrs)	0	1	2	3	4	5
at risk	1410	1172	852	526	298	160
Low risk (%)		98.3	96.2	94.3	92.7	90.1
SE (%)		0.4	0.6	0.8	1.0	1.4
at risk	1406	1158	779	491	287	135
Moderate risk (%)		97.2	92.7	88.6	84.7	78.6
SE (%)		0.5	0.8	1.1	1.4	2.0
at risk	114	80	55	26	16	8
High risk (%)		83.9	80.5	66.3	62.4	53.5
SE (%)		3.6	3.9	6.0	6.8	8.2



Time after Procedure(yrs)	0	1	2	3	4	5
at risk	1410	1158	834	514	293	155
Low risk (%)		96.7	93.8	91.6	89.4	87.0
SE (%)		0.5	0.7	0.9	1.1	1.4
at risk	1406	1140	760	477	274	130
Moderate risk (%)		95.5	90.3	85.3	79.5	72.3
SE (%)		0.6	0.9	1.2	1.6	2.2
at risk	114	78	54	31	15	8
High risk (%)		81.2	78.9	72.1	61.1	52.4
SE (%)		3.8	4.0	5.0	6.7	8.1