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Midterm Outcomes and Risk Stratification after Endovascular Therapy for Patients with Critical Limb Ischaemia due to Isolated Below-the-knee Lesions

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WHAT THIS PAPER ADDS

- Although many reports have proven the efficacy and safety of endovascular therapy (EVT) for critical limb ischaemia (CLI) in each arterial segment, few reports have supported the general effectiveness of EVT in patients with CLI due to isolated below-the-knee (BTK) lesions. Therefore, the purpose of this study was to investigate the total effectiveness of EVT on three long-term outcomes, namely overall survival (OS), freedom from major amputation (MA) and reintervention, in patients with CLI due to isolated BTK lesions, and to subsequently risk stratify each of these 'end' points.
- From our results, despite both high mortality and high reintervention rates, freedom from MA was acceptable after EVT for patients with CLI presenting with isolated BTK lesions. Risk stratification on outcomes plays an important role not only in estimating their future occurrence, but also in deciding which revascularisation strategy to pursue for patients with CLI due to isolated BTK lesions.

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ABSTRACT

Objectives: To assess and risk stratify midterm clinical outcomes after endovascular therapy (EVT) by angioplasty only of patients with critical limb ischaemia (CLI) due to isolated below-the-knee (BTK) lesions.
Design: Retrospective multicenter study.
Materials and methods: Between March 2004 and October 2010, 465 limbs (Rutherford 5 and 6: 79%) from 406 patients were studied. Overall survival, limb salvage, and re-intervention were examined out to 3 years by the Kaplan–Meier method and the log-rank test. Their independent predictors and risk stratification were analysed.
Results: Patient age was 71 ± 11 yrs, with 69% diabetics and 60% on dialysis. Mean follow-up was 18 ± 15 months. Overall survival was 76 ± 2 and 57 ± 4% at 1 and 3, years, respectively. Survival predictors were body mass index <18, non-ambulatory status and ejection fraction <45%. Two-year limb salvage rate was 80 ± 2%. Factors associated with major amputation were ulcers (Rutherford 6), diabetes mellitus, C-reactive protein>5 mg/dL, and age < 60 years. Two-year freedom from re-intervention was 66 ± 3%; age and below-the-ankle runoff number after angioplasty was negatively associated with re-intervention.
Conclusions: Despite relatively high mortality and re-intervention rates, limb salvage rate was acceptable after EVT for CLI patients with isolated BTK lesions. Risk stratification allows occurrence estimation for each end point.

The primary goals of the revascularisation by surgical bypass therapy (BSX) or endovascular therapy (EVT) in patients with critical limb ischaemia (CLI) are to relieve ischaemic pain, heal ischaemic ulcers, prevent, limb loss and improve patient function and quality of

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life.[1,2] Patients with CLI, especially those with diabetes mellitus (DM) and end-stage renal disease (ESRD) on dialysis, commonly present with long, diffuse arteriosclerotic disease in the BTK region, which is still considered best treated with saphenous vein graft BSX as first-line therapy.[3,4] However, these patients are often not suitable surgical candidates due to concomitant disease and advanced age, making EVT preferable. On the other hand, thus far there are no physiological data on risk stratification for clinical outcomes after EVT of patients with CLI due to isolated BTK lesion. While many reports have proven the efficacy and safety of EVT for CLI in each arterial segment,[5,6] few reports have supported EVT effectiveness in patients with CLI due to isolated BTK lesions. Moreover, there is a potential advantage for a simple adopted score for patients with CLI and isolated BTK lesions to predict patients/lesions less suitable for endovascular treatment and those who might benefit the most from this treatment. Therefore, this study investigated and risk-stratified EVT midterm outcomes: namely, overall survival, limb salvage, and re-intervention, in patients with CLI due to isolated BTK lesions.

Methods

Patients

We retrospectively analysed a prospectively maintained multicentre database from April 2004 to October 2010. The database excluded patients who were considered poor candidates for endovascular or surgical revascularisation due to severe comorbidities and impairment at the functional (bedridden without intractable rest pain), cognitive (dementia not requiring institutionalisation) and/or social (no family or professional career) levels, or who refused revascularisation. Although intervention was not attempted in patients with functionally unsalvageable limbs, non-ambulatory patients without cognitive and social problems were treated with angioplasty for limb salvage taking into consideration patient's preference and family co-operation, and lack of control of rest pain with anaesthetics. During this period, 1068 limbs in 900 consecutive CLI patients received EVT in one of six cardiovascular centres in Japan. After excluding patients with CLI due to BTK lesions combined with femoropopliteal (FP) lesions (47%, 498 limbs in 395 patients) or with aorto-iliac FP lesions (10%, 105 limbs in 99 patients), or who presented with acute limb ischaemia requiring emergent revascularisation or with functionally unsalvageable limbs, the data set used for the study included 465 limbs from 406 consecutive patients who underwent angioplasty alone for *de novo* BTK lesions, and who also gave consent to provide clinical follow-up during the chronic phase. All patients were symptomatic secondary to isolated BTK lesions (Rutherford categories 4–6) with threatened limb loss. During this period, 355 CLI patients were treated with crural bypass therapy by a vascular surgeon. Data on patients who did not undergo revascularisation or who underwent

Table 1
Baseline patient and lower limb characteristics in overall group, and comparison of those between death and alive group.

Variables as % (*n*)	Overall ($n = 406$)	Death ($n = 130$)	Alive ($n = 276$)	*P* value
Patients status				
Age, years	71 ± 11	72 ± 9	70 ± 12	0.16
Male gender	67% (274)	68% (89)	67% (185)	0.77
BMI	22 ± 3	21 ± 4	22 ± 3	0.0043
BMI <18	14% (57)	23% (30)	9% (27)	0.0002
Total protein (g/dL)	7.0 ± 0.8	6.9 ± 0.8	7.0 ± 0.8	0.67
Albumin (g/dL)	3.4 ± 0.6	3.3 ± 0.6	3.5 ± 0.5	0.0003
Non-ambulatory	43% (175)	60% (78)	35% (97)	<0.0001
Risk factors				
Hypertension	77% (314)	79% (103)	76% (211)	0.53
Dislipidemia	29% (117)	22% (29)	32% (88)	0.06
Diabetes mellitus	69% (280)	65% (85)	71% (185)	0.28
Current smoking	30% (121)	33% (43)	28% (78)	0.32
ESRD on dialysis	60% (242)	72% (94)	54% (148)	0.0003
Red blood cell count (/μl)	355 ± 80	348 ± 89/	359 ± 77	0.22/
Haemoglobin (g/dl)	11.0 ± 1.8	10.7 ± 1.9	11.1 ± 1.8	0.0051
Cardiovascular disease				
Coronary artery disease	52% (210)	58% (76)	49% (134)	0.06
Heart disease	56% (226)	64% (83)	52% (143)	0.02
Aortic valve stenosis	7% (30)	9% (12)	7% (18)	0.32
Mitral regurgitation	10% (41)	12% (16)	9% (25)	0.30
Heart rate (bpm)	81 ± 16	85 ± 19	79 ± 15	0.0008
Heart rate >80 bpm	52% (211)	65% (84)	46% (127)	0.0009
EF (%)	58 ± 14	53 ± 15	61 ± 13	<0.0001
EF<45%	15% (61)	29% (38)	9% (23)	<0.0001
Cerebrovascular disease	29% (118)	39% (51)	24% (67)	0.002
COPD	3% (12)	4% (5)	3% (7)	0.51
Lower limb status				
Rutherford classification	5.0 ± 0.6	5.2 ± 0.6	4.9 ± 0.6	<0.0001
ABI before angioplasty	0.76 ± 0.27	0.71 ± 0.28	0.79 ± 0.27	0.03
ABI < 0.6	19% (72)	29% (40)	15% (30)	0.0028
White blood cell count (/μl)	7600 ± 3100	8000 ± 3600	7300 ± 2900	0.03
CRP level (mg/dl)	2.5 ± 4.0 [1.0]	3.6 ± 4.8 [1.5]	2.0 ± 3.6 [0.8]	0.002
CRP >3 mg/dl	24% (98)	38% (40)	18% (50)	<0.0001
Medication				
Cilostazol	58% (236)	57% (74)	59% (162)	0.73
Statine	20% (81)	16% (21)	22% (60)	0.19
Vessel calcification	62%	72% (93)	58% (160)	0.0085
Number of below-the-knee runoff after angioplasty	1.6 ± 0.9	1.5 ± 0.8	1.7 ± 0.9	0.06
Reintervention	24% (98)	24% (31)	24% (67)	0.99
Major amputation	15% (59)	20% (26)	12% (33)	0.03

Comparison between patients who were either alive or dead at the end of the follow-up period. Data are presented as mean [median] or % (*n*).
ABI: Ankle/Brachial Index; COPD: congestive obstructive pulmonary disease.