Journal of the Formosan Medical Association (2014) 113, 688–695

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ORIGINAL ARTICLE

Endovascular intervention in Taiwanese patients with critical limb ischemia: Patient outcomes in 333 consecutive limb procedures with a 3-year follow-up

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Received 16 May 2012; received in revised form 13 September 2012; accepted 30 October 2012

KEYWORDS
critical limb ischemia;
endovascular intervention;
outcomes

Background/Purpose: Midterm outcomes of endovascular intervention (EVI) for critical limb ischemia (CLI) have not been previously reported in Taiwan. This study assessed the safety, feasibility, and patient-oriented outcomes for CLI patients after EVI.
Methods: From June 2005 to December 2011, 270 patients underwent EVI for CLI of 333 limbs. Primary patency (PP), assisted primary patency (AP), limb salvage, sustained clinical success (SCS), secondary SCS (SSCS), and survival were assessed using Kaplan-Meier analysis.
Results: The procedural success rate was 89%, and the periprocedural mortality and major complication rates within 30 days were 0.6% and 6.9%, respectively. During the mean follow-up time of 27 ± 20 months (1–77), 64 patients died and 25 legs required major amputation. Eighty-one percent of the patients with tissue loss had wound healing at 6 months and 75% of the patients were ambulatory, with or without assisting devices, at 1 year. The overall

Conflicts of interest: The authors have no conflicts of interest relevant to this article.

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http://dx.doi.org/10.1016/j.jfma.2012.10.022

survival and limb salvage rates at 3 years were 70% and 90%, respectively. The PP and AP at 1 and 3 years were 58% and 37% and 79% and 61%, respectively. The SCS and SSCS were 65% and 46% and 80% and 64% at 1 and 3 years, respectively.
Conclusion: In Taiwan, EVI was a safe and feasible procedure for CLI patients, with a high procedural success rate and lower complication rate. Sustained limb salvage and clinical success can be afforded with an active surveillance program and prompt intervention during midterm follow-up.

Introduction

Critical limb ischemia (CLI) is the most severe form of peripheral artery disease, defined as chronic ischemic rest pain, ischemic ulcers, and gangrene attributable to objectively proven arterial occlusive disease.[1] Without timely revascularization, CLI carries a 25% risk of mortality and another 25% risk of amputation over the next year.[2]

Revascularization therapy, either endovascular intervention (EVI) or bypass surgery, is indicated for patients with CLI. Remarkable technological advances in the past decade, along with patient preferences, have changed revascularization strategies from traditional bypass surgery to less invasive EVI.[3–5] EVI offers several advantages over surgical bypass for selected lesions.[6] Performed under local anesthesia, it enables treatment of patients who are at high risk for general anesthesia. Many physicians recommend EVI as the first-line therapy in patients with chronic lower limb ischemia, because of its low mortality, and acceptable midterm assisted patency and limb salvage rates.[7–9] In Taiwan, the midterm outcomes of EVI for CLI patients were not clear; with this study, we evaluated the safety, feasibility, and midterm outcomes of EVI for patients with CLI.

Materials and methods

Study population

From June 2005 to December 2011, 326 consecutive patients with 403 affected legs were referred to this institution for EVI, because of symptomatic low extremity arterial disease. A total of 270 patients presented with 333 limbs affected with CLI. The definition of CLI, derived from the current consensus of clinical presentation, consists of rest pains, ulcers, or gangrene. The exclusion criteria for EVI included patients with: (1) infrarenal aortic occlusion; (2) no target vessel below the knee; (3) end-stage renal disease (ESRD) without regular hemodialysis; (4) contraindications for aspirin or clopidogrel; (5) acute limb ischemia requiring emergent revascularization; (6) symptoms of intermittent claudication; (7) overwhelming infection threatening the patient's life; and (8) procedure refusal.

Pre-interventional study included a clinical examination, hemodynamic evaluation (ankle or toe pressure, pulse volume recording, duplex scanning), and anatomic assessment, including computed tomographic angiography, magnetic resonance angiography, or diagnostic angiography. Decisions on the revascularization strategy were based on the clinical examination, anatomic evaluation, and the patient's comorbidities. Usually, less invasive EVI was the first-choice revascularization strategy (including the tibial arteries) and open bypass surgery served as a back-up option. Toe pressures, pulse volume recording, and Doppler waveform patterns were performed to measure the hemodynamic changes in patients with falsely elevated ankle brachial index (ABI) values. A single-level intervention was defined as EVI for isolated aortoiliac, femoropopliteal, or below-the-knee (BTK) lesions. A multilevel intervention was defined as EVI in more than one area.

The diagnosis of diabetes mellitus (DM) was determined from the hospital records and confirmed by the patient's use of oral hypoglycemic agents or insulin. Chronic renal failure was defined as a serum creatinine level of $>$1.5 mg/dL, or if the patients received regular dialysis due to ESRD. History of coronary artery disease was defined as a diameter stenosis of $>$50% in one of the three main coronary arteries, or prior revascularization by percutaneous coronary intervention or bypass grafting. Hypertension and congestive heart failure were documented by medical records and confirmed by use of the appropriate medications. For each patient, we recorded demographic and interventional data, including clinical presentation according to the Rutherford classification (RC),[10] lesion anatomy based on the Trans-Atlantic Intersociety Consensus (TASC) I and II system, and follow-up ABIs, toe pressures, and duplex ultrasounds.

Interventions

The interventional procedure was usually conducted using either the antegrade or crossover approach, but also through multiple access sites (brachial or pedal puncture) for complex cases. All patients received 100 mg aspirin and 75 mg clopidogrel per day for 4 days before the EVI. Aspirin was administered continuously after the intervention. Clopidogrel was used for 3 months if the self-expandable nitinol or balloon-expandable bare-metal stent was implanted, or for 12 months if the drug-eluting stent was used. Unfractionated heparin (5000−10,000 units) was administered during the procedure, to maintain an activated coagulation time of around 250 seconds. Lesions were crossed intraluminally or subintimally with hydrophilic (0.014-, 0.018-, 0.035-inch) or platinum-tipped (0.014-, 0.018-, 0.035-inch) guidewires. The routine stenting strategy in iliac intervention was performed after reimbursement by National Health Insurance, and provisional stenting was used in infrainguinal management. Additional procedures, including such devices as cutting balloons, cryoballoons (cryoplasty), excimer lasers (atherectomy), or

drug-eluting balloons, were performed at the discretion of the operator to improve the immediate technical success.

Definitions

Technical success was defined as successful access and deployment of the device and $\leq$30% residual diameter stenosis by quantitative angiography, with evidence of at least one tibial artery to the foot. Procedural success was defined as technical success without periprocedural complications. Immediate hemodynamic success was defined as ABI improvement of $\geq$0.15, as compared to the baseline data. Periprocedural major complications were defined as death, myocardial infarction, stroke, unplanned bypass, contrast-induced acute kidney injury requiring dialysis, compartment syndrome requiring a fasciotomy, and groin complications, such as pseudoaneurysm or arteriovenous fistula sealed by ultrasound-guided manual compression or surgical repair.

Minor complications were defined as vessel perforation caused by the guidewire, and access site hematoma without blood transfusion (a fall in hemoglobin $<$2 g/dL). Primary patency (PP) was defined as persistent patency without recurrent symptoms in the face of worsening ABIs and a dampened Doppler waveform pattern due to recurrent disease. Assisted primary patency (AP) was achieved by reintervention for restenosis, reocclusion, or a new lesion on the treated leg. Sustained clinical success (SCS) was defined as continuous clinical improvement without the need for target extremity revascularization, recurrent ulceration, or major amputation. Clinical improvement was defined as an RC score improvement of $\geq$2+; an ABI increase of at least 0.15, and wound healing in $\leq$4 months of index intervention for patients with tissue loss. Secondary SCS (SSCS) was defined as clinical improvement with target extremity revascularization and without major amputation. Major amputation was defined as limb loss above or below the knee. Minor amputation included transmetatarsal or toe amputation. The protocol was reviewed and approved by the institutional review board, and written informed consent forms were obtained for all patients enrolled in this study.

Patient follow-up

After being discharged from the hospital, all patients with successful procedures were followed up at an outpatient clinic. Patients with tissue loss underwent wound debridement, free flap transplant, and hyperbaric oxygen therapy by a plastic surgeon or orthopedist, until their wounds healed. Clinical examination and duplex ultrasounds were performed at 1 week, 1 month, and 3 months after the index procedures, and every 3 months thereafter. Repeat interventions were conducted if recurrent symptoms, significant vessel stenosis ($\geq$ 70%) with dampened Doppler waveform patterns by duplex ultrasound, and an ABI decrease of $\geq$0.2, were observed. Major events (mortality, limb amputation, PP failure, and failure of SCS) were documented at the time of hospital discharge, or during the 3-month follow-up office visits. In the event office follow-up was not feasible, telephone interviews, data obtained from medical records, local electronic medical databases, and referring physicians were used as alternate data sources.

Analysis and statistics

Categorical variables were reported as counts and percentages, and continuous variables were reported as the mean $\pm$ standard deviation. Continuous variables were analyzed using t tests and χ^2 tests were used to compare the wound healing rate and ambulatory status before and after the EVI. PP, AP, limb salvage, SCS, SSCS, and survival were assessed using Kaplan-Meier analysis. For the survival analyses, a census of the surviving patients was done on the date of last clinical contact. Eighteen patients were excluded from the study because they did not keep their first follow-up appointment 1 month after the index procedure. All analyses were performed using Stata 10 (StataCorp, College Station, TX, USA). Statistical significance was set at $p < 0.05$.

Results

Baseline demographics (Table 1)

Our study population consisted of a total of 270 consecutive patients with 333 treated limbs. Forty-nine percent were male patients, with a mean age of 71 $\pm$ 11 years. Most of the study patients had multiple comorbidities. Using PIII CLI risk scoring,[11] 69% of the study patients were medium to high risk for bypass surgery. The most frequent

Table 1 Baseline demographics.

Patient numbers: n = 270
Sex: male, 132 (49%)
Age: 71 $\pm$ 11 y old
Underlying medical comorbidities
Diabetes mellitus: 222 (82%)
Hypertension: 230 (85%)
Chronic renal failure: 146 (54%)
Chronic kidney disease: 47 (17%)
Dialysis dependence: 99 (37%)
Hyperlipidemia: 145 (54%)
Coronary artery disease: 111 (41%)
Smoking: 95 (35%)
Cerebrovascular accident: 69 (26%)
Congestive heart failure: 40 (15%)
PIII risk score
Low (0—3): 83 (31%)
Medium (4—7): 111 (41%)
High ($\geq$ 8): 76 (28%)
Treated extremities: n = 333
Rest pain: 85 (25%)
Ulcer: 169 (51%)
Gangrene: 79 (24%)
Target extremity ABI: 0.48 $\pm$ 0.16

ABI = ankle brachial index; ESRD = end-stage renal disease.

presentation was a nonhealing ulcer (51%), followed by resting pain (25%) and foot gangrene (24%). The mean ABIs of the target extremity at initial presentation were 0.48 ± 0.16.

Lesion morphology of the treated limbs (Table 2)

The detailed lesion morphology of the treated limbs is listed in Table 2. Single-level endovascular treatment (EVT) was performed on 170 limbs (51%) and multilevel EVT on the remaining treated limbs. Thirty limbs had undergone previous bypass surgery, and eight had undergone failed EVIs at other institutions. A total of 680 lesions underwent EVT in 333 limbs and totally occluded arteries were observed in 252 (37%) vessel segments. Most of the infrapopliteal lesions belonged to TASC D diffuse diseased vessels. The mean lesion length of aortoiliac, femoropopliteal, and BTK vessel segments was 6.24 ± 3.29 cm, 11.92 ± 7.68 cm, and 13.47 ± 7.21 cm, respectively.

Procedural results (Table 3)

The overall technical and procedural success rates were 94% and 89%, respectively. There were 19 failures of the initial EVI; of these, seven limbs underwent bypass surgery, three immediate below-knee amputations, one minor amputation, four conservative treatments, and four second attempts at EVI. Of the four limbs undergoing a second EVI, three were successfully revascularized and one ultimately went into below-knee amputation. Patients with successful EVIs had significant, immediate hemodynamic improvement, with the ABIs increasing from 0.48 ± 0.16 to 0.87 ± 0.16 ($p < 0.001$). Subsidence of intractable pain was observed in 95% of the successfully revascularized limbs. All lesions were treated by angioplasty, but 53% of the limbs required stent implantation to optimize the angiographic results. Other additional devices were used in 64 legs (19%) for debulking, or where the area for the stent was unsuitable.

Table 3 Procedural results and complications.

Treated limbs: $n = 333$
Procedure success rate: 314 limbs (94%)
Failed treated limbs: 19
BK amputations: 3
Bypass surgery: 7
Minor amputation: 1
Conservative: 4
Second attempt of intervention: 4
ABI after intervention: 0.87 ± 0.16
Stent implantation in 177 legs intervention (53%)
Iliac artery: 59 stents in 47 lesions
FP artery: 178 stents in 115 lesions
BTK artery: 74 stents in 52 lesions
Additional devices:
Cutting balloon: 44 Excimer laser (atherectomy): 23
Reentry device: 1
Drug-eluting balloon: 2 Cryoballoon (cryoplasty): 3
Covered stent: 1
Death: 0
Vessel perforation: 23
Wire perforation: 22, stent graft: 1
Acute vessel closure requiring stent implantation: 3
Distal embolization: 13
Catheter aspiration: 11
IA urokinase: 2

BTK = below the knee; FP = femoropopliteal; IA = intra-arterial.

Table 2 Baseline lesion characteristics of treated limbs.

Treated limbs: $n = 333$
Previous bypass surgery: 30, previous EVI: 8
Single-level lesion: 170 (51%)
Iliac artery: 32 (9.6%)
FP artery: 52 (15.6%)
BTK artery: 85 (25.5%)
Multilevel lesions: 164 (49%)
Iliac and FP arteries: 8 (2.4%)
FP and BTK arteries: 146 (43.8%)
Iliac and FP and BTK arteries: 10 (3%)

Lesion characteristics:			
	Aortoiliac $n = 54$	FP $n = 217$	BTK $n = 409$
Stenosis:	45	144	239
Occlusion:	9	73	170
TASC			
A	5	16	8
B	22	108	49
C	17	58	65
D	10	35	287
Lesion length:	6.24 ± 3.29 cm	11.92 ± 7.68 cm	13.47 ± 7.21 cm

BTK = below-the-knee; EVI = endovascular intervention; FP = femoropopliteal; TASC = Trans-Atlantic Intersociety Consensus.

There were no procedure-related deaths. Of the 23 vessel perforations, 22 were caused by guidewire manipulation, but there were no sequelae after prolonged balloon inflation. One popliteal perforation during laser angioplasty required a stent-graft implantation. Three legs underwent immediate stent implantation, owing to acute vessel closure. Distal embolization was observed in 13 limbs (3.9%) and was successfully treated by catheter aspiration in 11, with adjuvant intra-arterial urokinase used in the other two limbs.

In-hospital and 30-day outcomes (Table 4)

Two patients died during hospitalization, one related to acute myocardial infarction and the other from decompensated heart failure. Three patients required urgent dialysis due to contrast-induced acute kidney injury and three suffered cerebrovascular events. Emergent surgery, with above-knee amputation, occurred in one patient, due to acute arterial thrombosis caused by procedure failure. Of the five patients affected with subacute arterial thrombosis within 30 days, four underwent successful reinterventions and one ultimately required an above-knee amputation. Of the eight groin complications, four cases of retroperitoneal bleeding needed blood transfusions, three pseudoaneurysms underwent ultrasound-guided manual compression, and one embolization of a collagen clot after dislodgement of the closure device required surgical repair. The mortality and major complication rates within 30 days were 0.6% and 6.9%, respectively. The ABIs 1 month after EVI increased to 0.92 $\pm$ 0.17.

Follow-up results

Of the 270 participants with 333 limbs, 14 patients were excluded, because of failed procedures (94% success rate), leaving a total of 256 patients (314 limbs) in the study. Eighteen patients with 20 limbs were lost (93% follow-up rate) during a mean follow-up time of 27 $\pm$ 20 months (range = 1–77), meanwhile, 64 patients died, 40 (62%) by noncardiovascular causes and 24 (38%) by cardiovascular causes. Of the 294 limbs monitored during the follow-up period, 25 required major amputations and 34 underwent minor amputations. Because of the failure of SCS, 74 repeat interventions were performed. Within 4 months, wound healing occurred in 67% of the patients with tissue loss and improved to 81% at 6 months. Patients with an RC 5 score had faster wound healing than patients with an RC 6 score at either 4 months (74% vs. 48%, $p < 0.001$) or 6 months (86% vs. 70%, $p = 0.003$) (Fig. 1). Following successful EVIs, 132 (52%) patients returned to independent ambulation, 44 (19%) were ambulatory with assistive devices, and 36 (15%) were wheelchair-bound. The EVI significantly improved the ambulatory status of CLI patients at 1 year as compared to their preoperative status ($p < 0.001$) (Fig. 2). EVI was also performed in 17 bed-ridden patients; of these, four returned to being wheelchair-bound, 12 remained bed-ridden, and one was lost to follow-up. The 1-year survival rate for bed-ridden patients was only 30.7%. The overall survival rates at 1 and 3 years were 88% and 70%, respectively (Fig. 3). The rates for being free from major amputation and any amputation were 90% and 78%, respectively, at 1 year and were sustained up to 3 years (Fig. 4). The PP and AP at 1 and 3 years were 58% and 37% and 79% and 61%, respectively (Fig. 5). The SCS and SSCS rates at 1 and 3 years were 65% and 46% and 80% and 64%, respectively (Fig. 6).

Discussion

This study is the first to report midterm outcomes using EVI in the management of CLI in Taiwan. It demonstrated that EVI was a safe and feasible procedure for CLI patients, with high procedural success and lower complication rates. Maintaining limb salvage and SCS can be accomplished during follow-up.

Traditionally, patients in Taiwan with CLI usually underwent primary amputation or bypass surgery. Tseng et al reported that DM accounted for 37% of the low extremity amputations.[12] Over the past decade, the most significant change in CLI treatment has been the shift from bypass surgery to less invasive EVI. The main advantages of EVI are low complication rates, ranging from 0.5% to 4.0%,

Table 4 In hospital and 30-day outcomes.

Deaths: 2
Myocardial infarction: 1
CVA/SDH: 3
Contrast nephropathy requiring hemodialysis: 3
Emergent surgery: 1
Subacute arterial thrombosis: 5
Groin complications: 8
Retroperitoneal bleeding: 4
Pseudoaneurysm: 3
Collagen clot embolization: 1
Periprocedural mortality: 2 (0.6%)
Periprocedural major complications: 23 (6.9%)
ABI 1 mo after intervention: 0.92 $\pm$ 0.17

ABI = ankle brachial index; CVA = cerebrovascular accident; SDH = subdural hematoma.

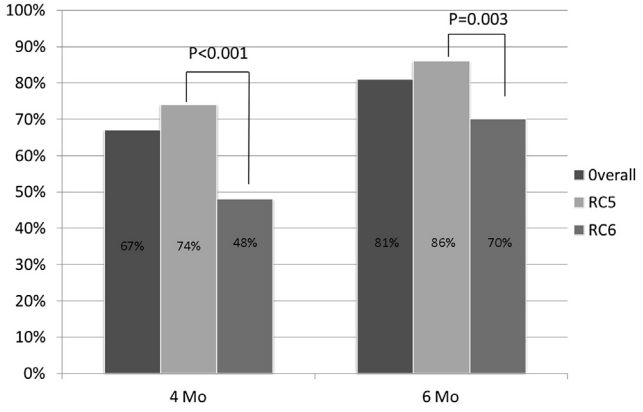

Figure 1 Change in wound healing rate between Rutherford classification (RC) 5 and RC 6 at 4 months, $p < 0.001$ and between RC 5 and RC 6 at 6 months, $p = 0.003$.

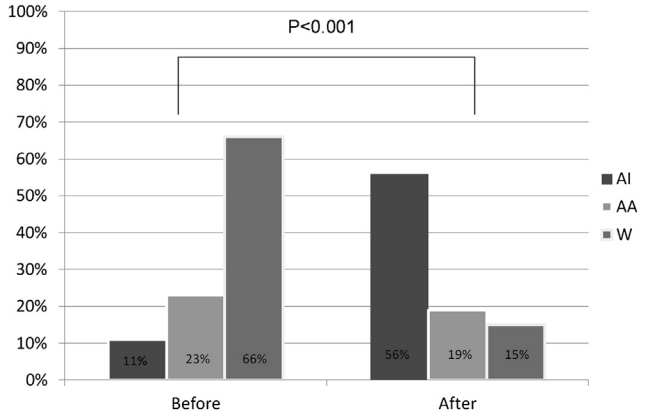

Figure 2 Change in ambulatory status before and after the intervention, $p < 0.001$. AI = ambulatory independently; AA = ambulatory with assistive device; W = wheelchair-bound.

high technical success rates (even in long occlusion) approaching 90%, and acceptable short-term clinical outcomes.[2] The BASIL trial demonstrated that the rates of amputation-free survival are similar for bypass surgery and balloon angioplasty for at least 2 years after the procedure.[13] In our study, the overall technical success rate (94%) was comparable to previous reports[14–16] and may be related to recent advances in endovascular devices and techniques. The mortality and major complication rates within 30 days were 0.6% and 6.9%, respectively, even though most of the study patients were elderly with multiple comorbidities or at high surgical risk. Our data demonstrate that EVI is safe and feasible for CLI patients in Taiwan. Mortality was rare and complications were low when the procedure was performed by a skilled interventionist.

Patency, clinical success, and limb salvage

When compared with bypass surgery, EVI has been criticized for its lower PP rates and higher reintervention rates. The 3-year PP in this series was 37%, similar to previous reports.[9,17] The high restenosis rates reflect advanced

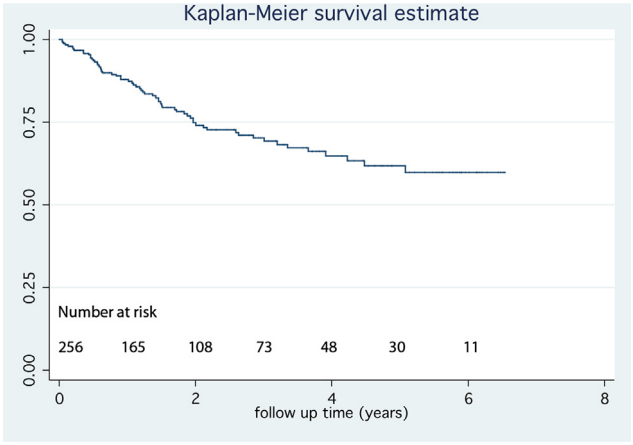

Figure 3 The overall survival of 256 patients.

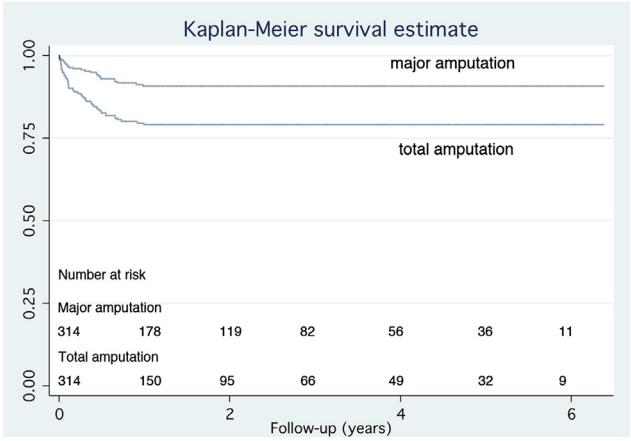

Figure 4 The Kaplan–Meier curve for patients free from major or minor amputation.

arterial disease in Taiwanese patients with CLI. The AP and SSCS rates at 3 years were 61% and 64%, respectively, which indicated that repeat EVI was required to maintain the midterm outcomes in these patients.

Our study showed that the limb salvage rate at 3 years was 90%, similar to the results of previous reports.[10,18,19] All amputations were performed in the 1st year, and 34 limbs originally designated for limb loss only required minor amputations. Thus, the limb salvage rate did not change significantly after the 2nd year. Intensive surveillance, followed by prompt assisted intervention, also prevented recurrent major tissue loss and supported the high limb salvage rate.

Survival

Without revascularization, 25% of the patients with CLI will die within 12 months and 32% within 24 months.[1] Conrad et al stated that there is a 12% annual death rate and 39% 5-year survival rate in CLI patients after EVI.[17] In Taiwan, information is scarce about the long-term survival of CLI patients after EVI. The 3-year survival rate (70%) was similar to previous reports,[8,18] and our results demonstrated

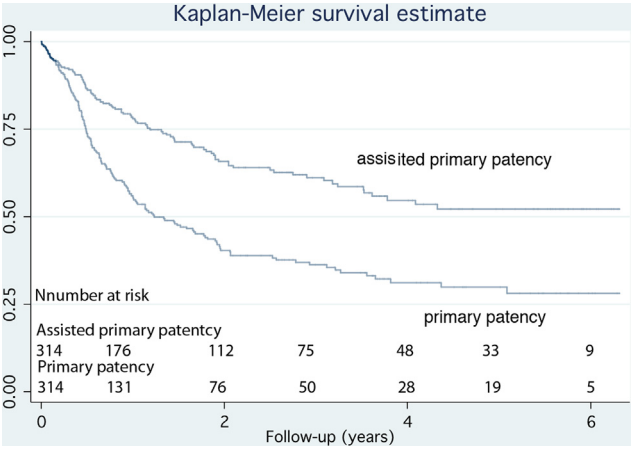

Figure 5 The Kaplan-Meier curve for primary patency and assisted primary patency.

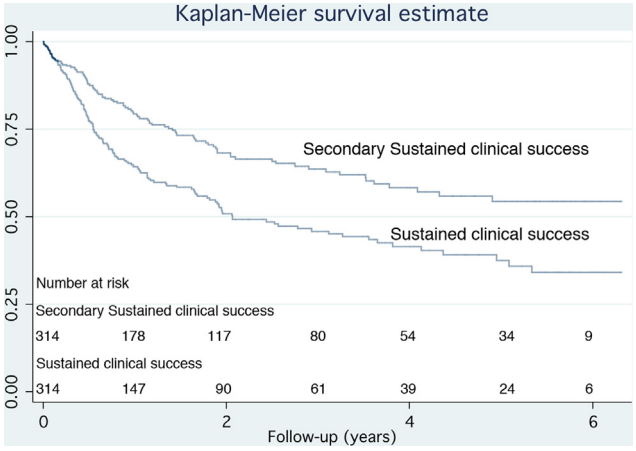

Figure 6 The Kaplan-Meier curve for sustained clinical success and secondary sustained clinical success.

that the midterm mortality rate in Taiwanese patients with CLI was higher. Interestingly, most of the patients in this series died from non-cardiovascular causes (62%), mainly from sepsis secondary to other sources, not a lower limb infection, followed by malignancy. This result reflects the multiple comorbidities and immunocompromised states in this patient group.

Wound healing

Without revascularization, ulcer healing was slow, with only 25% healed at 6 months and slightly more than 50% at 1 year.[20] In our results, wound healing occurred in 67% of the patients at 4 months (time frame for wound healing reported by Nicoloff et al).[21] Because of greater tissue loss at initial presentation, 33% of the study patients required a longer duration for wound closure. A lack of awareness of disease severity in Taiwan, and delays in the referrals that would have enabled early revascularization, also made wound care more difficult.

Ambulation

Functional capacity and independent living status remain a pertinent issue for the management of patients with CLI, because ambulation is an independent factor for long-term survival.[22,23] In our series, we found significant improvement in ambulatory status after successful revascularization. Resolution of resting pain, and closure of non-healing ulcers, helps CLI patients to be ambulatory or live independently.

There are some limitations in our study. First, it was a single-center, observational study from a prospective database. Treatment allocation was made at the discretion of the operator and the patient's policy of reimbursement. Second, the fact that all of the patients were treated at a single center opens up the possibility of referral/selection bias based on the current practice of the group. Third, no follow-up questionnaire analysis was conducted to assess the quality of life, as perceived by the patients. Moreover, the baseline clinical characteristics of the studied populations varied widely, and thus, drawing direct comparisons between studies may be difficult.

In conclusion, EVI was a safe and feasible procedure for patients with CLI in Taiwan. It offered a high procedural success rate and lower complication rate. An active surveillance program, multidiscipline team care, and prompt assisted intervention, maintained the limb salvage and clinical success during the midterm follow-up.

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