Clinical Efficacy of Infrapopliteal Endovascular Procedures for Hemodialysis Patients with Critical Limb Ischemia

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Purpose: To investigate 5-year clinical outcomes after infrapopliteal endovascular therapy (EVT) for critical limb ischemia (CLI) patients on or not on hemodialysis (HD), and compare the clinical efficacy of EVT between the 2 groups.

Methods: The subjects were 1091 CLI patients (1310 limbs) who underwent EVT for isolated infrapopliteal lesions from 2004 to 2012, and were classified into 2 groups for comparative study: the patients on HD group (670 patients, 830 limbs) and not on HD group (421 patients, 480 limbs).

Results: The HD group had a significantly lower rate of freedom from major adverse limb events or perioperative death (HD 78.4% vs. non-HD 86.0% at 1 year, HD 70.3% vs. non-HD 82.4% at 5 years, $P = 0.01$), or amputation-free survival (AFS) rate (HD 65.7% vs. non-HD 78.7% at 1 year, HD 34.4% vs. non-HD 59.8% at 5 years, $P < 0.01$) after EVT compared with the non-HD group. Independent predictors of AFS in HD patients were nonambulatory, diabetes mellitus, albumin <3.0 g/dL, ejection fraction ≤ 0.48, and no patent pedal arch arteries before EVT. AFS at 1 year was 81% in patients with 0 or 1 predictor, surpassing the suggested AFS objective performance goal (OPG) end points of 68%, but AFS in patients with 2 or more predictors failed to reach the OPG.

Conclusions: In comparison with non-HD patients, the clinical efficacy of infrapopliteal EVT for HD patients was poor. Preoperative risk stratification based on AFS predictors can be used as an index for predicting the prognosis.

The authors have no conflicts of interest to declare.
This study did not receive any funding from any external source.

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Ann Vasc Surg 2015; 29: 1225–1234
http://dx.doi.org/10.1016/j.avsg.2015.03.034

Manuscript received: November 17, 2014; manuscript accepted: March 5, 2015; published online: May 22, 2015.

INTRODUCTION

Japan has a large number of patients on chronic hemodialysis (HD) because all medical fees are covered by social insurance after the start of dialysis and because kidney transplantation is not widespread because of lack of donors. Moreover, as diabetic patients with end-stage renal disease (ESRD) resulting from diabetic nephropathy are increasing annually, HD patients are also increasing.[1] According to the Japanese Society for Dialysis Therapy Annual Report, the total HD population surpassed 300,000 at the end of 2011, with HD patients making up a high proportion of the total population at 0.24%.[2] Peripheral artery disease (PAD) is common among HD patients, and in HD patients it is often detected with the onset of critical limb ischemia (CLI) with recalcitrant ulcers or gangrene.[3] Moreover, in many cases, CLI in HD patients is attributable to isolated infrapopliteal artery disease.[4] In our multicenter retrospective study, we have reported that 60% of CLI patients who underwent endovascular therapy (EVT) for isolated infrapopliteal artery disease were dialysis dependent; this was a much higher percentage than that reported by other studies (8–21%).[5]

Recently, there has been a worldwide tendency for EVT to be selected over bypass surgery (BSX) as the primary revascularization strategy for infrapopliteal artery disease in CLI patients, and in revascularization for CLI in HD patients, there is a tendency to select the less invasive option of EVT as primary therapy over BSX.[4] However, the clinical efficacy of infrapopliteal EVT in HD patients has not been sufficiently investigated.

The Society for Vascular Surgery (SVS) suggested a set of objective performance goals (OPGs) for catheter-based therapies for CLI, and Conte et al. considered that any major adverse limb events (MALE) or perioperative death (POD), amputation-free survival (AFS), and any reintervention or above-ankle amputation of the index limb (RAO) were OPG end points for assessing therapeutic efficacy.[6,7]

The aim of our study was to investigate MALE + POD, AFS, and RAO after isolated infrapopliteal endovascular procedures for CLI patients on or not on HD and compare the clinical efficacy of infrapopliteal EVT between the 2 groups according to the SVS-suggested OPG end points.

METHODS

Patient Sample

The data for this study were obtained from a multicenter retrospective study conducted with the participation of 14 Japanese departments of cardiology or vascular surgery. Between April 2004 and June 2012, 2206 consecutive CLI patients with 2871 limbs underwent EVT for PAD. Of these patients, 1091 patients with 1310 limbs who underwent balloon angioplasty for isolated infrapopliteal artery lesions were the subjects of this study. The 1115 patients with 1561 limbs who underwent multilevel EVT because of tibial artery lesions combined with femoropopliteal (FP) lesions or aortoiliac FP lesions were excluded from this study. During the period of the study, 467 CLI patients underwent BSX as primary revascularization strategy. The protocol of this study was developed in accordance with the Declaration of Helsinki, and all patients gave their written informed consent before revascularization.

Protocols

CLI was diagnosed according to the TransAtlantic Inter-Society Consensus (TASC) guidelines.[8] Using the ankle–brachial index (ABI) or skin perfusion pressure (SPP), the hemodynamic status of the lower limb was assessed. SPP <40 mm Hg was defined as indicating ischemic tissue loss or rest pain.[9] Evaluation of lower limb arteries was conducted using duplex ultrasound imaging and digital subtraction angiography (DSA). Lesions were evaluated to be significant when DSA revealed >75% diameter stenosis. Revascularization was not performed on patients with functionally unsalvageable limbs with ischemic gangrene spreading past the ankle.

As a general rule, revascularization was also not performed on nonambulatory patients. However, revascularization with the objective of pain removal or wound healing was performed in cases where it was difficult to control rest pain with pain relievers or in patients who had temporary walking difficulties because of the CLI wounds.

The strategy of EVT for isolated infrapopliteal artery lesions was as reported above.[5] At the time of this study, target lesions were treated with balloon angioplasty without stenting, because stent and atherectomy devices were not approved in Japan for use in EVT for the below-the-knee area. Determination of the balloon size and length used was left to the operator's discretion. Patients received dual antiplatelet therapy, either aspirin (at 100 mg/day) and clopidogrel (at 75 mg/day) or chilostazol (at 200 mg/day). Treated patients were followed up by a cardiologist or vascular surgeon and a plastic surgeon at 1 week, 1, 3, and 6 months, and every 3 months thereafter. The plastic surgeon