

# Long-Term Clinical Outcomes of Infrapopliteal Drug-Eluting Stent Placement for Critical Limb Ischemia in Diabetic Patients

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## ABSTRACT

**Purpose:** To evaluate long-term clinical outcomes of infrapopliteal drug-eluting stent (DES) placement in insulin-dependent and non-insulin-dependent diabetic patients with critical limb ischemia (CLI).

**Materials and Methods:** A retrospective analysis was performed of all diabetic patients treated with infrapopliteal DES between January 2002 and September 2012. The study's primary outcome measures were patient survival and major amputation-free survival (AFS). Secondary outcome measures included technical success (defined as the creation of a straight line of blood flow to the foot arch with < 30%), identification of independent predictors of primary outcomes, infrapopliteal target limb repeat intervention-free survival, and procedure-related complications.

**Results:** In total, 214 patients with CLI (168 men [78.5%]; mean age, 70 y ± 9) in 311 limbs, 562 arteries, and 679 lesions were treated. According to Kaplan-Meier analysis, survival rates were 90.8%, 55.5%, and 36.2%, and AFS rates were 94.9%, 90.4%, and 90.4%, respectively, at 1, 5, and 10 years. Target limb repeat intervention-free survival rates were 79.7%, 55.2%, and 49.7%, respectively, at 1, 5, and 10 years. The overall technical success rate was 97.7%. Cox multivariate analysis demonstrated that procedural failure was the only independent predictor of decreased AFS (hazard ratio [HR], 61.3; 95% confidence interval [CI], 13.8–271.9), and statin use was associated with increased survival (HR, 0.55; 95% CI, 0.31–0.98). Coronary disease (HR, 1.9; 95% CI, 1.01–3.54), dialysis (HR, 2.2; 95% CI, 1.21–4.06), and duration of diabetes (HR, 1.5; 95% CI, 1.02–2.34) were identified as independent predictors of decreased survival. Major complications occurred in four of 479 procedures (0.8%).

**Conclusions:** Infrapopliteal DES placement for the management of CLI in diabetic patients resulted in a 55.5% 5-year survival rate, with a 90.4% AFS at 5 and 10 years and a 50.3% repeat intervention rate at 10 years. Technical failure was associated with reduced AFS, and statin intake was associated with increased survival.

## ABBREVIATIONS

ABI = ankle-brachial index, AFS = amputation-free survival, CI = confidence interval, CLI = critical limb ischemia, DES = drug-eluting stent, DSA = digital subtraction angiography, HR = hazard ratio, PAD = peripheral arterial disease, TLR = target limb repeat intervention

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In 2013, the estimated worldwide prevalence of diabetes mellitus was 8.3%, and the number of people with diabetes increased from 366 million to 382 million. Moreover, 5.1 million diabetes-related deaths were reported in the past 2 years (1,2). Diabetes is correlated with an increased risk of cardiovascular complications such as myocardial infarction, stroke, and advanced peripheral arterial disease (PAD), which are the most common causes of death and disability in the diabetic population. The last stage of PAD, critical limb ischemia (CLI), which manifests with rest pain and foot ulceration and/or gangrene, is among the main causes of major

amputation in diabetic patients and represents a medical emergency, as infection can rapidly compromise limb salvage and patient survival (3).

Major amputation rates are particularly high in patients with CLI not amenable to revascularization, especially in long occlusions with poor distal runoff (4). At present, peripheral endovascular procedures, mainly percutaneous angioplasty and stent placement, are considered the treatment of choice for a variety of atherosclerotic lesions that cause CLI, and they result in amputation-free survival (AFS) rates exceeding 80% after as long as 3 years of follow-up (5–7). Diabetes has been identified as a factor related to lower patency rates, increased repeat interventions, and amputation rates following peripheral endovascular revascularization procedures and open surgical bypass (8–12). Specifically, diabetic patients have long infrapopliteal and pedal-arch small-vessel disease with marked calcifications, characteristics that adversely affect stent placement and angioplasty.

Drug-eluting stents (DESs) have been recently introduced as a valid endovascular treatment option for the management of infrapopliteal arterial disease, and, according to meta-analysis (13,14), show superior midterm angiographic (primary patency, relative risk, 1.37; 95% confidence interval [CI], 1.18–1.58) and clinical outcomes (improvement of Rutherford–Becker class, relative risk, 1.13; 95% CI, 1.002–1.275) compared with plain balloon angioplasty or bare metal stent placement. Still, patient survival and limb salvage rates with infrapopliteal DES placement in patients with CLI and diabetes remains unclear because evidence is lacking, and procedural outcomes beyond 3 years after DES placement below the knee are not yet available in the literature. We sought to investigate long-term patient survival and limb salvage rates after infrapopliteal DES placement for the management of CLI in diabetic patients.

## MATERIALS AND METHODS

### Study Design

The study was approved by the hospital scientific and ethics committee. This was a single-center retrospective analysis of all diabetic patients treated with infrapopliteal DES placement in the interventional radiology department between January 2002 and September 2012 so that the minimum follow-up period recorded would be 2 years. Patients were followed until September 2014. An in-depth search was performed in a dedicated prospectively maintained electronic database of the interventional radiology department to detect all cases of patients with diabetes who were receiving oral drug therapy or insulin and treated with infrapopliteal DES placement for CLI. Moreover, the medical files of all patients who received an infrapopliteal DES within the study time period were scrutinized for baseline demographics, procedural variables, and follow-up data

regarding the primary and secondary outcome measures. Pre- and postprocedural department and hospital records were searched to identify patient demographics, baseline health status, medical management, clinical presentation, vascular therapeutic procedures, and outcomes. Within the study period, a total of 325 diabetic patients were treated with infrapopliteal DES placement. Among them, 111 received a DES because of severe lifestyle-limiting intermittent claudication and were therefore excluded from the analysis. All procedures were performed by one of seven interventional radiologists with 3–20 years of experience in peripheral arterial interventions. Data retrieval was performed by an interventional radiology fellow (V.T.) supervised by an interventional radiologist (S.S.) with 10 years of experience in below-knee interventions. Specific keywords such as “diabetes,” “drug-eluting stents,” “infrapopliteal stenting”/“drug-eluting stenting,” and “below the knee stenting”/“drug-eluting stenting” were used. Data from January 2002 to September 2012 were retrieved from the electronic database (DiRecANG, version 3; University of Patras, Greece). Patients with dietary-controlled diabetes were excluded from the study (Table 1). Baseline patient demographic characteristics, procedural details, and follow-up data were recorded and analyzed (Table 2). According to the department’s standard protocol after infrapopliteal endovascular interventions for CLI, a strict clinical follow-up was performed at 1, 3, 6, and 12 months and yearly thereafter unless clinical relapse or deterioration indicated differently. Patients’ evaluation in the clinic included ankle-brachial index (ABI), peripheral pulses, wound healing evaluation, Rutherford classification, medical therapy adjustment, and Doppler examination in cases of abnormal clinical findings. A telephone interview was performed to ensure that the patient was alive at the study follow-up end date (September 2014) in cases in which follow-up was performed before the follow-up end date and the patient was unable to undergo an unexpected/unscheduled follow-up site visit.

### Outcome Measures and Definitions

The study’s primary outcome measures were overall patient survival and major AFS, defined as the time period without any major amputation above the level of

**Table 1.** Study Inclusion and Exclusion Criteria

#### Inclusion criteria

- Diabetes treated with oral drug therapy or insulin
- Critical limb ischemia (Rutherford–Becker class 4–6)
- Infrapopliteal drug-eluting stent

#### Exclusion criteria

- Dietary-controlled diabetes
- Intermittent claudication (Rutherford–Becker class 1–3)
- Treatment with only balloon angioplasty or bare metal stent
- Acute limb ischemia

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