

Results: In multivariate Cox proportional hazard analysis, no direct blood flow to the wounds (HR 0.38, 95%CI 0.16-0.93, $p=0.034$), dependence on hemodialysis (HR 0.46, 95%CI 0.27-0.80, $p=0.006$), infectious wound (HR 0.54, 95%CI 0.30-0.99, $p=0.044$), heel wound (HR 0.38, 95%CI 0.16-0.91, $p=0.029$) and extensive wound extending onto the forefoot or midfoot along the dorsal or plantar surfaces (HR 0.09, 95%CI 0.02-0.39, $p=0.001$) were adverse predictors of wound healing. Each item's score ranged from 0 to 4 and the total score ranged from 0 to 10. The area under the receiver operating characteristics curve revealed that there was 90.5% accuracy in the total scores predicting the likelihood of wound healing. In the development group, the wound healing rates at 12 months were 83% in low-risk group (scores ≤ 2), 33% in moderate-risk group (scores 3-5), and 4.0% in high-risk group (scores ≥ 6) ($p<0.001$). In the validation group, the corresponding wound healing rates were 80%, 49%, and 12%, respectively ($p<0.001$).

Conclusions: This new scoring system is useful for the risk stratification of wound healing in patients with CLI.

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What are the Predictors of Wound Healing in Patients with Critical Limb Ischemia with Tissue Loss following Successful Endovascular Therapy?

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Background: Sometimes we can't achieve wound healing in patients with critical limb ischemia (CLI) with tissue loss even after successful endovascular therapy (EVT). Multiple factors including patient background, intervention outcomes, and also wound characteristics are associated with wound healing. Therefore we evaluated predictors of wound healing in CLI after successful EVT.

Methods: Between April 2007 and April 2012, 179 patients (217 limbs) with CLI classified to Rutherford 5 or 6 were treated with EVT in our institute. Of these, 128 patients (146 limbs) were successfully treated. Successful EVT was defined as revascularization of achievement of direct blood flow to the wounds evaluated by digital subtraction angiography just after EVT. Each variables were analyzed using the univariate Cox proportional hazards model for wound healing. All variables tested in univariate analysis with $p < 0.25$ were included in multivariate Cox hazards model.

Results: The mean follow-up period was 21 ± 17 months. Wound healing rates were 41%, 58%, 71%, and 72%, at 3, 6, 12, and 18 months, respectively. Multivariate Cox proportional hazard analysis revealed that insulin use (HR 0.47, 95%CI 0.30-0.73, $p=0.001$), dependence on hemodialysis (HR 0.35, 95%CI 0.23-0.53, $p<0.001$), wounds located only at toes (HR 2.79, 95%CI 1.78-4.38, $p<0.001$), gangrene (HR 0.66, 95%CI 0.44-0.97, $p=0.037$), and revascularization basing on angiosome concept (HR 1.53, 95%CI 1.16-2.02, $p=0.002$) were independent predictors of wound healing following successful EVT.

Conclusions: Achievement of direct blood flow to the wounds is important factor for wound healing, but that is not enough. Insulin use, dependence on hemodialysis, and gangrene can be predictors of wound healing failure. Furthermore, wounds located only at toes and revascularization basing on angiosome concept can be predictors of wound healing.

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Clinical efficacy of infrapopliteal balloon angioplasty for hemodialysis patients with critical limb ischemia

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Background: The clinical efficacy of infrapopliteal balloon angioplasty for hemodialysis patients with critical limb ischemia has not been systematically studied.

Methods: This study consisted of multi-center retrospective study. Subjects were 1093 CLI patients with 1314 limbs who underwent balloon angioplasty as primary treatment of isolated infrapopliteal lesions from 2004 to 2012. Subjects were classified into two groups for non-randomized comparative study: the patients on chronic hemodialysis: HD group (671 patients, 833 limbs, age: 69 ± 10 years) and without HD: No-HD group (422 patients, 481 limbs, age: 76 ± 10 years). Clinical outcome between two groups were examined with average for 4.0 ± 1.2 year. Outcome measures were freedom from major amputation (MA), major adverse limb events with perioperative death (MALE+POD) and amputation-free survival (AFS) at 1 and 5 years estimated using the Kaplan-Meier methods.

Results: For patient characteristics, the rate of diabetic patient was similar (73.1 vs. 69.4%, $P=0.691$) in both groups. The percentage of CLI with Rutherford category 5 or 6 (80.2 vs. 70.9%, $P<0.01$) and No-ambulation status (42.8 vs. 34.6%, $P<0.01$) was significantly higher in HD group than that of Non-HD group. For the target vessel, there was no significant difference in the rate of patent dorsal and planter artery flow after balloon angioplasty (48.9 vs. 50.9%). Complete healing rate of CLI wounds (56.3 vs. 69.1%, $P<0.01$) was significantly lower in HD group than that of Non-HD group. Regarding clinical results, The HD group had a significantly lower freedom from MA (86.0 \pm 1.5 vs. 90.6 \pm 1.5% at 1 year, 81.5 \pm 2.6 vs. 88.9 \pm 1.7% at 5 year, $P=0.033$), MALE+POD (77.9 \pm 1.7 vs. 85.3 \pm 1.8% at 1 year, 69.4 \pm 3.2 vs.

81.7 \pm 2.3% at 5 year, $P<0.001$.) and AFS (64.8 \pm 2.0 vs. 77.9 \pm 2.1% at 1 year, 32.0 \pm 3.0 vs. 59.9 \pm 3.3% at 5 year, $P<0.001$.) compared to Non-HD group. The AFS rate at 1 year in HD group was below the 71% suggested objective performance goal in catheter based therapies.

Conclusions: The clinical efficacy of infrapopliteal balloon angioplasty for hemodialysis patients with critical limb ischemia was not satisfactory because patients on hemodialysis had high mortality rates.

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Comprehensive Assessment of Prevalence and Distribution of Obstructive Pelvic Arterial Lesions by Computed Tomographic Angiography in Patients with Erectile Dysfunction

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Background: Recent studies showed that endovascular intervention of focal atherosclerotic lesions of the internal pudendal arteries can result in improvement of erectile function. However, studies regarding the prevalence and distribution of obstructive pelvic arterial lesions amenable to endovascular therapies are scarce.

Methods: This study included 80 consecutive patients (mean age 62.6 years) with erectile dysfunction underwent multi-detector computed tomography (CT). Pelvic CT angiograms of the arterial system supplying the penis were divided into 5 segments: common iliac artery, internal iliac artery, anterior division, internal pudendal artery, and penile artery. Obstructive arterial lesion was defined by a luminal stenosis of $\geq 50\%$ on CT.

Results: Among the 800 segments obtained, only 4 segments (0.5%) of penile arteries were identified as non-analyzable. 67 patients (67/80, 84%) had at least one obstructive lesion in their pelvic CT angiograms. A total of 157 obstructive segmental lesions were identified. The distribution of these obstructive pelvic arterial lesions was: 1 (0.01%) in common iliac artery segment, 4 (2.5%) in internal iliac artery segment, 13 (8.3%) in anterior division segment, 68 (43%) in internal pudendal artery segment, and 71 (45%) in penile artery segment. Bilateral obstructive lesions were present in 37 patients. The obstructive lesions were limited in penile artery segments in 18 patients (18/67, 27%), whereas only 9 patients (13%) with obstructive lesions limited in the internal pudendal artery segments. Fifteen patients (19%) had accessory penile blood supply.

Conclusions: Obstructive pelvic arterial lesions were highly prevalent in patients with erectile dysfunction. These obstructive lesions were most frequently present in the penile artery segment, followed by in the internal pudendal artery segment. Almost 30% of patients got their obstructive lesions limited in the penile artery segments. These findings not only demonstrate the feasibility of CT angiography as a diagnostic tool for patients with erectile dysfunction, but also suggest that the focus of interventional strategy should include penile arteries, rather than solely on internal pudendal arteries.

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Long-term Cost Patterns of Directional Atherectomy vs. Other Treatment Choices for Diabetes Patients with Peripheral Artery Disease: a 12-Month Analysis of Administrative Claims Data

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Background: Directional atherectomy is an endovascular therapy that is effective in the treatment of diabetes patients with peripheral artery disease (PAD). This study was undertaken to assess the prevalence of PAD treatments in a real-world diabetic population, and to compare all-cause healthcare costs of directional atherectomy with other therapies in diabetes patients over 12-months post-treatment.

Methods: PAD patients were selected from a large claims database with ≥ 1 CPT code for a lower extremity PAD procedure between 2005-2011. The date of the first CPT code was the index date. Patients were included with: ≥ 12 -months of pre-index date continuous medical and pharmacy eligibility; ≥ 1 PAD ICD-9 code within 6 months prior to the index date; ≥ 1 medical claim for Type 2 Diabetes Mellitus during baseline; and ≥ 18 years of age on index date. Multivariate models to evaluate risk of hospitalization during follow-up and all-cause health care cost at 12 months were constructed, controlling for covariates.

Results: 8,121 Patients had both diabetes and PAD, with a mean age of 67.6 years and 39% were female. Prevalence of PAD treatment was: stent(26%), bypass(23%), PTA+stent(22%), PTA(16%), PTA+atherectomy(4%), atherectomy(4%), unspecified(4%), and PTA+stent+atherectomy(1%). At 12-months post-procedure(N=5,660), the atherectomy group had the lowest mean healthcare costs (\$34,754) and bypass had the highest (\$45,181). There were no statistically significant differences between atherectomy and any of the treatments with respect to all-cause health care costs over 12 months, though the cost for atherectomy was lowest. Bypass patients were 33% more likely to be hospitalized during follow-up than atherectomy patients, but atherectomy patients were not statistically significantly different from any other therapies.

Conclusions: Because diabetics tend to re-stenose faster and are more complex than non-diabetic PAD patients, atherectomy is a good therapeutic choice, as it preserves future treatment options. Among PAD patients with diabetes in this large claims database, directional atherectomy was associated with similar re-hospitalization rates and similar or lower costs compared to other PAD therapies over 12 months.