

PERIPHERAL

# Clinical Outcomes of Pedal Artery Angioplasty for Patients With Ischemic Wounds

## Results From the Multicenter RENDEZVOUS Registry

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**CME Objective for This Article:** At the end of the activity the reader should be able to: 1) review the clinical outcomes of patients undergoing endovascular treatment for critical limb ischemia; 2) appraise the clinical benefits of adjunctive pedal artery angioplasty in both the timing and the extent of wound healing; and 3) recognize the limitations and evaluate the efficacy of this strategy in each risk stratified population.

**CME Editor Disclosure:** *JACC: Cardiovascular Interventions* CME Editor Bill Gogas, MD, PhD, has reported that he has no disclosures.

**Author Disclosures:** The authors have reported that they have no relationships relevant to the contents of this paper to disclose.

**Medium of Participation:** Print (article only); online (article and quiz).

#### CME Term of Approval

Issue Date: January 9, 2017

Expiration Date: January 8, 2018

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Manuscript received July 20, 2016; revised manuscript received October 3, 2016, accepted October 20, 2016.

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### ABSTRACT

**OBJECTIVES** The aim of this study was to investigate the clinical outcomes of pedal artery angioplasty (PAA) for patients with critical limb ischemia.

**BACKGROUND** Pedal artery disease is considered a predictor of delayed wound healing (DH) after endovascular therapy. Adjunctive PAA might improve the speed and extent of wound healing.

**METHODS** Consecutive patients with critical limb ischemia (n = 257) presenting with de novo infrapopliteal and pedal artery disease were retrospectively reviewed from a multicenter registry. Patients were divided into 2 groups according to whether PAA was performed (n = 140) or not (n = 117). The rate of wound healing and time to wound healing were compared between these groups. DH score was calculated using the number of independent predictors of DH. Patients were stratified into 3 groups according to DH score: low risk (DH score = 0), moderate risk (DH score = 1 or 2), and high risk (DH score = 3). Estimated efficacy was analyzed for each risk-stratified population.

**RESULTS** The rate of wound healing was significantly higher (57.5% vs. 37.3%, p = 0.003) and time to wound healing significantly shorter (211 days vs. 365 days; p = 0.008) in the PAA group. In a multivariate analysis, nonambulatory status, target wound depth (UT grade  $\geq 2$ ), and daily hemodialysis were revealed as predictors of DH. In the moderate-risk population, adjunctive PAA significantly improved the rate of wound healing (59.3% vs. 33.9%; p = 0.001). In the high-risk population, however, PAA did not affect wound healing.

**CONCLUSIONS** Patients who underwent PAA showed a higher rate of wound healing and shorter time to wound healing, especially in the moderate-risk population. With regard to wound healing, this aggressive strategy might become a salvage procedure for patients with critical limb ischemia presenting with pedal artery disease. (J Am Coll Cardiol Intv 2017;10:79-90) © 2017 by the American College of Cardiology Foundation.

Critical limb ischemia (CLI) is an unfavorable clinical consequence of peripheral arterial disease. Approximately 73% to 95% of patients lose limbs within 1 year after conservative treatment (1). Arterial revascularization, including surgical bypass and endovascular therapy (EVT), is the optimal treatment to prevent limb loss (2). Following the result of the BASIL (Bypass Versus Angioplasty in Severe Ischaemia of the Leg) trial (3), the latest American Heart Association and American College of Cardiology guidelines suggest that arterial revascularization strategies should be decided on the basis of the existence of adequate veins or patients' life expectancy (4). However, patients with CLI rarely qualify as surgical candidates, because of their

frailty, concomitant diseases, and advanced age. Percutaneous EVT, in contrast, has become popular because of its lower invasiveness and comparable limb salvage (LS) rate to surgical bypass (5-11). Recent clinical trials have reported sufficient LS, and these results have already achieved the objective performance goal (84% LS rate at 1 year), which was proposed by Conte et al. (12). Therefore, the role of EVT for patients with CLI has been significantly increasing in the current clinical setting.

However, even if major amputation is successfully avoided, achievement of complete wound healing is still challenging. Recent clinical reports have documented the apparent discrepancy between LS rate and rate of wound healing (8-11,13). Delayed or

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