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Diagnosis, classification, and treatment of femoropopliteal artery in-stent restenosis



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In-stent restenosis is a pervasive challenge to the durability of stenting for the treatment of lower extremity ischemia. There is considerable controversy about the criteria for diagnosis, indications for treatment, and preferred algorithm for addressing in-stent restenosis. This evidence summary seeks to review existing information on strategies for the treatment of this difficult problem. (J Vasc Surg 2017;65:545-57.)

Alea iacta est ("The die is cast")

—Julius Caesar, January 10, 49 BCE

The desire to alleviate symptoms and to maintain function with minimal morbidity and reduced hospitalization in patients with peripheral artery disease has led to an unabiding upward trend in endovascular lower extremity arterial procedures. Between 1996 and 2011, there was a 165% increase in angiographic lower extremity procedures in the Medicare population, including a fourfold increase in therapeutic endovascular interventions and a corresponding reduction (61%) in the number of surgical bypass procedures.¹ Technologic advances have allowed longer and more complex lesions to be treated with catheter-based therapy using anatomy-based guidelines.^{2,3} Despite a paucity of randomized clinical trial data to inform treatment decisions in the choice of endovascular vs open approaches, the high technical success rates and low morbidity (ie, lack of surgical wounds) of endovascular procedures have led to the popularity of an endovascular-first approach to leg ischemia.

Among the many treatment choices available for femoropopliteal (FP) arterial occlusive disease, the self-expanding bare-metal stent (BMS) has become the standard approach.⁴⁻⁷ Stents prevent early elastic recoil and late constrictive remodeling, and they are provisionally used to maintain lumen volume compromised by a flow-limiting dissection or residual stenosis after treatment with atherectomy or balloon angioplasty (percutaneous transluminal angioplasty [PTA]). Mechanical and

pharmacologic adjuncts to PTA may reduce dissections and improve patency. For example, drug-coated balloons (DCBs) have reduced stent use in shorter lesions,^{8,9} but longer and more complex lesions often require stenting in some portion of the treated segment to maintain lumen volume.

Despite recent technologic advances, stent use in leg arteries remains highly prevalent. The completion angiogram demonstrates an open-flow lumen in the stented segment with smooth contours devoid of irregularities, which stands in stark contrast to the remaining native artery that has been left untreated or unstented. However, the seductive angiographic appearance of the freshly stented femoral artery often belies a malady more malignant than the original stenosis itself: for once the stent is placed into the artery, the die is cast such that, in due course, a significant number will experience in-stent restenosis (ISR). The goal of this evidence summary is to provide an overview of current strategies for the treatment of this prevalent and difficult problem that all of us who treat patients with leg ischemia must contend with on a regular basis.

METHODS

A systematic literature review using MEDLINE (1990-2016) was performed with combinations of the keywords *in-stent restenosis*, *peripheral arteries*, *femoropopliteal artery*, *stent*, *stenting*, *superficial femoral artery*, *popliteal artery*, *pathophysiology*, *mechanism*, and *cellular pathway*. Randomized controlled trials, prospective non-randomized clinical trials and registry reports, retrospective cohort studies, and basic science reports pertaining to the etiopathophysiology of ISR in the lower extremity were included. Particular attention was given to short- and long-term patency, limb salvage rates, amputation-free survival, overall survival, and complications.

ISR: DEFINITION, ETIOLOGY, AND CLASSIFICATION

Definition. ISR refers to loss of luminal volume from an ingrowth of cells, extracellular matrix, and thrombus within the cylinder of the stented artery and 5-mm margins proximal and distal to the stent. The Society

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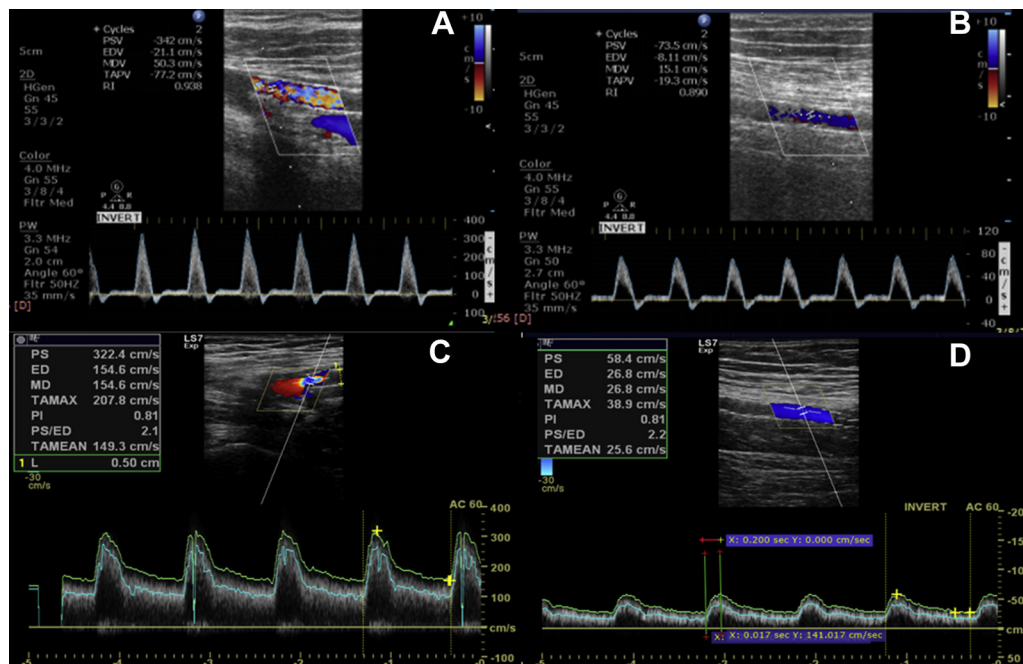


Fig 1. Duplex ultrasound Doppler spectral waveform of in-stent restenosis (ISR) in a superficial femoral artery (SFA) detected by **(A)** elevated peak systolic velocity (PSV), **(B)** normal upstroke and distal preservation of triphasic waveform and velocities, **(C)** elevated PSV but with delayed upstroke and spectral broadening, and **(D)** parvus et tardus waveform.

for Vascular Surgery practice guidelines for asymptomatic patients and claudicants¹⁰ who have undergone endovascular intervention recommend clinical surveillance with history, pulse examination, and resting or exercise ankle-brachial index (ABI) measurements (grade 2; level of evidence, C). However, many clinicians augment clinical surveillance with duplex ultrasound imaging using B-mode, color flow, and peak systolic velocity (PSV) mapping as indicators of restenosis despite the fact that ISR lesions have a natural history different from that of vein graft stenoses.^{11,12} Unfortunately, there are no randomized controlled trials examining the effect of duplex ultrasound surveillance on lesion-specific, limb-specific, or patient-level outcomes in individuals receiving peripheral stents. However, an Appropriate Use Criteria panel was charged with determining levels of appropriateness (appropriate, uncertain, or inappropriate) for vascular imaging surveillance of both de novo and treated pathologic processes.¹³ This document has been endorsed by the major vascular, radiology, and peripheral ultrasound imaging societies. Many have argued that questions addressed by rating panels such as this lack the granularity to inform individual patient-level decisions. Nevertheless, their consideration is warranted if only for the fact that government and third-party payers and plaintiff attorneys are aware of these documents. The Appropriate Use Criteria panel assigned an appropriate rating for duplex ultrasound surveillance within 1 month of the revascularization procedure in the setting of new or worsening symptoms and then

annually thereafter. For patients without symptoms or stable symptoms after angioplasty and stenting, the panel assigned a rating of inappropriate or uncertain for interim surveillance between 1 month and 1 year and inappropriate for surveillance more frequently than annually.

Advantages of duplex ultrasound surveillance are that it is noninvasive and relatively inexpensive, and the stented segment of artery is often readily identifiable with ultrasound. Duplex ultrasound-defined stenosis is most commonly assessed by either an absolute PSV cutoff (eg, >200 cm/s) or a velocity ratio (Vr) of the PSV in the proximal reference artery to the highest PSV within the stent. However, one significant limitation of duplex ultrasound-derived binary restenosis is that it does not provide any information on the extent of the stenosis or loss of luminal volume. For example, a focal restenosis in the midportion of the stent could produce the same Vr as a more diffuse restenosis along the entire stent length, which of course represents a far greater loss of postimplantation volume and larger burden of restenotic tissue. Furthermore, a focal stenosis is easily dispatched with, whereas diffuse stenosis is far more pernicious. B-mode ultrasound and color flow can provide some information in this regard (Fig 1). A parvus et tardus waveform in a segment of artery distal to the stent, for instance, is a reliable indicator of hemodynamically significant stenosis.¹⁴

Commonly used duplex ultrasound velocity criteria for ISR have been adopted from studies of de novo FP

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