The LifeStent Studies

An overview of the trials studying bare-metal stents in the superficial femoral and popliteal artery.

BY THOMAS ZELLER, MD

The LifeStent vascular stent systems (Bard Peripheral Vascular, Tempe, AZ) were commercially approved for use in the United States on February 13, 2009, for the treatment of de novo or restenotic lesions up to 160 mm in length in the native superficial femoral artery (SFA) and proximal popliteal artery with reference vessel diameters ranging from 4 to 6.5 mm. They are the only currently marketed bare-metal stent systems approved for use for this peripheral vascular application and come in lengths up to 170 mm.

RESILIENT

The Bard RESILIENT study, a randomized study comparing the self-expanding LifeStent versus angioplasty alone in lesions involving the SFA and/or proximal popliteal artery, was a prospective, multicenter, randomized study that enrolled 206 patients to either a percutaneous transluminal angioplasty control arm or primary stent arm (after predilation). Results from this study, conducted at 24 sites in the United States and Europe, were the basis for the approval in the SFA and proximal popliteal artery in the United States. The freedom from target lesion revascularization rate for the LifeStent treatment group was 87%, and the ultrasound-guided primary patency rate was 81% at 12 months after the procedure.

CONTINUUM

Plans are underway for a postmarket trial of the LifeStent vascular stent systems in the United States, CONTINUUM (Continuous Infrainguinal Stenting Using the Bard LifeStent Vascular Stent Systems), which is planned to start later this year.

ETAP

In Europe, the ETAP (Endovascular Treatment of Popliteal Artery–Balloon Angioplasty Versus Primary Stenting) trial—a prospective, multicenter, randomized study—evaluates the LifeStent vascular stent systems versus plain-old balloon angioplasty (POBA) to treat obstructive lesions of the popliteal artery, an area in which no prospective, randomized data exist. Preliminary information on this study was presented at the LINC meeting in January in Leipzig, Germany. The study is designed to enroll 250 popliteal artery cases, with no restriction on the length of lesion treated. The primary endpoint is the rate of ultrasound-guided restenosis at 12 months (peak systolic velocity ratio > 2.4), with secondary endpoints to include primary and secondary patency and major adverse cardiac events at 6, 12, and 24 months, as well as clinically driven target lesion revascularization and a stent fracture analysis at 6 and 12 months. Baseline data of the first 98 patients that had been enrolled showed that 24% of the POBA patients and 16.7% of the stent patients classified as Rutherford class 5 and 20% of POBA and 18.8% of stented lesions classified as chronic total occlusions. The crossover rate from POBA to stenting was 20%. To date, more than 230 patients are already enrolled, and the completion of study recruitment is expected for the end of March 2010. ■

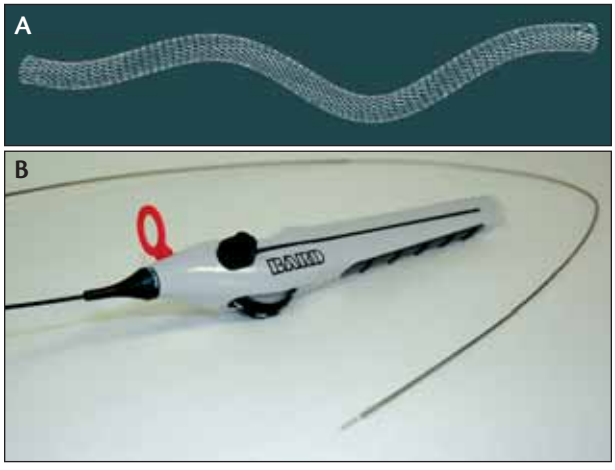

Figure 1. The 170-mm-long LifeStent (A) and LifeStent FlexStar XL vascular stent delivery system (B).

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