Nitinol Stents Safe, Effective in Femoral Arteries

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MIAMI BEACH — Nitinol stents were more effective than angioplasty alone for maintaining patency in the superficial femoral artery in a pair of randomized, controlled studies.

The stents were also safe, with no stent-related complications during follow-up periods of 6 or 12 months.

In one study, use of the Luminexx nitinol stent made by Bard resulted in a trend toward fewer episodes of binary restenosis after 6 months of follow-up, compared with balloon angioplasty and no stenting, Dr. Hans Krankenberg said at the 18th International Symposium on Endovascular Therapy. This was an interim analysis in a study designed to run for 12 months.

In a second study, a revascularization strategy of primary stenting with Guidant's Absolute or Dynalink nitinol stents was better than angioplasty plus optional stenting at both 6 and 12 months after treatment in a study with 104 patients, Dr. Martin Schillinger reported at the same meeting.

Restenosis occurred in 43% of patients who had angioplasty and an optional stent and in 24% of patients who had primary stenting with nitinol stents.

The Absolute and Dynalink study randomized patients with superficial femoral artery occlusions and peripheral artery disease during June 2003–August 2004 either to primary stenting or to angioplasty followed by stenting if the residual stenosis was more than 30%, if there was a flow-limiting dissection, or if there was significant elastic recoil.

The study's primary end point was the incidence of angiographic restenosis 6 months after treatment. Restenosis occurred in 23 (43%) of 53 patients in the optional stent group and in 12 (24%) of 51 patients in the primary stent group, a difference that was statistically significant, said Dr. Schillinger, a vascular medicine physician at the University of Vienna.

Primary stenting was also better than optional stenting for several secondary end points. The rate of binary restenosis after 12 months was 64% in the optional stenting group and 37% in the primary stenting group, a statistically significant difference. Primary stenting also led to significantly better improvements in maximum walking distance and resting ankle-brachial index. Of a total of 113 stents placed, 1 stent fractured during 12 months of follow-up.

Larger randomized studies with prolonged follow-up are needed to confirm a long-term benefit of primary stenting, Dr. Schillinger said. He reported no financial relationship with Guidant.

The Luminexx study enrolled 244 patients with a superficial femoral artery occlusion and peripheral artery disease at 11 centers in five European countries. The study randomized 121 patients to treatment with angioplasty only and 123 to stenting. Of those in the angioplasty-only arm, 13 also had stenting. Angioplasty alone produced technical, acute success (defined as a residual stenosis of less than 30%) in 79% of patients, compared with a 93% technical success rate in the stented patients. The study's primary end point is the incidence of binary restenosis after 12 months of follow-up. The 12-month data are not yet available, but after 6 months the restenosis rate was 38% in the angioplasty group and 26% in the stented group, a difference that missed statistical significance, said Dr. Krankenberg, a physician at the Center for Cardiology and Vascular Intervention, Hamburg University, Germany. But when the results were analyzed on a per protocol basis, the binary restenosis rate was 42% in the angioplasty group and 25% in the stented group, a difference that was statistically significant.

In the intention-to-treat analysis of secondary end points, stenting generally produced better results after 6 months, but in no case was the difference significant, compared with the angioplasty group. Stenting was linked to a lower rate of target lesion revascularization and a larger average increase in the ankle-brachial index. Angioplasty led to a larger average increase in walking distance, boosting this measure by a mean of 58 m, compared with a mean 48-m increase in the stented group.

Dr. Krankenberg reported no financial relationship with Bard. ■