Balloon Angioplasty versus Implantation of Nitinol Stents in the Superficial Femoral Artery

Martin Schillinger, M.D., Schila Sabeti, M.D., Christian Loewe, M.D., Petra Dick, M.D., Jasmin Amighi, M.D., Wolfgang Mlekusch, M.D., Oliver Schlager, M.D., Manfred Cejna, M.D., Johannes Lammer, M.D., and Erich Minar, M.D.

ABSTRACT

Background Because stent implantation for disease of the superficial femoral artery has been associated with high rates of late clinical failure, percutaneous transluminal angioplasty is preferred for endovascular treatment, and stenting is recommended only in the event of suboptimal technical results. We evaluated whether primary implantation of a self-expanding nitinol (nickel-titanium) stent yielded anatomical and clinical benefits superior to those afforded by percutaneous transluminal angioplasty with optional secondary stenting.

Methods We randomly assigned 104 patients who had severe claudication or chronic limb ischemia due to stenosis or occlusion of the superficial femoral artery to undergo primary stent implantation (51 patients) or angioplasty (53 patients). Restenosis and clinical outcomes were assessed at 6 and 12 months.

Results The mean (±SD) length of the treated segment was 132±71 mm in the stent group and 127±55 mm in the angioplasty group. Secondary stenting was performed in 17 of 53 patients (32 percent) in the angioplasty group, in most cases because of a suboptimal result after angioplasty. At 6 months, the rate of restenosis on angiography was 24 percent in the stent group and 43 percent in the angioplasty group (P=0.05); at 12 months the rates on duplex ultrasonography were 37 percent and 63 percent, respectively (P=0.01). Patients in the stent group were able to walk significantly farther on a treadmill at 6 and 12 months than those in the angioplasty group.

Conclusions In the intermediate term, treatment of superficial-femoral-artery disease by primary implantation of a self-expanding nitinol stent yielded results that were superior to those with the currently recommended approach of balloon angioplasty with optional secondary stenting. (ClinicalTrials.gov number, NCT00281060 [ClinicalTrials.gov].)

Source Information

From the Departments of Angiology (M.S., S.S., P.D., J.A., W.M., O.S., E.M.) and Angiography and Interventional Radiology (C.L., M.C., J.L.), Medical University of Vienna, Vienna.

Address reprint requests to Dr. Schillinger at the Department of Internal Medicine II, Division of Angiology, Vienna General Hospital, Medical University, Waehringer Guertel 18-20, Vienna A-1090, Austria, or at martin.schillinger@meduniwien.ac.at.