Clinical Application of the Xpert Stent

New data show effectiveness in the treatment of critical limb ischemia caused by infrapopliteal lesions.

BY MARC BOSIERS, MD; KOEN DELOOSE, MD; JÜRGEN VERBIST, MD; AND PATRICK PEETERS, MD

Peripheral arterial disease (PAD) remains a significant clinical problem in the US. More than 5 million Americans exhibit symptoms of PAD annually. Eighty percent (4 million patients) experience intermittent claudication, and nearly 1 million have critical limb ischemia.[1-3]

Catheter-based interventional techniques, such as straightforward percutaneous transluminal angioplasty (PTA) or subintimal PTA, have shown promising results in different case series.[4,5] Procedural success rates of standard balloon angioplasty vary from 80% to 100%[6-10] and are higher for stenoses than for occlusions—in one series 84% versus 61%, respectively.[11] The immediate technical success rate of subintimal PTA is somewhat lower, ranging from 78% to 85%.[12,13] Patency rates as reported in the literature vary tremendously. One series reported a primary patency of 48% at 18 months, with a secondary patency of 56%,[11] whereas other investigators report recurrent symptomatic stenosis at 1 and 3 years of 40% and 80%, respectively.[7,14] Limb salvage rates are in the range of 70% to 86%.[6,8,10,15] Results of subintimal PTA range similarly, with a reported primary and secondary patency of 56% at 1 year.[13]

One option is using balloon-expandable, coronary-type stents to treat small-diameter vessels. Stent implantation overcomes the most important drawbacks of PTA (eg, early plaque remodeling and vessel recoil), which tend to diminish the results of PTA fairly quickly and reduce the lumen diameter. Stents support the vessel wall to prevent early lumen loss, and the support continues until the vessel restores its original physiology. However, crushability and poor adaptablity are intrinsic disadvantages of balloon-expandable stents. Self-expanding stents have the potential to solve the limitations of balloon-expandable stents. First, crushability is not an issue. Furthermore, self-expanding stents offer high kink resistance, high radial force, and homogenous wall coverage.

This article evaluates the clinical outcome and stent performance of 42 consecutive cases in which the 4-F, self-expanding Xpert stent (Abbott Vascular Devices, Abbott Park, IL) was used. All cases were performed in the Department of Vascular Surgery of the AZ St-Blasius in Dendermonde, Belgium, and the Department of Cardiovascular and Thoracic Surgery of the Imelda Hospital in Bonheiden, Belgium.

MATERIALS AND METHODS

Vascular access was accomplished through a 4-F sheath introducer—120 cm long for contralateral (crossover) approaches and 80 cm long for antegrade approaches. The long introducer sheath was positioned in the popliteal area to optimize device handling and imaging. The stenoses were traversed, and occlusions were recanalized with a conventional hydrophilic .035-inch or .018-inch guidewire. Stent deployment was accom-

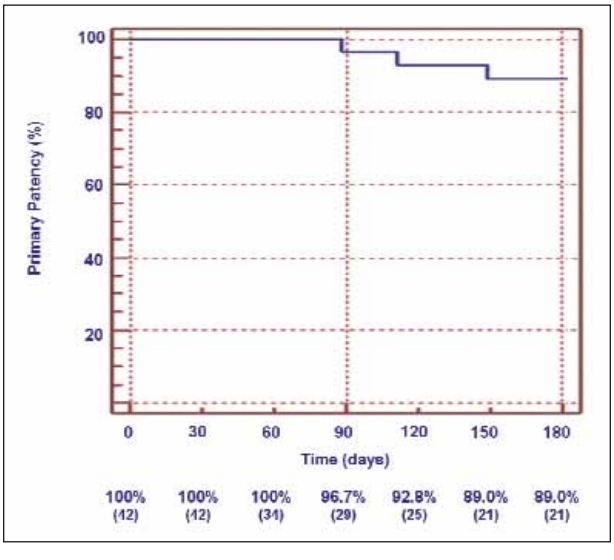

Figure 1. Kapan-Meier graph of primary patency results.

plished with a .018-inch wire to accommodate the low-profile stent system.

The lesion was dilated with a coronary-type balloon. In case of a suboptimal angiographic result after PTA (≥50% residual stenosis) and/or flow-limiting dissection, it was decided to implant a self-expanding Xpert stent. An optimum angiographic result (<10% residual stenosis) was defined as immediate procedural success.

Each patient was seen regularly after stent implantation. Physical examination was performed, and stent patency was evaluated by color flow duplex ultrasound. Daily aspirin therapy was initiated, and clopidogrel saturation (75 mg daily during at least 4 days or one loading dose of 300 mg the day before the procedure) was achieved prior to the procedure. Heparin was used during the procedure (bolus of 150 IU/kg body weight). The postprocedure antithrombotic regimen used accorded to the routine clinical practice of the hospital (75 mg clopidogrel daily for 1 month; 160 mg aspirin daily for life; fraxiparin 0.6 mL daily for 3 weeks).

Data collection and analysis for preoperative, hospitalization, and follow-up information were performed by means of a Microsoft Access-based dataset. During the follow-up, the patency of the treated areas was assessed based on duplex peak velocity ratios and the incidence of reinterventions for the same bed. Patients not receiving any endovascular or surgical below-the-knee reintervention and not exhibiting significant restenosis on duplex (peak velocity ratio ≥2.0) were regarded as having primary patency. The clinical status of the patients was followed according to the Rutherford class changes and the absence of major amputations after index procedure (ie, limb salvage). Primary patency and limb salvage life tables were calculated using the Kaplan-Meier estimate method, for a period starting on the date of the procedure up to and including the most recent follow-up visit.

RESULTS

Between July 2003 and February 2005, 42 patients (27 male) presenting with symptomatic critical limb ischemia (Rutherford categories 4 and 5) due to infrapopliteal arterial disease were treated by means of the 4-F, self-expanding Xpert stent. In total, 44 short below-the-knee lesions were stented. All patients had a diagnostic evaluation of suboptimal angiographic result after PTA (≥50% residual stenosis) and/or flow-limiting dissection, before enrollment into the evaluation.

The mean age of the treated patients was 74 years (range, 50-90 years). Risk factors were distributed according to what can be seen in similar patient populations. Hypertension was seen in 32 (76.2%) patients, diabetes in 16 (38.2%) patients, nicotine abuse in 18 (42.9%) patients, and hypercholesterolemia in 21 (50%) patients.

TABLE 1. STENT DISTRIBUTION BY ANATOMIC LOCATION*

Stented Vessel	Number of SE Xpert Stents		
	Total	5 mm	6 mm
Popliteal artery (P3)	11	8	3
Tibioperoneal trunk	25	25	
Anterior tibial artery	5	5	
Peroneal artery	1	1	
Posterior tibial artery	2	2	

*N=44

Contralateral access is the standard strategy for endovascular below-the-knee procedures. In this specific patient group, a contralateral approach was used in 36 (85.7%) cases, whereas an ipsilateral approach was preferred in six (14.3%) cases. On average, it took 48 minutes (range, 20-90 minutes) to perform a procedure (skin-to-skin). An average of 108 mL (range, 20-230 mL) contrast medium was used. On average, 13 minutes (range, 2-57 minutes) of fluoroscopy time were needed.

Preoperative lesion assessment showed an average stenosis percentage of 83% (range, 60%-100%) in arteries with a reference diameter of 3.6 mm (range, 3-5 mm). Calcification was seen in 27 (61.4%) occasions. Dissection, thrombus, and ulceration were observed in three (7%), three (7%), and one (2%) patient, respectively.

An analysis of the 44 stenoses showed 25 (57%) lesions in the tibioperoneal trunk, 11 (25%) in the popliteal P3 region, and five (11.4%), one (2%), and two (5%) in the anterior tibial, posterior tibial, and peroneal arteries, respectively (Table 1).

Angiographic procedural success was achieved in all patients. According to the Kaplan-Meier method, primary patency was calculated to be 100%, 96.7%, and 89.0% after 1, 3, and 6 months, respectively (Figure 1). Limb salvage rates of 100% were observed at each of these time points (Figure 2).

DISCUSSION

The data available on endovascular below-the-knee intervention are few, coming from only a few trials. To date, no data on stent use in this area have been published. A comparison can only be made with the data of Balmer et al[4] who selected intraluminal PTA as the treatment of choice for these infrapopliteal lesions and other publications that focused on subintimal PTA.[5,13]

Our results suggest that the use of stents results in a

higher immediate procedural success rate of the infrapopliteal endovascular intervention. We find a 100% immediate technical success rate after stenting. Several series on PTA alone report approximately a 90% immediate technical success for intraluminal PTA in treating stenosis, whereas it decreases to approximately 70% to 80% for occlusions, underlining the necessity of stents to cope with the potential side effects of PTA, such as dissections, early plaque remodeling, and vessel recoil.[6-10]

After 6 months, we can report an encouraging limb salvage rate of 100% and a primary patency rate of 89%. It remains to be seen whether this outcome will be sustained after a longer period of time. Balmer et al[4] reported 90% prevention of amputation at 1 year after PTA of below-the-knee arteries for patients with critical limb ischemia. Subintimal PTA for restoring blood flow in the below-the-knee vessels seems to be able to prevent amputation in 81% to 85% of cases.[5,13]

CONCLUSION

Our data suggest that the use of the self-expanding Xpert stent in infrapopliteal stenotic disease in patients with critical limb ischemia is safe and effective. The long-term results are promising, but more extensive series are mandatory to prove the superiority of stent use over PTA in below-the-knee vessels.

ACKNOWLEDGMENTS

The authors take great pleasure in thanking the staff of Flanders Medical Research Program (www.fmrp.be), with special regards to Koen De Meester and Erwin Vinck for performing the systematic review of the literature and providing substantial support to the writing of the article. ■

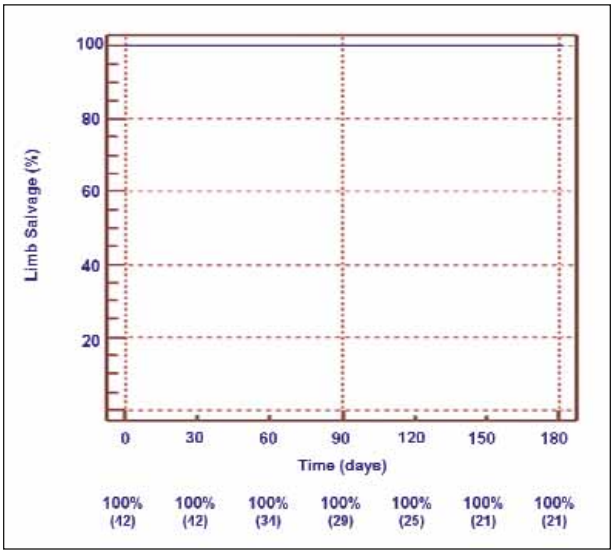

Figure 2. Kapan-Meier graph of limb salvage results.

Marc Bosiers, MD, is from the Department of Vascular Surgery, AZ St-Blasius, Dendermonde, Belgium. He has disclosed that he has no financial interest in any product or manufacturer mentioned herein. Dr. Bosiers may be reached at +32 52252735; marc.bosiers@telenet.be.

Koen Deloose, MD, is from the Department of Vascular Surgery, AZ St-Blasius, Dendermonde, Belgium. He has disclosed that he has no financial interest in any product or manufacturer mentioned herein. Dr. Deloose may be reached at +32 52252517; koen.deloose@telenet.be.

Jürgen Verbist, MD, is from the Department of Cardiovascular and Thoracic Surgery, Imelda Hospital, Bonheiden, Belgium. He has disclosed that he has no financial interest in any product or manufacturer mentioned herein. Dr. Verbist may be reached at +32 15506197; jurgen.verbist@imelda.be.

Patrick Peeters, MD, is from the Department of Cardiovascular and Thoracic Surgery, Imelda Hospital, Bonheiden, Belgium. He has disclosed that he has no financial interest in any product or manufacturer mentioned herein. Dr. Peeters may be reached at +32 15506197; patrick.peeters@imelda.be.

1. Weitz JI, Byrne J, Clagett P, et al. Diagnosis and treatment of chronic arterial insufficiency of the lower extremities: a critical review. Circulation. 1996;94:3026-3049.
2. McDaniel MD, Cronenwett JL. Basic data related to the natural history of intermittent claudication. Ann Vasc Surg. 1989;3:273-277.
3. Jaff M. Severe peripheral arterial disease and critical limb ischemia: incidence, pathophysiology, presentation, methods of diagnosis. Society of Vascular Medicine and Biology CME series; svmb.org/medpro/cme/p3/cme:5-10.
4. Balmer H, Mahler F, Do DD, et al. Balloon angioplasty in chronic critical limb ischemia: factors affecting clinical and angiographic outcome. J Endovasc Ther. 2002;9:403-410.
5. Nydahl S, Hartshorne T, Bell PR, et al. Subintimal angioplasty of infrapopliteal occlusions in critically ischaemic limbs. Eur J Vasc Endovasc Surg. 1997;14:212-216.
6. Dorros G, Jaff MR, Dorros AM, et al. Tibioperoneal (outflow lesion) angioplasty can be used as primary treatment in 235 patients with critical limb ischemia: five-year follow-up. Circulation. 2001;104:2057-2062.
7. Treiman GS, Treiman RL, Ichikawa L, et al. Should percutaneous transluminal angioplasty be recommended for treatment of infrageniculate popliteal artery or tibioperoneal trunk stenosis? J Vasc Surg. 1995;22:457-463.
8. Lofberg AM, Lorelius LE, Karacagil S, et al. The use of below-knee percutaneous transluminal angioplasty in arterial occlusive disease causing chronic critical limb ischemia. Cardiovasc Intervent Radiol. 1996;19:317-322.
9. Saab MH, Smith DC, Aka PK, et al. Percutaneous transluminal angioplasty of tibial arteries for limb salvage. Cardiovasc Intervent Radiol. 1992;15:211-216.
10. Hauser H, Bohndorf K, Wack C, et al. [Percutaneous transluminal angioplasty (PTA) of isolated crural arterial stenoses in critical arterial occlusive disease]. Rofo Fortschr Geb Rontgenstr Neuen Bildgeb Verfahr. 1996;164:238-243.
11. Soder HK, Manninen HI, Jaakkola P, et al. Prospective trial of infrapopliteal artery balloon angioplasty for critical limb ischemia: angiographic and clinical results. J Vasc Interv Radiol. 2000;11:1021-1031.
12. Tisi PV, Mirnezami A, Baker S, et al. Role of subintimal angioplasty in the treatment of chronic lower limb ischaemia. Eur J Vasc Endovasc Surg. 2002;24:417-422.
13. Vraux H, Hammer F, Verhelst R, et al. Subintimal angioplasty of tibial vessel occlusions in the treatment of critical limb ischaemia: mid-term results. Eur J Vasc Endovasc Surg. 2000;20:441-446.
14. Schillinger M, Exner M, Mlekusch W, et al. Endovascular revascularization below the knee: 6-month results and predictive value of C-reactive protein level. Radiology. 2003;227:419-425.
15. Brillu C, Picquet J, Villapadierna F, et al. Percutaneous transluminal angioplasty for management of critical ischemia in arteries below the knee. Ann Vasc Surg. 2001;15:175-181.