

Drug-eluting balloons and uncoated balloons perform equally to rescue infrainguinal autologous bypasses at risk

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ABSTRACT

Objective: Endovascular treatment of a significant stenosis in an infrainguinal autologous bypass prevents bypass occlusion and improves bypass patency. Drug-eluting balloons (DEBs) have been proven to possess antirestenotic features in the treatment of femoropopliteal stenoses and occlusions. This study evaluated the effects of DEB angioplasty vs uncoated balloon (UCB) angioplasty to rescue infrainguinal autologous bypass grafts at risk (BAR).

Methods: The study included all consecutive patients treated endovascularly for BAR from December 1, 2012, to July 31, 2015. As of April 1, 2014, the primary treatment of BAR was changed from UCBs to DEBs. Patients treated with DEBs were prospectively recorded in a database and retrospectively analyzed. Patients treated with UCBs were retrospectively collected from a historical cohort with a similar inclusion period length as the DEB cohort. The follow-up scheme did not differ between the two groups. The primary end point was the combined end point of freedom from recurrent stenosis or bypass occlusion. Secondary end points were primary assisted patency, secondary patency, technical success, major amputation, and mortality.

Results: Twenty-one patients were treated in the DEB group and 18 were treated in the UCB group. The two groups were evenly distributed in demographics, bypass, treatment, and lesion characteristics. No statistically significant differences were found in the combined end point of freedom from recurrent stenosis and the occlusion rate after 1 year between the UCB group (77.8%) and the DEB group (80.0%; $P = .76$). After 1 year, the primary assisted patency rate was 88.2% in the UCB group vs 95.2% in the DEB group ($P = .47$), and the secondary patency rate was 94.1% in the UCB group vs 95.2% in the DEB group ($P = .91$). During follow-up, restenosis developed in four patients (22.2%) in the UCB group and in four patients (19.0%) in the DEB group ($P = .80$). One bypass (5.6%) in the UCB group and one bypass (4.8%) in the DEB group occluded during follow-up ($P = .884$).

Conclusions: DEBs and UCBs perform equally in the treatment of significant stenosis in infrainguinal autologous bypasses with regard to freedom from restenosis or bypass occlusion, primary assisted patency, and secondary patency at 1 year. We suggest using a less expensive UCB in the treatment of BAR. (J Vasc Surg 2017;■:1-7.)

Autologous infrainguinal bypasses are widely used for the treatment of extensive femoropopliteal arterial occlusive disease because they show excellent long-term patency, with reported 5-year patency rates of 60% to 80%.¹⁻³ One-third of patients will develop a significant stenosis in the autologous bypass, predominantly in the first year after surgery.^{4,5} An autologous bypass with a significant stenosis is associated with an increased risk for bypass occlusion and is called a bypass at risk (BAR).^{4,6,7} Duplex ultrasound surveillance is performed to identify autologous bypass stenoses.^{8,9} Early

endovascular intervention is the preferred technique to rescue infrainguinal BAR. Although the freedom from recurrent stenosis after percutaneous angioplasty with uncoated balloons (UCBs) is disappointing, repeated endovascular revascularization results in patency rates of >80%.^{10,11}

In the past decade, drug-eluting balloons (DEBs) have been introduced to improve patency rates. Antiproliferative medication (paclitaxel) on the exterior of the balloon is transferred into the arterial wall using an excipient during inflation to reduce neointimal hyperplasia.^{12,13} Recent meta-analyses of randomized controlled trials comparing treatment of atherosclerotic lesions in femoropopliteal arteries with DEBs and UCBs show a significant reduction of binary restenosis, decreased late lumen loss, and reduction of target lesion revascularization after DEB angioplasty.^{14,15} However, whether endovascular treatment of autologous infrainguinal bypass stenoses with DEBs results in improved outcome compared with UCB angioplasty is still unclear. This study evaluated the effects of DEB angioplasty on significant stenosis in infrainguinal autologous bypass grafts compared with UCB angioplasty.

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METHODS

The Maasstad Hospital Institutional Review Board approved the study. The requirement for written patient consent was waived.

Study design. On April 1, 2014, primary treatment of infrainguinal autologous BAR changed from UCB angioplasty to DEB angioplasty in our institution. To obtain a minimal follow-up of 1 year, all consecutive patients with an autologous infrainguinal BAR treated with DEB angioplasty between April 1, 2014, and July 31, 2015, were included. Data on treatment with DEBs were prospectively collected and retrospectively analyzed. These results were compared with a historical cohort of patients with autologous infrainguinal BAR treated with UCB angioplasty, some of which have been published previously.¹⁰ A similar inclusion period length as the DEB cohort of 16 months was chosen for the UCB angioplasty cohort. Therefore, all consecutive patients with an autologous infrainguinal BAR treated with UCB angioplasty from December 1, 2012, to April 1, 2014, were included. Patients that were treated previously with percutaneous transluminal angioplasty (PTA) were all treated before December 1, 2012, ruling out crossover between the two groups.

Indication for endovascular treatment. Patients with peripheral arterial occlusive disease treated with an infrainguinal autologous bypass graft were monitored for at least 1 year according to the guidelines of the Dutch Vascular Society.¹⁶ Duplex ultrasound surveillance was performed at 6 and 12 months after surgery by ultrasound technicians from an accredited vascular laboratory. Thereafter, duplex ultrasound imaging was performed if the patient became symptomatic. A stenosis of >70% was considered a significant stenosis and was defined as a peak systolic velocity of >300 cm/s or a peak systolic velocity ratio >3.0.

Treatment. Patients with BAR were scheduled for digital subtraction angiography. The stenosis or multiple stenoses in the BAR were identified and classified as anastomotic or nonanastomotic. The bypass diameter proximal and distal to the stenosis was measured, and before April 1, 2014, an UCB with a diameter similar to the bypass diameter was used for angioplasty. After April 1, 2014, a Passeo-18 Lux DEB (Biotronik AG, Buelach, Switzerland) was used. All patients received 5000 IU of heparin. All lesions in the DEB group were predilated with an angioplasty balloon 1 mm smaller than the target vessel, and the inflation time was 3 minutes in all patients. No minimal balloon inflation time was indicated in the UCB group.

If a residual stenosis of >30% persisted, prolonged inflation with a UCB was performed. Treatment was considered a technical success if a residual stenosis of <30% was achieved after PTA, with or without prolonged

ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center retrospective cohort study
- **Take Home Message:** Significant stenoses of infrainguinal autologous bypasses were treated in 21 patients with drug-eluting balloon angioplasty and in 18 with uncoated balloon angioplasty, with similar freedom from restenosis, bypass occlusion, and patency rates at 1 year in both groups.
- **Recommendation:** The authors suggest that stenosis of failing autologous bypasses should be treated with uncoated balloon angioplasty.

balloon inflation. In case of flow-limiting dissection or residual stenosis of >30%, a self-expanding bare-metal stent was placed. Obstructive lesions in other arterial segments (ie, iliac or tibial) were treated simultaneously with PTA and optional stenting to obtain unimpeded runoff through at least one artery passing the ankle.

Patients received oral anticoagulation therapy for at least 2 years after bypass surgery.¹⁷ Antiplatelet therapy (aspirin) was prescribed for patients who were not eligible for anticoagulation therapy. All patients received a statin as primary cardiovascular protection.

Follow-up. The follow-up protocol was similar in both groups. After endovascular treatment of BAR, patients were routinely monitored in the outpatient clinic. Duplex ultrasound surveillance was performed at 6 and 12 months. In patients with clinical deterioration, duplex ultrasound or direct angiography was performed.

Our institution has adopted an endovascular-first approach for primary and recurrent stenosis. Patients with recurrent significant stenosis in the bypass on duplex ultrasound imaging were rescheduled for digital subtraction angiography, and PTA was performed if a stenosis of >70% was found during angiography. If a bypass occluded during follow-up, thrombolytic therapy or surgical embolectomy was performed. If thrombolytic therapy or surgical embolectomy was not successful or not performed, the bypass was considered failed.

Study end points. Comorbidities and outcomes were in accordance with those proposed by the reporting standards of the Society for Vascular Surgery for endovascular treatment of chronic lower extremity peripheral artery disease.¹⁸ Because primary patency according to the reporting standards was already lost during the first endovascular treatment of BAR, the primary end point of this study was a combined end point of freedom from recurrent stenosis or occlusion after angioplasty of the stenosis in the autologous bypass with a UCB or DEB. Secondary outcomes in this study were primary assisted patency, defined as freedom from any intervention to prevent bypass occlusion; secondary patency, defined as

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