

Results from a multicenter registry of heparin-bonded expanded polytetrafluoroethylene graft for above-the-knee femoropopliteal bypass



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ABSTRACT

Objective: The aim of the study was to retrospectively analyze early and follow-up results of above-the-knee femoropopliteal bypasses (AKb) performed with a bioactive heparin-bonded expanded polytetrafluoroethylene (HB-ePTFE) graft in patients with peripheral arterial obstructive disease in a multicentric retrospective registry involving seven Italian vascular centers.

Methods: During a 14-year period ending in March 2016, an HB-ePTFE graft was used in 1401 interventions performed for peripheral arterial obstructive disease. Comorbidities, risk factors, and follow-up outcomes were collected in a multicenter registry with a dedicated database. A post hoc analysis of the database was performed to identify 364 (25.9%) patients who underwent AKb. Early (intraoperative and <30 days) results were analyzed in terms of death, thrombosis, amputations, reinterventions, and the occurrence of major local and systemic complications. Follow-up results were analyzed by life-table analysis (Kaplan-Meier test) in terms of primary and secondary graft patency, assisted primary patency, limb preservation, and amputation-free survival. The analysis of follow-up results was stopped in December 2016.

Results: In 61 (16.7%) patients, AKb was performed after the failure of a previous ipsilateral revascularization. Critical limb ischemia was present in 164 (45%) cases; the remaining patients had life-limiting intermittent claudication. Perioperative mortality occurred in three (0.8%) patients: in the hospital (n = 2) due to acute myocardial infarction and after discharge (n = 1) due to fatal arrhythmia. Early thromboses occurred in six (1.6%) patients; all these patients had primary AKb for critical limb ischemia. The cumulative rate of perioperative amputations was 0.5% (2 cases), whereas the cumulative rate of early reinterventions was 3% (11 cases). Median duration of follow-up was 28 months (range, 1-168 months); the median cumulative follow-up index for survival was 0.75 (range, 0.05-1). Estimated survival at 5 years was 75.3% (standard error [SE], 0.03). Estimated 5-year primary patency was 64% (SE, 0.04); the corresponding figure in terms of assisted primary patency was 65% (SE, 0.035). Secondary patency rate at 5 years was 74.5% (SE, 0.03). The rate of limb preservation at 5 years was 95% (SE, 0.02); the corresponding figure in terms of amputation-free survival was 74% (SE, 0.04).

Conclusions: In an era of endovascular enthusiasm, with conflicting results for the treatment of long or complex lesions of the superficial femoral artery, AKb with the use of HB-ePTFE graft remains an effective option, with low rate of perioperative complications and satisfactory long-term results. (*J Vasc Surg* 2018;67:1463-71.)

In recent years, meta-analyses showed that endovascular treatments have supplanted bypass surgery as the preferred first technique for the treatment of peripheral arterial obstructive disease (PAOD), especially in the femoropopliteal segment.¹⁻⁴ Nevertheless, results were not completely satisfactory; costs increased fourfold in the last decades, and considering a composite end point that includes death and major amputation, this was significantly worse for endovascular revascularization compared with bypass surgery.⁵ These data are noteworthy because the majority of recent endovascular

series have been mainly weighted toward treatment of short femoropopliteal lesions, also using different techniques.⁷⁻¹¹ Most important, robust long-term data in the endovascular arm are questionable, especially for complex lesions, and evidence from randomized clinical trials has already shown that bypass surgery has better patency in the long-term outcomes.¹²⁻¹⁶ When it comes to open surgery, short-segment autologous great saphenous vein (GSV) has been reported to provide better long-term outcomes than prosthetic grafts for above-the-knee femoropopliteal bypass (AKb).¹⁷⁻²⁰ However

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*A full list of the PROPATEN Italian Registry Group is given in the [Appendix](#) (online only).

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this preferred conduit is not available or suitable in almost half of patients, and conflicting data still exist as to either alternative vein options or the best material to be used for prosthetic graft bypass.^{21,22}

The aim of this study was to evaluate early and long-term results of AKb performed with a bioactive heparin-bonded expanded polytetrafluoroethylene (HB-ePTFE) graft in patients with PAOD in a multicentric retrospective registry involving seven Italian vascular centers.

METHODS

Population of patients. During a 14-year period ending in March 2016, an HB-ePTFE graft (Gore Propaten; W. L. Gore & Associates, Flagstaff, Ariz) was used in 1401 interventions performed for PAOD in seven Italian hospitals. The registry was created in 2006; at the very beginning, it included three centers at which this type of graft was used for the first time in Italy.²³⁻²⁵ Then, starting from 2008, four other high-volume centers with a large use of this graft were invited to join the registry. Comorbidities, risk factors, and follow-up outcomes were collected in a multicenter registry with a dedicated database. The registry was approved by the local ethical committee of each center; all subjects gave informed consent to the treatment of their personal data. Data were collected in a multicenter registry with a dedicated database. Data collection was retrospective until 2008; it was prospective thereafter. Each center was asked to send its updated data to the coordinating center twice a year, where they were transformed into SPSS files and elaborated for the analyses. The reliability of the data contained in the registry was certified by an external independent commission (Castalia Group, ICT and Quality Management, Aosta, Italy) in two different sessions (2009 and 2013). A post hoc analysis of the database was performed to identify 364 (25.9%) patients who underwent AKb. In the same period, in the same centers, AKb with single-segment autologous GSV was performed in seven patients. Some (n = 101) of the AKb patients included in this study have been part of one previous study of the registry²⁶; however, although above-the-knee anastomosis was one of the variables included in both the univariate and multivariable analyses, AKb was not analyzed separately in that paper. The modalities of the choice of the type of graft and of data collection and insertion have already been described.^{26,27}

Preoperative workup, indications for surgery, surgical details, and follow-up protocol. In all the cases, preoperative diagnostic assessment consisted of ankle-brachial index (ABI) measurement, duplex ultrasound scanning, and computed tomography angiography of the aortoiliac axis and of the lower limbs. Patients were operated on in the presence of severe lifestyle-limiting intermittent claudication after the failure of other conservative

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective analysis of a multicenter registry
- **Take Home Message:** Femoral to above-knee popliteal artery bypass with heparin-bonded polytetrafluoroethylene was used in 364 patients (45% with critical limb ischemia) and resulted in 0.8% early mortality and an estimated 5-year survival of 75.3%, 5-year primary patency of 64%, and 5-year rate of amputation-free survival of 74%.
- **Recommendation:** This study suggests that heparin-bonded polytetrafluoroethylene can be used in femoral to above-knee popliteal artery bypasses with a 5-year primary patency of 64%.

measures or in the presence of critical limb ischemia (CLI). Apart from a native distal popliteal artery free from severe stenosis, anatomic indication for AKb has substantially changed during the years. In the first years of the registry experience, it was performed in patients with ≥ 10 cm of occlusion of the superficial femoral artery (SFA). In the most recent years, it was reserved for patients with ≥ 20 cm of occlusion or chronic total occlusion of the SFA starting from just below its origin, severe and diffuse calcifications of the SFA, and less complex lesions after the failure of a previous endovascular treatment.

The interventions were performed in the operating room under general anesthesia with standard technique, which consisted of a longitudinal approach to the femoral bifurcation and to the distal SFA-proximal popliteal artery. The anastomoses were performed in an end-to-side fashion at the level of the distal common femoral artery and of the distal SFA. In selected patients with concomitant occlusive disease of the femoral bifurcation, endarterectomy was accomplished with patching. Similarly, we considered an AKb feasible even in the presence of a diseased proximal popliteal artery, but with a good-quality distal popliteal artery as well as tibial vessels. In case of severely diseased above-knee popliteal artery, we performed an endarterectomy and an adjunctive Linton patch at the distal anastomosis. In case of tibial vessel disease, an adjunctive procedure in the form of angioplasty has been left to the surgeon's judgment. All the patients had intraoperative intravenous administration (30-40 units/kg) of sodium heparin at arterial clamping. At the end of the intervention, completion angiography or duplex ultrasound was routinely performed. Postoperative antithrombotic treatment consisted of single or double antiplatelet treatment or oral anticoagulation; it was determined on the basis of the surgeon's preference as well as according to the patient's comorbidities and risk factors, or it was driven by some particular technical aspects performed during the intervention. In general,

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