Distal Polytetrafluoroethylene Bypasses in Patients Older Than 75 Years

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Hypothesis: Polytetrafluoroethylene (PTFE) alone is justified for infrapopliteal arterial grafting in elderly patients with critical ischemia of the lower limbs who lack a suitable, autogenous saphenous vein.

Design: A consecutive sample clinical study with a mean follow-up of 16 months.

Setting: The surgical department of an academic tertiary care center and an affiliated secondary care center.

Patients: Thirty-one patients older than 75 years with critical ischemia of the lower limbs received 34 PTFE bypass grafts to the infrapopliteal arteries: 12 patients to the anterior tibial, 8 to the peroneal, 8 to the posterior tibial, and 2 to the dorsalis pedis artery.

Main Outcome Measures: Cumulative survival, primary graft patency, and limb salvage rates expressed by standard life-table analysis.

Results: Operative mortality rate was 3%. Cumulative survival rate was 80% at 2 years (SE, 9.2%) and 43% at 3 years (SE, 11.4%). Cumulative primary patency rate was 67% at 2 years (SE, 9.1%), and 61% at 3 years (SE, 12.7%). Cumulative limb salvage rate was 77% at 2 years (SE, 8.7%) and 70% at 3 years (SE, 12.8%).

Conclusion: Polytetrafluoroethylene alone is justified as graft material for infrapopliteal bypass grafts in elderly patients with critical ischemia of the lower limbs and without a suitable autogenous saphenous vein.

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INFRAINGUINAL revascularization for critical ischemia has proved effective in terms of patency rates, limb salvage rates, and quality of life. The conduit of choice for distal revascularization remains the autogenous saphenous vein. If an autogenous saphenous vein is lacking, alternative materials have been considered, including composite conduits of polytetrafluoroethylene (PTFE) and a saphenous vein segment, arm and lesser saphenous veins, and PTFE alone. Such alternative graft materials may allow results that are acceptable although inferior to those obtained with the autogenous saphenous vein. In a population of elderly patients requiring a rapid and safe distal revascularization for critical ischemia of the lower limbs but lacking an autogenous saphenous vein, a PTFE graft, without the adjunct of vein patch or cuff at the distal anastomosis, would be likely to allow good results in terms of patency and limb salvage rate.

In this study, we performed distal revascularization for critical ischemia with PTFE alone in patients older than 75 years without a suitable autogenous saphenous vein to determine whether the procedure would allow sufficiently good results to be considered a justified alternative material to the autogenous saphenous vein.

RESULTS

One patient died postoperatively of cardiac causes, resulting in a postoperative mortality rate of 3%. Nonfatal complications included 3 myocardial ischemic events and 1 renal failure, which could be successfully managed with appropriate medical treatment. No postoperative bypass occlusion occurred nor was a postoperative major amputation ever required.

The mean operating time was 160 minutes. The mean postoperative length of stay was 12 days (range, 6-16 days). Major cutaneous necroses that threatened the viability of the graft of the limb...
PATIENTS AND METHODS

From October 1994 to December 1998, 31 consecutive patients older than 75 years without suitable autogenous saphenous veins received 34 PTFE bypass grafts of the infrapopliteal arteries at the Department of Surgery, Rome University Hospital, Rome, Italy, and one affiliated center. This figure represents 14% of 236 infrapopliteal revascularizations performed in the same period.

The study was approved by the local ethics committee, and informed consent was obtained from all patients.

Nineteen patients were men and 12 were women, with a mean age of 78 years (range, 76-91 years).

Eleven patients (33%) were receiving oral antidiabetic treatment; 19 (61%) had a history of smoking; 13 (42%) were medically treated for arterial hypertension; 15 (48%) had evidence of coronary artery disease, defined as history, clinical symptoms, or electrocardiographic signs of myocardial ischemia; 7 (23%) had a history of previous transient ischemic attack or carotid endarterectomy; and 2 (6%) had chronic renal insufficiency that required dialysis. Nine patients (29%) had had a previous failed infrapopliteal revascularization.

Critical ischemia of the lower limbs7 (grades II and III, categories 4 and 58) was the indication for bypass in all patients.

Preoperative study of the patients included a complete arteriogram from the abdominal aorta to the pedal arch. Prerequisite for revascularization was the opacification of a receiving distal artery of at least 1.5 mm of diameter, with a late injection of at least a part of the pedal arch. Direct surgical exploration of a possibly existing, nonopacified artery was not attempted.

Bypass procedures were performed using a ringed, thin-walled, stretch PTFE graft 6 mm in diameter (W. L. Gore and Associates, Inc, Flagstaff, Ariz). The choice of a plain PTFE graft was based on the absence of a suitable length of great saphenous vein, either for a fully autogenous or a composite bypass conduit, at preoperative duplex scan and surgical exploration. Usually, a saphenous vein was deemed suitable if it had a diameter of at least 3 mm once dilated over its full length. The presence of hypoplastic or fibrous segments requiring more than 2 anastomoses, including that with a prosthesis for a composite configuration, determined discarding the saphenous vein as a suitable conduit. Reasons for lack of a convenient saphenous vein included fibrosis and other alterations that rendered the vein unsuitable for grafting in 12 patients (39%), previous infrainguinal revascularization in 9 (29%), previous coronary bypass grafting in 8 (26%), and previous stripping in 2 (6%). Search for alternative sources of vein material, ie, arm veins or lesser saphenous vein, was not attempted.

The inflow site was the limb of an aortofemoral Dacron graft in 2 cases, the common femoral artery in 15 cases, the superficial femoral in 11 cases, and the below-knee popliteal artery in 5 cases. The outflow site was the anterior tibial artery in 12 cases, the peroneal in 12 cases, the posterior tibial in 8 cases, and the dorsalis pedis artery in 2 cases.

Exposure of the donor and recipient sites was obtained through standard surgical accesses. The peroneal artery was always exposed through an internal access. The grafts were anatomically tunneled preferentially but sometimes were placed subcutaneously when directed to the anterior, posterior tibial, or the dorsalis pedis artery. The receiving artery was not clamped: hemostasis was obtained with an Esmarch band. Distal anastomoses were performed with running 7-0 polypropylene sutures under 2.5 loupe magnification. One concomitant inflow procedure was performed, consisting of a common iliac artery angioplasty. Completion arteriography was performed only if doubts existed about the technical performance of the bypass. Such controls never led to intraoperative revisions.

Postoperatively, patients underwent anticoagulation with intravenous heparin sodium for 72 hours and were then prescribed 100 mg/d of oral aspirin.

Early in the series, a control angiogram was always obtained before patients’ discharge, whereas in the latest 2 years, a duplex ultrasound evaluation was deemed sufficient.

Postoperative mortality was defined as any death occurring within 30 days of surgery.

Local status of the limb and patency of the bypass were assessed at 4 weeks after operation and twice every 12 months by clinical examination and duplex scanning. Failure to detect a pulse by physical examination, combined with duplex and/or arteriographic confirmation of graft occlusion, defined graft thrombosis. Obstructive lesions detected at duplex scanning and confirmed at arteriography defined a failing graft eligible for revision. Thrombectomy of an occluded graft was not attempted in this series.

As main results, patients’ survival, primary grafts’ patency, and limb salvage rate were considered. They were expressed by standard life-table analysis.9

Primary patency was defined as continuous graft patency uninterrupted by any surgical or radiologic revision. Limb salvage was defined as the preservation of a functional limb below the ankle level, and any amputation above the ankle level was defined a major amputation.
Elderly patients with critical ischemia who require distal arterial revascularization for limb salvage represent a particular population among those who are candidates for infrapopliteal bypass grafting for the same indication. They are a subset of fragile patients and often lack a suitable saphenous vein. Concomitantly, they need a means of safe and expeditious revascularization to obtain limb salvage, which means optimization of their quality of life before death.10-12

In the absence of a suitable saphenous vein, infrapopliteal arterial revascularization can be challenging6 and needs to be performed with alternative materials.

Initial experience with PTFE for infrapopliteal bypass yielded poor results, with primary patency rates of 12% to 22% at 3 years,13,14 and led some authors to suggest that a primary major amputation could be preferable to a distal PTFE bypass graft.15-17 However, other recent studies have reported results that justify the use of PTFE for infrapopliteal revascularization in the lack of a suitable saphenous vein: primary patency rates of 36% to 43%, with limb salvage rates up to 71%, at 3 years have been obtained.5,6,18,19

To further improve the patency rates of PTFE, the adjunct of distal anastomotic vein cuff,20 patch,21 and arteriovenous fistula22-24 has been proposed.

Comment

Elderly patients with critical ischemia who require distal arterial revascularization for limb salvage represent a particular population among those who are candidates for infrapopliteal bypass grafting for the same indication. They are a subset of fragile patients and often lack

grene that required a major amputation in 10 patients or because of lack of symptoms in 4.

Overall, cumulative primary patency rate was 87% at 1 year (SE, 5.8%) and 67% at 2 years (SE, 9.1%). At 3 years, the cumulative patency rate was 61% (SE, 12.7%) (Table 2 and Figure 2). Cumulative primary patency rate of additional bypasses was 43% at 3 years (SE, 23.0%); for these data, no statistically based conclusion could be made.

Overall, cumulative limb salvage rate was 87% at 1 year (SE, 5.8%) and 77% at 2 years (SE, 8.7%). A salvage rate of 70% was observed at 3 years (SE, 12.8%) (Table 3 and Figure 3).

Table 1. Survival After Polytetrafluoroethylene Bypass Grafting of Infrapopliteal Arteries

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Table 2. Overall Primary Patency of Polytetrafluoroethylene Bypass Grafting of Infrapopliteal Arteries

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Figure 1. Overall cumulative survival rates after bypass grafting to infrapopliteal arteries. The numbers above the dotted line indicate the number of patients at risk for each interval.

Figure 2. Overall cumulative primary patency rate of polytetrafluoroethylene bypasses to infrapopliteal arteries. The numbers above the dotted line indicate the number of bypasses at risk for each time interval.
### Table 3. Overall Limb Salvage After Polytetrafluoroethylene Bypass Grafting of Infrapopliteal Arteries

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<td>47</td>
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**Figure 3.** Overall cumulative limb salvage rate after polytetrafluoroethylene bypasses to infrapopliteal arteries. The numbers above the dotted line indicate the number of limbs at risk for each time interval.

A primary patency rate of 54% and a limb salvage rate of 60% have been reported with an adjuvant vein cuff.5 On the other hand, a retrospective study did not find any advantage in terms of patency and limb salvage rates between PTFE and vein cuff and PTFE alone.3

With a vein patch, a 3-year primary patency rate of 58%24 and, more recently, of 78%26 has been observed. However, a randomized trial comparing distal PTFE grafting alone and with vein interposition cuff at the distal anastomosis failed to demonstrate a statistically significant difference between the 2 techniques in limb salvage rates.27

With the adjunct of an arteriovenous fistula at the distal anastomosis, an assisted primary patency rate of 62% has been obtained,24 and a retrospective study reports superior patency rates for PTFE and arteriovenous fistula compared with PTFE alone, although it did not demonstrate any significant difference in limb salvage rates between the 2 techniques.28

Other autogenous vein materials have also been proposed as substitutes for the internal saphenous vein. In a retrospective study comparing the arm and the lesser saphenous veins with PTFE alone for distal bypasses, no significant advantage of any material over the other could be found; on the other hand, the operative time was almost the double for arm and lesser saphenous veins compared with PTFE.29

It can be added that in a population of elderly patients with critical ischemia, arm veins of convenient length are often nonexistent, since they are spoiled by the necessity of providing intravenous fluids and drug administration. Then multiple vein segments with multiple anastomoses are required, which unfavorably affect patency rates.3

In the present experience, a primary patency rate of 67% at 2 years and 61% at 3 years, together with a limb salvage rate of 77% at 2 years and 70% at 3 years, could prospectively be obtained in a population of elderly patients with PTFE grafts. Similar results were obtained in another study, questioning the dogma of all autogenous tissue policy for infragenual and infrapopliteal arterial reconstructions.30 Our population had a relatively limited life expectancy, which resulted in a cumulative survival rate of 43% at 3 years. The fact that a short survival after bypass grafting improves primary patency of arterial reconstructions is known.6 The low incidence of patients with chronic renal insufficiency, who exhibit the worse results of distal bypasses, might also have contributed to the good results obtained in this study.

Polytetrafluoroethylene allowed the revascularization procedures to be done with a short length of operation and hospital stay at costs less than the social costs of an amputation.31

Graft infections and major cutaneous necroses were not observed in this series. Possible explanations beside the low incidence of renal insufficiency may be the preference for anatomic tunneling of the graft whenever possible, particularly when directed to anterior tibial arteries,32 and the reduced surface of dissection compared with that required by harvesting the internal or external saphenous vein.

Only one failing bypass could be identified and revised in this series, and it developed asymptomatic thrombosis 2 months later. None of the grafts that developed thrombosis was deobstructed, since thrombosis was associated with either no recurrent signs of critical ischemia or advanced tissue loss, requiring a major amputation. Although sound evidence is lacking, this study does not support the use of close duplex scan surveillance of distal bypasses, which has already been questioned in other specifically directed studies.33,34

The reported results, although the SE limits reliability up to 2 years, support the use of PTFE alone for infrapopliteal arterial revascularization for critical limb ischemia when a saphenous vein is lacking. Whether other materials or adjuncts at the prosthetic distal anastomosis yield better results in terms of patency and limb salvage rates still needs to be proved.

It is our opinion that in the special setting of elderly patients without an autogenous saphenous vein, PTFE alone might be regarded as the material of choice to perform expeditiously a distal revascularization asso-
associated with a satisfactory limb salvage rate. This latter statement, however, needs to be proved by prospective randomized clinical trials that test PTFE alone against other currently available options.

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