Regarding “A comparative evaluation of polytetrafluoroethylene, umbilical vein, and saphenous vein bypass grafts for femoral-popliteal above-knee revascularization: a prospective randomized Department of Veterans Affairs cooperative study”

To the Editors:

Johnson et al report the fourth published series of patients requiring lower limb revascularization and undergoing a protocol of prospective randomization to saphenous vein, umbilical vein, or PTFE. Eickoff et al reported on 104 below-knee popliteal of prospective randomization to saphenous vein, umbilical vein, or PTFE. Eickoff et al reported on 104 below-knee popliteal procedures, and McCollum et al on 191 patients with an above-knee: below-knee ratio of 2:1. All of these data were accumulated and, with the exception of the delayed report by Johnson et al, reported in the 1980s. Several comments are in order:

1. Though these studies are dated and in many areas, flawed, they are, nonetheless, incredibly, the only ones carried out with more than one alternative to the saphenous vein, randomized, prospective, and performed at multiple surgical sites. This is in contradiction to the manuscript by Burger et al, which typifies the usual reporting of lower limb graft sites. This is in contradiction to the manuscript by Burger et al, which typifies the usual reporting of lower limb graft sites, a single graft compared with autologous vein, the usual inferior results obtained with a prosthetic and the standard conclusion that, despite differences in patency, use of the prosthetic is “reasonable” and “acceptable.” The Invited Comment by J. Mills, which should be required reading for all vascular surgeons, points to the deficiencies of statistical analysis in Burger’s paper and others based on inadequate power.

2. The Meadox product used in all these studies is no longer manufactured. The currently available UV graft is manufactured by BioVascular Inc, Minn. There are no available data showing absence of aneurysmal degloration with the latter product as well as a significant reduction in the early thrombotic events as documented by Johnson et al with the Meadox product. This is based on improved quality control during manufacture, reduction of residual aldehyde moities in graft and storage media, and appreciation of the surgical skills required for implantation. Our first decade of experience with the UV graft was reported in 1988, not in 1998 (reference 20 in Johnson et al). Additional experience and even better results with the improved UV graft were reported in 1995 and 1996.

3. Current evaluations of graft materials should include intraoperative completion duplex sonography and be complimented, as required, with completion angiography. This is the only way to establish the different materials and surgeons on an even keel.

4. The ultimate test for comparative function of materials is in the crural position. No such studies have been performed in a multihospital, randomized prospective manner and with more than one alternative material to the saphenous vein. The Advisory Council for Vascular Surgery to the American College of Surgeons has recently authorized the formulation of such a protocol. Its execution will depend on availability of funding from agencies, foundations, and industry. Hopefully, this will occur and provide some needed guidance in a field now clouded by personal bias and the industrial complex.

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REFERENCES


Reply

We welcome comments from the vascular community about our recently published article on the comparative performance of saphenous vein, PTFE, and HUV bypasses that were implanted between 1983 and 1988 and followed until October 1991. Dr Dardik is correct that the HUV bypasses were provided by Meadox and not by BioVascular. We apologize for the incorrect citation of his 1988 article (wrong year but correct volume of Journal of Vascular Surgery).

We concur with Dr Mill’s and Dr Dardik’s comments that the Burger report has inadequate “power” and inappropriately suggests a similar vein and PTFE bypass performance (P = .065) at 104 weeks’ follow-up (81% primary patency for vein as compared with 67% for PTFE). Note that in our report, the 2-year assisted primary patency was 80.7% in the vein group as compared with 69.4% in the PTFE group, results that were very similar to those of Burger but with more patients and longer follow up were significantly different (P = .03).

The major question raised by Dr Dardik’s letter is whether a new but similar randomized study needs to be performed in the 21st century with special postoperative duplex surveillance for patency and aneurysmal formation. I certainly endorse such an