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SHORT REPORT

Unreliability of Depopulated Bovine Ureteric Xenograft for Infra Inguinal Bypass Surgery: Mid-term Results from Two Vascular Centres

V. Tolva,[1] G.B. Bertoni,[1*] S. Trimarchi,[1] V. Grassi,[1] M. Fusari[2] and V. Rampoldi[1]

[1]*II Division of Vascular Surgery, Policlinico San Donato, University of Milan, Italy, and*
[2]*II Division of Vascular Surgery, Policlinico di Monza, Monza, Italy*

Introduction. *We report a two centre experience with a depopulated ureteric xenograft (SGVG 100®, CryoLife Inc., GA, USA) for femoropopliteal revascularization in 12 patients with chronic critical limb ischemia.*
Report. *Between 7 days and 18 months after implantation, 10 of 12 patients (1 lost to follow-up) had the graft explanted due to aneurysmal enlargement. At 5 years, only one graft was still patent and showed moderate signs of enlargement.*
Conclusion. *The SGVG 100® is not a safe conduit for femoropopliteal bypass surgery.*

Keywords: Critical limb ischemia; Bypass surgery; Graft; Xenograft; Infection.

Introduction

Chronic critical limb ischemia is a condition characterized by chronic ischemic pain at-rest, ulcers, or gangrene in one or both legs attributable to peripheral arterial occlusive disease (PAOD).

Limb preservation by means of revascularization is cost-effective, leads to a better quality of life for most patients and is associated with lower peri-operative morbidity and mortality than amputation. We report the experience of two referral centres in Northern Italy with the prosthetic graft SGVG-100® (CryoLife Inc., GA, USA).

Report

Between February and December 2001, twelve patients with advanced PAOD, category 3–6 as defined by Rutherford *et al*.,[1] were scheduled to receive either an above knee or a below knee femoropopliteal bypass graft with SGVG-100®. All patients presented with chronic critical limb ischemia (rest pain or ulceration) and absent or unsuitable saphenous vein.

Pre-operative angiography was routinely performed on all patients. Any stenosis that would limit the inflow was corrected either at the time of the diagnostic angiography or during the surgical procedure. In 3 cases, an on-table angioplasty of one of the calf vessels was necessary to increase the run-off. All anastomoses were routinely carried out using 6/0 polypropylene suture.

All patients were followed up at 3-monthly intervals, with Echo-color Doppler examination to check both the patency and size of the conduit.

Results

There were no surgical deaths. Satisfactory haemostasis of the anastomoses was achieved easily, also in part due to the distinctive texture of the conduit. All operations were straightforward.

One graft occluded a few days after implantation and the patient had to be brought back to theatre twice within the following 3 days. On all occasions, an on-table angiogram failed to reveal any technical

*Corresponding author. G.B. Bertoni, MD, II Division of Vascular Surgery, University of Milan, Policlinico San Donato, Via Morandi 30, San Donato Milanese, 20097 Milano, Italy.
E-mail address: gabriele_bertoni@yahoo.it

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problem at the anastomotic sites and the run off appeared to be normal. After the third thrombectomy, the patient was started on long-term anticoagulation. The graft was still patent 6 months later, but subsequently the patient was lost to follow-up.

Two patients required emergency surgery for severe haemorrhage due to graft disruption within 2 weeks after the initial operation. The first patient suffered from aneurysmal enlargement of the whole length of the xenograft and underwent a second procedure 15 days after implantation (Figs. 1 and 2). The second patient presented with massive haemorrhage for ruptured mid-graft aneurysm 7 days post operatively. On both occasions, the xenograft was explanted and replaced with an 8 mm PTFE conduit. We stopped using the xenograft after this second event occurred. All patients were contacted for tighter follow-up. Within 18 months, all grafts had significantly enlarged from baseline, and 10 out of 12 patients had the conduit explanted due to progressive enlargement (maximum diameter 51 mm).

The pathologist's report from the explanted xenograft showed extensive areas of granulation tissue around the rupture site, rich in lymphocytes and eosinophils. About half the circumference of the graft was involved in inflammatory response. The section with most disruption had a thicker wall with the opposite side being much thinner. All staining for bacteria and fungi in these sections were negative.

Discussion

The ideal bypass conduit is the greater saphenous vein, but other conduits include the lesser saphenous veins, the arm veins or a prosthetic conduit. Despite many efforts from industry, the reported primary and secondary patency rate for autologus saphenous vein grafts are significantly better than for synthetic grafts at 4 years.[2] Campbell and Field first used a bovine ureter with good long-term patency and low rates of infection and aneurysmal evolution.[3] The SGVG-100® is a user-friendly, non-glutaraldehyde fixed, acellular collagen and elastin matrix conduit capable of autologous cell repopulation by the recipient. Although it has proven to be resistant to infection, we do not believe that it represents a safe choice for extensive distal bypass.

In our view, one hypothesis that could explain the acute graft enlargement is a hyper-acute immunologic response. A chronic inflammatory process could justify the aneuriysmal evolution in all other cases, as recently proposed by Sharp and colleagues.[4] Another hypothesis to explain the chronic enlargement could focus on the factory process to remove cells. This may have disrupted the connective and elastic fibres, leading to a progressive enlargement due to a reduced compliance of the conduit wall to the arterial pressure. This hypothesis also is supported by the good results for the SGVG-100® when is used in different vascular beds with particular haemodynamic characteristics.[5] Although the SGVG-100® might be useful for short reconstructions, we do not advise its use for above knee or a below knee femoropopliteal bypass.

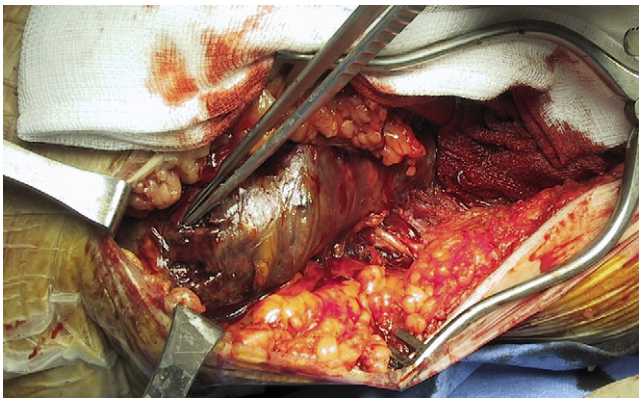

Fig. 1. Surgical demonstration of the site of rupture.

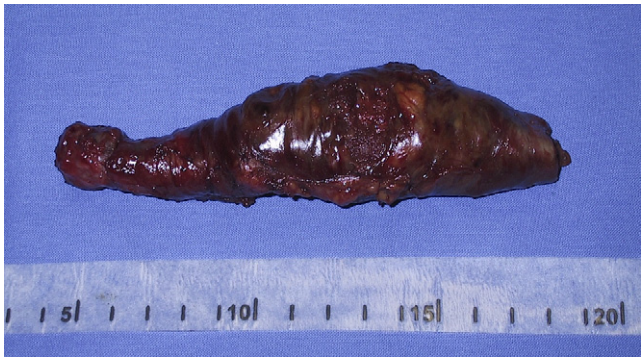

Fig. 2. Macroscopic appearance of the explanted xenograft.

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