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Preservation for Future use of the Autologous Saphenous Vein during femoro-popliteal Bypass Surgery is Inexpedient

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Abstract *Purpose:* To investigate the usefulness of greater saphenous vein preservation for future vascular reconstructions during femoro-popliteal bypass surgery.
Design: Post-hoc analysis of data acquired in a randomized multi-centre clinical trial comparing two different vascular prostheses (*ClinicalTrials.gov ID: NCT 00523263*).
Patients and methods: The true frequency of ipsilateral saphenous vein use in subsequent femoro-popliteal and coronary bypass surgery was investigated through case-record analysis with a median follow-up of 60 months in 100 consecutive patients, that received a prosthetic femoro-popliteal bypass between 1996 and 2001.
Results: An ipsilateral secondary femoro-popliteal bypass was performed in 11 patients (11%) at a mean interval of 34 months (range 1–96). The ipsilateral saphenous vein was applied for these procedures in 8 cases (8%). The cumulative probability of receiving a subsequent bypass was 8% at 3 years and 10% at 5 years follow-up respectively. One patient (1%) underwent CABG at 8 years follow-up with the use of ipsilateral lower leg saphenous vein segments only.
Conclusion: Preservation of the greater saphenous vein in supragenicular femoro-popliteal bypass surgery is not a valid argument for application of prosthetic material.

Introduction

The greater saphenous vein (SV) is considered the gold standard in graft material for femoro-popliteal bypass surgery with the distal anastomosis above and below the knee.[1] The genuine endothelial lining and autologous nature of the graft reduce thrombogenicity and postoperative morbidity, such as graft occlusion and infection.[2] The superiority of the SV for bypass surgery below the knee has not been subject of controversy. Prosthetic grafts such as polytetrafluoroethylene, knitted polyester (Dacron) and human umbilical vein are mainly recommended for bypasses with the distal anastomosis above the knee.[3] Generally, synthetic material is applied only when the SV is

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inadequate, absent or meant to be preserved for future coronary or more distal reconstructive arterial surgery and when alternative endovascular options or procedures such as endarterectomy of the superficial femoral artery are not feasible.[4–7]

The SV is easily harvested and a common autogenous source for coronary artery bypass grafting (CABG) and patch closure following carotid endarterectomy.[8–10] Also, the vein is often addressed for a secondary femoropopliteal bypass when a prosthetic graft fails.[6] This may constitute a reason to preserve the SV during femoro-popliteal bypass surgery for future use. However, no explicit evidence supports the appropriateness of this regimen.

The aim of the present study was to investigate the extent of future ipsilateral SV use in patients with a prosthetic femoro-popliteal bypass.

Patients and Methods

The study population consisted of the first 100 consecutive patients with a completed follow-up, who received a femoro-popliteal bypass for chronic lower extremity ischaemia in a prospective randomized controlled clinical trial (ClinicalTrials.gov ID: NCT00523263) comparing two different vascular graft prosthetic materials between 1996 and 2001.[11] A case-record analysis was carried out to determine the true frequency of ipsilateral SV use for subsequent femoro-popliteal or coronary bypass surgery.

Femoro-popliteal bypass was defined as the insertion of a bypass graft with the proximal anastomosis above the adductor canal to the common-, profunda- or superficial femoral artery and distal to the popliteal artery above or below the knee. All patients received a prosthetic bypass irrespective of SV presence or adequacy with either human umbilical vein (Dardik, Biograft, Bio-Vascular, Inc., Saint-Paul, MN) ($n = 53$) or heparin-bonded collagen coated polyester (Dacron, Intergard, Intervascular, Inc., La Ciotat, France) ($n = 47$).

Inclusion criteria for male and female patients were: age 31–89, chronic lower extremity ischaemia and an ankle-brachial index below 0.8 at rest. Exclusion criteria were: non-elective surgery, life expectancy below 2 years and contra-indicatios for anticoagulant therapy. The standards for reporting lower extremity ischemia were implemented in this study.[12] Critical limb ischemia was defined as ischemic rest pain and/or tissue loss combined with an ankle pressure <60 mm Hg with flat or barely palpable pulsations at the ankle or metatarsals. Preoperatively, we scrutinized patient history and cardiovascular risk factors. Patient co-morbidity is listed in Table 1.

Physical examinations, standard treadmill walking tests and calibrated angiography of the affected extremity were performed. Pre-operative duplex mapping of the ipsi- and contralatral SV was not carried out routinely. The patient population had a median age of 67 years (range 42–88) at the time of the initial bypass operation and 69 patients (69%) were of male gender. The median preoperative ipsilateral ankle-brachial index was 0.56 (range 0.16–0.80). Pre-operative median Rutherford classification was 4 (range 1–6). Critical limb ischemia was recorded in 40 patients (40%), including 19 patients (19%) who suffered minor tissue loss and 1 patient (1%) who suffered major tissue loss. The mean number of patent crural arteries was 2. A supragenicular bypass was performed in 94 patients (94%). Postoperatively, patients were randomized to receive life-long treatment by either acetylsalysilic acid (Aspirin) 80 mg daily or coumarin derivates (Sintrom) [target INR ratio 3.0–4.5], in accordance to local treatment protocols. Patient follow-up visits were at 3 monthly intervals during the first postoperative year and yearly thereafter. The study was approved by the local Institutional Review Board and fully informed consent, given in writing, was obtained from all patients.

Table 1 Co-morbidity in 100 patients receiving a femoro-popliteal bypass

Co-morbidity	
Patients (n)	100
- DM	34%
- Smoking	45%
- Hyperlipidemia	36%
- Angina/MI	28%
- Stroke	14%
- Hypertension	55%
- Hyperhomocysteinemia	3%

DM: Diabetes Mellitus, MI: Myocardial Infarction.

Statistical analysis

Yearly cumulative probability of receiving a subsequent femoro-popliteal bypass or CABG was calculated by life table analysis. Freedom of subsequent ipsilateral SV use, graft patency and limb salvage rates were assessed by the Kaplan-Meier method.

Results

Overall primary and secondary prosthetic femoro-popliteal bypass patency rates were 79%, 66%, 58% and 82%, 72%, 61% respectively at 1, 3 and 5 years follow-up. The cumulative limb salvage rate 5 years postoperatively was 89%. The cumulative mortality rate was 13% at 5 years.[12]

Previous SV use

The ipsilateral SV had been removed for vascular reconstructive purposes in 7 cases (7%) prior to the initial femoro-popliteal bypass operation. These cases involved CABG procedures. No SV were used for previous femoro-popliteal bypass surgery and none were removed in the treatment of varicosis.

Secondary femoro-popliteal bypass

An ipsilateral secondary femoro-popliteal bypass was performed in 11 patients (11%) at a mean interval of 34 months (range 1–96). The cumulative probability of receiving a subsequent bypass after initial femoro-popliteal reconstruction was 8% at 3 years and 10% at 5 and 8 years follow-up respectively. The SV was considered unfit for the

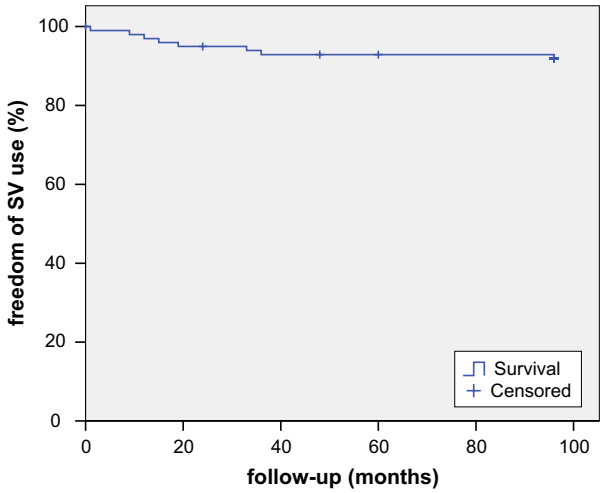
procedure in one case (1%), necessitating implantation of a prosthetic bypass. The contralateral SV was applied for femoro-popliteal bypass in one patient and a combined Dacron-venous bypass was inserted using the contralateral SV in another. The ipsilateral SV was actually used for a secondary femoro-popliteal bypass in the remaining 8 cases (8%) (Fig. 1).

CABG

One patient (1%) underwent CABG at 8 years follow-up. Only ipsilateral lower leg SV segments were addressed for this procedure. Cumulative probability of CABG performance after a femoro-popliteal bypass was 0% at 3 and 5 years follow-up and 1% at 8 years follow-up.

Discussion

Vascular surgeons prefer the SV as a conduit for femoro-popliteal bypass surgery. The vein provides superior long-term patency and limb salvage rates. SV primary patency rates vary from 59% to 77% at five years follow-up.[4] Johnson and co-workers described patency rates of 73%, 53% and 39% for SV, human umbilical vein and polytetrafluoroethylene at 5 years follow-up in a large prospective trial.[13] Compared to prosthetic graft implantation, fewer re-operations are required.[14,15] Graft infections are rare in SV bypasses and less wound morbidity is noted.[2,16] A minor disadvantage of SV use is a significantly longer operating time compared to the application of prosthetic grafts.[4] Furthermore, harvesting the SV implies more extensive surgical dissection and sacrifice of the largest superficial venous conduit. Fortunately, the vein accounts for only 5—10% of the total venous reflow, therefore excision seldom causes difficulty and subsequent reconstructive surgery is rarely required.[5]



Time (months)	Number at risk (n)
36	94
60	91
96	89

Figure 1 Freedom of ipsilateral SV use after prosthetic femoro-popliteal bypass (Kaplan-Meier analysis).

A prosthetic graft is implanted to bypass the femoro-popliteal trajectory when the SV is inadequate, absent or meant to be preserved. Currently polytetrafluoroethylene predominates, presumably because the material is easily implanted and is associated with relatively low rates of postoperative failure and wound complications.[16] Experience with grafts with heparin-bonded technology is also accumulating.[11,17]

The rationale behind SV preservation is a general concern that patients who require a femoro-popliteal bypass suffer concurrent coronary and carotid arterial disease.[13] The SV is considered conduit source of autogenous material for CABG and patch closure following carotid endarterectomy. However, feasible alternatives are available for these procedures. The left internal thoracic artery and mammary artery are widely applied for CABG, as well as the radial and gastroepiploic arteries. Additionally, advanced percutaneous revascularization techniques are rapidly developing.[8] Goldman and co-workers specified no difference in perioperative mortality, morbidity and recurrent stenosis rates between the SV, internal jugular vein and knitted Dacron as patch materials for carotid endarterectomy.[9] Furthermore, patch closure requires only a small SV segment. Such a segment can frequently be obtained from SV sites other than the proximal part.

The profound grades of lower extremity ischemia and the co-morbidity in femoro-popliteal bypass patients are most likely associated with a higher incidence of graft failure.[5] Ischemic symptoms such as claudication or tissue loss may rapidly reoccur after graft occlusion.[18] Consequently, secondary femoro-popliteal reconstruction might be needed for limb salvage. An increasing number of patients require such a redo-operation. The SV is the most suitable graft for this type of surgery due to its length and diameter compatibility with the tibial arteries, especially when used in an in-situ fashion.[14] One might argue that in absence or inadequacy of the ipsilateral SV, the contralateral vein is available in many patients and may serve equal purposes in femoro-popliteal bypass surgery. Some even suggest the contralateral vein as the conduit of first choice in such situations.[19] An additional groin wound and prolonged operation time are thereby unavoidable.[4]

An appropriate assessment of subsequent vascular reconstructions is essential if one is to determine whether SV preservation is warranted in femoro-popliteal bypass surgery. The present study analyzed patients who received a prosthetic bypass mostly with the distal anastomosis above the knee (94%). The ipsilateral SV was therefore present in the majority of patients (93%) and available for additional proximal or distal vascular reconstructions. CABG was performed prior to the initial femoro-popliteal bypass surgery in 7% of our patients. The ipsilateral SV was harvested for these procedures. Chew and co-workers determined that 46% of their patients had received CABG prior to femoro-popliteal bypass surgery.[20] Biancari and co-workers observed a 8.5% rate of vascular procedures for lower limb ischemia during a follow-up of 7 years of 1300 patients after CABG.[21]These observations may indicate that coronary arterial disease requires earlier intervention than arteriosclerotic lesions in the lower extremities.

Few trials have investigated the need for vascular reconstructions after femoro-popliteal bypass surgery in

the past. In 1984 Houser and co-workers addressed the occurrence of CABG and found that 5.4% of 74 patients required additional coronary reconstruction.[22] Poletti and co-workers analyzed a series of 440 infrainguinal bypass patients in 1998. The probability of receiving subsequent femoro-popliteal bypass or CABG was 27% and 2% respectively at 5 years follow-up.[23] The investigators did not distinguish between SV and alternative vein sites for secondary femoro-popliteal reconstruction. Both studies are retrospective evaluations of data acquired more than 10 years ago. Our results suggest a 10% cumulative probability of receiving a secondary femoro-popliteal bypass 5 years postoperatively. Burger and co-workers prospectively compared reversed SV to polytetrafluoroethylene for femoro-popliteal bypass surgery in 136 cases. The preserved veins were used for secondary femoro-popliteal reconstruction in 2% of the cases. No patients required the SV for CABG in the 2 year follow-up period.[4] In the present study, the ipsilateral SV was addressed for secondary femoro-popliteal bypass surgery in 8% of the patients. Only one patient underwent CABG at 8 years follow-up. Although adequate, the ipsilateral SV was not addressed for this procedure.

Herewith the prevalence of secondary femoro-popliteal bypass surgery and CABG proved to be quite low in our population. Most secondary femoro-popliteal bypasses were performed within 3 years postoperatively. Thus, it appears that few patients would benefit from SV preservation. Therefore, at present, we do not consider SV preservation a valid argument for application of prosthetic material in femoro-popliteal bypass surgery.

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