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Preoperative Duplex Vein Mapping (DVM) Reduces Costs in Patients Undergoing Infrainguinal Bypass Surgery: Results of a Prospective Randomised Study[☆,☆☆]

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ABSTRACT

Objectives: Surgical site infections (SSIs) after bypass procedures provoke major costs. The aim of this prospective randomised trial was to assess if preoperative duplex vein mapping (DVM) reduces costs generated by SSI.

Materials/methods: Patients undergoing primary infrainguinal bypass were randomised to DVM of the ipsilateral greater saphenous vein (group A) or none (group B). Costs were calculated by the hospital's accounting department.

Results: From December 2009 to April 2011, 130 patients (65 each group) were enrolled. Both cohorts were equal regarding demographics, risk factors and costs for primary bypass surgery, respectively. SSIs were classified minor (A: $n = 13$ vs. B: $n = 13$, $P =$ n.s.) and major (A: $n = 1$ vs. B: $n = 12$, $P = .0154$). Preoperative DVM was the only significant factor to prevent major SSI ($P = .011$). Theatre costs for SSI: A: 537 € versus B 6553 € ($P = .16$). Recovery room/intensive care unit (ICU) costs for SSI: A: 0 € versus B: 8016 € ($P = .22$). Surgical ward costs for SSI: A: 2823 € versus B: 22 386 € ($P = .011$). Costs for outpatient visits due to SSI: A: 6265 € versus B: 12 831 € ($P = .67$). Total costs of patients without SSI: 8177 € versus major SSI: 10 963 € ($P < .001$).

Conclusion: DVM significantly reduces costs generated by re-admission in patients suffering from major SSI.

The main cause for increased costs in vascular surgery are surgical site infections (SSIs), which may lead to extended hospital stay, revision surgery, prolonged antibiotic treatment and increased frequency of outpatient visits, respectively.[1,2] SSIs are reported in up to 43% after arterial reconstructions.[3] In the 1980s, duplex vein mapping (DVM) of the greater saphenous vein (GSV) was described as a preoperative diagnostic adjunct to gain information about anatomy and graft suitability in patients undergoing infrainguinal bypass surgery.[4,5] Further studies, all of which failed level-1 evidence, revealed that preoperative DVM of the ipsilateral GSV alleviates vein harvest and may reduce SSI after bypass procedures of the lower extremity.[6–9] The aim of this prospective randomised study was to evaluate if preoperative DVM is able to lower costs significantly by decreasing postoperative SSI.

Materials and Methods

Patients

From December 2009 until April 2011, all patients who were planned for primary infrainguinal bypass surgery underwent evaluation for inclusion into this study. Patient data were registered prospectively in a designated vascular database at a university-based tertiary care centre. Inclusion criteria were severe claudication and critical leg ischaemia[10] as well as patients with popliteal aneurysms. After written informed consent was provided, patients were randomly allocated to two groups: group A patients underwent preoperative DVM of the ipsilateral GSV and group B did not. SSIs were classified according to the American College of Surgeon's National Surgical Quality Improvement Program (ACS-NSQIP) as superficial or deep.[11] If oral antibiotics and topical treatment were sufficient, SSIs were regarded as minor. If intravenous antibiotic therapy and/or redo surgery (debridement, etc.) were necessary, SSIs were considered as major. In cases of primary ischaemic/gangrenous lesions of the leg and/or postoperative SSI, samples for bacterial culture were taken from the affected site. Primary study

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'end' points were: length of hospital stay (LOS), duration of operative procedure, development of postoperative SSI, costs due to re-admissions for SSI and costs due to outpatient visits for SSI, respectively. Secondary 'end' points were bypass patency, limb salvage and patient survival. Standard reporting guidelines were applied.[12] The study was approved by the Local Ethics Research Committee. Preliminary data regarding clinical outcome in smaller patient cohort were presented at the SVS in Chicago 2011.

Preoperative work-up, DVM and angiography

General work-up was identical for all patients and included physical examination, cardiac testing, carotid duplex, pulmonary evaluation upon the discretion of the attending cardiologist and laboratory testing including screening for hepatitis and human immunodeficiency virus (HIV).

Preoperative colour-flow duplex scanning (DS) of the ipsilateral GSV was performed in the vascular laboratory by three senior surgeons (KL, EB and AU) using a 13-MHz probe (GE Healthcare LOGIQ 7, Milwaukee, WI, USA) with the patient in supine position. After measuring venous diameter at four different levels (proximal and distal thigh, proximal and distal calf), using a high-thigh tourniquet,[13] the course of the GSV from ankle to groin and major side branches were marked with indelible dye, which was not antibacterial (e.g., gentian violet).

A vein >2.5 mm in diameter was considered as an adequate conduit in duplex mapping. This corresponded to a 3-mm distended vein bypass graft.

In all patients, assessment of distal run-off vessels was performed preoperatively.[14] The procedure was planned according to preoperative angiography.

Perioperative antibiotic regimen

Patients suffering from ischaemic ulceration or gangrene received continuous antibiotic therapy adapted to antibiogram from the day of admission. All other patients receive antibiotic prophylaxis with cefazoline 2 g intravenously at the time of induction and at 8 and 16 h postoperatively.

Bypass procedures (non-reversed, reversed, or in situ)

All patients underwent antiseptic prepping with coloured Dodesept®. After dissection of in- and outflow arteries, the ipsilateral GSV was harvested via multiple vertical skin incisions with intervening cutaneous bridges. Skin incisions were made with the knife, dissection of deeper layers with a cautery. In the case of non-reversed bypass, proximal valves were excised under direct vision, remaining valves lysed by valvulotome (Mill's type) introduced via the distal end of the vein. In cases of *in situ* bypasses, valvulotomy was performed with a flexible valvulotome (UreSil Tru-Incise, USA). In all types of bypasses, a calliper was used for intra-operative measurement of graft diameter and a ruler to measure graft length. Wound closure was performed with running single layer subcuticular sutures (Vicryl 3.0) and stainless skin staples.

The technique used for bypass surgery was at the discretion of the surgeon. Technical details have been reported previously.[15–17]

Postoperative follow-up

Assessors (vascular surgeons) in the ward were not blinded to the allocated treatment. After discharge clinical examination of the study patients with measurement of ankle-brachial pressure index (ABPI) and DS of the bypass were routinely carried out at 1, 3, 6 and 12 months postoperatively. In cases of SSI, patients were seen more frequently in the outpatient department. The personnel in the outpatient department (nursing staff and physician) had no access to randomisation data and were therefore blinded to the allocated treatment.

Cost calculation

Costs were calculated by our hospital's accounting department as follows: costs for hospitalisation on the surgical ward (201.68 €/day, costs for DS included), recovery room (922.32 €/day), intensive care unit (ICU) (1702.36 €/day), usage of operating room (OR) (16.26 €/min) and outpatient visit (60.24 €/visit). Medication during hospital stay was included into cost calculation. After discharge, antibiotic treatment was excluded from cost calculation. We distinguished four different types of costs: primary costs for admission due to primary infrainguinal bypass procedure (surgical ward, OR for primary bypass procedure, recovery room, ICU and overall), secondary costs for re-admission due to SSI (surgical ward, OR for revision surgery, recovery room, ICU and overall), costs for outpatient visits and total costs (primary, secondary and outpatient visits), respectively.

Randomisation

Randomisation was carried out using sealed envelopes with the allocation to DVM (group A) or not (group B).

Statistical methods

No power analysis was done. Data were presented as means ± standard deviation (SD) and percentages. Fisher's exact and Pearson's chi-square test were used for discrete variables, and two-sided, unpaired Student's *t*-test for continuously distributed data. Kaplan–Meier curves with 95% confidence intervals (CIs) were computed and compared using the log-rank test and Cox-F test. Relative risks and 95% CIs were computed for selected cross-tabulation tables. Computations for testing and estimation of relative risks were done with MATHEMATICA 7.0. To detect independent predictors of SSIs, in a first step binary univariate logistic regression analyses were done. Those variables in the model with a *P* value less than 0.1 were included to build a multivariate model. Odds ratios with 95% confidence intervals are given in the multivariate model to get an impression of the magnitude of the effect. All analyses were done by using Statistica 6.1 (StatSoft, Inc. 2004. Statistica data analysis software system version 6.1), Statistical Package for Social Sciences (SPSS) 10 (SPSS, Inc., 1999, Chicago, IL, USA), and MATHEMATICA 7.1 (Wolfram Research, Inc., Mathematica, Version 7.0, Champaign, IL 2008, USA). A *P* value less than 5% was considered statistically significant.

Results

Patients

From December 2009 until April 2011, in 199 patients primary infrainguinal bypass surgery was planned. As many as 135 of 199 (68%) patients met inclusion criteria (Table 1); 64/199 (32%) patients were excluded for different reasons (Fig. 1). Five of 135 (4%) eligible patients refused randomisation; 130/199 (65%) patients were randomly assigned to group A (with DVM, $n = 65$) or B (without DVM, $n = 65$) (Fig. 1). Both groups were equal regarding demographics, risk factors, surgical indication, preoperative ABPI and distal run-off, respectively (Table 1).