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In situ Reconstruction of Infected Groin Pseudoaneurysms in Drug Abusers With Biological Grafts

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WHAT THIS PAPER ADDS

Management of infected groin pseudoaneurysms in drug abusers is controversial, especially the reconstruction technique and the type of graft material to be used. This study shows that *in situ* reconstruction with biological material is a viable option with low early graft related morbidity. However, in the longer term, a significant number of patients develop re-infection, graft occlusion, or stenosis.

Objectives: The aim of this study was to evaluate outcomes after *in situ* reconstruction using biological grafts in infected groin pseudoaneurysms in drug abusers.

Methods: This was a single centre retrospective analysis of all patients undergoing *in situ* reconstruction with biological vascular grafts for infected groin pseudoaneurysms in drug abusers from 2000 to 2017. Outcome measures included wound healing problems, re-infection, graft patency, lower limb amputation, and mortality.

Results: Twenty-two patients (14 male) with a median age of 39 years (range 27—49) were identified. Fifteen patients (68%) underwent urgent *in situ* reconstruction with a xenograft, five patients (23%) with a homograft, and two patients (9%) with an autologous vein. There were no in hospital deaths, in hospital re-infections, or early major limb amputations. Four (18%) patients developed wound healing complications requiring re-operation. During a median follow up of 56 months (range 13—180 months), six patients (27%) developed re-infection requiring complete graft replacement with a new biological graft. Thereafter, three (14%) had re-re-infection. Seven patients (32%) had graft occlusions: two were treated endovascularly, two underwent re-operation, and three were treated conservatively. Two patients (9%) had patent grafts but significant stenosis: one had successful angioplasty and another one was left untreated. One patient required above knee amputation, resulting in an overall major amputation rate of 4%. Estimated primary patency was 87% after one year and 40% after five years. Six patients (27%) died during follow up from non-vascular causes.

Conclusions: *In situ* reconstruction using biological grafts of infected groin pseudoaneurysms in drug abusers can be achieved with no peri-operative graft related complications, although rates of wound complications may be high. In the longer term, a significant number of patients develop re-infection, graft occlusion, or stenosis, although the amputation rate remains low. The management of this demanding group of patients remains a major challenge.

Keywords: Biological grafts, Drug abusers, *In situ* revascularisation, Mycotic pseudo-aneurysm

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INTRODUCTION

The common femoral artery (CFA) is often used as an alternative to veins for drug injection by drug abusers. Repeated injection can result in an infected pseudoaneurysm associated with severe complications including haemorrhage, lower limb ischaemia from distal embolisation, amputation, sepsis, and death.[1] Management of these patients is challenging. Most surgeons agree on the necessity for excision and debridement of the infected vessel and surrounding tissue.[1—3] However, the need for reconstruction and the graft material to be used remain controversial.[4,5] Ligation of the involved vessels without arterial reconstruction has been reported to be an option, but critical limb ischaemia and high claudication rates are the main concern with this strategy.[2,4,6] Although limb salvage rates of 83—100% have been reported,[6—8] rates of critical limb ischaemia and claudication are significantly lower in patients undergoing *ex situ* or *in situ* arterial revascularisation.[3,9] However, some of these patients develop graft infection, rupture of the anastomosis with

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haemorrhage, or graft occlusion during the early and late post-operative periods.[2,3,9]

Prosthetic grafts used for arterial reconstruction in an infected field have shown high rates of graft infection.[8] Autologous veins, however, have shown favourable results for vascular reconstruction in contaminated operating fields,[10] but patent superficial or deep veins are often absent in drug abusers. This lack of autologous veins and the urgency of treatment in these patients call for alternative biological grafts. Cryopreserved arterial homografts, bovine artery, or vein grafts as well as Omniflow grafts (LeMaitre Vascular, Inc., Burlington, MA, USA) have been proposed.[1]

The aim of this study was to evaluate early and late outcomes of *in situ* vascular reconstruction using biological grafts used to repair infected groin pseudoaneurysms in drug abusers.

METHODS

All patients undergoing *in situ* revascularisation with biological vascular grafts for infected groin pseudoaneurysms in drug abusers between January 2000 and December 2017 were included in the study. Patients undergoing primary ligation of the involved vessel or extra-anatomic revascularisation were excluded from the analysis. Demographics, pre-operative and post-operative data were abstracted from a prospectively maintained database and analysed retrospectively. Outcomes were wound healing problems, re-infection, graft patency, lower limb amputation, and mortality. The study was performed according to the requirements of the local ethics committee (2018-01687).

Diagnostic assessment was made by clinical examination followed by a duplex ultrasound of the groin, or computed tomography (CT) angiography in cases with severe pain or more extensive clinical findings. Duplex ultrasound of superficial and deep veins of the upper and lower extremities was performed to detect any usable autologous graft material for vascular reconstruction. Urgent surgery (within 24 hours) was performed in all patients to avoid complications (e.g. sepsis, rupture, etc). In case of active bleeding, immediate surgery without further diagnostics was performed. Intra-operative samples of pus and tissue (including vessel wall) were collected for microbiological and histopathological analyses. Blood cultures were routinely obtained only in patients presenting with sepsis on admission or having fever $>$ 38 °C during their hospital stay.

Access to the femoral vessels was achieved via a longitudinal inguinal incision. In case of anticipated insufficient proximal vessel control, additional supra-inguinal access to the external iliac artery was performed. The infected vessel and surrounding tissue were removed completely, followed by *in situ* vascular reconstruction with different biological grafts: autologous vein graft, cryopreserved arterial homograft, bovine vein (ProCol Vascular bioprosthesis, LeMaitre Vascular, Burlington, MA, USA), bovine artery (Shelhigh Inc., Union, NJ, USA), or Omniflow (LeMaitre Vascular, Burlington, MA, USA).

Considering the extent of vessel wall destruction and whether the deep femoral artery (DFA) needed to be revascularised, three types of vessel reconstruction were used: (i) isolated defects of the anterior vessel wall were repaired with a xeno-pericardial patch plasty; (ii) in case of complete vessel destruction, an interposition graft between the CFA and the superficial femoral artery (SFA) was performed and the DFA was ligated. This reconstruction was defined as simple interposition; and (iii) re-implantation of the DFA, either directly or with an additional interposition graft, was defined as complete reconstruction of the femoral bifurcation.

When available, autologous vein grafts were the first choice for revascularisation. If no suitable vein material was available, the decision to use another biological graft was left at the discretion of the treating surgeon, depending on graft availability and intra-operative findings. Considering the degree of infection and the extent of soft tissue excision, primary or secondary wound closure was performed. Secondary wound closure followed repeated debridement, negative wound cultures, and negative pressure wound therapy. Reconstructive surgery with muscle and/or sub-/cutaneous flaps was necessary in case of large defects.

After obtaining intra-operative tissue samples, empiric broad spectrum intravenous antibiotic therapy was given. Definitive antibiotic therapy was based on the microbiology results and after consultation with an infectious disease specialist. The recommended duration of the antibiotic therapy depended on the identified pathogen, intra-operative extent and severity of the infection, and clinical evolution (including laboratory infection parameters) lasting between six weeks and three months.

Follow up

All patients were assessed by a multidisciplinary team (vascular surgeon, infectious disease specialist, and angiologist) six weeks, three months, and one year after surgery, including clinical examination, duplex ultrasound and/or CT angiography, and blood culture results. Antiplatelet therapy with acetylsalicylic acid was used in all patients for at least three months. Indications for anticoagulation with coumarin or rivaroxaban and the duration of post-operative thrombosis prophylaxis were based on patient factors (e.g. mobility, comorbidities). Follow up information on mortality, need for re-intervention, and lower limb amputation was obtained for all patients via hospital records and through a telephone survey with patients/relatives, general practitioners, or supervised drug consumption facilities by the end of December 2018.

Statistical analysis

Data are presented as median and range for continuous variables, and absolute numbers and percentages for categorical variables. For survival, freedom from re-infection, and patency, Kaplan—Meier analyses were used. Follow up was assessed using the follow up index.[11] All statistical analyses were performed using SPSS Statistics 22.0.0.0 (IBM, Armonk NY, USA).

Table 1. Patient characteristics

	$n = 22$
Age, years, median (range)	39 (27–49)
Male, *n* (%)	14 (63%)
Clinical presentation	
Swelling/pain in the groin, *n* (%)	22 (100%)
Acute bleeding, *n* (%)	15 (68%)
Sepsis, *n* (%)	2 (9%)
Pre-operative diagnostic testing	
Duplex ultrasound, *n* (%)	13 (60%)
CT angiography, *n* (%)	7 (31%)
None, *n* (%)	2 (9%)
Number of operations per patient, median (range)	3 (1–10)
Hospital stay, median (range)	21 (2–56)
Duration of antibiotic therapy, days, median (range)	42 (10–210)
Follow up, months, median (range)	56 (13–180)

CT = computed tomography.

RESULTS

A total of 22 patients (14 males) with a median age of 39 years (range 27–49) were identified (Table 1). No patients underwent primary ligation or extra-anatomic revascularisation during the observation period. All patients presented with swelling and pain in the groin. Two patients (9%) had sepsis at presentation. Sixteen of the 22 patients (72%) had positive blood cultures with the same bacteria as verified in the intra-operative specimens of the infected pseudoaneurysm. The microbiology and histology analyses confirmed the presence of bacteria in 20 patients (Table 2). Two (9%) patients presented with active bleeding requiring immediate operation without further diagnostic testing. Duplex ultrasound confirmed the diagnosis of infected pseudoaneurysm in 13 (60%) and CT angiography in 7 (31%) patients. All patients underwent surgery within 24 hours of admission. The median operating time was 200 min (range 90–495). In addition to a longitudinal groin incision, supra-inguinal access to achieve proximal vessel control was necessary in eight patients (36%). In all patients extensive debridement and resection of infected vessels and tissue was performed. Eleven patients (50%) had complete reconstruction of the femoral bifurcation, seven (32%) had simple interposition graft, and four patients (18%) had xeno-pericardial patch plasty. The type of reconstruction and grafts used for all patients are listed in Table 2. Five patients (23%) had primary and 17 (77%) had secondary wound closure, with eight of those needing plastic reconstruction: six sartorius muscle flaps, one tensor fascia lata muscle flap, and one rectus abdominis myocutaneous flap (Fig. 1). All 17 patients with secondary wound closure had negative pressure wound therapy until specimens from the wound were negative for microorganisms.

The median duration of antibiotic therapy was 42 days (range 10–210). One patient left the hospital against medical advice after 10 days without continuing antibiotics and was re-hospitalised for superficial wound infection after one month and for graft re-infection after three years. One patient started to use his biological graft for repeated drug injection after hospital discharge and therefore, antibiotic

Table 2. Detailed information on all patients at end of follow up

	Reconstruction	Type of graft	Bacteria	Re-infection	Primary patency (months)	Survival status (length of follow up/months)
Nr. 1	Interposition	Bovine vein	SA	No	Occlusion (60)	Alive (180)
Nr. 2	Interposition	Homograft	SA	No	Patent (154)	Alive (154)
Nr. 3	Bifurcated	Bovine MA	SA	No	Stenosis (12)	Dead (127)
Nr. 4	Interposition	Bovine MA	None	Yes (SA)	Occlusion (4)	Dead (121)
Nr. 5	Interposition	Homograft	SA	No	Patent (20)	Dead (20)
Nr. 6	Bifurcated	Bovine vein	PEPST	Yes (SA)	Patent (147)	Alive (147)
Nr. 7	Bifurcated	Bovine vein	STREP	No	Occlusion (14)	Alive (140)
Nr. 8	Bifurcated	Homograft	SA	No	Occlusion (62)	Alive (127)
Nr. 9	Bifurcated	Homograft	MRSA	No	Occlusion (42)	Alive (103)
Nr. 10	Bifurcated	Homograft	SA/EC	No	Patent (97)	Alive (97)
Nr. 11	Bifurcated	Autologous vein	SA	No	Occlusion (39)	Alive (94)
Nr. 12	Patchplasty	Pericardium	None	No	Stenosis (21)	Alive (74)
Nr. 13	Interposition	Omniflow	EF	Yes (SA)	Occlusion (36)	Dead (49)
Nr. 14	Bifurcated	Omniflow	SA	No	Patent (49)	Dead (49)
Nr. 15	Bifurcated	Autologous vein	SA	No	Patent (63)	Alive (63)
Nr. 16	Bifurcated	Omniflow	SA	Yes (SA)	Patent (59)	Alive (59)
Nr. 17	Interposition	Omniflow	SA	No	Patent (21)	Alive (21)
Nr. 18	Patchplasty	Pericardium	SA	No	Patent (16)	Dead (16)
Nr. 19	Bifurcated	Omniflow	SA	Yes (SA)	Patent (16)	Alive (16)
Nr. 20	Patchplasty	Pericardium	Mixed bacteria	No	Patent (14)	Alive (14)
Nr. 21	Interposition	Omniflow	SA	Yes (PAE)	Patent (13)	Alive (13)
Nr. 22	Patchplasty	Pericardium	SA	No	Patent (16)	Alive (16)

Bovine MA = bovine mammary artery; EC = *Escherichia coli*; EF = *Enterococcus faecalis*; MRSA = methicillin resistant *Staphylococcus aureus*; PAE = *Pseudomonas aeruginosa*; PEPST = *Peptostreptococcus*; SA = *Staphylococcus aureus*; STREP = *Streptococcus*.

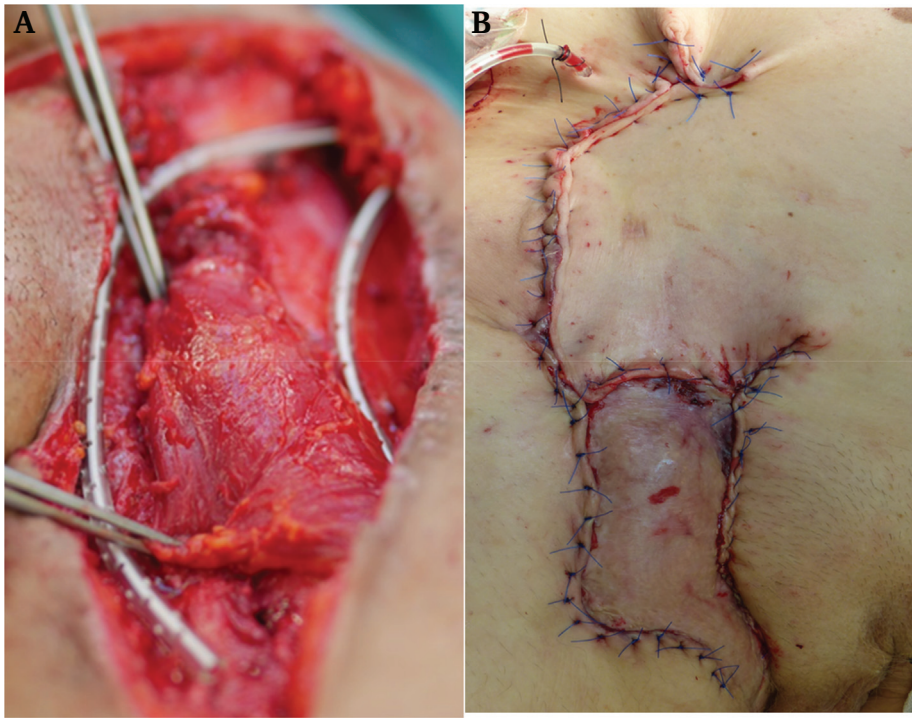

Figure 1. Coverage of the reconstructed vessel with rotated sartorius flap (A) and skin closure with rotation flap (B).

therapy was continued for 201 days. The patient ultimately suffered from re-infection in the groin and soft tissue necrosis of the foot because of repeated peripheral septic embolisation, resulting in above knee amputation. The median length of hospital stay was 21 days (range 2—56). There was no in hospital death, and no in hospital re-infection, anastomotic dehiscence, early graft occlusion, or major limb amputation occurred. Four patients (18%) required re-operation because of post-operative wound healing problems.

Median follow up was 56 months (range 13—180 months). Complete follow up information was obtained for all patients resulting in a follow up index of 1.0. Six patients (27%) suffered from graft re-infection after a median of six months (range 1—14 months). Four of those presented with sepsis combined with septic peripheral embolisation and minor soft tissue necrosis of the foot, and two presented with acute haemorrhage from a new pseudoaneurysm in the groin. All six patients had a history of ongoing intravenous drug abuse, but only the one patient who subsequently underwent above knee amputation used the biological graft in the groin for repeated drug injection. Four re-infections occurred after reconstruction with Omniflow grafts, one occurred after reconstruction with bovine vein, and one after reconstruction with bovine mammary artery. Of the six patients with re-infection, two had the same causative bacteria as during index treatment, three had different bacteria, and one patient who initially had negative tissue samples was newly diagnosed with *Staphylococcus aureus* infection. All details are listed in Table 2. Two patients with re-infection had at least six weeks of antibiotic therapy and the remaining four had a shorter duration of antibiotic therapy because of non- compliance (duration between 10 days and six weeks). All six were re-operated on with new *in situ* reconstructions: four with new Omniflow grafts, one with a homograft, and one with a self made xeno-pericardial tube graft. The latter was constructed from a xeno-pericardial patch, a technique previously described for *in situ* reconstruction in aortic infection.[12]

Re-re-infection occurred in three patients: all had received new Omniflow grafts after the first re-infection and all three had *Staphylococcus aureus* re-re-infection. One was treated with an extra-anatomic bypass using an Omniflow graft via the obturator foramen and two underwent redo *in situ* reconstruction using a short segment of patent contralateral femoral vein and a self made xeno-pericardial tube graft, respectively (Fig. 2).

Graft occlusion occurred in seven patients (32%): two bovine vein grafts, one bovine arterial graft, two cryopreserved homografts, one autologous vein graft, and one Omniflow graft after a median of 21 months (range 4—62). Two patients were re-operated on, two were managed endovascularly, and three with mild claudication were treated conservatively. Graft stenosis occurred in two patients (9%; one bovine arterial graft and one pericardial patch plasty) after a median of 15 months (range 12—19). One was managed endovascularly and the other one conservatively. Estimated primary patency was 87% at one and 40% at five years (Fig. 3). As mentioned above, one patient (4%) needed an above knee amputation because of

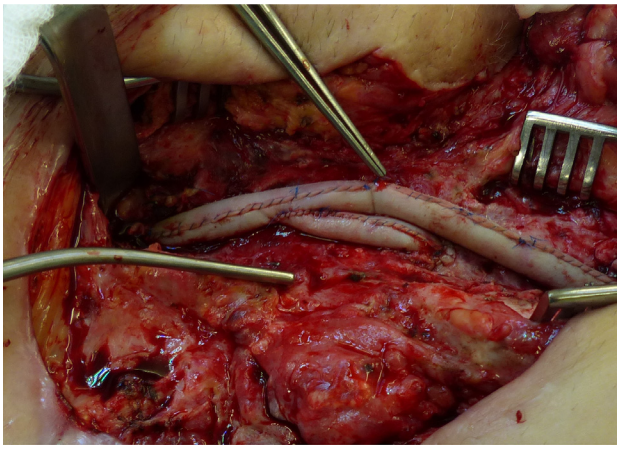

Figure 2. Complete reconstruction of the femoral bifurcation with self made xeno-pericardial tubes.

recurrent drug injection in the reconstructed groin and repeated peripheral embolism with occlusion of all crural arteries. Six patients (27%) died during follow up from non-vascular causes: two deaths due to lung disease (pneumonia) and four cardiac deaths (two arrhythmias, one endocarditis, one heart failure). Estimated survival after one, five, and 10 years was 100%, 80%, and 70%, respectively.

DISCUSSION

This retrospective study was performed to evaluate the concept of managing infected groin pseudoaneurysms in drug abusers with *in situ* reconstruction using biological grafts and to compare results with the current literature.

Revascularisation or ligation

Because of extensive vessel and soft tissue destruction, surgery is often performed in an emergency or urgent setting as a result of acute complications such as haemorrhage. Thus, simple ligation of the involved vessels without any arterial reconstruction has been proposed in this situation.[6,8] Naqi et al. presented 16 patients (median age of 34 years) treated by simple ligation of the involved artery, which led to three major amputations (19%) and severe claudication in four patients (25%).[8] Gan et al. treated 34 patients (median age of 28 years) with ligation and no major amputation was necessary, but 33 patients suffered from claudication with a median ankle brachial index of 0.61. Three patients with initial ligation developed a new false aneurysm, one requiring an above knee amputation thereafter.[6] These data underline the risk of severe claudication and potential critical limb ischaemia in these mostly young or middle aged patients with undeveloped collateral circulation.[2,5,8] With direct *in situ* revascularisation, neither critical limb ischaemia nor claudication was observed in the early post-operative course. Furthermore, to achieve the best possible limb perfusion, complete reconstruction of the femoral bifurcation was aimed for in the majority of patients. Preserving the DFA additionally allows for a variety of plastic reconstructions with different flaps. This is often necessary to cover the *in situ* vascular reconstruction with vital and well perfused tissue. In our opinion, this might prolong the index operating time but it helps to achieve healing in infected and poorly perfused scar tissue. As an alternative to *in situ* reconstruction, an extra-anatomic approach via the obturator foramen has been described.[2,3,9] This strategy has not been proven to be superior to the *in situ* approach regarding frequency of occlusions and re-infections. Additionally, extra-anatomic reconstruction may potentially traumatise surrounding structures.[3] Prosthetic grafts have been associated with a considerable risk of re-infection even with extraanatomic routing. Extra-anatomic reconstruction was used in only one case with re-re-infection.

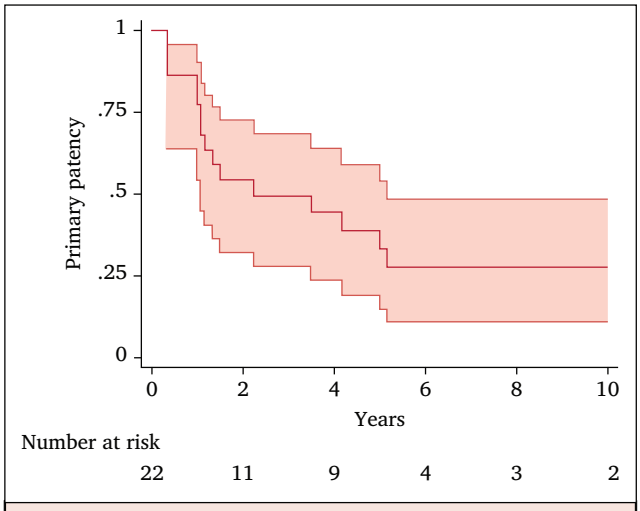

Figure 3. Kaplan–Meier curve estimating primary patency including 95% confidence interval bands.

Type of graft used and graft related complications

Because of the high risk of re-infection, the choice of graft is the main challenge. Previous studies reported very high rates of early graft related complications (anastomotic issues, occlusion, and re-infection) in up to 60%.[2,5,8] Autologous vein is generally considered the preferred conduit. Unfortunately, veins are frequently damaged in these patients from repeated injections and, therefore, are rarely an option.[10] Short segments of autologous vein were used in three patients, in two for the index operation and in one for the treatment of re-infection. No early graft related complications were observed; however, high rates of late re-infection and late graft occlusion/stenosis were recorded requiring re-intervention, although these rarely led to amputation. During the earlier years of the study period, cryopreserved homografts and bovine grafts were often used.[1] Both showed a low rate of re-infection, but several stenotic and occlusive complications during follow up. Thus, the decision was made to start using alternative grafts. Omniflow, a biosynthetic collagen graft, has shown good results in several infected

fields.[13,14] Another advantage is its off the shelf availability in different sizes. However, both Omniflow grafts and bovine vein grafts developed late re-infection, despite proper antibiotic therapy and completely healed groin wounds at discharge. Although it is difficult to draw conclusions from the small numbers in this study, it may be hypothesised that, because of its synthetic endoskeleton, Omniflow may be more susceptible to repeated bacterial exposure in the context of ongoing drug abuse. In more recent years, self made bovine pericardial tube grafts have been used for treatment of infections of the aorta, where they have proved to be a promising alternative.[12] Advantages of these self constructed pericardial grafts are the permanent availability, on table customizable size, and low cost. In this series, pericardial tube grafts were used in two patients after re-infection of their initially used biological graft. It remains the subject of further research to determine whether self made pericardial tubes represent an alternative as graft material in peripheral infections. Long term replacement of these grafts with a more durable conduit might be an option, but every redo procedure in the groin in these patients is extremely challenging, even in the hands of an experienced vascular surgeon.

Re-infection, antibiotic therapy, and wound management

Six of the present patients had re-infection (five with *Staphylococcus aureus*) and three of them had re-re-infection, again all three with *Staphylococcus aureus*. Of the six re-infections, only two had initially *Staphylococcus aureus* infection, and all were treated with adequate antibiotic therapy and discharged with completely healed wounds. The interval between index operation and re-infection varied between one and 14 months. All patients with re-infection were still drug abusers and re-infection may be attributed to the repeated transient bacteraemia occurring with continued intravenous/intra-arterial drug use.[2,9]

Regarding the duration of antibiotic therapy, the non-compliance of these patients remains an important issue. Every patient received an individual plan of antibiotic therapy for at least six weeks. However, four of the patients with re-infection stopped using antibiotics before their first follow up visit in the outpatient clinic. This inadequate duration of antibiotic therapy may have played a role, especially in those with early re-infection. However, in retrospect, no correlation was found between re-infection, type of bacteria, and duration of antibiotic therapy.

All 17 patients with secondary wound closure received negative pressure wound therapy prior to closure. The AIMS (Closed Incision Negative Pressure Therapy Reduces Surgical Site Infections in Vascular Surgery) trial recently reported a lower rate of surgical site infection in primarily closed groin wounds after use of epicutaneous negative pressure wound therapy. This approach was not used routinely in the present patient cohort, but this might help to reduce wound complications in this complex patient group in the future.[15] The rate of post-operative wound healing complications of 18% in the present series is considerable.

An endovascular approach for infected groin pseudoaneurysm has been reported.[16,17] This approach was not used in this cohort. Major drawbacks of endovascular therapy are the immediate infection of the endograft, the persistence of the infection, and the potential coverage of the DFA. However, this approach might be useful as a bridging therapy, especially in patients with active bleeding.

Limitations

This retrospective study has a small number of patients and only reports a single centre experience. The heterogeneity of grafts used for revascularisation makes any comparison and conclusions difficult. Because of non-compliance, management of these patients after discharge remains difficult and, therefore, the true duration of antibiotic therapy and appropriate wound care may differ from that recommended. Analysis of the causes of re-infection in this patient group is quite difficult. Poor patient compliance and ongoing drug abuse are most likely important factors influencing follow up. This also makes it difficult to differentiate between graft infection based on insufficient initial management, post-operative wound management, and antibiotic therapy *vs. de novo* infection resulting from ongoing drug injection.

CONCLUSION

In situ reconstruction using biological grafts is a valuable treatment option in drug injection induced mycotic pseudoaneurysm in the groin with a low rate of early graft related complications. However, high rates of post-operative wound complications must be expected. A significant number of graft re-infections and occlusions/stenoses requiring re-intervention occurred during follow up. The lower limb amputation rate remained low. New biological grafts may offer a promising option in the future.

CONFLICT OF INTEREST

None.

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