Silver-coated graft as bailout option in managing femoral artery-infected pseudoaneurysm: a review of 30 patients

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Context
Femoral artery-infected pseudoaneurysm (fa-IPA) is very common in modern societies, and it represents a difficult problem to the vascular surgeon, as surgical management remains controversial, which ranges from ligation with debridement to extra-anatomical bypass. The present study was carried out to evaluate the outcome of silver-coated grafts used for the management of fa-IPA secondary to illegal drug injections.
Aim
To assess the outcome of silver-coated graft as bailout revascularization conduit in patients with infected pseudoaneurysm regarding success of the procedure, limb salvage, infection rate, and primary patency rate.
Settings and design
A prospective study was conducted.
Patients and methods
The study included 30 patients who presented with fa-IPAs and were admitted to Emergency Department of Benha University Hospital, Ain Shams University Hospitals, and Security Forces Hospital, Makkah, Saudi Arabia, during a 30-month period. Overall, 24 (80%) patients were male and six (20%) patients were female, with age range from 25–46 years. Twenty-one (70%) patients underwent surgical resection and immediate revascularization using silver collagen-coated polyester graft (InterGard Silver; Maquet), whereas nine (30%) patients underwent surgical ligation, with delayed revascularization in four (13.3%) patients through transobturator bypass using the same graft.
Results
Immediate revascularization using either in situ or extra-anatomic bypass is associated with risk of graft infection [early, five patients of 21 (23.8%); late, two patients of 21 (9.5%), with limb salvage rate of 86.7%].
Conclusion
However, no surgical treatment for fa-IPA has been proved to be safe in terms of the overall surgical complications. Our study shows promising results for possibility of using silver-coated grafts as bailout option for limb revascularization. Long-term antimicrobial therapy is advised, and longer follow-up periods are needed to provide accurate results.

Keywords:
femoral artery, intravenous drug abuse, mycotic aneurysm, pseudoaneurysm, silver-coated grafts

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Introduction

Mycotic aneurysms are defined as a localized and irreversible dilation of an artery caused by damage to the vessel wall by infection, which may originate following an infection of a previously healthy artery wall or through secondary infection of a pre-existing aneurysm. The name mycotic aneurysm was coined by Osler [1] to describe aneurysms associated with bacterial endocarditis. A primary mycotic aneurysm is due to infection of a normal arterial wall, whereas infection of a pre-existing aneurysm is defined as a secondary mycotic aneurysm [2]. In the postantibiotic era, arterial trauma has been replacing endocarditis as the most common cause of mycotic aneurysm [3]. This is believed to be owing to increased intravascular drug use and catheters for intravascular monitoring. Femoral mycotic aneurysms are associated with increasing percutaneous arterial access procedures and intravenous drug use [4]. Pseudoaneurysms result from a variety of mechanisms including infection, trauma, intra-arterial injection of illegal substances, arterial access for diagnostic and endovascular procedures, closure device infections,

and synthetic graft infections [5]. Femoral artery-infected pseudoaneurysm (fa-IPA) is more commonly seen in the intravenous drug using population owing to repeated nonsterile needle groin punctures. However, it may also complicate iatrogenic pseudoaneurysms [6]. Most of the patients with femoral pseudoaneurysms typically present with pain and swelling of the affected groin, along with a palpable mass, which may be pulsatile with a thrill or bruit. Foul smelling discharge and profuse bleeding are the classic presentation in infected groin abscess [7]. Clinical diagnosis can be difficult in those who are obese, where a high index of suspicion is required to prompt further investigation. Pseudoaneurysms that persist may enlarge and lead to complications related to compression of the adjacent femoral vein, nerve, and overlying skin. This can lead to leg swelling, deep vein thrombosis, compressive neuropathy, and skin necrosis [8]. Considering the aneurysmal abscesses remain the most common vascular complication with a potential risk of sepsis, hemorrhage, limb loss or even death, management of the fa-IPAs is still controversial, with no consensus among vascular surgeons on whether it is necessary to revascularize the endangered limb and, if so, the timing and method of revascularization [9].

Several techniques, including simple ligation without revascularization, primary and delayed vascular reconstruction, and revascularization in cases with signs related to ischemia, have been recommended [10]. The surgical care of the patient with fa-IFPA includes a series of well-defined steps, starting with control of hemorrhage (if present), taking wound cultures, and wound swabs of the hematoma and the aneurysm sac (including of purulent drainage, if present) must be routinely taken in every case [11]. Many authors have used more than one of the classical treatment options:

(1) Primary amputation if reconstruction in any form is not feasible [12].
(2) Primary repair with standard vascular techniques, together with extensive local debridement of all necrotic tissue [12].
(3) Ligation and excision (Lig–Exc) of fa-IFPA and all infective tissues, followed by immediate (routine) arterial revascularization by either (i) an extra-anatomic bypass through noninfected tissues (the most commonly used materials are manufactured from polytetrafluoroethylene, but autogenous vein or rarely cryopreserved arterial and venous conduits have also been used) or (ii) an in-situ autogenous repair (anatomical reconstruction), in the form of angioplasty or bypass [11].
(4) Single Lig–Exc or triple Lig–Exc of the fa-IFPA together with aggressive local debridement, without arterial reconstruction. Revascularization is recommended if the pedal Doppler signals are absent after test clamping of the external iliac artery or ligation of the common femoral artery [9].
(5) Lig–Exc of the fa-IFPA and all necrotic tissues, followed by a period of observation and selective (delayed) revascularization where the viability of the leg is in danger owing to critical limb ischemia [13].

Patients and methods

Our case study was conducted from November 2014 to May 2017 in the Vascular Unit, Department of Surgery, Benha University/Department of Vascular Surgery, Ain Shams University, and Department of Vascular Surgery, Security Forces Hospital, Makkah, Saudi Arabia, on 30 patients for 18 months, and they followed up for another 12 months from the last patient operated upon. All hemodynamically stable patients were evaluated according to our protocol by full laboratory investigations (complete blood count, C-reactive protein, bleeding profile, kidney function test, and hepatitis and HIV markers) and duplex evaluation of arterial system that confirmed diagnosis of pseudoaneurysm with evaluation of ipsilateral, superficial, and deep venous system. Contrast-enhanced computed tomographic scan was performed for detailed anatomical evaluation of aneurysm extension with inflow and outflow vessels condition. Intraoperative selective angiography was done in three patients with renal impairment. All patients were on broad-spectrum antibiotics after blood cultures were drawn.

All patients were operated on under general anesthesia in a supine position. In patients with aneurysm size of at least 6 cm, a lateral abdominal pararectus incision was performed for retroperitoneal proximal control of the external iliac artery. Another separate skin incision was then made to the inguinal area for exposure and adequate control of the proximal part of the common femoral artery. Whenever possible, the superficial and profunda femoral arteries were also controlled. For patients with smaller aneurysm, direct inguinal vertical skin incision for exposure was used. Extensive debridement of the suppurative surgical field was performed, the groin mass was incised, and all necrotic material was excised. The cavity was then copiously irrigated with saline. Assessment of the arterial wall defect followed, and the decision for circulation restoration was made in 21 patients using

silver collagen-coated polyester graft (InterGard Silver; Maquet SARL, La Ciotat, France). Although decision was ligation and observation in nine patients, four of them were hemodynamically unstable owing to ruptured aneurysm and the other five patients owing to extensive abscess cavity; all excised masses were sent for culture and sensitivity.

In all immediately revascularized patients, graft was covered by sartorius muscle flap and skin closure over subcutaneous drain. All patients were on broad-spectrum parenteral antibiotics for 6 weeks and discharged from the hospital after screening for evidence of graft infection. Four patients of nine were operated upon for delayed revascularization through transobturator bypass using the same graft.

Results

Patient characteristics are shown in Table 1. Twenty-four (80%) patients were male, and six (20%) were female, with age range from 25–46 years. Twenty-three (76.7) fa-IPAs were on the right side, six (20%) were on the left, and one (3.3%) was bilateral. Twenty-five (83.3%) fa-IPAs occurred owing to intravenous drug self-injection and five (16.7%) owing to femoral artery catheterization for coronary intervention. Twenty-one (70%) patients underwent immediate revascularization using silver collagen-coated polyester graft (InterGard Silver; Maquet); nine (30%) patients underwent surgical ligation, with above-knee amputation in two (6.7%) patients owing to acute limb ischemia with gangrene; and four (13.3%) patients had delayed revascularization by transobturator bypass owing to symptomatic disabling claudication. The duration of symptoms ranged from 5 to 31 days (median: 14 days). All patients had a workup and were initiated on broad-spectrum antibiotics. The follow-up range was 6–12 months. In 14 cases, the pseudoaneurysm involved the bifurcation; in six, the mid; and in 10, the proximal common femoral artery (CFA) extending above the inferior border of the inguinal ligament. In 26 patients, the mass was pulsatile. Four (13.3%) patients were admitted with massive external bleeding from the right groin owing to a ruptured fa-IPA, whereas five (15.7%) patients were febrile on admission, those who

Table 1 Patient demographics and clinical characteristics

Patient nos	Age (years)	Sex	Presentation	Intraoperative culture
1	25	Male	Pulsatile groin mass	S. aureus
2	30	Male	Pulsatile groin mass, leg swelling, and DVT	S. aureus
3	27	Female	Pulsatile groin mass, leg swelling, and DVT	S. aureus
4	38	Male	Pulsatile groin mass	S. aureus (methicillin-resistant)
5	40	Female	Pulsatile groin mass and leg swelling	Negative
6	33	Male	Pulsatile groin mass, leg swelling, and DVT	Streptococcus spp.
7	29	Male	Pulsatile groin mass, fever, and contained ruptured aneurysm	S. aureus, E. coli
8	45	Female	Pulsatile groin mass and leg swelling	Negative
9	40	Male	Pulsatile groin mass and leg swelling	Negative
10	26	Male	Massive external bleeding	S. aureus
11	31	Male	Pulsatile groin mass, leg swelling, and DVT	S. aureus
12	36	Male	Pulsatile groin mass, leg swelling, fever, and DVT	S. aureus (methicillin-resistant)
13	25	Male	Pulsatile groin mass	S. aureus
14	26	Male	Pulsatile groin mass, fever, and contained ruptured aneurysm	S. aureus (methicillin-resistant)
15	28	Male	Pulsatile groin mass, leg swelling, and DVT	Streptococcus spp.
16	33	Male	Massive external bleeding	S. aureus
17	42	Male	Pulsatile groin mass, and contained ruptured aneurysm	S. aureus, E. coli
18	27	Male	Pulsatile groin mass, leg swelling, fever, and DVT	S. aureus (methicillin-resistant)
19	32	Male	Pulsatile groin mass, leg swelling, and DVT	Streptococcus spp.
20	30	Female	Pulsatile groin mass and leg swelling	S. aureus
21	39	Male	Pulsatile groin mass, leg swelling, and DVT	Negative
22	29	Male	Pulsatile groin mass	S. aureus
23	33	Male	Pulsatile groin mass and leg swelling	S. aureus
24	41	Male	Pulsatile groin mass, leg swelling, fever, and DVT	S. aureus (methicillin-resistant)
25	36	Female	Pulsatile groin mass, leg swelling, and DVT	Negative
26	32	Male	Pulsatile groin mass	S. aureus
27	26	Male	Massive external bleeding	S. aureus, E. coli
28	28	Male	Pulsatile groin mass and leg swelling	S. aureus
29	38	Female	Pulsatile groin mass, leg swelling, and DVT	S. aureus (methicillin-resistant)
30	31	Male	Massive external bleeding	Negative

DVT, deep venous thrombosis; E. coli, Escherichia coli; S. aureus, Staphylococcus aureus.

had abscess on exploration. In 24 (80%) patients, there were palpable pedal pulses. Skin involvement such as erythema, induration, or gangrene over the fa-IPA was present in 18 (60%) patients. Leg swelling was present in 18 (60%) patients, and 12 of 18 (66.7%) patients had chronic deep venous thrombosis (DVT): four patients at the ipsilateral popliteal vein and eight at the ipsilateral femoral vein. Overall, 20 (66.6%) patients had a damaged ipsilateral great saphenous vein (GSV) owing to previous superficial venous thrombosis. Fourteen (46.7%) patients were hepatitis C virus positive. Wound cultures showed Staphylococcus aureus in 18 (60%) patients (six methicillin resistant) and Streptococcus spp. in three (10%) patients, and three patients with S. aureus also had Escherichia coli (10%). No growth of any organisms was seen in six (20%) patient's culture. Five patients of 21 (23.8%) had a rupture of the proximal anastomosis of the ilio-femoral synthetic graft on the 10th and 13th postoperative day. They were treated with graft excision and distal external iliac artery ligation. Two of five patients were operated upon for amputation owing to limb ischemia. Two of 21 (9.5%) patients presented with graft thrombosis six and seven months later with skin sinus owing to perigraft chronic abscess. Surgical drainage of abscess with restoration of flow in the thrombosed graft was done by catheter direct thrombolysis. Limb salvage was achieved in twenty six (86.7%) patients, whereas overall amputation was performed in four (13.3%) patients: two patients owing to ruptured infected graft and the other two patients owing to immediate ligation of ruptured fa-IPA. All 26 patients were ambulatory, and 20 revascularized patients (16 were immediate and four were delayed) were free of claudication symptoms during the long-term follow-up period (12 months) (Table 2).

Table 2 Results

Patients (n)	30
Age [n (%)] (years)	
25–30	13 (43.3)
31–40	14 (46.7)
41–46	3 (10)
Male [n (%)]	24 (80)
Female [n (%)]	6 (20)
The etiology [n (%)]	
Intravenous drug self-injection	25 (83.3)
Coronary catheterization	5 (16.7)
Clinical presentation [n (%)]	
Pulsatile mass	26 (86.7)
Size <6 cm	18 (60)
Size ≥6 cm	8 (26.7)
Massive bleeding	4 (13.3)
Contained rupture	3 (10)
Associated leg swelling	18 (60)
Associated DVT	12 (40)
Skin involvement	18 (60)
Fever	5 (16.7)
Damaged GSV	20 (66.6)
Hepatitis C	14 (46.7)
Angiographic pattern of aneurysm [n (%)]	
Proximal CFA	10 (33.3)
Mid CFA	6 (20)
Bifurcation of CFA	14 (46.7)
Wound culture growth [n (%)]	
S. aureus	12 (40)
S. aureus (methicillin-resistant)	6 (20)
Streptococcus spp.	3 (10)
S. aureus, E. coli	3 (10)
Negative growth	6 (20)
Surgical management technique [n (%)]	
Ligation and immediate revascularization	21 (70)
Ligation only	9 (30)
Delayed revascularization	4 (13.3)
Nonrevascularized	5 (16.7)
Results and complication [n (%)]	
Early graft infection and ruptured anastomosis	5 (23.8)
Graft thrombosis with chronic abscess	2 (9.5)
Overall amputation	4 (13.3)
Amputation in surgical ligation	2 (22.2)
Primary graft patency	14 (87.5)
Target graft revascularization	2 (12.5)
Limb salvage	26 (86.7)
Revascularized	20 (76.9)
Nonrevascularized	6 (23.1)

CFA, common femoral artery; DVT, deep venous thrombosis; E. coli, Escherichia coli; GSV, great saphenous vein; S. aureus, Staphylococcus aureus.

Discussion

In the past two decades, the femoral artery has become the most common site for infected arterial aneurysms. fa-IPA formation is a well-documented complication of illicit drug use. These lesions are serious, having a definite threat to both life and limb, if left untreated. Their natural history is of rapid progression to rupture and hemorrhage [10]. There is no consensus regarding optimal management of fa-IPA, because results in most published series are based on small numbers of patients. Current treatment options include excision and debridement of the fa-IPA with ligation of the common femoral artery without revascularization and excision and debridement of the fa-IPA with routine or selective revascularization [14]. Primary repair with preservation of the native vessels is considered the best option when the infection is limited. However, it is not recommended by some authors because the extended destruction of the arterial wall usually results in secondary hemorrhage and infection [15]. Padberg et al. [16] presented two cases of primary repair with excellent results. Reddy et al. [17] reported high rates of limb loss, up to 33% in triple ligation involving the

femoral bifurcation in a group of patients with bifurcation fa-IPA. However, single-vessel ligation in false aneurysm of the common, superficial, or profunda femoral artery had significantly better clinical outcome with no resultant amputations. In our study, the overall amputation rate (revascularized and nonrevascularized) was 13.3%, with amputation rate of 22.2% in nonrevascularized group (100% of them owing to triple-ligation), which is comparable to amputation rate in different studies evaluating the outcome of femoral vessel ligation in fa-IPA. Khan et al. [18] reported the surgical outcome after ligation of femoral vessels in intravenous drug users in 19 patients, and their results were entire limb survived in 11 patients, four had toe amputations, three ended in below-knee amputation, and one in above-knee amputation. The overall major amputation rate was 21%. Naqi et al. [19] studied 17 patients of femoral artery pseudoaneurysm during a 1-year period. Parenteral drug abuse was the most common etiological factor. The femoral artery was most commonly involved at its bifurcation. Sixteen (94%) patients had excision of the pseudoaneurysm with ligation of vessel and debridement without any revascularization and one (6%) patient had reverse saphenous grafting after excision and ligation of vessels. Four (23%) amputations were performed. Three (17%) were major limb amputations, which included one above-knee and two below-knee amputations. For fa-IPA involving the femoral bifurcation, immediate vein interposition grafting proves more satisfactory than simple Lig–Exc alone, with an amputation rate of zero. Placing a graft in an infected field is recognized as potentially dangerous, but this practice minimizes limb loss associated with arterial ligation [15]. Although the autogenous graft is more resistant to infection, it unfortunately is not always available. Damage of the superficial veins (especially the great saphenous vein) owing to recurrent attacks of phlebitis and obstructions owing to the injection of inflammatory agents over a prolonged period are other surgical challenges specific to management of this problem [15]. In our series, 20 of 30 patients had no usable GSV. Consequently, the use of prosthetic grafts for delayed or immediate arterial reconstruction seems unavoidable. However, attempts to use prosthetic materials in the bed of the resected fa-IPA have produced uniformly poor results [16]. The rationale of using antimicrobial vascular grafts is obvious: vascular graft infection will only occur if viable bacteria approach the surface of the graft, are able to attach to the prosthetic material, and start becoming metabolically active. If the antimicrobial compound used in or on the graft is leaching, approaching bacteria will be killed off, while either a nonleaching antimicrobial graft will prevent formation of bacterial biofilm on its surface [20]. A vast number of different antimicrobial compounds, antibiotics, or antiseptics could be used to render a vascular graft antimicrobial. The antimicrobial compound must be toxicologically safe, should have no or very limited allergic potency, should possess a low rate of resorption, should not induce bacterial resistance, and must be antimicrobially active, even in the presence of organic load. Until now, the most frequently used antimicrobial compounds in vascular grafts are therefore the antibiotic rifampicin, antimicrobial elements such as silver, and the antiseptics triclosan and povidone iodine [20]. No RCT has proven the efficacy of silver grafts to prevent vascular graft infection. One retrospective study compares the performance of the InterGard Silver polyester graft (Maquet) with that of standard prostheses in routine use. The study showed good results with the silver prosthesis in the aortofemoral position, but it did not achieve a reduction of prosthetic infections in cases of femoropopliteal grafting [21]. Two recent clinical studies have shown the potential benefit of InterGard Silver grafts compared with arterial homografts in the treatment of infections of aortic prostheses. In the first study, Pupka et al. [22] evaluated the effectiveness of in-situ revascularization with the use of arterial homografts and silver-coated prostheses in the treatment of aortic graft infection. A total of 77 patients were studied. Patients were assigned to three groups: group 1 (n=24), fresh arterial homograft with subsequent immunosuppression; group 2 (n=26), fresh arterial homograft without immunosuppression; and group 3 (n=27), silver-coated prosthesis. After a mean follow-up of 22.8 ±10.1 months, the postoperative mortality rate in groups 1, 2, and 3 was 8, 23, and 11%, respectively. The postoperative morbidity was 35% in group 2, 16% in group 1, and 7% in group 3. This study suggests that silver-coated prostheses can be as effective as arterial allografts in the treatment of infections of vascular prostheses. Bisdas et al. [23] compared cryopreserved arterial homografts and silver-coated Dacron grafts for the treatment of abdominal aortic infections in a contaminated intraoperative field. Primary outcomes were survival and limb salvage, and secondary outcomes were graft patency and reinfection. The 30-day mortality rate was 14% in group A and 18% in group B ($P>0.99$), and 2-year survival rates were 82 and 73%, respectively ($P=0.79$). After 2 years, limb salvage was 96 and 100%, respectively ($P=0.50$), whereas graft patency was 100% for both groups.

Results showed comparable effectiveness between cryopreserved arterial homograft and silver-coated Dacron graft for the treatment of aortic infection with positive evidence of micro-organisms. In our study, limb salvage was (86.7%), primary graft patency was (87.5%), and secondary patency was (100%). The overall postoperative morbidity in immediately revascularized patients was 33.3%. Early ruptured anastomosis owing to graft infection was (23.8), whereas late graft thrombosis was 9.5%. The use of bactericidal antibiotics together with early surgical intervention and long-term suppressive antibiotic therapy has led to improved survival and decreased amputation rates [24]. High-dose bactericidal therapy should be maintained for at least 6 weeks and longer if inflammatory biomarkers such as C-reactive protein level, erythrocyte sedimentation rate, and white blood cell count do not subside [24]. Our patients were treated with 6 weeks of high-dose intravenous antibiotics and remained well at follow-up of 1 year.

Conclusion

An infected femoral aneurysm is a challenging clinical entity that should be diagnosed and managed promptly, because it is associated with high mortality and morbidity, including limb loss especially with triple-ligation of the aneurysm. However, no surgical treatment for fa-IPA has been proved to be safe in terms of the overall surgical complications. Our study shows promising results for possibility of using silver-coated grafts as bailout option for limb revascularization, with limb salvage rate of 86.7%. Long-term anti-microbial therapy is advised, and longer follow-up periods are needed to provide accurate results.

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Conflicts of interest

There are no conflicts of interest.

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