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Predilation technique with balloon angioplasty to facilitate percutaneous groin access of large size sheath through scar tissue

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Abstract

Purpose: Percutaneous remote access for endovascular aortic repair is an advantageous alternative to open access. Previous surgery in the femoral region and the presence of synthetic vascular grafts in the femoral/iliac arteries represent major limitations to percutaneous remote access. The aim of this study was to evaluate an original technique used for enabling percutaneous remote access for thoracic or abdominal endovascular aortic repair in patients with scar tissue and/or a vascular graft in the groin.

Methods: Twenty-five consecutive patients with a thoracic (11/25; 44%) or an aortic aneurysm (14/25; 66%) and with a synthetic vascular graft in the groin (16/25; 64%) or a redo groin access (9/25; 36%) were managed through the percutaneous remote access. In all patients, a percutaneous transluminal angioplasty balloon was used to predilate the scar tissue and the femoral artery or the synthetic vascular graft after preclosing (ProGlide®; Abbott Vascular, Santa Clara, CA, USA). In 10 patients, requiring a 20 Fr sheath, a 6 mm percutaneous transluminal angioplasty balloon was used; and in the remaining 15, requiring a 24 Fr sheath, an 8 mm percutaneous transluminal angioplasty balloon. Preclosing was exclusively performed using ProGlide®. Mean follow-up was 15 months.

Results: In all cases, stent-graft deployment was successful. There was one surgical conversion (4%; 1/25) due to bleeding from a femoral anastomosis. Two cases required additional percutaneous maneuvers (postclosing with another system in one patient and endoluminal shielding with stent-graft in the other patient). No pseudoaneurysm or access complication occurred during the follow-up.

Conclusions: Percutaneous access in redo groins with scar tissue and/or synthetic vascular graft using ultrasound-guided punction, preclosing with ProGlide® system and predilation with percutaneous transluminal angioplasty balloon to introduce large size sheath as used for endovascular aortic repair showed to be feasible, safe and with few local complications.

Keywords

Aneurysm, balloon angioplasty, calcification, complications, endovascular aneurysm repair, infection, prosthetic graft, sheath, ultrasonography, vascular closure devices

Introduction

Percutaneous transfemoral access is increasingly used to enable endovascular aortic or cardiac valve procedures, requiring large-size introducers (>16 Fr).[1] The method carries several advantages over femoral cutdown access, including fewer wound complications and shorter procedural time and length of stay. However, local complications, such as bleeding,

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pseudoaneurysm, thrombosis or infection, do occur also in percutaneous endovascular aneurysm repair (PEVAR).[2,3] Calcified groin arteries, limited operator technical expertise, female gender and age[4,5] have been identified as important risk factors. Moreover, severe fibrosis of the groin has been found to be a predictor of percutaneous access primary failure and need of late access site repair.[6] Thus, PEVAR is commonly avoided if it requires redo femoral access and when the ilio-femoral vessels have been replaced by a surgical graft. The main concern in the latter situation is commonly related to the risk of tearing or disrupting the graft or graft-to-native vessel anastomosis when introducing/advancing the sheath through the fabric. Moreover, there is no report about correct function of preclosing systems used in synthetic vascular grafts. In such situations, to ensure adequate vascular control, femoral access is typically achieved by open exposure.

The aim of this study was to analyze the outcome of the use of an original femoral percutaneous remote access (PRA) technique utilizing a preclosing system (ProGlide®; Abbott Vascular, Santa Clara, CA, USA) followed by scar tissue dilation with percutaneous transluminal angioplasty (PTA) balloon for successful and safe large-size sheath introduction in patients with prior groin exposure and/or with a vascular graft as access site.

Method

From August 2011 to December 2015, all patients with an aortic aneurysm treated by using PRA after previous vascular surgery in the groin region (vascular grafting, endarterectomy or vascular access) at the Zurich University Hospital, Switzerland were included in the study. Informed consent for the procedure and for the anonymous data collection and analysis was obtained from all patients. Clinical data were collected with the university hospital clinical information system (Dendrite, Dendrite Clinical Systems, Ltd, Henley-on-Thames, UK; KISIM 4.901, CISTEC AG, Zurich, Switzerland).

The PRA technique (Figure 1(a) to (h)) was completed in all patients under local anesthesia. Usually, 10 cc of lidocaine 1% diluted with 8.4% sodium bicarbonate was infiltrated in the femoral region. Prophylactic intravenous antibiotic (cefuroxime) and a bolus of 5000 heparin units were administered in all cases. A standard 18G puncture of the anterior wall of the artery or graft was performed and a 1 cm skin incision was made before the needle was withdrawn (Figure 1(a)). In the first five (20%) patients, puncture was performed without Duplex ultrasound (DUS); in the following 20 (80%) cases, puncture was done under DUS guidance. In all cases, two ProGlide® (Abbott Vascular) suture-mediated closure devices were subsequently advanced over the wire (Figure 2) and deployed in the 10 o'clock and 2 o'clock positions (Figure 1(b)). In all 25 patients, following the preclosing, a stiff J wire (Boston Scientific, Natwick, MA) was advanced and a 4 cm in length angioplasty balloon (FoxCross; Abbott Vascular) was introduced and positioned in the artery or graft (in case of vascular graft as the access site) so that half of the balloon remained intraluminal and half extraluminal (Figure 1(c)). The diameter of the PTA balloon was sized according to the sheath required: 6 mm for 20 Fr sheath and 8 mm for 24 Fr. The balloon was progressively inflated to nominal pressure and held for 15 s before deflating. The same PTA technique was employed in all cases independently from the fabric graft or previous intervention (Figure 1(d)). Manual compression of the groin allowed balloon removal and large size sheath advancement without significant blood loss. During the sheath insertion (Figure 1(e) and (f)), firm pressure was applied distal to the access site, maintaining the position of skin and soft tissue to prevent graft-anastomotic disruption (Figure 3). To ensure complete vessel or graft closure after removal of the sheath and slight tightening of the first two ProGlide® sutures, an extra ProGlide® device was deployed in the 12 o'clock position. At the end of the procedure, protamine was given to reverse the effects of heparin. In case of incomplete sealing, after additional use of preclosing devices shielding by using a stent-graft introduced just above the femoral bifurcation has been used (Figure 1(g) and (h)).

All patients underwent contrast-enhanced computer tomography (CT) angiography of the aorta from the neck to the thigh region, thus including the groins, prior to discharge and at one month, and, thereafter, annually or bi-annually depending upon the complexity of the procedure and the initial outcome. In association with each CT, the patients were examined in the outpatient department.

Results

Overall, the PRA technique was used in 25 patients with a mean age of 77 (SD: 7) years. PRA was used for thoracic aortic aneurysm treatment in 11/25 (44%) and in association with abdominal aortic repair in 14/25 (66%). In 13/25 (52%) patients the PRA was used with a Gore (W. L. Gore & Associates, Flagstaff, AZ) stent-graft and in the remaining 12/25 (48%) a Medtronic (Medtronic Cardiovascular, Santa Rosa, CA, USA) stent-graft. Comorbidities and risk factors are reported in Table 1. In 16 (64%) patients, PRA was performed through a vascular graft in the groin and in 9 (36%) patients PRA was used in a redo groin

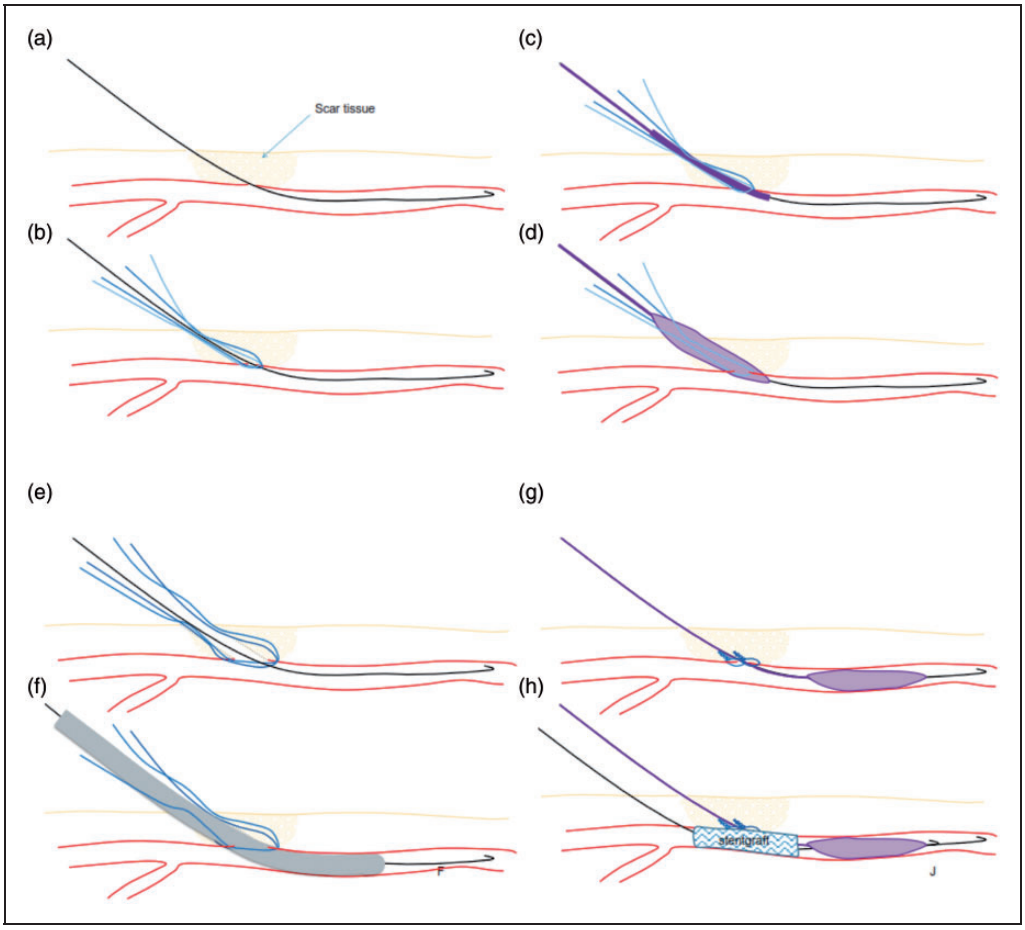

Figure 1. (a) and (b) puncture has been performed under ultrasound guidance approximately 2 cm proximal to the femoral artery bifurcation, the preclosing system is then applied using the common technique. (c) and (d) The PTA balloon (i.e. FoxCross; Abbott Vascular) is introduced into the artery or graft so that half of the balloon remains intraluminal and half extraluminal. Inflating the balloon achieves a channel of desired diameter. (e) and (f) The channel allows smooth passage of the large size sheath. (g) and (h). If the preclosing system fails at the end of the procedure, the PTA balloon is reintroduced and blocked inside the proximal femoral artery. A second access just proximal to the femoral bifurcation is performed under ultrasound control and the primary access site is shielded by using a stent-graft.

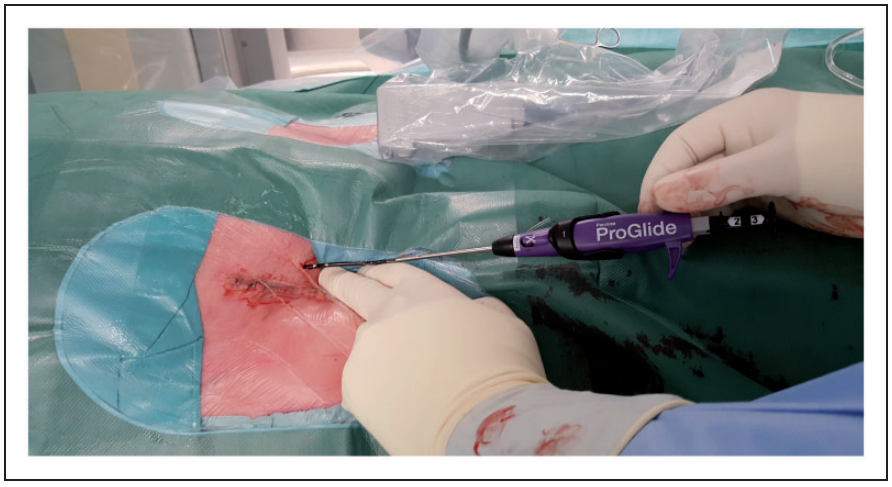

Figure 2. The ProGlide® (Abbott Vascular) suture-mediated closure devices are deployed in the 10 o'clock position thought a vascular graft.

Figure 3. A firm pressure is applied distal to the access site to maintain the position of skin and soft tissue and prevent a graft-anastomotic disruption.

Table 1. Demographics and risk factors.

	n (%)
Mean age (years)	77 (SD: 7)
Female gender	3 (12%)
Hypertension	21 (84%)
Coronary artery disease	11 (44%)
Peripheral arterial disease	22 (88%)
Cerebrovascular disease	10 (40%)
Groin with synthetic graft	16 (64%)
Previously accessed groin	9 (36%)

access (after prior open access for (T) EVAR ($n = 8$) or femoral endarterectomy ($n = 1$)).

In all 25 patients, the predilation with a non-compliant balloon was used to facilitate the large sheath introductions. In 11/25 (44%) patients, PRA was performed through a knitted polyester graft; in 5/25 (20%) through a polytetrafluoroethylene graft and in the remaining 9/25 (36%) patients through a redo groin without any synthetic vascular graft. A 24 Fr sheath dilated with an 8 mm balloon was used in 15/25 (60%) cases; a 20 Fr sheath dilated with a 6 mm balloon in 10/25 (40%).

A preclosing failure requiring open access control was necessary in only one case (1/25; 4%). In that patient, the percutaneous puncture was carried without ultrasound guidance and performed just at the level of the femoral anastomosis located at the femoral bifurcation, which prevented insertion of a stent-graft to seal the access site. In this case, bleeding during femoral surgical exposure was controlled by inflating proximally a PTA balloon in correspondence of the external iliac artery. Following that case, all PRA procedures were performed under ultrasound guidance and great care was taken to perform graft access about 2 cm proximal to the graft anastomosis. No other surgical graft access control was necessary in the other cases. An additional percutaneous procedure, to seal the remote access after sheath removal, was used in two patients because of sealing failure. In one patient, a Prostar® (Perclose, Menlo Park, CA) system was used in addition to the ProGlide® and in one patient endoluminal shielding using 8 mm/5 cm Viabahn®

(Gore, Flagstaff, AZ) was performed through a second distal access in the ipsilateral superficial femoral artery. No graft anastomosis disruption occurred with the predilation technique. Mean operative time was 104 (range: 85–130; SD: 37) min and discharge occurred at 2.5 (range: 1–6; SD: 2) post-operative day (POD). Clinical and radiological (CT angiography) controls showed no postoperative seromas, wound infections or pseudoaneurysms and/or access vessel stenosis during a mean follow-up of 15 (range: 3–24; SD: 6) months.

Discussion

To our knowledge, there has been no previous report in the literature specifically addressing PRA with large sheath (>16 Fr) insertion in redo groin or vascular grafts. This represents an important issue for vascular surgeons, as concomitant arterial occlusive disease (peripheral, coronary or carotid) occurs in up to 40% of aneurysm patients; thus, many patients presenting with aortic aneurysm may have already been treated by a percutaneous procedure or open vascular surgery in the groin.[7] Some patients will have been treated with open aorto-(bi)femoral graft or femoro-distal graft for aneurysmal or occlusive disease.[8–10]

Moreover, the large size of the sheath required for a thoracic stent-graft,[11,12] especially in patients presenting femoral or iliac peripheral disease, may require the creation of an ilio-femoral conduit prior to delivery of the stent-graft. Finally, many (T)EVARs have been performed by open surgical access and, therefore, eventual redo procedures, as for disease progression or technical failure, will challenge scar tissue.

The surgical exposure of the groin for vascular remote access in a redo situation can be time consuming and technically demanding. Furthermore, local anesthesia is less effective in scar tissue so that extensive dissection may require more invasive anesthesiology techniques.

In addition, redo surgery has been identified as a significant risk factor for surgical site and vascular graft infection,[13] bleeding from infected regions and septicemia.[14] To reduce the risk of such complications, a percutaneous approach was employed in all patients of this series.

In our initial experience with percutaneous large-size sheath introduction through scared tissue, the introduction of sequential dilators (Dotter's method)[15] was employed in association to the ProGlide® preclose technique. In that experience, resistance to pass scar tissue with the large sheath was typically very high and a graft-to-native femoral artery anastomosis disruption occurred in one patient. Subsequently, after this complication, the PRA technique was modified by predilating the access channel with angioplasty balloon after preclosing with ProGlide® devices. In the reported series of 25 patients, the introduction of the PTA tool in correspondence of the femoral scared tissue allowed smooth sheath introduction in all cases. The PTA ballooning is performed instead of the introduction of sequential dilatators while the ProGlide® preclose technique is performed in a standard fashion. In the ninth patient, however, the preclosing failed since the PRA site was situated at the femoral artery bifurcation precluding endovascular shielding. To avoid this issue, a standardized percutaneous puncture technique was then introduced. The latter technique included ultrasound-guided puncture of the graft or femoral artery at least 2 cm proximal to the femoral artery bifurcation. Since the introduction of this standardized technique, two additional access sealing failures occurred after sheath removal, but both could be managed using percutaneous endovascular solutions. As a consequence, we advocate ultrasound as an important tool to access the graft on the anterior wall and about 2 cm proximal to any anastomosis, thereby allowing endovascular shielding by using a stent-graft and avoiding problems with the graft anastomosis.[16] When compared to our historical series,[17] the PRA was found to have similar operative time and lower in hospital length of stay.

The balloon diameter for performing the dilatation of the subcutaneous access channel should be corresponding to the outer sheath size diameter to be able to smoothly introduce the sheath and achieve a good sealing. The use of non-compliant over compliant balloons to predilate the scared tissue and/or the surgical graft allows to reach the predefined diameter with a reduced risk to over-dilate structures at lower resistances as the arterial lumen. No differences were observed regarding to the graft fabric (polyester, PTFE) or the type of previous intervention for PTA dilation.

In our opinion and experience, the use of an insufflation device for the PTA balloon is not mandatory. The sheath should be inserted without undue force and during its insertion, firm traction should be applied on the skin above and below the puncture site by an assistant. This maneuver is necessary to avoid proximal vascular graft traction, and thus to protect the distal graft anastomosis from disruption while introducing the sheath. To minimize the risk of graft disruption early after its implantation, this procedure should be performed with the greatest care, when the graft is not well incorporated into the tissues. In case of preclosing system failure at the end of the procedure, a PTA balloon is introduced and inflated in the proximal femoral or external iliac artery. If feasible, a second access just proximal to the femoral bifurcation is performed under ultrasound control and the primary access site is

shielded by using a stent-graft. An open femoral conversion is alternatively performed, after the proximal PTA balloon inflation, if the endovascular solution is not feasible.

Despite this being a small series, our experience indicates that PRA is feasible through scar tissue as in redo groin and/or vascular graft. Moreover, we experienced not using ultrasound and/or predilation in large size PRA might lead to sealing issues and the need for surgical access control after sheath removal. In contrast, puncture with ultrasound guidance and the predilation technique allowed safe PRA and completion of (T)EVAR percutaneously in almost all cases (96%, 24/25). Although this study did not include patients undergoing transcatheter aortic valve implantation (TAVI), the PRA technique could be employed not only in vascular interventions but also in cardiac valve procedures.

We advocate not accessing the femoral artery proximally to the inguinal ligament as residual bleeding may propagate to the retroperitoneal space and stay clinically unrecognized till pains and/or hypovolemic shock develop. Finally, using percutaneous access is contra-indicated in porcelain access vessels and it should be used with caution in morbid obesity patients.

Conclusion

Percutaneous introduction of large sheaths, as used for EVAR or TAVI, in redo groins and/or through synthetic grafts with suture-mediated closure devices (ProGlide®) can be performed safely using an angioplasty balloon for predilation. Technical details and pitfalls are described.

Declaration of conflicting interests

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