Pledget reinforcement and traction compression as adjunctive techniques for suture-based closure of arterial cannulation sites in percutaneous endovascular aneurysm repair—initial experience

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ABSTRACT

Suture-based vascular closure devices are used in percutaneous endovascular procedures. However, failures are not uncommon. We have described our initial experience with two adjunct techniques to reinforce the suture-based vascular closure device (ProGlide; Abbot Vascular, Santa Clara, Calif) after percutaneous endovascular aneurysm repair. The threads of the ProGlide device (Abbot Vascular) were passed through a pledget with the help of a needle, which was secured to the puncture site to allow for traction compression. The use of the techniques can be helpful if the suture-based vascular closure devices fail to achieve immediate and complete hemostasis. The use of these adjuncts could reduce the incidence of closure-related complications after percutaneous endovascular procedures. (J Vasc Surg Cases and Innovative Techniques 2021;7:183-7.)

Keywords: Percutaneous EVAR; Pledget; Suture-based vascular closure device; Traction compression

The use of percutaneous access for endovascular aneurysm repair (EVAR) has resulted in shorter recovery times and reduced the incidence of wound complications compared with surgical femoral artery exposure.[1] Femoral artery closure during percutaneous EVAR (pEVAR) has often been performed using suture-based closure devices such as the ProGlide closure device (Abbot Vascular, Santa Clara, Calif). The failure of such devices to achieve complete hemostasis has not been uncommon,[2-5] and hemorrhage can necessitate emergency cutdown, fascial closure, or the prolonged use of external compression devices, introducing the risk of wound infection and/or damage to nearby neurovascular structures.[4,5] In the present report, we have described the use of two adjunct techniques to suture-based closure devices during pEVAR.

METHODS

The two adjuncts we have described were introduced as novel techniques in our unit. The first 20 patients who had undergone pEVAR with the use of these techniques were included in the present study. All the included patients provided written informed consent before the procedure. Any immediate and delayed complications were prospectively documented.

Patient selection. All the patients scheduled to undergo EVAR who had had common femoral arteries (CFAs) considered suitable for the use of a percutaneous technique were considered for the two techniques. The CFAs were required to be >7 mm in diameter with no significant stenosis and to have at least an ~1-cm segment of the anterior wall without calcification for consideration of the pEVAR technique. Patients with CFAs with severe calcification in their anterior wall without any gap and those with CFAs with significant stenosis were excluded. In addition, patients who had undergone previous groin open vascular surgery were not included in the present initial series, although we have subsequently performed this technique successfully for such patients requiring repeat groin surgery. Only one groin in our small series was excluded from percutaneous access, and this groin was scheduled and planned for open surgery with cutdown and femoral endarterectomy because of severe stenosis of the CFA.

Surgical technique. Every CFA was punctured using ultrasound guidance with the needle at a 45° angle. An adequate size skin incision (~8 mm) was made to accommodate the larger sheath required for EVAR. The tissue between the skin puncture site and the intended arterial puncture site was dissected using an artery clip under ultrasound guidance along the intended needle route toward the anterior wall of the artery. The puncture needle was then advanced without any undue

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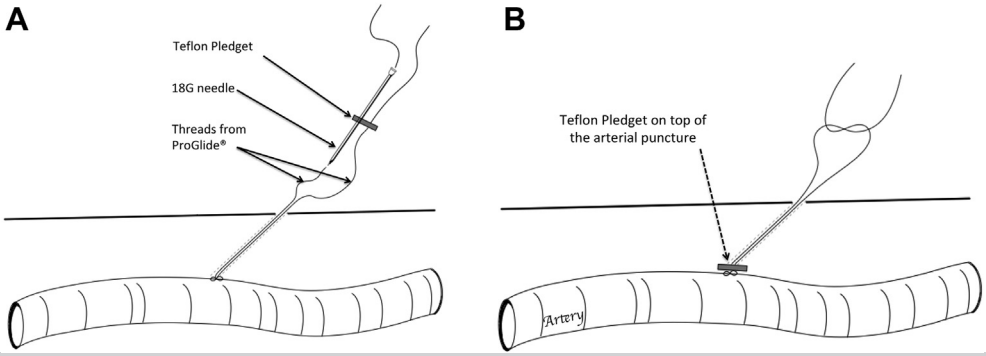

Fig 1. A, Threads of the suture-based closure device passed through the pledget using an 18-gauge needle. **B,** Pledget pushed onto the puncture site, and the sutures knotted to fix the pledget to the puncture site.

compression from the ultrasound probe to avoid puckering of the subcutaneous tissue. This helped the ProGlide knot (Abbot Vascular) to slip with less friction and allowed the polytetrafluoroethylene (PTFE) pledget (CR Bard, Tempe, Ariz) to slide over the thread toward the arterial puncture site. A 6F sheath was advanced initially over the wire to predilate the track before insertion of the ProGlide closure device (Abbot Vascular).

After percutaneous arterial access for EVAR, two suture-based closure devices (ProGlide; Abbot Vascular) were deployed as a preclosure technique.[6] EVAR was then performed without modification. Closure of the femoral artery was begun using a standard method with the suture-based closure device in accordance with the instructions for use[6]; however, the sutures were not cut. The puncture site was assessed to determine the presence of complete hemostasis. If complete hemostasis had not been achieved, the following adjunct procedure was initiated. If bleeding from the puncture site indicated that the ProGlide devices had not worked at all, we would consider placement of a third ProGlide device or the use of other methods such as surgical cutdown. We maintained the wire access until adequate hemostasis had been confirmed and we were sure we could achieve control using the adjunct techniques. We have used these techniques since June 2018 and have described the outcomes for the initial 20 patients in the present report.

Pledget reinforcement. None of the threads of the closure devices was cut. The two ProGlide devices (Abbott Vascular) have four threads. We chose to use the two longer threads of the four, although different combinations can be used. A square (7.9-mm × 3-mm) PTFE felt pledget (CR Bard) was pierced by an 18-gauge needle in two places (one at a time), and each pair of sutures was passed through the pledget from the sharp end of the needle toward the hub (Fig 1, *A*). The needle was withdrawn, and the pledget was pushed through the skin puncture site using surgical forceps. The knot pusher was then used to push down the PTFE pledget along the thread to seal the puncture site. The PTFE pledget was kept pushed against puncture site using the knot pusher for ≥1 minute to assess the extent of the hemostasis. The knot pusher could be pushed in different directions to achieve better hemostasis. Once hemostasis was considered to have occurred with the pledget, we removed the wire (if not previously removed). A second knot was then tied over the PTFE pledget (Fig 1, *B*) to secure the pledget over the arterial puncture site with six throws (Video). The knot pusher can be used for tightening after every throw of the knot over the pledget. Care should be taken to not fracture the threads during the knot tying.

Traction compression. If absolute hemostasis was not achieved with the use of the pledget, traction compression was applied instead of using traditional unidirectional manual compression or an external compression device (ie, FemoStop compression system; Abbot Vascular). For traction compression, a small gauze swab was wrapped around the closure device sutures (Fig 2, *A*), which were used to guide the swab through the soft tissue to the puncture site. All four threads from the two ProGlide devices were held taut and perpendicular to skin. An artery clip was used to grip the sutures at the lowest external point with adequate tension on the threads, thereby pulling the vessel and the PTFE pledget up toward the swab, with the swab held down by an artery clip to compress the puncture site for 5 to 10 minutes (Fig 2, *B*). This helps to obtain fine hemostasis by compressing the tissue between the puncture site and the artery clip. We assessed the hemostasis after 5 minutes. If blood were still oozing, an additional 5-minute period of compression was applied. Once absolute hemostasis had been achieved, the artery clip was detached, the swab was removed, and all four sutures were cut.

Once hemostasis was achieved, the skin was closed in accordance with surgeon preference such as the use of

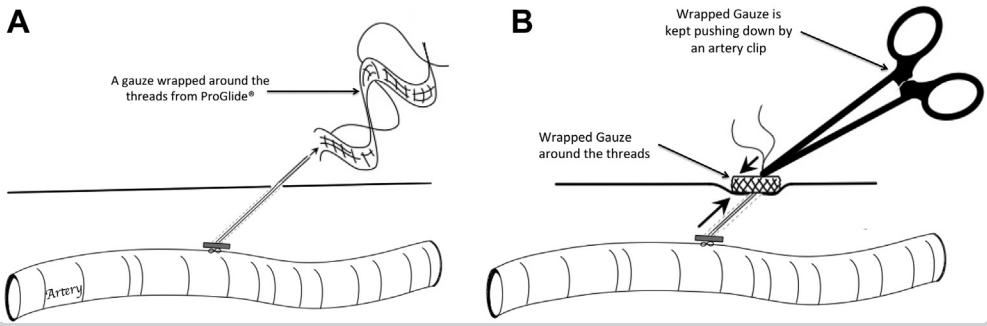

Fig 2. A, A gauze swab wrapped around the threads of the closure device. **B,** Thread pulled upward and gauze swab pushed downward, compressing the tissues and swab against the puncture site, achieving traction compression.

skin glue. Any immediate complications such as hematoma, a requirement for surgical cutdown, or fascial closure were all documented. All patients underwent duplex ultrasonography and computed tomography (CT) angiography at 1 month and were followed up in the outpatient clinic to assess for any complications related to the EVAR and for groin complications, including infection, hematoma, and pseudoaneurysm.

RESULTS

The first 20 patients (median age, 76 years; 15 men) who had undergone pEVAR in our unit were included in the present study. Of the 40 groins in the 20 patients, the femoral artery in 1 groin of 1 patient was heavily diseased with near occlusion and required a previously planned femoral endarterectomy. For the remaining 39 groins, percutaneous femoral access was successful. Only one ProGlide suture had broken during the initial deployment, and an additional ProGlide device was deployed in one groin. The patients had required 16F to 22F sheaths for pEVAR. All planned percutaneous access procedures were successful using the preclosure technique of two ProGlide devices and PTFE pledget in the present series. No immediate complications such as hematoma were encountered. No patient had required unexpected surgical cutdown. Although every patient who had undergone EVAR had received 5000 IU heparin during the procedure, protamine was not used for any of the patients to reverse the heparin.

All 20 patients were seen in our outpatient clinic and had undergone the routine 1-month postoperative CT scan and arterial duplex ultrasound scan to assess for any endoleaks, pseudoaneurysms, and stenosis. At the 1-month follow-up examination, no groin infection, significant stenosis, or pseudoaneurysm was found in any of the patients. All 40 groins, including the 1 that had undergone endarterectomy, remained healthy without any complications. The CT scan confirmed a healthy CFA, and the mean distance between the luminal edge of the CFA and the PTFE pledget was 2.9 mm (Fig 3), although the distance was >4 mm in six groins. The median distance between the anterior wall of the femoral artery and the skin was 32 mm (interquartile range, 28-42 mm). For the six groins in which the pledget had been situated >4 mm from the arterial lumen, the distance was 36, 40, 41, 41, 43, and 44 mm. However, no pseudoaneurysm of any size had developed in any of the patients even those with the pledget >4 mm from the arterial lumen.

DISCUSSION

The failure of closure devices after percutaneous access increases the morbidity and potential risks associated with EVAR.[1] The adjunctive procedures we have described have the potential to reduce the need for immediate or subsequent groin cutdown, manual compression, or the use of external compression devices.

The PTFE pledget was railed over two of the four threads from the two ProGlide devices (Abbott Vascular). Although in the present series, we used the two longer threads from the two ProGlide devices, it is possible to rail the pledget over the two threads of the first ProGlide or over the threads of the second ProGlide device. It is also possible to use a second PTFE pledget over the remaining two sutures if required. The effect of the pledget is primarily to apply pressure against the puncture site to seal the bleeding site.

The described technique is limited to reinforcing closure with suture-based closure devices such as the ProGlide device (Abbot Vascular) and would not be suitable for clip- or plug-based closure devices. Furthermore, it requires successful initial deployment of the suture-based device but could still be incorporated if the device does not achieve adequate hemostasis. The complications associated with pledgets are rare but include the possibility of infection. The use of biodegradable pledgets could represent an acceptable substitute in the future. The added cost of the procedure is equivalent to the cost of the pledget, which would be offset if the need for groin cutdown and surgical arterial closure is reduced.

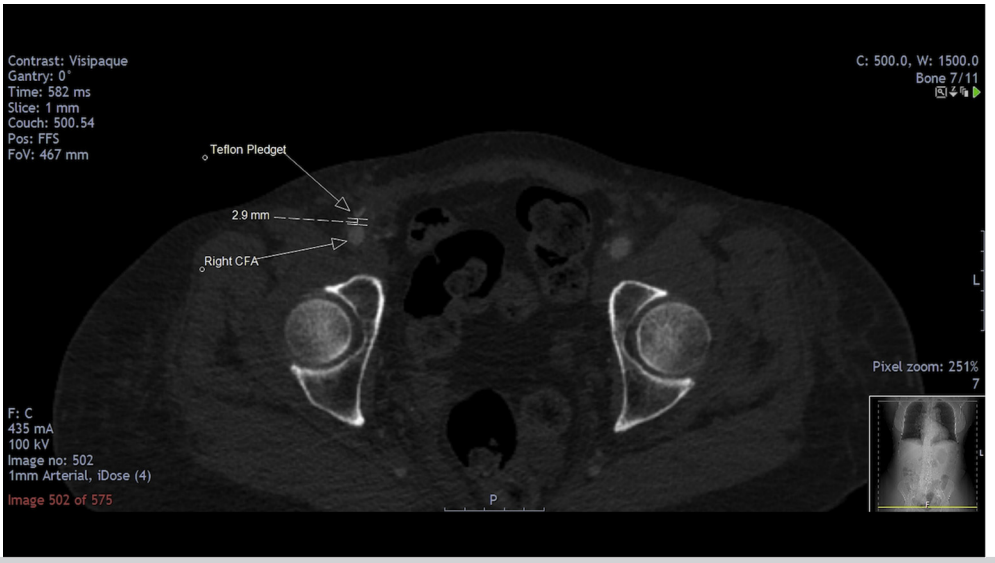

Fig 3. Computed tomography angiogram at 1 month showing the pledget in relation to the femoral artery (note the distance between lumen and the pledget was ~2.7 mm in this case).

External compression devices (eg, FemoStop; Abbot Vascular) can narrow the arterial lumen, especially if high pneumatic pressure is used. External compression also has the potential to deliver an inaccurate pressure or to impinge on neighboring structures such as the femoral nerve, its branches, or the common femoral vein. When applied after a procedure in the conscious patient, external compression devices can also serve as a considerable source of discomfort. The traction compression technique we have described allows for focal application of pressure to the puncture site without restricting the arterial lumen or compromising the neighboring structures. The use of traction compression provides additional hemostasis by compressing the tissue between the puncture site and skin by pulling the arterial wall up and pressing the skin down against the puncture site. The use of this technique could be especially valuable for low punctures that lack the underlying bony stability of the femoral head, against which the CFA has traditionally been compressed. Again, its use is limited to that of an adjunct to suture-based closure devices and cannot be incorporated once the sutures have been cut. Unlike manual compression, traction compression does not occupy the operator once applied.

Postoperative CT confirmed that the pledget was not in direct contact in some patients. However, the pledget helped to control the bleeding by acting as an external seal with target compression at the point of puncture. The mean distance between the anterior wall of the CFA and pledget was 2.9 mm. The distance included the arterial wall thickness and some fascial tissue, which acted as a buttress between the arterial wall and pledget. If the ProGlide knot is completely tight, the PTFE pledget might not be required to achieve prompt hemostasis. However, a common issue is that the knot will not be completely tight against arterial wall, leaving a bleeding puncture site. Thus, a PTFE pledget that is railed over the thread will help to exert direct compression, sealing the puncture site and achieving better hemostasis. None of the patients in our initial experience required any additional external compression beyond the maximum of 10 minutes (average, 5 minutes) of traction compression. All femoral percutaneous access sites were sealed successfully with the use of two ProGlide devices, a PTFE pledget, and the traction compression technique. These methods appear to be very promising adjunct techniques to complete percutaneous endovascular procedures that require a sheath size of ≤22F with confidence.

CONCLUSION

We have presented novel adjunct techniques (pledget reinforcement and traction compression) for suture-based percutaneous arterial closure. Their use results in minimal additional procedural costs or time and has the potential to reduce the need for external compression and surgical cutdown. Further comparative studies are underway to assess the objective benefits of these adjunct techniques.

REFERENCES

1. Huff CM, Silver MJ, Ansel GM. Percutaneous endovascular aortic aneurysm repair for abdominal aortic aneurysm. Curr Cardiol Rep 2018;20:79.

2. Heo YJ, Jeong HW, Baek JW, Lee SJ, Choo HJ, Jung HS, et al. Ultrasound evaluation of puncture sites after deployment of two different types of vascular closure devices: a prospective comparative study. Cardiovasc Intervent Radiol 2018;41:1654-63.
3. Biancari F, Romppanen H, Savontaus M, Siljander A, Mäkikallio T, Piira OP, et al. MANTA versus ProGlide vascular closure devices in transfemoral transcatheter aortic valve implantation. Int J Cardiol 2018;263:29-31.
4. Noori VJ, Eldrup-Jørgensen J. A systematic review of vascular closure devices for femoral artery puncture sites. J Vasc Surg 2018;68:887-99.
5. Karaolanis G, Kostakis ID, Moris D, Palla VV, Moulakakis KG. Fascia suture technique and suture-mediated closure devices: systematic review. Int J Angiol 2018;27:13-22.
6. Abbott eLabeling Site. Perclose ProGlide® suture-mediated closure (SMC) system. Instructions for use. Available at: http://eifu.abbottvascular.com/content/dam/av/eifu-us/EL2105174%20Artwork.pdf. Accessed August 2, 2019.

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