PEVAR on the Rise

An interview and case report from Prof. Giovanni Pratesi, MD, on the utility of suture-mediated closure after percutaneous endovascular aneurysm repair.

With the availability of low-profile devices on the rise, can you discuss some of the clinical benefits of percutaneous aortic aneurysm repair (PEVAR) compared to traditional surgical cutdown?

Percutaneous endovascular aneurysm repair has a great advantage to further minimize the invasiveness of endovascular aortic procedures. Compared to femoral exposure, a percutaneous approach allows for a broader use of local anesthesia, a shorter operation, and an earlier ambulation time. By avoiding skin incision in the groin, PEVAR contributes to reduced overall patient discomfort, length of stay, and wound complications.

The continuous improvement of PEVAR’s clinical safety and effectiveness can be explained by two main factors: First, advances in stent graft technology have allowed for a progressive profile reduction, which culminated in the commercialization of ultra-low-profile stent grafts with a 14-F outer diameter delivery system. Secondly, the growing operator experience with suture-mediated closure devices has permitted more accurate patient selection and a fully standardized procedure.

Despite the fact that several patient-, operator-, and procedure-related factors (eg, common femoral artery [CFA] calcification, obesity, scarred groins, sheath size, and operator experience) have been identified as potentially able to affect PEVAR outcomes, device profile and operator learning curve have been shown to have the strongest association with an improved technical success rate, which is currently around 98%.

Could you share some insight into the history of the preclose technique?

PEVAR was first described in 1999 by Haas et al, who demonstrated the feasibility of closing large access sites with the Prostar XL closure device (Abbott Vascular) using the preclose technique. This technique necessitates that a suture-mediated closure device be deployed before the insertion of a large-bore sheath; otherwise, the needles of the device will not be engaged through the vessel wall, and vessel closure will not be possible. Prostar was CE Mark approved to close up to 24 F. More recently, a modification of this technique using two Perclose ProGlide closure devices (Abbott Vascular), has been proposed and received US Food and Drug Administration approval for the closure of femoral access sites up to 21 F.

Despite the previous lack of high-level clinical evidence based on randomized, controlled trials, PEVAR applicability continues to grow and is now suitable for use in approximately 90% of EVAR cases. In our center’s opinion, the introduction of ProGlide played a major role in the escalation of PEVAR use. We have performed 100% of our PEVAR cases using ProGlide for many years, and this trend has been observed in many European and international centers.

Several reasons can be cited to support this paradigm shift. First, ProGlide has a lower profile compared to Prostar (6 F vs 10 F, respectively) and could be safer to use in the presence of smaller femoral arteries and iliac tortuosity. Secondly, the ProGlide system is based on a single 3–0 monofilament polypropylene suture; it offers better performances compared to the 3–0 braided polyester sutures of the Prostar XL in terms of progression in the subcutaneous tissues, which often require a preventive, time-consuming channel preparation. Additionally, the pre-tied knot of the ProGlide device eliminates any potential problems related to the formation of the slip knot needed with the Prostar XL.

What are the benefits of using suture-mediated closure devices?

The use of suture-mediated closure devices has the great advantage of performing a real surgical suture in an endovascular fashion without the need of surgical cutdown. In this way, it is possible to reduce patient discomfort and prevent any wound-related complications.

Using a polypropylene suture exactly like in open surgery has the advantage of avoiding the need for...
any additional hemostatic materials. Effectiveness of hemostasis can be tested immediately at the end of the procedure without the risk of late failure due to dislodgment of anchors or plugs. Moreover, when sutures are placed in tension, it is possible to downsize the profile of the sheath from 24 F to 6 or 10 F, for example, in order to keep vascular access during complex procedures like branched thoracoabdominal aortic aneurysm repair without compromising blood flow to the limbs. This keeps arterial access available for a few days after the procedure in case additional procedures are expected, without risk of bleeding or need for additional punctures. Future access in the groin, which can be performed without temporal limits, will be in almost virgin territory because of the minimal reaction to prolene suture.

More recently, a wide spectrum of new closure devices has been proposed for percutaneous closure of large-bore femoral access. All these systems are based on different kinds of technologies and are still under investigation and not yet approved for clinical use.

**How is the learning curve with this technique? Do you have any clinical tips for optimizing outcomes?**

Although there is no consensus in the literature on the number of procedures needed to be identified as an expert operator, operator experience is one of the most important keys to successful PEVAR. Expertise in the use of ProGlide for peripheral procedures with small-bore sheaths, like carotid stenting or peripheral revascularization, can be useful but not mandatory.

From our center’s point of view, the learning curve for this technique is multifactorial. First of all, as for any endovascular technique, patient selection is crucial for the success of the procedure. Scarred groins, obesity, small-diameter CFAs, anterior calcified spot plaques, and high femoral bifurcation do not represent absolute contraindications to PEVAR but indicate needs to be analyzed on preoperative CT scan. Furthermore, accurate selection of the puncture site is mandatory. When one or more of the previously mentioned factors are identified, ultrasound-guided puncture is strongly recommended in order to locate the healthier segment of the CFA. Finally, proper knowledge of the device and meticulous execution of the closure technique are important points as well.

It is crucial to always leave the guidewire in place until acceptable hemostasis is achieved. In case of suboptimal hemostasis, another ProGlide device can be advanced and deployed over the wire; in case of failure with major bleeding, a sheath or a balloon can be advanced into the external iliac artery and used to endovascularly clamp the vessel while preparing for a more relaxed femoral cutdown.

Another useful tip is to advance a small Teflon pledget over the two sutures touching the arterial wall to increase the hemostasis. This is particularly useful when approaching a CFA with anterior plaque, which can experience some minor persistent bleeding not solved solely with additional manual compression.

**What are the economic advantages of ProGlide?**

Despite representing an additional cost for the procedure, the use of suture-mediated closure devices has several economic advantages. Considering only economic factors, the shortening of operation time and length of stay is associated with EVAR cost reduction. In addition, progressive decrease in endograft profile allows the use of a single ProGlide for each femoral access, leading to further cost reduction.

However, in order to evaluate the overall cost effectiveness of EVAR, we cannot look at the femoral access modality alone; a global evaluation of pre-, intra-, and postoperative periods needs to be considered. In our unit, all the preoperative assessments, including duplex ultrasonography, CT scan, and laboratory tests, are performed in an outpatient setting, and patients are admitted the same day of surgery or the day before. Our standard-risk EVAR protocol includes local anesthesia with mild sedation, totally percutaneous EVAR in the angi-suite with a fixed C-arm, and transfer to the ward at the end of the operation. All patients undergo aortic and femoral access site duplex evaluation before ambulation, which normally occurs within 6 hours of the procedure, and are discharged on the first or second postoperative day based on the clinical risk of the individual patient.

When you consider all these aspects together, you can easily understand the economic advantages of percutaneous access, which have to be combined with the improvement of patients’ quality of life that is derived from a less-invasive operation.

**What were the most significant takeaways from your Italian PEVAR registry (IPER) data?**

The IPER registry is a prospective multicenter registry carried out to provide real-world data on the contemporary management of PEVAR with the aims of reporting intraoperative and 30-day technical success and complication rates and to identify patient, operator, and procedural factors affecting outcomes. It is the first and largest prospective multicenter study carried out on a cohort of unselected patients who underwent PEVAR with differ-
ent endografts in well-trained centers by highly experienced operators.

Between January 2010 and December 2014, 2,381 PEVAR procedures were performed at seven Italian high-volume centers (operators with an experience of at least 50 PEVAR procedures) in 1,322 consecutive patients. Results of the IPER registry confirm the high technical success rate of PEVAR when performed by experienced operators, even in the presence of demanding anatomies. Percutaneous access was technically successful in 96.8% (2,305 CFAs) of procedures. The causes of surgical conversion in 3.2% of procedures included acute bleeding (54 cases) and acute CFA occlusion (22 cases) as a result of suture break, not sliding knot or detachment of the atheromatous plaque in the posterior wall. The 1-month PEVAR failure rate was 0.25% (six cases) consisting of two pseudoaneurysms and four CFA occlusions that required surgical open femoral repair in all the cases. No infection, arteriovenous fistula, or neurological damage was observed. Femoral calcification represents the only independent predictor of percutaneous access failure at multivariate analysis. No significant association was observed with sex, obesity, CFA diameter, level of CFA bifurcation, and sheath size.

**CASE REPORT**

**Percutaneous EVAR in an Obese Patient**

A 69-year-old man was admitted to our unit with a diagnosis of an asymptomatic abdominal aortic aneurysm (AAA) with a maximum diameter of 7 cm. He had multiple atherosclerotic risk factors including hypertension, type 2 diabetes mellitus, chronic atrial fibrillation treated with oral anticoagulant therapy, severe obesity (weight, 145 kg; height, 1.9 m; body mass index, 40.2 kg/m$^2$), and a previous smoking habit. Preoperative CT angiogram evaluation showed the presence of an appropriate proximal aortic neck (diameter, 28.3 mm; length, 23 mm) and distal iliac landing zones (right side: diameter, 16.2 mm and length, 58.8 mm; left side: diameter, 16.5 mm and length, 60.6 mm) without significant angulations and tortuosity, confirming the feasibility of standard EVAR. A detailed evaluation of the femoral access vessels with 3D reconstruction and vessel analysis revealed the presence of regular CFA diameters (right CFA, 10.8 mm; left CFA, 10.9 mm) with a normal position of the femoral bifurcation in relation to the inguinal ligament and minus calcified plaques on the posteromedial wall bilaterally (Figures 1 and 2). Based on the aneurysm and access vessel anatomy, PEVAR was planned despite the fact that the subcutaneous tissue at the level of the CFAs was more than 10 cm bilaterally (Figure 3).

![Figure 1. Preoperative CT angiogram with axial image and 3D reconstruction of the right and left CFA with soft tissue visualization (A, B); red line with measurements refers to the distance between the inguinal ligament and CFA bifurcation; green transverse line in the target indicates the ideal puncture level.](image1)

![Figure 2. Preoperative CT angiogram with axial image and 3D reconstruction of the right and left CFA with bone landmark (A, B); red line with measurements refers to the distance between the inguinal ligament and CFA bifurcation; green transverse line in the target indicates the ideal puncture level.](image2)
The operation was performed in the angiosuite, which was fully equipped with a flat-detector x-ray system (Allura Xper, Philips Healthcare), and the patient was placed under local anesthesia with mild sedation. Ultrasound guidance (MyLab ClassC, Esaote) was used to get access to both CFAs (Figure 4), and a short 6-F sheath was advanced over a standard 0.035-inch guide-wire bilaterally. After angiographic control of the correct puncture site (Figure 5), a single 6-F ProGlide was deployed (Figure 6) using the preclose technique and subsequently exchanged with a short 10-F sheath on both sides. EVAR was successfully carried out with standard technique using a new-generation, ultra-low-profile endograft, characterized by suprarenal active fixation, tri-modular design, and 14-F outer-diameter delivery system (Incraft, Cordis Corporation). According to preoperative sizing, a 34-mm proximal aortic body (AB3498) and two 20-mm iliac limbs were used (IL2010, bilaterally).

Final angiography showed AAA exclusion with normal patency of the endograft, visceral arteries, and access vessels.
access vessels without signs of endoleak or limb kinking (Figure 7). Successful percutaneous hemostasis was obtained on both sides (Figure 8) by tightening the predeployed polypropylene sutures of the ProGlide closure system, and the patient was transferred directly to the ward. After 6 hours, a duplex ultrasound evaluation of the aorta and access vessels revealed the regular AAA exclusion with normal patency of both CFAs in absence of active bleeding, hematoma, or stenosis. The patient was therefore allowed to ambulate and was discharged in good health on the second postoperative day. A routine 30-day CT angiogram confirmed persistent clinical success of the PEVAR procedure concerning aneurysm exclusion and access vessel management (Figure 9).

DISCUSSION

This case clearly underlines the utility of PEVAR even in more challenging CFA anatomies, such as an obese patient. From a surgical point of view, it is well recognized that these patients, in cases of femoral cutdown, are at increased risk of wound complications, including lymphocele, infection, and dehiscence. On the other hand, obesity has long been considered a risk factor for technical failure of percutaneous access as well. However, conflicting data are reported in the literature on this issue, and more recent experiences do not confirm this observation anymore.

In our unit, decision making for access vessel modality in obese patients is part of a multifactorial approach to the disease. First of all, we perform an accurate evaluation of the inguinal region and CFA’s preoperative anatomy. We look at CFA diameter, level of the CFA bifurcation, and presence of calcification; when more than one of the previous factors is observed, we contraindicate the use of PEVAR. Endograft selection is finalized to confirm EVAR feasibility using a low-profile endograft. In fact, in obese patients, we routinely use ultra-low-profile endografts with 14- to 15-F outer-diameter delivery systems that allow for preimplantation of just one single ProGlide. By avoiding the need for multiple femoral accesses and sheath exchanges, it is possible to additionally reduce the risk of PEVAR technical failure. Finally, ultrasound-guided access is mandatory in all obese patients in order to perform a correct femoral puncture, which is well recognized as the strongest predictor for a successfully percutaneous procedure.

In conclusion, PEVAR is a safe and effective procedure and can be used with high technical success rates even in the presence of more demanding anatomy only if an accurate multifactorial evaluation of pre-, intra-, and postoperative factors is performed.