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CLINICAL MANAGEMENT

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The PIGTAIL paradigm for a fast and safe transfemoral transcatheter aortic valve replacement

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Abstract

Transfemoral transcatheter aortic valve replacement is the preferred primary access route whenever possible. Despite advancements in expertise and delivery system profiles, complications associated with the primary femoral access still significantly affect procedural morbidity and outcomes. The current standard for accurate main access planning involves proper preprocedural evaluation guided by computed tomography. Several baseline clinical and anatomical features serve as predictors for the risk of vascular injury occurring during or after transcatheter aortic valve replacement. In this paper, we aimed at reviewing the most up-to-date knowledge of the topic for a safe transfemoral access approach according to a paradigm we have called "PIGTAIL."

KEYWORDS

aortic valve disease, percutaneous intervention, transcatheter valve implantation, vascular access complications

1 | INTRODUCTION

Transfemoral transcatheter aortic valve replacement (TF-transcatheter aortic valve implantation [TAVR]) has become a well-established but continuously evolving technique to treat high to intermediate risk as well as elderly low risk patients presenting with severe symptomatic aortic stenosis (AS). A further rise in the number of procedures is expected in the near future, largely propelled by the favorable outcomes observed in randomized clinical trials exploring the feasibility and efficacy of the procedure also in younger low-risk patients.[1,2] Additionally, advancements in operators' expertise and refinements of the latest generation devices contribute to this growth.

Nevertheless, vascular complications (VCs), categorized as major or minor according to the Valve Academic Consortium-3 (VARC-3) definitions[3] along with life-threatening bleedings, still have a major impact on procedural outcomes, in terms of morbidity, mortality, length of hospital stay, blood transfusion requirements and overall quality of life.

The reported incidence of major VCs falls between 5% and 23.3%, while minor VCs are reported within a range of 5.6%–28.6%[4,5]; in the cited studies both VARC-1[4,6] and VARC-2[5,7] definitions were used as a reference; then a positive trend toward reduction, achieved through the implementation of third-generation devices, was observed in the past few years, according to VARC-2 definition.[8]

The successful implementation of preclosure techniques, primarily utilizing suture-mediated vascular closure devices (VCDs), originally employed to close large arteriotomy in endovascular aneurysm repair,[9] has led to widespread adoption of VCDs to perform truly percutaneous TF-TAVRs[10] without the need for surgical cut-down.

Federico De Marco and Maurizio Taramasso share the same contribution for this study.

Thus, in the current era, the majority of access-related injuries stem from various degrees of VCDs failure and/or an inappropriate preoperative evaluation of patient' vascular risk.

2 | ARTERIAL ACCESS CLOSURE

Fully percutaneous femoral accesses require an efficient mechanism to achieve hemostasis at the access site. Manual compression for femoral arterial vascular accesses remains a good method for achieving that, but it is clearly uncomfortable for both patient and caregiver, and, most importantly, it is not applicable to larger-bore TAVR devices. This is the reason why VCDs have been introduced. The primary aim of VCDs is to minimize bleeding time by directly acting at the arterial puncture site, reducing VCs after the procedures and also to enable earlier ambulation improving comfort of the patient.[11,12] Currently, several access closure systems are available. The distinction is made according to the type of mechanism used to achieve hemostasis: there are collagen-based VCDs – most importantly AngioSeal (St. Jude Medical), MANTA (Teleflex) – or suture mediated closure devices, such as Perclose Prostar (Abbott Vascular), Perclose AT (Abbott Vascular), Perclose ProGlide (Abbott Vascular) or its latest iteration, ProStyle (Abbott Vascular).

As far as vascular closing devices are concerned, we hereby present a brief overview of the most commonly used tools in routine clinical practice (summarized in Figure 1).

It is noteworthy to highlight recent evidence that compares vascular access-related complications rate between pure plug-based and suture-based VCDs. These findings have revealed that, even if observational studies appear to favor plug-based devices, notably MANTA, randomized clinical trials lean toward suture-based devices.[13,14] However, it is common practice to use a combination of both methods for challenging vascular accesses. For instance, two suture-based devices are typically knotted perpendicularly to initially close the artery. If residual access leaks persist, a plug-based device, such as AngioSeal, is often employed to definitively close the artery.

2.1 | AngioSeal

AngioSeal is a passive approximator collagen-based closure device that displays a closure mechanism based on the placement of a hemostatic

MAIN VASCULAR ACCESSES CLOSING DEVICES

DEVICE	COMPANY	CLOSING METHOD	SHEATH SIZE	DEVICE IMAGE
ANGIOSEAL	Abbott Vascular	Collagen plug and anchor	6F and 8F	
MANTA	Teleflex	Collagen plug and anchor	14F and 18F	
PROSTAR XL	Abbott Vascular	Braided suture	10F	
PROGLIDE	Abbott Vascular	Monofilament suture	8F	
PROSTYLE	Abbott Vascular	Monofilament suture	8F	
STARCLOSE	Abbott Vascular	Nitinol Clip	5F and 6F	

FIGURE 1 Summary of the main vascular closing devices currently in use. [Color figure can be viewed at wileyonlinelibrary.com]

(collagen) plug outside the artery held in place by a suture that holds together a small, molded polymer toggle positioned inside the artery, accurately deploying the collagen plug over the arteriotomy site.[11] The AngioSeal has been approved to close arteriotomy sites up to 8F. The use of this device has been associated with a higher incidence of pseudoaneurysms than sutured-based devices.[15] The introduction of the AngioSeal as a method of femoral access closure has not provided a great advantage in terms of decreased VCs compared with manual compression; however, it has certainly been shown to increase patient comfort achieving faster hemostasis, shorter bedding time, and quicker recovery and discharge.[16] Importantly, it can be used together with suture-mediated devices to optimize vascular accesses' closure when residual bleeding is present.

2.2 | MANTA

The MANTA VCD is a collagen plug-based device dedicated for large bore arteriotomy closure.[17] It consists of a delivery system and an implantable closing unit which comprises a bioresorbable toggle inside the vessel and a hemostatic bovine collagen plug outside the vessel. Two recent randomized controlled clinical trials compared the performance of the MANTA device with respect to ProGlide. Despite device failure was observed less frequently in the plug-based closure group with respect to the suture-based device, which instead required more often the use of additional closure devices, MANTA was associated with a higher incidence of access-site and access-related VCs and a higher rate of implanted covered stents and surgical bailouts.[14,18] The advantage of the MANTA device, described as an “easy to use” device, is the rapid learning curve, at the cost of a higher economic burden.

2.3 | StarClose

The StarClose SE device (Abbott Vascular) is an active approximator that deploys a 4-mm extravascular nitinol clip over the arteriotomy site, and it has been approved to close 5F to 6F arteriotomy sites.

2.4 | ProGlide or ProStyle

As far as suture mediated systems are concerned, one of the most widely used devices is the Perclose ProGlide which is a 6F suture based hemostatic device using polypropylene sutures. It is an active approximator that percutaneously deploys a suture on both sides of the arteriotomy working on the principle of a pretied slip knot which is percutaneously delivered at the site of arteriotomy to close the access site.[11] It has been approved to close 5F to 21F arteriotomy sites. Before their availment, a control sweep is always carried out to assess any calcifications and patency of the vessel. The closure system offers greater ease of knot placement due to the polypropylene suture's higher tensile strength.[19] There are some patients in whom the use of these devices is not recommended, such as in cases of small femoral arteries (<5 mm), access site above the inferior border of the inferior epigastric artery (IEA), in case visible vessels' calcifications are present at fluoroscopy, in particular if the calcific plaque is present on the femoral artery for more than >50% of the circumference. Difficulties in the deployment of this type of device occur when BMI > 30 kg/m^2, when calcifications at the level of the vessel wall are present, and when there is a deep puncture site. Specifically, challenges arise with thick subcutaneous tissue in the groin, hindering smooth advancement of the knot toward the arterial wound and potentially leading to slackening of the knots.[20]

2.5 | ProStar

The ProStar suture-based closure system can be considered as the ProGlide system's progenitor. The deployment mechanism of the ProStar suture-based closure system is intricate, and the use of a braided suture may potentially increase the risk of infection at the access site. All these aspects have been improved in the ProGlide system. Several studies have shown a better performance of the ProGlide device, with a significantly greater reduction of the composite endpoint of cardiovascular mortality, bleeding and VCs at 30 days together with a higher procedural success with ProGlide as compared to ProStar XL.[17]

Despite significant differences in the design and functioning of the two classes of devices (plug-based vs. suture-based), they have maintained very similar rates of complications in the past few years. Age, female gender, severity of calcification or peripheral vascular disease (PVD), increased sheath size, higher sheath-to-femoral artery ratio (SFAR), depth of arteriotomy site, and femoral artery size have been shown to predict worse vascular outcomes with both VCDs types.[17] The presence of calcifications at the level of the artery can lead to the failure of the closure system for both; suture-based due to suture laceration or incomplete apposition of the excessively calcified wall flaps, while for collagen-based there can be the failure of the toggle-plug placement due to the presence of calcium on the arterial wall.

In summary, due to lack of strong evidence of absolute better performance of a VCD, the standard of treatment is mainly based on anatomical characteristics, operators or center's preferences and eventually on the economic burden.

Regarding the use of heparin reversal agents (such as Protamine), their role in reducing bleeding complications rates without increasing thrombotic risk remains unclear, and there are no precise indications on this topic. In general, protamine administration (typically just before vascular access closure) may be considered[21,22] as it has been associated with fewer life-threatening bleedings without increasing the thrombotic risk.[23]

3 | THE PIGTAIL PARADIGM

While ideal femoral accesses exist and are desirable for every interventional cardiologist (Figure 2), the reality is that the majority of cases presents challenges that must be carefully addressed and overcome.

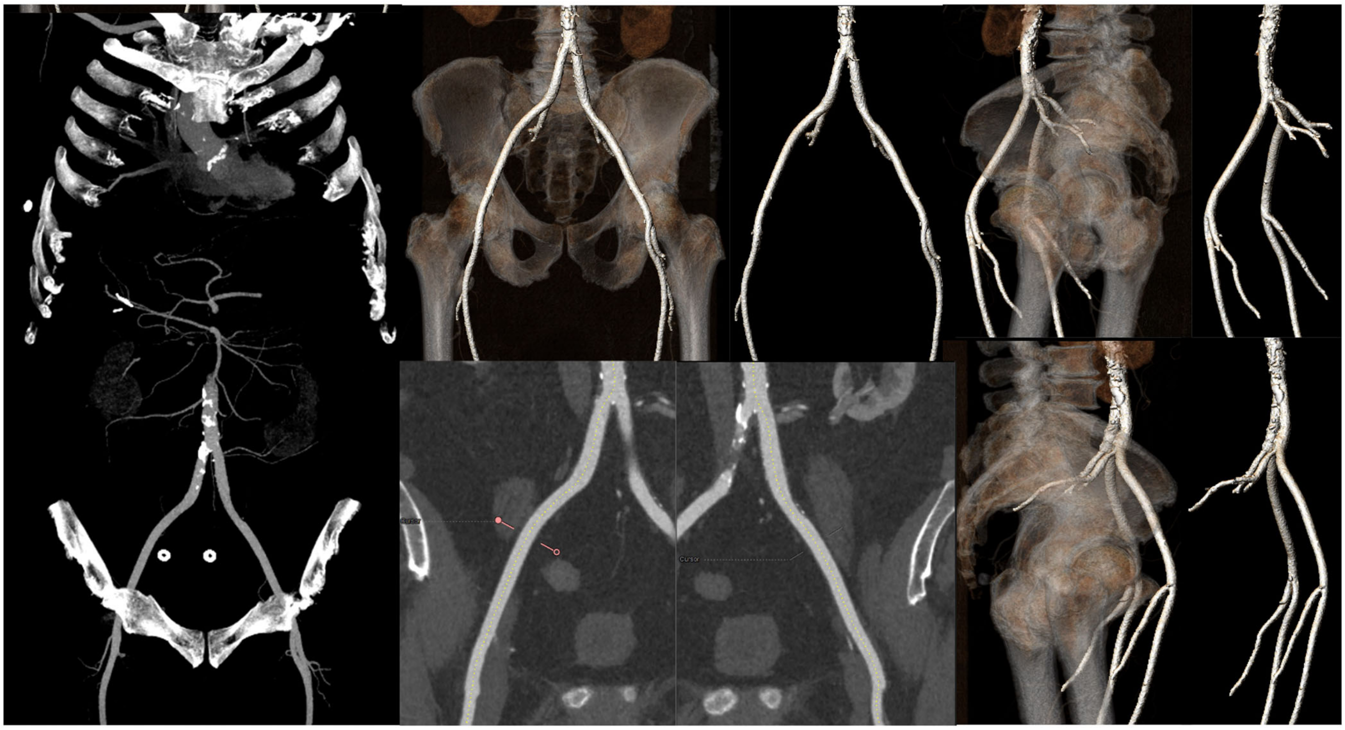


FIGURE 2 Computed tomography maximum intensity projection (MIP) and 3D reconstruction of a patient presenting with ideal straight accesses without calcifications nor tortuosity. [Color figure can be viewed at wileyonlinelibrary.com]

Given this background, to facilitate a proper preoperative analysis and intraprocedural management of the main femoral access we have developed what we have called *the PIGTAIL paradigm* (summarized in Figure 3). The acronym PIGTAIL stands for:

P = Profunda (femoral bifurcation) location

I = IEA location

G = Graft puncture (if present)

T = Tortuosity

A = Arterial diameter

IL = Inner Layer calcifications

If what will be discussed in the forthcoming discussion remains applicable to both the primary and secondary accesses during TAVR procedures, numerous medical centers have recently transitioned toward a less intrusive methodology concerning the chosen secondary access for most of the procedures. Specifically, the adoption of radial access has garnered favor due to its capacity to obviate the necessity for a dual femoral puncture, and typically both right and left radial arterial accesses can be employed depending on patients' and aortic arch characteristics and/or operators' preferences and expertise. Moreover, this approach facilitates earlier patient ambulation, in part attributable to diminished incidence of VCs. Noteworthy advantages encompass the ability to execute balloon angioplasty in the event of complications arising from the primary access (long-shaft peripheral covered stents deployable through radial access are still being developed). Furthermore, the utilization of radial access provides operators with a greater flexibility in selecting the side for the primary access without necessitating a secondary contralateral femoral puncture.

Nevertheless, it is imperative to acknowledge that a radial secondary access introduces certain limitations that warrant consideration. In fact, in instances where the probability of VCs is heightened, opting for a second femoral access becomes a judicious choice, offering a safer procedural course, simplified crossover, and possibility of covered-stent deployment.

As far as the evaluation of the vascular accesses-associated risk is concerned, multislice computed tomography (MSCT) currently represents the gold standard for an accurate preprocedural TAVR planning by virtue of a wide evidence-based literature on the topic.[24] The main advantages belonging to preprocedural MSCT, allowing a precise vascular injury risk estimation, are as follows: accurate vessels study (diameters, tortuosity, amount al extent of calcifications, etc.), volume-rendering reconstruction capability and sufficient planning capability even in noncontrast enhanced CT setting.[25] With this tool, several anatomical and clinical features could be accurately estimated to optimize access management. The aim of this paper is to review the preprocedural planning and the intra-procedural management of the femoral access for TAVR incorporating evidence-based references and practical insights derived from field experience. In the subsequent discussion, we present an in-depth evaluation looking into the characteristics of the PIGTAIL vessels' characteristics, offering different strategies to mitigate the likelihood of dreaded VCs as much as feasibly possible.

MINIMALLY-INVASIVE VASCULAR ACCESSES MANAGEMENT

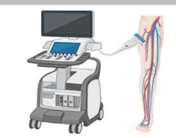
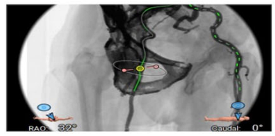
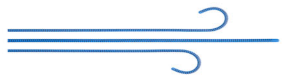
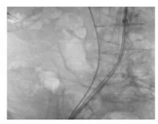
PROLEM (PIGTAIL)	Aim	Solution	Technique hardware
Profunda femoral artery location	Perform an appropriate puncture in the best place to be compressed	Fluoroscopy coupled with ultrasound-guided puncture	
Inferior epigastric artery location	Avoid the catastrophic puncture of inferior epigastric artery (IEA)	Contralateral guided road mapping in case pre-procedural CT shows dangerous features (i.e. large-curved and deep IEA)	
Graft puncture (if present)	Ways to perform an effective graft puncture	Direct puncture of an aorto-bifemoral bypass graft coupled with progressive dilatation over the wire[b]	
Tortuosity	To straighten the vessel in order to allow both an easier procedure and to avoid vascular complications	Long, flexible and hydrophilic delivery sheaths (i.e. Gore DrySeal)	
		Extra-stiff guidewire (i.e. the Lunderquist R Extra Stiff, Amplatz Ultra Stiff, Back-up MeierTM)	
		Double stiff wire approach (Buddy wire technique)	
Arterial diameter	To avoid possible traumatism and vascular complications caused by the large bore sheaths and delivery systems	Low-profile design sheats	
Inner Layer calcifications	To avoid potential vascular complications	Long, flexible and hydrophilic delivery sheaths (i.e. Gore DrySeal)	
		Balloon angioplasty	
		Intravascular litothripsy	
		Orbital Atherectomy	

FIGURE 3 Brief overview of the PIGTAIL paradigm with the possible management strategies. [Color figure can be viewed at wileyonlinelibrary.com]

3.1 | Profunda (femoral bifurcation) location

The identification of the profunda and in general of the common femoral artery (CFA) bifurcation is of pivotal importance when panning a percutaneous TF-TAVR procedure. Although the superficial femoral artery may be a feasible option in selected patients,[26] the CFA is classically the main and preferred route, normally being larger and easily palpable. We propose a fluoroscopic-based classification of the bifurcation height relative to the femoral head: *type I* if it lies from the infra-inguinal region to midpoint of the femoral head bone, *type II* when the bifurcation is between the mid-portion of the femoral head and its lower contour, and finally *type III* low bifurcations below the distal cortical edge of the femoral head.

Type I bifurcations are recognized as risk factors for postoperative VCs, due to the short infra-ligament segment of the CFA. Fluoroscopic or ultrasound-guided (or both) cannulation of CFA may offer significant value in ensuring safe access.[27–35]

The use of fluoroscopy is a fundamental tool in interventional procedures, with the femoral head commonly serving as a key landmark for puncture. The classical technique involves accessing the CFA below the inguinal ligament, typically at the mid to distal portion femoral head height, with or without road mapping.[36] Performing the puncture in this site is essential due to the hemostatic assistance offered by the vessel compression against the rigid bone.

In recent years, an ultrasound-based method has gained popularity due to its simplicity (after adequate training), effectiveness in determining the anatomical relationships and capability to identify the exact location of femoral artery calcifications.[27,28] Normally a micro puncture, or a standard 18-gauge needle is advanced under ultrasound guidance, either longitudinally or transversely, to achieve precise anterior-wall puncture. Numerous studies have investigated the efficacy of ultrasound-guidance for femoral access.[29–31] The largest trial, the FAUST study,[29] a prospective, multicenter, randomized clinical study comparing ultrasound-guided versus fluoroscopy-guided femoral accesses, clearly demonstrated the advantages of the former method. It showed improved success rates in cannulating patients with high CFA bifurcations, reduced number of attempts, enhanced venipuncture, and notably, lower rates of VCs. The benefit of US-guided technique was confirmed in a subsequent meta-analysis as well.[32] Numerous observational studies have investigated this issue too. A recent meta-analysis including eight of the most impactful studies on this topic with a total of 3875 patients concluded that gaining femoral access through an ultrasound-guided technique was associated with lower rates of total, major, and minor VCs.[33]

A mixed fluoro-ultrasound guidance has been also described[34] indeed, the CFA bifurcation was found to be at or below the center of the femoral head in 98.5% of cases in a consecutive series of 200 patients,[35] proving the usefulness of fluoroscopy (together with femoral angiography). The combination of these two techniques leverages the strengths of each, rather than depending solely on one method.[28] This is why it is currently implemented in numerous medical centers.

Upon completion of the procedure, it is crucial to conduct an angiographic evaluation of the femoral access using digital subtraction angiography. This enables the detection of potential complications that can be effectively tackled percutaneously. Additionally, prompt angiographic assessment facilitates early mobilization and discharge of the patient, which has been correlated with improved outcomes.[37]

3.2 | IEA location

Locating the IEA is crucial to prevent puncture-related bleedings that could end up in catastrophic retroperitoneal hemorrhage. The IEA, a distal continuation of the internal mammary or thoracic artery, courses laterally to the rectus abdominal muscle and terminates at the level of the external iliac artery, within the peritoneal space above the inguinal ligament.

As it enters the external iliac system, it generally makes a "U" turn, with the lower curvature near the inguinal ligament. A too highly located puncture may transfix the IEA at this level, causing massive bleeding complication. To mitigate this risk, it is advisable to perform the puncture at the inguinal fold, as the recommended needle-to-skin angle for cannulation is 45°.

In cases where the preoperative CT reveals large-curved and deep IEA, a contralateral guided road mapping is advisable to prevent an unwanted damage to this artery. This "hybrid" approach, with respect to sole echo-guided puncture, can improve access' safety in this setting.[38]

3.3 | Graft puncture (if present)

Given the significant overlap in risk factors between calcific AS and PVD, it is not uncommon to handle TAVR patients who had previously undergone open or endovascular peripheral vascular interventions. Percutaneous management of vascular grafts or stent-grafts may be challenging. When alternative access routes beyond femoral ones are not viable, an accurate access management becomes mandatory. Classically, this was achieved by either cannulation of CFA distal to the graft (when feasible) or by surgical cut-down.[39]

Currently, moving toward a less invasive percutaneous approach, the use of VCDs is becoming appealing, even when dealing with femoral prosthesis.[40]

We do not recommend this approach if a femoral stent-graft is in situ. In case of a classical Dacron graft, the standard preclosing technique with suture-mediated VCDs works on many occasions; if needed, an adjunctive plug-based device could optimize the hemostasis. As it has been previously described in the literature, the use of Perclose (Abbott Vascular) can be a viable option for achieving hemostasis after a direct puncture of an aorto-bifemoral bypass graft during transfemoral TAVR.[41]

Since the Dacron material is quite hypo-elastic, a progressive dilatation over the wire is needed; we suggest proceeding until a dilation <1–2 Fr of the TAVR introducer sheath's outer diameter is reached.

A good pragmatic trick in selected cases is a direct cannulation below the distal anastomosis. In this way, a medium contrast injection could guide the operator to the correct point of prosthesis puncture.

3.4 | Tortuosity

Vessel tortuosity presents a significant obstacle to the success of a transfemoral TAVR and, in extreme cases, is associated with heightened risks of VCs including dissection, rupture and life-threatening bleeding. For these reasons effective management of tortuous access routes is imperative to mitigate these risks and circumvent the need for alternative approaches (i.e., the transapical one).[24]

As there are no predefined cut-offs for prohibitive vessel tortuosity, the optimal access strategy should be established on a case-by-case basis, remaining heavily reliant on the expertise of the operator. Given the aforementioned risks associated with vessels' tortuosity, thorough pre-and postprocedural assessment including CT, aortography and/or ultrasound is required. One potentially useful metric is the measurement of the angulation between the external iliac and common iliac arteries; an angle <90° may indicate challenges with femoral access route suitability. This is a direct data of the tortuosity of femoral access. Examples of tortuous accesses are provided in Figure 4, Supporting Information: Videos 1 and 2.

Another important predictive score related to periprocedural access complications and bleeding complications after TAVR is represented by the iliofemoral tortuosity score, that effectively identifies patient at risk when it is greater than 21.2. It is represented by the measurement of the length of the curved vascular centerline (true vessel length) divided by the direct distance between the two reference points (ideal vessel length) at each side. It can be calculated using the following formula[42]:

$$\text{IFT} = \left(\frac{\text{True vessel length}}{\text{Ideal vessel length}} - 1\right) \times 100.$$

In case of pronounced tortuosity of the iliofemoral arteries or the aorta (including an S-shaped aorta), an extra-stiff guidewire, such as the Lunderquist R Extra Stiff, Amplatz Ultra Stiff (Cook Medical) or Back-up MeierTM (Boston Scientific) may be employed to straighten the aorto-ilio-femoral axis.[43]

In these cases, the use of a long introducer sheath on a stiff wire allows for a safe TF access. In extreme scenarios, a double stiff wire approach, commonly referred to as the "buddy wire technique" (Figure 5), can help to overcome extreme tortuosity by increasing the support for the valve delivery system and facilitating its advancement without the occurrence of wedging or prolapse.[44]

An effective strategy that could be helpful to tackle the challenges posed by vessel tortuosity is the utilization Gore DrySeal sheaths (Figure 6, Supporting Information: Videos 3 and 4). These sheaths are specifically designed to navigate tortuous anatomies with ease, offering improved flexibility and trackability compared to traditional sheaths. Its effectiveness in these scenarios stems from the ability to expand and straighten 25–35 cm of vasculature

FIGURE 4 Computed tomography 3D reconstruction of a patient presenting with severe accesses' tortuosity. [Color figure can be viewed at wileyonlinelibrary.com]

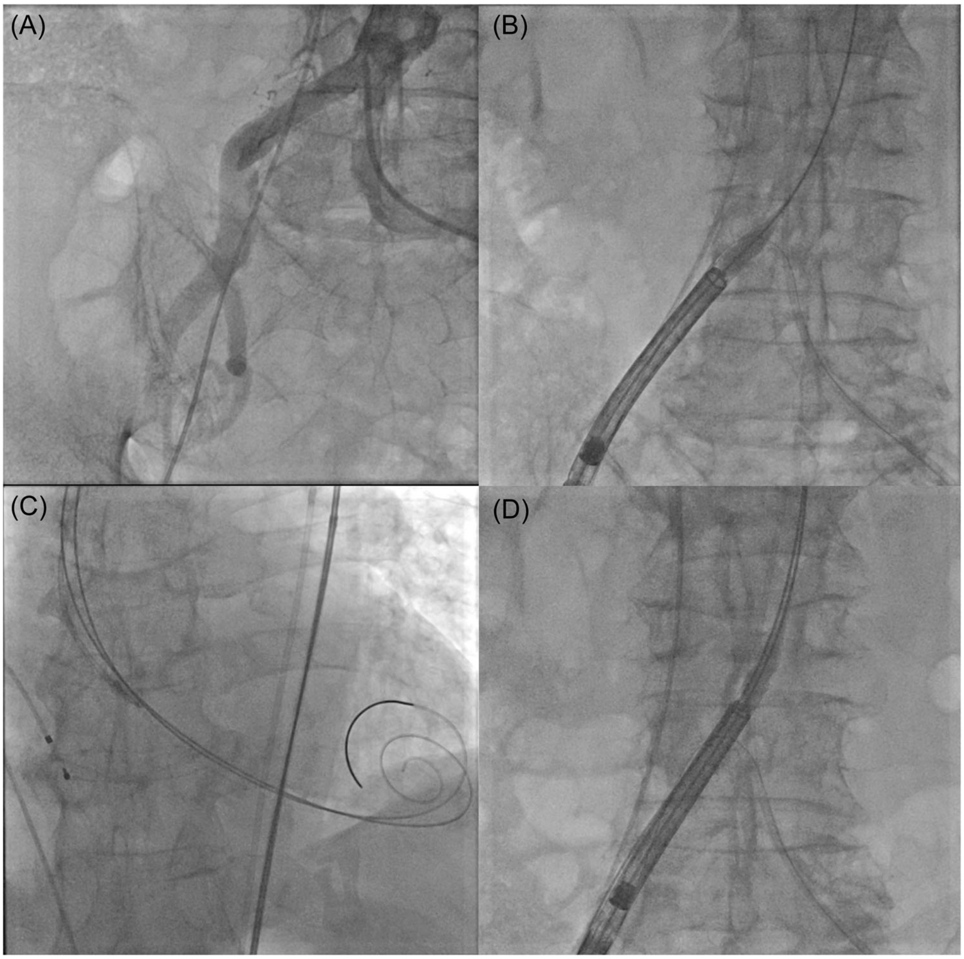


FIGURE 5 (A) Angiography showing tortouous and calcified accesses; (B) careful advancement of the equipment halted by the anatomical complexity; (C) second extrastiff wire advanced up to the left ventricle; (D) safer and easier equipment advancement.

proximal to the arterial insertion site, and navigation in tortuous vasculature is facilitated by the sheath's malleable structure and hydrophilic coating, allowing for a minimal endothelial trauma.[45]

3.5 | Arterial diameter

The diameter of the femoral and iliac vessels is pivotal to determine the appropriate approach for performing transfemoral TAVR. Alternative approaches (transapical, transaortic, trans-subclavian, or retroperitoneal) should be considered in patients with borderline femoral artery diameters (6.0–6.5 mm) following careful vascular screening with selective iliofemoral angiography, or if possible, MSCT.[46] Presence of calcifications necessitates careful consideration of the minimal luminal area in the calcified vessel section to prevent potential catastrophic complications. Access-management becomes particularly challenging when calcifications encircle the artery for over 180° and when they coincide with acute-angle tortuosities. A dedicated section on calcification follows in the subsequent part of the manuscript.

As far as VCs after TAVR are concerned, vessel's diameter assessment by contrast CT provides greater predictive value than angiography (Figure 7). This finding suggests that access route selection should be based, if possible on the contrast-CT assessment with three-dimensional reconstruction, to best determine the luminal diameter and possible anatomical challenges.[24,47]

Minimal vessel dimensions required for successful transfemoral access largely depend on the delivery system and the size of the chosen transcatheter heart valve (THV). Using contemporary low-profile sheath designs, the minimal vessel diameter may be as low as 5.0 mm (Medtronic Evolut FX system when using Model ENVEOR-U – Medtronic) and 5.5 mm (14F eSheath; Edwards Lifesciences). With the integrated sheath of the novel FlexNav delivery system (FlexNavTM DS) of the Navitor (Abbott Vascular) THV system, the insertion diameter is quite similar as that of the Evolut R system, allowing a TF access as small as 5.0 mm vessels.[43]

To use a predictor of vascular access complications, it is useful to calculate the SFAR, defined as the ratio of the outer diameter of the sheath (in millimeters) and the smallest iliofemoral lumen diameter (in millimeters). SFAR has been demonstrated to be a valid criterion for TF-TAVR eligibility and values ≥1.05 were identified as univariable predictors of VCs occurrence.[48]

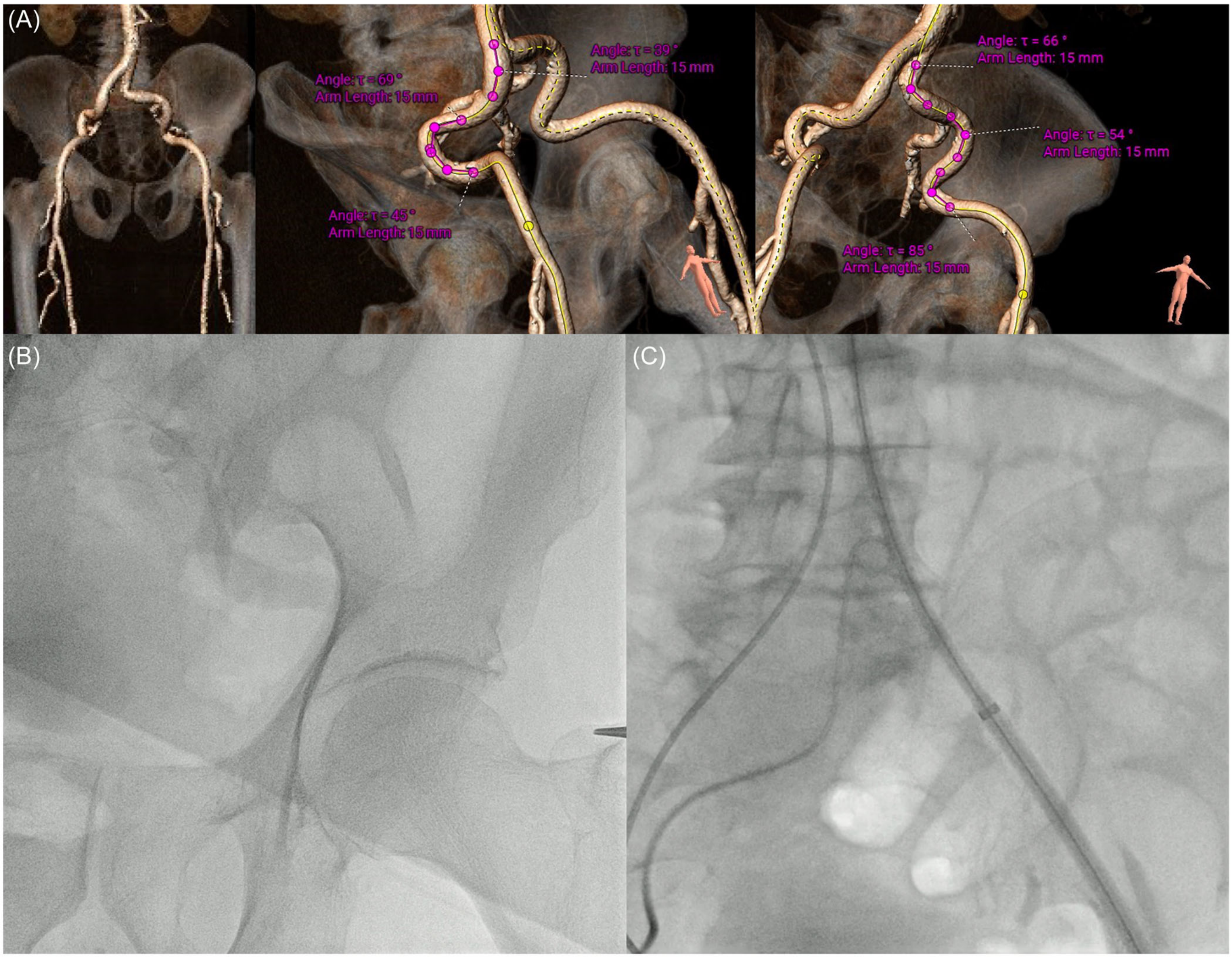


FIGURE 6 (A) Computed tomography 3D reconstruction of a patient presenting with severe accesses' tortuosity and measurement of tortuosity angle; (B) tortuosity by angiography of the left iliac-common femoral artery; (C) Gore DrySeal advancement safely straightens the tortuosity. [Color figure can be viewed at wileyonlinelibrary.com]

3.6 | Inner layer calcifications

As previously mentioned, peripheral artery disease (PAD) is frequently found in patients eligible for TAVR, as both entities share common cardiovascular risk factors such as age, smoking, hypertension, diabetes, and chronic kidney disease. PAD is associated with increased mortality, bleeding complications and readmission rates after TAVR.[49] In most of the studies, the presence of circumferential iliofemoral calcifications (not just spotting calcifications) are an important risk factor for VCs and also an independent predictor of increased mortality after TF-TAVR. This is of particular interest in patients with a high calcium burden, as the risk for major VCs is significantly increased.

In addition, anterior, posterior and, especially, circumferential calcification of the femoral artery reduce the efficacy of percutaneous suture-based closure devices. Examples of severely calcified accesses are provided in Figures 8 and 9. Strategies such as balloon angioplasty using the contralateral femoral artery or radial artery as well as intravascular lithotripsy have been suggested to expand TF access in patients with significant PAD. Intravascular lithotripsy is particularly effective when circumferential calcifications are present, whereas it is less indicated if vessels' lumen reduction is secondary to eccentric calcifications. For this purpose, orbital atherectomy (OA) can be of value as it effectively tackles noncircumferential calcifications. OA is composed of a solid, diamond-coated, 2 mm crown for a maximal calcium plaque removal; it targets vessels of 5–10 mm of diameter, the shaft length is 145 cm and has a 6F introducer sheath. However, drawbacks include the inability to target medial vessels' calcifications, the need of a specific guidewire (Viper wire™), a longer learning curve and procedural time (details are provided in Figure 10). Alternatively, surgical femoral cut-down with or without surgical endarterectomy may be used for heavily calcified and tortuous peripheral vessels as it allows for direct visualization of the arterial access site and surgical vessel repair, if needed. However, there is a lack of sufficient data to promote this approach.[43]

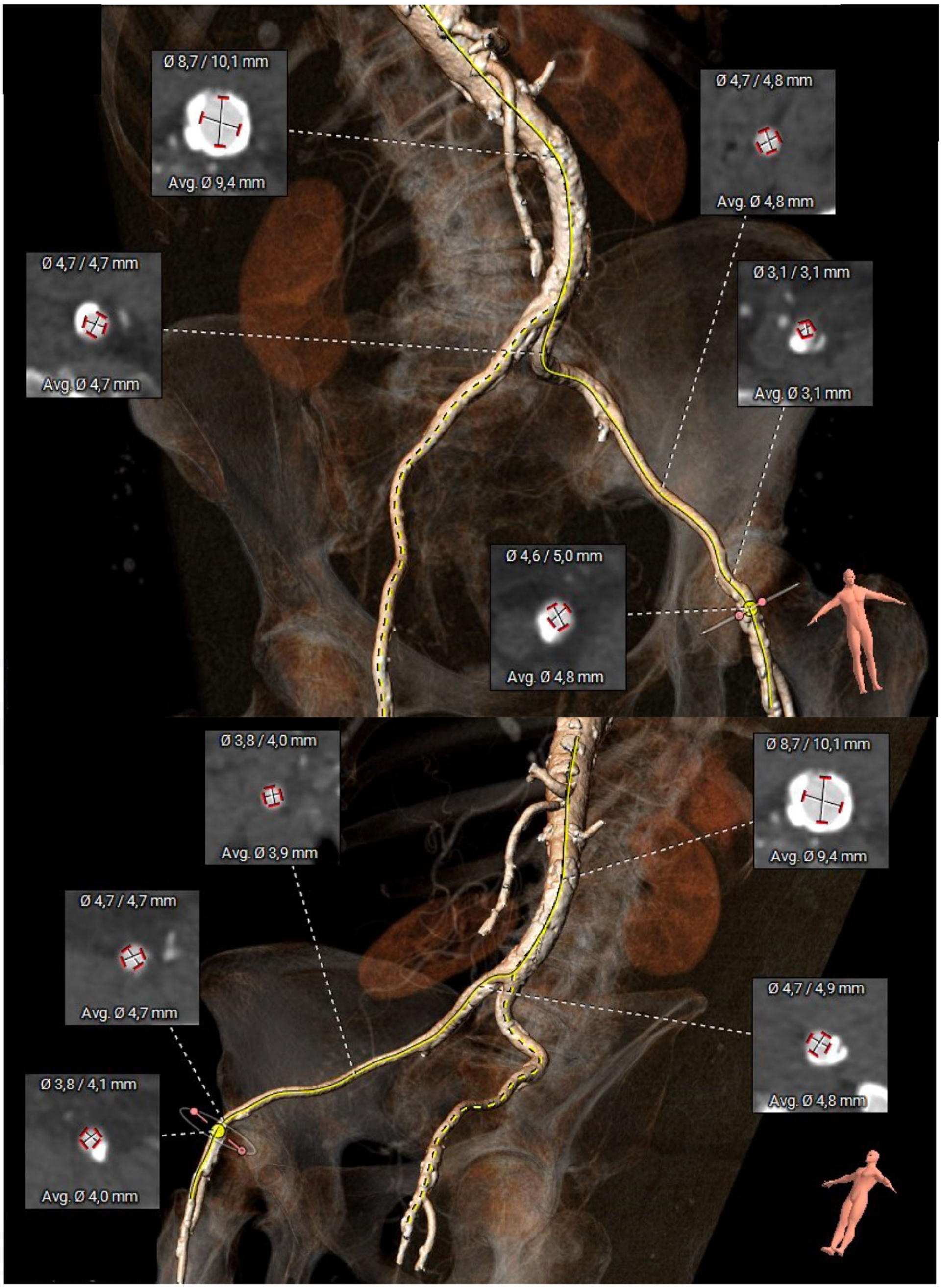


FIGURE 7 Computed tomography 3D reconstruction of a patient presenting with small accesses with vessels' diameters. [Color figure can be viewed at wileyonlinelibrary.com]

4 | BAILOUT STRATEGIES IN VASCULAR ACCESS COMPLICATIONS DURING TAVR

Despite the increasing use of smaller diameter and innovative introducer sheaths, a more accurate preprocedural planning and echo-guided femoral artery puncture, minor and major VCs still remain one of the most common adverse events occurring during TAVR.[50] Iliac dissection, rupture, or avulsion represent rare but often fatal subgroup VCs that could ensue during TAVR, especially when dealing with the complex anatomies that were previously described. When these complications occur, they must be promptly tackled through endovascular and/or surgical bailout strategies or a combination of both of them.

Fluoroscopy, with digital subtraction analysis, is usually enough to detect vascular accesses' complications when patient's clinical conditions raise the suspicion.

When an access-related complication is detected, a possible strategy could be to perform a cross-over balloon technique from the accessory arterial access (contralateral femoral or radial access) to inflate a slightly oversized balloon just proximal to the

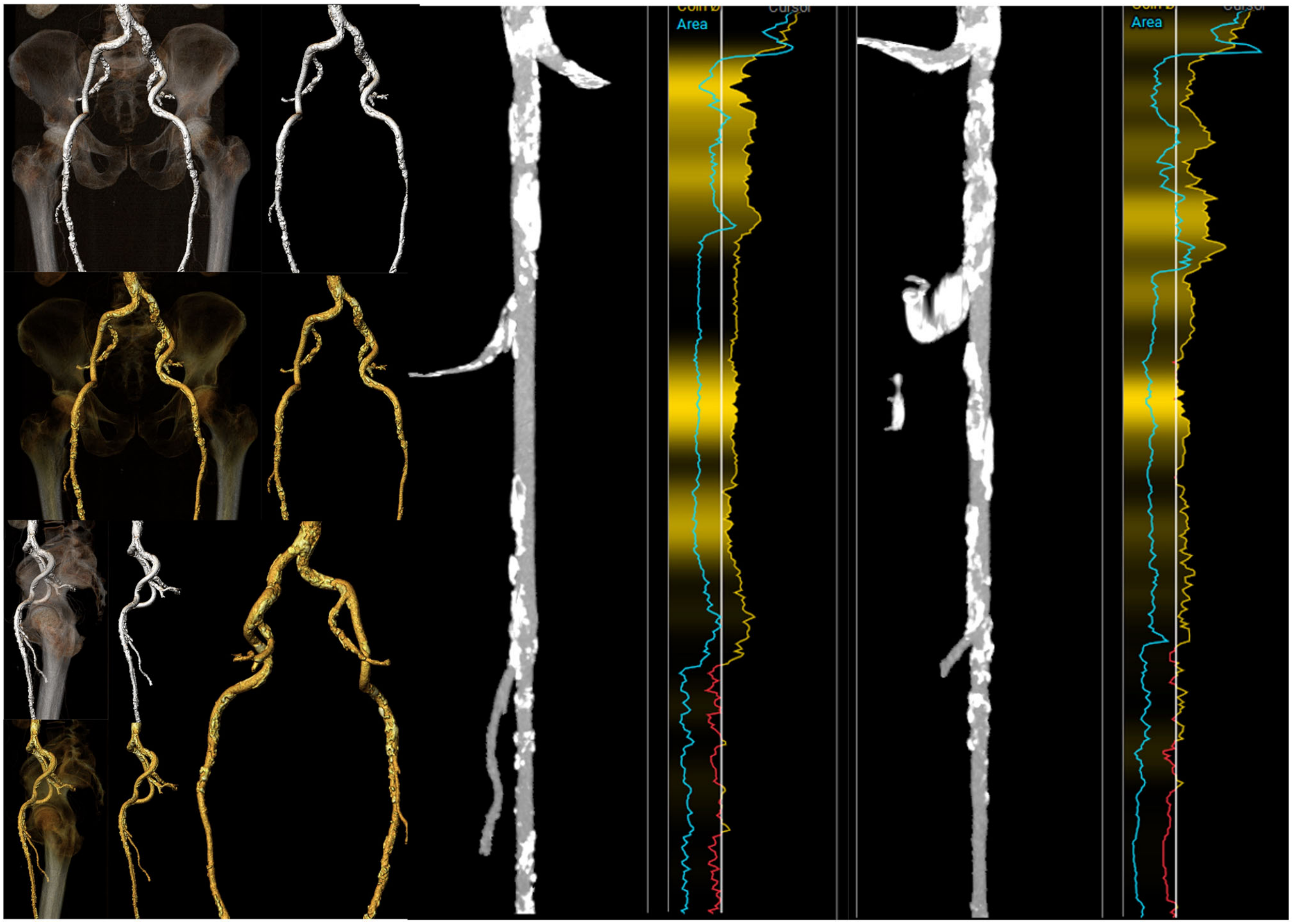


FIGURE 8 Computed tomography 3D reconstruction and snake views of a patient presenting with severely calcified femoral accesses. [Color figure can be viewed at wileyonlinelibrary.com]

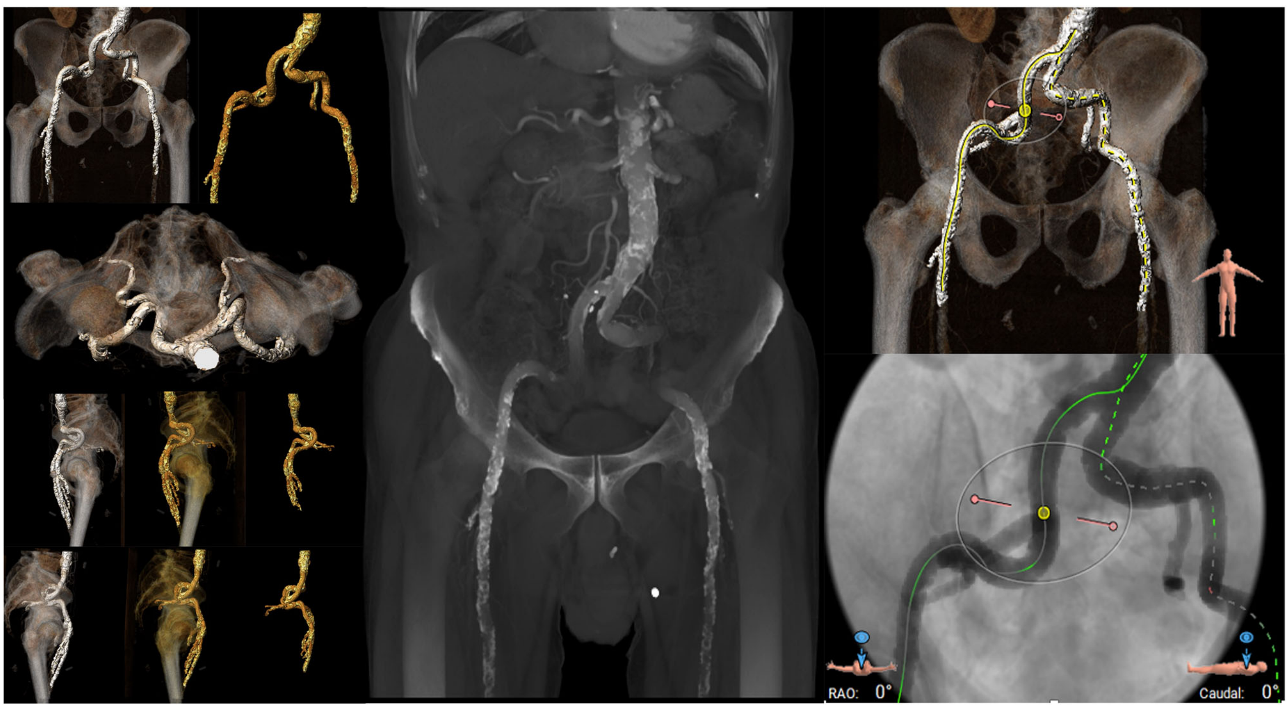


FIGURE 9 Computed tomography 3D reconstruction of a patient presenting with severely calcified and tortuous femoral accesses. [Color figure can be viewed at wileyonlinelibrary.com]

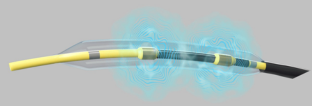
Technologies tackling peripheral accesses' calcifications in preparation to TF-TAVR		
	Intravascular lithotripsy 	Orbital Atherectomy 
Debulcking mechanism	Calcium Fracturing	Calcium sanding + Fracturing
Type of calcifications - Efficacy		
• **Concentric calcifications**	++	++
• **Eccentric calcifications**	+/-	++
• **Intimal/intraluminal calcifications**	++	++
• **Medial calcifications**	++	-
Target vessel diameter	Up to 8 mm	5mm - 10 mm
Sheath compatibility	7F	6F
Wire	0.014'' coronary wire	0.014'' – 0.018'' Viper wire™
Post-dilation	Recommended	Recommended
Ease of use/time consumption	High/minimal	Intermediate/moderate

FIGURE 10 Summary and comparison of the different characteristics of intravascular lithotripsy versus orbital atherectomy. [Color figure can be viewed at wileyonlinelibrary.com]

lesion over a "0.018" or "0.035" guide-wire.[51] This allows provisional hemostasis while open surgical repair can be performed safely; at the same time, an oversizing of at least 15% is usually done to avoid endoleaks. When the preprocedural risk of VCs secondary to difficult anatomies is deemed high, cross-over wiring could be a safe preventive measure to shorten the time to bailout intervention in case of necessity.

An additional technique that can be implemented in case of very complex accesses' anatomy is to puncture the superficial femoral artery ipsilaterally and distally to the main access site. This allows to open the stent retrogradely in case of necessity; however, the distal puncture must be sufficiently far from the main access to avoid hampering procedural fine movements.[50]

Ileofemoral avulsion could be addressed through an hybrid technique encompassing hybrid stent grafts placement (i.e., Viabahn – W. L. Gore & Associates) and a subsequent bypass graft technique.[52] However, when it occurs, it is associated with a high degree of morbidity and mortality.

Lacerations can be often treated endovascularly employing peripheral self-expanding covered stents, whereas small and localized dissections can be effectively resolved by prolonged balloon inflation (at least 15 min).

Nevertheless, when facing difficult accesses' anatomies, the involvement of a vascular surgeon early or pre-emptively may be life-saving in case these dangerous complications arise, in which rapid and expert intervention is absolutely necessary.

5 | CONCLUSION

Currently, more than 90% of TAVRs procedures are conducted via transfemoral access. Despite substantial improvements in the operators experience and technical refinements of both delivery catheters (smaller and smaller) and VCDs, VCs and major bleedings persist as the most common procedural complications, exerting a significant impact on outcomes and follow-up care. The prevention of these adverse events remains therefore crucial.

To do so, accurate preoperative assessment referring to the PIGTAIL paradigm alongside meticulous intraoperative management of those vascular characteristics is essential to achieve safer outcomes.

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CONFLICT OF INTEREST STATEMENT

Dr. M. Taramasso has been a consultant for Abbott, Edwards Lifesciences, Boston Scientific, Medtronic, Shenqi Medical, Simulands, MTEx, Occlufit, MEDIRA, VentriMend, and Hi-D Imaging. The remaining authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

As the manuscript belongs to "clinical management" category, a data set was not necessary. Images as well as videos are available at our institution.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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