

## Review

## Tips and tricks in the prevention and management of vascular complications in TAVI



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## ABSTRACT

Transcatheter aortic valve implantation (TAVI) has become a standard treatment for severe aortic stenosis, especially in elderly patients or those considered high-risk for surgery. Despite its increasing success, TAVI still presents challenges, particularly in the management of access site. Advances in procedure planning, device miniaturization and operator experience have mitigated these issues, but vascular complications are still common.

The transfemoral approach is the most common for TAVI, although it varies widely depending on operator experience and center protocols, ranging from surgical to fully percutaneous methods. Minimally invasive techniques are increasingly favored to improve the results of the procedure. Effective management of access site complications is critical and requires careful pre-procedure planning and skilled intervention.

Recent developments in ultrasound-guided access and the refinement of vascular closure devices have shown promise in reducing complications. It has also been shown that radial access as an axillary approach has a lower complication rate compared to contralateral femoral access. The integration of new devices and techniques, such as the less invasive approach, will further improve patient outcomes.

This review emphasizes the importance of a comprehensive, multidisciplinary approach to TAVI and highlights the need for continued innovation and collaboration to further reduce vascular complications and improve the safety and efficacy of the procedure. As TAVI indications expand to younger populations, refinement of access management strategies and incorporation of advanced imaging and predictive tools will be critical to optimizing patient care and outcomes.

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## Consejos y trucos para la prevención y manejo de las complicaciones vasculares en TAVI

## RESUMEN

La implantación de válvula aórtica transcáteter (TAVI) se ha convertido en un tratamiento estándar para la estenosis aórtica severa, especialmente en pacientes ancianos o aquellos considerados de alto riesgo para cirugía. A pesar de su éxito creciente, el TAVI todavía presenta desafíos, particularmente en la gestión del sitio de acceso. Los avances en la planificación del procedimiento, la miniaturización de dispositivos y la experiencia del operador han mitigado estos problemas, pero las complicaciones vasculares siguen siendo comunes.

El abordaje transfemoral es el más común para el TAVI, aunque varía ampliamente dependiendo de la experiencia del operador y los protocolos del centro, que van desde métodos quirúrgicos hasta completamente percutáneos. Las técnicas mínimamente invasivas son cada vez más favorecidas para mejorar los resultados del procedimiento. La gestión efectiva de las complicaciones en el sitio de acceso es crítica y requiere una cuidadosa planificación previa al procedimiento y una intervención hábil.

## Palabras clave:

Implante de válvula aórtica transcáteter

Complicación vascular

Acceso guiado por ultrasonido

Acceso por arteria radial

Equipo cardiovascular

**Abbreviations:** TAVI, transcatheter aortic valve implantation; ESC, European Society of Cardiology; TF, transfemoral; TF-TAVI, transfemoral transcatheter aortic valve implantation; IFT, iliofemoral tortuosity; VARC, Valve Academic Research Consortium; BARC, Bleeding Academic Research Consortium; CTA, computed tomography angiography; CT, computed tomography; US, ultrasound; CFA, common femoral artery; BOT, balloon occlusion technique; VCD, vascular closure device; SAVR, surgical aortic valve replacement; HT, Heart Team.

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Los desarrollos recientes en el acceso guiado por ultrasonido y el refinamiento de los dispositivos de cierre vascular han mostrado promesa en la reducción de complicaciones. También se ha demostrado que el acceso radial como un abordaje axilar tiene una tasa de complicaciones más baja en comparación con el acceso femoral contralateral. La integración de nuevos dispositivos y técnicas, como el enfoque menos invasivo, mejorará aún más los resultados de los pacientes.

Esta revisión enfatiza la importancia de un enfoque integral y multidisciplinario para el TAVI y destaca la necesidad de una continua innovación y colaboración para reducir aún más las complicaciones vasculares y mejorar la seguridad y la eficacia del procedimiento. A medida que las indicaciones del TAVI se expanden a poblaciones más jóvenes, el refinamiento de las estrategias de gestión del acceso y la incorporación de herramientas avanzadas de imagen y predictivas serán críticos para optimizar el cuidado y los resultados de los pacientes.

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## Introduction

Transcatheter aortic valve implantation (TAVI) is an established treatment option for patients with severe aortic stenosis who are 75 years of age or older or are considered high-risk (STS-PROM/EuroSCORE II  $> 8\%$ ) or are not candidates for surgery. The current guidelines of the European Society of Cardiology (ESC) recommend TAVI as a class I indication with evidence level A for these patient groups.<sup>1</sup> Despite the increasing popularity of TAVI, its high success rates and its significant clinical and hemodynamic benefits, procedural challenges remain a major concern. Among the various technical aspects, access site management is a factor with critical clinical implications. Over time, improvements in procedure planning, device miniaturization and operator experience have reduced the overall burden of vascular and bleeding complications. However, these issues are still remarkably common.<sup>2</sup> A recent meta-analysis limited to the latest generation TAVI prosthesis systems estimated the rate of major vascular complications at 4.5% and the rate of life-threatening or major bleeding at 20.8%. Even minor vascular complications or bleeding deserve attention in clinical practice, as they may affect the clinical outcome and require diagnostic investigations or endovascular/surgical interventions.<sup>3</sup>

The transfemoral (TF) is the most used approach for TAVI procedures. However, there is considerable difference in techniques for TF-TAVI, depending largely on operator experience and center protocols, ranging from a surgical approach under general anesthesia to a fully percutaneous approach with local anesthesia. Recently, minimally invasive approaches are increasingly being considered as a potential strategy for TAVI evolution technique.

It is critical for operators to prioritize prevention, early detection and effective management of potential procedural complications to ensure successful TAVI outcomes. Every step of the procedure carries potential risks and can lead to clinically significant complications. Careful pre-procedure planning also plays a critical role in minimizing the occurrence of vascular and bleeding complications.<sup>4</sup>

### Vascular complication risk factors and definitions

The independent predictors of vascular complications associated with TF-TAVI can be categorized as follows<sup>5–9</sup>:

- Patient-dependent factors: female gender, chronic kidney disease, iliac-femoral calcifications (especially if circumferential), and peripheral artery disease.
- Procedure-dependent factors: iliac-femoral axis diameter smaller than the outer diameter of the introducer (“sheath-to-femoral artery ratio”  $> 1.05$ ), iliofemoral tortuosity (IFT) score greater than 21.2.

- Operator/center-dependent factors: individual operator experience and center experience.

Interestingly, the STS and EuroSCORE risk scores, and the different types of latest-generation prostheses are not associated with the risk of access-related complications.

Of note, 23% of vascular complications at 30 days and 13% of major/potentially fatal vascular complications are associated with the secondary femoral artery access.<sup>10,11</sup>

Originally, there were no standard definitions for the description and classification of vascular complications. The criteria used in different studies and registries were very heterogeneous and caused confusion in both research and clinical practice. The first attempt to standardize the definitions of clinical endpoints was the Valve Academic Research Consortium (VARC-I) classification.<sup>12</sup> The objectives of this classification were: (a) to identify clinical endpoints that can adequately reflect the safety and efficacy of the procedure; (b) to propose standard definitions for future clinical trials.

In general, a completely percutaneous approach should be the reference strategy in the absence of prohibitive femoral artery access. Compared to surgical isolation, it is associated with a similar rate of vascular complications, a lower incidence of access site infection and bleeding, and a shorter hospital stay. However, femoral artery complications at the puncture site, along with arrhythmias, are the most common and are characterized by a very wide range of clinical severity. Currently, the VARC-3 classification (Table 1) is used to identify the most important vascular complications, while bleeding complications are classified according to the corresponding BARC (Bleeding Academic Research Consortium) type.<sup>12</sup>

### Selection of vascular access

While the first introduced bioprosthetic valve (Edwards SAPIEN) was characterized by a larger diameter (inner diameter 22–24F and outer diameter 8–9 mm) and required a minimal arterial outer diameter of 7–8 mm, the newer available delivery systems (Table 2) are characterized by an outer diameter of about 6–7 mm and require a minimal arterial outer diameter of about 5.5–6.5 mm. These improvements have contributed to significantly reduce the incidence of access site complications.<sup>13–16</sup>

Pre-procedural assessment of the vascular anatomy using computed tomography angiography (CTA) of the iliac-femoral arteries is essential for TAVI.<sup>17</sup> It makes it possible to determine the presence and extent of atherosclerotic disease and to assess the suitability of the arterial access. The ideal iliac-femoral arteries for TAVI should have minimal calcified plaque, low tortuosity, and sufficient diameter to accommodate large femoral sheaths.<sup>18,19</sup>

**Table 1**  
Vascular complications according to VARC 3 criteria.

Major	<p>Aortic dissection</p> <p>Vascular (arterial or venous) injury (perforation, rupture, dissection, stenosis, ischemia, arterial or venous thrombosis including pulmonary embolism, arteriovenous fistula, pseudoaneurysm, hematoma, retroperitoneal hematoma, infection) or compartment syndrome resulting in death, VARC type <math>\geq 2</math> bleeding, limb or visceral ischemia, or irreversible neurologic impairment</p> <p>Distal embolization (non-cerebral) from a vascular source resulting in death, amputation, limb or visceral ischemia, or irreversible end-organ damage</p> <p>Unplanned endovascular or surgical intervention resulting in death, VARC type <math>\geq 2</math> bleeding, limb or visceral ischemia, or irreversible neurologic impairment</p> <p>Closure device failure‡ resulting in death, VARC type <math>\geq 2</math> bleeding, limb or visceral ischemia, or irreversible neurologic impairment</p>
Minor	<p>Vascular (arterial or venous) injury (perforation, rupture, dissection, stenosis, ischemia, arterial or venous thrombosis including pulmonary embolism, arteriovenous fistula, pseudoaneurysm, hematoma, retroperitoneal hematoma, infection) not resulting in death, VARC type <math>\geq 2</math> bleeding, limb or visceral ischemia, or irreversible neurologic impairment</p> <p>Distal embolization treated with embolectomy and/or thrombectomy, not resulting in death, amputation, limb or visceral ischemia, or irreversible end-organ damage</p> <p>Any unplanned endovascular or surgical intervention, ultra-sound guided compression, or thrombin injection, not resulting in death, VARC type <math>\geq 2</math> bleeding, limb or visceral ischemia, or irreversible neurologic impairment</p> <p>Closure device failure‡ not resulting in death, VARC type <math>\geq 2</math> bleeding, limb or visceral ischemia, or irreversible neurologic impairment</p>

VARC: Valve Academic Research Consortium.

**Table 2**  
Delivery systems.

Name	Sheath size	Outer diameter (mm)	Minimum vessel diameter requirement (mm)
FlexNav™ Delivery System DS-SM Abbott Cardiovascular	14 F	6.0 mm	5.5 mm
FlexNav™ Delivery System DS-LG Abbott Cardiovascular	15 F	6.3 mm	5.5 mm
iSLEEVE Introducer Set expands ACURATE neo Boston Scientific	14 F	6.0 mm	5.5 mm
DEvolut-TFx inLine Sheath 23-29 Medtronic	14 F	6.0 mm	5.5 mm
DEvolut-TFx inLine Sheath 34 Medtronic	18 F	7.33 mm	>6.5 mm
Edwards SAPIEN 3 Ultra expandable eSheath (20–26 mm)	14 F	6.0 mm	5.5 mm
Edwards SAPIEN 3 Ultra expandable eSheath (29 mm)	16	6.7 mm	6.0 mm

The sheath-to-femoral artery ratio has been identified as an independent predictor of VARC major vascular complications and 30-day mortality, with a cut-off value of 1.05.<sup>8</sup>

During the TAVI procedure, fluoroscopic guidance is essential when advancing large diameter catheters and introducer catheters to ensure safe navigation through the complex vascular anatomy. For a long time, the main access has been punctured under fluoroscopic guidance, also thanks to a 0.018-in. wire advanced into the common femoral artery via the secondary access.

However, the use of ultrasound (US) may help identify the optimal common femoral artery (CFA) puncture site and has been suggested to reduce access site complications. A first multicenter randomized controlled trial comparing routine real-time US guidance with standard fluoroscopic guidance found that US guidance improved CFA puncture only in patients with high CFA bifurcations. However, recent evidence suggests that ultrasound-guided catheterization has been shown to increase the safety of TF access and improve the first-step success rate, reduce the number of attempts, time to access, risk of femoral vein puncture, and vascular complications.<sup>20</sup>

While randomized clinical trial data is currently lacking, a number of observational studies have yielded encouraging findings. Kotronias et al.<sup>21</sup> examined data from the Oxford TAVI perspective registry and identified procedural factors that were linked to complications. The primary endpoint of their analysis was a composite of mortality, pericardial effusion/pericardial tamponade, major bleeding, and vascular complication. The authors observed

that the use of ultrasound to guide vascular access was associated with a reduction in the primary endpoint, particularly driven by a reduction in vascular complications. Polturi et al.<sup>22</sup> also noted that the use of ultrasound to guide vascular access during TAVI was associated with lower rates of vascular complications. Moreover, a recent meta-analysis encompassing eight observational studies and 3875 patients demonstrated that ultrasound is associated with a lower rate of both minor and major vascular complications, as well as less access-related bleeding.<sup>23</sup>

**Ancillary access sites**

The selection of the secondary/“ancillary” arterial access site for TAVI, which is required for TAVI access management and prosthesis implantation, carries specific additional risks. The classic selection of contralateral femoral access is known to be associated with an increased risk of vascular complications, with up to 25% of vascular access site complications in TAVI related to this “secondary” access.<sup>10</sup>

Radial access is a very attractive way to reduce “secondary” access-related complications, as it has been shown to increase safety in various percutaneous cardiovascular procedures.<sup>24–28</sup> A large multicenter study comparing the selection of “ancillary” radial or femoral access in 906 patients undergoing complex structural, coronary and peripheral percutaneous interventions (50% structural procedures with a high prevalence of TAVI) found that transradial ancillary approach, used in patients of similar com-

plexity, was associated with a significantly lower incidence of major bleeding events. In the specific TAVI setting, several groups have started to use radial access with promising initial results.<sup>29</sup> Allende et al. reported that the use of the femoral artery as a secondary access was associated with a higher rate of vascular complications than the radial approach, with all major vascular complications associated with the secondary access occurring in patients in whom the contralateral femoral approach was used.<sup>11</sup> Similarly, Wynne et al. reported their experience with TAVI performed with a preferred radial secondary access, reserving the secondary femoral access for failed radial access, anatomic anomalies, operator/proctor preference, or trial requirements. In their single-center study, secondary arterial access was transradial in 74% of patients and was not associated with any local vascular complications.<sup>30</sup>

Despite these promising reports, the use of “secondary” radial access has not yet become established in many centers. The need to deal with anatomical variants of the upper arm and the potential limitation in the treatment of lower limb vascular complications are the major drawbacks of secondary radial access in TAVI.

In this context, dedicated devices are required that are compatible with 6 or 7 Fr radial sheaths. Current wires include the 400 cm Ply-wire Soft Tip (OptiMed Ettlingen, Germany) and the 380 cm Roadrunner Extra Support guidewire (Cook Medical LLC Bloomington, USA). Despite their supportive properties, these wires have suboptimal handling characteristics.

To enable transradial access, balloons and stents with extended catheter shafts are required. While a length of 180 cm is considered optimal, balloons with a shaft of 150 cm are usually sufficient to reach the common femoral artery in most patients. Medtronic's Pacific Plus and Extreme product lines include catheters with 180 cm shafts and balloon diameters of up to 7 mm. Similarly, Cook Medical's Advance series offers catheters with 170 cm shafts and balloon diameters up to 7 mm, as well as options with 150 cm shafts and balloon diameters up to 9 mm. These balloons can be easily navigated through a 6 French coronary guide catheter (i.e. a 125 cm multipurpose catheter), although it should be noted that larger winged balloons (8–9 mm) may encounter some resistance during withdrawal.

Self-expanding nitinol stents with 180 cm shafts, such as the VasculFlex (Braun, Berlin, Germany) and the Sinus Superflex-518 (Optimed), can be inserted via a 6-French catheter. However, a notable limitation is that there are currently no covered stents with sufficiently long catheter shafts that allow deployment in the CFA via the transradial approach.

Although the radial artery is not suitable for the insertion of covered stents, it is almost always possible to occlude the main femoral access with a balloon. Balloon occlusion via a radial crossover can be performed either electively (dry closure technique) or as a bailout. If a covered stent is required, hemostasis must be maintained via the radial artery while an additional femoral access is created.

This approach allows adequate control of major/fatal bleeding. With a radial crossover, it can sometimes be even easier and faster to reach the iliac-femoral axis with guidewires and catheters, especially in calcified and particularly angulated carotifours. In this context, it is advisable to position a catheter or guidewire in the iliac artery before or during removal of the introducer or delivery system to be able to intervene immediately as soon as a complication is detected.

If radial access is not feasible or if there is a specific risk of complications at the main access that could require stent implantation (focal stenosis, diffuse disease with borderline SFA, severe calcifications or tortuosity), it is better to use the contralateral femoral access or alternatively the ipsilateral femoral access (including the superficial one) with the micropuncture technique.

## Minimally invasive approaches

Recently, several groups have reported promising clinical efficacy of planned percutaneous transfemoral TAVI performed in selected patients using a “minimalist” approach. In the evolving landscape of TAVI advancements and expanding clinical indications, the less invasive, totally endovascular (LITE) technique stands out as a valuable technical option for operators experienced in transradial approaches and endovascular interventions.<sup>31</sup> Briefly, the LITE technique integrates various technical solutions aimed at minimizing vascular complications. It uses the radial access as a “secondary access” to control valve positioning, check the hemostasis of the femoral access and manage potential complications at the access site. Puncture of the CFA is performed with precision using a combination of angiographic, guidewire and ultrasound guidance. Femoral hemostasis is routinely attempted using a double preclosure technique with two ProGlide suture devices (Abbott Vascular, CA, United States). After implantation of the prosthesis and removal of the TAVI sheath, hemostasis is achieved with parallel double ProGlide sutures. Before the sutures of the ProGlide device are cut, hemostasis is verified by selective iliac-femoral angiography via the radial access using a multipurpose guiding catheter. Digital subtraction angiography of the iliac-femoral arteries allows assessment of vascular integrity and diagnosis of vascular damage or bleeding complications that may have occurred.

## Pacing-related vascular complication

The implantation of transvenous temporary pacing is a crucial step in TAVI because it allows rapid pacing for stabilization of valvuloplasty balloons and prostheses as well as effective rhythm management in case of bradyarrhythmia. Unfortunately, transvenous temporary pacing is not without specific complications. In a study examining the incidence of complications in over 360,000 transvenous temporary pacing procedures performed in the United States between 2004 and 2014, pericardial tamponade was reported in 0.6% of patients, pneumothorax in 0.9% and non-pericardial bleeding in 2.4%.<sup>32</sup> In the specific context of TAVI, electrical stimulation of the heart can be achieved using a stiff guidewire placed in the left ventricle. This technique has been used by several groups in patients undergoing both balloon aortic valvuloplasty and TAVI.<sup>33</sup> These issues prompted the adaptation of the radial access technique to the specific context of TAVI.

## Closure technique and devices

The use of large sheaths in TAVI procedures exceeds the recommended size for suture-based hemostatic devices such as Perclose-ProGlide (Abbott's Perclose ProGlide™ SMC System). To solve this problem, the “Preclosure” technique was developed to allow complete percutaneous hemostasis with these devices. With this technique, the suture is deployed before the large arterial sheath required for valve implantation is introduced. At the end of the procedure, the sutures are closed by pushing down the knot(s) to achieve percutaneous hemostasis. A study by Kahlert et al. suggests that the use of a single ProGlide™ device followed by manual compression may provide more efficient and safer hemostasis compared to multiple ProGlide™ technique.

The Perclose-ProGlide is a 6 F suture-based hemostatic device consisting of a monofilament suture and a preformed knot. To achieve hemostasis after removal of large sheaths, two ProGlide devices are used in a “double preclosure” technique. The two devices are inserted one after the other at an angle of 30–45° rotated in opposite directions, creating an interrupted X-figure. At the end of the procedure, the arteriotomy is closed by tying the two knots

one after the other with the knot sliders. Recent data suggest that this technique is associated with a low incidence of early and late complications at the closure site. Recently, the use of three devices has also been reported.

Another technique that can be used in conjunction with the closure device-based techniques is the balloon occlusion technique (BOT). This involves lowering local blood pressure at the level of entry into the large sheath by blocking flow with an inflated peripheral angioplasty balloon in the iliac artery via the crossover technique. BOT has been reported to provide safe and successful percutaneous closure in patients undergoing TAVI using larger sheaths.<sup>34</sup>

Despite the popularity of suture-based pre-implanted closure devices, vascular complications and residual bleeding at the access site are still common, occurring in up to one third of patients. Strategies to manage vascular closure device (VCD) failure are used daily based on local expertise, but the best technique to manage residual bleeding after failure of a suture based VCD is not yet known. A novel “pledget-assisted hemostasis” technique has been described in which a surgical, non-absorbable polytetrafluoroethylene pledget is placed over the two ProGlide sutures (one from each device). The pledget is slid over the sutures with the ProGlide knot pusher and knotted with a handmade slider knot to achieve a stable approximation to the surface of the vessel wall. Once the pledget is in place, selective iliac-femoral digital subtraction angiography is repeated to verify that hemostasis has been achieved. In cases of massive bleeding, a peripheral balloon can be advanced into the iliac-femoral artery via the radial route and inflated to prevent significant blood loss during pledget-assisted hemostasis.<sup>35</sup>

### **Surgical femoral artery exposure: indication and technique**

Despite the impressive results achieved with percutaneous approach for the large bore arterial access required by TAVI (and aortic endografts), not all the common femoral artery (CFA) could be safely managed without surgical approach.

A planned CFA surgical exposure for TAVI is still the first-choice approach in several scenarios: severely obese patients, previously surgically treated CFA requiring puncture of a synthetic graft, severely diseased CFA needing endarterectomy, circumferential calcifications preventing effective closure systems application, high femoral bifurcation (above the inguinal ligament).<sup>36</sup>

As for standard vascular interventions performed for femoral artery reconstruction, CFA preparation for direct puncture requires a 3–5 cm vertical or oblique skin incisions at Scarpa's triangle. Regardless of the incision, the fascia is incised vertically to facilitate arterial dissection and exposure. While both incisions allow optimal selection of the arterial puncture site, the former allows easy extension of the incision for urgent iliac artery or infrainguinal revascularization; the latter is believed to have lower morbidity because a lower risk of inguinal nodes disruption. At the end of the procedure, CFA arteriotomy could be directly repaired via prolene suture or by patch or graft interposition.<sup>37,38</sup>

The surgical exposure of the CFA could be effectively performed under general, regional, or local anesthesia according to the preferences of patients and operators and to the operative requirements.<sup>39</sup>

The major drawbacks related to CFA surgical exposure are related to prolonged hospital stay, and risk of wound dissection and infection in elderly and fragile patients.<sup>40</sup>

### **Postprocedural vascular complications management**

Optimization of hemostasis techniques and management strategies is crucial in TAVI procedures. Effective management of vascular

access complications requires rapid diagnosis and timely, appropriate treatment. At the end of the procedure, it is advisable to perform digital subtraction angiography of the iliac-femoral arteries. This involves either a non-selective (via a pigtail catheter inserted into the aorta via the contralateral femoral artery or via the left transradial artery) or a selective (via a diagnostic right Judkins catheter or an internal mammary artery catheter, introduced from the contralateral femoral artery using the “crossover” technique, or a 135 cm multipurpose catheter via the left radial artery). This allows assessment of vessel integrity and immediate treatment of potential complications. Percutaneous treatment of vascular complications after TAVI as a bailout procedure is feasible and safe, with a high technical success rate and comparable long-term clinical outcomes to patients without vascular complications.

A broad spectrum of vascular damage has been described, ranging from minor vascular complications such as localized femoral artery dissection to major complications such as vascular occlusion or perforation. Localized vascular damage without impairment of lower limb perfusion should be treated conservatively, with careful clinical and ultrasonographic monitoring in the hours that follow. Specific treatment strategies for major vascular access complications are discussed below.

#### *Perforation*

Perforation leading to a retroperitoneal hematoma is a serious complication of TAVI. It may be detected by angiography before removal of the large sheath or may occur after removal of the sheath or after tying the knots of the closure device. Once the arterial perforation has been visualized by angiography, timely hemostasis can be achieved by positioning an occlusion balloon proximal to the vascular lesion or placing a large sheath over the ruptured segment. Protamine can be used to neutralize the effect of heparin and facilitate hemostasis.<sup>4</sup> If the arterial laceration persists after removal of the balloon or sheath, percutaneous implantation of a covered stent can be performed to avoid the risks associated with urgent vascular surgery. Post-procedure digital subtraction angiography of the iliac-femoral arteries can also reveal rare complications with insidious diagnoses, such as perforation of the lateral circumflex femoral artery. While perforation of the femoral artery in most cases is related to failure of the closure device and can cause a visible hematoma on the leg, perforation of the iliac artery can cause a retroperitoneal hematoma in the hours following the procedure, indicated by low back pain and confirmed by CTA. This can be treated by prolonged balloon inflation or coil embolization.

For a major rupture in the pelvic or abdominal cavity, a life-saving strategy is to place a highly flexible occlusion balloon in the aorta (Reliant™ Stentgraft Balloon Catheter, Medtronic Vascular, Santa Rosa CA, USA; Berenstein Occlusion Balloon Catheter™, Boston Scientific, Natick, MA, USA; Coda® Occlusion Balloon Catheter, Cook Medical Inc, Bloomington, IN, USA; Gore® Molding and Occlusion Balloon Catheter, Gore Inc., Flagstaff, AZ, USA), which has the ability to stretch and not exert radial force once it reaches the vessel diameter.

Repair of a perforation or rupture with balloon angioplasty alone is challenging, and if the lesion is proximal, covered stent repair should always be considered to avoid the risk of late occult bleeding. For extraperitoneal lesions, a more conservative strategy may be an option. Although endovascular repair is effective in most cases, surgical revision should be performed if bleeding persists.

#### *Dissection*

Dissection of the iliac-femoral arteries may occur as a result of overly traumatic insertion of the sheath through fragile or diseased arterial vessels. Limited, non-occlusive and retrograde arterial dis-

sections can usually be treated conservatively, as the antegrade flow usually maintains patency of the artery by pushing the dissection flap against the vessel wall. Larger arterial dissections may be associated with vascular occlusion (due to superimposed acute thrombosis or obstructive valves) and cause acute limb ischemia requiring immediate treatment to restore antegrade flow. Percutaneous angioplasty and implantation of a self-expandable or balloon-expandable stent may allow successful treatment by the crossover technique via the contralateral femoral artery or via the left transradial artery with dedicated devices (long shaft stent). To reduce the occurrence of vessel wall injuries, it is advisable to pay particular attention to the movement of the vessel calcification during the insertion of the large sheath. If the operator encounters resistance during this maneuver, it is recommended to insert the sheath slowly, stopping every 2 cm and using a substance to reduce friction, such as sterile Vaseline. At the end of the TAVI, it is better to retract the sheath after inserting the dilator to avoid a traumatic effect of the tip of the introducer on the arterial walls, especially in sharp arterial curves.

### Pseudoaneurysm

A pseudoaneurysm consists of a pulsating hematoma that connects to an artery through a disruption in the arterial wall. At the end of the procedure, standard or digital subtraction angiography of the iliac-femoral arteries may reveal an arterial leak as a precursor to the pseudoaneurysm or a true pseudoaneurysm, depending on the time of formation. If an angiographic diagnosis has not been made at the end of the procedure, close clinical monitoring may reveal an increase in new tingling or murmur, pulsatile hematoma, or marked pain or tenderness, and the pseudoaneurysm may be confirmed by ultrasound. Possible complications of a pseudoaneurysm include rupture, distal embolization, infection, neuropathy and local skin ischemia. However, it generally does not affect lower limb circulation and can be treated by ultrasound-guided compression, which is a safe and cost-effective method of achieving pseudoaneurysm thrombosis. However, it has significant disadvantages, including long treatment times, patient discomfort and high recurrence rates, particularly in cases requiring anticoagulant therapy. If probe compression fails, other treatment options include ultrasound-guided thrombin injection, which has a high success rate and is more comfortable for patients, coil embolization, stent grafting and surgical repair.<sup>39</sup>

### Vascular complication: prognosis

There was a notable incidence of vascular complications in the early phases of TAVI. In the PARTNER 1 study, 27% of cases were affected. Over time, however, these complications have significantly decreased (Table 3), probably due to the combined efforts of the manufacturers to improve the delivery system and the increasing experience of the operators.<sup>14</sup>

Indeed, the results of subsequent studies such as PARTNER 3 show that the incidence of these complications has decreased significantly. Nevertheless, VCs still occur with considerable frequency and have a non-negligible impact on prognosis.<sup>41</sup>

According to Lunardi et al., major vascular complications have been shown to have a more detrimental impact on long-term outcomes than minor vascular complications. Specifically, the 2-year MACCE-free survival rate was 71.9% for major complications and 89.0% for minor complications, with a log-rank *p*-value of 0.022, an adjusted HR of 2.07, a 95% CI of 1.01–4.25 and a *p*-value of 0.048.<sup>42</sup> Currently, vascular complications are classified into major and minor categories based on the VARC 3 criteria. A detailed description of this classification can be found in Table 1. Identifying

patients at higher risk for vascular complications and optimizing techniques to prevent these complications are critical factors in achieving a positive outcome.

### Role of heart team

The Heart Team (HT) at Sant'Andrea Hospital of Sapienza University of Rome works according to specific internal rules introduced in November 2022 and consists of clinical cardiologists, interventional cardiologists, cardiologists specialized in echocardiography, cardiac and vascular surgeons and cardiac anesthesiologists. Any physician in our hospital and affiliated sites can refer a patient to HT for discussion and shared decision-making.

Every patient with severe/symptomatic aortic valve stenosis is evaluated in order to establish the right indication between medical or invasive treatment. Surgical risk scores are assessed using both the EuroSCORE II and the STS-PROM risk calculator, while frailty is assessed using the Essential Frailty Toolset and the Activities of Daily Living scales. All clinical features, and relevant imaging and data from echocardiograms, cardiac catheterization, angiograms, CTA scans and other diagnostic tests are reviewed by the HT components.

Finally, a clinical recommendation is made for each patient based on the best risk–benefit ratio as to whether TAVI or SAVR is the most appropriate treatment option.

Once the decision for TAVI has been made, we determine the best vascular access based on the results of angio-CT and ultrasound examinations. These imaging techniques allow us to assess important parameters such as the diameter of the femoral artery and its bifurcation site, the presence and extent of atherosclerotic disease, the burden of calcified plaques and the degree of tortuosity of the iliac arteries as well as the morphology of the aortic carrefour to determine the optimal choice for ancillary access.

In cases where a percutaneous transfemoral approach is deemed unsuitable, alternative approaches will be considered. Depending on the specific findings, a surgical incision to expose the femoral artery or an alternative percutaneous approach such as the subclavian, axillary, carotid, transcaval or transapical approach may be considered.

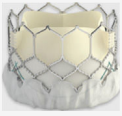



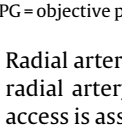
This individualized approach to vascular access allows us to choose the most appropriate strategy for each patient. As a result of this careful planning, our institution has achieved a significant reduction in the vascular access complication rate over time.

### Tips and tricks to reduce complications at the access site

Reducing access site complications in TAVI procedures requires a multifaceted approach that includes careful patient selection, careful planning of the procedure and the use of advanced techniques and devices. Below are some key strategies to minimize the risk of vascular complications:

- Careful pre-procedure planning: Perform a comprehensive assessment of the iliac-femoral artery anatomy with a high-quality CTA. Assess vessel diameter, calcification, tortuosity and the presence of atherosclerotic disease. This information is critical to determine the feasibility of transfemoral access and to select the appropriate access site.
- Ultrasound-guided puncture: Perform femoral artery puncture by ultrasound to ensure precise cannulation of the common femoral artery. This technique has been shown to reduce the risk of vascular complications, increase the first-step success rate and minimize the number of attempts compared to fluoroscopic guidance alone.

**Table 3**  
vascular complication rates according to the different types of transcatheter aortic valves.

	Study	Year	Population	Age	Risk score	Arms	Sheaths size (Fr)	Vascular complication (%)
<i>Balloon-expanding THVs</i>								
	Partner 1B	2010	358 pts	83 + 6.6	STS: score: 11.2% Euroscore: 26.4%	TAVR with Edwards-Sapien Heart Valve vs standard therapy	22 Fr (23 mm) 24 Fr (26 mm)	16.2% at 30 days 16.8% at 1 year
	Partner 1A	2011	699 pts	83.6 + 6.8	STS score: 11.8% Euroscore: 29.3%	TAVR with Edwards-Sapien Heart Valve vs SAVR	22 (23 mm) 24 (26 mm)	11.0% at 30 days 11.3% at 1 year
	Partner II	2016	2032 pts	81.5 + 6.7	STS score: 5.8% Euroscore: N/A	TAVR with Sapien XT vs SAVR	16 Fr (23 mm) 18 (26 mm) 20 (29 mm)	7.9% at 30 days 8.4% at 1 year
	Partner III	2019	1000 pts	73.3 + 5.8	STS score: 1.9% Euroscore: 1.5%	TAVR with Sapien 3 vs SAVR	14 Fr (20;23;26 mm) 16 Fr (29 mm)	2.2% at 30 days 2.8% at 1 year
<i>Self-expanding THVs</i>								
	Core valve extreme risk	2014	489 pts	83.2 + 8.7	STS score 10.3% Euroscore 22.6%	TAVR with Corevalve vs OPG	18 Fr	8.2% at 30 days 8.4% at 1 year
	Core valve high risk	2014	747 pts	83.2 + 7.1	STS score 7.3% Euroscore 17.3%	TAVR with Corevalve vs SAVR	18 Fr	5.9% at 30 days 6.2% at 1 year
	SURTAVI	2017	1160 pts	79.8 + 6.2	STS score 4.4% Euroscore 11.9%	TAVR with Evolout R (n = 139) or Corevalve (n = 724) vs SAVR	Evolout R: 18 Fr (23–26–29 mm) 20 Fr (34 mm)	6.0% at 30 days
	Evolout low risk	2019	1000 pts	74.0 + 5.9	STS score 1.9% Euroscore N/A	TAVR with Corevalve (3.6%) or Evolout R (74.1%) or Evolout Pro (22.3%) vs SAVR	Evolout Pro: 14 Fr (23,26,29 mm) 18 Fr (34 mm)	3.8% at 30 days 3.8% at 1 year
	SCOPE II	2020	796 pts	83.2 + 4.3	STS: 4.6 + 2.9	TAVR with ACURATE (398) Neo vs Evolout R (398)	Acurate Neo: 18 Fr and 19 Fr	9% in the Acurate Neo group vs 6% in the Evolout R group at 3.4%
	The Early neo2 Registry	2023	554 pts	81.6 + 5.9	STS 4.0 + 3.2 Euroscore II 4.5 + 3.8	TAVR with Acurate Neo 2	14 Fr	
	Portico NG	2023	120 pts	83.5 ± 5.4	STS score 4.0 ± 2.0%	TAVR with Navitor	14 Fr (23,25 mm) 15 Fr (27,29 mm)	0.8% at 30 days 0.8% at 1 year

OPG = objective performance goal; SAVR = surgical aortic valve replacement; STS = Society of Thoracic Surgeons; TAVR = transcatheter aortic valve replacement; pts = patients.

- Radial artery access as a secondary approach: Consider using the radial artery as a secondary access for TAVI procedures. Radial access is associated with a lower risk of major vascular complications and bleeding compared to femoral access. It allows effective management of potential complications at the primary access site.
- Pre-closure technique: Apply the preclosure technique by using suture-based vascular closure devices (VCDs). In this technique, the sutures are placed before inserting the large sheath and knotted at the end of the procedure to achieve hemostasis. Proper execution of the preclosure technique is critical to minimize the risk of VCD failure and subsequent complications.
- Balloon occlusion technique (BOT): Consider BOT as a complementary technique to improve the efficacy of hemostasis. BOT involves inflating a peripheral angioplasty balloon via the contralateral femoral or left radial access in the iliac artery to lower local blood pressure at the primary access site. This technique can be particularly useful in cases of VCD failure or residual bleeding.
- Operator experience and training: Ensure that TAVI operators have sufficient experience and training in vascular access management and complication prevention. Familiarity with different

vascular closure devices, bailout techniques and endovascular interventions is critical. Regular simulation-based training and proctoring can help maintain and improve surgeons' skills.

- Minimalist approach: Use a minimalist approach to TAVI whenever feasible, which includes early mobilization. This approach has been associated with fewer vascular complications and shorter hospital stays than the traditional approach.
- Continuous quality improvement: Implement a robust quality improvement program to monitor and analyze vascular complications. Regular multidisciplinary meetings to review cases, discuss root causes and identify areas for improvement can help refine techniques and optimize outcomes over time.

As TAVI continues to evolve, the development of new strategies and devices for access site management will likely further reduce the incidence of vascular complications. Continued research and innovation in this area will be critical to improving the safety and efficacy of TAVI procedures in the future.

## Conclusions

Vascular complications are still a significant concern in TAVI procedures despite advances in device technology and operator experience. These complications can have a profound impact on patient outcomes, including increased morbidity, mortality and healthcare costs. Therefore, a comprehensive approach to minimizing the risk of vascular complications and optimizing patient care is critical.

Key factors for reducing vascular complications in TAVI include systematic pre-procedure planning, the use of advanced imaging techniques for vascular assessment and the application of best practices for access site management.

With the expansion of TAVI indications to younger patients, the need for a refined and personalized approach to vascular access is becoming increasingly important. The development of novel strategies for access site management, such as the use of dedicated TAVI access kits and further miniaturization of delivery systems, may help to reduce the incidence of vascular complications in the future.

The role of artificial intelligence and machine learning in the prediction and prevention of vascular complications is another active area of research. Integrating these advanced computational tools into clinical decision making can help identify high-risk patients, guide device selection and optimize procedural techniques.

Finally, ongoing collaboration between interventional cardiologists, vascular surgeons and device manufacturers is essential to drive innovation and improve patient outcomes. Sharing best practices, creating standardized protocols, and continuous monitoring and reporting of vascular complications will be critical to advancing the field of TAVI and ensuring its long-term success.

## Ethical disclosures

**Protection of human and animal subjects.** The authors declare that no experiments were performed on humans or animals for this investigation.

**Confidentiality of data.** The authors declare that no patient data appears in this article.

**Right to privacy and informed consent.** The authors declare that no patient data appears in this article.

## Ethical considerations

Not applicable.

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## Authors' contribution

AT, PS, MT and EB designed the research study. FDA and VF conducted the bibliographic research. AT, PS, FDA, VF, FG, MC, SR wrote the manuscript. AB contributed to study conception. EB and MT critically reviewed the manuscript, contributing to its increased value. All authors read and approved the final manuscript. All authors have participated sufficiently in the work to take public responsibility for appropriate portions of the content and agreed to be accountable for all aspects of the work in ensuring that questions related to its accuracy or integrity are addressed.

## Conflict of interest

Prof E. Barbato reports speaker fees from Boston Scientific, Abbott, and Insight Lifetech. Prof. M. Taurino is a consultant for Medtronic, Endologix and InspireMD. Prof. P. Sirignano is a consultant for Medtronic. The remaining authors have no conflict of interest “including any financial, personal or other relationships with other people or organizations within three years of beginning the submitted work that could inappropriately influence, or be perceived to influence, their work.”

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