Overcoming the Challenges of the Transfemoral Approach in Transcatheter Aortic Valve Implantation

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Abstract

Transcatheter aortic valve implantation (TAVI) is performed through a retrograde transfemoral approach in approximately 80–90 % of cases thanks to the improvements in delivery catheter profile, size and steerability compared with the first generation devices. The aim of this review article is to describe the challenges of transfemoral TAVI and the options to overcome them. The difficulties may be related to the access itself or the placement of the valve using the transfemoral route. Comprehensive patient screening using multislice computed tomography and crossover techniques to prevent bleeding should result in low complication rates even for fully percutaneous procedures. Horizontal ascending aorta and severely calcified aortic valves remain a challenge for retrograde valve crossing, device advancement and accurate positioning during deployment. The buddy balloon technique is a simple option in the case of difficult aortic valve crossing with a delivery catheter, whereas an antegrade approach using the transapical route is a reasonable alternative in such anatomy.

Keywords

Transcatheter aortic valve implantation, transfemoral approach, vascular access, vascular complications, buddy balloon technique, horizontal aorta

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Since the first human transcatheter aortic valve implantation (TAVI) performed through an antegrade transfemoral approach (i.e. femoral venous access, transseptal puncture advancement of the device to the left ventricle and antegradely through the aortic valve), the venous approach has been abandoned and different arterial access routes such as the transfemoral, transapical, subclavian or direct aortic have been developed. At present, TAVI is performed through a retrograde transfemoral approach in approximately 80–90 % of cases thanks to the improvements in delivery catheter profile, size and steerability compared with the first generation devices. Furthermore, transfemoral TAVI has the advantage of offering the option for a fully percutaneous procedure, performed under local anaesthesia with mild sedation, via a puncture of the common femoral artery using the Seldinger technique and a closure device used with a pre-closure technique to achieve haemostasis. The aim of this review article is to describe the challenges of transfemoral TAVI and the options to overcome them. The challenges may involve either the access itself or the valve insertion and implantation.

Challenges in the Vascular Approach of Transfemoral Transcatheter Aortic Valve Implantation

In order to successfully perform transfemoral TAVI, the operators should not only have appropriate knowledge on the devices they use and good training in femoral access and management of its specific complications, but they should also perform comprehensive screening of patients and careful evaluation of vascular access. Genereux et al. showed in a post hoc analysis of the 419 transfemoral patients from the Placement of AORTic TraNscathetER Valves trial (PARTNER

A and B) that vascular complications adversely impacted 30-day and one-year outcomes.¹ In this analysis, major vascular complications (the most frequent being vascular dissection, vascular perforation and access site haematoma) occurred in as often as 15.4 % of cases with the use of the first generation Edwards SAPIEN® valves (Edwards Lifesciences Corporation, Irvine, California, US) and were associated with bleeding events, transfusions and increased mortality. Importantly, major vascular complications were associated with more than a fourfold increase in 30-day mortality.¹ However, as shown by the Vancouver single-centre experience (137 patients), the incidence of major vascular complications can be dramatically reduced over time. Indeed, major vascular complications (22/24 were iliofemoral) in this centre fell from 8 % in 2009 to 1 % in 2010, thanks to increased operator experience, sheath size reduction (22 and 24 French size [Fr] for the first Edwards SAPIEN generation as opposed to 19 and 18 Fr for the second generation) and improved screening using multislice computed tomography (MSCT).

Furthermore, distinction between major and minor vascular complications is of importance since in the PARTNER trial, vascular subanalysis minor vascular complications, which occurred in 11.9 % of cases, were not associated with higher mortality, major bleeding, transfusions or need for dialysis at 30 days and one year.¹

Vascular Screening

Using angiography and MSCT comprehensive vascular screening should determine the degree and localisation of calcifications, the presence of relevant iliofemoral atherosclerotic disease, major tortuosity and the minimal lumen vessel diameter that must be

Figure 1: A) Iliofemoral Tortuosity with a Marked Pigtail Inside the Vessel. B) Vessel Straightened by the Insertion of a 0.35" Hi-Torque SupraCore Wire (Abbott Vascular) into the Pigtail. Case from Our Experience

Figure 2: Example of Difficult Anatomy for Crossover Approach. A) EN Snare Endovascular Snare System (Merit Medical Systems, South Jordan, Utah, US) with its Three Loops Opened. B) Regular 0.035" Wire Grabbed by the EN Snare System. C) Mammary Catheter (6 Fr) Advanced in the Right Iliac Artery

at least >6 millimetres (mm) to accommodate an 18 Fr sheath. MSCT is very important in assessing the distribution of vascular calcification. Indeed, in the presence of circumferential calcification and/or tortuosity, the minimum iliofemoral arterial diameter should be larger (preferably >6.5 mm). In the setting of tortuous iliofemoral vessels the feasibility of transfemoral approach can be determined by the ability to straighten the tortuous vessel with a stiff wire (see Figure 1). Vavuranakis et al. developed an index to define the significance of vessel tortuosity – the Total arterial Tortuosity/Access vessel Diameter ratio (TT/AD). This ratio corresponds to the sum of angles from the puncture site divided by the minimum femoral artery diameter at the puncture site. In their analysis, a TT/AD >27.7 predicts major vascular complications with 50.8 % sensitivity and 70.6 % specificity. This index, although not commonly used in clinical practice, supports the concept that larger arteries are less prone to vascular complications.²

Different 18 Fr Sheaths Used for the Medtronic CoreValve

Different 18 Fr sheaths are available when implanting a CoreValve® (Medtronic Inc, Minneapolis, Minnesota, US). The Cook sheath (Cook Medical, Indiana, US) is the most commonly used. It is robust enough to allow recapture of a partially deployed valve. The latter manoeuvre is more challenging when using the St Jude 18 Fr sheath (ST Jude Medical, Minnesota, US), which is softer and with a better profile, but has the tendency to invaginate during recapture of a partially deployed CoreValve.

The recently available SoloPath™ Balloon Expandable sheath (Terumo Corporation, Japan) represents an interesting option in the presence of difficult vascular anatomy. The concept of this sheath is a reduced profile when folded (outer diameter of 13 Fr) allowing facilitated vessel entry, it is subsequently expanded by balloon inflation up to an inner and outer diameter of 19 Fr and 22 Fr, respectively. It provides enhanced manoeuvrability, utilises the natural elasticity of vessels and thus enables delivery through difficult anatomy.^{3,4} Also, it is designed to collapse upon withdrawal. The SoloPath sheath is an interesting option for borderline iliofemoral access in terms of vascular diameter. However, caution should be paid in the presence of tortuous vessels because of a possibly limited kinking resistance observed in our preliminary experience.

Lubrication with Propofol

To facilitate large bore sheath insertion in calcified vascular access, lubrication of the sheath with sterile propofol may be of help. This tip and trick was also successfully described in the case of stent delivery failure in coronary arteries.⁵ Indeed, propofol is a short-acting intravenous hypnotic/amnestic agent with lubricating properties, as it is an emulsion of 1.0 % propofol, 10.0 % soybean oil, 1.2 % purified egg phospholipids, 2.25 % glycerol and sodium hydroxide.

Pre-closure Technique Using the Prostar 10XL Device

Surgical femoral cut-down may at first glance seem safer than a fully percutaneous approach. However, surgery may be associated with adverse events such as haematoma, seroma, lymphoceles and infection, and may lengthen the intervention, the timing to ambulation and hospital stay.⁶ On the other hand, a fully percutaneous approach has been used for many years in the field of endovascular aortic aneurysm repair and has the advantage of being performed under local anaesthesia with mild sedation. At present, with the reduction of sheath size, many centres favour this latter approach.

When using a percutaneous approach, a closure device – either the Prostar 10XL device (Abbott Vascular, Santa Clara, California, US) or three 6 Fr Perclose devices (Abbott Vascular)⁷ – should be inserted before the large sheath; the so-called pre-closure technique. Of note, both devices are only approved for closure of ≤10 Fr sheath holes by the Food and Drug Administration in the US. However, 24.9 % of the PARTNER A and B transfemoral procedures were performed with a fully percutaneous approach using the Prostar XL device. Furthermore, in 2009, Prostar 10XL received a CE Mark and Canada Health approvals to close puncture sites when sheaths up to 24 Fr are used.

At the beginning of the procedure, the sutures of the Prostar device are deployed at the arteriotomy site without tying the knots. At the end of the procedure, the sutures of the pre-closing system are knotted while retrieving the large sheath using either the crossover balloon technique (see below) or with a crossover access to the

external iliac artery ready in case of incomplete haemostasis. Failure of the Prostar XL device seems to be associated with obesity, small-diameter vessels with significant calcification or a high puncture site.⁸⁻¹⁰ The failure rate of the Prostar device has been reported to be between 7.4 and 15.0 % in TAVI and endovascular aortic aneurysm repair series.^{6,10-12} In a series of 142 patients from Paris, the rate of failure clearly decreased from early experience (14.3 %) to later experience (4.3 %) whereas the total failure rate was 9.4 %.¹⁰ Interestingly, in this series, all Prostar failures could be managed without surgical intervention, namely with prolonged balloon inflation (3.6 %) or covered stent implantation (3.6 %) and no Prostar failure led to a major vascular complication according to the Valve Academic Research Consortium (VARC) criteria.¹⁰

Crossover Balloon Occlusion Technique

Some operators routinely advance a peripheral balloon in the external or common iliac artery from the contralateral access and inflate it when retrieving the sheath and knotting the sutures – the so-called crossover balloon occlusion technique. This approach permits bleeding control and offers a bloodless field for percutaneous or surgical repair if needed.^{9,13} In our experience, the need to inflate a balloon to achieve haemostasis is rarely needed and we therefore do not use it prophylactically. However, we strongly advise having a diagnostic catheter in place in the external iliac artery using a contralateral approach. This can be easily done by advancing a 6 Fr internal mammary artery catheter over a 0.035" wire (usually a stiff Terumo wire, Terumo Inc, Japan). If the aortic bifurcation is narrow-angled and it is not possible to easily advance a wire into the contralateral limb, we advise snaring it (e.g. with EN Snare® Endovascular Snare System [Merit Medical Systems, South Jordan, Utah, US]) from the large bore introducer site. This technique may be the only way to 'secure' the contralateral limb in challenging cases (see *Figure 2*). From the 6 Fr mammary, a final angiogram is performed to document complete haemostasis at the Prostar site (see *Figure 3*).

Crossover Final Angiography

It is essential to perform a final angiography of the vascular access by a crossover approach to verify the haemostasis and to exclude local complications such as dissection or vessel occlusion. Small leaks are not seen from the skin and they may contribute to the formation of a false aneurysm or become the source of delayed major bleeding. If small vascular leakages are seen, prolonged manual compression is usually effective in sealing the leak and a final angiographic check is required to confirm the sealing. Large leaks or tears often require covered stenting or surgical intervention. In this setting, proximal balloon occlusion is a valuable bridge to endovascular or surgical repair.

In summary, careful patient screening associated with device size reduction and expertise in advanced percutaneous techniques should result in very low complication rates when using the transfemoral approach, even for fully percutaneous procedures. Most local complications can be treated by endovascular methods, surgery is rarely needed.

Challenges in Valve Crossing and Positioning During Transfemoral Transcatheter Aortic Valve Implantation

Despite improvements in delivery catheter profile, size and steerability compared with the first generation devices, retrograde aortic valve

Figure 3: Final Angiography by Crossover Approach of the Case Shown in Figure 2. Arrow Showing the Puncture Site

crossing during transfemoral TAVI may be challenging especially in the presence of a severely calcified native aortic valve or horizontal ascending aorta.

Sheiban et al. first reported the use of the buddy balloon technique to successfully deliver a transcatheter aortic valve through a severely calcified aortic valve. Despite repeated balloon valvuloplasty, several attempts to deliver a 23 mm Edwards SAPIEN device were unsuccessful, probably due to calcified spiculae and/or recoil. Finally the buddy balloon technique using a 23 x 40 mm NuCLEUS valvuloplasty balloon (NuMed, New York, US) inflated at low pressure was successful. The valvuloplasty balloon was used as a shoehorn to enable successful delivery of the Edwards SAPIEN valve.¹⁴ Balkin et al. also reported two cases of failure to cross highly calcified aortic valves with the Retroflex catheter, used to deliver the Edwards SAPIEN device.¹⁵ The buddy balloon technique using an 8 Fr 20 x 40 mm valvuloplasty balloon (OSYPKA AG, Rheinfelden, Germany) allowed successful valve crossing.

At the congress of the European Association of Percutaneous Cardiovascular Interventions (EuroPCR) 2013, we presented a case of retrograde aortic valve crossing with the AccuTrak CoreValve device (Medtronic Inc, Minneapolis, Minnesota, US) requiring the buddy balloon technique to be successful.¹⁶ The difference with the previous reports is that we used a 6 Fr compatible 8 x 80 mm Admiral peripheral balloon (Medtronic Inc) instead of a valvuloplasty balloon. The difficulty of crossing the native aortic valve in this case was probably due to the horizontal orientation of the ascending aorta. The main advantage of using a 6 Fr compatible balloon is that we do not need to oversize our contralateral access since we routinely insert a 6 Fr introducer in the contralateral femoral side in order to be ready to perform

a crossover balloon inflation technique in case of major vascular complication when the large sheath is retrieved.

The buddy balloon technique is a simple and easy tip and trick for challenging retrograde valve crossing. Of note, the buddy wire technique was not effective in the report by Sheiban et al.,¹⁴ similarly as in our own experience. Finally, the buddy balloon technique may avoid excessive manipulations with the delivery system and wire, and potentially reduce the risk of left ventricle perforation by the wire and embolisation of calcific particles when struggling to cross the valve. Another option in such cases is to convert to transapical approach or even surgical aortic valve replacement. The former is the only TAVI approach using an antegrade crossing of the valve with the device, which is technically easier than the retrograde crossing required with all the other TAVI approaches.

Conclusions

At present the transfemoral approach is the most commonly used approach for TAVI worldwide. Alternative access routes such as direct aortic, subclavian or transapical approaches are of interest when the iliofemoral arteries are diseased, highly calcified or extremely tortuous. Comprehensive patient screening using multislice computed tomography and crossover techniques may reduce complication rates when using transfemoral approach, even for fully percutaneous procedures. Horizontal ascending aorta remains a challenge for retrograde valve crossing and device advancement as well as for accurate positioning during deployment. The buddy balloon technique is a simple option in the case of difficult aortic valve crossing with a delivery catheter, whereas the antegrade approach using the transapical route is a reasonable alternative in such anatomy. ■

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