

PERCUTANEOUS TRANSAXILLARY TRANSCATHETER AORTIC VALVE IMPLANTATION

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Abstract

The transaxillary (TAX) approach for transcatheter aortic valve implantation (TAVI) results in comparable short and long-term clinical results compared to the transfemoral (TF) approach. However, adequate closure of the axillary artery is the most critical issue when performing the percutaneous approach. Compared to surgical transaxillary approach, the percutaneous approach was used only in selected cases due to this closure limitation.

In the present paper, we aim to demonstrate the feasibility of implanting the CoreValve Evolut Pro transcatheter heart valve via percutaneous transaxillary approach and make a literature review of procedure particularities and outcome.

We describe the case of a patient with severe aortic stenosis in the presence of small calibre and severely calcified femoral arteries. A CoreValve Evolut Pro 26 was successfully implanted percutaneously through the left axillary artery.

Percutaneous transaxillary transcatheter aortic valve implantation is a feasible and safe alternative in patients who have suboptimal iliofemoral vessels.

Keywords: Percutaneous transaxillary approach; Percutaneous subclavian approach; Transcatheter aortic valve implantation

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) is a well-established treatment option for patients with severe aortic stenosis (AS), specially in those who are at high or extreme surgical risk for conventional surgical aortic valve replacement (SAVR). Interestingly, in recent years its potential benefit has been proven even in lower risk patients. In 2011 and 2016, meta-analyses of randomized controlled trials (PARTNER and PARTNER 2) comparing TAVI to SAVR in high and intermediate-risk patients indicate a survival benefit of TAVI compared to surgical aortic valve replacement¹. In accordance with this, in May 2019, two trials (PARTNER 3 and

EVOLUT Low Risk) showed that TAVI was at least equivalent or even better (in rehospitalization) to SAVR in patients who were at low surgical risk^{2,3}.

The most commonly used access route for TAVI is the femoro-iliac access (transfemoral approach, TF), because it is minimally invasive and it is feasible under conscious sedation in a totally percutaneous fashion. Nevertheless, the TF approach is not possible in all patients warranting alternative access techniques for TAVI. In this regard, the transapical, direct aortic, transcarotid, transcaval, and transaxillary (TAX) implantation routes currently serve as alternative access options. However, the relative 'invasiveness' of one alternative approach compared with another is subject to

debate. Invasiveness relates to the need for a surgical cut-down, general anaesthesia (GA), vascular or heart lesion required for delivery system crossing, and potential impact on the other major systems such as the cerebral, respiratory and renal systems.

Since its introduction, the transaxillary approach results in comparable short and long-term clinical results compared to the TF approach. The short distance to the valve landing zone allows good control of the delivery system. Moreover, data suggests superiority of the TAX access compared to other non-TF access approaches⁴.

The axillary artery can be reached either by surgical cut-down or by direct percutaneous puncture.

A truly percutaneous approach without the need for surgical cutdown is feasible and can be done under local anaesthesia with conscious sedation. Adequate closure of the axillary artery is the most critical issue when performing the percutaneous approach, because, due to the anatomical conditions, in most instances manual compression of the puncture site is not efficient. Thus, detailed planning of the vessel puncture and precise usage of closure devices (pre-closure) is of utmost importance⁴.

In the present paper, we report a patient with severe aortic stenosis in the presence of small calibre and calcified femoral access. A CoreValve Evolut Pro 26 was successfully implanted percutaneously through the left axillary artery. We also make a literature review of procedure particularities and outcome. MEDLINE database was used to search for eligible studies published up to November 10, 2019.

CASE REPORT

The patient was an 80-year-old woman (height, 152 cm; weight, 54 kg) with symptomatic (NYHA class II) aortic disease, comprising moderate stenosis and severe regurgitation.

Her medical history included arterial hypertension, dyslipidemia, former smoking, alveolar hypoventilation syndrome, sleep apnea and cerebrovascular disease, with a history of stroke without sequelae in 1996.

The patient had concomitant coronary artery disease with stenting of the left anterior descending and the right coronary arteries 4 years prior to the latest presentation. The last one was occluded over 1 year ago.

The echocardiography showed mild dilatation of left cardiac chambers, mild and moderate mitral and tricuspid regurgitation, respectively; moderate aortic stenosis with severe aortic regurgitation conditioning a peak transvalvular pressure gradient of 50 mmHg and a mean transvalvular pressure gradient of 27 mmHg (Fig. 1). Left ventricular systolic function was preserved.

The chest computed tomography (CT) scan showed a calcified ascending aorta, which contraindicated SAVR (Fig. 2). Considering the patients' severe peripheral vasculopathy and the fact that CT scan of the great arteries demonstrated

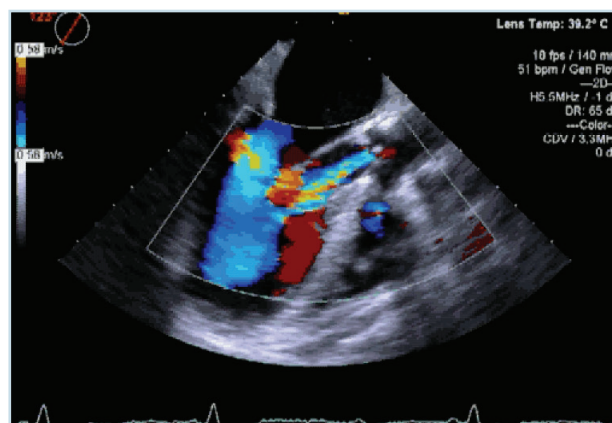


Figure 1 *Echocardiography before TAVI.*

iliofemoral artery diameters smaller than 5 mm, the femoral approach was excluded (Fig. 2). Surgical accesses using minithoracotomy or sternotomy (for transaortic or transapical approach), although not contraindicated, did not appear to be good options due to the lung disease. Moreover, thinking about the patient's cerebrovascular disease, with a history of stroke and impairment of vertebral and carotid blood flow in imaging studies, the team did not favor the carotid approach. Moreover, it is a technique with which this team has no experience. On the other hand, the axillary arteries had a good caliber, were not calcified nor tortuous. For these reasons we opted for a completely percutaneous axillary access (Fig. 2). The patient provided detailed informed written consent.

In accordance with our institutional protocol, the patients were jointly evaluated by a Heart Team composed of a cardiac surgeon, an interventional cardiologist, the imaging cardiologist, and a cardiac anesthesiologist. In line with the statement of the European Association of Cardio-Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC), transcatheter aortic valve implantation was preferred because of the high risk score, the patients' comorbidities and aortic calcification (logistic Euroscore of 13.7 % and Society of Thoracic Surgeons risk of mortality of 9.2 %).

The anesthetic goal was to be the least invasive possible, hence choosing to perform sedation while maintaining spontaneous ventilation. After admission to the procedure room, we monitored O₂ saturation, conventional ECG tracing and noninvasive blood pressure. BIS® and INVOS® were used to monitor anesthetic depth and detect ischemic brain complications (aware of its limitation as it only allows regional monitoring).

After initial preparation, fentanyl 0.05 mcg was administered and a target controlled infusion of propofol (Schneider model infusion for BIS value of 40-60) was started. During the procedure the patient maintained spontaneous breath and oxygenation was given by nasal cannula. The goals in terms of oxygenation / ventilation were: O₂ Sat

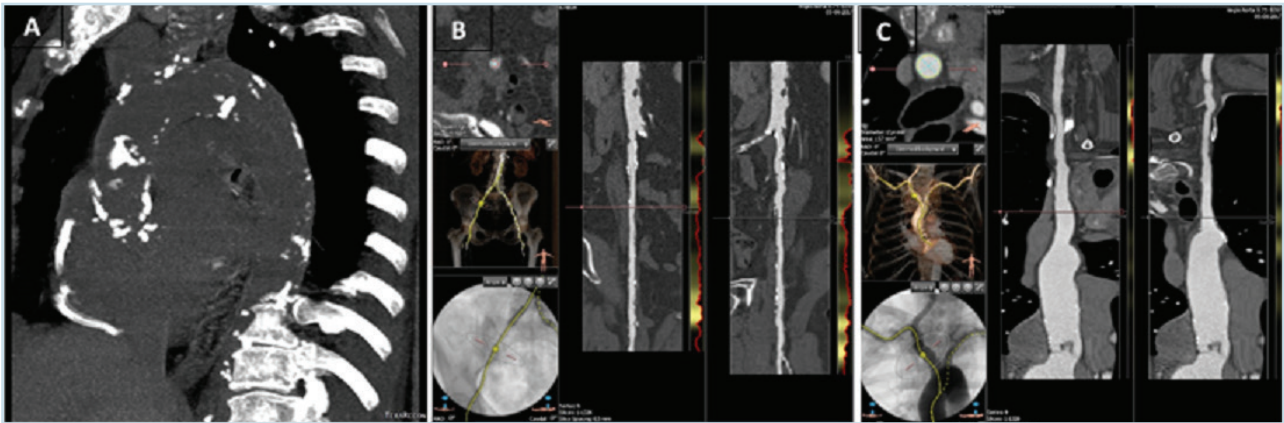


Figure 2

A) Heavy calcification of the ascending aorta. B) Inadequate iliofemoral access. C) Subclavian artery bilateral (lateral view).

> 95% and nasal capnography value between 35-40mmHg.

A 6-Fr pigtail catheter was inserted through the right femoral artery for hemodynamic monitoring and landmark aortic angiography.

From the left femoral artery a 6 Fr guiding catheter was placed through which a guidewire was passed to the left subclavian / axillary. For safety, through this guidewire a 6mm diameter peripheral balloon (matching the size of the subclavian artery proximal to the puncture site) was kept in place and inflated when changing the introducers for the valve delivery system and at the end of the procedure to obtain the so-called 'dry sealing'. This transitional area between

the subclavian and axillary arteries is difficult to compress, so the second femoral access increases the safety of the procedure, minimizing blood loss and controlling with the balloon a possible hemorrhagic complication.

Some centers advocate exteriorization of the guidewire introduced by the femoral through the left radial artery, giving more support in case of vascular complication requiring the placement of a stent. However we considered that, in this case, exteriorization of the guide was not necessary.

A truly percutaneous approach was achieved without the need for vascular surgery. The approach of the left axillary artery was performed with the aid of ultrasound and fluoroscopy (Fig. 3).

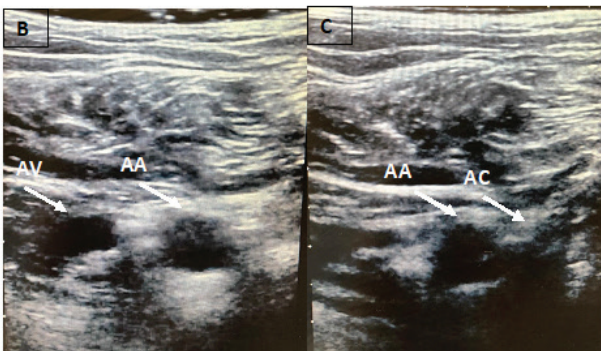
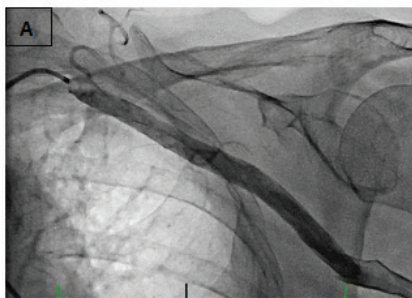


Figure 3

A) Angiography of the axillary artery pre-procedure; B) and C) ultrasonography of axillary artery (AV Axillary vein; AA axillary artery; AC Axillary catheterization).

Local infiltration with 20ml lidocaine 2% was performed and vascular puncture was obtained at the first attempt. Two Perclose ProGlide® vascular closure systems were placed. After initial placement of a 6 Fr introducer, progressive dilatations were performed until a 16 Fr sheath was introduced. The fact we were able to place a 16 Fr sheath in this artery allowed us to advance with the Evolut Pro system, the latest generation of this valve, designed to minimize the risk of paravalvular regurgitation - which was of interest in this particular patient who had mainly aortic insufficiency.

Aortic valvuloplasty was performed using a 22-mm balloon (NuMED) and rapid pacing was successfully made over the wire without complications. A 26-mm CoreValve Evolut Pro prosthesis was carefully inserted over a super-stiff guidewire and retrogradely implanted under angiographic and fluoroscopic guidance. Immediately after CoreValve Evolut Pro deployment, angiography of the ascending aorta was performed to assess the patency of the coronary arteries and the presence and location of any paravalvular leakage (Fig.4).

During the procedure heparin was administered for an activated coagulation time > 200sec, which was reversed at the end of the procedure with protamine sulfate.

Procedural success was obtained. After valve de-

DISCUSSION

The standard approach for TAVI is through the transfemoral retrograde route, because it is minimally invasive and it is feasible under conscious sedation in a totally percutaneous fashion. Although significant technical improvements in sheath diameter and delivery catheter design have been achieved, the transfemoral approach is contraindicated in case of vessel diameter less than 5.5 mm (plus 1mm if calcification). In addition, the transfemoral approach should be considered cautiously in case of severe tortuosity or calcification of the femoral or iliac arteries or of the distal aorta, previous iliofemoral surgery or stent implantation, or in patients with an aneurysm of the thoracic or abdominal aorta. Under these conditions, choosing the transfemoral access for TAVI increases the risk of periprocedural and postprocedural vascular complications, with a negative impact on clinical outcome⁵.

Since alternative TAVI approaches have not been studied in a comparative fashion, the choice depends mainly on the experience and judgment of the heart team. Clearly, in selected cases the TAX access can serve as an alternative route.

The most obvious advantage of a direct TAX access for TAVI is: that it maintains the left ventricular integrity (in contrast to the transapical access), comes without opening the chest cavity (in contrast to a direct aortic and transapical access) and, when compared with the transfemoral approach, transaxillary access has the advantages of providing a less remote access to the aortic valve. The valve delivery catheter covers a shorter distance, and avoids bending in the tortuosities of the iliofemoral axis and of the thoracoabdominal aorta, with the potential to improve the control of the prosthesis during deployment. Therefore, the transaxillary approach may theoretically allow for a more accurate device positioning, reducing the incidence of paravalvular leak and the development of complete heart block requiring permanent pacemaker implantation⁶.

Nevertheless, a possible limitation of the TAX approach is the assumed risk of vascular complications being frequently associated with significant bleeding, transfusion and renal failure. All these factors are proven to be independent predictors of short and long-term mortality in patients treated by TAVI. Hence, there is some reluctance to actively pursue the TAX approach. In addition, a lower threshold for stent graft implantation can be assumed (prevention of clinical significant bleeding), possibly explaining a higher vascular repair rate compared to other transvascular approaches⁴.

Importantly, the transaxillary access did not require a significant learning curve in terms of procedural duration and complication rates, allowing for a quick shift from the initial use of general anaesthesia to the current standard of local anaesthesia with sedation. In fact, the possibility of performing TAVI under local anaesthesia is a major advantage of the transaxillary over the transapical

and transaortic accesses considering the risks of general anaesthesia in elderly patients who suffer from multiple comorbidities⁶.

Anatomical Specificities

The axillary arteries often show little calcification and tortuosity as well as larger lumina, even in the presence of diseased iliofemoral arteries. Particular care has to be taken as the axillary arteries are more delicate than the iliofemoral ones and effective manual compression is hampered by the anatomical conditions.

The left axillary artery is generally preferred over the right one due to a more favourable implantation angle providing better axial alignment of the device with the aortic root. An angle $>30^\circ$ between the annular plane and the horizontal axis is regarded as a significant limitation for right-sided TAX access.¹ For the EvolutPro valve (which has 16Fr delivery catheter) the artery should have a minimum diameter of 5.5mm and for the EvolutR valve (with 14Fr delivery catheter) it should have a minimum diameter of 5mm. These measurements are considered in noncalcified arteries. In the presence of circumferential calcium the minimum size plus 1mm margin should be given.

Specific conditions such as a patent left internal mammary artery (LIMA) graft or a pacemaker are not strict contraindications, but have to be considered when evaluating patients for a TAX approach.

In the former case, verification of a sufficiently large vessel diameter (at least 7-8 mm) is recommended to ensure perfusion of the graft during the intervention. In fact, positioning an almost occlusive sheath in front of the origin of the LIMA may cause myocardial ischaemia. To prevent such an occurrence, the axillary artery diameter should be at least 7 mm, free of atherosclerotic disease, especially proximal to or at the ostium of the LIMA, and with minimal tortuosity at the origin of the LIMA. An injection of dye can confirm a good antegrade flow in the LIMA. To minimise the potential limitation in LIMA flow during TAVI, the sheath can be withdrawn distal to the origin of the LIMA immediately after the advancement of the CoreValve prosthesis across the aortic valve. Experience reports in this subset of patients confirms the safety of CoreValve implantation through the left axillary artery, with no case of periprocedural myocardial ischaemia⁶.

In the case of permanent pacemaker in the ipsilateral pectoral region, the left or right transaxillary access is feasible. The artery is usually medial enough to the pacemaker pocket not to interfere with the pacemaker generator and wires⁶.

Importantly, although there was an association between iliofemoral and axillary artery diameters, axillary arteries were larger ($>5.0\text{mm}$) in the subset of patients with small ($<5.0\text{mm}$) and presumably diseased iliofemoral arteries suggesting that axillary access was feasible in these patients. In general, the upper extremity arteries were also comparatively free of calcification, stenosis and tortuosity

even when the iliofemoral arteries were diseased⁷.

Technical Specificities

The transaxillary approach is currently approved as an alternative to the transfemoral approach for the CoreValve.

At the moment, the transaxillary route is also being tested for the Edwards SAPIEN⁶.

Apart from procedural aspects, meticulous pre-procedural assessment of the access site by contrast-enhanced CT further supports patient safety. It enables adequate patient selection for the TAX approach by 3D-reconstruction of the supra-aortic branches and the subclavian/axillary artery and exact measurements of the vessel diameter and calcification pattern.

Ultrasound guidance has advantages over palpation and fluoroscopy, allowing the operator to directly visualize the artery and its anatomy, identify the needle puncture directly and to avoid posterior vessel wall puncture, inadvertent puncture of adjacent vein, and luminal atherosclerotic and calcified plaque. The use of ultrasound results in less number of attempts, and therefore contributes in reducing the potential risk of hematoma formation and neuronal lesion. It also contributes to diminish radiation exposure. While there is a learning curve for ultrasound use, we decided to use ultrasound in combination with fluoroscopy in the access' approach for a better outcome.

Risks and complications

Given the anatomic surroundings, manual compression of the axillary artery at the puncture site is usually not effective, potentially leading to severe bleeding or even hemorrhagic shock. Moreover, the axillary artery wall properties (a markedly thinner vessel wall) make severe vessel trauma after insertion of a large introducer sheath more likely (4). Thus, prevention of major vascular complications is crucial for this approach.

Schafer et al⁶, in a population of 24 high-risk patients, observed closure device failure in 29.2% of patients, who subsequently received a stent graft implantation. In all cases with failed vessel closure, the ProStar[®] system had been used, whereas the use of the ProGlide[®] system resulted in a 100% vessel closure success rate. However, in the updated study cohort (additional 76 patients)⁴ vessel closure was exclusively performed with two ProGlide[®] systems and resulted in 94.8% successful access site closures.

Such a difference in performance of the two closure device systems seems to be specific for the TAX approach, since it has not been reported for the transfemoral approach, where use of either system has been recommended. The superiority of the ProGlide[®] system for the percutaneous TAX approach may be explained by the different vessel wall properties of the axillary artery (elastic type) compared to the femoral artery (muscular type) and the less traumatic

nature of the ProGlide[®] system compared to the ProStar[®] system⁴. In accordance with these findings, in our patient we chose to use 2 ProGlide[®] for vessel closure and there were no complications.

New arterial closure devices have been launched in the market with promising results, and their application in axillary artery closure post-TAVI has been studied. Examples of this devices are the MANTA[™] (a collagen-based closure device); the InSeal (a membrane-based device consisting of a self-expanding nitinol frame, a biodegradable membrane and a bioresorbable polyglycolic acid tether); and PerQseal (a flexible intravascular patch supported by a scaffold).^{9,10} Another aspect is that our team's technical success improved over time, demonstrating a clear learning curve for this technique associated with ultrasound guidance. Ultrasound allows the differentiation of non-compressible and pulsatile arteries from compressible veins, specifically identifies and avoid surrounding nerves and pleura when performing the arterial puncture, and helps avoid a calcified arterial entry point.

Outcome

In 2010, Petronio and co-workers¹¹ published multicenter registry data of 54 high-risk patients, in whom the CoreValve was implanted by TAX access and surgical cut-down. Procedural and clinical outcome of TAX TAVI were excellent and mortality did not differ in comparison to a TF control group. In consideration of these results, the authors concluded that the TAX approach might be more liberally chosen in cases with a difficult TF access.

In 2018, Gleason et al¹² published data results that were completely in line with these findings, supported by low complication rates and a more than acceptable long-term mortality.

More recently, the results of the CoreValve ADVANCE study¹³, a multicentre prospective fully monitored TAVI study (with 96 patients), showed a higher incidence of major adverse cardiovascular and cerebrovascular events (13.5% vs. 7.9%, $p=0.05$) compared to patients treated by TF TAVI, but they also had a higher mean logistic EuroSCORE (data presented at ESC 2012, Munich). However, for individual endpoints, differences in 30-day rates did not reach statistical significance.

A meta-analysis¹⁴ encompassing 618 patients treated by TAX and 3,886 patients treated by TF TAVI reported no difference in 30-day mortality, stroke, major vascular complications or life-threatening bleeding despite a higher mean logistic EuroSCORE and a higher prevalence of coronary and peripheral artery disease in the TAX group.

With these results we can assume that the outcome between the transaxillary and transfemoral approach is at least similar. However in the vast majority of patients evaluated in these studies vascular access was surgically approached. In our case report and bibliographic review, we want to point out that the percutaneous approach does not interfere with the patient's outcome and does not add perioperative morbidity.

Percutaneous approach

Shafer⁸ in 2012 described for the first time the true percutaneous TAX approach in a population of 24 high-risk patients (mean logistic EuroSCORE I $35.3 \pm 22.8\%$). Device success was 95.8% (23/24) and 30-day mortality rate was 8.4% with no major adverse cardiac and cerebrovascular events and no major vascular complications according to the Valve Academic Research Consortium (VARC2) criteria.

In 2017, Schäfer included more 76 patients⁴ in whom access vessel closure was performed with two Perclose ProGlide® systems (Abbott Vascular) achieving successful closure in 94.8%; 11% required covered stent implantation, but no major access-site complications occurred. Thirty-day mortality was 6% and life-threatening bleeding 3%; no strokes were reported. There were no major vascular complications according to the VARC2 criteria. However, a lower threshold for stent graft implantation was chosen (prevention of clinically significant bleeding), possibly explaining a higher vascular repair rate compared to other transvascular approaches. No injury of the neuronal plexus or any other neuronal complications were experienced in this study.

With the surgical approach, we believe that surgical exposure of the vessel is more time consuming and could be associated a higher complication rate (hematoma, pseudoaneurysm, ipsilateral arm neurologic deficit, and stroke). Moreover, this exposure has an added risk of infectious complications. However, the worldwide experience for large bore percutaneous axillary artery access remains relatively small. More recently, the Axillary Registry to Monitor Safety was completed. Axillary Registry to Monitor Safety was a prospective multicenter registry of percutaneous upper extremity access for mechanical circulatory support devices. This registry, implemented across 10 institutions in the United States, was developed to evaluate the procedural and short-term safety of percutaneous axillary access for Impella devices (Abiomed, Danvers, MA) and intra-aortic balloons pump and represent the largest prospective series to date. Formal publication of the completed dataset is expected soon, and an interim analysis of the first 80 patients has been presented, suggesting very favorable bleeding and complication rates and no cases of ischemic upper extremity or significant neurological injury.¹⁵

Anesthetic management

General anesthesia is associated with potential complications, particularly cardiovascular and respiratory-related. Patients referred to TAVI are elderly and many have comorbidities which place them at higher risk with general anesthesia¹⁶. Need of inotropic support seems to be higher in centers performing GA.

However, general anesthesia can be advantageous in patients who have hemodynamic compromise or other periprocedural complications when patient intubation is needed for more extensive rescue procedures¹⁷.

As TAVI centers have gained experience, minimal

approaches have been employed whereby the procedure is completed percutaneously on an awake patient, with only local anesthesia (LA) and monitored anesthesia care (MAC). The type of the anesthetic management has increasingly switched from GA to LA, especially in European centers. Sedation shortens procedural time, time to ambulation and hospital stay duration. In addition, the use of vaso-pressors in sedation is not as frequent as in GA procedures, which can be attributed to the vasodilating effects of the anesthetic agents. Furthermore, emergency intubation and switching to GA can be achieved in the procedure room to surgically handle cardiac or vascular complications should they arise during TAVI. LA has the unique benefit of real-time evaluation of the patient's mental status and cognitive function. This approach has been shown to be safe and effective and is potentially cost-saving: the cost for general anesthesia is eliminated, the patient is mobilized sooner, length of time in the intensive care unit (ICU) is decreased, and discharge is sooner^{18,19,20}.

Previous data showed that incidence of vascular complications is unrelated to the anesthetic technique. Transfusions, in the same way, present a similar percentage when GA or LA is used.¹⁹

In this case we used a moderate sedation with propofol, which translated into hemodynamic stability and maintenance of ventilatory dynamics throughout the procedure. Brain oxygenation also remained constant by INVOS® monitoring. This type of monitoring helps us determine the impact on the cerebrovascular system.

Although there were no complications to register, the anesthetic team was prepared to approach the airway at any time and convert to a general anesthesia.

CONCLUSION

The availability of alternative vascular accesses for TAVI should not modify the principle for which this procedure was conceived, that is the attempt to implant an aortic prosthesis in the least invasive fashion possible.

Percutaneous transaxillary transcatheter aortic valve implantation is a feasible and safe alternative access in patients who have suboptimal iliofemoral conduits. The ultrasound may become an indispensable tool for safe achievement of vascular access.

The ProGlide® system was effective in vascular closure, with no periprocedural and postprocedural vascular complications. Neuronal or respiratory complications were not experienced too.

A truly percutaneous approach is feasible and can be done under local anaesthesia with conscious sedation. This promotes hemodynamic stability, lower perioperative morbidity and increases patient safety and satisfaction.

Conflict of interest:

There is no affiliation, interpersonal relationship or financial interest from the authors that may constitute a source of bias or conflict of interest.

REFERENCES

- Lanz, J., Greenbaum, A., Pilgrim, T., Centre, S. C., & Hospital, H. F. (n.d.). Current state of alternative access for transcatheter aortic valve implantation. *EuroIntervention*. 2018 Aug 31;14(AB):AB40-AB52. doi: 10.4244/EIJ-D-18-00552.
- Mack MJ, Leon MB, Thourani VH, Makkar R, Kodali SK, Russo M, Kapadia SR, Malaisrie SC, Cohen DJ, Pibarot P, Leipsic J, Hahn RT, Blanke P, Williams MR, McCabe JM, Brown DL, Babaliaros V, Goldman S, Szeto WY, Genereux P, Pershad A, Pocock SJ, Alu MC, Webb JG, Smith CR; PARTNER 3 Investigators. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med* 2019;380:1695–1705.
- Popma JJ, Deeb GM, Yakubov SJ, Mumtaz M, Gada H, O'Hair D, Bajwa T, Heiser JC, Merhi W, Kleiman NS, Askew J, Sorajja P, Rovin J, Chetcuti SJ, Adams DH, Teirstein PS, Zorn GL, Forrest JK, Tchétché D, Resar J, Walton A, Piazza N, Ramlawi B, Robinson N, Petrosian G, Gleason TG, Oh JK, Boulware MJ, Qiao H, Mugglin AS, Reardon MJ; Evolut Low Risk Trial Investigators. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. *N Engl J Med* 2019;380:1706–1715.
- Schäfer, U., Deuschl, F., Schofer, N., Frerker, C., Schmidt, T., Kuck, K. H., Conradi, L. (2017). Safety and Efficacy of the Percutaneous Transaxillary Access for Transcatheter Aortic Valve Implantation using various Transcatheter Heart Valves in 100 Consecutive Patients. *International Journal of Cardiology*. <https://doi.org/10.1016/j.ijcard.2017.01.010>
- Amat-santos, I. J. (2018). Transubclavian approach: A competitive access for transcatheter aortic valve implantation as compared to transfemoral, (October 2017), 1–10. <https://doi.org/10.1002/ccd.27485>
- Petronio, A., Giannini, C., Carlo, M., Caro, F., Bortolotti, U. (2019). Subclavian TAVI: more than an alternative access route., 24025955. <https://doi.org/10.4244/EIJV9SSA7>
- Rogers, T., & Lederman, R. J. (2019). Percutaneous transaxillary access for TAVR: another opportunity to stay out of the chest, 91(1), 157–158. <https://doi.org/10.1002/ccd.27458>.
- Schäfer U, Ho Y, Frerker C, Schewel D, Sanchez-Quintana D, Schofer J, Bijuklic K, Meincke F, Thielsen T, Kreidel F, Kuck KH. Direct percutaneous access technique for transaxillary transcatheter aortic valve implantation: “the Hamburg Sankt Georg approach”. *JACC Cardiovasc Interv*. 2012;5:477-86.
- Palma, R. De. (2017). Percutaneous axillary arteriotomy closure during transcatheter aortic valve replacement using the MANTA device, (July), 1–4. <https://doi.org/10.1002/ccd.27383>
- Wiechen, M. P. Van, Ligthart, J. M., & Mieghem, N. M. Van. (2019). Structural Large-bore Vascular Closure : New Devices and Techniques, 17–21. <https://doi.org/10.15420/icr.2018.36.1>
- Petronio AS, De Carlo M, Bedogni F, Marzocchi A, Klugmann S, Maisano F, Ramondo A, Ussia GP, Ettori F, Poli A, Brambilla N, Saia F, De Marco F, Colombo A. Safety and efficacy of the subclavian approach for transcatheter aortic valve implantation with the CoreValve revalving system. *Circ Cardiovasc Interv*. 2010;3:359-66.
- Gleason TG, Schindler JT, Hagberg RC, Deeb GM, Adams DH, Conte JV, Zorn GL, Hughes GC, Guo J, Popma JJ, Reardon MJ. Subclavian/Axillary Access for Self-Expanding Transcatheter Aortic Valve Replacement Renders Equivalent Outcomes as Transfemoral. *Ann Thorac Surg*. 2018;105:477-83.
- Brecker S. Result from the ADVANCE study. ESC 2012. Munich, Germany.
- Amat-Santos IJ, Rojas P, Gutiérrez H, Vera S, Castrodeza J, Tobar J, Goncalves-Ramirez LR, Carrasco M, Catala P, San Román JA. Transubclavian approach: A competitive access for transcatheter aortic valve implantation as compared to transfemoral. *Catheter Cardiovasc Interv*. 2018 Jan 3.
- McCabe J, Khaki A, Nicholson W, Blank N, Grantham JA, Lombardi W, Tayal R. TCT-99 safety and efficacy of percutaneous axillary artery access for mechanical circulatory support with the Impella® devices: an initial evaluation from the axillary access registry to monitor safety (ARMS) multiCenter registry. *J Am Coll Cardiol*. 2017;70:B43. DOI: 10.1016/j.jacc.2017.09.1123
- Ben-dor, I., Looser, P. M., Maluenda, G., Weddington, T. C., Kambouris, N. G., Barbash, I. M. Waksman, R. (2012). Transcatheter aortic valve replacement under monitored anesthesia care versus general anesthesia with intubation. *Cardiovascular Revascularization Medicine*, 13(4), 207–210. <https://doi.org/10.1016/j.carrev.2012.02.002>
- Mathur, M., Krishnan, S. K., Levin, D., Aldea, G., McCabe, J. M., Mathur, M., Aldea, G. (2017). A Step-by-Step Guide to Fully Percutaneous Transaxillary Transcatheter Aortic Valve Replacement A Step-by-Step Guide to Fully Percutaneous Transaxillary Transcatheter Aortic Valve. *Structural Heart*, 1(5–6), 209–215. <https://doi.org/10.1080/24748706.2017.1370156>
- Grubb KJ, Fields T, Cheng A, Settles DM, Stoddard M, Flaherty MP (2016). Transaxillary Transcatheter Aortic Valve Replacement with a Self-Expanding Valve under Conscious Sedation : Case Discussion and Review of the Literature, *Clinics in Surgery* 1, 1–6.
- Ruggeri, L., Gerli, C., Franco, A., Barile, L., Magnano, M. S., Lio, S., Zangrillo, A. (2012). Anesthetic management for percutaneous aortic valve implantation : an overview of worldwide experiences. *HSR Proceedings in Intensive Care and Cardiovascular Anesthesia* 2012; 4(1): 40-46
- Melidi, E., Latsios, G., Toutouzas, K., Vavouranakis, M., Tolios, I., Gouliami, M. Tousoulis, D. (2016). Cardio-anesthesiology considerations for the trans-cathe-

- ter aortic valve implantation. *Hellenic Journal of Cardiology*, 57(6), 401–406. <https://doi.org/10.1016/j.hjc.2016.10.001>
21. Overtchouk, P., & Modine, T. (2018). Structural Alternate Access for TAVI : Stay Clear of the Chest, 145–150.
 22. Mack, M. J. (2012). Access for Transcatheter Aortic Valve Replacement, 5(5). <https://doi.org/10.1016/j.jcin.2012.03.009>
 23. Hamburg, T., & Georg, S. (2012). Direct Percutaneous Access Technique for Transaxillary Transcatheter Aortic Valve Implantation, 5(5). <https://doi.org/10.1016/j.jcin.2011.11.014>
 24. Fraccaro, C., Napodano, M., Tarantini, G., Gasparetto, V., Gerosa, G., Bianco, R. Isabella, G. (2019). Expanding the eligibility for transcatheter aortic valve implantation the trans-subclavian retrograde approach using: the III generation CoreValve revalving system., 2(9), 19778770. <https://doi.org/10.1016/j.jcin.2009.06.016>
 25. Oteo JF, Trillo R, García-Touchard A, Fernández-Díaz JA, Cavero MA, Goicolea J. A first case of totally percutaneous transaxillary aortic valve implantation. *Rev Esp Cardiol (Engl Ed)*. 2013 Mar;66(3):220-2. doi: 10.1016/j.rec.2012.06.012. Epub 2012 Oct 4.
 26. Bojara, W., Gerckens, U., & Fritz, M. (2009). Implantation of the CoreValve self-expanding valve prosthesis via a subclavian artery approach : a case report, 204, 201–204. <https://doi.org/10.1007/s00392-009-0750-5>
 27. Bruschi, G., Fratto, P., Marco, F. De, Oreglia, J., Colombo, P., Botta, L., Klugmann, S. (2009). The trans-subclavian retrograde approach for transcatheter aortic valve replacement: Single-center experience. *The Journal of Thoracic and Cardiovascular Surgery*, 140(4), 911–915. e2. <https://doi.org/10.1016/j.jtcvs.2010.01.027>
 28. Bruschi, G., Marco, F. De, Fratto, P., Oreglia, J., Colombo, P., Botta, L. Martinelli, L., (2011). Alternative approaches for trans-catheter self-expanding aortic bioprosthetic valves implantation: single-center experience §. *European Journal of Cardio-Thoracic Surgery*, 39(6), e151–e158. <https://doi.org/10.1016/j.ejcts.2011.01.014>
 29. Caceres, M., Braud, R., & Roselli, E. E. (2012). The Axillary / Subclavian Artery Access Route for Transcatheter Aortic Valve Replacement : A Systematic Review of the Literature. *ATS*, 93(3), 1013–1018. <https://doi.org/10.1016/j.athoracsur.2011.10.056>