Trans-catheter aortic valve implantation (TAVI) in the catheterization laboratory: challenges and problem solving

Implante transcatéter de válvula aórtica en el laboratorio de cateterismo: retos y resolución de problemas

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Abstract

Despite the less invasive nature of trans-catheter aortic valve implantation (TAVI) compared to conventional surgical aortic valve replacement, the trans-catheter procedure is not free of relevant complications such as vascular complications, renal function impairment, stroke, coronary occlusions and aortic rupture.

Vascular complications significantly influence the immediate, mid and long-term clinical outcome; renal function impairment is also serious concern since most TAVI candidates have poor kidney function; stroke is the most threatening pitfall of TAVI since so far, its occurrence is largely unpredictable and hardly avoidable and lastly coronary occlusions and aortic rupture are rare but potentially fatal events. But all of these can likely be contained with an accurate pre-intervention selection of patients and techniques.

In this article, we describe some challenging cases as examples to disclose the strategies applied for the management or prevention of complications in the experience with TAVI started in mid2010 and since over 100 patients with high risk symptomatic aortic stenosis were treated in the University of Verona, Italy, using full percutaneous transfemoral approach with the use of closure device.

Key words: *aortic stenosis, trans-catheter aortic valve implantantation, aortic valve surgery.*

Abbreviations			
AVS	aortic valve stenosis	MG	mean gradient
AVA	aortic valve area	PG	peak gradient
CABG	coronary artery bypass surgery	PVD	peripheral vascular disease
CFA	common femoral artery	TAVI	transcatheter aortic valve implantation
CKD	chronic kidney disease	TEE	transesophageal echocardiography
CT	computerized tomography	TTE	transthoracic echocardiography
LVEF	left ventricle ejection fraction	SAVR	surgical aortic valve replacement
		SFA	superficial femoral artery

INTRODUCTION

Following experimental work with transcatheter valves in the 1990s,[1,2] the first-in-man transcatheter aortic valve implantation (TAVI) was performed by Alain Cribier and colleagues in 2002.[3] Recently, technology has developed very rapidly and, to date, more than 40,000 transcatheter valves have been implanted worldwide.[4] The results of the prospective, randomized Placement of Aortic Transcatheter Valves (PARTNER) trial have provided definitive data confirming this therapeutic option as an

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alternative to standard surgical aortic valve replacement (SAVR) in inoperable and high surgical risk patients.[5,6]

Despite the less invasive nature of TAVI compared to conventional surgical aortic valve replacement (SAVR), the trans-catheter procedure is not free of relevant complications; among these, vascular complications are the most common, and significantly influence the immediate, mid and long-term clinical outcome.[5-7] Renal function impairment is a serious concern since most TAVI candidates have poor kidney function, which is a strong predictor of adverse outcome at long-term.[5-9] Contrast administration and embolization of atherosclerotic debris may cause either contrast-induced nephropathy or embolic renal damage; therefore, implementation of preventive measures to minimize the risk of renal damage is of outmost importance. Stroke is the most threatening pitfall of TAVI since so far, its occurrence is largely unpredictable and hardly avoidable.[5-8] Coronary occlusions and aortic rupture are rare but potentially fatal events, but these can likely be contained with an accurate pre-intervention selection of patients and techniques.[8-12] Although complication rates increase with patient's co-morbidities and frailty, operators experience and technical advancements are key for preventing them and improving immediate and long-term TAVI outcomes.

Our TAVI experience started in mid 2010 with an invited proctor, and since over 100symptomatic, high-risk aortic stenosis patients have been treated by trans-femoral approach (mean age 82±7 yrs; mean BMI 27±4.9 kg/m^2; 64% female; 84% hypertensive; 21% had previous cardiac surgery and 39% were in atrial fibrillation; mean logistic EuroSCORE (%) was 28±21. Pre-TAVI echocardiography showed mean aortic valve area (AVA) 0.53±0.21 cm^2/m^2; peak gradient (PG) of 69±23 mm Hg; mean gradient (MG) 42±16 mmHg; and left ventricle ejection fraction (LVEF) was 53±14 %. The surgical femoral vascular access was used in the first 14 cases, subsequently the operators switched to a fully percutaneous approach with the assistance of the Prostar XL (Abbott Vascular Inc, Red City, CA, USA) closing device in most cases with some exceptions in patients with severe peripheral vascular disease (PVD).

Both, the Edward Sapien (Edwards Lifesciences Corporation, Irvine, CA, USA) and CoreValve (Medtronic, Milwaukee, Wisconsin) prosthesis have been deployed. The CoreValve was also used in patients with some particular clinical settings like severe aortic regurgitation and degenerated bioprosthesis (valve in valve).[13]

During the implementation of this new technique at our Centre, we came across several challenging cases and associated complications, which were overcome by applying specific interventional coronary, structural, and peripheral skills as well as an accurate clinical monitoring of the patients conditions during their hospital stay.In this article, we describe some challenging cases as examples to disclose the strategies applied for the management or prevention of complications.

CHALLENGES FROM THE FEMORAL VASCULAR ACCESS

TAVI can be achieved by several accesses, such as the trans-femoral, trans-apical, trans-aortic, sub-clavian and trans-axillary.[4,15] Among these, the trans-femoral is the most preferable route as it is the less invasive. We believe that during the initial phase of a "TAVI learning curve" the femoral access should be managed surgically so that interventional cardiologists could concerte in learning tips and tricks of the valve implantation exclusively, without adding complexity to the procedure related to the percutaneous management of the vascular access with the Prostar XL closure device. It is obvious that such recommendation does not apply to operators that are already proficient with the use of this closing device.

Before selectingthe femoral approach, the operator should well analyse diameter, tortuosity, and calcification of the common femoral artery (CFA), external, and common iliac arteries.[3,15] Furthermore, the exact location of the calcium with respect to the anterior wall of the CFA is crucial during implantation of a closure device. The operator must know the vascular situation of the inferior limbs, in particular patency of the superficial femoral artery (SFA), or collateral circulation, and the quality of the infra-renal aortic wall.

To this aim, both, computerized tomography (CT) scan and contrast angiography are essential pre-TAVI examinations. CT scan offers accurate information about the vessels anatomy and disposition, the severity and localisation of calcifications, it offers reliable measurements in non-calcified tracts, but tends to under-estimate vessel diameter in calcified segments.[14,15] Contrast angiography as a screening for potential TAVI candidates should be ideally performed by the radial access to avoid complications at the femoral puncture site during the diagnostic examination. Angiography adds an important perception to the estimations of the vessels diameter, and being a dynamic imaging, shows the degree of rigidity or flexibility of the aortic-iliac-femoral axe by analysing its systolic-diastolic excursions. The more flexible the vascular axe, the more likely it will accommodate the large introducer sheath despite relatively small diameters, or marked tortuosity. Apparently challenging tortuosity as shown in **(Figures 1A-B),** can be easily afforded when the vessel is elastic and not severely calcified. Also small arteries (less than 5.5 mm) can safely accommodate

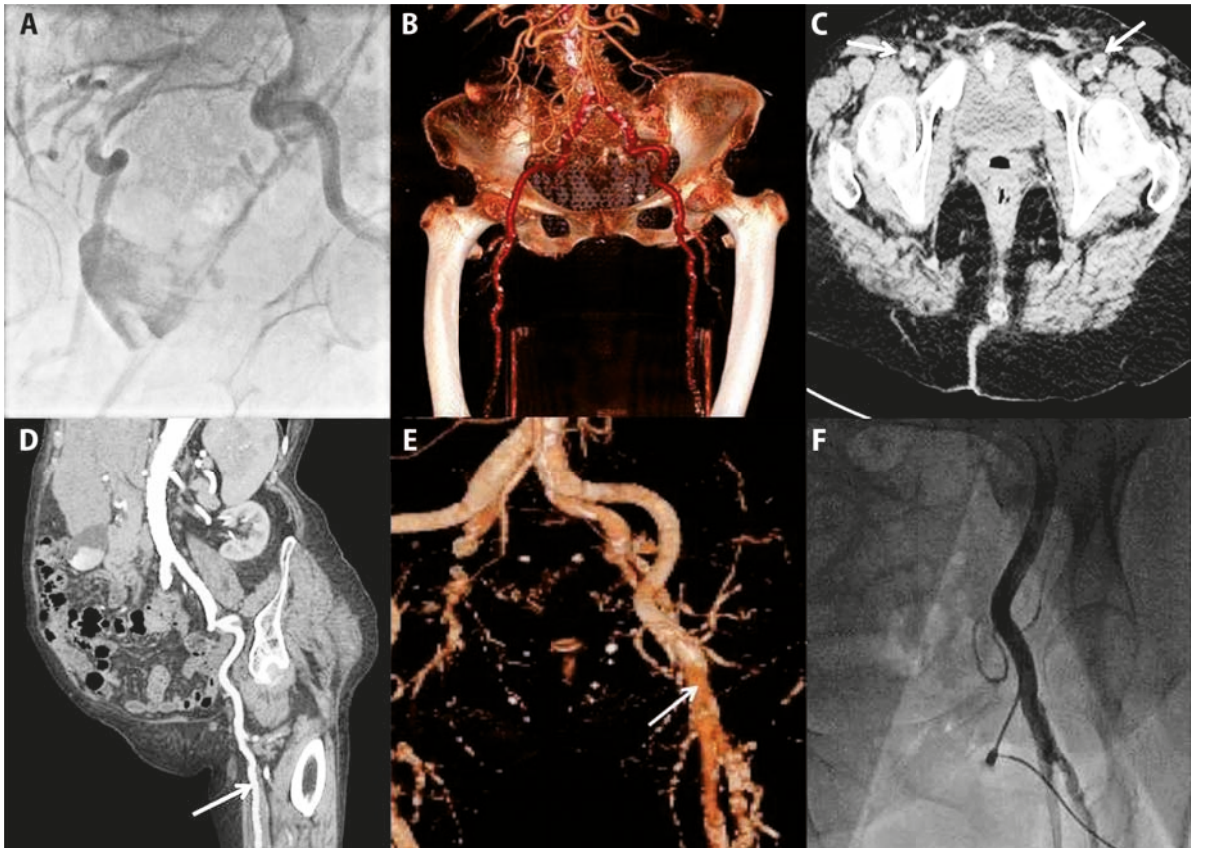

Figure 1. *Vessel anatomy.* ***A.*** *Angiography showing bilateral tortuous ilio-femoral arteries.* ***B.*** *CT Scan showing bilateral tortuous ilio-femoral arteries. Despite marked tortuosity a 21 F introducer sheath was advanced into the right iliac axe without dificulties.* ***C.*** *CT Scan showing relatively small iliac arteries without calcification* ***(arrows).*** *The maximum diameter measured in the comon iliac was 5.5 mm. However, a 21 F introducer sheath was advanced without complications.* ***D.*** *CT Scan sagittal section showing relatively small iliac arteries without calcification* ***(arrow).*** ***E.*** *CT Scan reconstruction showed severe calcification on left CFA with a small area withou calcification* ***(arrow).*** ***F.*** *The fluoroscopic view shows the accurate position of the puncture site taking account of the CT Scan in the same patient shown in Figure 1E.*

the 18 or 19F sheath when are not calcified (**Figures 1C-D).** However, much caution is required in these cases with delicate advancement of the dilators and introducer, avoiding energic pushing that may cause arterial rupture. Angiography provides also valuable information about the run off of the contrast media along the SFA and the dynamic of collateral circulations when important vessels are occluded. Knowledge of the SFA angiographic anatomy is essential for the positioning of a contralateral safety guide-wire, as discussed later in this article. Last, accurate selection of the exact point for the puncture of the CFA (well above the bifurcation of the SFA and the profunda) is clue, avoiding sites with calcium in the anterior arterial wall where the introducer and then the Prostar needles will be implanted (**Figures 1E-F).**

The most challenging situations for the femoral vascular access are dictated by the presence of severely calcified stenosis in the iliac-femoral axe. These may be a contra-indication to the femoral route, but with the continuos improvement in delivery systems and skills in peripheral artery interventions, the success without serious complications can be achieved in most cases as shown in the following examples.

"Tunnelling" of femoral arteries

An 85-year old man with severe aortic stenosis was repeatedly admitted in hospital with syncope and heart failure. He had previous cardiac bypass surgery and a severe impairment of the LV function and chronic atrial fibrillation, hypertension, diabetes mellitus, moderate chronic kidney disease (CKD) (calculated clearance 35 ml/h/m^2) and severe PVD. The logistic EuroSCORE was 55%. Pre-TAVI transthoracic echocardiography (TTE) showed aortic annulus 23 mm, EF=27%, pulmonary artery pressure (PAP) 65 mmHg and CT scan and angiography showed adequate iliac-femoral diameters with multiple calcified plaques. A 26 mm Edward prosthesis was scheduled by trans-femoral route.

Procedure

An aorto femoral angiography showed apparently suitable vasculature for femoral access (left and right common iliac artery diameter was 9.5 mm and 10 mm respectively; CFA diameter was 6 mm and 6.5 mm on left and right side respectively) **(Figure 2A).** The procedure was performed under general anaesthesia and with surgical exploration of right CFA. Due to the extensive calcifications, and the extreme vascular rigidity, it

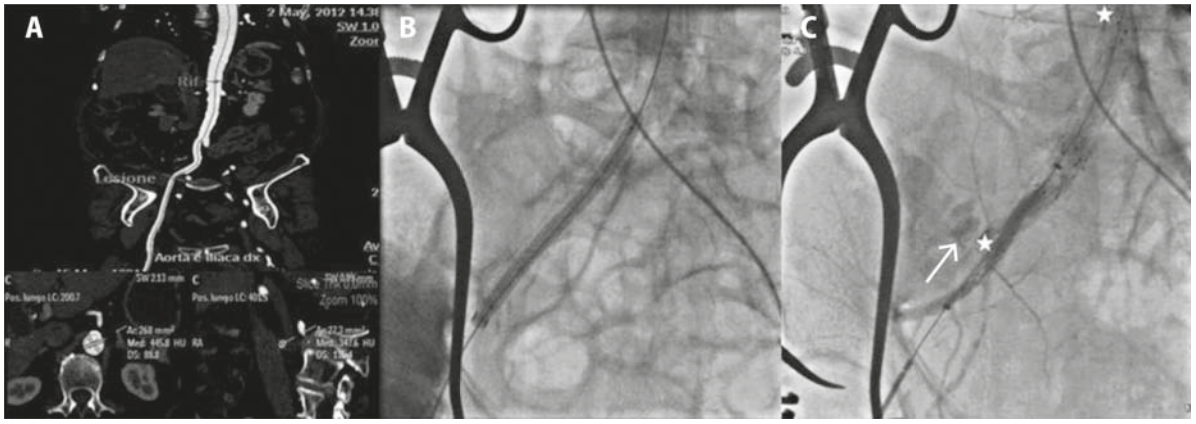

Figure 2. *Femoral artery tunnelling.* ***A.*** *AngioCT showing measurement of right iliac-femoral arteries.* ***B.*** *Fluroscopic view showing balloon dilatation of ilic-femoral axis.* ***C.*** *Fluroscopic view showing stented iliac-femoral axis* ***(segment between asterisks)*** *and contrast media that exits the vessel lumen due to a perforation* ***(arrow).***

was not possible to introduce the 14F dilator in the era of retroflex 22F sheath. The right femoral artery was dilated using 8 mm and 10 mm balloons over the extra-stiff wire (**Figure 2B**) but without success in introducing the dilator. After several dilations, there was a clear evidence of bleeding due to vascular rupture, therefore, despite the fact that implantation of stents before passing the large 22F sheath may cause stent dislodgement and embolization in aorta, two self-expandable covered stents of 10 mm each were rapidly implanted through the same extra-stiff wire to control bleeding (**Figure 2C**). Additional high-pressure balloon dilatations were needed to allow the 22F sheath pass into the common iliac artery. A 26 mm Edward-Sapien prosthesis was implanted after balloon valvuloplasty without difficulties. The vascular access site was repaired surgically with the need of a short vascular Teflon prosthesis to reconstruct the anterior wall of the CFA. Post-operative course was uneventful.

Message

Although the diameter of ilio-femoral axis by angiography and CTscan were adequate, the diffuse atherosclerotic disease, and the use of a "first generation" introducer sheath created a serious obstacle to the TAVI procedure. Tunnelling the vascular axe with aggressive balloon angioplasty and implanting self-expanding covered stents allowed both, to solve the bleeding complication, and to implant the prosthesic valve successfully. However, implanting stents before placing the introducing sheath is not recommended, and should be reserved for emergency to avoid life threatening bleeding. This technique is an option when a surgical cut down of the artery is used as vascular access, but as described later in this article, a different technique is recommended if a totally percutaneous approach is selected.

The use of a totally percutaneous technique for transfemoral TAVI has several advantages over the surgical exploration.[15] First is the spared time compared to the surgical preparation of the vascular access that requires, even for expert teams, more than 60 to 90 minutes to open and close the vascular access as compared to percutaneous the technique. Furthermore, it can be performed with local anesthesia, and allows rapid patient mobilisation after 2 or 3 days of the procedure, depending on the patinet's general conditions. However, a totally percutaneous management of the femoral access route requires accurate pre-intervention screening, confidence with the use of the Prostar closure device, experience with peripheral vascular interventions, and the availability of a wide array of dedicated material. We believe that all cases performed percutaneously with the pre-implantation of the Prostar device must be prepared with a contralateral implantation of a safety guide-wire before the implantation of the introducing sheath. This wire warrants a rapid access to the true lumen of the iliac-femoral vessels in case of occlusion or vascular rupture before or after TAVI (**Figure 3A**).

"Limb-saving" contra-lateral implantation of a protection guide-wire

An 87-year old obese female with medical history of hypertension, type II diabetes mellitus and CKD was admitted in hospital with heart failure. A TTE showed severe aortic valve stenosis (PG-56 mmHg, MG-38 mmHg, AVA 0.3 cm^2/m^2) with important left ventricular dysfunction (LVEF=35%). Coronary angiography showed mild atherosclerotic disease, peripheral angiography visualized moderate atherosclerotic stenosis with severe degree of calcification. Logistic EuroSCORE was 45%. PreTAVI screening with TTE and CTscan showed the following measurement: aortic annulus 21 mm, CFA diameter 7 mm and 8 mm on right and left side respectively. Implantation of 26 mm Edward Sapien XT prosthesis was planned.

Procedure

The procedure was performed under general anaesthesia. The Prostar suture mediated closing device was implanted on the right CFA after positioning a 0.018" ex-

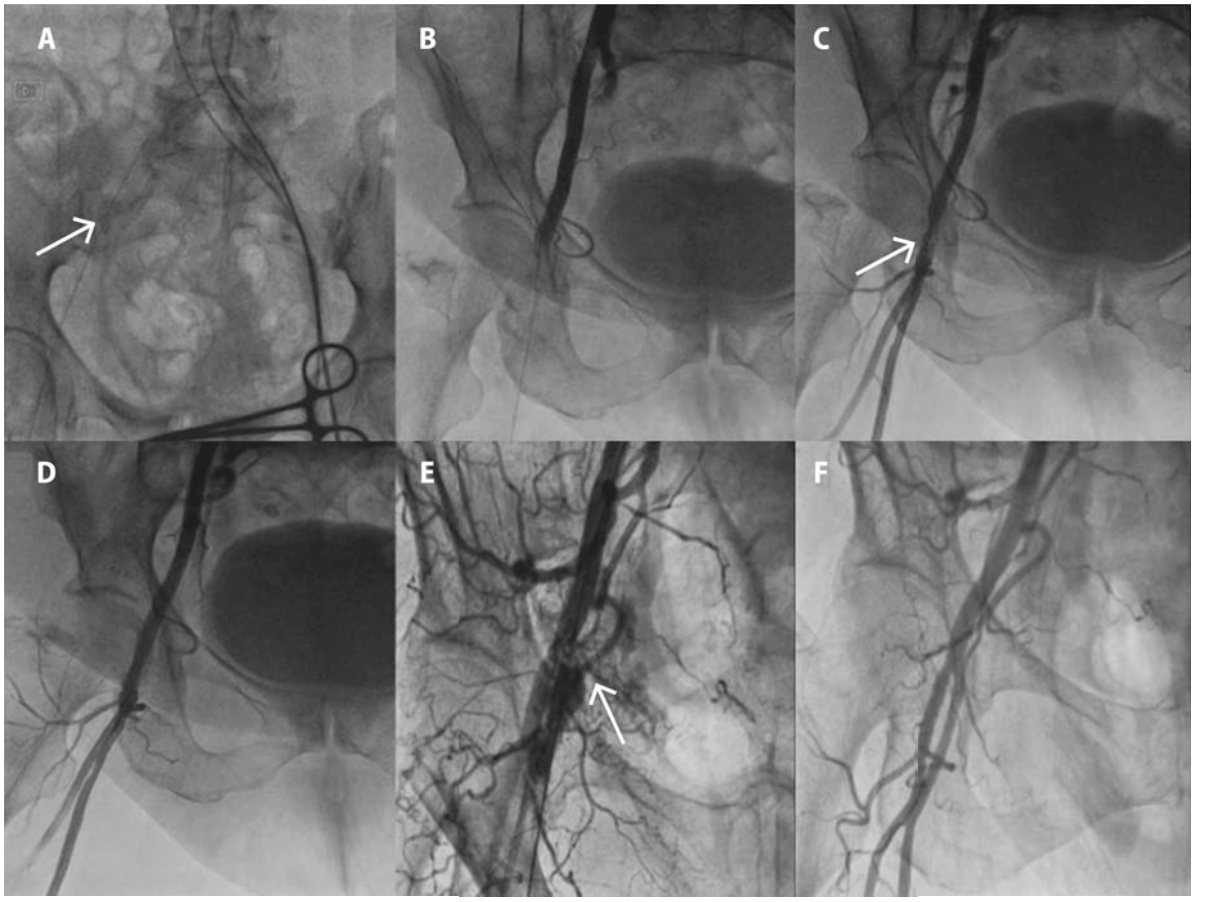

Figure 3. *Safety guide-wire from contralateral side for rescue peripheral artery angioplasty.* ***A.*** *0.0018" guide wire in the rigth femoral artery advanced from the left femoral puncture* ***(arrow). B.*** *Occlusion of right external iliac artery.* ***C.*** *Angiography after balloon dilatation. Residual stenosis and dissection at puncture site* ***(arrow). D.*** *Angiography after implantation of self-expandable stent.* ***E.*** *Rupture of right common femoral artery. Constrast media is evident outside the artery* ***(arrow).*** *F. Final angio after positioning a covered self expandable stent in ruptured right CFA.*

tra-support, 200 mm length guide wire (Control V, *Boston Scientific* Corp*., Natick, Massachusetts*) from the contralateral CFA. Due to the impossibility of advancing the 20F introducer sheath through the extra-stiff 0.035 wire, several balloon dilatations of increased diameters were performed on the external and common iliac arteries. The Edward Sapien XT prosthesis was then successfully deployed under rapid pacing. The delivery system was retrieved and puncture site was closed with Prostar device. The final angiographic control showed the total occlusion of the right iliac artery **(Figure 3B).** A peripheral angioplasty balloon 9×60 mm was inflated at the occluded site over the contralateral "limb saving" guide wire with rapid recovery of blood flow along the right femoral artery **(Figure 3C).** Due to the presence of dissection and residual stenosis, a 9×40 mm self-expandable Wallstent (*Boston Scientific* Corp., Natick, MA) was inserted which resulted in normal flow **(Figure 3D).** Further clinical evolution was un-eventful and the patient was discharged 7 days later.

The rapid access to the vascular entry site of the large introducer sheath from a contralateral "safety wire" allows relatively simple management of complications that, otherwise, may prove life threatening, or that may require emergency major vascular surgery with potentially severe post-operation complications.[7,8] The positioning of a balloon at the point of the percutaneous access site for a trans-femoral TAVI procedure from the contralateral vascular access allows for example the rapid interruption of bleeding in case of arterial rupture or failure of the Prostar suture, or the resolution of stenosis created by the closing device itself **(Figure 3C).** When simple balloon inflations are not sufficient, naked stent implantation may become necessary (like in the previously described case, **Figure 3D**), or even in some more dramatic situations covered stents may be required like in the case of a 95-year old lady that, despite apparently excellent vascular conditions, experimented a large rupture of the CFA after removal of the introducer sheath and Prostar closure **(Figure 3E).** This potentially severe complication was easily managed with the rapid implantation of an 8×40 mm self-expandable covered stent that permitted a rapid recover and uneventful hospital course **Figure 3F.**

Message

Vascular complications are common with calcified, atherosclerotic iliac-femoral arteries.[5-9] However, pro-

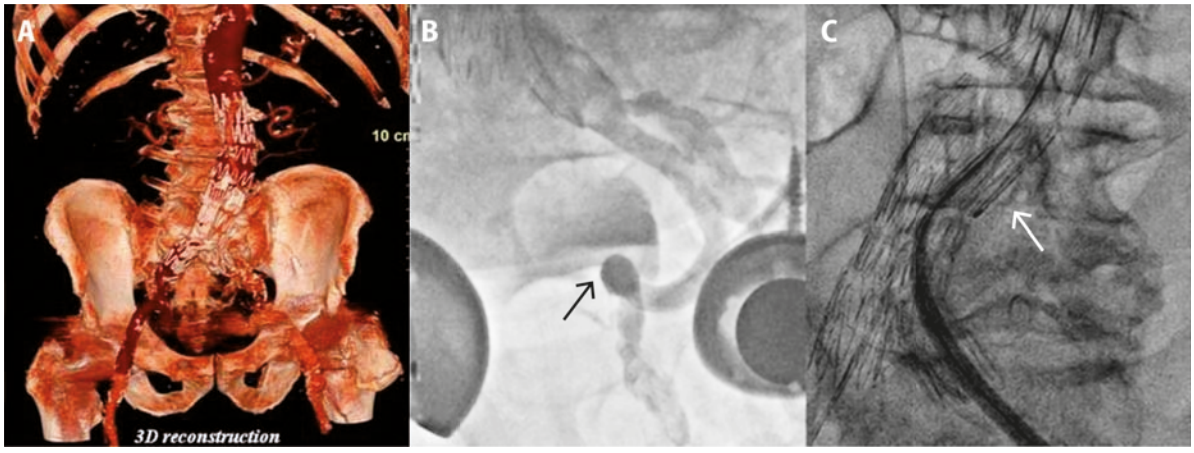

Figure 4. *Railing tract technique.* ***A.*** *CT Scan showing aortic-bi-iliac endoprosthesis and severe tortuosity of the ilio-femoral axes.* ***B.*** *Angiography showing severely tortuous left ilio-femoral axis* ***(arrow).*** ***C.*** *Insertion of introducer over the extrastiffs guidewires, one from right brachial artery up to left common femoral artery, and one from the SFA* ***(arrow).***

per selection of patient andaccess route, and adequate preventive measures reduce the risk. Apparently "normal" iliac-femoral arteries may give rise to severe complications in the elderly. Insertion of a safety wire from the contralateral artery is a "must" when planning a totally percutaneous trans-femoral TAVI.

"Railing tract" technique for severely tortuous and atherosclerotic accesses

A symptomatic 82-year old male with a known severe AVS was admitted in emergency with episodes of syncope and overt heart failure. He was rejected for SAVR in view of a severe pulmonary disease with bilateral emphysematous lungs (GOLD classification stage III), left anterior descending coronary artery disease, moderate CKD and high EuroSCORE (43%). He had also severe PVD with previous implantation of an aortic-bi-iliac endo-prosthesis. Heart Team opted for a trans-femoral approach because of the severe lung disease despite presence of an aortic-bi-iliac endo-prosthesis and severe tortuosity of the ilio-femoral axes, determining an approximately 360° loop on the right external iliac artery and a 260° loop on the left side, respectively **(Figures 4A-B).**

Procedure

TAVI was undertaken with surgical exposure of left CFA. An extra-stiff wire was inserted upwards through the CFA to straighten the left iliac tortuosity. The 22F Edward introducer however, could not advance beyond the endoprosthetic part of left common iliac. After several attempts the introducer was removed, its tip was found damaged likely because of friction against the calcium and the struts of the endoprosthesis. Another extra-stiff wire was therefore advanced from the right brachial artery to the left SFA through a multipurpose catheter for additional support. A new 22F Edward introducer was finally advanced as "railing track" with two extra-stiff wires **(Figure 4C).** After conventional balloon valvuloplasty, a 23 mm Edward-Sapien XT aortic valve was successfully implanted. The femoral access was surgically repaired without complications.

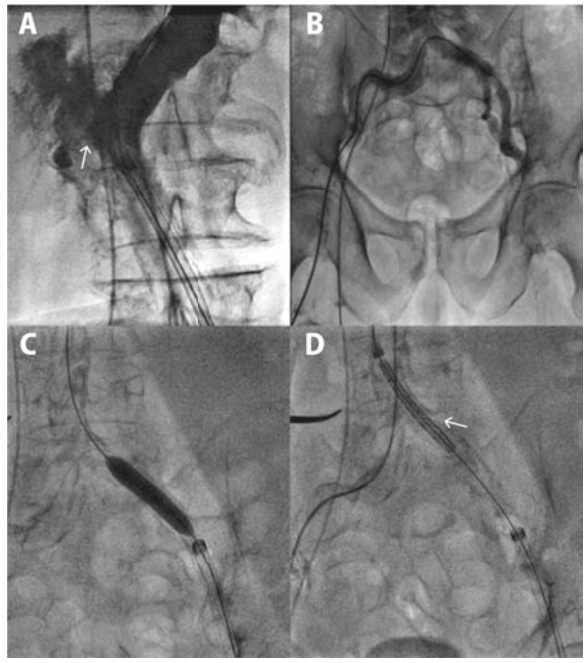

Figure 5. *Valve insertion without introducer.* ***A.*** *Fluoroscopic view showing ruptured abdominal aorta (arrow).* ***B.*** *Angiography showing tortuous and severely calcified ilio-femoral axis.* ***C.*** *Fluroscopic view showing iliac artery balloon dilatation.* ***D.*** *Fluroscopic view showing insertion of CoreValve delivery system without introducer* ***(arrow).***

Message

This case is a successful example of an extremely challenging trans-femoral TAVI, managed with a special technique in a patient with clear contra-indications to the femoral access, but with no alternative options. The technique of inserting a second extra stiff wire down from the right brachial artery up to the femoral artery together with an ascending extra stiff wire from the femoral access to the ascending aorta which acts as "railing track" may be useful in specific TAVI candidate.[16]

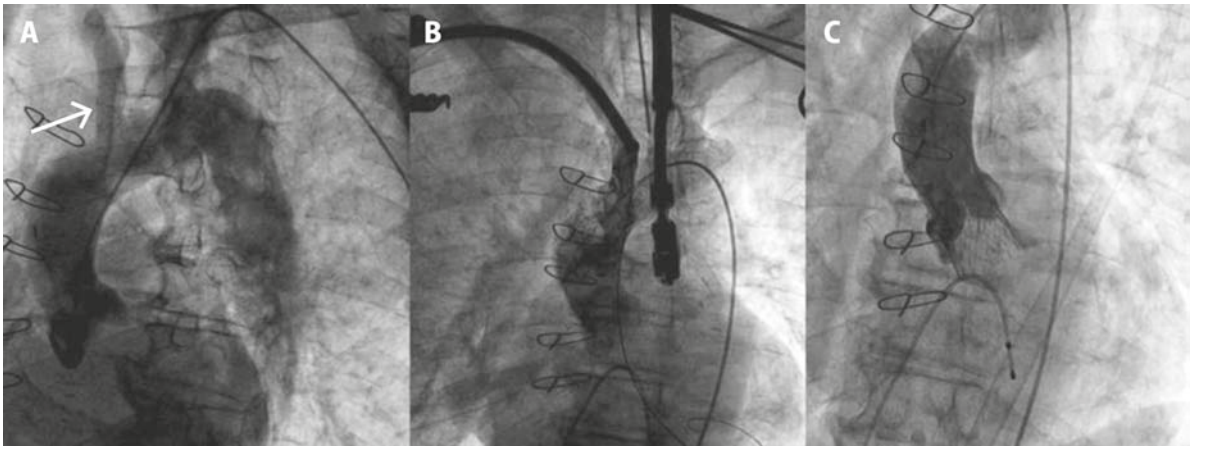

Figure 6. *Subclavian approach.* ***A.*** *PreTAVI angiography of right subclavian artery* ***(arrow). B.*** *Fluoroscopic view showing introduction of the 18F sheath through right subclavian artery.* ***C.*** *Insertion of device through right subclavian artery.*

Valve insertion without introducer sheath

Positioning the large introducing sheath from the CFA to the aorta in patients with severe PVD is the most challenging step of the trans-femoral procedure in these patients.Technically, the Edwards-Sapien prosthesis should not be pushed out of the introducer sheath, if it has not been fully advanced up to the thoracic-abdominal aortic segment.[15] Indeed, the rigidity of the catheter and valve device unit may cause aortic wall rupture if strongly pushed in direct contact to the vessel without the protection of the sheath **(Figure 5A).** The CoreValve system instead, due to its particularly flexible structure and self-expanding stent, can "cautiously navigate" into the iliac arteries even without the protection of the introducer sheath, that being larger than the valve itself, may not advance into a severely calcified and stenotic iliac axe. This was the case of a 79-year old man with medical history of hypertension, dyslipidemia and smoking habit, with previous coronary artery bypass grafts (CABG) and aortic valve replacement with a Toronto 25 mm biological prosthesis implanted 13 years before. He presented with heart failure due to severe aortic regurgitation, moderate AVS and well preserved LVEF (63%). Pre-TAVI screening showed important athero-calcific iliac-femoral vascular disease **(Figure 5B).** Logistic EuroSCORE was 30%, and he was scheduled for a 26 mm trans-femoral CoreValve implantation.

Procedure

TAVI was performed by surgical exploration of left CFA under general anaesthesia. The difficulty encountered was, as expected, to insert the 18F introducer through the left common iliac artery due to severe calcifications and diffuse stenoses. Aggressive balloon angioplasty was performed with 8×30 mm and 10×40 mm peripheral balloons **(Figure 5C)** but no further advancement of the 18F was possible. Considering the low profile of the CoreValve, the device was carefully advanced through the iliac artery without introducer **(Figure 5D).** A 26 mm CoreValve was successfully implanted within the previous aortic valve prosthesis (valve in valve). The access site was repaired surgically without complications.

Message

Treating patients with previous cardiac surgery is challenging, and in this particular case with a patent left internal thoracic bypass graft and a degenerated aortic bio-prosthesis and important PVD the access site requires cautious evaluation. The CoreValve device offers an excellent alternative allowing negotiation of severely diseased iliac arteries without the need for fully implanting the large introducer sheath. This may be a valuable alternative to the more complex subclavian access, in particular in patients with a patent mammary bypass graft that may contraindicate the use of such vascular route.

The Subclavian approach

This vascular access may prove useful in some selected cases and when operators have developed high levels of expertise with TAVI.[17,18]

We report as an example, the case of an 82-year old man with symptomatic AVS admitted for heart failure. He had two previous cardiac coronary bypass surgeries in 1979 and 1999 and severe PVD, with multiple iliac-femoral artery stenosis including a previous stenting of the left external iliac artery and right SFA angioplasty in 2005, a totally occluded right internal carotid artery, and a previous left carotid artery endoartheriectomy. The right subclavian artery was deemed to be the only possible vascular access due to its acceptable diameter (6.2 mm at angio CT scan) despite moderate tortuosity **(Figure 6A),** in a patient with a logistic EuroSCORE 59%. A trans-succlavian implantation of 29 mm CoreValve prosthesis was planned.

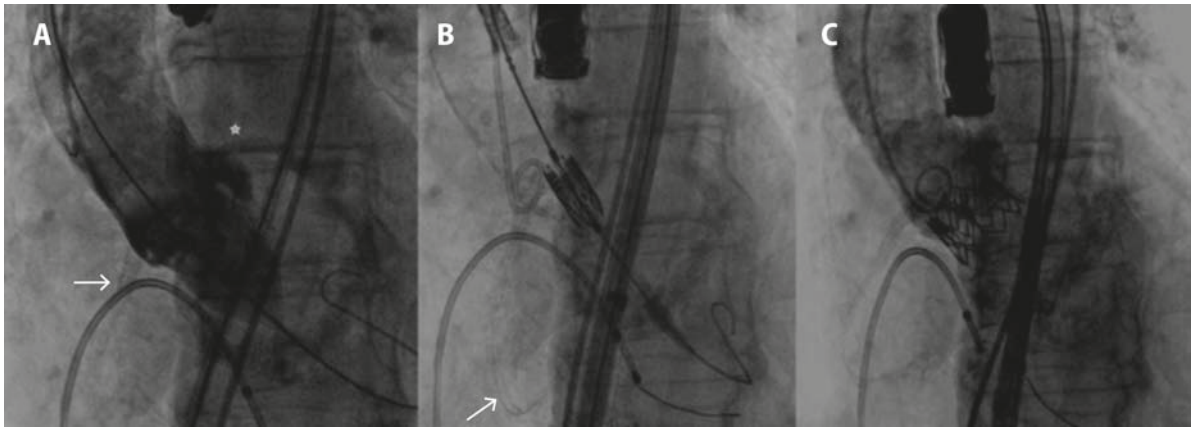

Figure 7. *Bailout guidewire in coronary artery.* ***A.*** *Aortography during balloon valvuloplasty showing occluded right coronary artery* ***(arrow)*** *along with normal flow in left coronary artery* ***(asterisk). B.*** *Guide-wire in right coronary artery during device placement* ***(arrow). C.*** *Aortography after device deployment showing normal coronary flow.*

Procedure

The procedure was performed in general anesthesia with surgical exploration of the right suclavian artery. An 18F introducer sheath was passed over an extra-stiff 0.035" wire **(Figure 6B),** and the 29 mm CoreValve delivery system was successfully implanted under fluoroscopic control and rapid ventricular pacing **(Figure 6C).** Intra-operative post implant TEE showed a properly placed and well functioning valve. The subclavian artery access site was closed surgically without complication and the patient was discharged uneventfully 7 days later.

Message

The subclavian artery approach may be an option in patients with no other alternatives. Severe complications have been reported with the subclavian access as well,[17] and therefore it should not be proposed as a routine alterative to the simpler femoral route; furthermore, no dedicated material is available to be used though the subclavian access and its use is recommended only after an extensive TAVI experience.

CHALLENGES FROM THE CORONARY ARTERIES TAKE OFF

Coronary artery occlusion is a dreadful complication of TAVI and it has been reported in 0.4% to 1% of cases with either Edwards-Sapien and CoreValve systems.[5-10,14] Accurate pre-TAVI diagnostic screening is, again, a crucial step to avoid this complication. In particular, CT scan measurements from the aortic annulus to the coronary take off should be performed in all cases before considering a patient for TAVI. A safe distance rom the lower part of left main coronary artery to the aortic annular ring is 14 mm an at least 10 mm is the minimum recommended space. However, coronary occlusion may ensue even when these safety distances are preserved. This may happen because of the presence of redundant aortic leaflet that, after being apposed between the prosthetic valve and the aortic wall in fully opened position may reach e coronary ostium causing its occlusion. Similarly, a tight sino-tubular junction diameter may not fully accommodate the crashed leaflets of the native valve that may reach with its more distal segment the origin of the coronaries. A practical trick before deciding whether to implant a valve in doubtful cases is performing an aortic angiogram while the balloon for aortic valvuloplasty is fully inflated in the aortic root. **Figure 7A** shows a case of a widely patent left coronary artery during balloon inflation and a complete occlusion of the right coronary artery. In cases with no other therapeutic options, and with the developing of growing experience, TAVI in such cases can be afforded with reasonable safety. It is absolutely recommended hawever, to place a long (300 cm) 0.0014" coronary guide-wire along the coronary at risk of occlusion. The guide-wire alone can be introduced through the diagnostic femoral access using an 8 or 9F sheath and a 6F guiding catheter that is then removed **(Figure 7B),** leaving the wire alone as a rapid access to advance a coronary balloon in case of coronary occlusion to rapidly restore the flow in the artery. If further intervention is need a guiding catheter can be advanced through the wire to complete the job. Alternatively, both, the wire and a guiding catheter can be left in place using a different vascular access, preferable through the radial route.

Procedure

An 89-year old female with medical history of hypertension, dyslipidemia, and severe AVS had several episodes of syncope in last 3 month. Six months before, she had been admitted to another hospital with an acute coronary syndrome that required emergent angioplasty of the right coronary artery with implantation of a stent at the right coronary artery ostium. TTE during hospitalization showed severe AVS (PG 70 mmHg, MG 44 mmHg, AVA 0.6 cm^2/m^2, AA 18 mm) with moderate aortic and mitral regurgitation and a

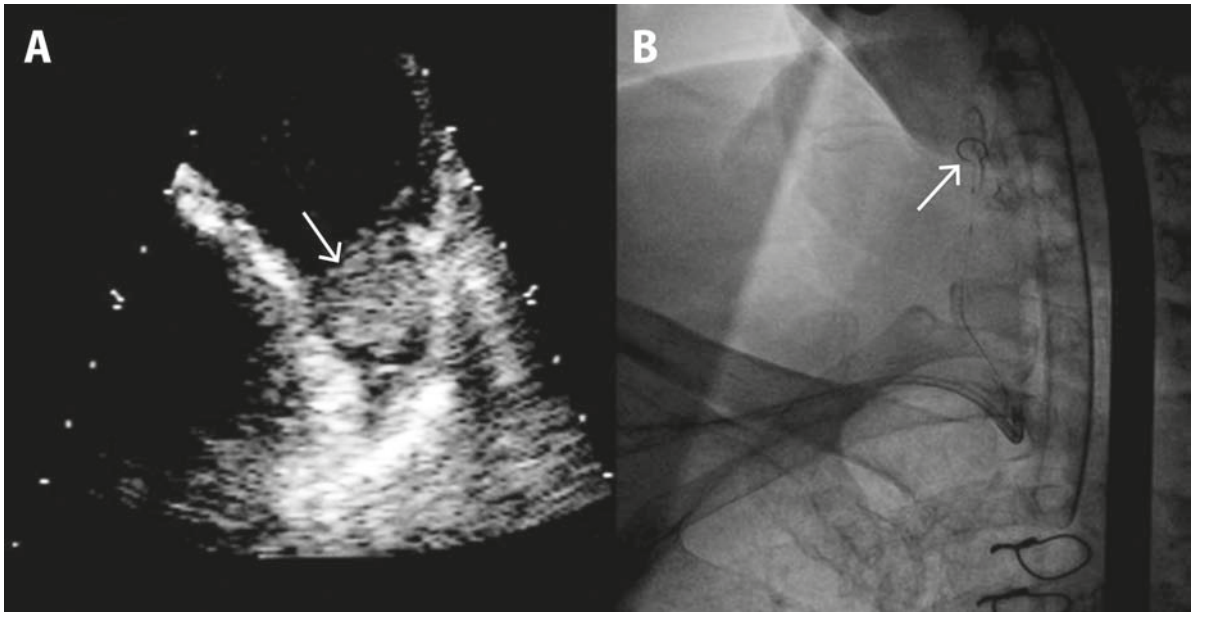

Figure 8. *Accidental left atrial thrombus detection in TAVI suite.* ***A.*** *TEE showing thrombus in left atrium (arrow).* ***B.*** *Insertion of filter device in right carotid artery* ***(arrow).***

well preserved left ventricular function (LVEF=60%). TAVI screening with angio-CT showed good femoral artery diameters, but a rather low right coronary artery take-off (7-8 mm). After implantation of a Prostar XL 10F closure device, balloon valvuloplasty with a 20×40 mm balloon was performed, and the aortography during balloon inflation demonstrated a totally occluded right coronary artery **(Figure 7A).** Due to the ostial lesion, the stent, and the risk of coronary occlusion, a 300 cm coronary angioplasty guide-wire was placed along the right coronary artery **(Figure 7B).** The aortic prosthesic valve was properly positioned under fluoroscopic and TEE monitoring without apparent coronary complication and normal ECG. The guide wire was removed and angiography showed normal flow in the coronary arteries **(Figure 7C).**

Message

Coronary artery occlusion is an infrequent but serious complication of TAVI.[5-12] Similar cases as the one described above are regularly performed in our center using protection wires when there is any suspicion of a possible acute coronary occlusion after valve deployment. This awareness prolongs the procedure by only a few minutes, but permits a rapid management of the massive ischemia caused by coronary occlusion that may rapidly evolve into irreversible haemodynamic impairment or arrhythmic storm in these old and fragile patients.

CHALLENGES IN CEREBRAL PROTECTION

Accidental finding of left atrial thrombus in TAVI suite

Stroke is the most dreadful complication of aortic valve interventions, either surgical or trans-catheter.[5-12,15] So far, dedicated devices to protect the cerebral circulation of TAVI patients are under development but still not available. Intra-cardiac thrombosis is a major contra-indication to TAVI due to the risk of thrombus embolization during rapid pacing and during energic post-arrhythmic beats.[14,15]

A frail 84-year old woman with hypertension, diabetes, chronic hepatic disease, chronic atrial fibrillation in oral anticoagulation and a previous CABG surgery was admitted for a recurrent episode of heart failure. TTE showed severe AS (MG 45 mmHg, AVA- 0.4 cmq/mq) and pulmonary hypertension. Coronary angiography showed patent bypass grafts, peripheral angiography showed 50% stenosis in severely tortuous left common iliac artery, however right iliac and femoral axis was free of significant stenosis. EuroSCORE was 59% and a trans-femoral TAVI with 23 mm Edward- Sapien valve was scheduled.

Procedure

The procedure was started with general anaesthesia.TEE examination revealed a large thrombus of 5×10 mm in the left atrium **(Figure 8A).** Due to the high risk of cerebral emobilization during TAVI, two carotid embolic protection devices (*EPI EZ. FilterWire*, *Boston Scientific Corp.*) were placed into the right and left common carotid arteries through the right and left brachial arteries respectively **(Figure 8B).** After implantation of a 23 mm Edward- Sapien XT prosthesis, the intra-operative TEE showed properly positioned and well functioning aortic prosthesis and a persisting left atrial thrombosis. After closure of the femoral access site, the two carotid artery filters were

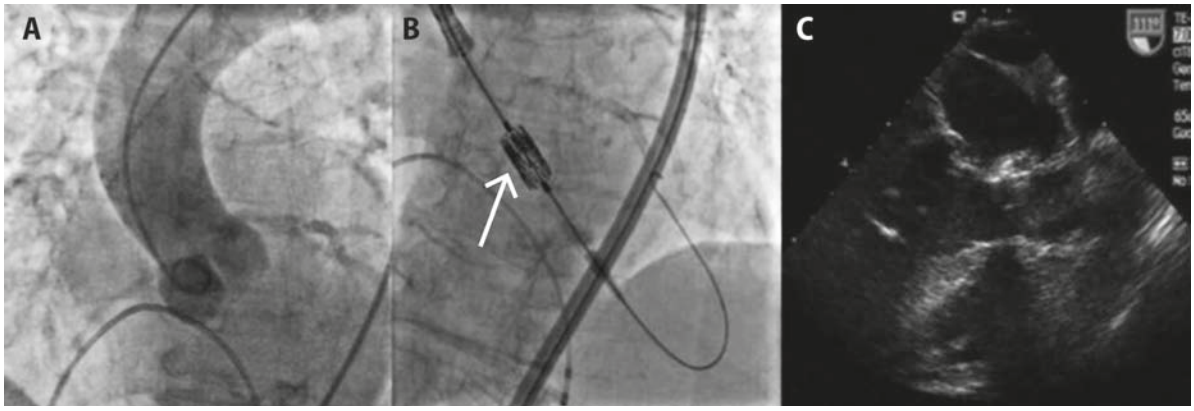

Figure 9. *Severe renal failure.* ***A.*** *Projection selected for prosthesis implantation.* ***B.*** *Fluoroscopic guided device deploymentwithout contrast injection* ***(arrow). C.*** *TEE guided device deployment.*

retrieved without clear images of embolic debris. The patient was discharged in optimal clinical and hemodynamic conditions.

Message

Stroke is the most severe complication of TAVI, a persistent data that emerges from either randomized studies and large Registries.[5-12] An Intra-cardiac thrombus is an absolute contra-indication for TAVI.[15] Usually during TAVI screening, transthoracic echocardiography is not sensitive for intracardiac thrombus detection. The reported case is an example of accidental left atrial thrombus detection and its management in the catheterization suite. Placing two embolic protection filters is technically challenging and time consuming. A dedicated device to protect the brain from embolic debris is still an unmet need of TAVI that requires urgent development from the Industry to further enhance safety of TAVI.

THE CHALLENGE OF RENAL FUNCTION

Renal function is one of the most important predictors of long-term outcome of patients with cardiovascular disease.[19] Transcatheter interventions and contrast media administration can both exert deleterious effects on renal function and the risk is in direct relationship with the baseline renal function. According to recent guidelines, general preventive measures must be applied as in any catheter-based intervention.[20] However, some additional precautions may help to avoid or reduce the risk of renal impairment in patients with diffuse atherosclerosis of the aorta needing contrast media administration to implant the transcatheter valves.[21-23] Intense saline hydration during the procedure can be better managed in patients treated under general anaesthesia, since mechanical ventilation can facilitate the management of peri-operative volumes overload that, in patients with severe AVS, impaired left ventricular function, and often secondary mitral insufficiency, may otherwise ensue pulmonary edema of difficult management without the assistance of well monitorized mechanical ventilation. Of utmost importance remains however, the limited administration of contrast media. In cases of severe renal dysfunction, performing a successful TAVI without the use of contrast media may be an ideal goal, but this requires a great experience of the heart team.

TAVI without contrast media in severe renal failure

A 77 year-old female with a known history of severe AVS (AVA 0.6 cm^2/m^2, PG 45 mmHg), severe coronary artery disease with previous stent implantation and a recent anterior myocardial infarction, diabetes, severe CKD-class IV (without dialysis), and liver failure as a consequence of profound cardiogenic shock was transported by the Emergency Service to our Intensive Care Unit. During transportation the Emergency Medical Services reverted several episodes of sustained ventricular tachycardia with DC shocks. On admission blood pressure was 65/40 mmHg with atrial fibrillation; LVEF was 14%, serum creatinine-4.7 mg/dl, total plasma-bilirubin-44.3 umol/l [N-(1-17)] and serum alkaline phosphatase-1900 U/l [N-(5-40)].

Procedure

An emergency aortic balloon-valvuloplasty was performed through the left CFA with a 25 mm balloon. The trans-valvular gradient was reduced from 33 to 5 mmHg, blood pressure raised immediately to 95/60 mmHg. Subsequently, coronary angiography showed a patent left circumflex and right coronary artery and a thrombotic sub-occlusion of a previously implanted drug eluting stent in the mid left anterior descending artery with TIMI flow grade 1. Aortic-iliac angiography showed moderately tortuouse and calcified arteries with non significant stenosis. Coronary angioplasty was not performed as the amount of contrast media given was near to the 4mL/kg limit. Three days later although signs of renal and liver failure persisted, balloon angioplasty of left anterior descending artery was performed. During a 2-week hospital stay, left ventricular function improved up to 40% and serum crea-

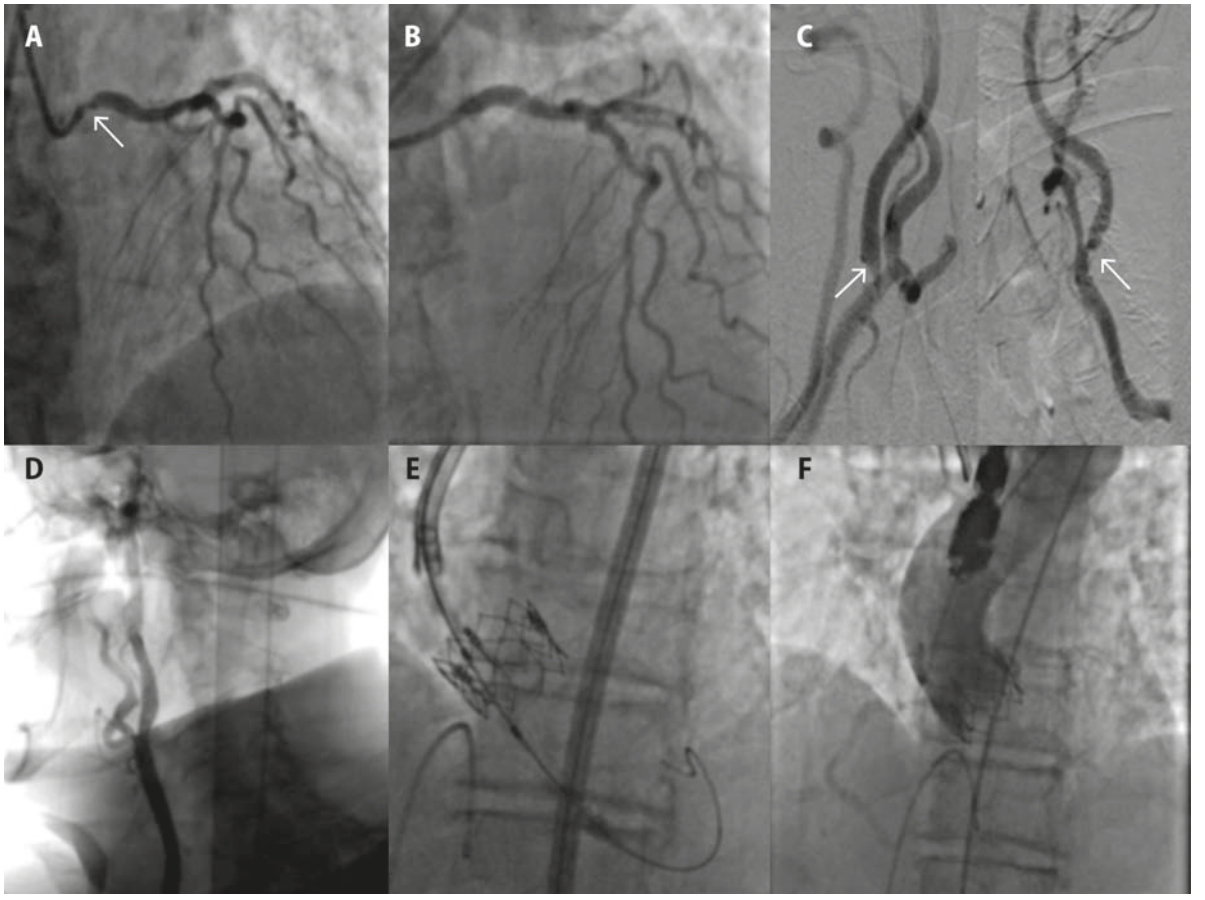

Figure 10. *Multi-level vascular disease and TAVI.* ***A.*** *Severe left main stenosis* ***(arrow). B.*** *Angiography after left main stenting.* ***C.*** *Right and left internal carotid artery stenosis* ***(arrows). D.*** *Right internal carotid artery after stenting.* ***E.*** *Aortic prosthesis at aortic root level.* ***F.*** *Angiography after deployment of prosthesis.*

tinine dropped to 1.9 mg/dl. Aortic gradient however increased from 5 mmHg after valvuloplasty to 20 mmHg suggesting both a partial valve recoil and left ventricular function recovery. Due to the high operative risk (Euro SCORE 68%) she was disqualified for conventional aortic valve surgery and the patient accepted a TAVI attempt.

The procedure was performed under general anesthesia through a surgically explored right femoral artery. A 12° cranial 10° left anterior oblique projection obtained by angiography at the time of the emergency valvuloplasty was selected to properly visualize the severely calcified aortic valve **(Figure 9A).** A "stand by" pig-tail catheter was placed in the ascending aorta (in case of need for contrast injection). A 23 mm Edwards SAPIEN XT transcatheter valve was successfuly implanted under fluoroscopy control only, using the calcifications of the aortic annulus as landmarks **(Figure 9B)** and TEE imaging **(Figure 9C).** Intraoperative TEE confirmed the good position and functioning of the prosthesis valve. The patient had a favorable clinical evolution and was discharged one month later.

Message

The present case demonstrates the feasibility of guiding a trans-femoral TAVI with fluoroscopy and TEE without administration of contrast media, and may represent a step further on the possibilities offered by TAVI in patients with severe renal insufficiency. Due to the extraordinary setting of this procedure, the case has been published elsewhere.[24]

PUTTING ALL TOGETHER IN COMPLEX TAVI CANDIDATES

With the development of a conspicuous TAVI program, operators with a solid previous experience in coronary, structural and peripheral trans-catheter interventions may afford challenging cases after a relatively short learning curve, observing the standard TAVI techniques applied in cases with no particular difficulties, and under stricttutoring. After nearly one year experience with more than 30 cases performed without external support, operators can consider less conventional or "off label" situations. As a result of this growing training, particularly challenging cases can be safely and effectively managed with TAVI in the catheterization laboratory. We report here some of the cases that we consider "educative" and that should be taken into consideration when deciding about treatment of severely sick patients with no other options.

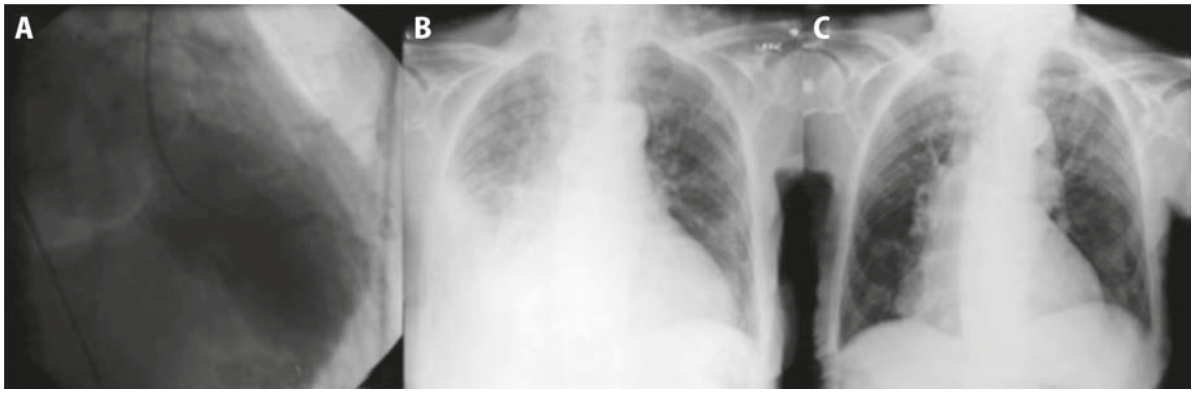

Figure 11. *TAVI in severe mitral regurgitation.* ***A.*** *Left ventricular angiography showing severe regurgitation in left atrium.* ***B.*** *Chest X-ray showing bilateral pleural effusion before balloon valvuloplasty.* ***C.*** *Chest X-ray showing resolution of pleural effusion 2 weeks after balloon valvuloplasty.*

A case of severe multi-level vascular disease

A 79-year old lady with medical history of hypertension, dyslipidemia, CKD class III with a known severe AVS was referred to our Laboratory for pre-operative catheterization. She was symptomatic for angina during daily activities, had a previous history of TIA, and was recently admitted for syncope. TTE confirmed the severe AVS (MG-55 mmHg with preserved LVEF=65%). Angiograms revealed a severe left main stenosis at the ostium **(Figure 10A)** and severe bilateral internal carotid artery stenosis **(Figure 10C).**
After discussion within the Heart Team, the decision was made of treating the left main stenosis with a relatively simple angioplasty to avoid combined CABG and SAVR. Logistic EuroSCORE was 45%.

Procedure

The coronary procedure was performed by the radial route with optimal result **(Figure 10B).** One week after coronary angioplasty, the right internal carotid artery was treated with a 7×40 mm self expandable meshed stent implanted after positioning an EPI EZ filterwire embolic protection device (*Boston Scientific Corp., Natick, Massachusetts*) **(Figure 10D).**
After these multi-level endovascular treatments, and considering the good quality of the aorto-iliac and femoral vessels, a staged TAVI was considered as a rapid and less invasive alternative to SVAR. Indeed, some days later a 26 mm Edward- Sapien prosthesis was implanted under rapid pacing with a good immediate result **(Figure 10E-F)** confirmed by the intra-operative TEE. Post-operative course was uneventful and the patient was discharged one week later.

Message

Treatment of the elderly patient with multi-level vascular disease is complex and needs thorough evaluation by a multi-disciplinary team. This case shows the feasibility, safety, and reduced invasiveness of staged endovascular procedures that may be particularly appropriate in old and fragile patients with multi-level vascular disease and severe symptomatic AVS.

A case of AVS with associated severe mitral regurgitation, coronary artery disease, and heart failure

Severe mitral regurgitation associated to AVS has been considered a contra-indication for TAVI.[5,15] In particular, patients with impaired LVEF and severe mitral disease may not improve their long-term prognosis even after aortic valve replacement. However, mitral regurgitation itself does not pose technical difficulties to the TAVI, and releasing the left ventricle from the outflow obstruction caused by the AVS may result in a significant reduction of the mitral regurgitant volume with subsequent clinical improvement.[25]
This is the case of an 83-year old lady with a previous large anterior myocardial infarction and severe secondary mitral regurgitation that later developed severe AVS. She was admitted with refractory heart failure, in NYHA class IV despite continuous i.v. infusion of furosemide, and inotropes, with no clinical improvement after two months of hospitalization in the Geriatric Department. She was transferred to our Center for coronary angiogram and eventually balloon aortic valvuloplasty. Left ventriculography showed severe mitral valve regurgitation **(Figure11A).** LVEF was 23%, the mitral regurgitant volume was 60ml and the pulmonary artery systolic pressure was 56 mmHg.

Procedure

During a single catheterization suite the patient underwent coronary artery angioplasty of a co-dominant left circumflex; the left anterior descendent artery was chronically occluded. After angioplasty, aortic valve valvuloplasty was performed with a 23 mm balloon under rapid pacing. PG was reduced from 38 mmHg to 10 mmHg and the subsequent clinical evolution was impressive, with rapid weaning from inotropes and i.v. diuretics and resolution of the chronic bilateral pleural effusions in about two weeks **(Figure 11B-11C).** She had rapid clinical improvement and returned to walk after several months of bed resting, and was discharged. After two months she had retur-

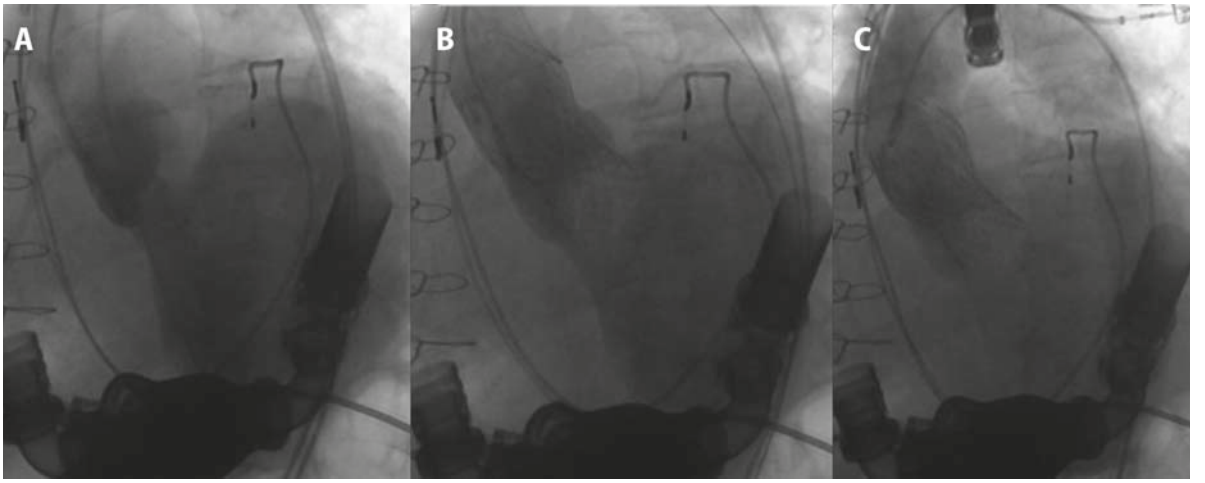

Figure 12. *Life saving TAVI for aortic insufficiency in Heart Mate II.* ***A.*** *Pre-TAVI severe aortic insufficiency.* ***B.*** *Moderate aortic insufficiency after first device implantation.* ***C.*** *Mild aortic insufficiency after second device implantation.*

ned to her previous activities. The mitral regurgitant volume was reduced to 48ml, and the EF increased to 36% after aortic valvuloplasty. The case was considered for TAVI and the procedure was performed successfully with the implantation of 23 mm Edwards-Sapien prosthesis through the femoral route by using a totally percutaneous approach and on local anesthesia. At 3 months follow up the patient was in functional class I, EF was 40%, pulmonary artery pressure was 28 mmHg and mitral regurgitation was further reduced to 38 ml in the left atrium. After 2 years of follow-up the patient is still doing well.

Message

This is a case of end-stage heart failure due to major cardiac contra-indications to TAVI and extremely fragile clinical conditions: severe mitral regurgitation and severe left ventricular impairment, associated to severe coronary artery disease. In such a case, percutaneous myocardial revascularization and aortic balloon valvuloplasty may serve as an effective atempt to improve the general clinical conditions and offer a bridge to a definitive treatment.

A case of life saving TAVI for aortic insufficiency in Heart Mate II

TAVI has enhanced the therapeutic spectrum far beyond expected, and as stated before, with growing experience of the heart team, patients in difficult conditions and perhaps no other option, may benefit from "off label" use of transcatheter valves. In particular the versatility of the CoreValve allows the treatment of difficult cases of aortic regurgitation as the one presented below.

A 53-year-old male patient with end-stage dilated cardiomyopathy was uneventfully implanted with a Thoracic HeartMate II left ventricular assistance device intended as a bridge to transplantation. Ten months post-operatively, he showed progressively worsening of symptoms. In view of the unfavourable anthropometric characteristics, any attempt to anticipate transplantation was unsuccessful for lack of appropriate donors. Ineffective ventricular assistance output enssued due to severe aortic regurgitation (**Figure 12A**). Pulmonary edema with desaturation, and major arrhythmias ultimately required endotracheal intubation and cardiopulmonary resuscitation. Since neither optimal medical therapy nor ventricular assistance adjustments provided hemodynamic stability, the Heart Team decided for emergency trans-catheter aortic valve implantation.

Procedure

Through an 18-F introducer, an extra-stiff guidewire was positioned in the left ventricle, and a 29-mm CoreValve (Medtronic, Milwaukee, Wisconsin) was implanted under fluoroscopy and echo control. Due to a moderate residual periprosthetic regurgitation (**Figure 12B),** a second 29-mm CoreValve was deployed within the previous valve prosthesis with minimal residual leak **(Figure 12C),** and no complications. (of note, at the time of this procedure, the 31-mm CoreVale was not yet available). The femoral access was repaired by the Prostar XL Closure device. The patient's hemodynamics improved immediately after procedure. On discharge, echocardiography showed mild periprosthestic regurgitation. The patient was transplanted 6 months later.

Message

Use of TAVI technique for severe aortic regurgitation in Heart Mate II resulted in a life-saving procedure that allowed management of an acutely occurred hemodynamic instability. Being the first, ever reported case of this nature, it has been published elsewhere.[13]

DISCUSSION

Since the first TAVI in 2002, the technique has encountered an extraordinary development, and

by the end of 2011 an estimated 40.000 TAVI procedures have been done.[4,14] Although randomized studies and multicentre registries have consistently demonstrated that the procedure is safe and effective it is not free of risks, and serious complications may occur despite its much less invasive nature compared to conventional SAVR.[4] However, continuous technical improvement in device technology and delivery systems, as well as the increasing experience of the Heart Team, has dramatically reduced the incidence of serious complications compared to the initial experiences. Indeed, despite a procedure success rate was >90%, mortality ranged between 11.3% for the trans-femoral approach and 16.9% in trans-apical patients.[5-12] In the PARTNER trial, 30-days mortality was 3.4% in TAVI group, compared with 6.5% in the SVAR group (p=0.07).[5] Notably, the definition of major complication associated with TAVI has not been standardized, which may explain lack of uniformity in different studies. However, several studies mention vascular complications, stroke, coronary obstruction, myocardial infarction, acute kidney injury and intra-ventricular conduction abnormalities as major peri-procedural complications. Among these, vascular complications were the most common and ranged between 6-13% in different studies.[5-9] Stroke is most worrisome complication with an incidence of 3.5% in multicentre registries. Coronary artery obstruction during TAVI is life treating but incidence is low <1%, rate of TAVI associated myocardial infarction ranges from 0% to 16%, but in most cases referrs to enzyme release in hearts with severe hypertrophy.[6-12] On top of this, a large number of TAVI patients developed acute kidney injury (11.7% to 28%) and half of these needed haemodialysis.[21-23] Even intra-ventricular conduction disturbance,particularly new left bundle brach block, is not rare after SAVR, but their incidence was remarkable with TAVI, particularly with the CoreVale system (7-18% with Edwards valve, 30-83% with CoreValve).[26-29]

There is no doubt that with technology development and learning experience these complications rates are much lower nowadays and will likely continue to drop.

In our own experience, vascular complications encountered in the first year where much more common, and with the switch to totally percutaneous procedures, these have been practically avoided despite the challenging nature of most TAVI patients.

Prevention of stroke remains yet an unmet need to improve the safety of the procedure and new devices, currently under development, are eagerly expected.

CONCLUSION

TAVI represents a less invasive strategy than SVAR. It offers an extraordinary option for symptomatic patients with severe AVS who are either, no candidates to SAVR, or present an unacceptable surgical risk. The rapid development of the technique is making of TAVI a "routine" practice in high-volume centres. By now, all efforts should be made to improve procedural success by reducing peri-procedural complications. Along with other important factors, patient's selection is clue. Procedure planning, using proper approach, interventional materials, and application of coronary, structural and peripheral interventional skills, in the context of an accurate clinical management will certainly help to obtain optimal results. Nonetheless, a fundamental key for the success of a TAVI program remains the effective and respectful cooperation between cardiologists and surgeons, and the observation of the available evidence-based indications. TAVI procedures beyond this context, imposes thoughtful discussion within the Heart Team and a great deal of experience.

RESUMEN

Pese al carácter menos invasivo del TAVI comparado con la sustitución valvular aórtica quirúrgica convencional, el procedimiento de transcatéter no está libre de complicaciones relevantes como las vasculares, el deterioro de la función renal, el accidente cerebrovascular, las oclusiones coronarias y la ruptura aórtica. Las complicaciones vasculares influyen significativamente en los resultados clínicos inmediatos y a mediano y largo plazo; el deterioro de la función renal también es preocupante, ya que la mayoría de los candidatos a TAVI tiene función renal deficiente; el accidente cerebrovascular es el problema más amenazante del TAVI puesto que, hasta ahora, su ocurrencia es muy impredecible y difícilmente evitable; y, por último, las oclusiones coronarias y la ruptura aórtica son eventos raros pero potencialmente fatales. Sin embargo, todas estas complicaciones pueden ser prevenidas y tratadas si se realiza una precisa selección previa a la intervención de pacientes y técnicas. En este artículo, describimos algunos casos difíciles como ejemplos para mostrar las estrategias aplicadas en el tratamiento o prevención de las complicaciones en la experiencia con TAVI, que comenzó a mediados del año 2010. Desde entonces, más de 100 pacientes con estenosis sintomática severa de válvula aórtica fueron tratados en la Universidad de Verona, Italia, por vía transfemoral percutánea con el uso del dispositivo de cierre percutáneo.

Palabras clave: *estenosis aórtica, implantantación transcatéter de válvula aórtica, cirugía de válvula aórtica.*

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