Featured Article

Access options for transcatheter mitral valve implantation in patients with prior surgical bioprosthesis

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Background: Transcatheter mitral valve-in-valve (TMVIV) procedure, either transapical (TA) or trans-septal (TS) has become a valuable alternative to conventional redo surgery in case of failing mitral bioprosthesis with good clinical outcomes. Here we present our fourteen-year institutional experience.

Methods: All consecutive patients treated with TMVIV with either TA or TS access at our centre between July 2007 and July 2020 were included. Periprocedural and 30-day follow-up (FU) results are reported and TA and TS data are compared.

Results: Eighty-two patients were included, of those 60 (73.2%) were TA while 22 (26.8%) were TS. Men represented 51.2% of the population with a mean age of 77.3±9.0 years. STS score and EuroSCORE II were 11.4%±6.2% and 11.5%±6.5% respectively. Baseline characteristics of TA and TS groups were comparable. TMVIV was performed at a median time of 9.3 years [interquartile range (IQR), 7.9–12.0 days] from the initial mitral valve surgery. Balloon expandable transcatheter heart valve (THV) prostheses (Edwards LifeSciences Corp., Irvine, CA, USA) were used exclusively. Technical success was 97.6% (96.7% and 100.0% for TA and TS respectively) with two (2.4%) periprocedural death, both in the TA group (P=0.533). We observed four (4.9%) left ventricular outflow tract (LVOT) obstructions with one being hemodynamically significant. Six (7.3%) major bleeding occurred in the TA group, not significantly different from TS group (P=0.279). The median length of stay was 6 days (IQR, 4–12 days, 1.5 *vs.* 7.0 days for TS and TA groups respectively, P=0.001). The overall 30-day mortality rate was 3.7%. We also observed three (3.7%) structural valve deteriorations and in one (1.2%) case the patient required redo mitral surgery at two months. Eighty-seven-point-eight percent of patients were I–II New York Heart Association (NYHA) class. At 30-day FU mean transmitral valve gradient was 7.3±2.7 mmHg and one patient (1.2%) had mitral regurgitation greater than mild. TA and TS groups were comparable.

Conclusions: Our 14-year single-center experience with TMVIV confirms procedural safety and is an effective alternative to redo surgery with comparable results with both TA and TS. With device, technical improvements and increasing operators' experience, TS is the preferred option for TMVIV. However, in some highly selected patient, TA may still play an important role.

Keywords: Valve-in-valve; mitral bioprosthesis dysfunction; transcatheter therapies; transapical (TA); transeptal

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Introduction

Structural valve deterioration (SVD) is reported in up to 30% of patients who underwent surgical mitral valve replacement (MVR) with a bioprosthesis at 10–15 years after the index procedure (1,2). Historically, the only treatment option for SVD has been surgical redo MVR, however this procedure is associated with moderately high mortality and prohibitive in some, including the elderly and patients with multiple comorbidities (3,4). For this reason, based on the encouraging outcomes of transcatheter aortic valve replacement (TAVR), transcatheter mitral valve-in-valve implantation (TMVIV) has become a valuable alternative in particularly high-risk patients (5-9). Back in 2007, Walther *et al.* described their preclinical experience with TMVIV with a transatrial approach (10). Shortly thereafter our group performed the first in human TMVIV transapically (11) and more recently via a percutaneous fashion transfemorally and trans-septally (12,13). In the last few years, the transfemoral (TF) approach has gained more and more relevance, with operator familiarity and advance in technology that allowed the development of smaller and highly steerable delivery systems (12). Other approaches have been proposed, as direct left transatrial and transjugular puncture, however these options were abandoned because of their invasiveness or complexity in favour of more reliable and safer accesses. Indeed, the transapical (TA) and trans-septal (TS) accesses are well known to cardiac surgeons and interventional cardiologists since they were widely used to perform TAVR and transcatheter mitral valve (MV) interventions (*Table 1*). The aim of the present article is to discuss the available accesses to perform TMVIV and to report our fourteen-year institutional experience.

Methods

Population and patient selection

We retrospectively collected clinical and procedural data of all patients who underwent MIVIV in our institution between July 1st, 2007 and July 31st, 2020. Periprocedural and 30-day clinical outcomes were assessed. Patients were considered for MVIV in case of bioprosthesis dysfunction resulting in symptomatic prosthetic stenosis, regurgitation or mixed pathology when conventional redo surgery was deemed too high-risk. Feasibility and candidacy were confirmed by the Heart Team after careful review of clinical data, transthoracic (TTE) and transesophageal (TEE) echocardiography, coronary angiography and gated MV computed tomography (CT). Patients with significant mitral paravalvular leak (PVL), active endocarditis or needing other cardiac procedures were turned down. Cardiac CT provides valuable information, including prosthesis dimensions and predicting the risk of left ventricular outflow tract (LVOT) obstruction. The risk of LVOT obstruction was assessed preoperatively by mean of virtual valve implant of the desired device using dedicated software and measuring the residual neo-LVOT (Circle cvi42, Circle Cardiovascular Imaging Inc., Calgary, AB, Canada) (14,15). TA MVIV through mini left anterolateral thoracotomy was the only approach until 2016, when TF access with transseptal puncture became the preferred access approach. Exclusion criteria for the TF transseptal approach were previous atrial septal defect (ASD) closure, previous MVR via transseptal incision and the presence of thrombus in the left atrium (LA) and inferior vena cava (IVC) interruption.

Different transcatheter prosthesis types have been used by different groups, however, the most commonly used are the balloon-expandable Edwards valves (Edwards LifeSciences Corp., Irvine, CA, USA) followed by the self-expandable devices as Lotus (Boston Scientific, Natick, MA, USA) and Direct Flow (Direct Flow Medical Inc., Santa Rosa, CA, USA). Cribier-Edwards prostheses were used in our initial experience, and shortly after Sapien and Sapien XT, and since 2017 Sapien 3 were used exclusively with respectively the Ascendra and Certitude delivery sheaths for TS and TA accesses respectively. Prosthesis sizes ranges between 20 and 29 mm for the Sapien XT and for the Sapien 3 valve. The Certitude introducer sheath has an 18-Fr size for the 20–26 mm delivery systems and a 20-Fr size for the 29 mm system. The Ascendra introducer sheath (eSheath) is smaller, sizing 14 Fr for the 20–26 mm valves and 16 Fr for the 29 mm valves and with a special hydrophilic coating easing the insertion and advancement through the femoral system.

Procedures

Direct transatrial and transjugular access have been described before. In our center, transatrial approach was attempted once in our first in-human case in 2007, but ultimately abandoned and converted to apical access (11). Briefly, transatrial MVIV is performed through a small right anterior thoracotomy in the 4th intercostal space, the pericardium is opened and the LA surgically exposed. Two hemostatic purse strings sutures are placed. Heparin is

Table 1 Access-related features for transapical and trans-septal approaches

Features	Transapical	Trans-septal
Operator experience	Large experience coming from TAVR	Increasing experience coming from MitraClip Procedure
Device positioning/alignment	Easier	Might be challenging in particular anatomies
Mitral valve crossing	Retrograde, could result, difficult	Antegrade, easier
LVOT obstruction risk	Might be lower thanks to a better control on the delivery system	Might be higher due to reduced control on the delivery system
Risk of bleeding	Higher	Lower
Access complications	Possible LV function impairment, LV apex pseudoaneurysm	Iatrogenic ASD
Combined procedures	Concomitant TAVR can be performed through the same access	Concomitant TAVR has to be done though a different access
Hospital stay	Usually longer	Usually shorter

TAVR, transcatheter aortic valve replacement; LVOT, left ventricle outflow tract; LV, left ventricle; ASD, atrial septal defect.

administered to achieve an activated clotting time (ACT) >300 seconds. The LA is punctured within the purse-strings using the classic Seldinger technique. A 6-Fr sheath is placed inside the LA and then a soft J-guidewire is advanced in the LV crossing the mitral prosthesis in an antegrade fashion. The J-guidewire is then replaced by a Safari wire (Boston Scientific, Marlborough, Massachusetts, USA) over a 6-Fr pigtail catheter and the transcatheter heart valve (THV) delivery system is then advanced over it and crossing the failed prosthesis. The THV is then deployed under rapid pacing with fluoroscopic and TEE guidance. Post implant valve performance and position is evaluated TEE.

TA MVIV was used exclusively until 2015 since our operators had extensive experience with TA TAVR. All the procedures were performed in the hybrid operating room with stand-by cardiopulmonary bypass machine. All patients were performed under general anesthesia. LV apex is approached through a mini left anterolateral thoracotomy usually in the 5^{th}–6^{th} intercostal space. The proper incision site is confirmed using fluoroscopy and TTE. Once the apex is exposed, the operator confirms the puncture site to achieve the best possible alignment to the MV with TEE. Two U-shaped perpendicular purse-strings are placed and after systemic heparinization, the apex is punctured, a short soft J-guidewire is inserted in the LV crossing the mitral prosthesis and followed by a 6-Fr sheath. A 0.035" Amplatz Extra Stiff wire (Cook Medical, Bloomington, Indiana) was exchanged by Seldinger technique, followed by the introduction of the delivery sheath. The THV is positioned 1–5 mm atrially relative to the sewing cuff of the failed valve and deployed under rapid pacing with fluoroscopic and TEE guidance. No contrast is used during the procedure. Proper positioning, transvalvular gradient and the presence of paravalvular leakage are checked with TEE. In rare occasions, post-deployment balloon dilatation was performed in cases of incomplete deployment and presence of significant PVL despite optimal positioning (*Video 1*).

TF/TS TMVIV is performed in the same manner as the TA procedure other than the access. In this case, a temporary pacemaker is first placed into the right ventricle with a 7-Fr femoral venous access and the MV is approached puncturing the contralateral femoral vein and placing a 7-Fr short sheath via Seldinger technique. The 7-Fr sheath is then exchanged for a Baylis Medical system (Baylis Medical, Burlington, MA, USA) over a Baylis guidewire and advanced up to the superior vena cava under fluoroscopy. The Baylis wire is then retracted inside the sheath and redirected toward the interatrial septum at the level of the fossa ovalis and ideally positioned superior and posteriorly. The transeptal puncture is then performed using radiofrequency to allow the introduction of the wire into the LA under fluoroscopic and transesophageal echography guidance. The patient is then fully heparinized to reach an ACT of greater than 300 seconds. The Baylis system is then steered toward the MV and subsequently crossing of the MV with a 6-Fr pigtail over a soft J-guidewire. The J-guidewire is then exchanged with a Safari wire (Boston Scientific Corp., Marlborough, MA, USA) and positioned

over the LV apex. The Edwards eSheath is then introduced and a 12- or 14-mm balloon septostomy was performed. The Edwards Commander delivery system is advanced into the right atrium, the balloon is loaded and alignment is performed in the IVC. The THV is then advanced toward the MV and the SAPIEN 3 prosthesis is positioned. The flex catheter is retracted and the final positioning of the THV is made and deployed under rapid ventricular pacing. The iatrogenic ASD is closed with a percutaneous closure device only in case of a significant residual shunt, pre-existing pulmonary hypertension and right ventricle dysfunction (*Video 2*).

Statistical analysis

Continuous variables were summarized using mean ± standard deviation (SD) or median with interquartile range (IQR) and compared between the type of access (TS *vs.* TA) with the use of the Student's *t*-test or Wilcoxon rank sum test. Categorical variables were summarized using frequencies and percentages and compared between access type with the use of the Fisher exact test or Chi-square test. All tests were two-sided, and a P value <0.05 was considered statistically significant. All statistical analyses were performed using SPSS software, version 20 (IBM Corp., Armonk, New York, USA).

Results

From July 2007 to July 2020, 82 TMVIV were performed in our institution, of those 42 (51.2%) were male. Sixty (73.2%) patients had their procedure done through the apical access while 22 patients (26.8%) were treated with TF/TS approach. Mean age was 77.3±9.0, mean STS Risk Score and EuroSCORE II for reoperative MVR were 11.4±6.2 and 11.5±6.5 respectively. Complete baseline features were reported in *Table 2*.

Median time between the surgical MVR and TMVIV was 9.3 years (IQR, 7.9–12.0 years). There were no significant differences in terms of baseline characteristics between TA and TF groups. Our early experience was exclusively TA and since 2017, 65% of the procedures were performed in a TF fashion. In 46 patients (56.1%), a SAPIEN XT THV was used while SAPIEN3 THV was implanted in 24 (29.3%) patients. Prior to 2011, SAPIEN prostheses were implanted in 11 (13.4%) patients and the very first (1.2%) patient received a Cribier-Edwards valve. Nine (11.0%) patients had concomitant TMVIV and TAVR. Technical success was achieved in 80 patients (97.6%) and there were two (2.4%) periprocedural death (within 72 hours from the procedure) secondary to massive stroke and the other to severe LVOT obstruction requiring conversion to sternotomy. We observed two other cases of LVOT obstruction but both were partial with no significant hemodynamical consequence. Complete periprocedural data were listed in *Table 3*. There were no significant differences in perioperative complications and clinical outcomes between TA and TS patients. Median length of stay (LOS) was six days (IQR, 4–12 days) with shorter hospitalization time for TS patients. (1.5 *vs.* 7.0 days, P=0.001). At 30 days there was one additional death with heart failure requiring new hospitalization and resulting multiorgan failure. We observed four (4.9%) repeat hospitalization and two patients (2.4%) developed THV thrombosis. SVD was observed in three patients (3.7%), in two cases caused by THV thrombosis and one by valve endocarditis. One patient (1.2%) required redo surgery at two months for late valve migration with significant PVL and successfully underwent a repeat TA TMVIV. Even though complications were observed more frequently in the TA group, they were not statistically significant (*Table 4*). At 30-day echocardiographic follow-up (FU), mean transmitral valve gradient was 7.3±2.7 mmHg and one patient (1.2%) had mitral regurgitation greater than mild.

Discussion

TAVR performed through the TA and the TF access are well established procedures to treat severe aortic stenosis in all surgical risk classes with satisfying early and mid-term outcomes (16,17). Following this encouraging results and experience acquired from TA access, transcatheter replacement of degenerated bioprosthetic valves has been developed, first performed for the aortic position (18,19) and shortly after for the MV (5,8). Preclinical TMVIV was first described by Walther *et al.* (10) through a direct LA puncture to avoid the retrograde access to the mitral prosthesis and the potential interference of the subvalvular apparatus. However, this route was quickly abandoned in favour of the more direct TA access (6,7,11). Moreover, surgeons were already familiar with the LV access favoured by years of experience with TAVR and TAVIV. In our population, TA was the preferred access (67.2% *vs.* 32.8%). After 2016, TS access became the predominate access route with nearly 70% of cases. This evolution is probably related to the increasing knowledge and skills of operators

Table 2 Baseline characteristics

Characteristics	All patients (n=82)	TA (n=60)	TS (n=22)	P value
Age (years), mean ± SD	77.3±9.0	77.5±9.3	76.6±8.1	0.687
Male gender, n (%)	42 (51.2)	32 (53.3)	10 (45.5)	0.351
Diabetes mellitus, n (%)	21 (25.6)	14 (23.3)	15 (68.8)	0.305
Hypertension, n (%)	52 (63.4)	35 (58.3)	17 (77.3)	0.603
PVD, n (%)	7 (8.5)	6 (10.0)	1 (4.5)	0.391
CAD, n (%)	46 (56.1)	29 (48.3)	17 (77.3)	0.017
Previous PCI, n (%)	9 (11.0)	4 (6.7)	5 (22.7)	0.054
Previous CABG, n (%)	35 (42.7)	25 (41.7)	10 (45.5)	0.476
Previous SAVR, n (%)	16 (19.5)	11 (18.3)	5 (22.7)	0.436
Previous TAVR, n (%)	5 (6.1)	5 (8.3)	0	<0.001
PPM, n (%)	27 (32.9)	19 (31.7)	8 (36.4)	0.441
Atrial fibrillation/flutter, n (%)	51 (62.2)	35 (58.3)	16 (72.7)	0.176
COPD, n (%)	19 (23.2)	16 (26.7)	3 (13.6)	0.174
CKD (eGFR <45 mL/min/1.73 m^2), n (%)	39 (47.6)	31 (51.7)	8 (36.4)	0.164
eGFR, mL/min/1.73 m^2, mean ± SD	57.8±18.9	57.2±18.6	59.5±17.2	0.627
STS score (%), mean ± SD	11.4±6.2	11.3±6.3	11.7±6.6	0.824
EuroSCORE II (%), mean ± SD	11.5±6.5	11.2±5.8	12.3±7.9	0.487
NYHA class, n (%)				0.864
I	1 (1.2)	1 (1.7)	0	
II	6 (7.3)	4 (6.7)	2 (9.1)	
III	61 (74.4)	44 (73.3)	17 (77.3)	
IV	14 (17.1)	11 (18.3)	3 (13.6)	

CABG, coronary artery by-pass; CAD, coronary artery disease; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; eGFR, estimated glomerular filtration rate; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; PPM, permanent pace-maker; PVD, peripheral vascular disease; SAVR, surgical aortic valve replacement; SD, standard deviation; STS, society of thoracic surgeons; TA, transapical; TS, trans-septal; TAVR, transcatheter aortic valve replacement.

in managing the femoral and transseptal access as the result of the experience acquired with transcatheter MV repair with MitraClip device. In addition, the improvement in THV delivery system that are lower profile reduces the size of the iatrogenic ASD and fully steerable sheath, allowing the operator to achieve a better coaxiality and alignment with the MV plane. Similar findings were described by Whisenant *et al.* (20) from the VIVID Registry who evaluated a large population of patients who underwent TMVIV between 2015 and 2019 and found the number of TS cases surpasses TA ones after 2016. Whisenant and investigators reported higher incidence of access complications, bleeding, conversion to open surgery and 30-day and one-year mortality observed in TA patients (21-23). On the other hand, access site and other complications are mainly operator-dependent and can be safely managed by increased experience. Suri *et al.* showed that the learning curve for TA procedures is around 30–45 procedures resulting in improvement in outcomes (24); Tabata *et al.* showed that after performing at least 40 procedures, surgeons in his institution had optimal results with no open surgery conversion, major apical bleeding, permanent pace-

Table 3 Periprocedural results

Variables	All patients (n=82)	TA (n=60)	TS (n=22)	P value
Index surgery-TMVIV delay (years), median (IQR)	9.3 (7.9–12.0)	10.1 (7.9–12.0)	9.2 (7.9–11.4)	0.868
Valve type, n (%)				<0.001
Cribier-Edwards	1 (1.2)	1 (1.7)	0	
Sapien	11 (13.4)	11 (18.3)	0	
Sapien XT	46 (56.1)	45 (75.0)	1 (4.5)	
Sapien 3	24 (29.3)	3 (5.0)	21 (95.5)	
Valve size, n (%)				0.534
23 mm	10 (12.2)	8 (13.3)	2 (9.1)	
26 mm	33 (40.2)	26 (43.3)	7 (31.8)	
29 mm	39 (47.6)	26 (43.3)	13 (59.1)	
Balloon predilatation, n (%)	4 (4.9)	0	4 (18.2)	0.004
Balloon postdilatation/fracture, n (%)	5 (6.1)	3 (5)	1 (4.5)	0.407
Iatrogenic ASD closure, n (%)	6 (27.3)	0	6 (27.3)	<0.001
Technical success, n (%)	80 (97.6)	58 (96.7)	22 (100.0)	0.386
Periprocedural mortality, n (%)	2 (2.4)	2 (3.3)	0	0.533
Access site complications, n (%)	0	0	0	–
LVOT obstruction, n (%)	4 (4.9)	4 (6.7)	0	0.279
Device malposition/embolization, n (%)	0	0	0	–
Conversion to surgery, n (%)	1 (1.2)	1 (1.7)	0	0.732
Need of ECMO, n (%)	2 (2.4)	2 (3.3)	0	0.533
Stroke, n (%)	2 (2.4)	2 (3.3)	0	0.533
Myocardial infarction, n (%)	1 (1.2)	1 (1.7)	0	0.732
AVB, n (%)	2 (2.4)	2 (3.3)	0	0.533
Major bleeding, n (%)	6 (7.3)	6 (10.0)	0	0.143
eGFR (mL/min/1.73 m^2), mean ± SD	65.6±26.1	64.3±26.7	69.1±24.7	0.459

ASD, atrial septal defect; AVB, atrio-ventricular block; ECMO, extracorporeal membrane oxygenator; eGFR, estimated glomerular filtration rate; IQR, interquartile range; LVOT, left ventricular outflow tract; SD, standard deviation; TA, transapical; TS, trans-septal; TMVIV, transcatheter mitral valve-in-valve.

maker (PPM) implantation and no intraoperative and 30-day mortality (25). In our 10-year experience we report a 97% technical success, 3% intraoperative mortality and a 4.5% 30-day mortality with no difference between TS and TA patients. Our technical success rate is similar to that previously reported in literature, however, our periprocedural and 30-day mortality is lower (8,9). We believe that our better results can be explained by our long experience with THV with first TAVR procedures started in 2005 (26). Similarly, perioperative complications were low and comparable between the two groups. The incidence of new hospitalization was low at 6%, and the majority was valve-related following THV thrombosis or endocarditis.

Most of the patients had significant symptomatic improvement with New York Heart Association (NYHA) class I–II at FU with no difference between TA and TS

Table 4 Thirty-day results

Variables	All patients (n=82)	TA (n=60)	TS (n=22)	P value
Cardiovascular mortality, n (%)	3 (3.7)	3 (5.0)	0	0.386
New hospitalization, n (%)	4 (4.9)	3 (5.0)	1 (4.5)	0.697
Heart failure, n (%)	3 (3.7)	3 (5.0)	0	0.376
Stroke, n (%)	0	0	0	–
Myocardial infarction, n (%)	0	0	0	–
New AKI (AKIN >2), n (%)	2 (2.4)	1 (1.7)	1 (4.5)	0.477
SVD, n (%)	2 (2.4)	1 (1.7)	2 (9.1)	0.182
Device thrombosis, n (%)	3 (3.7)	1 (1.7)	1 (4.5)	0.477
Endocarditis, n (%)	2 (2.4)	1 (1.7)	1 (4.5)	0.477
MV reintervention, n (%)	1 (1.2)	1 (1.7)	0	0.725
NYHA class, n (%)				0.519
I	48 (58.5)	37 (61.7)	11 (50.0)	
II	24 (29.3)	15 (25.0)	9 (40.9)	
III	5 (6.1)	3 (5.0)	2 (9.1)	
IV	2 (2.4)	2 (3.3)	0	

AKI, acute kidney injury; AKIN, Acute Kidney Injury Network; MV, mitral valve; NYHA, New York Heart Association; SVD, structural valve deterioration; TA, transapical; TS, trans-septal.

patients. Patients in the TS had a significantly shorter LOS in respect to TA patients and is consistent with previously reported results (9,12,13).

Concerns have risen about the impact of apical puncture on LV function in particular in patients with reduced LV ejection fraction (LVEF). Some studies reported a higher LVEF improvement after TS TMVR respect to TA TMVR (27). However, D'Onofrio *et al.* showed that TA TAVR is associated with good outcomes as TF TAVR in patients with LVEF <35% with similar postoperative LVEF improvement in the two groups (28,29). Optimal alignment with the MV plane and therefore more precise THV deployment is better achieved through the apical access since the LV apex is closer to the MV and the THV deployment sheath is inserted coaxially to the valve plane without the need of steering. This might be related to a lower incidence of valve malposition and LVOT obstruction since the proximity allows the operator to fine tune the position and deployment. In particular, in case of increased risk of LVOT obstruction a slightly more atrial deployment of the valve might be helpful. However, gated MV cardiac CT remains as a mainstay in pre-procedural planning in order to minimize the risk of this potentially deathly complication. In our series the incidence of LVOT obstruction was low, 4.5% and only haemodynamically significant in 3% of cases. Our findings are consistent with those reported in literature where the incidence of significant LVOF obstruction causing hemodynamic impairment is reported between 2.2% to 6.9% (8,12,30) and lower than those reported for Valve-in-Ring and Valve-in-MAC procedures (5,8,13). Unfortunately, we did not observe any difference between TA and TS cases in support of our hypothesis and in literature the incidence of THV embolization or LVOT obstruction after TMVIV is similar between these two groups (31).

Conclusions

In conclusion, our fourteen-year institutional experience with TMVIV confirms the safety and effectiveness of the procedure, and should be offered as an alternative to redo surgery in high-risk or inoperable patients. Percutaneous TS access has consistently demonstrated excellent periprocedural and clinical results since the introduction

of smaller and fully steerable THV systems as showed by our case series. Nevertheless, the superior control on valve alignment and deployment provided by TA access should be carefully considered when approaching patients with complex anatomy, high risk of LVOT or those requiring combined TMVIV and TAVR.

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Footnote

Conflicts of Interest: Dr. Webb is consultant for Edwards Lifesciences. The other authors have no conflicts of interest to declare.

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