Original Research

Transaortic Aortic Valve Replacement Using the Edwards Sapien-XT Valve and the Medtronic CoreValve: Initial Experience

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Introduction: Transcatheter aortic valve replacement (TAVR) is now an established treatment for certain patients with severe aortic valve stenosis (AS). However, as the number of patients screened for TAVR increases, many are found to have absolutely no option for peripheral artery access. Transaortic valve replacement (TAoVR) has been proposed as a new alternative route in patients deemed unsuitable for conventional approaches. We present our first series of TAoVR cases using the Edwards Sapien-XT and the Medtronic CoreValve prostheses.

Methods: Twenty-five (25) symptomatic patients (mean age 78 ± 8 years, mean logistic EuroSCORE I 25 ± 11%) with severe AS underwent TAoVR using the Sapien-XT valve (10 patients) or the CoreValve (15 patients).

Results: The mean fluoroscopy time was 15.6 ± 4.2 minutes, the mean time in the intensive care unit was 1.9 ± 1.0 days, and the mean hospital stay was 6.4 ± 1.6 days. The mean effective aortic valve area increased (from 0.68 ± 0.15 cm^2 to 1.82 ± 0.34 cm^2, $p<0.001$) and the mean transvalvular pressure gradient declined (from 48 ± 15 mmHg to 9 ± 5 mmHg, $p<0.05$) post implantation. The procedural mortality was 0% and the in-hospital mortality was 4% (one death at day 3 due to cardiogenic shock). The mean NYHA functional class improved from 3.2 ± 0.4 to 1.5 ± 0.9 at 30 days.

Conclusions: Our initial experience with the TAoVR approach using both the Edwards Sapien-XT and the Medtronic CoreValve prosthesis demonstrated that it could be performed safely, resulting in substantial acute echocardiographic and early clinical improvement.

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Transcatheter aortic valve replacement (TAVR) is a novel procedure for the management of patients with severe symptomatic aortic stenosis (AS) who are at prohibitive or high operative risk for conventional surgical aortic valve replacement (sAVR).[1] TAVR improves survival and quality of life in patients at prohibitive surgical risk with severe AS (as compared to standard medical therapy) and is comparable or even superior to sAVR in patients at high surgical risk.[1-3] TAVR using the Edwards Sapien-XT (Edwards LifeSciences, Irvine, CA, USA) or the CoreValve (Medtronic, Minneapolis, MN, USA) prosthesis is usually performed via the transfemoral (TF) approach. For those with unsuitable peripheral arteries, the transapical approach for the Sapien-XT valve and the subclavian approach for the CoreValve are available alternatives. Recently, transaortic valve replacement (TAoVR) was introduced as a safe and feasible alternative retrograde

approach for both valves that can avoid complications related to the other access routes.[4] Herein we present our initial experience with TAoVR using both devices.

Methods

Patients deemed not to be candidates for routine sAVR and unsuitable for percutaneous TF approach were considered for TAoVR. Patients' comorbidities were characterised according to the EuroSCORE I and the Society of Thoracic Surgeons (STS) risk score definitions.[5,6] Patients were assessed and accepted by our Hospital Heart Team and their medical files were evaluated and approved by a government committee consisting of senior cardiologists and cardiac surgeons.

Device description

Edwards SAPIEN XT valve

The Sapien-XT valve is a tri-leaflet valve of bovine pericardium. Its cobalt-chromium balloon-expandable frame provides improved radial strength, an important factor in long-term valve durability. The valve is available in 3 sizes: 23 mm (for annuli measuring 18-22 mm), 26 mm (for those measuring 22-25 mm), and 29 mm (for those measuring 25-28 mm). The prosthesis is mounted on the balloon stent under fully sterile conditions immediately prior to implantation. Food and Drug Administration (FDA) approval for the Sapien valve was granted in 2011 for use in inoperable patients and in 2012 for use in high-risk patients.

Medtronic CoreValve

The CoreValve is a tri-leaflet bioprosthetic porcine pericardial tissue valve, mounted and sutured in a self-expandable nitinol (nickel titanium alloy) stent frame. The valves are available in 4 sizes: 23 mm (for annulus range 18-20 mm), 26 mm (for annuli measuring 20-23 mm), 29 mm (for those measuring 23-27 mm), and 31 mm (for those measuring 26-29 mm). FDA approval for the CoreValve was granted in 2014 for use in inoperable patients.

Patient selection

Patients were evaluated by a multidisciplinary Heart Team consisting of echocardiographers, interventional cardiologists, cardiac surgeons and a cardio-anaesthesiologist. Patients had a standard diagnostic work-up, including physical examination, functional capacity assessment (New York Heart Association [NYHA] class), electrocardiogram, blood tests, echocardiography, coronary angiography and peripheral angiography, as well as chest, abdominal and pelvic computer tomography (CT) scans. All patients had severe symptomatic degenerative AS (effective aortic valve orifice less than 0.8 cm^2), with an aortic valve annulus between 18-29 mm, and were at high operative risk or considered inoperable. Our preferred default access route is the TF approach. Patients with peripheral arteries not deemed suitable for TF implantation were considered for alternative access. Those with suitable left subclavian anatomy and size were assigned to subclavian access (provided they did not have previous left internal mammary to coronary grafting). Those who had a disease-free area in the ascending aorta allowing its safe cannulation were assigned to TAoVR. In all the remaining patients transapical access was used.

Procedure

The procedure was performed in the hybrid operating room with the patient placed in the supine position and under general anaesthesia. After upper mini-sternotomy or upper mini-thoracotomy with a small expansion, usually at the second right intercostal level, the ascending aorta was visualised. A calcification-free spot on the right anterolateral aspect of the ascending aorta (at a height of at least 50 mm above the aortic annulus) was identified for transaortic access using manual, fluoroscopic and echocardiographic evaluation and after a careful review of the anatomy on CT aortography. Two 2/0 Prolene purse-string sutures reinforced with pledgets were placed in calcification-spared aortic wall. After an initial puncture within the area defined by the purse-string sutures, a 6 F sheath was inserted into the ascending aorta and the aortic valve was crossed initially with a soft 0.035-inch straight guidewire. This was then exchanged for a 6F Amplatz left or Judkins right catheter with a long (260 cm) J-tipped Amplatz extra stiff wire that had additional loop shaping at its tip. The proximity between the puncture site in the ascending aorta and the aortic valve provides a stable straightforward platform for the procedure. The 6F sheath was then exchanged for a 24F Ascendra sheath for the Sapien-XT or an 18F sheath (Cook Medical,

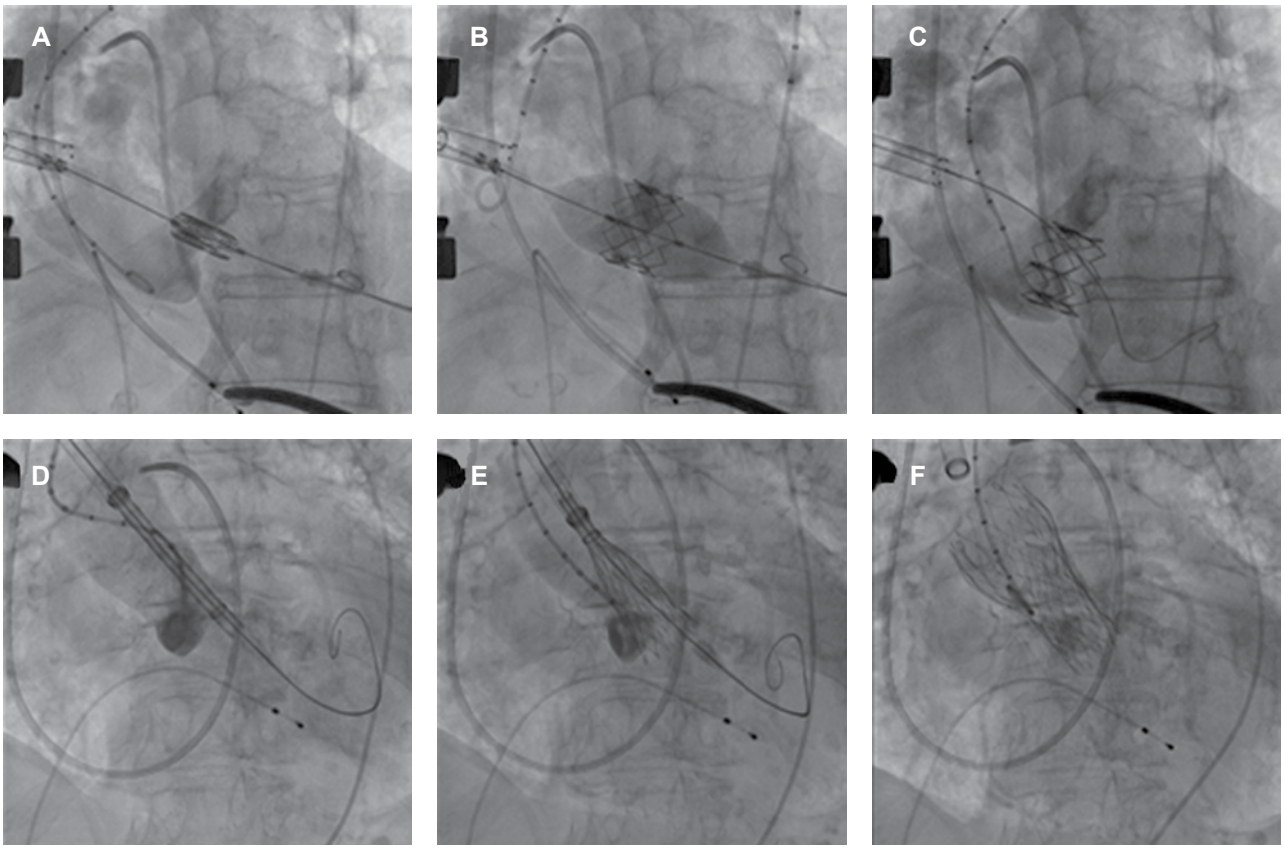

Figure 1. A to C: An example of transaortic implantation of the balloon expandable Sapien-XT Edwards valve. The Sapien-XT device was introduced via the 24 F Ascendra sheath and advanced to the level of the aortic annulus. After the correct position had been established by aortography, the valve was deployed during rapid ventricular pacing. D to F: An example of transaortic implantation of the self expandable Medtronic CoreValve. The CoreValve device was introduced via an 18 F Cook sheath and advanced into the aortic root. After the correct position had been established by serial aortograms, the valve was fully released.

Bloomington, IN, USA) for the CoreValve. Balloon valvuloplasty was then performed with a 20 or 22 × 40 mm balloon. Subsequently, a 23 mm (patients #1, 2, 3 and 5) or 26 mm (patients #4, 8, 11, 13, 14 and 24) diameter Sapien-XT valve, or a 23 mm (patients #16, 25), 26 (patients #7, 17 and 22), 29 mm (patients #6, 9, 10, 15, 18, 19, 20, 21 and 23) or 31 mm (patient #12) CoreValve was advanced and successfully implanted. Both balloon valvuloplasty and valve implantation were performed during short bursts of rapid ventricular pacing (160-200 beats/minute for valvuloplasty and for the Sapien-XT implantation and selectively 120-140 beats/minute for the middle part of the CoreValve implantation) (Figure 1). Aortography and intraoperative transoesophageal echocardiography confirmed the correct positioning and functionality of the bioprosthetic valve.

After removal of the sheath, the puncture site in the aortic wall was closed by pulling and tying the purse-string sutures. The sternum was closed with steel wires or the intercostal space with sutures. Postoperatively, the patients were transferred to the intensive care unit (ICU). All patients received antithrombotic therapy with heparin during the procedure (target activated clotting time >250 s) and all had received prophylactic antimicrobial therapy prior to the procedure.

Results

Table 1 summarises the clinical data of the first 25 patients with severe AS who underwent TAoVR procedures in our centre. The mean age was 78 ± 8 years, the mean logistic EuroSCORE I was 25 ± 11%, the mean STS mortality score was 5.7 ± 2.7%, the mean STS mortality & morbidity score was 28 ± 8.2% and the average functional NYHA class was 3.2 ± 0.4. In two cases (8%) the TAoVR was combined with off-

Table 1. Clinical characteristics.

Age (years)	78 ± 8
Female (%)	32
BMI (kg/cm^2)	26.6 ± 3.6
NYHA Class	3.2 ± 0.4
Log. EuroSCORE I (%)	25 ± 11
STS (%)	5.7 ± 2.7
STS m&m (%)	28 ± 8.2
Comorbidities:	
CAD (%)	76
Atrial fibrillation (%)	21
Diabetes (%)	28
HT (%)	68
PAD (%)	84
CPD (%)	44
PHT (%)	56
CRD (%)	40

BMI – body mass index; NYHA – New York Heart Association functional classification; STS – Society of Thoracic Surgeons; m&m – mortality & morbidity; LVEF – left ventricular ejection fraction; CAD – coronary artery disease; HT – hypertension; PAD – peripheral artery disease; CPD – chronic pulmonary disease (obstructive and restrictive); PHT – pulmonary hypertension (>60 mmHg); CRD – chronic renal disease.

pump full sternotomy coronary artery bypass graft surgery (CABG: the left internal mammary artery was grafted in an end-to-side fashion onto the left anterior descending artery). One of these patients (patient #7) was complicated by haemodynamic instability (cardiac index 1.3 L/min/m2) immediately after induction of general anaesthesia and required inotropic and vasopressor support and the insertion of an intra-aortic balloon pump (IABP). Three (12%) patients had a heavily calcified aorta (porcelain aorta), but a calcification-free spot at the right anterolateral aspect of the ascending aorta was identified from prior CT aortography. The majority (76%) of the patients had documented coronary artery disease, and five (20%) had prior CABG surgery. Nine patients (36%) had impaired left ventricular systolic function (LVEF<50%), and five of them (20%) had LVEF<35%. Nine (36%) patients had chronic obstructive pulmonary disease, two (8%) had moderate restrictive pulmonary disease, and ten (40%) had chronic renal disease. In five (20%) patients access was achieved via a small upper (second or third right intercostal space) mini-thoracotomy because of the lateral positioning of the ascending aorta. In one patient (4%) the upper mini-sternotomy was converted to a full sternotomy because of uncontrolled bleeding from the puncturing site in the ascending aorta. The patient was placed on extracorporeal circulation, the bleeding was controlled successfully, and the procedure was completed by accessing the aorta at a higher point.

Table 2. Procedural characteristics.

Fluoroscopy time (min.s)	15.6 ± 4.2
Contrast volume (mL)	108 ± 50
Valve diameter (mm)	26.5 ± 2.8
Size 23/26/29/31(%)	24/36/36/4
LOS ICU (days)	1.9 ± 1.0
Total LOS	6.4 ± 1.6
LOA (hours)	16 ± 14

LOS – length of stay; ICU – intensive care unit; LOA – length of anaesthesia.

The mean fluoroscopy time was 15.6 ± 4.2 minutes and the mean volume of iodinated X-ray contrast agent was 108 ± 50 mL. The mean ICU stay was 1.9 ± 1.0 days and the mean hospital stay was 6.4 ± 1.6 days (admission on day before procedure) (Table 2). Table 3 presents the preoperative and discharge echocardiographic data. The effective aortic valve orifice increased and the mean transvalvular pressure gradient decreased post implantation in all patients (from 0.68 ± 0.15 cm^2 to 1.82 ± 0.34 cm^2, $p<0.001$, and from 48 ± 15 mmHg to 9 ± 5 mmHg, $p<0.05$, respectively).

The procedural and device success rate was 100%. The procedural mortality was 0%. Patient #7, (Logistic EuroSCORE I 48% and STS score 31%) who underwent combined off-pump CABG and TAoVR, expired on day 3 from progressive cardiogenic shock, despite maximum haemodynamic support (with inotropes, vasopressors and IABP). Almost half of our patients (48%) required transfusion of at least two units of packed red cells. The postoperative course was complicated in one patient (4%) by paroxysmal atrial fibrillation that converted to sinus rhythm after intravenous amiodarone infusion, and in another one (4%) by supraventricular tachycardia (maximum heart rate 160 /min) associated with haemodynamic instability requiring DC cardioversion with no further sequel. Three patients (12%) were

Table 3. Preoperative and discharge echocardiographic data.

	Preoperative	Discharge
LVEF (%)	53 ± 13	55 ± 11
Mean PG (mmHg)	48 ± 15	9 ± 5
EAVO (cm^2)	0.68 ± 0.15	1.82 ± 0.34
AVR (+)	1.5 ± 0.7	1.0 ± 0.9
PAPs (mmHg)	50 ± 14	42 ± 9

LVEF – left ventricular ejection fraction; Mean-PG – mean transvalvular pressure gradient; EAVO – effective aortic valve orifice; AVR – aortic insufficiency; PAPs – systolic pulmonary artery pressure.

complicated by high degree conduction abnormality requiring permanent pacemaker implantation. In two of them a CoreValve bioprosthetic aortic valve was implanted and in one a Sapien-XT. One patient (4%) was complicated by a low cardiac index (1.9 L/min/m^2) and low diastolic blood pressure (<50 mmHg) due to incomplete CoreValve expansion, resulting in high paravalvular regurgitation between the right and left cusps. Post-dilation through a repeated TAoVR approach resulted in a significant decrease of the regurgitation to moderate grade 2, with uneventful recovery. No other in-hospital complications occurred (Table 4).

Table 4. Thirty-day clinical outcomes.

Mortality (%)	4
Procedure success (%)	100
Device success (%)	100
Major bleeding events (%)	48
Stroke (any) (%)	0
New pacemaker (%)	12
Renal failure (%)	12
NYHA Class	1.5 ± 0.9

Discussion

AS is the most frequent acquired heart valve disease and has well defined surgical indications.[7,8] Although the technique of median sternotomy, cardiopulmonary bypass and cardioplegic arrest remains the gold standard for conventional aortic valve replacement (sAVR), this may prove a high-risk procedure in patients with a "porcelain" ascending aorta, previous CABG, or multiple other cormobidities.[9,10] Patients with severe AS considered unsuitable for sAVR had better outcomes with transfemoral TAVR compared to medical treatment.[11] In addition, TAVR has been shown to be non-inferior or even superior to sAVR for patients at high surgical risk.[1,3] As the number of patients screened for TAVR increases, many are found to have absolutely no option for peripheral artery access. TAVR using the Sapien-XT device is performed via a retrograde (transfemoral), or antegrade transapical approach, while the CoreValve can be implanted only retrogradely (transfemoral or via the subclavian artery). The retrograde transaortic route of implantation for both valves has been added more recently. The SOURCE Registry (Sapien Aortic Bioprosthesis European Outcome) showed 9% 30-day mortality in transapical access patients, mainly due to major access site complications.[12] Thus, in addition to the CoreValve, where alternative access for those with peripheral arteriopathy would be welcome, such an access route would also be welcome for the Edwards valve.

TAoVR was described as a new, safe and feasible alternative retrograde approach that may have certain advantages over the other access routes.[11] The proximity between the puncture site in the ascending aorta and the aortic valve creates a very stable platform. This minimises motion and facilitates effective balloon valve dilation and valve deployment. The transapical approach via a low mini-thoracotomy is usually undesirable in patients with severe chest deformity, poor lung function, previous pulmonary complications, and poor LVEF. In contrast, TAoVR can be performed through an upper mini-sternotomy. The upper mini-sternotomy has advantages with respect to respiratory function (due to preservation of the diaphragm), postoperative bleeding and postoperative pain.[13] In addition, TAoVR avoids opening the left pleura and the subsequent necessity for pleural drainage, compared with the transapical intercostal approach. In addition, the upper mini-sternotomy can be easily converted to a full sternotomy in case of catastrophic complications, such as annular rupture, valve migration, or coronary ostia obstruction, allowing prompt access for conventional surgery. Also, after TAoVR, haemostasis in the ascending aorta and withdrawal of catheters can be more easily achieved compared to haemostasis of the apical muscle. Closure of the apex could represent a challenge in some cases and fragility of the ventricle has even been suggested as a contraindication for this approach. In patients with a very low LVEF, additional scarring on the apex resulting from haematoma or myocardial sutures could adversely affect postoperative LVEF. Indeed, after transapical TAVR, approximately 33% of the patients developed new apical hypo- or akinesia, affecting the LVEF in 7-13% of the patients.[11] For this reason, ventriculotomy incisions are usually avoided in cardiac surgery if not absolutely mandatory. Moreover, the transapical approach carries a relatively high risk of severe apical bleeding requiring extracorporeal bypass and/or complete sternotomy, termination of the procedure without valve implantation, or surgical re-exploration.[13,15] In contrast, a technical consideration for the upper mini-sternotomy TAoVR approach can be patients with patent vein grafts or with the right internal thoracic artery crossing the aorta anteriorly, which can be anticipated with a review of a 3D reconstruction of the chest CT scan.

Also, the absence of specifically designed delivery systems for TAoVR represents a relative technological limitation. However, both Edwards and Medtronic are currently developing such systems.

Although a "porcelain" ascending aorta can be a relative contraindication to the TAoVR approach, very often a small calcification-free spot in the anterior-lateral aortic wall can be sufficient to achieve secure insertion of the devices, as highlighted in three of our patients. Moreover, in comparison with the TF approach, manipulation of the aortic arch, which is known to be the primary source of atherosclerotic emboli, is avoided. Therefore, with a careful manual and imaging examination of the ascending aorta, the subsequent risk of stroke can be minimised.

The low number of patients and the short follow up represent limitations for our case series study. Almost half of our patients (48%) were complicated by major bleeding, according to the Valve Academic Research Consortium (VARC) definitions,[16] but in all but two patients this end-point was reached by virtue of blood transfusions and was not a specific bleeding complication. Anticoagulants are needed peri-procedurally to prevent clotting and stroke risk; however, they carry a certain risk of bleeding complications.

In conclusion, when transfemoral TAVR is not feasible, the transaortic route of access can be a safe and reproducible hybrid surgical/interventional technique with minimal operative risks and satisfactory haemodynamic and clinical outcomes in carefully selected patients. Our experience shows that the transaortic access can be easily combined with CABG and can be performed even in certain patients with incomplete porcelain aorta.

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