



Transaxillary Transcatheter Aortic Valve Replacement with a Self-Expanding Valve under Conscious Sedation: Case Discussion and Review of the Literature

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Abstract

Aortic stenosis is one of the leading causes of structural heart disease in the western world. Transcatheter aortic valve replacement (TAVR) has become the procedure of choice for patients deemed high-risk or inoperable for traditional aortic valve replacement and is rapidly proving to be suitable for lower risk patients. The technology has transformed the management of aortic stenosis. With growing expertise and more advanced devices, established TAVR programs have adopted a minimalist approach to TAVR and now routinely perform the transfemoral procedure on patients with only local anesthetic and monitored anesthesia care (MAC) to facilitate a totally percutaneous technique. For patients with inadequate iliofemoral access, the risk of vascular injury is extremely high and alternative techniques have been utilized and include the transapical, transaortic, and transsubclavian or transaxillary routes. Alternative approaches often require open surgical exposure under general anesthesia. Herein we describe a unique transaxillary TAVR with a self-expanding device utilizing only local anesthesia and MAC. To our knowledge, this is the first case in the United States to describe an awake TAVR with an axillary artery cut down.

Keywords: Transcatheter aortic valve replacement (TAVR); Transcatheter aortic valve implantation (TAVI); Transcatheter heart valve (THV); Transsubclavian; Transaxillary; Minimalist TAVR

Introduction

Transcatheter aortic valve replacement (TAVR) has become the standard of care for high-risk and inoperable patients with severe symptomatic aortic stenosis (AS) and has shown excellent outcomes compared to surgery in intermediate risk patients [1-3]. Since the first in man TAVR in 2002, over 200,000 Transcatheter Heart Valves (THV) have been implanted worldwide with excellent outcomes [4-7]. In the United States, two THV systems are commercially available, the balloon expandable Edwards SAPIEN S3 valve (Edwards LifeSciences, Inc., Irvine, California, USA) (SAPIEN) and the Medtronic CoreValve Revolving System, including the newer EvolutR (Medtronic CV, Santa Rosa, California, USA) (CoreValve), a self-expanding nitinol frame with a porcine pericardial valve. Both valve systems have been extensively utilized in the treatment of AS with excellent outcomes and a significant decrease in mortality compared to medical management [7-14].

As TAVR centers have gained experience, minimalist approaches (MA) have been employed whereby the procedure is completed percutaneously on an awake patient, with only local anesthesia and monitored anesthesia care (MAC) [15-17]. The MA-TAVR has been shown to be safe and effective and potentially offers cost-savings: the cost for general anesthesia is eliminated, the patient is mobilized sooner, length of time in the intensive care unit (ICU) is decreased, and discharge is sooner [15]. The MA-TAVR is most often described from the transfemoral (TF) approach with a totally percutaneous technique [15,18,19]. However, for TAVR candidates with inadequate iliofemoral access (<5 mm iliofemoral arteries, severe tortuosity or angulation, and heavy calcium burden) an alternative approach is necessary to avoid vascular injury [18-20]. It was previously

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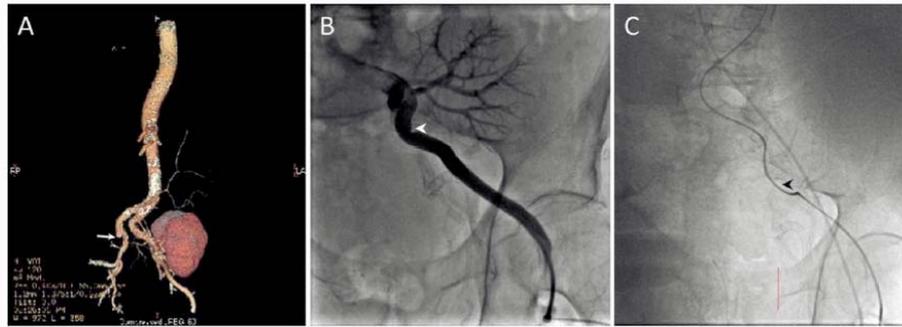


Figure 1: Inadequate iliofemoral access. A. Total occlusion of the right iliac and femoral arteries. B & C. Heavily calcified and tortuous left iliac artery with angulation due to the anastomosis of his transplant kidney as well as a short segment dissection.

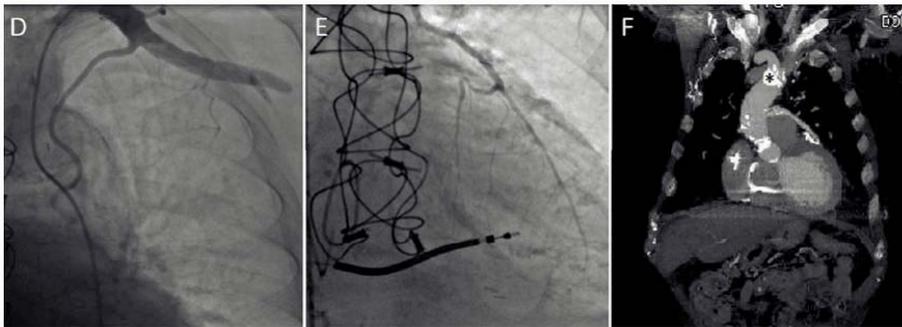


Figure 2: Challenging anatomy. D. The left auxiliary artery measured 7.5 mm. E. There was presence of a patent LIMA-LAD bypass graft. F. Heavy calcification of the ascending aorta with patient bypass grafts and a ridge of calcium at the base of the innominate artery.

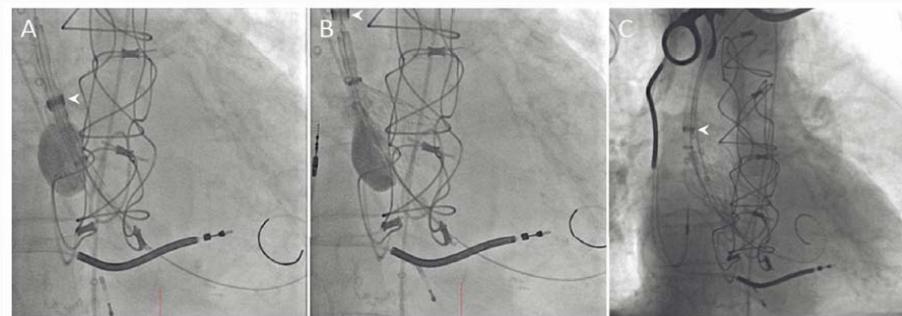


Figure 3: The Core Valve system was positioned across the aortic valve annulus at 0 mm ventricular and deployed.

estimated that one-third of candidates for TAVR have severe peripheral artery disease necessitating alternative access, however this number has significantly decreased since smaller delivery systems are available [21].

As newer devices with smaller delivery systems become available, alternative access TAVR may become obsolete. However, with the devices currently available, the SAPIEN S3 (deployed through a 16F, or 18F, inner diameter sheath) and CoreValve (requiring an 18F sheath for a 31mm Valve) necessitate iliofemoral arteries at least 5.5-7 mm. Alternative access TAVR has been well described with the transapical (TA) approach being the initial alternative route for the SAPIEN valve and the transaxillary (T_{ax}), also called transsubclavian, for CoreValve [9,18,19,22,23]. Both THVs can also be deployed via a direct transaortic (TAo) approach, a select few centers have described a transcarotid approach, and early experience with larger deliver systems even necessitated the use of an iliac

conduit [22,24-27]. Most alternative access routes have required surgical exposure via a minithoracotomy for TA, auxiliary cut down for T_{ax}, or ministernotomy for TAo and thus are typically completed under general anesthesia [18,28].

Herein we present the case of a patient with severe symptomatic AS, multiple comorbid conditions including pulmonary hypertension, at extreme-risk for open surgery that had inadequate access for a MA-TAVR from the TF approach. The patient was treated with a T_{ax} TAVR with local anesthesia for the auxiliary artery cutdown facilitated with MAC by a cardiac anesthesiologist. We present this case as the first case of this kind described in the US.

Case Report

An 80-year-old male presented with worsening symptoms of congestive heart failure (CHF). He was no longer able to complete his activities of daily living and had multiple admissions for exacerbation

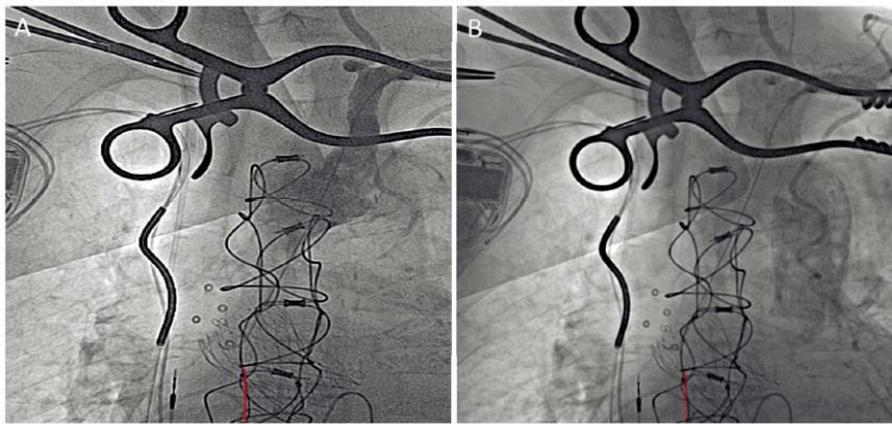


Figure 4: The delivery system was removed and the sheath withdrawn to allow flow into the LIMA, the patency was confirmed with angiography.

of CHF (New York Heart Association Class III-IV). His past medical history was significant for polycystic kidney disease resulting in end-stage renal disease for which he had twice undergone renal transplantation, coronary artery disease status post myocardial infarction and coronary artery bypass grafting (with a left internal mammary artery to left anterior descending (LIMA-LAD) and four saphenous vein graft bypasses) as well as repair of the mitral and tricuspid valves, hypertension, hyperlipidemia, peripheral artery disease, tachy-brady syndrome requiring placement of a defibrillator and permanent pacemaker, a history of deep vein thrombosis managed with Coumadin, hyperparathyroidism, obstructive sleep apnea requiring CPAP at night, and paroxysmal atrial fibrillation.

During his most recent hospitalization he presented with atypical chest pain, complaining of worsening fatigue and underwent a full cardiac evaluation and was found to have patient bypass grafts on coronary catheterization, pulmonary hypertension (pulmonary pressure 49/22 mmHg, mean 33 mmHg), and an echocardiogram revealed left ventricular dysfunction with an ejection fraction of 20-25%, severe aortic stenosis (aortic valve area 0.7 cm², mean gradient 43 mmHg, peak gradient 78.1 mmHg, and velocity across the valve of 442 m/s), as well as aortic insufficiency, moderate mitral regurgitation, and moderate tricuspid insufficiency. He was medically optimized and the Heart Valve Team was consulted for evaluation for TAVR.

During TAVR work up he was found to have moderate pulmonary dysfunction on pulmonary function testing (FEV1: 54% predicted and DLCO: 43%) and 3 of 4 unsatisfactory frailty metrics (albumin of 3.3, decreased grip strength, and a 15-meter walk of 7.6 seconds). His Society of Thoracic Surgery (STS) risk of mortality was calculated at 15.3% for open AVR.

A preoperative TAVR CT confirmed a large valve annulus (diameter 28.5 X 33.9 mm, perimeter 97.9, area 752.7 mm²). Assessment of his iliofemoral access showed a totally occluded right iliac and femoral artery, heavily calcified and tortuous left iliac artery with angulation due to the anastomosis of his transplant kidney and a short segment dissection (Figure 1). His ascending aorta was heavily calcified with patient bypass grafts and a ridge of calcium at the base the innominate artery (Figure 2). The left auxiliary artery measured 7.5 mm. After extensive discussion, TAx TAVR with local anesthesia and a 31mm CoreValve was deemed the most prudent and viable option.

The patient was positioned supine and MAC anesthesia with

low dose dexmedetomidine was induced for patient comfort. Local anesthesia was injected in the left infraclavicular region and a 3cm incision was made parallel to the mid-portion of the left clavicle. The pectoralis muscle was incised and the exposure was carried down to the auxiliary vein, well away from the brachial plexus. The vein was retracted cephalad to expose the axillary artery and vessel loops were placed proximally and distally. The LIMA was visualized and the arteriotomy planned medially. Two 4-0 Prolene purse string sutures were placed in the anterior surface of the auxiliary artery. A 5-F pigtail catheter was advanced to the aortic root via a 6F sheath placed in the left common femoral artery and a transvenous pacer was placed through the left common femoral vein. The patient was systemically heparinized to an ACT of >250 sec. After conformation of the deployment angle with angiography the left subclavian artery was cannulated using the Seldinger technique. A long 7F precurved destination sheath was placed, the aortic valve was crossed, and a precurved Lunderquist wire was advanced into the ventricle. The 7F sheath was exchanged for an 18F sheath advanced to the ascending aorta under direct vision. The Core Valve system was positioned across the aortic valve annulus at 0 mm ventricular and deployed (Figure 3). The delivery system was removed and the sheath withdrawn to allow flow into the LIMA, the patency was confirmed with angiography (Figure 4) the valve was evaluated with transesophageal echocardiography and noted to have a mild inferior paravalvular leak but excellent function. The wire and sheath were removed and the incision closed in layers.

The postoperative course was unremarkable. He was ambulating with physical therapy within 8 hours of the operation and transferred out of the ICU the following morning. Although he was ready for discharge, at the request of the transplantation service, he was monitored an additional 24 hours and discharged to home the morning of the second postoperative day. At 30-day follow up he was doing well, able to complete all activities of daily living and in NYHA Class I heart failure.

Discussion

Transcatheter aortic valve replacement has been one of the most disruptive technologies in the management of cardiovascular disease in the past ten years. Not only has TAVR allowed for the treatment of hundreds of thousands of patients once deemed too high-risk for surgery but the technology has also established a collaborative approach to heart care.

In this case, the Heart Valve Team, including two cardiac surgeons, an interventional cardiologist, the valve coordinator, an echocardiologist, and a cardiac anesthesiologist had an extensive discussion regarding the patient and the case. Although his aortic valve perimeter was beyond the published range for the CoreValve, due to heavy calcification of the leaflets a seal would likely be possible. In regard to the access route, initially a TF approach was discussed but the severe angulation of the proximal left common iliac artery in conjunction with an additional area of tortuosity at renal artery anastomosis of his transplanted kidney made the approach risky. The Team further discussed a TAO approach, but with a questionable site for cannulation and the need for general anesthesia, this too was a suboptimal route of access. Alternative access with a TAX approach seemed the least risky. Employing the routine MA-TF protocol and avoiding general anesthesia in this patient would be very beneficial.

Alternative access via the TAX approach is well described and has many advantages over other alternative access options [28-34]. First described in 2008, the TAX approach became the alternative access route of choice for the CoreValve [18,23]. Early experience with TAX TAVR was summarized by Caceres et al. [35] who highlight high device success rates and relatively low risk of stroke. Laflamme et al. [36] published a single-center retrospective study of 174 TAVR procedures with the CoreValve system, 10% were completed via a TAX approach under general anesthesia, the authors report the approach is associated with high procedural success (94%), no stroke or vascular complications, and no in-hospital or 30-day mortality. Further, they conclude the TAX approach, due to the shorter distance between the delivery sheath and the aortic annulus provides better control of the device and allows more precise positioning [36]. Muenstere et al. [32] similarly demonstrated the safety of TAX access for a CoreValve in 40 patients and showed no difference in survival between the TF and TAX groups ($p = 0.355$) at 30 day, 6-month, and 1-year follow-up (respectively, 94.1, 77 and 67.4% in the TAX group). Reardon et al. [18] describe the utilization of alternative access techniques in the CoreValve Extreme Risk US Pivotal Trial, including 70 patients who underwent TAVR via a TAX approach; no event of device migration or embolization occurred, there was no conversion to open surgery, and the subclavian access resulted in lower 30-day all-cause mortality rate than TAO access (8.6% vs. 13.7%) but a greater stroke rate (8.6% vs. 6.5%). A meta-analysis published in 2014 included 1526 patients, 228 with transsubclavian access and showed no significant difference for 30-day mortality (OR 0.64; 95% CI 0.31-1.32; $p = 0.23$), stroke (OR 0.74; 95% CI 0.27-2.01; $p = 0.55$), or new pacemaker implantation (OR 0.88; 95% CI 0.58-1.35; $p=0.56$) as compared to the TF approach. However, there was a decreased risk of vascular complications (OR 0.53; 95% CI 0.29-0.95; $p=0.03$) in the TAX group [17]. Although a direct comparison between TAX and TA TAVR was not undertaken, the authors indirectly suggest that TAX may be a better access than TA for patients without adequate femoral artery access. A report of the 2-year results of CoreValve implantation through the TAX approach from the Italian CoreValve Registry included 141 TAX patients matched to TF and found similar outcomes in regard to procedural success rate (97.9% vs. 96.5%; $p = 0.47$), major vascular complications (5.0% vs. 7.8%; $p = 0.33$), life-threatening bleeding (7.8% vs. 5.7%; $p = 0.48$), and 2-year freedom from cardiovascular death ($87.2 \pm 3.1\%$ vs. $88.7 \pm 2.8\%$) [21].

Initially, a patient LIMA-LAD was deemed a contraindication to TAX TAVR, but many centers have utilized this approach in previously bypassed patients with low morbidity [31,32,37]. Multiple

case reports have described the case of successful THV implantation via the left subclavian artery in the presence of a patent LIMA graft to LAD and suggested this is not an absolute contraindication for TAX TAVR [37,38]. Modine et al. [31] were the first to publish a series of patients treated via a TAX approach with patent LIMA-LAD and proved the technique to be feasible and safe with satisfactory outcomes. Caution must be taken with the use of this approach in patients with small caliber subclavian arteries as the 18 F sheath could be occlusive and result in myocardial ischemia during the THV deployment [39].

In Europe, the MA-TAVR has transitioned to include the TAX approach. Cioni et al. [29] described the short- and mid-term results in an Italian single-center performing the TAX TAVR in the cardiac catheterization laboratory with local anesthesia and mild sedation: procedural success rate 96.8%, 30-day mortality 6.4%, and actual survival at 6 months 82.95%. The authors believe the MA-TAX approach is a feasible and technically simple TAVR technique. Schafer et al. [40] described the German totally percutaneous technique to access the auxiliary artery for TAVR with 37.5% of the patients undergoing the procedure with local anesthesia and conscious sedation, however 29% of patients experienced percutaneous closure failure and required treatment with endovascular stent grafts.

Herein we have described an alternative access strategy for a patient with inadequate iliofemoral access in which general anesthesia could be avoided. We believe the TAX TAVR under local anesthesia with MAC support is a feasible procedure with low risk. We offer this case for further discussion and believe this approach should be added to the armamentarium of US TAVR Teams for the treatment of challenging cases.

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