Single Center TAVR Experience With a Focus on the Prevention and Management of Catastrophic Complications

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Background: Transcatheter aortic valve replacement (TAVR) is an important treatment option for patients with severe symptomatic aortic stenosis (AS) who are inoperable or at high risk for complications with surgical aortic valve replacement. We report here our single-center data on consecutive patients undergoing transfemoral (TF) TAVR since the inception of our program, with a special focus on minimizing and managing complications.

Methods: The patient population consists of all consecutive patients who underwent an attempted TF-TAVR at our institution, beginning with the first proctored case in May 2006, through December 2012. Clinical, procedural, and echocardiographic data were collected by chart review and echo database query. All events are reported according to Valve Academic Research Consortium-2.

Results: During the study period, 255 patients with AS had attempted TF-TAVR. The procedure was successful in 244 (95.7%) patients. Serious complications including aortic annular rupture (n = 2), coronary occlusion (n = 2), iliac artery rupture (n = 1), and ventricular embolization (n = 1) were successfully managed. Death and stroke rate at 30 days was 0.4% and 1.6%, respectively. One-year follow-up was complete in 171 (76%) patients. One-year mortality was 17.5% with a 3.5% stroke rate. Descending aortic rupture, while advancing the valve, was the only fatal procedural event. There were 24.4% patients with ≥2+ aortic regurgitation.

Conclusions: TAVR can be accomplished with excellent safety in a tertiary center with a well-developed infrastructure for the management of serious complications. The data presented here provide support for TAVR as an important treatment option, and results from randomized trials of patients with lower surgical risk are eagerly awaited.

Key words: aortic stenosis; percutaneous intervention; TAVR; complications; vascular access; comparative effectiveness/patient centered outcomes research

INTRODUCTION

Transcatheter aortic valve replacement (TAVR) has revolutionized the management of patients with aortic stenosis (AS) since the first valve was implanted by Professor Alan Cribier in 2002 (Rouen, France). Our understanding of the procedure and insights into patient outcomes have significantly advanced since then. TAVR provides a viable alternative to surgical aortic valve replacement for high-risk patients.

Conflict of interest: Nothing to report.

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selection has rapidly evolved, supported by encouraging retrospective and prospective clinical outcomes data [1–6]. Cardiologists and cardiac surgeons have worked together in an unprecedented manner to ensure the success of this joint venture, resulting in the first US Food and Drug Administration (FDA) approval for a transcatheter valve in November 2011.

Since commercial approval, many centers in the US have begun offering TAVR to patients with AS. Essential criteria for the performance of TAVR by these sites have been carefully delineated through a joint effort by cardiology and cardiac surgery organizations, including the American College of Cardiology (ACC), the Society of Thoracic Surgery (STS), and the Society for Cardiovascular Angiography and Interventions [7–9]. An imperative for the performance of commercial TAVR is the comprehensive reporting of patient and procedural data to the STS/ACC Transcatheter Valve Therapies (TVT) national database. This will provide an understanding of patient selection and outcomes as TAVR is applied on a broader scale [7,10].

These newer centers face important challenges including team-building, patient selection, physical infrastructure, and procedural education and competency, all while maintaining the high standard to which this new therapy must be held. One of the most difficult challenges to overcome is unexpected complications. The potentially catastrophic complications of TAVR can be managed successfully only when the entire team is fully prepared. Although guidelines for this exist, many insights can be gained by analyzing a single-center’s comprehensive experience with TAVR. We have learned a great many lessons in our performance of transfemoral (TF)-TAVR and other access sites including TA, TAo, etc. In order to analyze our experience in a methodical fashion and focus on specific organizational and learning points, we have divided our experience into TF cases (presented here) and surgical (TA/TAo) cases.

Therefore, we provide here data on all patients undergoing TF-TAVR at our institution since the procedure’s introduction to the US in 2006, with a special focus on our processes for the successful management of complications.

**METHODS**

**Patient Population**

The patient population consists of all consecutive patients who underwent an attempted TF-TAVR at our institution, from the first proctored case on May 5, 2006 (as part of the three center FDA feasibility trial) through December 2012. This includes patients enrolled in various clinical trials, as well as patients undergoing commercial valve replacement. The trials in which patients were enrolled include: transcatheter endovascular implantation of valves (REVIVAL), placement of aortic transcatheter valve (PARTNER) trial (randomized cohorts A and B as well as continued access registries), and PARTNER II (randomized cohorts A and B as well as continued access registries); the inclusion and exclusion criteria for these trials have been previously published [2–5]. All patients who underwent TF-TAVR were assessed by both cardiologists and cardiac surgeons.

The following evaluations were performed: clinical assessment, complete metabolic profile, complete blood count, CT scan to evaluate the aortic annulus and iliofemoral access, transthoracic echocardiogram, coronary angiography, and full pulmonary function testing. In patients with impaired renal function, noncontrast CT scan was used to assess the chest, but iliofemoral access was assessed using a CT scan performed with intra-arterial contrast injection (total 12–14 cc dye) via a pigtail catheter placed in the infrarenal aorta. After 2009, all patients underwent trans-esophageal echocardiography (TEE) before the procedure to assess the aortic annulus size, the presence of other valvular heart disease, aortic atheroma, and intracardiac masses including thrombus. In some patients with “borderline” iliofemoral vasculature for the TF approach, intravascular ultrasound was used to further evaluate vessel diameter.

**Procedural Details**

All TF-TAVR procedures but one were performed under general endotracheal anesthesia and TEE guidance. A Swan-Ganz catheter and a radial or brachial arterial line were used in all patients at the time of the procedure. All procedures were performed in a hybrid catheterization laboratory with biplane fluoroscopic imaging.

In our initial experience, femoral cut-down was used until February 2010, after which percutaneous preclosure of the arteriotomy with Perclose devices (one 10 F Prostar™ or two perpendicular 8 F Proglide™, Abbott Vascular, Santa Clara, CA) was performed. In the percutaneous era, femoral cut-down was used only for patients with prior surgical aortobifemoral grafting. Bilateral arterial access was obtained in all patients with confirmation angiogram to confirm optimal puncture at a site in the common femoral artery proximal to the femoral bifurcation and distal to the inferior epigastric artery takeoff. As above, preclosure was performed for both arterial access sites. Femoral venous access was obtained on both sides; a temporary pacemaker wire was placed via the left venous access and the right venous access was kept available in case of emergency cardiopulmonary bypass (CPB). Since July 2011, a 0.018” crossover wire was routinely placed in all cases via the femoral artery access contralateral to the intended side of TAVR delivery sheath insertion (and extending to the ipsilateral superficial femoral...
artery) in order to secure wire access to the true lumen in case of vascular complication due to delivery sheath insertion and manipulation. This was performed before delivery sheath insertion but after the preclosure. A 5 F pigtail catheter was always placed in the noncoronary sinus from the contralateral femoral access to perform aortic root angiography to confirm valve positioning before deployment. All patients were anticoagulated before insertion of the large sheath. In 253 patients, unfractionated heparin (UFH) was used with a target ACT of 300 sec; in two patients with contraindication to UFH use, bivalirudin was substituted.

The aortic valve was crossed using a 5 F AL-1 diagnostic catheter and an 0.035° straight wire. After obtaining initial hemodynamics, an 0.035° extra-stiff Amplatz wire (curved to provideatraumatic placement in the left ventricle (LV)) was advanced to secure position across the valve. Balloon aortic valvuloplasty (BAV) was performed with a balloon smaller than the intended valve size (20 mm balloon for 23 mm valve and 22 or 23 mm balloon for 26 or 29 mm valve, respectively). BAV was performed under rapid ventricular pacing, usually at a rate of 180 bpm. Lower rates (170 or 160 bpm) were used in a few patients who demonstrated inconsistent capture at 180 bpm. The valve was prepped and ready to implant before performance of the BAV, in case severe aortic regurgitation (AR) complicated the BAV. All patients at our center underwent TAVR using the Edwards SAPIEN balloon-expandable prosthesis (Edwards Lifesciences, Irvine, CA).

Fluoroscopic angles perpendicular to the AV plane were determined by prior angiography or CT scan in all patients. At the time of valve implantation, position in the annulus was confirmed by aortic root injection under biplane imaging (typically one camera in RAO Caudal and another in LAO Cranial projection) and TEE. For all procedures, at least one cardiovascular surgeon and two interventional cardiologists with structural and peripheral procedures, at least one cardiovascular surgeon and two interventional cardiologists were present in all cases at the time of valve deployment. AR and valve placement were assessed by comprehensive hemodynamic analysis; simultaneous pressure measurement in the LV and aorta was obtained in all patients after valve deployment. After removal of the delivery sheath, selective angiography of the delivery-side iliofemoral tree was performed in all patients. Patients received protamine if access site closure was successful without vascular complications. The majority of patients were exubatated in the catheterization laboratory before transfer to an intensive care unit.

Clopidogrel was continued through the periprocedural period if patients were already taking clopidogrel. For those patients who were not on clopidogrel, a 300 mg bolus was given after valve replacement. Clopidogrel was continued for 6 months (unless there was a strong contraindication to its use), and aspirin 81 mg prescribed indefinitely. In patients requiring warfarin, clopidogrel was given for 7 days postprocedure or until patients demonstrated a therapeutic international normalized ratio.

All patients were scheduled for clinical follow-up at 30 days, 6 months, and 1 year. If patients could not travel to Cleveland, local physicians were contacted for follow-up. Echocardiograms were performed on follow-up visits.

Data Collection

Data collection was performed under approval by the institutional review board. All patients who had attempted TF-TAVR were identified in our institutional database of AS patients. Baseline characteristics, complications, and events were collected by an extensive review of the individual patient medical records and adjudicated by S.R.K., E.M.T., L.G.S., and A.K. The social security death index and the institutional clinical databases were analyzed for every patient to ensure comprehensive and complete clinical outcomes data.

Definitions

All outcomes were defined according to the standardized Valve Academic Research Consortium-2 (VARC-2) guidelines [11]. Stroke was defined as duration of a focal or global neurological deficit ≥24 h; or <24 h if available neuroimaging demonstrated a new hemorrhage or infarct; or the neurological deficit resulted in death. Major bleeding included life-threatening bleeding, disabling bleeding, or major bleeding as per VARC-2 [11]. Renal failure events were defined as chronic dialysis of any sort (hemodialysis, CVVHD, and peritoneal) for a duration of greater than 30 days. In addition, any episode of renal replacement therapy, either transient or greater than 30 days duration, was considered as renal failure. The date of event was based on the date of the first treatment with renal replacement therapy. Clinical data were collected from systematic follow-up of all patients.

Peripheral vascular disease was defined as documented severe (>50%) stenosis of the arch vessels, lower extremity vessels, renal arteries, or aortic aneurysmal disease. Catastrophic complications were defined as those complications that would most likely result in death if not promptly diagnosed and treated within minutes. These included: coronary artery occlusion, annulus rupture, aortic rupture, vascular rupture, cardiac perforation, severe AR, and valve embolization.

Statistical Analysis

Continuous variables are reported as mean ± standard deviation and categorical variables are reported as

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a percentage (%). T-test, chi square test, survival analysis, and other statistical analysis were performed according to standard methods using SPSS 18.0 statistical software (IBM Corporation). Baseline variables (Table I) were used in the multivariate analysis to determine predictors of mortality.

RESULTS
Patient Population
Between 2006 and 2012, a total of 255 patients with AS underwent attempted TF-TAVR. Eleven patients were enrolled in the REVIVAL study, 25 in PARTNER IB, 105 in PARTNER IA, 42 in PARTNER IIB, and six patients in PARTNER IIA. Sixty-six patients underwent attempted commercial-approved TF-TAVR. All patients were designated as either inoperable (N = 144, 56.5%) or operable with moderate or high surgical risk (N = 111, 43.5%) after a thorough heart team assessment before the procedure. Baseline characteristics of these patients are listed in Table I. The patients were elderly (mean age 80.71 ± 9.86) and 58% of them were male. They demonstrated multiple comorbidities including diabetes, coronary artery disease, COPD, and impaired LV systolic function. Figure 1 indicates the volume of TF-TAVR procedures and individual complications encountered during each year from 2006 to 2012.

Procedural Outcomes
The procedure was successful in 244 (95.7%) patients. There was one intraprocedural death which was the result of descending aortic rupture; the patient died during emergent open surgical repair due to friable tissues and uncontrolled bleeding. Procedural outcomes are listed in Table II.

Unsuccessful Procedures
The majority of unsuccessful procedures were due to the inability to insert the delivery sheath successfully, whereas others were due to an inability to cross the native AV with the TAVR prosthesis. We were unable to insert the delivery sheath in eight patients. Four of eight (50%) of them had successful BAV, whereas transapical TAVR (TA-TAVR) was successfully performed in the remaining 4/8 (50%) patients. In three patients, we were unable to cross the native valve with the prosthetic valve; all three of these patients had successful BAV. The decision to perform TA-TAVR in these patients was governed by their operative risk and granting of pre-procedural consent.

Catastrophic Complications
Acute, life-threatening complications encountered in our experience included: ventricular valve embolization (n = 1), iliac artery rupture (n = 1), annular rupture (n = 2), descending aorta rupture (n = 1), and coronary occlusion (n = 2). The management of these patients in the cardiac catheterization laboratory is outlined in Table III. Aside from the descending aorta rupture, all other complications were managed successfully without 30-day mortality or stroke. A valve-in-valve was placed in 10 (3.9%) of patients during the index TAVR procedure. Severe valvular regurgitation was the reason for a 2nd valve in two patients. In eight patients, the second valve was placed due to severe paravalvular leak that resulted from malpositioning of the first valve.
30-Day Outcomes

One patient (0.4%) died within 30-days, and four patients (1.6%) suffered a stroke within 30-days. Outcomes of patients according to the year in which the procedure was performed are shown in Fig. 1.

1-Year Outcomes

One-year outcomes are listed in Table II. Overall actuarial mortality at 1-year was 17.5% (17.3% among operable patients and 17.9% among inoperable patients) of the 171 patients with 1-year follow-up. In these patients, two additional strokes occurred between 30 days and 1 year. Most patients (76.6%) had NYHA class I or II symptoms, 19.9% had class III symptoms, and 3.5% had NYHA IV symptoms. Kaplan-Meier estimates revealed no significant difference in mortality or the combination of mortality and stroke between the operable and inoperable groups. Total outcomes for each year, along with number of patients at risk at the start of the year, are shown in Fig. 2.

Echocardiographic Follow-Up

Echocardiograms were independently reviewed by imaging specialists not involved in the TAVR procedure, and severity of valve disease pre- and post-procedure was graded based upon the consensus definitions of the American Society of Echocardiography [12]. Echocardiographic data at baseline and follow-up are reported in Table IV. The peak and mean aortic valve gradient was 76.73 ± 25.10 mm Hg and 45.05 ± 15.04 mm Hg, respectively. Baseline aortic insufficiency ≥2+ was present in 31.4% patients. On 30-day or pre-discharge echocardiogram, mild (2+)
TABLE II. 30-Day and 1-Year Outcomes

| Outcomes                        | 30-Day outcomes | 1-Year outcomes |
|---------------------------------|-----------------|-----------------|
|                                 | Total (n = 255) | Inoperable (n = 144) | Operable (n = 111) | Total (n = 171) | Inoperable (n = 67) | Operable (n = 104) |
| Mortality                       | 1 (0.4)         | 1 (0.7)          | 0 (0.0)           | 30 (17.5)      | 12 (17.9)          | 18 (17.3)          |
| Stroke                          | 4 (1.6)         | 2 (1.4)          | 2 (1.8)           | 6 (3.5)        | 2 (3.0)           | 4 (3.8)           |
| Rehospitalization               | 12 (4.7)        | 7 (4.9)          | 5 (4.5)           | 31 (18.1)      | 15 (22.4)         | 16 (15.4)         |
| NYHA III/IV                     | 20 (7.8)        | 10 (6.9)         | 10 (9.0)          | 40 (23.4)      | 17 (25.4)         | 23 (22.1)         |
| NYHA III                        | 18 (7.1)        | 9 (6.3)          | 9 (8.1)           | 34 (19.9)      | 15 (22.4)         | 19 (18.3)         |
| NYHA IV                         | 2 (0.8)         | 1 (0.7)          | 1 (0.9)           | 6 (3.5)        | 2 (3.0)           | 4 (3.8)           |
| MI                              | 2 (0.8)         | 2 (1.4)          | 0 (0.0)           | 2 (1.2)        | 2 (3.0)           | 0 (0.0)           |
| Renal failure                   | 6 (2.4)         | 4 (2.8)          | 2 (1.8)           | 4 (2.3)        | 1 (1.5)           | 3 (2.9)           |
| Cr > 3 mg/dL (>265 μmol/L)      | 5 (2.0)         | 4 (2.8)          | 1 (0.9)           | 1 (0.6)        | 0 (0.0)           | 1 (1.0)           |
| Major bleeding                  | 14 (5.5)        | 6 (4.2)          | 8 (7.2)           | 9 (5.3)        | 1 (1.5)           | 8 (1.0)           |
| Major vascular complications    | 24 (9.4)b       | 11 (7.6)         | 13 (11.7)         | 18 (10.5)      | 6 (9.0)           | 12 (11.5)         |
| BAV only                        | 3 (1.2)         | 2 (1.4)          | 1 (0.9)           | 2 (1.2)        | 1 (1.5)           | 1 (1.0)           |
| Surgical AVR                    | 2 (0.8)         | 1 (0.7)          | 1 (0.9)           | 2 (1.2)        | 1 (1.5)           | 1 (1.0)           |
| Endocarditis                    | 1 (0.4)         | 1 (0.7)          | 0 (0.0)           | 1 (0.6)        | 1 (1.5)           | 0 (0.0)           |
| Pacemaker                       | 10 (3.9)        | 6 (4.2)          | 4 (3.6)           | 9 (5.3)        | 5 (7.5)           | 4 (3.8)           |
| Valve embolization              | 2 (0.8)         | 0 (0.0)          | 2 (1.8)           | 2 (1.2)        | 0 (0.0)           | 2 (1.9)           |

aAll cases of major bleeding within 30 days occurred either during the procedure or before discharge. All numbers are actuarial outcomes.
bMajor vascular complication after the procedure.

TABLE III. Management of Catastrophic Complications During TF-TAVR

| Details of complication | Management | Learning point |
|-------------------------|------------|---------------|
| LM occlusion            | TandemHeart Successful stenting of LM | Prediction of this complication by measurement of coronary ostium height versus coronary leaflet length. Emergent use of support devices until perfusion is restored |
| RCA occlusion           | Successful, brief AV ECMO support | Occlusion from aortic hematoma, managed conservatively as RCA was small; patient weaned from ECMO in the cath. lab. |
| Ventricular valve embolization | Successful conversion to open AVR | Capability of open AVR in the hybrid room |
| Rupture of tortuous descending aorta when advancing Sapien XT | Immediate thoracotomy with attempt to control bleeding and Fem-Fem support was unsuccessful | Inability to suture due to friable tissue in the setting of old age (91 years) and chronic steroid use. Immediate stent graft from contralateral groin could have been useful; now included in our “perforation cart.” |
| Rupture of aortic annulus during valve deployment | Successful conversion to surgical AVR and control of bleeding. | Valve sizing was appropriate, but calcification of the LVOT should be assessed. |

AVR, aortic valve replacement; ECMO, extracorporeal membrane oxygenation; LMT, left main trunk; LVOT, left ventricular outflow tract; RCA, right coronary artery.

AR was present in 22.4% of patients. Moderate or severe AR (>2+) was present in 2% of patients. Moderate or severe mitral regurgitation was present in 12.9% of the patients at baseline but in 7.9% at 30 days follow-up. Also, ejection fraction was <40% in 59 (23.1%) patients at baseline.

DISCUSSION

This single-center report of all consecutive patients undergoing TF-TAVR (including the initial US experience) highlights several points. TF-TAVR can be accomplished with extremely low 30-day mortality (0.4%) in sick patients in a well-organized cardiovascular facility, mainly because of expeditious management of catastrophic complications. Preparedness of the entire team to manage uncommon, life-threatening complications is critical for patient survival. The collaboration of specialists in cardiac imaging, cardiac anesthesia, nurses, and technicians, in addition to interventional cardiologists trained in peripheral, structural, and coronary intervention, cardiac surgeons, and the immediate availability of cardiopulmonary support were thought to be important for patient survival.

Our TAVR program began in 2006 as part of the REVIVAL study of inoperable patients [6,12]. Subsequently, inoperable patients were treated as part of the PARTNER I and II Cohort B study groups, and high surgical risk patients were treated under the PARTNER I Cohort A study [4,5]. More recently, inoperable patients have been treated with commercial availability.
of the Sapien valve since October 2011, and a small number of moderate surgical risk patients were treated in 2012 as part of the PARTNER II Cohort A study. The program initially began with two interventional cardiologists, two cardiac surgeons, three imaging cardiologists, two cardiac anesthesiologists, and one research nurse; it has now grown to include four interventional cardiologists, four cardiac surgeons, more than 12 imaging cardiologists, three clinical cardiologists, more than eight cardiac anesthesiologists, and four nurses.

Importantly, with the evolution of our infrastructure to handle increasing demands, good outcomes persisted. We believe that the outstanding communication in the “TAVR community” that has been fostered by PARTNER trial conference calls to aide patient selection, and multicenter and international conferences to discuss the prevention and management of complications contributed to the absence of a “learning curve” phenomenon seen in our experience (Fig. 1). Another important contribution, although difficult to quantify, came from our center’s surgical experience in treating AS. This created an existing infrastructure into which the TAVR procedure was welcomed, and catastrophic complications were often dealt with emergently and effectively by our surgical partners.

The set-up and procedural resources deserve special attention. All TF-TAVR procedures were performed with at least two interventional cardiologists, two cardiac surgeons, three imaging cardiologists, two cardiac anesthesiologists, and one research nurse; it has now grown to include four interventional cardiologists, four cardiac surgeons, more than 12 imaging cardiologists, three clinical cardiologists, more than eight cardiac anesthesiologists, and four nurses.

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to reduce resource utilization, although the impact of this intervention remains to be seen.

As TAVR evolves with next-generation devices and is applied to lower risk patient populations, it will be important to see how programs adapt to the changing landscape. Several new programs are emerging under close monitoring by the STS and ACC using the TVT registry [7–9]. In order to maintain the historically low complication rates demonstrated in ours and others’ early experience, thorough patient assessment and selection, advanced peripheral and structural interventional training, continued multi-center discourse, and institutional teamwork is imperative.

While not directly comparable, the data from our single center demonstrate lower mortality than most reported series, with higher survival at 12 months in both operable and inoperable patients. Although the average STS score in our group (9.74) was slightly lower than the average in the PARTNER Cohort A (11.8) and Cohort B (11.2) trials, it remains well within the range of high-risk or inoperable, as also deemed by our surgical team [3–5]. Interestingly, the mortality of patients who were operable versus inoperable is not substantially different. This suggests that there are other factors that determine mortality [3]. We found that the STS score was one of the most important factors determining 1-year mortality, confirming the contribution of comorbid conditions to long-term outcome and as demonstrated in recent analyses of the PARTNER I trial [13]. Prior BAV was also a predictor of higher mortality after TF-TAVR, likely due to the fact that BAV was invariably performed in patients whose comorbidities precluded a direct pathway to an AVR procedure [14,15].

Limitations

The most important limitation of this report is that generalizability of single-center findings may be limited. Our institution has a very large surgical experience in aortic valve surgeries and cardiovascular surgeries in general. This provides a unique infrastructure that may be difficult to duplicate in other programs. Further, our collaborative model and the utilization of multiple physicians in the same procedure are difficult to sustain. Finally, the ability to learn from our experience was influenced by several physicians who have dedicated their practices to this newer treatment modality, which may be difficult to do in other centers for a procedure with a complicated reimbursement scheme.

CONCLUSIONS

In summary, this single-center experience details several important messages for centers starting their initial experience in TAVR, including procedural techniques and strategies to manage life-threatening complications. It highlights several challenges including resource utilization and infrastructure setup in the current health care environment. The encouraging outcomes presented herein provide support to previously published multicenter randomized and registry data of TF-TAVR among high-risk and inoperable patients. Given the broad base of data in these groups, more data supporting TAVR among lower risk surgical groups is eagerly awaited.

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