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Evolution of Veterans Affairs Transcatheter Aortic Valve Replacement Program: The First 100 Patients

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Abstract

Background and Aim of Study: Transcatheter aortic valve replacement (TAVR) is a widely established alternative to surgery in intermediate- and high-risk patients. We previously described TAVR program development within the Veterans Affairs (VA) system. However, national TAVR registries do not capture VA outcomes data, and little is published regarding TAVR outcomes at lower volume federal institutions. Our objective was to demonstrate evolution of a successful VA TAVR program.

Materials and Methods: We performed retrospective analysis of our first 100 TAVR patients at San Francisco VA Medical Center. Mortality and major complications were evaluated.

Results: Between November 25, 2013 and August 31, 2016, 100 TAVR procedures were performed. Patient age was 79.7±8.7years. Patients underwent TAVR via percutaneous-transfemoral (90), surgical cutdown-transfemoral (8), or transapical (2) approach. Edwards SAPIEN (16), SAPIEN XT (31), SAPIEN 3 (23), and Medtronic Corevalve (16), and Corevalve Evolut R (14) valve systems were used. Device success was 96%. TAVR in TAVR was required in remaining 4% and was successful. All-cause procedural mortality was 1%. Complications included tamponade (1%), stroke (2%), temporary hemodialysis (1%), vascular injuries requiring intervention (4%), and permanent pacemaker implantation (14%). There were no conversions to surgical aortic valve replacement. Twenty-two (22%) patients had mild, two (2%) had moderate, and zero (0%) had severe paravalvular leakage. Post-procedure aortic valve gradient by echocardiography was 8.6±4.5mmHg. Follow-up was 100% complete and survival was 99%, 93% and 89% at 1, 6 and 12 months, respectively.

Conclusions: We demonstrated successful outcomes from our VA TAVR program that compare favorably with benchmarks established by national Transcatheter Valve Therapies Registry. These results provide necessary transparency of TAVR outcomes at a federal institution.

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Keywords

transcatheter aortic valve; outcomes; federal facility

INTRODUCTION

Transcatheter aortic valve replacement (TAVR) is an established alternative to surgical aortic valve replacement (SAVR) in intermediate- and high-risk patients with severe symptomatic aortic stenosis (AS), and standard of care for patients at prohibitive risk for SAVR. Initially reserved for inoperable patients or surgical candidates at high-risk for operative mortality, Placement of AoRTic TraNscathetER Valve trial (PARTNER) (1, 2) and Corevalve US Pivotal (3, 4) trials demonstrated better survival with TAVR compared to medical therapy, and equivalent or better survival with transfemoral-TAVR when compared to SAVR. With PARTNER II(5) and Surgical or Transcatheter Aortic Valve Replacement in Intermediate Risk (SURTAVI)(6) trials, TAVR indications have expanded to intermediate-risk surgical patients, with results demonstrating equipoise with surgery with respect to mortality and disabling stroke. With increased operator experience, TAVR device modifications to decrease paravalvular leak, reduction in device profiles for vascular access, and improved delivery systems, TAVR outcomes from clinical registries continue to improve(7–11). Society of Thoracic Surgeons/American College of Cardiology (STS/ACC) Transcatheter Valve Therapies (TVT) Registry has provided insights from US clinical practice which has helped to shape discussions of real world outcomes regarding TAVR(9–11). Notably, from 2012 to 2015, STS predicted risk of mortality for TAVR patients in the United States decreased from 7.1% to 6.3%, while thirty-day mortality also decreased from 5.7% to 2.9%(9). With integration of commercially available and US Food and Drug Administration (FDA) approved TAVR devices, multi-society guidelines have been developed for institutional and operator requirements for TAVR programs in the United States(12, 13). However, questions remain regarding outcomes of TAVR in lower volume institutions and whether volume vs. “crowd wisdom”, reflected as the collective experience of a specialty is important for safe and effective dissemination of TAVR to needed patients. Veterans Affairs (VA) hospitals are considered low volume institutions and notably do not submit outcomes to the national TVT registry. VA hospitals do nonetheless report TAVR outcomes to dual national VA databases including VA cardiac surgical and VA cardiac catheterization laboratory databases. The VA medical system also developed its own white paper guidelines for TAVR programs within the VA(14). Since December 2011, TAVR has been available in the VA, beginning at Michael E. DeBakey VA Medical Center in Houston, TX(15). Using the first-generation Edwards SAPIEN valve, they demonstrated that TAVR could be performed safely and with good outcomes by a multidisciplinary heart team within the VA system(16). Our center, San Francisco VA Medical Center (SFVAMC) was one of the first five VA approved TAVR sites. Based on specifications outlined by the VA, we developed a custom hybrid operating room (OR) within the cardiac catheterization laboratory(14) and began performing TAVR in November 2013. Given the relatively little data published on TAVR outcomes in lower volume federal institutions, the goal of this study was to demonstrate the evolution of our program by evaluating short-term outcomes of our first 100 consecutive patients undergoing TAVR at our VA approved site.

PATIENTS AND METHODS

Patient Population

This study was approved by Committee for Human Research at University of California San Francisco Medical Center and Institutional Review Board of SFVAMC. We retrospectively reviewed TAVR at SFVAMC and collected data into TVT registry forms using VA-Computerized Patient Record System (CPRS) to assess risk profiles, demographics, procedural characteristics and outcomes. Severity of AS was determined by transthoracic echocardiogram or invasive hemodynamics measured by cardiac catheterization.

Candidates were evaluated by a multidisciplinary heart team including two cardiac surgeons, who deemed patients to be intermediate-, high- or prohibitive-risk for SAVR. All patients underwent coronary angiography prior to TAVR, either at our institution or locally to determine need for pre-procedural revascularization. In all cases, electrocardiogram (ECG)-gated computed tomographic angiography was used to determine aortic annulus size, coronary heights, sinus dimensions, left ventricular outflow tract calcification, as well as vascular access suitability to ascertain approach.

Operative Procedures

Between November 25, 2013 and August 31, 2016, 100 TAVR procedures were performed at SFVAMC. During the same period, there were 82 surgical aortic valve replacement procedures performed at SFVAMC. All cases were performed in a hybrid OR built within the cardiac catheterization laboratory. Edwards SAPIEN, SAPIEN XT, SAPIEN 3 (Edwards Lifesciences, Inc, Irvine, CA); as well as Medtronic Corevalve and Corevalve Evolut R (Medtronic, Inc, Minneapolis, MN) TAVR platforms were used as each became commercially available. Percutaneous-transfemoral, surgical cutdown-transfemoral, and transapical approaches were used. In six cases, planned concomitant percutaneous coronary intervention or vascular intervention was also performed as hybrid procedures. Procedures were performed either with general anesthesia or monitored anesthesia care (MAC). Transesophageal echocardiography was used in cases that had general anesthesia. Patients were observed in intensive care unit (ICU) for at least 24 hours post-procedure.

Outcomes

Procedural all-cause mortality and major complications including stroke, renal failure requiring dialysis, unplanned cardiopulmonary bypass, vascular injury requiring repair, and necessity for permanent pacemaker were evaluated based on standardized Valve Academic Research Consortium-II (VARC-2) definitions(17). Post-procedure echocardiography was performed before hospital discharge. Retrospective data analysis was performed using VA-CPRS.

Statistical Analysis

Statistical analyses were performed using SPSS version 21.0 (IBM, Somers, NY). Results are presented as mean±standard deviation.

RESULTS

Baseline Patient Characteristics

Between November 25, 2013 and August 31, 2016, 100 TAVR were performed. Men comprised 98% of patients. Mean age of patients was 79.7±8.7 years (range: 57–99 years). Six patients had undergone prior bioprosthetic SAVR and underwent valve-in-valve implantation with TAVR. Ninety-nine patients had severe symptomatic AS with mean transvalvular gradient of 44.5±8.6mmHg and aortic valve area of 0.7±0.2cm^2 (Table 1). The remaining patient had severe central regurgitation through a degenerated bioprosthetic aortic valve. Baseline left ventricular ejection fraction (LVEF) was 56.6±14.4% and 18% of patients had at least moderately-reduced LVEF <45%. STS predicted risk of mortality score was 5.3±5.2%. Ninety-three patients were New York Heart Association (NYHA) functional class III or IV. Forty patients had undergone prior cardiac surgery. Comorbidities included prior stroke in 13%, peripheral arterial disease in 24%, and atrial fibrillation/flutter in 24% of patients. Chronic lung disease was common with 38% having moderate-to-severe disease and 11% being oxygen-dependent. Two patients had end-stage renal disease on hemodialysis but serum creatinine was 1.2±0.4mg/dl for the entire cohort. All patients evaluated by the multidisciplinary heart team were deemed to be intermediate-, high- or prohibitive-risk, based not only on STS predicted risk of mortality, but also other uncaptured variables, such as cirrhosis, malignancy, pulmonary hypertension, and frailty.

Procedural Characteristics

First 16 patients were treated with Edwards SAPIEN. Subsequent patients included 31 with Edwards SAPIEN XT, 16 with Medtronic Corevalve, 23 with the Edwards SAPIEN 3, and 14 with Medtronic Corevalve Evolut R. Ninety cases were performed via percutaneous-transfemoral, eight with surgical cutdown-transfemoral, and two patients via transapical access. Commercial availability of SAPIEN XT and its successor, SAPIEN 3, as well as Medtronic Corevalve and Corevalve Evolut R platforms led to rapid transition to nearly all cases performed via percutaneous-transfemoral approach. General anesthesia was used for 80% of cases and remaining 20 cases were performed under MAC. Six hybrid cases involved planned simultaneous percutaneous coronary intervention (n=2), carotid stenting (n=1), iliac stenting (n=2), or endovascular aortic repair (n=1).

Procedural Outcomes

Device success occurred in 96% of cases. TAVR in TAVR deployment for suboptimal position or function of original device was required in four patients, with implantation of more than one device but with satisfactory hemodynamic outcomes. In one case, three valves were used due to device migration, but the procedure was ultimately successful. Two patients underwent planned cardiopulmonary bypass during TAVR. There was one all-cause procedural mortality, despite use of unplanned emergent cardiopulmonary bypass. In this patient, transapical approach was complicated by ventricular rupture, life-threatening bleeding, and cardiac arrest. There were no conversions to SAVR, but one patient did require subsequent sternotomy and exploration after TAVR, for development of tamponade. There were two major vascular complications and three minor vascular complications requiring unplanned iliac stenting (Table 3).

Follow-up Morbidity and Mortality

All patients were initially transferred to ICU for monitoring. Mean duration of ICU stay was 3.6±3.4 days, post-procedure. Two patients suffered strokes. Two patients had life threatening bleeding, requiring massive transfusions: the ventricular rupture patient received 32 units of packed red blood cells; while another patient was serially transfused for gastrointestinal bleeding in the setting of mesenteric ischemia and end-stage renal disease, requiring a total of 18 units over a prolonged hospitalization. Three patients had major bleeding. Five patients had minor bleeding. In total, fifteen patients required blood transfusions. Overall, mean units of packed red blood cells were 4.0±8.6 (Table 3). One patient required temporary hemodialysis during their hospitalization. Highest serum creatinine through the post-TAVR hospitalization was 1.3±0.7mg/dl and mean serum creatinine at discharge was 1.1±0.3mg/dl. Eight patients had acute kidney injury. New onset atrial fibrillation/flutter occurred in 5% of patients and 14% of patients developed heart block requiring permanent pacemaker (PPM) placement (Table 3). Pre-existing conduction abnormalities were present in 51% of patients, and 14% of patients had prior implanted pacemakers or defibrillators. Therefore, new pacemaker requirement was 16.2%. Transthoracic echocardiography was performed on all patients before discharge. Mean gradient across implanted TAVR valves was 8.6±4.5mmHg. Seventy-five patients had trace or no aortic regurgitation, 22% had mild and 2% had moderate aortic regurgitation. No patients had severe paravalvular leak. Post-TAVR, patients were hospitalized for 5.5±5.5 days with a range of 2 to 44 days (median: 4 days) post-procedure. Follow-up was 100% complete; mortality was 1%, 7%, and 10.8% at one, six, and twelve months, respectively. At up to greater than 36 months of total follow-up in our cohort, there were 17 deaths overall, with survival of 10.6±10.3 months amongst these patients (Table 3).

COMMENT

While TAVR has excellent outcomes as demonstrated by STS TVT registry, less is known regarding TAVR outcomes in lower volume federal institutions whose outcomes are not included in the STS registry. Our colleagues at the Michael E. DeBakey VA Medical Center in Houston, TX previously reported the early successes in creating and developing a TAVR program within the VA system, with use of the original Edwards SAPIEN valve to treat veterans with severe symptomatic aortic stenosis(15, 16). Subsequently, the VA constructed guidelines for the further development of other TAVR programs, including the hybrid OR requirement which we previously described(14). As one of the first five VA approved sites, we retrospectively reviewed results of our first 100 patients, demonstrating the continuing evolution of TAVR in the VA community. In this series, 70% of valves were Edwards devices, and the remaining 30% were Medtronic, reflecting the time course of commercialization of these devices. Our results compare favorably to the original PARTNER(1, 2) and Corevalve US Pivotal Trials(3, 4), as well as the TVT registry(9–11). These results are also comparable to more recent findings from the PARTNER-II(5, 18) and SURTAVI(6) trials with intermediate-risk patients. Overall survival was excellent with mortality rates of 1%, 7%, and 10.8% at one, six and twelve months respectively. One procedural mortality in 30 days occurred with ventricular rupture via transapical access. One device migration was treated successfully with two valve-in-valve implantations. There was

no device embolization into the ventricle and no conversions to SAVR. One patient required surgical exploration shortly after TAVR, for development of late tamponade from LV wire perforation. Thirty-day stroke rate was low at 2%. At one year, an additional 2% of patients were hospitalized for cerebrovascular accidents. Rate of vascular complications was low at 4%. With commercial introduction of Edwards SAPIEN XT and Medtronic Corevalve platforms, which significantly reduced delivery system profiles, transfemoral access was expanded broadly in our patient population. Planned hybrid procedures were performed in two patients who underwent iliac stenting to facilitate transfemoral access, while an additional patient underwent concomitant endovascular abdominal aneurysm repair. With further TAVR platform development to SAPIEN 3 and Corevalve Evolut R, this practice mirrors findings from the TVT registry(9). Increasing numbers of patients nationally have undergone transfemoral access with 86.6% of patients undergoing TAVR via this approach in 2015(9). Given the demonstrated superior mortality results with transfemoral over transapical TAVR, we have attempted to maximize the number of patients that can undergo TAVR via transfemoral approach. Coupled with smaller delivery systems, the majority of veterans appear to have suitable access for transfemoral TAVR. The relative lack of need for alternative access is likely affected by the disproportionately low number of women in the veteran population(19).

In this series, 16.2% of patients that did not have prior pacemaker/defibrillator (14% in the overall cohort), required PPM implantation, which was slightly higher than data from TVT registry(9). Notably, there was also variation depending on valve platform used, with patients receiving SAPIEN 3 valve having lowest PPM rate. From recent TVT registry data, PPM rate increased from 8.8% in 2013 to 12% in 2015(9), which was attributed to FDA approval of self-expanding valves and the higher proportion of conduction abnormalities with these systems. The results here, similarly demonstrated a trend towards greater percentage of pacemakers required with self-expanding valve platforms. Overall percentage of patients that ultimately required PPM was slightly higher in our series compared to PARTNER trials(1, 2, 5) and TVT registry data(9–11), but lower than Corevalve US Pivotal(3) and SURTAVI(6) trials. Thirty percent of patients received self-expanding valves in this study, which is similar to contemporary TVT registry data(9). From available TVT registry data, 21% of TAVR patients from 2014 had previously placed pacemakers or defibrillators(10), which was higher than the 14% in our cohort. Additionally, among patients in the TVT registry without prior implanted devices, 27.3% of the overall patients had conduction defects; and of the patients that required post-TAVR pacemaker, 40.9% had pre-existing conduction system disease(20). This percentage of patients with conduction system abnormalities prior to TAVR was lower than the 51% observed in the overall cohort here. These factors together therefore likely contribute to the higher pacemaker rate seen in this study. Nevertheless, since the need for permanent pacemaker implantation has been associated with increased one-year mortality in the TVT registry(20), further follow-up of this post-procedure complication is required.

Based upon minimalist approaches advocated by others(21), our program has also transitioned away from standard use of general anesthesia (Table 4). With Edwards SAPIEN 3 and Medtronic Corevalve Evolut R platforms, nearly 50% of cases were performed using MAC and without routine transesophageal echocardiography.

Post-procedure by transthoracic echocardiography, 98% of patients had mild or trace aortic regurgitation, only 2% of patients had moderate paravalvular leakage, and no patients had severe aortic regurgitation. The percentage of patients with mild or moderate aortic regurgitation decreased for both Edwards and Medtronic TAVR systems as the platforms evolved to SAPIEN 3 and Evolut R. SAPIEN 3 has a polyethelene terephthalate skirt that is sewn to the bottom portion of the valve frame to decrease paravalvular leak(18, 22). Corevalve Evolut R has a delivery system that allows for recapturing and redeployment of the valve(23, 24). These factors, as well as increased operator experience have likely impacted reduction in paravalvular aortic regurgitation seen here with the newer valve systems (Table 4).

In this study, all patients were evaluated by a multidisciplinary heart team including two cardiac surgeons and deemed to be intermediate-, high- or prohibitive-risk for SAVR. Mean STS predicted risk of mortality in our study was 5.3% and was similar to the most recent TVT data of 6.3% risk nationally(9). Fifty-one percent of the patients had an STS predicted risk of mortality >4%. Of the remaining patients with low calculated STS risk scores, the most common reasons for choosing TAVR over SAVR included: prior sternotomy with unfavorable anatomy, frailty, concomitant malignancy with <5 years but >1-year estimated survival, oxygen-dependent lung disease, and cirrhosis. These risk factors are not accounted for using STS calculator alone.

This study is limited by its retrospective nature, as well as inherent characteristics of the VA population (i.e. predominantly male population, with age influenced by service years). Nevertheless, the results presented here confirm that TAVR can be safely and effectively performed in the VA system with improved outcomes as valve platforms continue to evolve. Outcomes for TAVR in the VA system are not reported to the TVT registry, as is required for civilian institutions, but instead are doubly reported to the national VA surgical and cardiology outcomes databases. As one of the first five VA sites to be approved for TAVR, we have demonstrated that through a multidisciplinary approach, development of operator experience, and progression to utilizing all FDA-approved valve platforms, our program has been able to achieve excellent clinical outcomes in the VA system, with results comparable to previously reported TAVR clinical trials and the TVT Registry. We have been able to safely and effectively use all commercially available systems in 100 patients, with evolution to primarily percutaneous transfemoral access and increasing minimalist approach with MAC. These results provide necessary transparency of TAVR outcomes in lower volume federal institutions not captured within the TVT registry.

CONCLUSIONS

Our colleagues at the Michael E. DeBakey Houston VA Medical Center were the first to introduce TAVR in the VA system. We previously described the process for development of a new VA TAVR program and the requirements for a hybrid OR. Since VA data is not captured within national TVT registry, in this study, we presented our results of the first 100 TAVR patients with low morbidity and mortality, comparable to published results from the TVT registry.

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ABBREVIATIONS:

TAVR	transcatheter aortic valve replacement
SAVR	surgical aortic valve replacement
AS	aortic stenosis
STS	Society of Thoracic Surgeons
ACC	American College of Cardiology
TVT	Transcatheter Valve Therapies
FDA	Food and Drug Administration
VA	Veterans Affairs
CPRS	Computerized Patient Record System
ECG	electrocardiogram
ICU	intensive care unit
LVEF	left ventricular ejection fraction
NYHA	New York Heart Association
TIA	transient ischemic attack
PARTNER	Placement of AoRTic TraNscathetER Valve trial
SURTAVI	Surgical or Transcatheter Aortic Valve Replacement in Intermediate Risk
SFVAMC	San Francisco Veterans Affairs Medical Center
OR	operating room
MAC	monitored anesthesia care
PPM	permanent pacemaker

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Table 1.

Baseline characteristics of patients who underwent TAVR.

Age, mean (SD), years	79.7 (8.7)
Female Gender, No. (%)	2
Hypertension, No. (%)	90
Diabetes, No. (%)	45
Moderate-to-Severe Chronic Lung Disease (%)	61
Home Oxygen, No. (%)	11
Immunocompromised, No. (%)	11
Stroke/TIA, No. (%)	13
Peripheral Arterial Disease, No. (%)	24
Atrial Fibrillation/Flutter, No. (%)	24
Conduction System Disease, No. (%)	51
Prior Pacemaker/Defibrillator, No. (%)	14
Chronic Anticoagulation, No. (%)	17
End-Stage Renal Disease on Hemodialysis, No. (%)	2
Serum Creatinine, mean (SD), mg/dl	1.2 (0.4)
NYHA Functional Class, No. (%)	
II	7
III	81
IV	12
Prior Cardiac Surgery, No. (%)	40
Prior Percutaneous Coronary Intervention, No. (%)	42
Coronary Artery Disease, No. (%)	70
Single Vessel	20
Two Vessel	9
Three Vessel	41
Left Ventricular Ejection Fraction, mean (SD), %	56.6 (14.4)
Severe Aortic Stenosis, No. (%) *	99
Aortic Valve Area, mean (SD), cm^2	0.7 (0.2)
Mean Gradient, mean (SD), mmHg	44.6 (8.6)
Aortic Regurgitation, No. (%)	
Mild	25
Moderate	7
Severe	3
STS Score, mean (SD)	5.3 (5.2)

TIA: Transient ischemic attack; NYHA: New York Heart Association; STS: Society of Thoracic Surgeons.

* One patient who was treated with valve-in-valve TAVR for severe aortic regurgitation in a previously placed bioprosthetic valve, without significant aortic stenosis.

Table 2.

Procedural characteristics of TAVR.

Percutaneous Transfemoral, No. (%)	90
Cutdown Transfemoral, No. (%) *	8
Transapical, No. (%) **	2
Valve Platform	
SAPIEN, No. (%)	16
SAPIEN-XT, No. (%)	31
Corevalve, No. (%)	16
SAPIEN-3, No. (%)	23
Corevalve Evolut-R, No. (%)	14
Anaesthesia	
General, No. (%)	80
Monitored Anaesthesia Care, No. (%)	20
Hybrid Procedures	
Percutaneous Coronary Intervention, No. (%)	2
Carotid Stenting, No. (%)	1
Iliac Stenting, No. (%)	2
Endovascular Aortic Repair, No. (%)	1

* In the group that underwent surgical cutdown for transfemoral access, seven received SAPIEN and one received Corevalve.

** The two transapical access cases were performed using the SAPIEN valve.

Table 3.

Procedural outcomes of patients that underwent TAVR.

Perioperative Mortality, No. (%)	1
TAVR in TAVR Deployment, No. (%)	4
Conversion to Surgical Aortic Valve Replacement, No. (%)	0
Tamponade, No. (%)	1
Stroke, No. (%)	2
Cardiopulmonary Bypass	
Planned, No. (%)	2
Unplanned, No. (%)	1
New Hemodialysis, No. (%) *	1
Acute Kidney Injury, No. (%)	8
Peak Serum Creatinine, mean (SD), mg/dl **	1.3 (0.7)
Serum Creatinine at Discharge, mean (SD), mg/dl **	1.1 (0.3)
Post-Procedure Mean Gradient, mean (SD), mmHg	8.6 (4.5)
Post-Procedure Aortic Regurgitation	
None/Trace, No. (%)	75
Mild, No. (%)	22
Moderate, No. (%)	2
Severe, No. (%)	0
Permanent Pacemaker Requirement, No. (%)	14
New Atrial Fibrillation/Flutter, No. (%)	5
Major Vascular Complications, No. (%)	2
Minor Vascular Complications, No. (%)	4
Hematoma, No. (%)	1
Valve Malpositioning (Device Migration), No. (%)	1
Endocarditis, No. (%)	1
Gastrointestinal bleeding, No. (%)	2
Genitourinary bleeding, No. (%)	1
Other bleeding, No. (%)	2
Life Threatening Bleeding, No. (%)	2
Major Bleeding, No. (%)	3
Minor Bleeding, No. (%)	5
Blood Transfusion Required, No. (%) ***	15
Red Blood Cell Transfusions, mean (SD), units	4.9 (8.6)
Length of Hospital Stay Post-TAVR, mean (SD), days	5.5 (5.5)
Post-Procedure ICU stay, mean (SD), days	3.6 (3.4)
Mortality at 6 months, No. (%)	7
Mortality at 1 year, No. (%)	10.8

Overall Cohort Mortality, No, (%)	17
Duration of Survival among Deaths, mean (SD), months	10.6 (10.3)

*In the patient requiring hemodialysis post-TAVR, renal replacement therapy was temporary and renal function returned to baseline by discharge.

**p-value of 0.16 by ANOVA analysis when compared to pre-TAVR serum creatinine values.

***In the one operative mortality, patient received 32 units of packed red blood cells intra-procedure. One additional patient required serial blood transfusions and received 18 units. All other patients were transfused between one and three units.

Table 4.

Procedural and outcome variation by valve platform.

	SAPIEN*	SAPIEN XT	Corevalve	SAPIEN 3	Corevalve Evolut R
Total cases, No. (%)	16	31	16	23	14
Anesthesia					
General, No. (%)	16 (100)	29 (93.5)	16 (100)	11 (47.8)	8 (57.1)
Monitored Anesthesia Care, No. (%)	0 (0)	2 (6.5)	0 (0)	12 (52.2)	6 (42.9)
Post-TAVR Aortic Regurgitation					
None/Trace, No. (%)	8 (53.3)	24 (77.4)	10 (62.5)	20 (87)	13 (92.3)
Mild, No. (%)	6 (40)	7 (22.6)	5 (31.3)	3 (13)	1 (7.2)
Moderate, No. (%)	1 (6.7)	0 (0)	1 (0.7)	0 (0)	0 (0)
Permanent Pacemaker Required, No. (%) **	1 (7.1)	6 (20.7)	3 (30)	1 (5)	3 (23.1)

*The single intra-operative mortality occurred within the SAPIEN group.

**Percentage of pacemakers required, excludes patients that had permanent pacemakers prior to their TAVR procedures.