

Comparison of Transfemoral Transcatheter Aortic Valve Replacement Performed in the Catheterization Laboratory (Minimalist Approach) Versus Hybrid Operating Room (Standard Approach) Outcomes and Cost Analysis

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CME Objective for This Article: At the completion of this article, the learner should be able to: 1) describe the current standard approach to transcatheter aortic valve replacement in the United States; 2) evaluate

the 2 approaches for a patient who is planning to undergo transcatheter aortic valve replacement so that procedural success is optimized; and 3) compare the minimalist approach to the standard approach with regards to procedural outcomes, post-procedural care, and cost.

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ABSTRACT

OBJECTIVES The aim of this study was to compare transfemoral transcatheter aortic valve replacement (TF TAVR) performed in a catheterization laboratory (minimalist approach [MA]) with TF TAVR performed in a hybrid operating room (standard approach [SA]).

BACKGROUND A MA-TF TAVR can be performed without general anesthesia, transesophageal echocardiography, or a surgical hybrid room. The outcomes and cost of MA-TF TAVR compared with those of the SA have not been described.

METHODS Patients who underwent elective, percutaneous TF TAVR using the Edwards Sapien valve (Edwards Lifesciences, Irvine, California) were studied. Baseline characteristics, outcomes, and hospital costs of MA-TF TAVR and SA-TF TAVR were compared.

RESULTS A total of 142 patients were studied (MA-TF TAVR, $n = 70$ and SA-TF TAVR, $n = 72$). There were no differences in baseline comorbidities (Society of Thoracic Surgeons score, 10.6 ± 4.3 vs. 11.4 ± 5.8 ; $p = 0.35$). All procedures in the MA-TF TAVR group were successful; 1 patient was intubated. Three patients in the SA-TF TAVR group had procedure-related death. Procedure room time (150 ± 48 min vs. 218 ± 56 min, $p < 0.001$), total intensive care unit time (22 h vs. 28 h, $p < 0.001$), length of stay from procedure to discharge (3 days vs. 5 days, $p < 0.001$), and cost ($\$45,485 \pm 14,397$ vs. $\$55,377 \pm 22,587$, $p < 0.001$) were significantly less in the MA-TF TAVR group. Mortality at 30 days was not significantly different in the MA-TF TAVR group (0 vs. 6%, $p = 0.12$) and 30-day stroke/transient ischemic attack was similar (4.3% vs. 1.4%, $p = 0.35$). Moderate or severe paravalvular leak and device success were similar in the MA-TF TAVR and SA-TF TAVR groups (3% vs. 5.8%, $p = 0.4$ and 90% vs. 88%, $p = 0.79$, respectively) at 30 days. At a median follow-up of 435 days, there was no significant difference in survival (MA-TF TAVR, 83% vs. SA-TF TAVR, 82%; $p = 0.639$).

CONCLUSIONS MA-TF TAVR can be performed with minimal morbidity and mortality and equivalent effectiveness compared with SA-TF TAVR. The shorter length of stay and lower resource use with MA-TF TAVR significantly lowers hospital costs. (J Am Coll Cardiol Intv 2014;7:898-904) © 2014 by the American College of Cardiology Foundation.

As experience with transcatheter aortic valve replacement (TAVR) has increased, some centers have performed transfemoral (TF) TAVR in a standard cardiac catheterization laboratory without general anesthesia or transesophageal echocardiography (TEE) (1-3). In this study, we compare the safety, efficacy, and cost of such a minimalist approach (MA) with the current standard approach (SA) performed in a hybrid operating room.

METHODS

We reviewed all cases of TAVR at our center from November 2010 to September 2013 for patients who

underwent elective percutaneous treatment with the Edwards Sapien valve (22- and 24-French delivery systems, Edwards Lifesciences, Irvine, California). The study was approved and performed in accordance with the regulations of the hospital institutional review board (Emory University, Atlanta, Georgia).

In May 2012, an MA-TF strategy was adopted for TF TAVR at our institution. TF TAVR procedures were performed thereafter using the MA except in rare cases when the patient was unable to lie down for the procedure or the schedule prohibited use of the catheterization laboratory. MA-TF used local anesthesia, minimal conscious sedation, fully percutaneous access site entry and closure, and transthoracic

ABBREVIATIONS AND ACRONYMS

ICU = intensive care unit

MA = minimalist approach

PCI = percutaneous coronary intervention

SA = standard approach

TAVR = transcatheter aortic valve replacement

TEE = transesophageal echocardiography

TF = transfemoral

TTE = transthoracic echocardiography

echocardiography (TTE). A sonographer performed the TTE, and an attending imaging cardiologist was present to aid with the placement and post-deployment function of the TAVR. Procedures were performed in a standard cardiac catheterization laboratory. A catheterization laboratory nurse, under the direction of the operating physician, administered sedation with fentanyl and midazolam. A condom catheter was used for men, and some women had Foley catheters placed. Pulmonary artery catheters were not used for monitoring. Femoral access was obtained using a micropuncture kit with fluoroscopic guidance, which included a roadmap angio-

gram performed from the contralateral iliac artery for placement of the delivery sheath. Pre-closure was performed with Perclose devices (Abbott Vascular, Abbott Park, Illinois). Two Perclose devices were placed at slight angulation before sheath placement and a third Perclose device was placed after sheath removal. Wire and catheter techniques were used to align the delivery system through the center of the stenotic valve and allow for coaxial deployment. Patients early in the experience were transferred from the catheterization laboratory to an intensive care unit (ICU). All subsequent patients were sent to a regular telemetry floor.

The SA performed in a hybrid operating room included endotracheal intubation, bladder catheterization, pulmonary artery catheter hemodynamic monitoring, general anesthesia, TEE, and percutaneous femoral artery access and closure. An anesthesiologist administered general anesthesia. Patients were transferred from the operating room to an ICU for extubation and recovery.

Baseline characteristics, procedural and outcomes data were expressed using Society of Thoracic Surgeons or Valve Academic Research Consortium-2 definitions when applicable. Cost was calculated using Sunrise EPSi software (Enterprise Performance Systems, Inc., Allscripts, Chicago, Illinois) for the index procedure hospitalization, which included \$32,500 for the valve (standard cost for the Edwards Sapien commercial valve in the United States).

STATISTICAL METHODS. Continuous variables are presented as mean \pm SD and categorical variables as proportion (%). Non-normally distributed data are presented as median (interquartile range). The Student t test, chi-square analyses, or Fisher exact test were performed when appropriate. Mann-Whitney 2-independent sample tests were performed for comparison of non-normally distributed data across 2

groups. Robust regression analysis was performed to determine univariate correlates of the length of stay and the cost variables given their non-normal distribution. Univariate correlates with $p < 0.05$ were included in multivariable models to determine independent predictors of both cost and length of stay. Survival estimates were compared between MA-TF and SA-TF using Kaplan-Meier survival analysis after groups were balanced for length of follow-up. p Values <0.05 from 2-sided tests were considered statistically significant. Statistical analyses were performed using SAS statistical software version 9.3 (SAS Institute, Cary, North Carolina).

RESULTS

From November 2010 to September 2013, 142 patients with aortic stenosis underwent percutaneous TF TAVR at our center using the Edwards Sapien valve. Patients implanted with the SAPIEN XT or SAPIEN 3 valve (Edwards Lifesciences) and patients who underwent emergent TAVR for cardiogenic shock were not included in this analysis.

BASELINE PATIENT CHARACTERISTICS. MA-TF was performed in 70 and SA-TF in 72 patients. Baseline patient characteristics and comorbidities were similar between the 2 groups (Table 1), with both groups having a mean patient age older than 80 years and mean Society of Thoracic Surgeons mortality risk score of $>10\%$. All patients were classified as high risk or inoperable for surgical aortic valve replacement by the structural heart team (cardiothoracic surgeon, interventional cardiologist, cardiac imager, and structural heart mid-level provider/coordinator). A higher percentage of patients in the MA-TF group had previous mitral valve replacement (10% vs. 1%, $p = 0.038$). Baseline B-type natriuretic peptide level was higher in the SA-TF group (310 pg/l vs. 547 pg/l, $p = 0.01$).

PROCEDURE EVOLUTION. After we started the MA in May 2012, the majority of TF TAVR cases were performed as MA-TF TAVR (86%) (Fig. 1). In the 11 cases of SA-TF performed after May 2012, 8 patients underwent SA-TF because of scheduling issues and early adaptation of the MA-TF technique. Two patients underwent SA-TF because of concomitant morbid obesity (>100 kg) and severe lung disease with inability to lie down and breath comfortably. We performed SA-TF in another patient with previous vascular cut downs and abdominal endografts. Complications developed in none of these 3 patients. Although we performed MA-TF on patients with decompensated heart failure or poor lung function using a wedge to elevate their head and back, we did not think we could safely access and

close the femoral artery percutaneously in the 2 patients with morbid obesity if they were in an inclined position. Because of the scar tissue in the groin of the patient with previous cut down, we were not sure that the patient could have a percutaneous TAVR and did not need a repeat cut down. In the last year, 94% of TF-TAVRs were performed as MA-TF.

PROCEDURAL DATA. All MA-TF patients had a successful procedure. One patient required intubation and intra-aortic balloon pump support due to wire entanglement of the papillary muscles causing severe mitral regurgitation. Hemodynamics normalized after the wire was removed. Three patients in the SA-TF group had procedure-related deaths (1 patient with massive aortic insufficiency despite a second valve placement and 2 patients with major vascular complications). There was a trend toward more frequent TAVR post-dilation in the MA-TF group. Fluoroscopy time (28 ± 10 min vs. 32 ± 11 min, $p = 0.01$), procedural time (93 ± 32 min vs. 125 ± 46 min, $p < 0.0001$), and room time (150 ± 48 min vs. 218 ± 56 min, $p < 0.0001$) were significantly less in the MA-TF group. There was no significant difference in contrast use. Other procedural variables were similar in the 2 groups (Table 2).

OUTCOMES DATA. Rates of stroke, bleeding complications, and new pacemaker implantation were low and similar between groups (Table 3). Patients in the MA-TF group had reduced ICU stay and length of hospital stay. There was no in-hospital mortality with the MA-TF group, whereas there was 4.2% mortality in the SA-TF group ($p = 0.24$). Mortality at 30 days was not significantly different between the 2 groups (0% in MA-TF group vs. 6% in SA-TF group, $p = 0.12$). Moderate or severe paravalvular leak at 30 days was low and similar in both groups (MA-TF, 3% and SA-TF, 5.8%, $p = 0.4$).

In addition to differences in the length of stay, cost ($\$45,485 \pm 14,397$ vs. $\$55,377 \pm 22,587$, $p < 0.001$) (Fig. 2) was significantly less in the MA-TF group. Multivariate predictors of length of stay (Table 4) included MA-TF, body mass index, abnormal baseline troponin, hours spent in the ICU, and concomitant percutaneous coronary intervention (PCI). Multivariate predictors of cost (Table 4) were MA-TF, hours spent in ICU, length of stay, need for second valve implantation, concomitant PCI, and urgent procedure. The contribution of each multivariate predictor to hospital cost was estimated at \$2,869 per approach, \$33.37 per ICU hour, \$1,032 per hospital day, \$27,403 per additional valve, \$6,740 for concomitant PCI, and \$7,126 per urgent case (Table 4). At a median follow-up of 435 days, no significant difference was seen in

TABLE 1 Baseline Patient Characteristics

Characteristic	Minimalist Approach (n = 70)	Standard Approach (n = 72)	p Value
Age, yrs	82 ± 8	83 ± 8	0.58
Male sex	43 (61)	38 (53)	0.29
STS PROM score, %	10.6 ± 4.3	11.4 ± 5.8	0.35
Body mass index	27 ± 5	28 ± 6	0.23
Diabetes	30 (43)	32 (44)	0.85
Hypertension	69 (99)	70 (97)	0.58
Angina	17 (24)	16 (22)	0.84
NYHA functional class III or IV	61 (87)	64 (89)	0.45
Need for urgent procedure	2 (3)	2 (3)	1.00
Severe COPD	11 (16)	9 (13)	0.93
Sleep apnea	6 (9)	7 (10)	0.81
Coronary artery disease	58 (83)	57 (81)	0.91
Previous myocardial infarction	21 (30)	27 (38)	0.34
Previous CABG	21 (40)	29 (40)	1.00
Previous mitral valve surgery	7 (10)	1 (1)	0.038
Previous PCI	53 (76)	55 (76)	0.92
Previous BAV	20 (29)	20 (28)	0.26
End-stage renal disease	4 (6)	4 (6)	1.00
Cerebrovascular disease	22 (31)	26 (36)	0.55
Previous TIA or CVA	14 (20)	20 (28)	0.27
Atrial fibrillation or flutter	33 (47)	32 (44)	1.00
Peripheral vascular disease	15 (21)	17 (24)	0.75
Immunocompromised	12 (17)	7 (10)	0.19
Liver disease	5 (7)	2 (3)	0.46
Echocardiogram			
LVEF, %	49 ± 15	49 ± 15	0.82
RV dysfunction (moderate-severe)	9 (13)	11 (15)	0.67
Functional bicuspid valve	5 (7)	4 (6)	0.69
Aortic valve area, cm ²	0.7 ± 0.2	0.7 ± 0.1	0.14
Mean aortic gradient, mm Hg	43 ± 13	46 ± 12	0.20
Grade 3/4 MR	32 (46)	44 (61)	0.11
Grade 3/4 TR	32 (46)	38 (53)	0.44
DSE performed	10 (14)	11 (15)	0.86
Blood			
Hemoglobin, g/dl	11.5 ± 1.7	11.2 ± 1.3	0.22
Creatinine, mg/dl*	1.3 (1.0-1.52)	1.2 (1.0-1.5)	0.51
BNP, pg/l*	310 (182-739)	547 (328-1297)	0.01
Troponin I, ng/ml*	0.03 (0.02-0.06)	0.03 (0.02-0.05)	0.75

Values are number (%), mean ± SD for normally distributed numeric variables, or median (interquartile range) for non-normally distributed variables. *Non-normally distributed variables.
 BAV = balloon aortic valvuloplasty; BNP = B-type natriuretic peptide; CABG = coronary artery bypass grafting; COPD = chronic obstructive pulmonary disease; CVA = cerebrovascular event, DSE = dobutamine stress echocardiography; LV = left ventricular; LVEF = left ventricular ejection fraction; MR = mitral regurgitation; NYHA = New York Heart Association functional classification; PCI = percutaneous coronary intervention; PROM = predicted risk of mortality; RV = right ventricular; STS = Society of Thoracic Surgeons; TIA = transient ischemic attack, TR = tricuspid regurgitation.

survival between groups (MA-TF, 83% and SA-TF, 82%, $p = NS$) (Fig. 3).

DISCUSSION

Our data support an MA-TF strategy for the treatment of high-risk and inoperable patients with aortic stenosis. The advantage of MA-TF compared with SA-TF includes a shorter length of stay and a lower initial

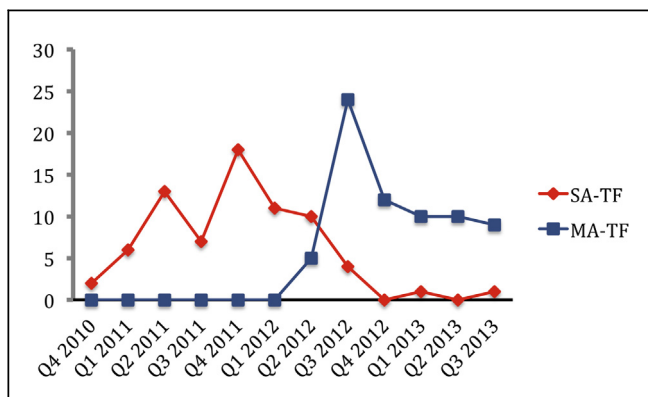


FIGURE 1 Adaptation of an MA-TF Compared With SA-TF TAVR Over Time

The number of transfemoral transcatheter aortic valve replacement (TAVR) cases plotted over time from the fourth quarter (Q4) 2010 to the third quarter (Q3) 2013 are shown. After May 2012, MA-TF largely replaced SA-TF as our default approach for transfemoral TAVR. MA-TF = minimalist approach to transfemoral TAVR; SA-TF = standard approach to transfemoral TAVR.

hospital cost without compromising safety or efficacy. Our data suggest that TAVR programs that have a similar, considerable experience with SA-TF as our center can safely perform MA-TF.

In 2012, Durand et al. (4) reported a series of 151 patients (SAPIEN, n = 78; SAPIEN XT, n = 73) who underwent TF TAVR safely using only local anesthesia, conscious sedation, and fluoroscopy. The conversion rate to general anesthesia was low (3.3%) and only occurred in patients who had a procedural complication. In Europe, 40% of TF TAVRs are currently performed in this manner (5,6). At our center, the vast

TABLE 2 Procedural Characteristics

Characteristic	Minimalist Approach (n = 70)	Standard Approach (n = 72)	p Value
Procedure success	70 (100)	69 (96)	0.24
Procedure mortality	0 (0)	3 (4)	0.24
Second valve implanted	4 (6)	2 (3)	0.43
Concomitant PCI	5 (7)	1 (1)	0.11
No. of BAVs performed*	1.7 ± 0.8	2.1 ± 1.3	0.16
Post-dilation	27 (39)	16 (22)	0.06
Coronary obstruction	0 (0)	0 (0)	—
Intubation	1 (1)	72 (100)	<0.001
Intra-aortic balloon pump	1 (1)	2 (3)	0.57
Conversion to SAVR	0 (0)	0 (0)	—
X-ray time, min	28 ± 10	32 ± 11	0.01
Contrast volume, ml	126 ± 64	135 ± 73	0.39
Procedural time, min	93 ± 32	125 ± 46	<0.001
Room time, min	150 ± 48	218 ± 56	<0.001

Values are number (%) and mean ± SD. *BAV numbers include pre- and post-dilation. SAVR = surgical aortic valve replacement; other abbreviations as in Table 1.

TABLE 3 Outcomes

Outcome	Minimalist Approach (n = 70)	Standard Approach (n = 72)	p Value
In-hospital mortality	0 (0)	3 (4.2)	0.24
Patients receiving ICU care	53 (75)	69 (100)	<0.001
Total ICU time, h*	22 (2-28)	28 (23-48)	<0.001
Length of stay, days*	4 (3-7)	6 (4-9)	0.01
Length of stay: procedure to discharge, days*	3 (2-4)	5 (3-6.5)	<0.001
30-day mortality	0 (0)	4 (6)	0.12
30-day stroke or TIA	3 (4.3)	1 (1.4)	0.35
TIA	0 (0)	1 (1.4)	—
Minor stroke	2 (2.9)	0 (0)	—
Major stroke	1 (1.4)	0 (0)	—
Bleeding			
Life-threatening	1 (1.4)	2 (2.8)	1.00
Major	2 (2.9)	3 (4.2)	0.67
Minor	0 (0)	0 (0)	NS
Vascular complication	3 (4)	8 (11)	0.30
Major vascular complication	1 (1)	2 (3)	0.57
Minor vascular complication	2 (3)	6 (8)	0.27
Concomitant vascular PCI	3 (4)	4 (6)	0.72
Concomitant vascular surgery	0 (0)	3 (4.2)	0.24
New left bundle branch block	4 (6)	5 (7)	0.71
Pacemaker	2 (3)	4 (6)	0.44
30-day echocardiography			
Aortic valve area, cm ²	1.77 ± 0.46	1.75 ± 0.37	0.79
Aortic valve mean gradient, mm Hg	10.0 ± 3.3	10.3 ± 5.1	0.68
Mean gradient <20 mm Hg	70 (100)	66 (96)	0.24
Moderate or severe PVL	2 (3)	4 (5.8)	0.40
Device success	63 (90)	63 (88)	0.79
LVEF, %	53 ± 11	52 ± 14	0.58
Blood			
Peak creatinine, mg/dl*	1.3 (1.1-1.7)	1.2 (1.0-1.65)	0.19
Peak troponin I, ng/ml*	1.0 (0.50-1.77)	0.85 (0.57-2.67)	0.74
Discharge BNP, pg/L*	256 (130-414)	494 (245-1,219)	<0.001
Discharge location			
Home	58 (83)	58 (84)	0.84
Extended care	10 (14)	8 (12)	0.63
Other hospital	2 (3)	1 (1)	1.00
Nursing home	0 (0)	2 (3)	0.24

Values are number (%), mean ± SD for normally distributed numeric variables, or median (interquartile range). *Non-normally distributed variables. ICU = intensive care unit; PVL = paravalvular leak; other abbreviations as in Table 1.

majority of TF TAVR is performed as MA-TF (>96% in the past 6 months). However, there are certain patients that present a real challenge to performing the MA. Morbidly obese patients with concomitant comorbidities such as severe lung disease and complex vascular access, mentally challenged patients, and chronic pain

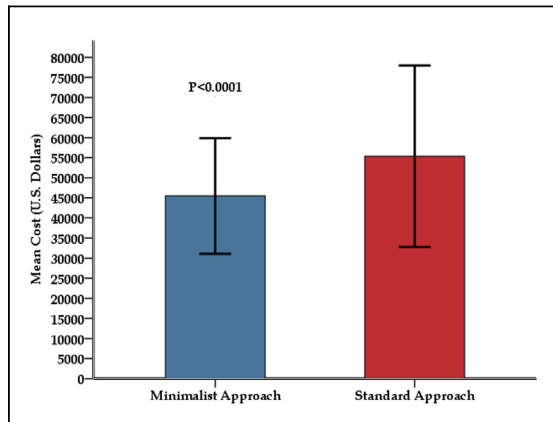


FIGURE 2 Comparison of Cost in U.S. Dollars Between Minimalist Approach and Standard Approach Groups

Hospital costs during the initial procedure hospitalization in the minimalist approach transfemoral transcatheter aortic valve replacement (TF TAVR) group compared with standard approach TF TAVR group. Hospital costs include the cost of the transcatheter valve (\$32,500) but not physician fees.

patients represent this group. Excluding this smaller cohort of patients, we anticipate that MA-TF will become very prevalent as centers in the United States accumulate TAVR experience.

Data from this report may help to develop cost-effective TAVR programs in the United States. Length of stay (\$1,032 per day by multivariate analysis estimate) has been a main focus for cost savings in TAVR programs. Same-day admissions for TAVR and next-day discharge strategies have been reported (7). We recommend pre-procedure planning with multimodality imaging (TTE, TEE, and computed tomography) to minimize the risk of a second valve, and we avoid unnecessary concomitant procedures (PCI, Swan-Ganz catheter, and Foley catheter). We currently do not send patients to the ICU after TAVR unless a complication occurs. Balloon aortic valvuloplasty can be used to avoid urgent TAVR procedures. The MA-TF strategy decreases the cost of TAVR (\$2,869 estimate) and can be used frequently to prevent the overhead associated with hybrid operating rooms and general anesthesia. We believe that the cost savings realized with the MA-TF strategy will become even greater with the approval of newer generation, low-profile TAVR systems, allowing more patients to undergo TF TAVR (8,9). Using the above financial information, we are also trying to develop a fast-track protocol for patients undergoing TAVR in the hybrid operating room to decrease ICU use, cost, and length of stay.

TABLE 4 Multivariate Analysis of Length of Stay and Cost

Patient/Procedural Characteristics	Predictors of Cost				Predictors of Length of Stay			
	Univariate		Multivariate		Univariate		Multivariate	
	Estimate	p Value	Estimate	p Value	Estimate	p Value	Estimate	p Value
Standard vs. minimalist approach	6,639	<0.001	2,869	0.002	1.87	<0.001	1.20	0.002
Age	124.57	0.142	–	–	<0.001	0.80	–	–
Male sex	787	0.55	–	–	0.91	0.02	0.59	0.08
STS PROM score	149	0.29	–	–	0.13	<0.001	0.04	0.14
Diabetes	1,581	0.23	–	–	0.75	0.07	–	–
Severe COPD	762	0.23	–	–	0.28	0.15	–	–
LVEF	–8.69	0.853	–	–	–0.01	0.33	–	–
Atrial fibrillation	12,675	0.002	807	0.28	0.49	0.35	–	–
End-stage renal disease	2,300	0.47	–	–	0.15	0.87	–	–
Body mass index	38.6	0.73	–	–	0.11	0.001	0.10	<0.001
Baseline BNP level	0.55	0.46	–	–	0.0007	<0.001	–0.0004	0.14
Abnormal baseline troponin I (>0.4 ng/ml)	1,678	0.29	–	–	1.17	0.01	1.09	0.006
Vascular complications	9,654	<0.001	3093	0.13	1.08	0.10	–	–
Procedure time	98.4	<0.001	17.54	0.18	0.01	0.008	–0.005	0.24
ICU stay, h	99.5	<0.001	33.37	0.003	0.03	<0.001	0.03	<0.001
Postoperative BNP	1.6	0.03	0.57	0.24	0.0011	<0.001	0.0003	0.27
Pacemaker required	5,201	0.12	–	–	0.13	0.90	–	–
Length of stay	1,279	<0.001	1032	<0.001	–	–	–	–
ICU care required	4,922	0.003	50	0.96	1.61	0.02	0.27	0.57
Need for second valve implantation	25,825	<0.001	27403	<0.001	1.16	0.46	–	–
Concomitant PCI	8,982	0.005	6740	<0.001	2.37	0.025	3.15	<0.001
Need for urgent procedure	11,263	0.0093	7126	0.002	2.79	0.019	1.21	0.23

Abbreviations as in Tables 1 and 3. Values of p < 0.05 in the multivariate analysis are in boldface.

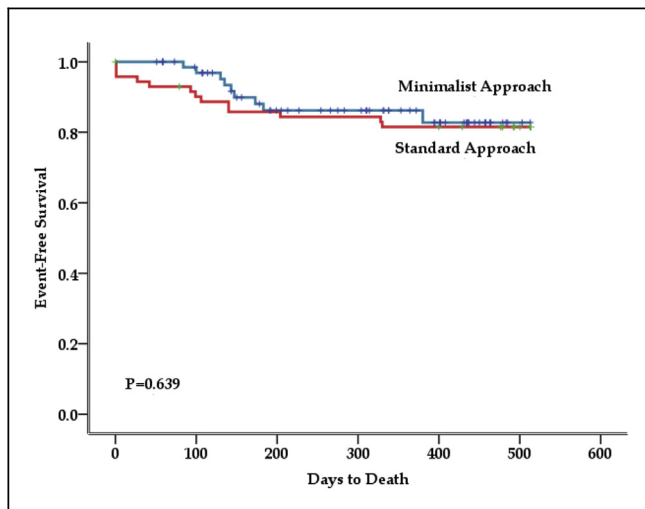


FIGURE 3 Kaplan-Meier Survival Analysis of the Treatment Approach in Relation to the Outcome of Death

No statistically significant difference in mortality was seen in the minimalist approach transfemoral transcatheter aortic valve replacement (TF TAVR) group compared with the standard approach TF TAVR group after mid-term follow-up. The corresponding number of patients at risk for each 100-day interval and the median follow-up for each group are included.

STUDY LIMITATIONS. The study limitations of the data presented here are consistent with limitations of any retrospective study from a single center. Although we have tried to control for all variables that may have introduced bias, we recognize that the experience of the heart team and patient selection bias could not be controlled for. We performed >100 TAVRs (combined TF and transapical) with the Edwards Sapien valve before the first SA-TF patient included in this analysis. Thus, the learning curve associated with new TAVR centers had passed well

before the patients reported in this study. We had performed 300 TAVRs (combined TF and transapical) before the MA-TF experience was started. The patients who did not undergo MA-TF after starting our minimalist program were done in the hybrid room for scheduling reasons or comorbidities that prevented lying flat comfortably. However, most patients who could tolerate routine TF heart catheterization could also tolerate MA-TF. Differences in baseline B-type natriuretic peptide levels were not considered clinically important for our patient selection and did not affect length of stay or cost by multivariate analysis. Centers that will attempt MA-TF should have appropriate experience in TAVR and be responsible with their patient selection and procedures to maintain quality and outcomes.

CONCLUSIONS

We report the first mid-term mortality outcomes and cost of an MA to TAVR in the United States. In appropriately selected patients, MA-TF is associated with equivalent safety and efficacy outcomes compared with SA-TF in a very experienced TAVR center. MA-TF results in lower costs due to a shorter length of stay and less resource use. We believe that these results have important implications for the financial viability of U.S. TAVR programs in the future.

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