# Minimalist transcatheter aortic valve replacement: The new standard for surgeons and cardiologists using transfemoral access?

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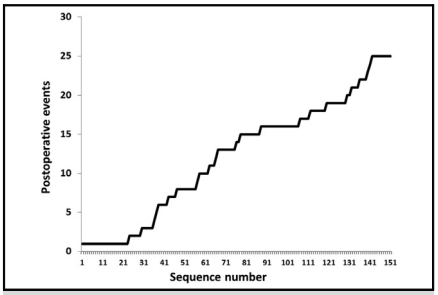
## ABSTRACT

**Background:** A minimalist approach for transcatheter aortic valve replacement (MA-TAVR) utilizing transfemoral access under conscious sedation and transthoracic echocardiography is increasing in popularity. This relatively novel technique may necessitate a learning period to achieve proficiency in performing a successful and safe procedure. This report evaluates our MA-TAVR cohort with specific characterization between our early, midterm, and recent experience.

**Methods:** We retrospectively reviewed 151 consecutive patients who underwent MA-TAVR with surgeons and interventionists equally as primary operator at Emory University between May 2012 and July 2014. Our institution had performed 300 TAVR procedures before implementation of MA-TAVR. Patient characteristics and early outcomes were compared using Valve Academic Research Consortium 2 definitions among 3 groups: group 1 included the first 50 patients, group 2 included patients 51 to 100, and group 3 included patients 101 to 151.

**Results:** Median age for all patients was 84 years and similar among groups. The majority of patients were men (56%) and the median ejection fraction for all patients was 55% (interquartile range, 38.0%-60.0%). The majority of patients were high-risk surgical candidates with a median Society of Thoracic Surgeons Predicted Risk of Mortality of 10.0% and similar among groups. The overall major stroke rate was 3.3%, major vascular complications occurred in 3% of patients, and greater-than-mild paravalvular leak rate was 7%. In-hospital mortality and morbidity were similar among all 3 groups.

**Conclusions:** In a high-volume TAVR center, transition to MA-TAVR is feasible with acceptable outcomes and a diminutive procedural learning curve. We advocate for TAVR centers to actively pursue the minimalist technique with equal representation by cardiologists and surgeons. (J Thorac Cardiovasc Surg 2015;150:833-40)




Cumulative sum analysis of postoperative events (ie, death, stroke, renal failure, or paravalvular leak greater than mild) according to chronological patient sequence number.

**Central Message**

Minimalist TAVR is associated with only a diminutive procedural learning curve and can lead to improved resource use.

**Perspective**

This largest series of minimalist TAVR to date shows that in a high volume TAVR site no significant learning curve is apparent when the minimalist protocol is implemented. Minimalist TAVR can be done with less or no ICU support, leading to improved resource use. We encourage TAVR centers and their heart teams to actively pursue the implementation and development of minimalist TAVR.

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***Read at the 95th Annual Meeting of The American Association for Thoracic Surgery, Seattle, Washington, April 25-29, 2015.***

Received for publication May 5, 2015; revisions received July 1, 2015; accepted for publication July 22, 2015; available ahead of print Aug 26, 2015.

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0022-5223/$36.00



http://dx.doi.org/10.1016/j.jtcvs.2015.07.078

Transcatheter aortic valve replacement (TAVR) is becoming an established treatment of aortic stenosis.[1-5] With the success of TAVR in prior randomized trials in high- and extreme-risk patients, ongoing trials are exploring its use in patients with intermediate risk. The target population of TAVR will grow as operative details are refined and device development evolves.[6] One of the main benefits of TAVR over surgical aortic valve replacement is its minimally invasive nature—especially when undertaken via the most used transfemoral route (TF-TAVR). In patients who are eligible for TAVR done percutaneously, there is

**Abbreviations and Acronyms**

CUSUM = cumulative sum analysis
ED = early discharge
ICU = intensive care unit
MA-TAVR = minimalist transcatheter aortic valve replacement
PVL = paravalvular leak
SD = standard discharge
STS PROM = Society of Thoracic Surgeons Predicted Risk of Mortality
TAVR = transcatheter aortic valve replacement
TEE = transesophageal echocardiogram
TF-TAVR = transfemoral transcatheter aortic valve replacement
TTE = transthoracic echocardiogram



growing momentum to explore settings that would allow for TF-TAVR to be done in a more noninvasive manner.

Our institution implemented a minimally invasive TF-TAVR (MA-TAVR) during May 2012. MA-TAVR is performed in the catheterization laboratory without general anesthesia or transesophageal echocardiography (TEE) using local anesthesia, minimal conscious sedation, and fully percutaneous access femoral artery entry and closure. We have previously reported that MA-TAVR is safe and effective in 70 patients, and can provide a cost benefit compared with standard TF-TAVR.[7] In the present study, we report the contemporary outcomes in MA-TAVR patients, whether an institutional learning curve influenced results, and whether resource use has changed since the adoption of the minimalist technique.

## METHODS

### Data Harvest

This retrospective study was approved and performed in accordance with the regulations of the Emory University institutional review board. The Society of Thoracic Surgeons (STS) institutional database was queried for all patients who underwent TF-TAVR in a catheterization laboratory under the minimalist protocol in our institution between May 2012 and July 2014. Patients enrolled in active clinical trials were excluded. The identified cohort of 151 patients was then divided according to chronological operation date into 3 groups: group 1 consisting of the first 50 patients; group 2 defined as patients 51 to 100; and finally group 3, including the last 51 patients in the studied time period. Patient chart reviews were conducted to minimize missing data as well as collect TAVR-specific data not reported in the STS database. Updated Valve Academic Research Consortium 2 criteria were used to classify clinical outcomes.[8] For cumulative sum (CUSUM) sequential analysis all patients were assigned a consecutive sequence number in the chronological order of operation date, and adverse postoperative events were defined as death, stroke, renal failure, or paravalvular leak (PVL) greater than mild.

As a subgroup analysis among the operative survivors, patients who were discharged within the first 48 postoperative hours (early discharge [ED]) throughout the experience were compared with those discharged after 48 hours (standard discharge [SD]).

### Minimalist TAVR

The procedural details of MA-TAVR at our institution have been previously described.[7] Briefly, procedures were performed by a cardiologist and a cardiac surgeon in a cardiac catheterization laboratory with conscious sedation (midazolam and fentanyl) and local 2% lidocaine for the groin. Patients were washed, draped, and prepared by operating room standards and sterility of the procedure was rigorously maintained. Femoral access was obtained using a micropuncture kit with fluoroscopic guidance, which included a roadmap angiogram performed from the contralateral iliac artery for placement of the delivery sheath. Preclosure was performed with 2 Perclose devices (Abbott Vascular, Abbott Park, Ill). All valves used in the study cohort were Edwards Sapien or Sapien XT valves (23, 26, or 29 mm) with 20F, 23F, 26F, and 29F delivery systems (Edwards LifeSciences, Irvine, Calif). Patients early in the experience were transferred from the catheterization laboratory to an intensive care unit (ICU). However, currently our routine is to send our patients directly to a regular telemetry floor. Patients taking vasopressor agents or those in whom there was a concern for vascular arterial closure or the potential need for a pacemaker were sent to the ICU postoperatively.

### Statistical Methods

Baseline patient characteristics and early outcomes were compared between groups using SAS Version 9.3 (SAS Inc, Cary, NC) and SPSS version 21 (IBM-SPSS Inc, Armonk, NY). All significance tests were 2-sided. Continuous data are presented mean $\pm$ standard deviation for normally distributed variables and median (interquartile range) otherwise. Categorical and binary data are presented as the number and percentage of patients. Comparisons across groups using continuous data were performed using analysis of variance for normally distributed data and the Mann-Whitney $U$ test otherwise. For categorical or binary data these comparisons were made using a $\chi^2$ test or Fisher exact test when appropriate.

## RESULTS

From May 2012 to January 2013, a total of 76 TF-TAVR procedures were performed in our institution; of which 50 (66%, group 1) were performed using the MA-TAVR technique. From February 2013 to August 2013, 59 TF-TAVR procedures were done and 50 (85%, group 2) were minimalist TF-TAVR. The last 51 minimalist patients (group 3) underwent TAVR between September 2013 and July 2014 (11 months) and represent 77% of all TF-TAVR cases.

Table 1 shows the preoperative demographic characteristics of the minimalist study cohort. The only significant difference between the 3 groups was the increasing prevalence of patients with New York Heart Association functional class III and IV in groups 2 and 3. Operative details are presented in Table 2. The use of second-generation Sapien XT valve increased in groups 2 and 3, affecting the distribution of valve sizes, because the 29-mm valve was not available in the first-generation Sapien valve system. One patient required cardiopulmonary bypass support and 1 patient was converted into a transapical TAVR due to vessel complications (both in group 3). Clinical outcomes are presented in Table 3. No postoperative endocarditis was observed in the study cohort.

The CUSUM graph describing the occurrence of adverse postoperative events according to chronological

**TABLE 1. Preoperative characteristics of the minimalist transcatheter aortic valve replacement cohort***

| Characteristic | All (n = 151) | Group 1 (n = 50) | Group 2 (n = 50) | Group 3 (n = 51) | *P* value |
|---|---|---|---|---|---|
| Age | 84 (79-88) | 83 (77-88) | 84 (79-87) | 86 (80-88) | .390 |
| Female | 66 (44) | 17 (34) | 23 (46) | 26 (51) | .210 |
| White | 128 (85) | 46 (92) | 41 (82) | 41 (80) | .215 |
| Society of Thoracic Surgeons Predicted Risk of Mortality | 10 (7-13) | 10 (7-13) | 9 (8-14) | 9 (6-13) | .857 |
| New York Heart Association functional class III or IV | 139 (93) | 41 (82) | 49 (98) | 49 (98) | .002 |
| Body mass index | 26 (23-30) | 25 (23-30) | 27 (24-31) | 27 (23-29) | .299 |
| Immunocompromised | 21 (14) | 8 (16) | 6 (12) | 7 (14) | .845 |
| History of | | | | | |
| Chronic lung disease | | | | | .356 |
| None | 79 (52) | 27 (54) | 22 (44) | 30 (59) | |
| Mild | 32 (21) | 13 (26) | 13 (26) | 6 (12) | |
| Moderate | 14 (9) | 2 (4) | 6 (12) | 6 (12) | |
| Severe | 26 (17) | 8 (16) | 9 (18) | 9 (18) | |
| Diabetes | 63 (42) | 22 (44) | 28 (48) | 17 (32) | .302 |
| Renal dialysis | 5 (3) | 3 (6) | 1 (2) | 1 (2) | .430 |
| Hypertension | 149 (99) | 49 (98) | 50 (100) | 50 (98) | .605 |
| Coronary artery disease | 90 (60) | 28 (56) | 27 (54) | 35 (69) | .266 |
| Prior myocardial infarction | 42 (28) | 14 (28) | 15 (30) | 13 (26) | .879 |
| Prior percutaneous coronary intervention | 64 (42) | 17 (34) | 21 (42) | 26 (51) | .225 |
| Prior coronary artery bypass grafting | 47 (31) | 17 (34) | 14 (28) | 16 (31) | .810 |
| Prior aortic valve replacement | 15 (10) | 2 (4) | 5 (10) | 8 (16) | .146 |
| Cerebrovascular disease | 44 (29) | 18 (36) | 13 (26) | 13 (26) | .426 |
| Previous cardiac surgery | 61 (40) | 24 (48) | 17 (34) | 20 (29) | .354 |
| Blood work | | | | | |
| Serum creatinine (mg/dL) | 1.2 (0.9-1.5) | 1.3 (0.9-1.5) | 1.2 (0.9-1.4) | 1.2 (0.9-1.4) | .762 |
| Hematocrit | 35 (32-38) | 34 (31-37) | 36 (32-39) | 35 (33-39) | .065 |
| Troponin (ng/mL) | 0.03 (0.02-0.06) | 0.03 (0.02-0.06) | 0.02 (0.01-0.04) | 0.04 (0.02-0.08) | .111 |
| Preoperative echocardiogram data | | | | | |
| Ejection fraction (%) | 55 (38-60) | 55 (33-60) | 55 (42-60) | 55 (38-60) | .982 |
| Aortic valve area ($cm^2$) | 0.7 (0.6-0.8) | 0.7 (0.6-0.8) | 0.7 (0.6-0.8) | 0.7 (0.6-0.9) | .404 |
| Mean aortic gradient (mm Hg) | 42 (35-50) | 42 (37-52) | 43 (36-50) | 40 (27-47) | .098 |
| Moderate/severe preoperation mitral regurgitation | 65 (44) | 24 (50) | 19 (40) | 22 (43) | .533 |
| Moderate/severe preoperation tricuspid regurgitation | 61 (42) | 25 (54) | 17 (35) | 19 (37) | .122 |
| Moderate/severe preoperation aortic insufficiency | 38 (25) | 7 (14) | 17 (34) | 14 (28) | .063 |

Values are presented as median (interquartile range) or n (%). *Group 1 = first 50 patients. Group 2 = patients 51 to 100. Group 3 = patients 101 to 151.

patient sequence number is displayed in Figure 1, demonstrating a steady rate of complications throughout the experience. The main difference between the 3 groups was the reduction in the need for an ICU stay and the length of an ICU stay if such occurred (Table 3). There was also a trend toward shorter length of hospital stay in group 3 compared with groups 1 and 2 (Table 3). The rate of the composite adverse outcomes was similar throughout the experience (Table 3), also when group 1 and group 3 were directly compared (95% confidence interval, 0.31-2.53; $P = .825$).

Detailed subgroup analysis of patients who were discharged within the first 48 hours (ED, n = 65) versus patients discharged after 48 hours (SD, n = 82) can be found in Table 4. The main differences were that ED patients had lower median STS Predicted Risk of Mortality (PROM) scores (8.3% [interquartile range, 5.9-11.2] vs 10.3% [interquartile range, 7.9-14.2]; $P = .04$) and were less frequently diabetic (31% vs 49%; $P = .027$). The vast majority of the SD cohort received the first-generation valve (74%), whereas the corresponding percentage in the ED group was 59% ($P = .04$). No other operative differences were observed between the groups. Whereas most clinical outcomes were similar between ED and SD patients, the SD group received new permanent pacemakers more frequently than ED patients (13% vs 1.5%; $P = .012$) and were more often readmitted to the discharging hospital within 30 days of the procedure (13% vs 1.5%; $P = .012$).

## DISCUSSION

Our report shows that MA-TAVR was not associated with a significant learning curve in our institution. Although clinical outcomes have remained similar in patients undergoing MA-TAVR, the need for ICU stay postoperatively has significantly decreased over time. The clinical outcomes

**TABLE 2. Operative data***

| Variable | All (n = 151) | Group 1 (n = 50) | Group 2 (n = 50) | Group 3 (n = 51) | *P* value |
|---|---|---|---|---|---|
| Valve type | | | | | |
| Sapien† | 103 (68) | 47 (94) | 25 (50) | 31 (61) | >.01 |
| Sapien XT† | 48 (32) | 3 (6) | 25 (50) | 20 (39) | |
| Valve size (mm) | | | | | |
| 23 | 68 (45) | 20 (40) | 25 (50) | 23 (45) | .042 |
| 26 | 66 (44) | 29 (58) | 17 (34) | 20 (39) | |
| 29 | 17 (11) | 1 (2) | 8 (16) | 8 (16) | |
| Second valve implanted | 16 (11) | 5 (10) | 6 (12) | 5 (10) | .925 |
| Postoperative balloon dilation | 46 (31) | 15 (30) | 19 (38) | 12 (24) | .286 |
| Ventilation required | 10 (7) | 2 (4) | 4 (8) | 4 (8) | .660 |
| Intra-aortic balloon pump | 4 (3) | 1 (2) | 1 (2) | 2 (4) | .785 |
| Operation time | 97 (80-119) | 87 (75-120) | 95 (79-113) | 92 (80-102) | .049 |

Values are presented as n (%) or median (interquartile range). *Group 1 = first 50 patients, Group 2 = patients 51 to 100, and Group 3 = patients 101 to 151. †Edwards LifeSciences, Irvine Calif.

in the population of MA-TAVR patients who were deemed eligible for early discharge (within 48 hours of the procedure) were comparable to those with a longer hospital stay. Not surprisingly, the ED cohort was characterized by lower STS PROM scores, less need for postoperative pacemakers, and less frequent rehospitalization. This implies that in selected MA-TAVR patients early discharge is feasible and safe, but larger studies are required to identify the optimal profile of patients who can be sent home within the first 2 postoperative days.

When MA-TAVR was implemented in May 2012, our institution had performed more than 300 TAVR procedures. Characteristics of patients selected for MA-TAVR did not significantly vary over the 2-year study period, save for a significantly larger portion of patients in New York Heart Association functional classes III and IV in groups 2 and 3. Whereas one might conclude that patients in groups 2 and 3 were more symptomatic, their operative risk did not differ when analyzed using the STS PROM score. The use of MA-TAVR in patients eligible for TF-TAVR varied, potentially reflecting variation in patient suitability for TAVR not captured in this study. With the lower delivery profile of the Sapien XT system, more patients have become eligible for TF-TAVR, yet not all are suitable for MA-TAVR due to factors such as morbid obesity, complex vascular access, low-lying main coronary arteries, or mental disorders precluding conscious anesthesia.

The increased use of the second-generation balloon expandable valves is an unavoidable confounder in this study. Operation time differed between the 3 patient groups analyzed, but there is likely no clinical relevance because the differences were only minutes. Early in the MA-TAVR experience protocol dictated that all patients were

**TABLE 3. Postoperative outcomes***

| Outcome | All (n = 151) | Group 1 (n = 50) | Group 2 (n = 50) | Group 3 (n = 51) | *P* value |
|---|---|---|---|---|---|
| In-hospital outcomes | | | | | |
| Stroke | | | | | |
| Major | 5 (3.3) | 1 (2) | 3 (6) | 1 (2) | .430 |
| Minor | 2 (1.3) | 1 (2) | 1 (2) | 0 (0) | .596 |
| Renal failure | 2 (1.3) | 1 (2) | 0 (0) | 1 (2) | .605 |
| Vascular complication | | | | | |
| Minor | 20 (13) | 7 (14) | 7 (14) | 6 (12) | .929 |
| Major | 4 (3) | 1 (2) | 1 (2) | 2 (4) | .785 |
| New pacemaker | 12 (8) | 2 (4) | 6 (12) | 4 (8) | .335 |
| Need for intensive care unit | 92 (61) | 43 (86) | 27 (54) | 22 (43) | <.001 |
| Total intensive care unit hours | 18 (0-27) | 25 (18-30) | 2.5 (0-25) | 0 (0-26) | .001 |
| Length of stay | 3 (2-4) | 3 (2-5) | 3 (2-4) | 2 (2-3) | .07 |
| 30-d outcomes | | | | | |
| 30-d mortality | 3 (2) | 1 (2) | 0 (0) | 2 (4) | .369 |
| Readmission | 12 (8) | 5 (10) | 5 (10) | 2 (4) | .429 |
| Aortic valve mean gradient | 10 (8-13) | 11 (8-14) | 9 (7-12) | 10 (8-13) | .149 |
| Paravalvular leak | | | | | .604 |
| None | 76 (53) | 22 (46) | 25 (51) | 29 (62) | |
| Mild | 58 (40) | 22 (46) | 20 (41) | 16 (34) | |
| Moderate | 10 (7) | 4 (8) | 4 (8) | 2 (4) | |
| Composite outcome† | 25 (17) | 8 (16) | 8 (16) | 9 (18) | .567 |

Values are presented as n (%) or median (interquartile range). *Group 1 = first 50 patients, Group 2 = patients 51 to 100, and Group 3 = patients 101 to 151. †Death, stroke, renal failure, or paravalvular leak greater than mild.

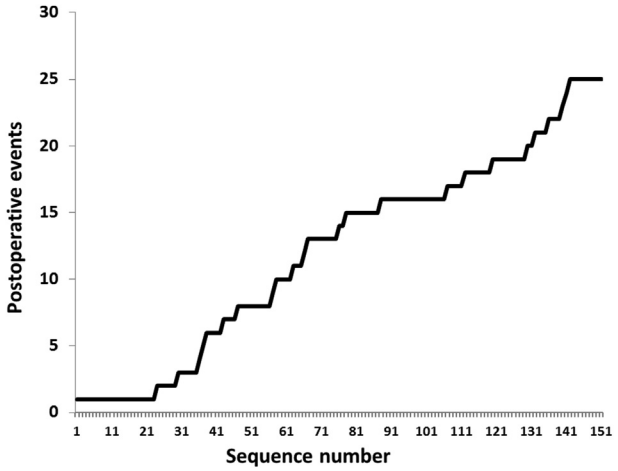


**FIGURE 1.** Cumulative sum analysis of postoperative events (ie, death, stroke, renal failure, or paravalvular leak greater than mild) according to chronological patient sequence number.

to be sent to an ICU after the procedure; this accounts for the first 30 patients. In our current clinical practice, all patients are sent to a regular telemetry floor, and only those patients who have ongoing vasopressor requirement, issues with vascular closure, or potential need for a pacemaker are transferred to the ICU. The remaining patients are transferred to a routine telemetry cardiology or cardiac surgery ward. Thus, whereas group 1 experienced this early protocol bias, it is nevertheless evident that the need for ICU stay has considerably decreased over time. This was the only indication of an institutional learning curve that was discovered, and demonstrated improved resource use over time. There was a corresponding trend for shortening of overall hospital stay that did not reach statistical significance. Clinical outcomes were similar throughout the experience, and the rate of major adverse postoperative events was stable as demonstrated by the steady coefficient of the CUSUM curve.

Concerns has been voiced that transthoracic echocardiography (TTE), as used primarily in our MA-TAVR protocol, underestimates the severity of PVL after TAVR.[9] Because studies have shown that PVL greater than mild is associated with both short- and long-term mortality post-TAVR,[10-12] minimizing paravalvular regurgitation is of utmost importance also in the MA-TAVR setting. In our protocol we use preoperative TTE and computed tomography scans, or 3-dimensional TEE if appropriate, to ensure optimal sizing of the transcatheter valve before the operation. If any concerns arise, our threshold is low to perform intraoperative balloon-sizing.[13] After valve deployment we obtain long-axis, short-axis, and apical views with TTE and supplement that information with a postdeployment root angiogram. We also perform invasive monitoring to measure an aortic regurgitation index both before and after deployment.

Using these practices, we have previously shown that in our institution there is no significant increase in mild and moderate PVL in patients who undergo TEE- or TTE-guided valve deployment[14] and that the contrast volume load in MA-TAVR does not differ from standard TF-TAVR.[7] Our present results support these findings because 93% of patients in this study had no or mild PVL (Table 3); however, further studies are needed to directly compare the efficacy of TTE to TEE in identifying PVL.

Recently Marcantuono and colleagues[15] published their experience with fast-track TAVR. In their study, the fast-track pathway was defined as TF-TAVR (regardless of anesthesia type) with extubation in the operating room, avoidance of ICU stay whenever possible, and early ambulation. They reported that patients who successfully completed the fast-track pathway had significantly shorter hospital stay and lesser costs than TAVR patients receiving standard care, and stressed that diligent patient selection by the heart team and thorough education of the entire care staff of a patient's fast-track status were the keys to success.

It has been shown that TF-TAVR results in cost savings of approximately $1250 per patient and leads to a modest gain on quality-adjusted life years compared with SAVR.[16] This is notable because 1 of the strongest criticisms surrounding TAVR is its hefty price tag. Strategies such as MA- and fast-track TAVR continue to have a significant role in health economics in countries with higher hospitalization costs such as the United States.[17] A previous publication from our institution[7] demonstrated that the mean cost of MA-TAVR was approximately $10,000 less than standard TF-TAVR ($45,500 ± $14,400 vs $55,400 ± $22,600; $P < .001$).

Overall it is apparent that optimizing patient selection by comprehensive heart team review, using the least-invasive approach as well as minimal anesthesia and ventilatory support, and adopting a streamlined postoperative care process will be keys to cost-effective TAVR without compromising patient safety and procedure efficacy.

## CONCLUSIONS

This study represents the largest series of MA-TAVR to date and we have shown that in high-volume TAVR sites, no significant learning curve is apparent. As experience grows, we believe that this procedure can be done with less or no ICU support, leading to a shorter hospital stay and improved resource use. Beyond any potential cost benefit, MA-TAVR avoids general anesthesia and thus may result in faster ambulation, regaining of functional status, discharge, and overall patient recovery. Early discharge is feasible, and further studies are needed to determine the characteristics that make a patient most suitable for a short admission. We encourage centers performing TAVR and

**TABLE 4. Pre-, peri-, and postoperative characteristics of early discharge and standard discharge patients**

| Characteristic | All (n = 147) | Early discharge (n = 65) | Standard discharge (n = 82) | *P* value |
|---|---|---|---|---|
| Age (y) | 84 (79-88) | 84 (80-88) | 84 (79-88) | .882 |
| Female | 63 (43) | 23 (35) | 40 (49) | .103 |
| White | 125 (85) | 58 (89) | 67 (82) | .204 |
| Society of Thoracic Surgeons Predicted Risk of Mortality (%) | 9.6 (7.1-13.2) | 8.3 (5.9-11.2) | 10.3 (7.9-14.2) | .004 |
| New York Heart Association class III or IV | 135 (93) | 61 (94) | 74 (91) | .755 |
| Body mass index | 26 (23-30) | 26 (23-30) | 26 (24-30) | .782 |
| History of | | | | |
| Chronic lung disease | | | | .615 |
| None | 78 (53) | 40 (49) | 38 (58) | |
| Mild | 31 (21) | 20 (24) | 11 (17) | |
| Moderate | 13 (9) | 7 (9) | 6 (9) | |
| Severe | 25 (17) | 15 (18) | 10 (15) | |
| Diabetes | 60 (41) | 20 (31) | 40 (49) | .027 |
| Renal dialysis | | | | |
| Hypertension | 145 (99) | 63 (97) | 82 (100) | .194 |
| Coronary artery disease | 88 (60) | 29 (45) | 30 (37) | .324 |
| Prior aortic valve replacement | 15 (10) | 9 (14) | 6 (7) | .194 |
| Cerebrovascular disease | 43 (29) | 17 (26) | 26 (32) | .462 |
| Blood work | | | | |
| Serum creatinine (mg/dL) | 1.2 (0.9-1.5) | 1.2 (1.0-1.4) | 1.2 (0.9-1.5) | .967 |
| Hemoglobin (g/dL) | 11.3 (10.3-12.5) | 11.7 (10.8-13) | 11.1 (10.1-12.2) | .019 |
| Preoperative echocardiogram data | | | | |
| Ejection fraction (%) | 55 (40-60) | 55 (40-60) | 55 (35-60) | .933 |
| Aortic valve area ($cm^2$) | 0.7 (0.6-0.8) | 0.7 (0.6-0.9) | 0.7 (0.6-0.7) | .004 |
| Mean aortic gradient (mm Hg) | 42 (35-50) | 42 (34-49) | 43 (35.5-52) | .359 |
| Moderate/severe preoperation mitral regurgitation | 61 (42) | 29 (45) | 32 (40) | .521 |
| Moderate/severe preoperation aortic insufficiency | 37 (25) | 19 (29) | 18 (22) | .312 |
| Valve type | | | | .04 |
| Sapien* | 99 (67) | 38 (59) | 61 (74) | |
| Sapien XT* | 48 (33) | 27 (42) | 21 (26) | |
| Valve size (mm) | | | | .710 |
| 23 | 67 (46) | 28 (43) | 39 (48) | |
| 26 | 63 (43) | 28 (43) | 35 (43) | |
| 29 | 17 (12) | 9 (14) | 8 (10) | |
| Second valve implanted | 14 (10) | 3 (5) | 11 (13) | .092 |
| Postoperative balloon dilation | 44 (30) | 18 (28) | 26 (32) | .598 |
| Operation time | 97 (80-118) | 93 (79-107) | 98 (80-123) | .137 |
| In-hospital outcomes | | | | |
| Stroke | | | | |
| Major | 5 (3.4) | 0 (0) | 5 (6.1) | .067 |
| Minor | 2 (1.4) | 0 (0) | 2 (2.4) | .503 |
| Vascular complication | | | | |
| Minor | 19 (13) | 6 (9) | 13 (16) | .235 |
| Major | 2 (1.4) | 0 (0) | 2 (2.4) | .503 |
| New pacemaker | 12 (8.2) | 1 (1.5) | 11 (13.4) | .012 |
| 30-d outcomes | | | | |
| Readmission | 12 (8.2) | 1 (1.5) | 11 (13) | .012 |
| Aortic valve mean gradient | 10 (8-13) | 10 (8-14) | 10 (7.7-12) | .234 |
| Paravalvular leak | | | | .287 |
| None | 76 (53) | 37 (57) | 39 (49) | |
| Mild | 58 (40) | 22 (34) | 36 (46) | |
| Moderate | 10 (6.9) | 6 (9.2) | 4 (5.1) | |

Values are presented as n (%) or median (interquartile range). *Edwards LifeSciences, Irvine, Calif.

their heart teams to actively pursue the implementation and development of MA-TAVR.

### Conflict of Interest Statement

Dr Thourani, Dr Babaliaros, Ms. Simone, and Ms. Keegan are research consultants for Edwards LifeSciences. All other authors have nothing to disclose with regard to commercial support.

You can watch a Webcast of this AATS meeting presentation by going to: http://webcast.aats.org/2015/Video/Wednesday/04-29-15_6B_0835_Jensen.mp4.

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**Key Words:** aortic valve, replacement, transapical, percutaneous

## Discussion

**Dr Michael Reardon** *(Houston, Tex).* There are a number of sites that have really kind of pushed the minimalist approach: Cribier in Paris, David Wood and John Webb in Canada, and Vinod Thourani and the group at Emory have pushed it in the United States and are really pushing us forward. We have followed in your footsteps. We started after about 200 and done about 110 so far, and we found that eliminating the intensive care unit (ICU) has done 3 things: it has made for happier patients, happier families, and it has finally given us a positive contribution margin. I have a couple of questions for you, Dr Jensen.

You started this after 300 cases, you say there is no learning curve, but that is kind of funny after you have already done 300 cases. You learned most of your early ones in investigational device exemption trials, we learned most of our early ones in investigational device exemption trials, but right now this is growing very rapidly across the country, and there are a lot of sites that are doing their first cases as commercial with no trial learning experience.

Is there a minimum number of cases that you recommend for sites that are just starting a transcatheter aortic valve replacement (TAVR) program before they switch to a minimalist approach?

**Dr Jensen.** That is a very good point and maybe our site is not the best to note a learning curve for minimalist because we started after we had performed the procedure on approximately 300 patients, because we had passed our internal learning curve with the TAVR devices. You are absolutely right in saying that it is probably not fair to extrapolate that to programs that are just starting out. Unfortunately, that does not give a good answer to your question. I know that colleagues from the Mayo Clinic published a general TAVR learning curve article a couple of years ago where they indicated that about 30 patients is usually what you need to reach proficiency in TAVR, and that is probably the closest data that have been published on this subject. So it would be maybe safe to say that it is at least 30 transfemoral cases. Probably, however, it is a lot more. I don't know if Vinod has a good guesstimate of an actual number.

**Dr Vinod Thourani.** I think it is hard to say. Mike, you have a good point. I will tell you for sites that are starting up and sites that come to us for our training course, if you have not done at least 50 cases, we really do not think you should be even starting this. So I

use a bar of about 50 transfemoral cases before I think you should start doing this type of stuff.

**Dr Reardon.** We agree, Vinod. And for another reason, too. Craig Smith just gave us a very interesting talk on innovation, and 1 of the things he mentioned was transesophageal echocardiogram (TEE) and what it has meant to cardiac surgeons and learning about what we do as surgeons. And the same thing was true for TAVR. All our early experience was done under general anesthesia as part of an IDE trial, in both PARTNER and CoreValve almost everybody was done under general, and now we are switching to other ways of doing this.

Do you think there is going to be a loss in not having TEE and are you doing anything different to look for paravalvular leak (PVL)? The CoreValve people have always been heavily dependent on hemodynamics; PARTNER less so. Are you really starting to look more at hemodynamics as part of your assessment?

**Dr Jensen.** That is a very relevant comment and we talk about this a lot when we talk about the minimalist approach. Yes, we do a lot of things to try to minimize PVL in our patients. At Emory the patients before TAVR get a computed tomography sizing and a transthoracic echocardiogram. If they cannot get a computed tomography scan, they will get a 3-dimensional TEE before the procedure. If the operator is still not quite sure about sizing or there is a discrepancy in the preoperative modalities, we have a very low threshold of doing intraoperative balloon sizing. So those things insure us that we get as optimal sizing as possible.

Now, in terms of detecting PVL, we measure the aortic regurgitation index after we cross the valve and also after valve deployment. After valve deployment we attempt to detect PVL using 3 views on transthoracic echocardiogram: long axis, short axis, and transapical. Lastly, we perform a root angiogram after all the wires are out of the valve to ensure no significant PVL. Using these modalities, we have felt quite confident in our detection of PVL.

Most recently we have submitted research where we compared our minimalist TAVR cohort with transthoracic echocardiogram to the standard TAVR cohort that received TEE. We did not see any difference between those 2 groups in terms of complications or PVL. So we are quite confident that doing what we do right now there is as little PVL as possible.

**Dr Reardon.** As someone who has been interested in training for a long time, I have found it is fairly easy to teach resident physicians and young faculty when to operate. It is much harder to teach them when not to operate. I was going to ask you who not to do this on because I did not see it, but you beat me to it in your presentation. You did a nice job of laying that out. So I'm going to stop with just a final comment.

Now that the 5-year PARTNER-A data are out and the 2-year CoreValve data are out, a lot of us think that is changing the field. In our guidelines, TAVR is seen as a reasonable alternative to surgical patients and appropriate heart team-selected patients who are stage 2A. A lot of us think it should be a stage 1A. And I want everybody to remember that they heard it here from you first in your background slide that it is the preferred treatment. I think you are really brave to stick that in your background slide. You're a leader now.

**Dr Jensen.** Thank you.