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

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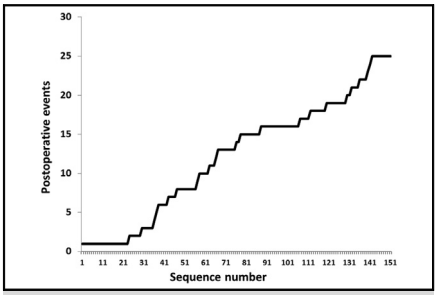
ABSTRACT

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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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 χ^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