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Transfemoral transcatheter aortic valve insertion-related intraoperative morbidity: Implications of the minimalist approach

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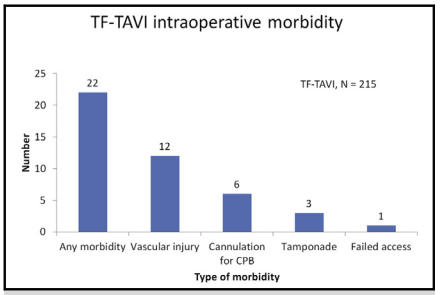
ABSTRACT

Objectives: Transfemoral transcatheter aortic valve insertion may be performed in a catheterization laboratory (ie, the minimalist approach). It seems reasonable when considering this approach to avoid it in patients at risk for intraoperative morbidity that would require surgical intervention. We hypothesized that it would be possible to associate baseline characteristics with such morbidity, which would help heart teams select patients for the minimalist approach.

Methods: We reviewed the records of 215 consecutive patients who underwent transfemoral transcatheter aortic valve insertion with a current commercially available device from November 2008 through July 2015. Demographic characteristics of the patients included a mean age of 78.9 ± 10.6 years, female sex in 73 patients (34.0%), and a mean Society of Thoracic Surgeons predicted risk of mortality of 8.7% ± 5.4%. Valve prostheses were balloon-expandable in 126 patients (58.6%) and self-expanding in 89 patients (41.4%).

Results: Significant intraoperative morbidity occurred in 22 patients (10.2%) and included major vascular injury in 12 patients (5.6%), hemodynamic compromise requiring cardiopulmonary bypass support in 4 patients (1.9%), cardiac tamponade requiring intervention in 3 patients (1.4%), ventricular valve embolization in 2 patients (0.9%), and inability to obtain percutaneous access requiring open vascular access in 1 patient (0.5%). Intraoperative morbidity was similarly distributed across all valve types ($P = .556$) and sheath sizes ($P = .369$). There were no baseline patient characteristics predictive of intraoperative morbidity.

Conclusions: Patient and valve characteristics are not predictive of significant intraoperative morbidity during transfemoral transcatheter aortic valve insertion. The finding has implications for patient selection for the minimalist approach. (J Thorac Cardiovasc Surg 2016;151:1026-9)



Transfemoral transcatheter aortic valve insertion (TF-TAVI) intraoperative morbidity.

Central Message

Intraoperative morbidity requiring immediate surgical intervention occurs in 10% of TF-TAVI procedures.

Perspective

Transfemoral transcatheter aortic valve insertion is associated with a 10% rate of significant intraoperative morbidity, with no patient characteristics being predictive of such an event. This has implications for selecting patients who will undergo an operation in the catheterization laboratory, especially in the context that performing an operation in a hybrid operating room provides a safety net for dealing with such morbidity.

See Editorial Commentary page 1030.

Transfemoral transcatheter aortic valve insertion (TF-TAVI) may be performed with less-invasive anesthesia and monitoring, and without a surgical hybrid operating room (ie, the minimalist approach).[1,2] It seems reasonable when considering this approach to avoid it in patients at risk for intraoperative morbidity requiring immediate surgical intervention. There is, unfortunately, a lack of guidance regarding who is at risk for these limb- and/or life-threatening complications. We hypothesized that it would be possible to identify baseline patient- and/or valve-related characteristics that would be associated with intraoperative morbidity. Such characteristics could be used by multidisciplinary heart teams to select patients for the minimalist approach.

METHODS

The purpose of this study was to identify baseline patient and valve characteristics associated with intraoperative complications during TF-TAVI. The study was limited to transcatheter devices currently approved for commercial use in the United States. The primary end point of the study was intraoperative complication and the secondary end point was major vascular injury. The local institutional review board approved this study.

We reviewed the records of 614 consecutive patients who underwent transcatheter aortic valve insertion using the "transfemoral-first" paradigm at Mayo Clinic Rochester by our multidisciplinary heart team from November 2008 through July 2015. There were 363 consecutive patients

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Abbreviation and Acronym
TF-TAVI = transfemoral transcatheter aortic valve insertion

(59.1%) who underwent TF-TAVI. From the transfemoral group, we excluded 135 patients who received a first-generation Sapien valve (Edwards Lifesciences, Irvine, Calif) and 13 patients who refused research authorization. The study cohort included 215 patients treated with a commercially available, clinically approved transcatheter device.

Patients were assigned to undergo transfemoral access based on determination by the multidisciplinary heart team that there was adequate femoral and iliac artery anatomy. Standard definitions used for acceptable arterial anatomy were as outlined in the respective company's Food and Drug Administration submitted valve and sheath instructions for use.[3-5] There were 3 cardiac surgeons who performed operations as part of the multidisciplinary heart team. Case volumes of the 3 surgeons were 111 cases (51.6%), 65 cases (30.2%), and 39 cases (18.1%), respectively.

Statistical analysis was performed using Statistical Analysis System software version 9.4 (SAS Institute Inc, Cary, NC). Continuous variables are reported as the mean ± standard deviation and median (minimum, maximum). Categorical variables are described as count (percentage). Fisher exact test, Wilcoxon rank-sum test, and logistic regression were used for univariate analysis.

RESULTS

Baseline patient characteristics stratified by occurrence of intraoperative morbidity are reported in Table 1. For the most part, characteristics were similar in patients regardless of the occurrence of an intraoperative complication with a few exceptions. Patients who experienced intraoperative morbidity had less peripheral vascular disease (31.8% vs 64.8%; $P = .005$) and left main coronary artery stenosis of 50% or more (0% vs 16.0%; $P = .050$) compared with patients who did not experience intraoperative morbidity.

The implanted valve type was Sapien XT (Edwards Lifesciences) in 85 patients (39.5%), Sapien S3 (Edwards Lifesciences) in 41 patients (19.1%), and CoreValve (Medtronic, Minneapolis, Minn) in 89 patients (41.4%). Sheath sizes were 14-Fr in 30 patients (14.0%), 16-Fr in 33 patients (15.4%), 18-Fr in 127 patients (59.1%), and 20-Fr in 25 patients (11.6%).

Significant intraoperative morbidity occurred in 22 patients (10.2%). The primary complication included major vascular injury in 12 patients (5.6%), hemodynamic compromise requiring cardiopulmonary bypass support in 4 patients (1.9%), cardiac tamponade requiring intervention in 3 patients (1.4%), ventricular valve embolization in 2 patients (0.9%), and inability to obtain percutaneous access requiring open vascular access in 1 patient (0.5%). No coronary artery interventions occurred.

Intraoperative morbidity was similarly distributed across all surgeon operators ($P = .198$), valve types ($P = .560$) (Table 2), and sheath sizes ($P = .369$) (Table 3). Major vascular injury occurred similarly across all sheath sizes ($P = .718$) and specifically occurred in 2 patients (6.7%) who received a 14-Fr arterial sheath, in 3 (9.1%) who received a 16-Fr sheath, in 6 (4.7%) who received an 18-Fr sheath, and in 1 (4.0%) who received a 20-Fr sheath. There were 2 (0.9%) in-hospital deaths, and mean length of stay was 5.1 ± 4.0 days.

Because there were only 22 end point events, logistic regression was limited to univariate analysis. There were 4 baseline patient characteristics with differences significantly associated with intraoperative morbidity at the $P < .10$ level of significance with Fisher exact text: creatinine, peripheral vascular disease, previous coronary artery bypass graft operation, and left main coronary artery stenosis of 50% or more. Left main coronary artery stenosis could not be analyzed with logistic regression because of a lack of events within the intraoperative morbidity group. Univariate logistic regression analysis identified a significant association of intraoperative complication with peripheral vascular disease (odds ratio [OR], 0.25; 95% confidence interval [CI], 0.10-0.65; $P = .004$), but not with previous coronary artery bypass graft operation (OR, 0.32; 95% CI, 0.09-1.15; $P = .074$), nor with creatinine (OR, 0.54; 95% CI, 0.19-1.51; $P = .238$).

DISCUSSION

This study highlights several important points about TF–TAVI-related intraoperative morbidity: incidence is significant (about 10% of patients); magnitude is substantial (major vascular injury and emergency cardiopulmonary bypass support); occurrence is similarly distributed across all respective arterial sheath sizes ($P = .369$) and valve types ($P = .556$) and smaller and/or self-expanding does not necessarily equal safer; morbidity is well managed with the standard surgical approach (operative mortality, 0.9% and observed/expected mortality, 0.10); and, complication is not associated with most baseline patient or valve characteristics.

Our intraoperative complication rate is similar to that reported by other minimalist approach investigators. In a study of 151 patients treated with the minimalist approach in France, Durand and colleagues[2] reported major vascular injury in 12 patients (7.9%) and conversion to emergency cardiovascular surgery in 5 patients (3.3%). Babaliaros and colleagues[1] reported vascular injury in 11 of 142 patients (7.7%), 2 of whom experienced procedure-related death. Although vascular injury makes up most of the intraoperative morbidity, nonvascular events should not be discounted because they accounted for 30% to 45% of morbidity.[2] In unity, these events are adequately managed in the hybrid operating room.

Our analysis identified peripheral vascular disease to be protective against all intraoperative complications and major vascular injury. This finding initially seems counterintuitive; however, examination of the literature fails to