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Clinical Investigation

"Simple" Transcatheter Aortic Valve Replacement With Conscious Sedation: Safety and Effectiveness in Real-World Practice

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Transcatheter aortic valve replacement (TAVR) is a well-established alternative to open surgical replacement. Strictly selecting low-risk patients and using conscious sedation during TAVR has enabled hospital stays to be safely shortened. We evaluated the safety and effectiveness of a less rigorous patient-selection process involving multidisciplinary case discussions, percutaneous procedures with the use of conscious sedation, and post-procedural care outside an intensive care unit, with the goal of discharging patients from the hospital early. We call this "simple TAVR."

We retrospectively reviewed the records of patients who underwent TAVR from March 2015 through February 2020 at our center. The procedures were performed by 2 high-volume operators. Of 524 total procedures, 344 (65.6%) qualified as simple TAVR.

All 344 procedures were successful. The most frequent complication at 30 days was new permanent pacemaker implantation (7.3%, 25 patients); the rates of major vascular complications, stroke, and all-cause death were less than 3% each. Of note, 252 patients (73.3%) were discharged from the hospital the day after TAVR, and 307 (89.2%) within 48 hours.

Simple TAVR is safe, economical, and feasible in real-world practice, and it does not necessitate a rigorous perioperative protocol or patient-selection process. **(Tex Heart Inst J 2021;48(4):e207528)**

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Transcatheter aortic valve replacement (TAVR) is a well-established therapy for severe aortic stenosis. Improved prosthesis design has decreased the entry profile of the device, facilitating percutaneous access through a femoral approach, and leading to higher success rates and fewer complications. After TAVR was approved for use in patients with low surgical risk,[1,2] the number of patients undergoing TAVR was expected to increase markedly. Of note, TAVR-related perioperative processes, including patient selection, preoperative testing, anesthesia mode, technical procedural steps, postprocedural care, and outpatient follow-up, vary widely among institutions. Some of these differences may contribute to prolonged hospital stays that may have been avoidable.

Shorter hospital stays, as in TAVR[3] and in fast-track endovascular aortic repair, are more satisfying to patients and save more money in comparison with traditional repair involving general anesthesia.[4] The average cost savings associated with conscious sedation and early discharge have been estimated to be $14,000 per case.[3] The Vancouver Multidisciplinary, Multimodality, but Minimalist (3M) Clinical Pathway investigators[5] and others[6,7] have shown that early hospital discharge after TAVR is safe and feasible for most patients when a somewhat rigorous perioperative protocol and patient-selection process is followed. We investigated whether a streamlined approach to TAVR is similarly safe and feasible in real-world practice.

We describe our single-center experience with fast-track "simple TAVR," in which we expedite case evaluation, use conscious sedation whenever feasible, avoid open

surgical arterial access, and transfer the patient to a telemetry unit instead of an intensive care unit (ICU) after the procedure.

Patients and Methods

We retrospectively reviewed the electronic health records of patients who underwent TAVR performed by 2 high-volume operators from March 2015 through February 2020 at the Texas Heart Institute and CHI St. Luke's Health–Baylor St. Luke's Medical Center, where more than 300 TAVR procedures are performed annually.

Most TAVR candidates are referred to us by regional healthcare professionals and represent a real-world, all-comers patient population. Before we approve a patient for TAVR, we discuss the case during a weekly meeting in which at least 2 cardiac interventionalists, 2 cardiac surgeons, 2 cardiac imaging specialists, and an anesthesiologist participate. Patients must meet the diagnostic criteria for severe aortic stenosis. For most case discussions, a transthoracic echocardiogram (TTE), a computed tomographic angiogram, and basic laboratory results are available.

This study was approved by our local institutional review board. All data were handled securely and included no information that identified patients. For this retrospective review, requirements for informed consent were waived. Patients were not involved in the design or conduct of this research or in the dissemination of study results.

Simple Transcatheter Aortic Valve Replacement

Simple TAVR is performed percutaneously through the femoral artery with the patient under conscious sedation, after which the patient is taken to a standard hospital room and then discharged the next day. After the team discussion, each operator proceeds if simple TAVR is feasible and reasonable.

Temporary transvenous pacemakers are removed at the end of the procedure if no high-grade atrioventricular block is identified during or after deployment, regardless of preexisting His bundle branch block. Large-bore vascular closure devices, chosen by the operator, are used for hemostasis. Secondary arterial access sites, whether femoral or radial, are closed at the operator's discretion with use of devices or manual hemostasis. Procedural success is defined as valve implantation that results in no-to-mild residual aortic regurgitation and a postoperative mean transaortic pressure gradient <10 mmHg.

The patient is discharged from the hospital the day after the procedure if there are no access-related bleeding complications, if laboratory data reveal no substantial blood loss or renal dysfunction, and if TTEs confirm a well-functioning bioprosthesis. Medical therapy may include antiplatelets, anticoagulants, or both, depending on the patient's clinical status.

Results

From March 2015 through February 2020, 524 patients underwent TAVR performed by the 2 operators. Of these patients, 344 (65.6%) underwent simple TAVR.

The patients' mean age was 78 ± 9.1 years (Table I). Their mean Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) score was 5.7% ± 3.6%; 61 (17.7%) of the patients had an STS-PROM score ≥8%. An Edwards SAPIEN 3 (Edwards Lifesciences Corporation) valve was implanted in 307 patients (85.2%), a device from the CoreValve family (Medtronic) in 28 (8.1%), and an Edwards SAPIEN XT (Edwards Life-

TABLE I. Baseline Characteristics of the 334 Patients and Types of Valves Implanted

Variable	Value
Age (yr)	78 ± 9.1
Male sex	208 (60.5)
STS-PROM score	5.7 ± 3.6
History	
Aortocoronary bypass	94 (27.3)
PCI	108 (31.4)
COPD	117 (34)
Chronic kidney disease	154 (44.8)
Diabetes	123 (35.8)
Peripheral vascular disease	177 (51.5)
Atrial fibrillation	91 (26.5)
Pulmonary hypertension	78 (22.7)
Previous pacemaker implantation	57 (16.6)
Aortic valve area (cm^2)	0.8 ± 0.2
Mean gradient across aortic valve (mmHg)	38.1 ± 11.5
Peak velocity across aortic valve (m/s)	3.9 ± 0.6
Left ventricular ejection fraction (%)	55.4 ± 8.9
Aortic valve calcium score*	2,396 ± 1,212
Valves Implanted	
Edwards SAPIEN S3	293 (85.2)
Medtronic CoreValve family	28 (8.1)
Edwards SAPIEN XT	23 (6.7)

COPD = chronic obstructive pulmonary disease; PCI = percutaneous coronary intervention; STS-PROM = Society of Thoracic Surgeons Predicted Risk of Mortality; TAVR = transcatheter aortic valve replacement

*Available for only 290 patients

Data are expressed as mean ± SD or as number and percentage.

sciences) in 23 (6.7%). Fourteen patients (4.1%) underwent valve-in-valve procedures.

All procedures began by placing patients under conscious sedation. Only 3 patients (0.9%) needed conversion to general anesthesia. Postoperatively, 333 (96.8%) were transferred to a telemetry unit instead of the ICU.

All procedures were successful. Complications within 30 days included new permanent pacemaker implantation in 25 patients (7.3%), major vascular complications in 9 (2.6%), clinically manifest stroke in 8 (2.3%), and all-cause death in 4 (1.2%) (Table II).

Hemostasis after large-bore arterial access was achieved with use of the PROSTAR XL (Abbott Vascular) in 253 patients (73.5%), the MANTA (Teleflex) in 87 (25.3%), and the Cross-Seal (Medeon Biodesign, Inc.) in 4 (1.2%). Most of the contralateral femoral access sites were closed by using the MYNXGRIP device (Cardinal Health, a Cordis company). The technical success rate of main arterial access closure was 96.8%. Open surgical arterial access management was needed in 17 patients (4.9%). Of 18 failed closures (5.2% of all closures), 16 were associated with the PROSTAR XL (6.3% of 253 cases), 2 with the MANTA (2.3% of 87 cases), and none with the Cross-Seal.

The median postoperative hospital length of stay (LOS) was 1 day: 252 patients (73.3%) were discharged the day after the procedure, and 307 (89.2%) within 48 hours.

Discussion

Most of the patients evaluated by our team were accurately identified as appropriate candidates to undergo simple TAVR. In our streamlined procedure, the patient is under conscious sedation, access is gained percutaneously through the femoral artery, and very early discharge from the hospital is anticipated.

Overall, few patients had complications. Despite variability in baseline patient characteristics, including a higher mean STS-PROM score, our results compared favorably with findings from large intermediate-risk[8,9] and low-risk[1,2] device trials conducted by Edwards Lifesciences and Medtronic, as well as with the data reported by the 3M investigators[5] (Table II).

Only 3 patients (0.9%) approved for simple TAVR in our study needed conversion to general anesthesia. In contrast, general anesthesia was used in 75.7% of cases in the Surgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI) trial,[9] 57% in the Evolut Low-Risk trial,[2] and 33.3% in the Placement of Aortic Transcatheter Valves (PARTNER) 3 trial.[1] To our knowledge, the percentage of patients given general anesthesia during the PARTNER 2 trial[8] was not reported. Of note, all TAVR procedures performed by the 2 operators during the 2020 portion of our study involved conscious sedation.

Along with the reduced use of general anesthesia, median LOS decreased from 6 days in the PARTNER 2 trial to 3 days in the PARTNER 3 trial. The 3M Investigators reported a median LOS of only 1 day for patients placed under conscious sedation,[5] and our LOS was consistent with theirs.

The increasing use of conscious sedation signifies a major shift in TAVR perioperative management. Once considered a complex procedure, TAVR has become streamlined and is associated with low morbidity and mortality rates, particularly when performed by experienced operators. Patients can often be discharged early from the hospital.

TABLE II. Comparison of Simple TAVR Outcomes With Those of Conventional TAVR in Other Trials

Variable	Simple TAVR (N=344)	3M[5] (N=411)	PARTNER 2[8] (N=1,011)	PARTNER 3[1] (N=496)	SURTAVI[9] (N=864)	Evolut Low-Risk[2] (N=725)
Mean STS-PROM score	5.7%	4.9%	5.7%	1.9%	4.4%	1.9%
30-day complications						
All-cause death	4 (1.2)	6 (1.5)	39 (3.9)	2 (0.4)	19 (2.2)	4 (0.6)
Any stroke	8 (2.3)	6 (1.5)	56 (5.5)	3 (0.6)	29 (3.4)	25 (3.4)
Major vascular complications	9 (2.6)	10 (2.4)	80 (7.9)	11 (2.2)	52 (6)	28 (3.9)
New pacemaker implant	25 (7.3)	23 (5.6)	86 (8.5)	32 (6.5)	224 (25.9)	126 (17.4)
General anesthesia use	3 (0.9)	6 (1.5)	NR	165 (33.3)	654 (75.7)	413 (57)
Median length of stay (d)	1	1	6	4	5.75*	NR

3M = Vancouver Multidisciplinary, Multimodality, but Minimalist Clinical Pathway; NR = not reported; PARTNER = Placement of Aortic Transcatheter Valves; STS-PROM = Society of Thoracic Surgeons Predicted Risk of Mortality; SURTAVI = Surgical Replacement and Transcatheter Aortic Valve Implantation; TAVR = transcatheter aortic valve replacement

*Mean

Data are expressed as number and percentage.

Some cardiologists and cardiovascular surgeons remain concerned about several facets of simple TAVR. First, TTE images may not be as adequate as transesophageal echocardiograms for evaluating perivalvular regurgitation and valve positioning. Second, consciously sedated patients may move during the procedure, risking vascular complications and interfering with emergency cardiopulmonary bypass. Finally, late complications (after 48 hr) may occur in patients who were discharged early. Indeed, anecdotal evidence suggests that the cautious traditional approach to performing TAVR is still taught by device manufacturers during training programs.

Our data and those in previous reports confirm that these concerns are largely not well founded. If TTEs do not clearly reveal suspicious residual aortic regurgitation, an aortogram with a little iodinated contrast medium can be obtained. In addition, intracardiac echocardiography provides high-quality images in patients placed under conscious sedation and theoretically could be used; however, using this method during TAVR is not well established. In regard to patient discomfort and movement, we have had no substantial issues, especially with the anesthesiology team's assistance. In the unlikely event that cardiopulmonary bypass is necessary, it can be started within minutes regardless of the sedation method.

We also think that the rate of late complications that may preclude early discharge is low. Postprocedural cardiac pacing leads to longer LOS for many patients, especially those with transient postprocedural arrhythmia or heart block. Pacemaker implantation rates have steadily declined in recent years consequent to device improvements and new deployment techniques. These techniques focus on prosthesis depth at the level of the noncoronary cusp.[10] Implantation depth can also be minimized according to the length of the membranous septum, as measured during preoperative computed tomographic scanning.[11]

Modern low-profile valve-delivery systems, along with newer closure devices that are easy to use and produce high success rates, should further simplify TAVR. Our closure success rates were high, and they improved during the study period. Our low failure rate with the MANTA device was consistent with recently published data.[12] Although the Cross-Seal has been tested during a clinical trial and all of our procedures with this device were successful, more experience and additional trials are needed.

Simple TAVR is now our preferred procedural strategy. Our evaluation team does not exclude patients from the procedure on the basis of any specific criterion or strict eligibility protocol; we focus instead on factors that may preclude its use in individual patients. Perhaps further technological improvements, including narrower access sheaths and even better closure devices, will enable same-day discharge from the hospital.

Study Limitations

This observational study included procedures performed by 2 operators in a single center, so the external validity of our data is limited. In addition, comparing data between studies is unreliable because of substantial differences in study methodology and baseline patient characteristics.

Conclusion

We found that simple TAVR is safe and effective. Team discussion enables the decision to use conscious sedation and femoral artery access with the intent to discharge the patient early. More data are needed to determine which patients may not be ideal candidates.

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