

EXPEDITED PUBLICATIONS: CLINICAL RESEARCH

Transcatheter Aortic Valve Implantation

Assessing the Learning Curve

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Objectives The aim of this study was to assess the learning curve for the implantation of the percutaneous aortic valve via the transfemoral route.

Background Transcatheter aortic valve insertion is a fundamentally new procedure for the treatment of aortic valve stenosis. The number of cases needed to gain proficiency with concomitant ease and familiarity (i.e., the “learning curve”) with the procedure is unknown.

Methods We performed a retrospective analysis of the first 44 consecutive patients who underwent transcatheter aortic valve implantation as part of the PARTNER (Placement of Aortic Transcatheter Valves) trial at our institution between November 2008 and May 2011.

Results The median age of the patients was 83 years (interquartile range: 77 to 87 years) and a median Society of Thoracic Surgery risk score of 9.6. Pre-procedural assessment of the aortic valve revealed a mean gradient of 53.5 mm Hg, mean aortic valve area of 0.7 mm², and a median ejection fraction of 59.5%. Patients were divided into tertiles based on sequence. Significant decreases in median contrast volume (180 to 160 to 130 ml, $p = 0.003$), valvuloplasty to valve deployment time (12.0 to 11.6 to 7.0 min, $p < 0.001$) and fluoroscopy times, from 26.1 to 17.2 and 14.3 min occurred from tertiles 1 to 3, $p < 0.001$. Significant decreases in radiation doses were also seen across the 3 tertiles, $p < 0.001$. The 30-day mortality for the entire cohort was 11%.

Conclusions Experience accumulated over 44 transfemoral aortic valve implantations led to significant decreases in procedural times, radiation, and contrast volumes. Our data show increasing proficiency with evidence of plateau after the first 30 cases. More studies are needed to confirm these findings. (J Am Coll Cardiol Intv 2012;5:72–9) © 2012 by the American College of Cardiology Foundation

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Severe symptomatic aortic stenosis is a lethal condition if left untreated (1–5). Definitive treatment for this condition has been surgical aortic valve replacement (AVR) as medical therapy is palliative in nature (6,7). Unfortunately, there are an increasing number of patients with significant comorbidities that preclude them from undergoing surgical AVR or that confer a marked increase in surgical risk. Therefore, many of these patients are either not referred to a surgeon or are turned down for surgery because of the prohibitively high surgical risk (7–10).

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Transcatheter aortic valve implantation (TAVI) has emerged as an alternative for these high risk or inoperable patients (11–14). The first TAVI with a balloon expandable valve was performed in 2002 (15) and over 10,000 valves have been implanted percutaneously in Europe. In the United States, the results of the recently concluded PARTNER (Placement of Aortic Transcatheter Valves) study have been presented and published (16). Among inoperable patients with severe aortic stenosis treated with TAVI, there was a 20% absolute risk reduction in mortality with a concomitant reduction in the composite endpoints of cardiac mortality, repeat hospitalization, or cardiac symptoms compared with standard medical therapy (16). The recently released PARTNER Cohort A results demonstrated noninferiority of TAVI compared with surgical AVR in high-risk patients (17).

Because percutaneous valve therapies are a new field, physicians and surgeons involved in the implantation of these valves need to undergo training and accumulate experience and knowledge to achieve optimal procedural performance. There have been several studies detailing the implantation, performance, and outcomes of these valves (16,18–28); however, there is paucity of data regarding the actual learning experience associated with the technique.

The aim of this study was to assess the learning curve of the physicians and team involved in the implantation of the transcatheter aortic valve via the transfemoral route at a single institution involved in the PARTNER trial. We hypothesized that a quantifiable learning curve exists for TAVI and that process measures of procedural proficiency would improve with case numbers. We defined proficiency as a significant ($p < 0.05$) reduction in the process measures of procedure time, radiation dose, and contrast volume.

Methods

The study was approved by the Mayo Clinic Institutional Review Board and was a retrospective review of 44 consecutive patients ($n = 22$ in Cohort A, $n = 22$ in Cohort B)

undergoing transfemoral aortic valve implantation as part of the PARTNER trial at our institution between November 2008 and May 2011. During this period, approximately 670 patients with severe aortic stenosis were seen and evaluated: 565 patients did not meet study criteria, whereas 98 patients received the Edwards Sapien valve (Edwards Lifesciences, Irvine, California) via either the transfemoral or the transapical approach. All adverse events are confirmed by reviewing the medical records of the patients followed at Mayo Clinic and by contacting the patients' physicians and reviewing the hospital records of patients treated elsewhere.

All patients were seen and managed by a heart team, including general cardiologists, interventional cardiologists, nurses, cardiac anesthesiologists, and cardiac surgeons. Pre-operative echocardiography was obtained to determine the severity of aortic stenosis and patients were offered TAVI based on the protocol of the PARTNER trial (29).

After enrollment, all patients underwent a systematic evaluation, including coronary angiography with revascularization as indicated and Doppler echocardiography. Computed tomography (CT) was performed to determine the size and the anatomy of the iliofemoral and aortic vasculature. Other tests included pulmonary function testing, complete blood counts, serum electrolytes, liver function tests, and coagulation studies. Medications were modified and adjusted as necessary, and baseline comorbidities were appropriately managed to ensure the optimization of their medical status before the procedure.

Assessment of the learning curve. This study was not powered to examine outcome variables as a reflection of procedural proficiency and learning. Process measures, such as procedure times, radiation exposure, and contrast administration were chosen as markers for increased procedural proficiency.

Study device and procedure. The aortic valve implantation is performed in the cardiac catheterization laboratory by 1 to 2 interventionalists and a cardiac surgeon. The technical details of the transfemoral procedure have been previously described (30). This current analysis details patients treated with either the 23-mm or 26-mm Edwards Sapien XT valve with the retroflex 3 delivery system using the 22- or 24-F sheaths.

Statistical analysis. Procedure order was assessed as a continuous variable, and patients were further divided into tertiles according to procedure order for ease of presentation of summary statistics. However, to increase statistical power, hypothesis tests involving procedure order were conducted on the absolute order value, rather than on the tertiles. Continuous variables were summarized as median

Abbreviations and Acronyms

AVR = aortic valve replacement

CT = computed tomography

IQR = interquartile range

TAVI = transcatheter aortic valve implantation

TEE = transesophageal echocardiography

(25th, 75th percentiles). Discrete variables were presented as frequency (percentage). Temporal trends were tested in continuous variables using Spearman correlation coefficient. For binary variables, temporal trends were tested using a Wilcoxon 2-sample test to test the distribution of patient order between the 2 groups (e.g., with vs. without coronary artery disease). A locally weighted scatterplot smoother was used to demonstrate temporal trends on scatterplots with patient order as the variable on the horizontal axis.

Results

Table 1 shows the baseline characteristics of the cohort. Similar to the overall PARTNER trial, the median age was 83 years (interquartile range [IQR]: 77 to 87 years) with a median Society of Thoracic Surgeons risk score of 9.6; 22 (50%) were men, 30 (68%) had coronary artery disease, and 24 (55%) had hypertension. Pre-procedural assessment of the aortic valve revealed a mean gradient of 53.5 mm Hg (IQR: 50 to 61 mm Hg), with an aortic valve area of 0.7 mm² (IQR: 0.6 to 0.8 mm²) and ejection fraction of 59.5% (IQR: 43% to 67.5%) (Table 2).

Table 3 details the procedural characteristics for the entire cohort.

Patients were divided into tertiles, with approximately 15 patients in each group, based on sequence number (Table 4). Patients in tertiles 2 and 3 compared with patients in tertile 1 were significantly older ($p = 0.016$) but were less likely to be obese ($p = 0.019$) or suffer from sleep apnea ($p = 0.023$). There were no significant differences in pre-procedural valve characteristics between the 3 groups (Table 5). Technical success, defined as successful valve implantation was achieved in all but 1 patient, who had small iliac arteries that precluded placement of the large bore sheath. One patient had a repeat valve-in-valve procedure for severe prosthetic aortic regurgitation with congestive heart failure. Five pa-

Age, yrs	83 (77, 87)
Male	22 (50%)
Coronary artery disease	30 (68%)
Hypertension	24 (55%)
Cerebrovascular disease	7 (16%)
Pulmonary hypertension	9 (20%)
Dyslipidemia	22 (50%)
Diabetes mellitus	10 (23%)
Obstructive sleep apnea	9 (20%)
Obesity	6 (14%)
Atrial fibrillation/flutter	14 (32%)
Anemia	9 (20%)
Chronic kidney disease	12 (27%)
Aortic calcification	6 (14%)
Chronic obstructive pulmonary disease	13 (30%)

Values are median (Q1, Q3) or n (%).

Mean gradient before	53.5 (50.0, 61.0)
Aortic valve area before	0.7 (0.6, 0.8)
Ejection fraction before	59.5 (43.0, 67.5)
RVSP before	44.0 (32.0, 53.0)
Valve size, mm	23.0 (23.0, 26.0)
Mean gradient after	6.0 (4.0, 8.0)
Aortic insufficiency after	1.0 (1.0, 2.0)
Mean gradient at follow-up	13.0 (10.0, 16.0)
Aortic valve area at follow-up	2.0 (1.7, 2.3)
Ejection fraction at follow-up	64.0 (56.0, 69.0)
RVSP at follow-up	40.5 (32.0, 56.5)
Aortic insufficiency at follow-up	2.0 (1.0, 2.0)

Values are median (Q1, Q3). Aortic insufficiency: trivial AI = 1, mild AI = 2, mild to moderate AI = 3, moderate AI = 4.
Q = quartile; RVSP = right ventricular systolic pressure.

tients died by 30 days (11%). The causes of death included acute aortic valve thrombosis, large ischemic/embolic cerebrovascular accident, sudden cardiac death, severe retroperitoneal bleed, and acute hypoxic respiratory failure.

The learning curve was assessed by measurement of intraprocedural process parameters. As shown in Table 6, there was a nonsignificant decrease in pacing runs and the number of aortograms across the 3 tertiles. Significant differences were seen in cutdown-to-sheath and cutdown-to-valvuloplasty times, from medians of 42.5 to 43.1 to 19.0 min and 61.5 to 51.7 to 42.5 min, $p = 0.002$ and $p < 0.001$, respectively. The continued trend toward decreases in intraprocedural times is shown in Figure 1. A significant decrease in contrast volume was seen across the 3 tertiles (median: 180 to 160 to 130 ml, $p = 0.003$). Similarly significant decreases were also seen in valvuloplasty-to-valve deployment time decreasing from 12.0 to 11.6 and 7.0 min from tertiles 1 to 3, respectively, $p < 0.001$, and fluoroscopy times, from 26.1 to 17.2 and 14.3 min, respectively, from tertiles 1 to 3, $p < 0.001$. Concomitant, significant decreases in radiation doses were also seen across the 3 tertiles,

Contrast volume	150.0 (120.0, 180.0)
Inflation count	1.0 (1.0, 1.0)
Aortogram count	6.0 (5.0, 8.0)
Pacing count	3.0 (2.0, 4.0)
Cutdown to sheath, min	39.2 (28.0, 46.4)
Cutdown to valvuloplasty, min	51.0 (43.0, 64.0)
Valvuloplasty to deployment, min	10.5 (7.0, 12.3)
Fluoroscopy time	17.9 (14.7, 25.7)
Total dose	849.0 (585.0, 1822.0)
Vascular complication	7.0 (16%)
30-day survival	39.0 (89%)
Length of stay	6.0 (4.0, 8.0)

Values are median (Q1, Q3) or n (%).

Table 4. Baseline Characteristics by Tertile

	Patients #1-#15 (n = 15)	Patients #16-#29 (n = 15)	Patients #30-#44 (n = 14)	p Value
Age, yrs	79 (73, 83)	85 (77, 90)	85.5 (78.0, 87.0)	0.016
Male	8 (53%)	8 (53%)	6 (43%)	0.99
Coronary artery disease	12 (80%)	10 (67%)	8 (57%)	0.16
Hypertension	7 (47%)	7 (47%)	10 (71%)	0.36
Cerebrovascular disease	3 (20%)	1 (7%)	3 (21%)	0.95
Pulmonary hypertension	3 (20%)	4 (27%)	2 (14%)	0.73
Dyslipidemia	9 (60%)	6 (40%)	7 (50%)	0.23
Diabetes mellitus	4 (27%)	1 (7%)	5 (36%)	0.73
Obstructive sleep apnea	5 (33%)	3 (20%)	1 (7%)	0.023
Obesity	5 (33%)	1 (7%)	0 (0%)	0.019
Atrial fibrillation/flutter	5 (33%)	5 (33%)	4 (29%)	0.93
Anemia	3 (20%)	2 (13%)	4 (29%)	0.58
Chronic kidney disease	4 (27%)	2 (13%)	6 (43%)	0.28
Aortic calcification	2 (13%)	3 (20%)	1 (7%)	0.69
Chronic obstructive pulmonary disease	4 (27%)	5 (33%)	4 (29%)	0.55

Values are median (Q1, Q3) or n (%).

$p < 0.001$. This is also shown in Figure 2, where the scatterplot shows a clear downward trend. The scatterplots demonstrate less variation with more of a plateau at approximately 30 cases with maintenance of this consistency going forward. There was a nonsignificant decrease in the rates of vascular complication from tertiles 1 to 3.

Discussion

The main findings of the current study are: 1) physicians and teams performing TAVI procedures became more proficient and measures of the learning curve effect improved with an increasing number of procedures performed, including, specifically; 2) a clear decrease in intraprocedural times; and 3) significant decreases in contrast and radiation dose with increasing case volumes.

TAVI should have a significant impact on the care and management of patients with aortic stenosis who are either inoperable or at high risk for conventional aortic valve surgery. These procedures, however, are technically complex and require a skill set markedly different from coronary interventions. The safe introduction of TAVI into the clinical environment will require careful training and case number guidelines. This percutaneous procedure requires close collaboration between cardiac surgeons and the interventional cardiologists, with both specialties bringing to bear their expertise with cutdown and exposure of the femoral artery, insertion of large bore arterial sheaths, balloon aortic valvuloplasty, and careful placement of the aortic valve prosthesis during rapid ventricular pacing.

Numerous interventional procedures, such as percutaneous coronary interventions, carotid artery stenting, endovascular aortic aneurysm repair, pulmonary valve implantation, and

Table 5. Pre- and Post-Echocardiographic Parameters by Tertile

	Patients #1-#15 (n = 15)	Patients #16-#29 (n = 15)	Patients #30-#44 (n = 14)	p Value
MG before	57.0 (50.0, 60.0)	52.0 (47.0, 65.0)	55.5 (50.0, 62.0)	0.70
AVA before	0.8 (0.6, 0.8)	0.7 (0.6, 0.9)	0.7 (0.7, 0.8)	0.76
EF before	58.0 (50.0, 67.0)	57.0 (42.0, 69.0)	64.0 (56.0, 68.0)	0.52
RVSP before	41.0 (32.0, 60.0)	44.0 (37.0, 49.0)	42.0 (30.0, 53.0)	0.73
Valve size	23.0 (23.0, 26.0)	26.0 (23.0, 26.0)	23.0 (23.0, 23.0)	0.40
MG after	5.0 (4.0, 8.0)	6.0 (4.0, 10.0)	6.0 (4.0, 7.0)	0.39
AI after	1.0 (1.0, 2.0)	1.0 (1.0, 2.0)	1.0 (1.0, 2.0)	0.25
MG at follow-up	14.0 (11.0, 17.0)	13.0 (9.0, 18.0)	11.0 (10.0, 13.0)	0.074
AVA at follow-up	2.0 (1.7, 2.2)	1.8 (1.6, 2.3)	2.2 (2.0, 2.5)	0.064
EF at follow-up	61.0 (56.0, 68.0)	65.0 (56.0, 69.0)	64.0 (48.0, 69.0)	0.82
RVSP at follow-up	35.0 (29.0, 41.0)	41.0 (34.0, 57.0)	44.0 (32.0, 58.0)	0.064
AI at follow-up	1.0 (1.0, 2.0)	2.0 (1.0, 4.0)	2.0 (1.0, 2.0)	0.33

Values are median (Q1, Q3). Aortic Insufficiency: trivial AI = 1, mild AI = 2, mild to moderate AI = 3, moderate AI = 4.
 AI = aortic insufficiency; AVA = aortic valve area; EF = ejection fraction; MG = mean gradient; RVSP = right ventricular systolic pressure.

Table 6. Procedural Characteristics by Tertile

	Patients #1-#15 (n = 15)	Patients #16-#29 (n = 15)	Patients #30-#44 (n = 14)	p Value
Contrast volume	180.0 (130.0, 250.0)	160.0 (140.0, 200.0)	130.0 (105.0, 150.0)	0.003
Inflation count	2.0 (1.0, 2.0)	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)	0.020
Aortogram count	8.0 (4.0, 9.0)	6.0 (4.0, 8.0)	6.0 (5.0, 6.0)	0.52
Pacing count	4.0 (3.0, 7.0)	3.0 (2.0, 4.0)	3.0 (2.0, 3.0)	0.057
Cutdown to sheath, min	42.5 (33.4, 46.4)	43.1 (37.5, 52.8)	19.0 (18.0, 35.9)	0.002
Cutdown to valvuloplasty, min	61.5 (51.0, 68.0)	51.7 (45.7, 65.7)	42.5 (38.0, 46.4)	<0.001
Valvuloplasty to deployment, min	12.0 (11.0, 19.4)	11.6 (7.1, 12.3)	7.0 (5.0, 8.0)	<0.001
Fluoroscopy time	26.1 (19.6, 30.5)	17.2 (14.7, 21.3)	14.3 (12.1, 16.3)	<0.001
Total dose	1822.0 (1,109.0, 3,803.0)	849.0 (610.0, 1245.0)	585.0 (506.0, 728.0)	<0.001
Vascular complication	3.0 (20%)	3.0 (21%)	1.0 (7%)	0.13
30-day survival	11.0 (73%)	15.0 (100%)	13.0 (93%)	0.22
Length of stay	5.0 (4.0, 9.0)	6.0 (4.0, 9.0)	5.0 (5.0, 8.0)	0.96

Values are median (Q1, Q3) or n (%).

percutaneous balloon mitral valvuloplasty have evidence of a clear learning curve (31–35). The present study also shows that this is true for TAVI; a definite procedure-related learning curve was seen as evidenced by our decreased procedural and fluoroscopy times with reduced contrast volume and complications. The

observed 30-day mortality rate in the current study is comparable to those of other trials of TAVI (20,23–25).

We believe the reasons for improvement are multifactorial, including refinement of procedural techniques, patient selection, and coordination of patient care among all the

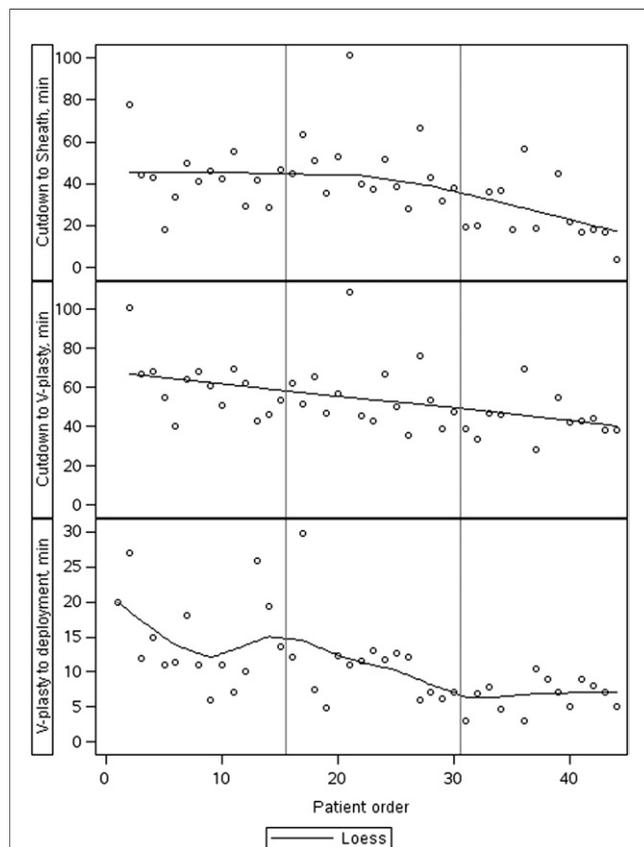


Figure 1. Scatterplot Showing the Trend Toward a Decrease in Intraprocedural Parameters Measured

Loess = locally weighted scatterplot smoothing; V-plasty = valvuloplasty.

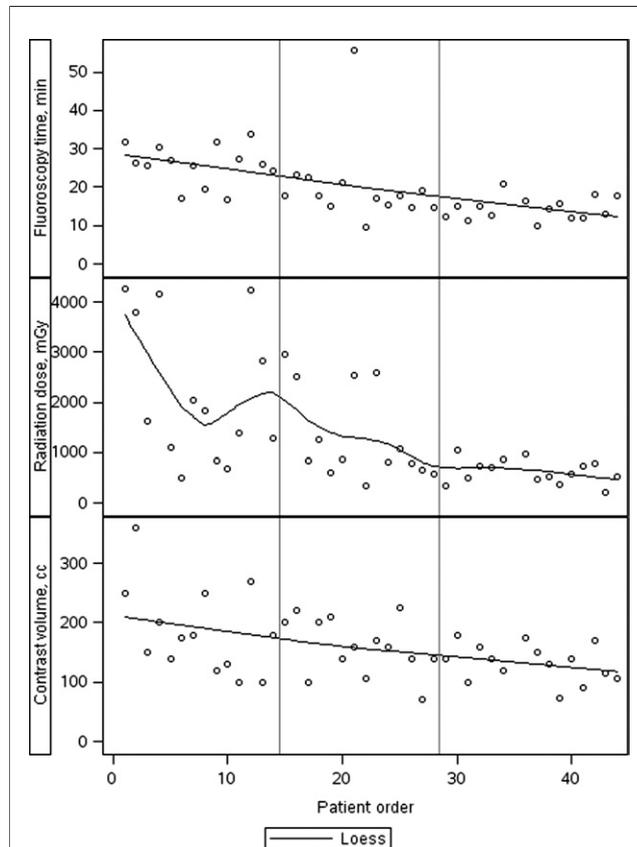


Figure 2. Scatterplot Showing the Trend Toward a Decrease in Contrast Volume and Radiation Exposure

Loess = locally weighted scatterplot smoothing.

caregivers. Numerous aspects to a learning curve exist. We took a holistic approach to the learning curve and incorporated case selection, cognitive learning, and technical proficiency. We are not able to parse out which aspect of learning was most important. Our study was not powered to detect differences in hard outcomes following TAVI. Patient selection is critical and an extremely important aspect of a successful TAVI program. In our experience, more patients are turned down for TAVI than are accepted into the program, as we look to critically select patients who will do well post-procedure and in the long term. Reasons for declining enrollment into the trial include the presence of significant comorbidities, borderline peripheral vessels with concomitant poor surgical candidacy, and significant mitral or tricuspid valve disease. At our center, a large number of patients evaluated for the PARTNER trial were offered and underwent surgical AVR. We have gained enormous experience in being able to select patients who are likely to do well, and improvement in patient selection is part of our learning curve related to case selection.

Because the TAVI team is large, effective communication before, during, and after the procedure has been crucial. The patient is usually seen pre-procedure by a cardiologist, interventional cardiologist, cardiac surgeon, anesthesiologist, and the coordinating nurse with the purpose of recognizing and treating all baseline comorbidities as appropriate. Similarly, the pre-procedural tests and imaging procedures have been refined using transesophageal echocardiography (TEE) to determine left ventricular outflow tract and aortic annular size, using CT imaging for assessment of peripheral vasculature. In our practice, borderline caliber peripheral vessels that technically meet enrollment criteria require subjective assessment of whether they are likely to straighten and accept the large-caliber vascular sheaths. With experience, we tended to preferentially shunt such patients to the transapical approach, thus reducing the risk of potentially catastrophic vascular complications in these patients. The use of smaller delivery sheaths in the future may obviate the need for a surgical cutdown and exposure of the femoral vessels and make access site complications less frequent and easier to manage.

In our experience, as well as that of others, an overall increase in the comfort level of the entire team involved in the procedure occurs based on ease and familiarity with the procedure details and sequences. All patients in the cohort had the same sequence of procedures performed during valve implantation; however, we observed less repetition of aortograms and fewer pacing runs as selection of optimal projections became easier and quicker with experience. Similarly, cardiac catheterization technicians are familiar with the equipment and setup necessary; nurses/cardiac anesthesiologists are more comfortable and easily troubleshoot and manage intraprocedural changes in patients' hemodynamics; and the interventional cardiologists/cardiac

surgeons are increasingly aware of and are able to recognize and manage complications.

It should be noted that all our patients obtained pre-procedural imaging consisting of contrast CT of the heart and peripheral vasculature, TEE, and coronary angiography. The use of pre-procedural CT to pre-plan our angiographic views for valve deployment has also decreased the use of multiple aortograms to determine the appropriate angiographic views, subsequently decreasing our contrast volume and radiation dose. With increasing experience, less time is spent positioning the valve, which has led to a decrease in the frequency of pacing runs before valve deployment. The use of the information obtained from our pre-procedural imaging techniques aid in planning the procedure beforehand. The best access site for the valve delivery system is predetermined. The optimal projection for visibility of all 3 aortic cusps is also predetermined with the aid of 3-dimensional CT reconstruction. Planning for and managing potential complications like left main occlusion or major vascular complications is easier as a detailed assessment of the cardiac and peripheral vasculature is performed before performing the procedure.

Intraprocedural imaging using TEE to assess the valve immediately after valve deployment has also improved; the noninvasive physician is able to quickly determine valve position and severity of periprosthetic aortic regurgitation on TEE as they have become more comfortable visualizing these valves. This has decreased the time interval in which hardware has been left across the new valve, potentially decreasing thromboembolic complications/events.

In the last 6 years, there has been tremendous improvement in the valve delivery system and the aortic valve prosthesis. Smaller, less bulky, and more user-friendly delivery systems and devices have made the valve implantation process easier. Translation of the experience and knowledge gained from highly experienced centers and operators has been crucial in the training of subsequent centers. In their recently published series, the Vancouver group describes the impact of learning curve on procedural and patient outcomes (36). They report significant improvement in in-hospital and 30-day mortality with increasing experience but there was no difference in procedural complications between the first and second halves of their series. The Society of Thoracic Surgeons score in the second half of their series was also lower than that in the first half, which likely reflects better patient selection based on experience. Our series was not powered to detect differences in hard endpoints such as morbidity and mortality, due to the small sample size. However, we did clearly observe improvements in the process measures of procedural time, contrast volume, and radiation exposure. At our center, the rigorous training and proctorship along with the benefit of early experience of sites such as Vancouver have made the

adoption and transition of this technology to the patient rather seamless with a significant reduction in the adverse outcomes seen in the sites that pioneered this technology.

Once the Edwards Sapien valve is approved in the United States and available for commercial use, issues of training, proctorship, and credentialing will be vital. The impact of a significant learning curve cannot be overlooked, as the efficacy of these devices will depend on both short- and long-term outcomes of patients treated compared to the standard surgical aortic valve implantation. Operators involved in implanting these devices will have to be familiar with the technique of performing aortic valvuloplasty, management of large bore arterial sheaths and vascular complications. The number of procedures required to be performed before operators can be certified as being competent remains to be determined. The current data reveal a plateau of the proficiency curve with less variation in means (Figs. 1 and 2) suggest that even in experienced centers a learning curve of at least 20 aortic valvuloplasties and at least 25 to 30 TAVI procedures will be needed for procedural proficiency. Modes of training will continue to evolve and will include the use of simulators, industry-sponsored training, proctorship, and dedicated interventional/structural heart fellowship training as being proposed by experts in the field (37).

Study limitations. This is a retrospective single-center analysis and is subject to the limitations of such analyses. The sample size is small and may be a limitation in the interpretation of the data. This study does not account for the experience and comfort level of physicians performing the procedure, which may vary by institution. It also does not account for variation in local practices concerning the field of percutaneous valve implantation.

Conclusions

A learning curve was clearly demonstrable for percutaneous valve implantation. There were significant decreases in procedural times, radiation dose, and contrast volume. Our data show increasing proficiency with evidence of plateau after the first 30 cases. More studies are needed to confirm these findings.

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