Learning Alternative Access Approaches for Transcatheter Aortic Valve Replacement: Implications for New Transcatheter Aortic Valve Replacement Centers

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Background. Smaller transcatheter aortic valve replacement (TAVR) delivery systems have increased the number of patients eligible for transfemoral procedures while decreasing the need for transaortic (TAo) or transapical (TA) access. As a result, newer TAVR centers are likely to have less exposure to these alternative access techniques, making it harder to achieve proficiency. The purpose of this study was to evaluate the learning curve for TAVR approaches and compare perioperative outcomes.

Methods. From January 2008 to December 2014, 400 patients underwent TAVR (transfemoral, n = 179; TA, n = 120; and TAo, n = 101)). Learning curves were constructed using metrics of contrast utilization, procedural, and fluoroscopy times. Outcomes during the learning curve were compared with after proficiency was achieved.

Results. Depending on the metric, learning curves for all three routes differed slightly but all demonstrated proficiency by the 50th case. There were no significant differences in procedural times whereas improvements in contrast use were most notable for TA (69 ± 40 mL versus 50 ± 23 mL, $p = 0.002$). For both TA and TAo, fewer patients received transfusions once proficiency was reached (62% versus 34%, $p = 0.003$, and 42% versus 14%, $p = 0.002$, respectively). No differences in 30-day or 1-year mortality were seen before or after proficiency was reached for any approach.

Conclusions. The learning curves for TA and TAo are distinct but technical proficiency begins to develop by 25 cases and becomes complete by 50 cases for both approaches. Given the relatively low volume of alternative access, achieving technical proficiency may take significant time. However, technical proficiency had no effect on 30-day or 1-year mortality for any access approach.

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Transcatheter aortic valve replacement (TAVR) has revolutionized the treatment of aortic stenosis and is currently an effective treatment for patients who are deemed either inoperable or at high surgical risk [1–4]. Under current indication guidelines, there are projected to be approximately 190,000 TAVR candidates in 19 European countries, with an additional 100,000 in North America. That represents an estimated $22 billion dollar industry in North America and Europe alone. With current guidelines, those numbers are anticipated to grow by nearly 18,000 and 9,200 new TAVR candidates annually in Europe and North America, respectively—these numbers will undoubtedly increase as the indications for TAVR grow to include low-risk and moderate-risk patients [5].

In this fertile economic environment, the number of new TAVR centers has grown considerably since achieving Food and Drug Administration approval in November of 2011 and subsequent Centers for Medicare and Medicaid Services coverage in May 2012. More than 250 clinical sites in the United States alone were reported in 2013, and now there are currently more than 400 clinical sites participating in The Society of Thoracic Surgeons (STS)/American College of Cardiology Transcatheter Valve Registry [6–8].

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The preferred access approach for new and old centers alike is the transfemoral (TF) approach. As many as 30% of patients who would otherwise be TAVR candidates were historically excluded, however, because of inadequate iliofemoral access [9]. That led to the development of alternative access approaches, including transapical (TA), transaortic (TAo), transaxillary, transsubclavian, and transcarotid, to accommodate TF ineligible cases.

Second-generation TAVR delivery systems and valves have smaller sheath sizes and lower profiles that have increased the number of patients eligible for TF procedures while decreasing the need for TAo and TA access [10, 11]. Newer TAVR centers are likely to have less exposure to these alternative access techniques, making it harder to achieve proficiency with these procedures. Learning curves for TAVR approaches have been incompletely evaluated, and the number of cases to achieve technical proficiency is unknown. The purpose of this study was to evaluate the learning curve for TAVR approaches and to assess its impact on perioperative and 1-year outcomes.

Patients and Methods

This study was approved by the Washington University School of Medicine Institutional Review Board. Written informed consent was obtained from each patient before enrollment. All data were entered prospectively into a longitudinal database maintained at our institution. The database contained more than 400 demographic and perioperative variables.

Patient Selection

A total of 400 patients who underwent TAVR at our institution (TF, n = 179; TA, n = 120; and TAo, n = 101) from January 2008 to December 2014 were retrospectively reviewed (Fig 1). All patients had symptomatic (New York Heart Association functional class II to IV) and severe aortic stenosis, and were deemed appropriate candidates for TAVR by a multidisciplinary team that included two cardiac surgeons and cardiologists. All procedures were performed in a fully equipped hybrid operating room with backup cardiopulmonary bypass immediately available for conversion.

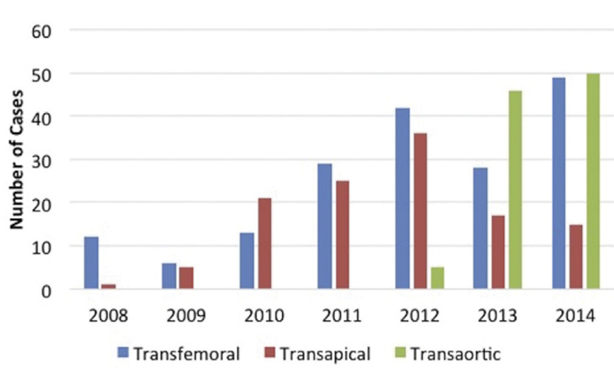

Fig 1. Access approach—transfemoral (blue bars), transapical (red bars), or transaortic (green bars)—by year.

Learning Curves

To construct a graphical representation of a learning curve, experience must be plotted against a continuous learning variable that changes over time. The accurate portrayal of a learning curve relies on the assumption that the learning variable will improve with experience until a plateau or asymptote is reached. When applied to new technologies or new procedures in surgery, procedural variables are commonly used to construct learning curves [12–15].

In this study, patients within each access approach were sequentially numbered by the order in which they underwent TAVR, and were used as the x-axis variable of experience. Procedural time, contrast utilization, and fluoroscopy times were chosen as the learning variables because they were most likely to improve with experience and their utilization in learning curve models has been previously described for TAVR [13]. Learning curves for all three access approaches were constructed using nonlinear, semilog, best-fit curves (GraphPad Prism, La Jolla, CA) based on the scatter plots of procedural time, contrast dose, and fluoroscopy time. Semilog equations derived from these curves were used to calculate the linear slope of the tangent at each point on the curve. For metrics based on time (procedure and fluoroscopy times), a cutoff of less than 0.1 slope was used as a cutoff to determine proficiency.

To further evaluate the technical learning curve, we divided each access group into two groups: cases completed before proficiency (labeled "early"), and those completed after proficiency (labeled "late"). Demographics and periprocedural outcomes including survival were compared before and after proficiency was achieved.

Access Approach Selection

The default approach to TAVR is TF. Patients who are not candidates for the TF approach secondary to small iliofemoral vessel diameter or vascular abnormalities undergo alternative access approaches. The most recent alternative access is TAo, and it is the current preferred route of alternative access at our institution except for patients with heavily calcified aortas, previous sternotomies, or redo cardiac surgery. In our experience, these patients are generally treated with the transapical approach to avoid hazardous scar tissue and potentially dangerous cannulation of a heavily calcified aorta.

Statistical Analysis

Continuous variables were expressed as mean ± SD or as median with range. Categoric variables were expressed as frequencies and percentages with outcomes compared using the χ^2 test or Fisher's exact test. Continuous outcomes were compared using Student's t test for means of normally distributed continuous variables and the Mann-Whitney U nonparametric test for skewed distributions. All data analyses were performed using SYSTAT 13 (Systat Software, Chicago, IL). Kaplan-Meier curves were created and compared using log rank analysis in Prism (GraphPad). Nonlinear best-fit curves were created from scatter plots in Prism (GraphPad).

Results

Learning Curves

The same team of cardiac surgeons, cardiologists, and cardiac anesthesiologists preformed all TAVR procedures. Overall, there were no significant differences in average procedure time between access approaches. However, the TF group had significantly more fluoroscopy usage and contrast usage than the alternative access approaches (21.4 ± 11.3 minutes versus 13.2 ± 7.2 minutes, $p < 0.001$, and 84.7 ± 55.4 mL versus 56.8 ± 29.8 mL, $p < 0.001$, respectively), but the TF group had the greatest improvement. When evaluating the learning curves for each metric (Fig 2), we see that no significant learning curve was identified utilizing procedural time for TA or TF approaches. However, learning curves for all three approaches differed slightly depending on the metric, but all approached their asymptote between the 25th and 50th case (Fig 2).

When comparing the first 50 cases to subsequent cases within each access approach group, the TA and TF approaches demonstrated significant improvements in contrast use (69 ± 40 mL versus 50 ± 23 mL, $p = 0.002$, and 104.8 ± 60.3 mL versus 77.0 ± 51.6 mL, $p = 0.007$, respectively). All three access approaches had decreased fluoroscopy times, although they were not statistically significant (Fig 2).

Demographics

To evaluate whether patient selection had changed over time, baseline demographic data were compared before and after proficiency (Table 1). Overall, demographic data were similar, both before and after proficiency was reached for all three access approaches. However, patients who underwent TAVR after proficiency had lower average STS risk scores for TF (10.3 ± 3.8 versus 8.5 ± 4.8, $p = 0.027$), TA (12.5 ± 4.9 versus 9.5 ± 5.7, $p = 0.004$), and TAo (10.9 ± 5.8 versus 9.7 ± 4.7, $p = 0.254$).

Perioperative Outcomes

For the TA approach, fewer intraoperative packed red blood cell transfusions were required after proficiency was reached (62% versus 34%, $p = 0.003$), and there was less utilization of cardiopulmonary bypass (16% versus 1%, $p = 0.004$; Table 2). Moreover, TAo had fewer intraoperative packed red blood cell transfusions after proficiency was reached (42% versus 14%, $p = 0.002$) and also fewer postoperative packed red blood cell transfusions (70% versus 10%, $p < 0.001$). There were no significant differences before and after proficiency in postoperative complications, including intensive care unit readmission, hospital length of stay, cerebrovascular accidents, renal failure, and pneumonia.

Mortality

There were no significant differences in 30-day mortality before or after proficiency for any approach (Table 2). When comparing Kaplan-Meier 1-year survival curves for all three access approaches before and after proficiency, there were no significant differences (Fig 3).

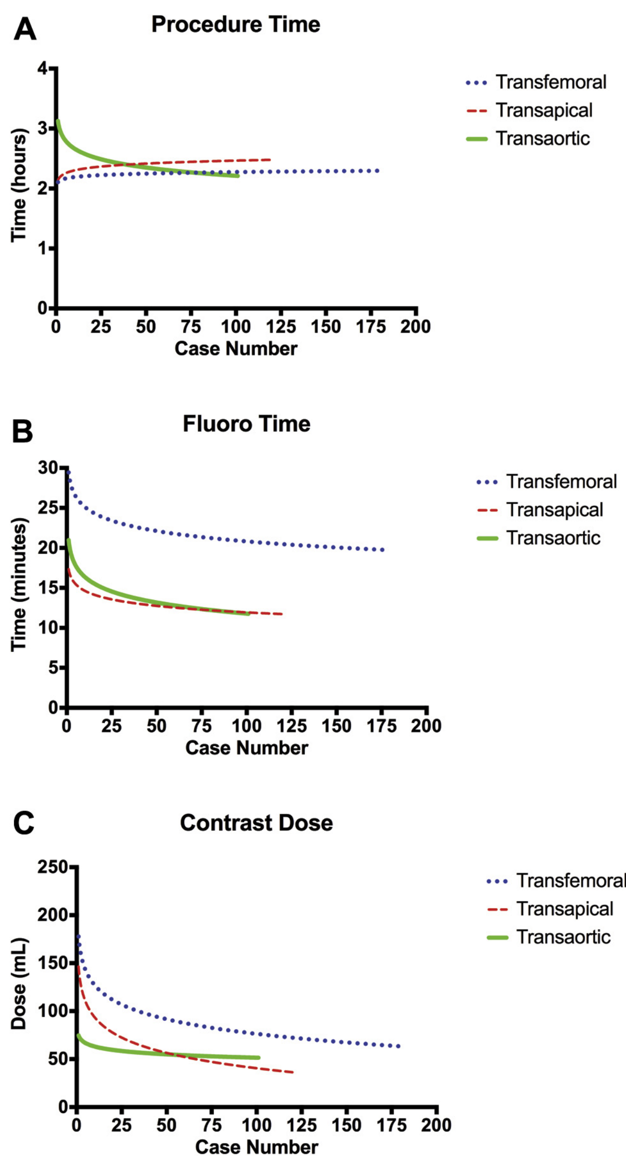

Fig 2. Learning curve metrics: (A) procedure time; (B) fluoroscopy (Fluoro) time; and (C) contrast dose. Blue lines indicate transfemoral approach; red lines, transapical; and green lines, transaortic.

Overall 30-day mortality regardless of access approach was not significantly different before and after proficiency was reached (5 of 150 [2%] versus 12 of 250 [5%], $p = 0.612$). When evaluating the Kaplan-Meier 1-year survival curves of all three TAVR approaches combined, there were no differences between survival before proficiency and after proficiency (Fig 4).

Comment

Overall, the learning curves for all three access approaches were slightly different, but proficiency seemed to be reached between 25 and 50 cases, particularly when evaluating fluoroscopy time and contrast dose. However, when comparing the outcomes of the cases before

Table 1. Demographics

Variable	TF Early (n = 50)	TF Late (n = 129)	*p* Value	TA Early (n = 50)	TA Late (n = 70)	*p* Value	TAo Early (n = 50)	TAo Late (n = 51)	*p* Value
Female	30 (60)	53 (41)	0.03	25 (50)	24 (34)	0.093	37 (74)	26 (51)	0.024
Age, years	83.1 ± 8.3	81.2 ± 9.5	0.225	84.2 ± 5.9	77.0 ± 9.0	<0.001	80.6 ± 8.8	82.4 ± 8.9	0.289
STS risk score, %	10.3 ± 3.8	8.5 ± 4.8	0.027	12.5 ± 4.9	9.5 ± 5.7	0.004	10.9 ± 5.8	9.7 ± 4.7	0.254
Diabetes mellitus	19 (38)	48 (37)	1.000	22 (44)	31 (44)	1.000	25 (50)	23 (45)	0.692
Creatinine	1.13 ± 0.46	1.27 ± 1.04	0.364	1.29 ± 0.40	1.22 ± 0.70	0.501	1.38 ± 1.17	1.38 ± 1.13	0.997
Renal failure	2 (4)	8 (6)	0.728	3 (6)	9 (13)	0.355	6 (12)	4 (8)	0.525
Hypertension	41 (82)	125 (97)	0.002	43 (86)	67 (96)	0.091	49 (98)	50 (98)	1.000
Hyperlipidemia	41 (82)	115 (89)	0.218	45 (90)	68 (97)	0.127	46 (92)	47 (92)	1.000
PVD	17 (34)	34 (26)	0.357	33 (66)	61 (87)	0.007	37 (74)	41 (80)	0.484
CVD	12 (24)	27 (21)	0.689	20 (40)	24 (34)	0.567	15 (30)	17 (33)	0.831
COPD	24 (48)	72 (56)	0.405	31 (62)	43 (61)	1.000	32 (64)	27 (53)	0.314
Ejection fraction, %	52.1 ± 16.5	52.9 ± 15.0	0.750	51.9 ± 13.5	51.3 ± 14.5	0.804	54.9 ± 15.6	55.9 ± 14.5	0.754

Values are n (%) or mean ± SD.

COPD = chronic obstructive pulmonary disease; CVD = cerebrovascular disease; PVD = peripheral vascular disease; STS = The Society of Thoracic Surgeons; TA = transapical; TAo = transaortic; TF = transfemoral.

proficiency with those after proficiency was reached, there were no significant differences in outcomes, including 30-day mortality, 1-year mortality, major complications, and lengths of stay.

The methodology and results of this study are consistent with other studies that evaluate learning curves. Similar procedural variables are commonly used to construct learning curves, and the technical curves produced by our data are similar to those from other new technologies, including robotic pancreaticoduodenectomy, robotic mitral valve surgery, and carotid artery stenting [12, 14, 15]. The only two metrics that did not follow classic learning curve distribution were the procedural times for both the TA and TF approaches. That is likely due to the complexity in room preparation for the TAo approach that is entirely different from the TA and TF approach. The TAo approach was the last introduced at our institution, but it still demonstrated a significant learning curve despite early experience with TA and TF approaches.

Other groups have attempted to identify TAVR learning curves, particularly for the TF approach. A recent

Table 2. Perioperative Outcomes

Variable	TF Early (n = 50)	TF Late (n = 129)	*p* Value	TA Early (n = 50)	TA Late (n = 70)	*p* Value	TAo Early (n = 50)	TAo Late (n = 51)	*p* Value
Intraoperative									
CPB use	0 (0)	0 (0)	…	8 (16)	1 (1)	0.004	0 (0)	0 (0)	…
PRBC	12 (24)	17 (13)	0.112	31 (62)	24 (34)	0.003	21 (42)	7 (14)	0.002
Extubated in OR	46 (92)	115 (89)	0.783	38 (76)	57 (81)	0.501	44 (88)	49 (96)	0.160
Postoperative									
ICU time, hours	37.0 ± 28.9	36.3 ± 39.3	0.907	78.1 ± 113.8	52.2 ± 76.3	0.166	52.0 ± 79.5	38.9 ± 35.2	0.290
PRBC	6 (12)	25 (19)	0.279	19 (38)	21 (30)	0.433	35 (70)	5 (10)	<0.001
ICU readmission	1 (2)	2 (2)	1.000	3 (6)	4 (6)	1.000	2 (4)	4 (8)	0.678
Reintubation	0 (0)	2 (2)	1.000	3 (6)	5 (7)	1.000	1 (2)	2 (4)	1.000
Length of stay, days	5.4 ± 3.6	5.9 ± 3.4	0.380	8.2 ± 6.2	6.8 ± 3.6	0.166	7.8 ± 8.3	8.4 ± 5.0	0.645
CVA	1 (2)	1 (1)	0.482	1 (2)	1 (1)	1.000	1 (2)	1 (2)	1.000
Renal failure	1 (2)	1 (1)	0.482	2 (4)	1 (1)	0.570	0 (0)	0 (0)	…
Atrial fibrillation	1 (2)	16 (12)	0.044	14 (28)	9 (13)	0.058	6 (12)	9 (18)	0.577
Pneumonia	0 (0)	2 (2)	1.000	3 (6)	1 (1)	0.307	2 (4)	2 (4)	1.000
Thirty-day readmission	5 (10)	13 (10)	1.000	2 (4)	7 (10)	0.302	6 (12)	3 (6)	0.318
Thirty-day mortality	1 (2)	3 (2)	1.000	3 (6)	6 (9)	0.733	1 (2)	3 (6)	0.617

Values are n (%) or mean ± SD.

CPB = cardiopulmonary bypass; CVA = cerebrovascular attack; ICU = intensive care unit; OR = operating room; PRBC = packed red blood cells; STS = The Society of Thoracic Surgeons; TA = transapical; TAo = transaortic; TF = transfemoral.

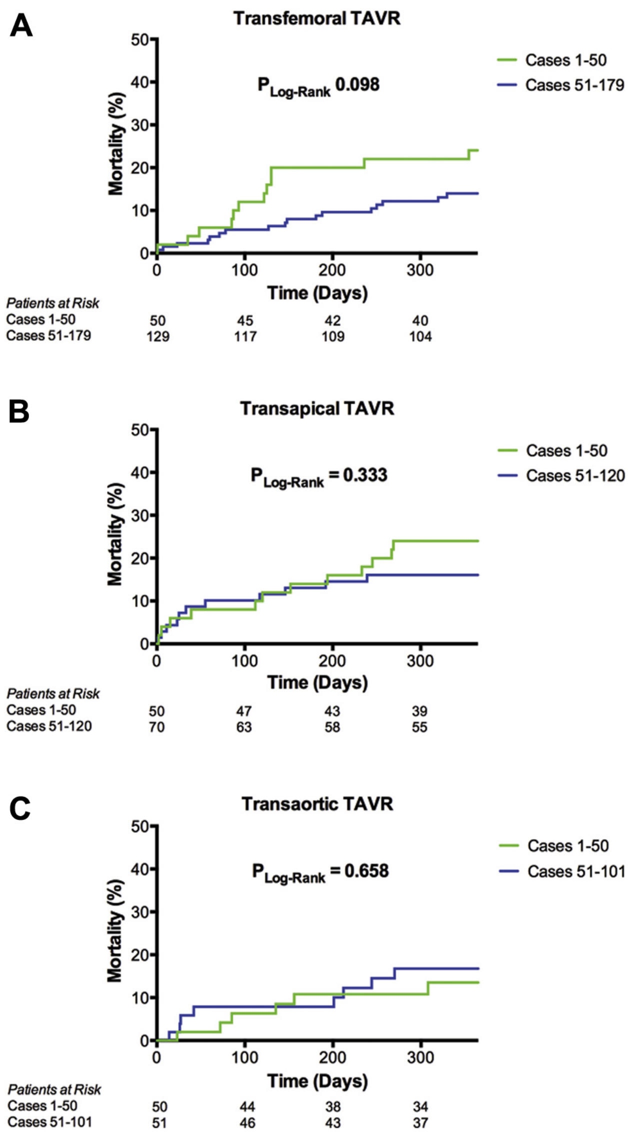

Fig 3. Kaplan-Meier estimates of survival comparing survival of cases performed before proficiency, namely, cases 1 to 50 (green lines) versus those performed after proficiency was reached: (A) transfemoral transcatheter aortic valve replacement (TAVR [blue line = cases 51 to 179]); (B) transapical TAVR (blue line = cases 51 to 120); and (C) transaortic TAVR (blue line = cases 51 to 101).

study evaluating the Placement of Aortic Transcatheter Valve Trial-1 (PARTNER-1) transfemoral data demonstrated that as experience was gained, there were significant reductions in procedure time, fluoroscopy time, and contrast dosage [13]. The investigators also found significant variation in the number of cases required to reach procedure time plateau among institutions, with a range between 21 and 52 cases. These results are consistent with other groups who have demonstrated decreased procedural time, fluoroscopy use, and contrast doses with experience in both the TA and TAo approaches; however, there are no data on the specific number of cases needed to achieve proficiency [9, 16].

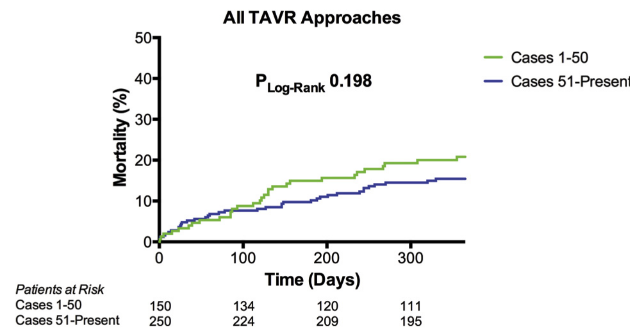

Fig 4. Kaplan-Meier estimates of overall survival of all three transcatheter aortic valve replacement (TAVR) access approaches combined, comparing before proficiency (cases 1 to 50 [green line]) to after proficiency (cases 51 to present [blue line]).

Although several groups have reported data on TAVR learning curves in both single and multiple institutional trials, there remains no evidence-based data to formulate clinical competency guidelines for TAVR [9, 13, 14, 16–19]. However, there is a consensus statement released by the American Association for Thoracic Surgery, American College of Cardiology Foundation, Society for Cardiovascular Angiography and Interventions, and STS in 2012 that recommends that a program perform more than 1,000 catheterizations per 400 percutaneous coronary interventions with more than 50 surgical aortic valve replacements before the introduction of TAVR. The consensus statement also contends that cardiac surgeons should have performed more than 100 surgical aortic valve replacements (at least 10 of which were considered high risk), and interventional cardiologists should have performed at least 100 left-side heart catheterizations before gaining TAVR privileges [20]. Furthermore, the Centers for Medicare and Medicaid Services has laid out strict guidelines to maintain TAVR credentialing, including maintaining more than 20 TAVRs per year or more than 40 TAVRs every 2 years [7, 21].

The current study and others have highlighted the weakness of guidelines for new TAVR centers. There remain no current formal guidelines as to how many cases need to be performed to be technically competent. This problem is compounded by the development of newer second and third generation devices that can be deployed utilizing smaller sheaths, and will likely decrease the availability of alternative access cases [22]. With fewer numbers of alternative access cases, it may take newer TAVR centers several years to achieve proficiency. Furthermore, there are increasing data suggesting that better TAVR outcomes are achieved at higher volume centers, which would support a more centralized referral network or increased proctoring [7]. However, the emergence of newer structural heart interventions such as transcatheter mitral valve replacement will still require surgeons to be proficient in alternative access [23].

Despite demonstrating a technical learning curve, our data suggests technical proficiency does not impact outcomes, as evident by the lack of differences in mortality

before and after achieving proficiency. However, both the TA and TAo approaches demonstrated decreased transfusions after proficiency was reached. Reductions in blood product utilization over time could reflect changes in institutional transfusion practices over time; however, isolated aortic valve replacement and coronary artery bypass graft surgery at our institution demonstrated no significant change in either intraoperative or postoperative transfusions throughout the study. Other groups have reported better 30-day mortality with experience, but once risk factors were accounted for, outcomes were not adversely affected by the technical performance learning curve [17, 24]. Perhaps a larger sample size would demonstrate a significant difference.

This study was limited by its relatively small sample size and by its being a retrospective, single-institution study. This institution is also a very experienced center and participated in early device trials establishing TAVR in the United States, which utilized mainly TF and TA approaches and may confound learning curve results. This is also a training institution with both cardiac surgery and interventional cardiology trainees, and that may also confound learning curve results. Lastly, TAVR technology has advanced significantly over the duration of the study, including newer valves, newer delivery systems, and a new imaging modality called 3mensio (Pie Medical Imaging, Maasricht, Netherlands) that was introduced in June of 2014. This imaging modality has allowed for better operative planning, which could have affected procedure time, fluoroscopy time, and contrast dosage.

In conclusion, the technical learning curves for each of the three access approaches are distinct, but all curves demonstrated a plateau between 25 and 50 cases. The technical learning curve for all three access approaches had no affect, however, on outcomes without risk adjustment. These data can help guide TAVR training, credentialing, and accreditation of future TAVR centers.

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Author Interview: The Author Interview can be viewed in the online version of this article [http://dx.doi.org/10.1016/j.athoracsur.2016.08.068] or from *The Annals* YouTube channel [https://youtu.be/tOjKlZrbgig].

References

1. Smith CR, Leon MB, Mack MJ, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med 2011;364:2187–98.
2. Leon MB, Smith CR, Mack M, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med 2010;363:1597–607.
3. Kodali SK, Williams MR, Smith CR, et al. Two-year outcomes after transcatheter or surgical aortic-valve replacement. N Engl J Med 2012;366:1686–95.
4. Adams DH, Popma JJ, Reardon MJ, et al. Transcatheter aortic-valve replacement with a self-expanding prosthesis. N Engl J Med 2014;370:1790–8.
5. Osnabrugge RL, Mylotte D, Head SJ, et al. Aortic stenosis in the elderly: disease prevalence and number of candidates for transcatheter aortic valve replacement. A meta-analysis and modeling study. J Am Coll Cardiol 2013;62:1002–12.
6. Mack MJ, Brennan JM, Brindis R, et al. Outcomes following transcatheter aortic valve replacement in the united states. JAMA 2013;310:2069–77.
7. Badheka AO, Patel NJ, Panaich SS, et al. Effect of hospital volume on outcomes of transcatheter aortic valve implantation. Am J Cardiol 2015;116:587–94.
8. 2015 STS/ACC TVT registry. Available at https://www.ncdr.com/webncdr/tvt/home/participantdirectory. Accessed October 31, 2015.
9. Lardizabal JA, O'Neill BP, Desai HV, et al. The transaortic approach for transcatheter aortic valve replacement: initial clinical experience in the united states. J Am Coll Cardiol 2013;61:2341–5.
10. Piazza N, Martucci G, Lachapelle K, et al. First-in-human experience with the Medtronic CoreValve Evolut R. EuroIntervention 2014;9:1260–3.
11. Binder RK, Rodes-Cabau J, Wood DA, et al. Transcatheter aortic valve replacement with the SAPIEN 3: a new balloon-expandable transcatheter heart valve. J Am Coll Cardiol Intv 2013;6:293–300.
12. Ahmadi R, Willfort A, Lang W, et al. Carotid artery stenting: effect of learning curve and intermediate-term morphological outcome. J Endovasc Ther 2001;8:539–46.
13. Alli O, Rihal CS, Suri RM, et al. Learning curves for transfemoral transcatheter aortic valve replacement in the PARTNER-I trial: technical performance. Catheter Cardiovasc Interv 2016;87:154–62.
14. Boone BA, Zenati M, Hogg ME, et al. Assessment of quality outcomes for robotic pancreaticoduodenectomy: identification of the learning curve. JAMA Surg 2015;150:416–22.
15. Suri RM, Burkhart HM, Daly RC, et al. Robotic mitral valve repair for all prolapse subsets using techniques identical to open valvuloplasty: establishing the benchmark against which percutaneous interventions should be judged. J Thorac Cardiovasc Surg 2011;142:970–9.
16. Kempfert J, Rastan A, Holzhey D, et al. The learning curve associated with transapical aortic valve implantation. Ann Cardiothorac Surg 2012;1:165–71.
17. Gurvitch R, Tay EL, Wijesinghe N, et al. Transcatheter aortic valve implantation: lessons from the learning curve of the first 270 high-risk patients. Catheter Cardiovasc Interv 2011;78:977–84.
18. Hayashida K, Romano M, Lefevre T, et al. The transaortic approach for transcatheter aortic valve implantation: a valid alternative to the transapical access in patients with no peripheral vascular option. A single center experience. Eur J Cardiothorac Surg 2013;44:692–700.
19. Kempfert J, Rastan A, Holzhey D, et al. Transapical aortic valve implantation: analysis of risk factors and learning experience in 299 patients. Circulation 2011;124(Suppl):124–9.
20. Tommaso CL, Bolman RM, Feldman T, et al. Multisociety (AATS, ACCF, SCAI, and STS) expert consensus statement. Operator and institutional requirements for transcatheter valve repair and replacement, part 1: Transcatheter aortic valve replacement. J Thorac Cardiovasc Surg 2012;143:1254–63.
21. Centers for Medicare & Medicaid Services. Decision memo for transcatheter aortic valve replacement (TAVR) (CAG-00430N). Available at https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=257&ver=4&NcaName=Transcatheter+Aortic+Valve+Replacement+(TAVR)&bc=ACAAAAAAIAAA&. Accessed November 1, 2015.
22. Taramasso M, Pozzoli A, Latib A, et al. New devices for TAVI: technologies and initial clinical experiences. Nat Rev Cardiol 2014;11:157–67.

23. Cheung A, Webb JG, Barbanti M, et al. 5-year experience with transcatheter transapical mitral valve-in-valve implantation for bioprosthetic valve dysfunction. J Am Coll Cardiol 2013;61:1759–66.

24. Minha S, Waksman R, Satler LP, et al. Learning curves for transfemoral transcatheter aortic valve replacement in the PARTNER-I trial: success and safety. Catheter Cardiovasc Interv 2016;87:165–75.

DISCUSSION

DR ERIC L. SARIN (Atlanta, GA): I would like to thank the program committee for the opportunity to discuss this paper. Dr Henn, I would like to congratulate you on a very nice presentation and thank you again for getting me the manuscript in advance to review. I think you have highlighted a very interesting consequence of improving transfemoral technology in the sense that newer centers are going to have less opportunities to perfect their alternative access approaches. With that in mind, I have a few questions for you.

You have highlighted the time to technical proficiency and certainly there is a precedent there, the recent data from the Placement of Aortic Transcatheter Valve Trial (PARTNER) experience looked at the same metrics you did in terms of contrast utilization, operating room time, fluoroscopy time, but, as you know, there are obviously other very important metrics that we consider to measure success of a procedure. I wonder if you have any of those data that you could share with us. Specifically, I am interested in knowing your degree of paravalvular leak or need for a second valve. Obviously, I think, most of us in the room would trade an extra 10 cc of contrast or an extra 10 minutes in the room for an improved result.

DR HENN: Thank you for the question. It is an interesting question and one that is particularly relevant to this talk. We did not specifically look at echocardiographic data; instead we chose to focus on technical efficiency with the primary outcome of mortality.

DR SARIN: You have also highlighted your change in packed red blood cell usage over time, which I think is really admirable. As you know, though, that era of your study period, 2008 to 2014, represented a period in cardiac surgery when there was really heightened scrutiny across the board for any and all red blood cell transfusions regardless of the procedure. So I wonder if what you are showing us is not so much reflective of the technical proficiency for the alternative access TAVR procedure per se but is it reflective of just an evolution in St. Louis of getting stricter about your transfusion criteria?

DR HENN: That is also a great question and it certainly brings up a confounding variable in our analysis. There certainly has been increased scrutiny of blood transfusions, which has likely changed over time, and our analysis did not account for this increased scrutiny.

DR SARIN: It is an admirable change, nonetheless. My last question is really more of a philosophical one. The data that you presented to us today, where do we go with that? Do you think that 10 years from now alternative access transcatheter aortic valve replacement (TAVR) is going to be a tertiary referral kind of thing? You will have a community program that does straightforward transfemorals, and then if someone needs alternative access, they get sent to a high-volume place like your own? Or do you think that in your data there are transferrable lessons, if you will, kind of in the same way that in the PARTNER experience, the late arriving centers had a shorter learning curve because they were able to benefit from the cumulative experience and education of the centers that had gone before them?

DR HENN: Although this is just one institutional experience, I think it highlights the need to establish some sort of training paradigm, particularly for alternative access. In the future, it is difficult to predict whether or not alternative access procedures are going to be referred to tertiary referral centers, but I think all trainees should be able to be proficient in doing alternative access.

DR SARIN: Thank you.

DR TOM C. NGUYEN (Houston, TX): The 25- to 50-case plateau, although it seems like a low number, is actually a pretty high number. With decreasing sheath sizes, it is rare that we do a TAVR through either a transapical or transaortic approach. In programs that are not able to reach that 25 to 50 number, what is your recommendation for them? Should they not be doing TAVR, or should they just refer the patient to a tertiary care center?

DR HENN: That is a great question. I think we will see more programs in that situation, and the question of whether they should be referred to a tertiary referral center is, I think, yet to be answered. However, it is important for trainees to have exposure to all access approaches moving forward.