# 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.

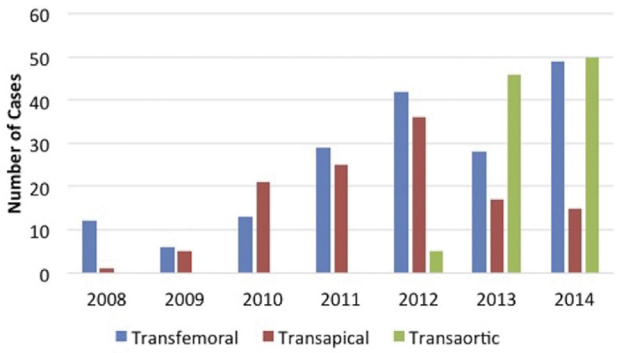


*Fig 1. Access approach—transfemoral (blue bars), transapical (red bars), or transaortic (green bars)—by year.*

### *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 $\chi^2$ 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).