Learning curves for transapical transcatheter aortic valve replacement in the PARTNER-I trial: Technical performance, success, and safety

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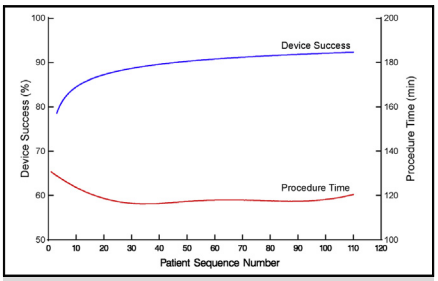
ABSTRACT

Objectives: Introduction of hybrid techniques, such as transapical transcatheter aortic valve replacement (TA-TAVR), requires skills that a heart team must master to achieve technical efficiency: the technical performance learning curve. To date, the learning curve for TA-TAVR remains unknown. We therefore evaluated the rate at which technical performance improved, assessed change in occurrence of adverse events in relation to technical performance, and determined whether adverse events after TA-TAVR were linked to acquiring technical performance efficiency (the learning curve).

Methods: From April 2007 to February 2012, 1100 patients, average age 85.0 ± 6.4 years, underwent TA-TAVR in the PARTNER-I trial. Learning curves were defined by institution-specific patient sequence number using nonlinear mixed modeling.

Results: Mean procedure time decreased from 131 to 116 minutes within 30 cases ($P = .06$) and device success increased to 90% by case 45 ($P = .0007$). Within 30 days, 354 patients experienced a major adverse event (stroke in 29, death in 96), with possibly decreased complications over time ($P \sim .08$). Although longer procedure time was associated with more adverse events ($P < .0001$), these events were associated with change in patient risk profile, not the technical performance learning curve ($P = .8$).

Conclusions: The learning curve for TA-TAVR was 30 to 45 procedures performed, and technical efficiency was achieved without compromising patient safety. Although fewer patients are now undergoing TAVR via nontransfemoral access, understanding TA-TAVR learning curves and their relationship with outcomes is important as the field moves toward next-generation devices, such as those to replace the mitral valve, delivered via the left ventricular apex. (J Thorac Cardiovasc Surg 2016;152:773-80)



Device success increased and procedure time decreased within 30 to 45 cases.

Central Message

The learning curve for TA-TAVR did not compromise patient safety.

Perspective

The learning curve for TA-TAVR was 30 to 45 cases and technical competence was achieved without compromising patient safety. Although fewer patients are undergoing TAVR via non-TF access, understanding TA-TAVR learning curves and their relationship with outcomes is important as the field moves toward next-generation devices delivered via the left ventricular apex.

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The nonlinear mixed-effects models were developed with support from National Institutes of Health grant 1R01HL103552-01A1, Ancillary Comparative Effectiveness of Atrial Fibrillation Ablation Surgery.

Data used for this study were from a December 20, 2012, locked data extract provided to the PARTNER Publications Office by Edwards Lifesciences. These data have been approved for use in research by institutional review boards at each institution. All patients provided written informed consent. Data analysis was performed by investigators at Cleveland Clinic, with no sponsor involvement in study proposal or design, analyses, interpretation, or the decision to publish.

Clinical Trial Registration: http://clinicaltrials.gov/ct2/show/NCT00530894; NCT00530894.

Received for publication Oct 6, 2015; revisions received March 30, 2016; accepted for publication April 7, 2016; available ahead of print May 20, 2016.

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0022-5223/$36.00

http://dx.doi.org/10.1016/j.jtcvs.2016.04.028

Abbreviations and Acronyms

AR = aortic regurgitation
PARTNER = Placement of Aortic Transcatheter Valves
TA = transapical
TAVR = transcatheter aortic valve replacement
TF = transfemoral

Scanning this QR code will take you to the appendices, supplemental figures, tables, and video for this article.

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Transcatheter aortic valve replacement (TAVR) has revolutionized treatment of patients with severe senile calcific aortic valve stenosis. As with introduction of any complex procedure, particularly one requiring a team approach, a set of skills must be mastered to achieve technical competence: the learning curve.[1,2] To date, the time necessary to traverse this learning phase for transapical (TA) TAVR remains unknown, and it is uncertain whether this learning curve compromises successful valve replacement and patient safety.

International TAVR trials have been designed to mandate a "transfemoral (TF) first" access strategy, with alternative access, such as the TA approach, reserved for patients with severe peripheral vasculopathy.[3,4] Because clinical risk factors associated with peripheral vascular disease may preclude TF access, understanding learning curves associated with TA-TAVR is necessary to ensure this procedure is performed successfully and safely. In this study, we sought to answer the following questions: (1) Was there a technical performance learning curve for TA-TAVR in the Placement of Aortic Transcatheter Valves (PARTNER) I trial? (2) Were there associated consequences during this period, such as occurrence of adverse events early after TA-TAVR? (3) Did the technical performance learning curve compromise successful valve replacement and patient safety?

METHODS

Patients

From April 2007 to February 2012, 1100 patients from 24 PARTNER-I trial institutions underwent TA-TAVR. Average age was 85.0 ± 6.4 years and mean transaortic gradient was 44 mm Hg, with a mean aortic valve area of 0.64 cm^2, consistent with severe senile calcific aortic stenosis. Nearly all patients had peripheral vascular disease (98%), hypertension (96%), and hyperlipidemia (87%), and 51% had undergone previous coronary artery bypass grafting and 46% previous percutaneous coronary intervention; 43% had cerebral vascular disease, 45% chronic pulmonary disease, and 36% diabetes (Table E1). Median number of cases performed per institution was 48, with 2 the lowest and 112 the highest (Figure E1). Because prevalence of TA-TAVR steadily increased during the PARTNER-I trial (Figure E2) and the interval between TA-TAVR cases decreased at nearly all institutions, that is, institution volume increased (Figure E3), we included all as-treated TA-TAVR patients who were part of both randomized and nonrandomized cohorts (Table E2).

Study Device and Procedure

The Edwards SAPIEN transcatheter heart valve system (Edwards Lifesciences, Irvine, Calif) used in the PARTNER-I trial consisted of a trileaflet bovine pericardial valve (model 9000TFX) and a balloon-expandable, stainless steel support frame. Technical details of TA-TAVR have been previously described.[5] The procedures themselves were performed by the institution's own team. An experienced industry technical representative was also in attendance for each case, along with qualified interventional cardiologists. Cardiac surgery proctors observed, on average, the first 3 procedures.

Study Design

This is an as-treated analysis. Before start of the PARTNER-I trial, 40 patients underwent TA-TAVR with the SAPIEN device at 3 institutions: Columbia University (n = 13), Cleveland Clinic (n = 12), and Baylor Health Care System (n = 15). For purposes of learning curve analyses, sequential numbering of patients for these 3 institutions was adjusted to reflect the number of procedures that had been performed before the PARTNER-I trial; however, patient-level data were unavailable for these 40 patients. To illustrate, 12 patients underwent TA-TAVR at Cleveland Clinic before the trial, so patient sequence number for analysis started at 13.

Data

Data used for this study were from a December 20, 2012, locked data extract provided to the PARTNER Publications Office by Edwards Lifesciences. These data have been approved for use in research by institutional review boards at each institution. All patients provided written informed consent.

Endpoints

Technical performance. Among the many technical performance measures for which learning curves were assessed, we selected those that would illustrate technical efficiency and the influence on the learning curve of accumulating external experience: procedure time, fluoroscopy time, contrast volume used, and number of postdeployment dilatations. Procedure time was the time from surgical incision until incision closure. Influence of external experience on technical performance was assessed by the institution's date of entry into the trial.

Outcomes. Intra- and postprocedure events assessed included device success, adverse events occurring during the procedure, length of postprocedure hospital stay, and major adverse events occurring within 30 days. All were adjudicated by a clinical events committee and defined as follows:

1. Device success: Delivery and deployment of the prosthesis and retrieval of the delivery catheter, resulting in an aortic valve area larger than 0.9 cm^2, with less than 3+ aortic regurgitation (AR) in the earliest evaluable echocardiogram and only a single valve deployed and implanted in the correct anatomical position. Even if another valve was required that successfully treated, for example, severe paravalvular leak, this was classified as device failure. This definition closely parallels that of the Valve Academic Research Consortium.[6]
2. Adverse events during procedure: Intraprocedural events included vascular hemorrhage, bleeding, arrhythmia, hypotension, conduction defects, abnormal laboratory values, and paravalvular leak (Table E3). Definitions of these adverse events followed PARTNER-I trial protocol definitions.[7]