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EDITORIAL COMMENT

Lessons From the Learning Curve*

Peter C. Block, MD

Atlanta, Georgia

Transcatheter aortic valve insertion (TAVI) has taken center stage, but TAVI is not easy to do, has limitations, and is a complex procedure requiring multiple operators. Thus, interventional cardiologists, cardiac surgeons, echocardiographers, anesthesiologists, and vascular surgeons have formed "teams" that come together to work in hybrid operating rooms or catheterization laboratories to perform TAVI in what have been selected investigational centers in the United States. Published results of the first U.S. trial and, of course, multiple reports from European centers, which have had the opportunity of using TAVI for far longer, have uniformly supported the notion that TAVI is successful therapy for selected patients. But there is no free lunch—TAVI has associated risks of stroke, vascular complications, heart block, and so on. So, the questions are "How difficult is TAVI really?"; "How does experience with TAVI influence risk?"; and "With experience, does TAVI become 'easy' enough so that it can be performed by large numbers of practitioners?" In short, "What is the learning curve for this procedure?"

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In this issue of *JACC: Cardiovascular Interventions*, researchers from the Mayo Clinic report on "Transcatheter Aortic Valve Implantation: Assessing the Learning Curve" (1), which begins to give us some insight into the answers. The analysis of data from 44 patients does not tell us about patient outcomes but does give us considerable insight into the TAVI procedure itself. Patients were divided into early, mid, and latest tertiles. Since each tertile had only 14 or 15 patients, percentage differences in baseline characteristics between tertiles are not meaningful, though the uniformity of the echocardiographic variables across tertiles indicates that patients were similar. The most intriguing part of the report shows scatter plots of contrast volume, fluoroscopy time, and time from valvuloplasty to valve deployment versus patient number. In their report, as TAVI experience increases, there are smaller variable ranges, with a "smoothing" of the curve. The operators at Mayo became progressively "better" at doing the TAVI procedure, and the authors conclude that it takes about 30 cases to achieve proficiency. Significant decreases in median contrast volume, valvuloplasty to valve deployment time, and fluoroscopy time occurred from the first to third tertile. Intertertile 30-day outcomes are not different, and the implication of decreased complications over time is not shown by their data. A recent report from the Vancouver, BC, group (2) showed improvement in TAVI 30-day mortality with increasing experience, but arguably this was due to better case selection rather than to operators being more proficient with the procedure.

Aside from the information that operators doing TAVI need about 30 cases to become "better," I feel that there is an additional message in the Mayo report. The data allow a peek into the near future that may be either troubling, or not. The Edwards Sapien transcatheter valve (Edwards Lifesciences, Irvine, California) was given Food and Drug Administration (FDA) approval for treatment of selected nonoperative candidates with aortic stenosis, on November 2, 2011. The Mayo data should add fuel to the fire of what happens now. If it takes 30 cases to achieve procedural proficiency and ultimately that relates to patient outcomes, we should consider what might happen. The number of sites that plan on performing TAVI now that a device is FDA-approved is unknown. Projections have been as high as 4 or 5 new sites per state. With approximately 100 sites already doing TAVI in the United States, the total number of sites performing TAVI will be around 350. If that number holds up, around 7,500 patients will be part of the learning curve as additional site operators become "proficient." That also assumes that becoming "proficient" is not influenced by the time span in which those 30 learning-curve patients per site actually have their TAVI. In addition, we know nothing about how proficiency, once achieved, will be maintained—particularly by low-volume operators. If there were innumerable TAVI candidates out there for the proposed TAVI sites, it would not be an issue, but there are not. Estimates of how many total patients might undergo TAVI once a device is approved is fraught with error, but 25,000 to 30,000 patients per year (at least for the first few years after approval) seems reasonable. If 1 or possibly 2 sites per state continue as high-volume sites (100 cases/year), those 100 sites will account for at least 10,000 cases per year. That leaves about 15,000 cases to be divided among 200 sites (or 75 cases/year/site), but it is highly unlikely that distribution of patients among sites will be equal. Some sites will do more, and many will do fewer cases. Assuming 2

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From the Department of Cardiology, Emory University Hospital, Atlanta, Georgia. Dr. Block is a participant in the PARTNER trials and Emory University is an investigational site for the PARTNER trials sponsored by Edwards Lifesciences; he is also a consultant for Medtronic and DirectFlow Medical, and has equity in DirectFlow Medical.

operators need to be "competent" per site, an operator will do <1 case/week in a best-case scenario, but many sites will have TAVI volumes far lower. Is this acceptable and safe? Designation of "inoperable" patients, which will likely be mandated by the FDA as appropriately treated with TAVI (at least for now), will be strict and further limit patient accessibility as will the presence of peripheral vascular disease, which may decrease potential patient numbers further. If one now returns to the Mayo "Learning Curve" data (1) for procedure proficiency, under this scenario, it may take more than a full year for an operator to become procedure "proficient." The question of maintenance of proficiency is totally unanswered at present.

So what does all this boil down to? The FDA, the Society of Thoracic Surgeons, and the American College of Cardiology have all supported limiting the number of U.S. centers, center certification, minimum volume requirements, and operator credentialing. There will clearly be tension between centers that are already doing TAVI and those that simply cannot be credentialed—causing a have/have-not environment. How all this will play out over the next year should concern every center and operator contemplating the addition of TAVI to their list of available therapies. My feeling is that many centers that would like to do TAVI now that a device is approved will quickly recognize that putting together the personnel and facilities is only a first step. Doing TAVI well is a second hurdle, as pointed out by the Mayo paper. Third, caring for complex patients with aortic stenosis and multiple comorbidities is labor intensive, resource rich, and time consuming. Lastly, whether reimbursement for TAVI will even begin to cover the cost of the enterprise remains to be seen. TAVI may well be a center-stage diva, but it is also a jealous, high-maintenance mistress. It should be an interesting roll out.

Reprint requests and correspondence: Dr. Peter C. Block, Department of Cardiology, Emory University Hospital, 1364 Clifton Road, North East, Suite 606, Atlanta, Georgia 30322. E-mail: pblock@emory.edu.

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