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Editorial

Disseminating TAVR Across the World – And Optimizing Outcomes While It's Done

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Over the past 20 years, it is hard to imagine a more transformative therapy within cardiovascular medicine than transcatheter aortic valve replacement (TAVR). From the first case performed in April 2002 to the pivotal trials, overseas adoption, FDA approval, device iteration, technique evolution, and guideline recommendations, TAVR has become a standard and increasingly routine therapy for a growing proportion of patients with trileaflet aortic stenosis. Undeniably, the evolution of TAVR is a testament to partnerships between the various members of multidisciplinary teams, carefully designed and executed clinical trials, genuine critical appraisal, and steadfast drive to improve technology, procedural performance, and patient outcomes.

It is no surprise that regional TAVR adoption over the past decade has correlated closely with the timing of regulatory body approval and payor reimbursement. As seen in Europe with early commercialization from 2007 through 2011, the number of patients treated and treating centers increased, with 445 patients treated at 37 centers in 2007 and 14,946 patients treated at 342 centers in 2011 [1]. The same trends were seen in the United States. After formal FDA approval of TAVR in 2011, the number of patients treated and treating centers increased, with 4627 patients treated at 198 centers in 2012 and 24,808 patients treated at 414 centers in 2015 [2]. With expanding indications and improved technology, between January 2015 and December 2017, 113,662 patients were treated at 555 United States centers [3].

A particular concern after commercialization and widespread adoption of any technology is whether the outcomes seen in the pivotal trials leading to approval can be replicated in real-world application. To this end, regulatory bodies, insurers, and societies alike have worked together to propose and stipulate operator and institutional requirements, multidisciplinary evaluation and procedure performance, and reporting in national registries in order to understand trends and optimize outcomes [4–8]. Arguably, these instruments have been successful, as real-world outcomes have been similar to the pivotal trials and continue to improve over time [2,9].

In the current issue of the journal, Yamamoto and colleagues report TAVR outcomes in Japan collected through the Optimized CathEter vAlvular iNtervention (OCEAN) Japanese Multicenter Registry. In October 2013, TAVR was officially approved in Japan for patients with aortic stenosis at elevated risk for surgical aortic valve replacement. For all 14 centers performing TAVR, the Pharmaceuticals and Medical Device Agency (PMDA) mandated minimum training, screening and proctored cases. The balloon-expandable prosthesis (Sapien XT, Edwards LifeSciences, Irvine, CA) was initially approved, with subsequent iteration to Sapien 3, and the self-expanding prosthesis (CoreValve, Medtronic, Minneapolis, MN) was approved in January 2016. For purposes of reporting and comparison, the authors divided their collective experience of 1613 cases at these 14 centers into quartiles of both experience and time (with each quartile comprising just over 400 patients) [10].

The 1613 TAVR procedures were performed between January 2013 and July 2016 with the majority of patients receiving treatment with the Sapien XT device (82.3% Sapien XT, 8.7% Sapien 3, 8.9% CoreValve). Corresponding to device iteration and smaller access sheaths required to perform TAVR, the percentage of patients undergoing transfemoral TAVR increased over the study period from 77% to 84.6% ($p<0.001$). Annular rupture occurred in 16 cases (1%) overall, and moderate to severe paravalvular insufficiency occurred in 9% of cases, with a 0.8% occurrence of severe insufficiency. Thirty-day mortality overall was 1.9% and did not differ between quartiles, while 30-day non-safety (defined as combination of mortality, stroke, life-threatening bleeding, acute kidney injury stage 2-3, coronary obstruction requiring intervention, major vascular complication, and valve-related dysfunction requiring repeated intervention) improved from quartile 1 to quartile 4, and this improvement was statistically significant with regard to both operator experience and time [10].

In essence, this report summarizes the early Japanese experience with TAVR. However, and arguably of greater importance, it addresses

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a mechanism for introduction of technology that is associated with impressively successful outcomes. The PMDA outlined requirements for these 14 centers to begin treating patients. Training requirements, live screening of the early cases and global proctoring brought the collective worldwide experience to Japan. Proactively, this had the goal of smoothing out the learning curve associated with novel technology, and it appears to have been effective. From the beginning in January 2013 and across four quartiles of time and experience, overall complications improved over time while mortality rates were low and essentially unchanged [10].

The results presented in the OCEAN registry are both interesting and relevant. A learning curve clearly existed with regard to procedural complications (non-safety outcomes). While the relative influence of operator, institutional, or national learning is not specified, it stands to reason that a combination of all levels was manifest. However, 30-day mortality was low and unchanged across all quartiles. This latter point is likely the result of the deliberate roll-out the PMDA mandated with regard to didactics, screening, and proctored cases. Additionally, the low mortality throughout distinguishes the Japanese experience from previously published examples in which both morbidity and mortality learning curves were noted [11,12].

The reported experience is relavent in our current environment. With further evolution of indication toward lower-risk patients, the bar continues to rise, and the premium on optimal outcomes is constantly increasing. At the same time, the availability of TAVR continues to spread across the world, from high-volume centers with experienced operators to lower-volume centers with new operators. This can be a good thing, as underserved geography and/or populations will ultimately have access to treatment, but it also carries potential negatives. Over time, the societies have partnered to put forth minimum operator and institutional requirements [5,7], which the regulatory bodies have largely adopted as eligibility criteria for reimbursement [13]. This is a clearly positive in that it demonstrates the ability of the professional societies to come together and make meaningful recommendations that regulators and insurers are willing to embrace. The potential negative is that arbitrary cutoffs are often surrogates for true quality, and they occasionally obscure the underlying motivations for these requirements. That said, volume-outcome relationships in TAVR are well enough established to justify minimum standards [3].

On balance, the OCEAN registry summarizes the Japanese experience with TAVR over the first 42 months after approval by the PMDA. It serves as another example of a procedural learning curve, but it also demonstrates that good outcomes with regard to morbidity and mortality can be achieved with new sites when appropriate teaching, screening, proctoring, and reporting are in place. As TAVR becomes more ubiquitous and available to lower-risk patients across the world, experiences like that in Japan can serve as an example to emulate.

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