Point/Counterpoint: Does the United States Have Enough TAVR Centers?

TAVR HAS MATURED AND IS READY FOR MANY MORE UNITED STATES SITES

BY PAUL J. PEARSON, MD, PHD

In deep sea diving, when a panicked diver rushes to the surface without undergoing decompression, the ultimate outcome has already been determined before the unfortunate diver makes his first step on the apparent safety of the dive boat. All discussions about clinical status are irrelevant as Boyles law sets up the catastrophic momentum of gas insolubility, stoke, and cardiovascular collapse. In a similar but less dramatic fashion, a momentum has already started that will guarantee the dissemination of transcatheter aortic valve replacement (TAVR) to many more United States sites. Ironically, this momentum is built upon the complex system of checks and balances that were set in place when TAVR was first introduced into the United States through national clinical trials—systems that will make arguing about volume minimums and institutional requirements for TAVR increasingly less relevant.

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PROLIFERATION OF APPROVED TAVR CENTERS IN THE UNITED STATES: RATIONAL DISPERSION RUN AMOK

BY D. CRAIG MILLER, MD

While high-risk patients with aortic stenosis (AS) were enrolling in the randomized PARTNER IA trial comparing TAVR with AVR,[1,2] Holmes and Mack, perspicacious leaders of the American College of Cardiology and Society of Thoracic Surgeons, posited, "In order to address the challenges ahead for the responsible diffusion of this innovative transformational technology, it is critical that the professional societies, industry, payers, and regulatory agencies work together."[3,4] This germinated the seed to mandate multidisciplinary heart valve teams (MDTs) to ensure that all facets of the patient selection and diagnostic process, TAVR technical performance, and postoperative management were optimized, including a United States national registry. This notion included restriction of TAVR devices and reimbursement only to centers that met the criteria to be established. The American Association for Thoracic Surgery (AATS) and Society for Cardiovascular Angiography and Interventions (SCAI) joined this effort in a multisociety expert consensus statement[5] published in 2012, which led to the Centers for Medicare and Medicaid Services (CMS) Decision Memo for Transcatheter Aortic Valve Replacement (TAVR) CAG-00430N, published on May 1, 2012, the CMS "National Coverage Decision" (NCD).[6] For the first time, commercial use of an US Food and Drug Administration (FDA)-approved device or drug would be monitored such that appropriate use and outcomes could be analyzed under the aegis of the STS-ACC Transcatheter Valve Therapy Registry (TVT).

The unwritten premise was that CMS would not continue hospital or physician TAVR reimbursement if outcomes in various patient subsets, from specific hospitals, or those performed by specific operators did not meet a reasonable quality outcome metric at 30 days and 1 year.

This NCD contained qualifying requirements to begin a TAVR program, including hospital infrastructure and commitment and clinical volume minimal prerequisites (eg, 1,000 catheterizations, 400 PCIs, 30 left-sided structural interventional procedures, and 50 AVRs in the past year), as well as ongoing minimum TAVR volumes (20 cases per year, or 40 over 2 years).[6] Importantly, the TAVR approval process relied solely on individual hospitals self-reporting their volumes of requisite procedures without any verification or audit mechanism. This constituted the foundation for "rational dispersion"[3,4] of this new technology to ensure that TAVR was accomplished safely and performed in properly selected patients who were likely to benefit in terms of quality of life and survival.

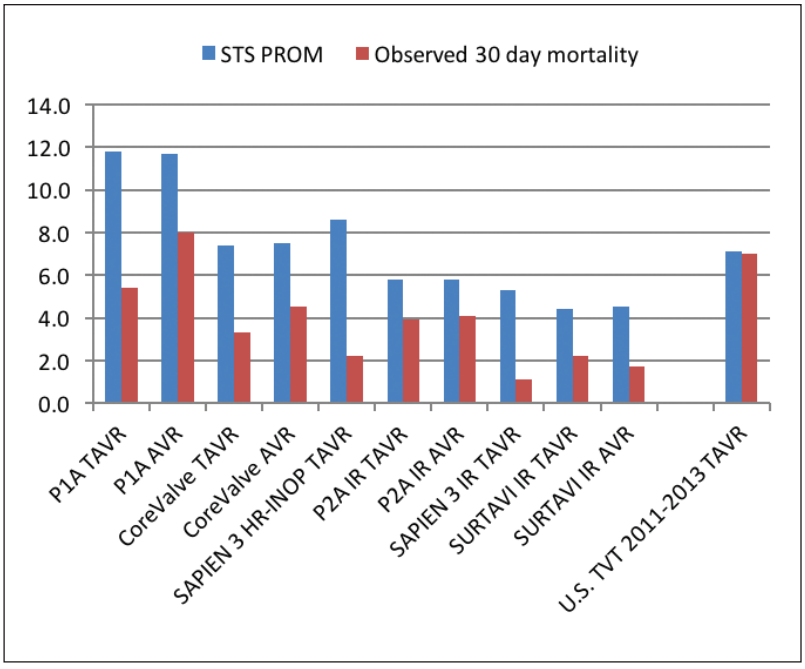

Figure 1. Thirty-day STS PROM expected mortality rates (surgical AVR) and observed 30-day mortality rates for TAVR and open AVR in various TAVR trials and the 2011-2013 initial TVT US-wide commercial TAVR experience.

WHAT EARLY TAVR TRIALS SHOWED

The initial TAVR controlled trials included only a small number of carefully selected institutions in the United States (17 in PARTNER IB, 25 in PARTNER IA, 41 in the CoreValve extreme-risk study, and 45 in the CoreValve high-risk trial). Previous TAVR experience before commercialization was important as all new centers experienced a steep initial learning curve, ranging from 25 to 90 cases. Whereas the observed-to-expected (O:E) 30-day mortality rates for TAVR (using the STS Predicted Risk for Operative Mortality [PROM] score for open AVR as the denominator) in the early high-risk trials were remarkably low considering how old and sick these patients were (PARTNER IA: STS PROM = 11.8, O:E = 0.46; CoreValve pivotal trial: STS PROM = 7.4, O:E = 0.45), the commercial introduction of TAVR across the United States was not nearly as salutary.[7] In the initial 20 months of United States commercial experience from November 2011 to June 2013, 12,182 patients who could be CMS-linked underwent TAVR with the Sapien transcatheter heart valve (THV; Edwards Lifesciences) in 299 hospitals. The average STS PROM score was 7.1, despite the fact that only inoperable and prohibitive-risk patients were FDA-approved until October 2012, when the Sapien THV was approved for high-risk patients. Despite selecting centers based on NCD requirements and tremendous investment from industry in terms of education and proctoring, the 30-day O:E mortality ratio was 0.99,[7] more than double what it had been in the trial experience (Figure 1).

This indicated that nationwide there was no early survival advantage to TAVR over AVR. It is unknown whether technical learning problems or poor patient selection was responsible for these unsatisfactory results. Even though the average STS PROM score for these initial TVT patients was far lower than that in the PARTNER IA trial, 1-year overall mortality in this early TVT experience was 23.7%, similar to that for PARTNER IA higher-risk patients. The CoreValve (Medtronic) was approved in January 2014. Early on, centers were competing for the same very high-risk patients to establish themselves as a TAVR hospital; it is likely that this enthusiasm led to "cohort C" patients receiving a TAVR, a mistake that hopefully was identified and corrected over time. For example, within the TVT registry, TAVR patients on dialysis or with a creatinine > 2 (end-stage renal disease [ESRD]) had a dismal prognosis, with 1-year mortality rates of 46% and 33%, respectively, compared to 25% for patients with a creatinine

< 2.[8] These poor results or even worse outcomes were corroborated by others,[9] prompting many experienced TAVR centers to deny TAVR to patients on dialysis or with ESRD, as it is futile.

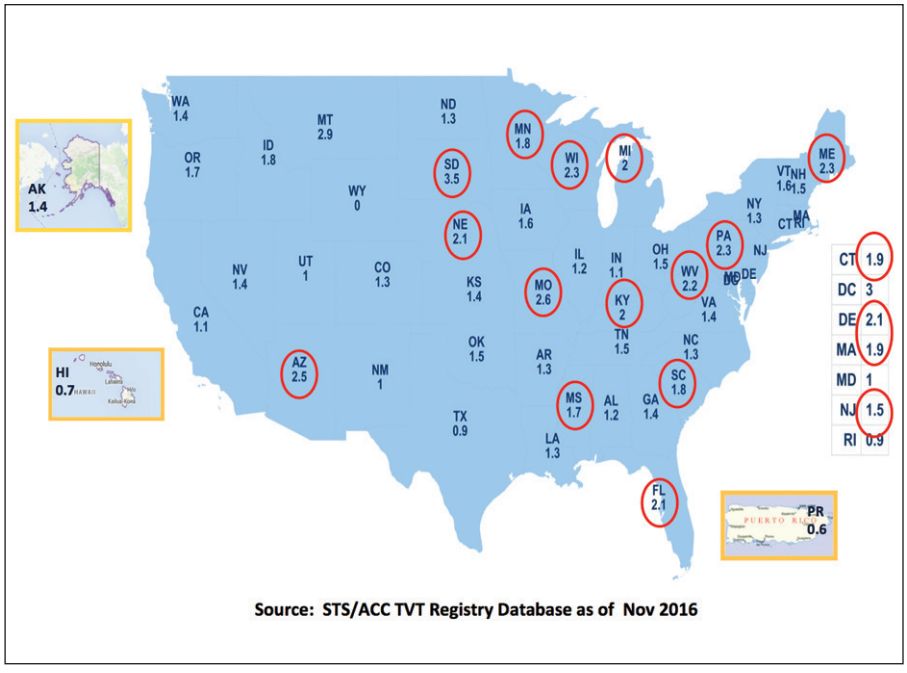

Figure 2. Number of approved TAVR centers by state per million population in 2015.

TOO MANY TAVR CENTERS

The number of "approved" TAVR centers has grown exponentially from 156 in 2012 to 511 now; an estimated 35,000 patients underwent TAVR in the United States in 2016. Whether this approval process aimed at "rational dispersion" of TAVR has been effective is dubious. Efforts are underway today using the NCDR and STS databases to audit the case numbers of AVR, PCI, and left-sided interventional procedures submitted by hospitals when they applied for TAVR approval; whether CMS will act when these validated numbers become known remains unknown, as is whether reimbursement for TAVR will be denied at centers who do not meet the 20 TAVR/y minimum volume threshold. The revised 2017 CMS NCD will most likely establish a 50 TAVR/y minimum volume threshold. Doing less than one TAVR case a week does not make sense in terms of optimizing collaboration, communication, and technical skills of the entire team. The number of centers has expanded tremendously, but most are not busy enough. In 12 states there are more than two TAVR centers per million population and Washington, DC has three centers per million (Figure 2); not what one would call "rational dispersion."

Even considering that intermediate-risk AS patients are now eligible for TAVR pivoting on the deliberations of the MDT, this number of centers will probably dilute quality, compromise patient selection, impair outcomes, and result in futile TAVRs being done in "cohort C" patients. The extreme case of Germany's explosive TAVR growth pattern (13,264 TAVR in 2014 for a population of 81 million, or 164 TAVR procedures/million inhabitants, a penetration rate exceeding 50%–60%)[10] illustrates a more reasoned approach both medically and economically. TAVR was performed in about 100 centers in Germany and averaged 132 TAVR cases/center per year; 25% of these centers performed fewer than 100 cases a year, while 21% performed more than 500 per year. The number of centers decreased in 2016 when TAVR in hospitals without cardiac surgery was banned; if 90 hospitals performed TAVR, there would be one center for every 900,000 people in Germany. Given the recent GARY registry findings[11] that a substantial minority of patients did not benefit from TAVR at 1 year, TAVR volume is likely to decrease in Germany as patient selection becomes more strict. If one assumes that half of the 2014 peak German TAVR volume is appropriate use, the need in the United States is 26,240 TAVR procedures per year. Five hundred United States centers dividing this volume equally means a TAVR volume of only 53/y per center. Including intermediate-risk patients, the peak German rate might be more germane: 52,480 TAVR procedures, or 105/y per center if 500 TAVR centers exist. Applying the current German model would mean about 350 centers in the United States, ample for satisfactory geographical access.

WHAT RESULTS CAN BE EXPECTED FROM LOW-VOLUME TAVR CENTERS?

The effect of hospital TAVR volume on outcome in the TVT registry was examined by O'Brien et al[12] and by Carroll and colleagues.[13] O'Brien's report focusing on variation in hospital mortality risk during 2011 to 2014 estimated hospital-specific risk-adjusted mortality rates (RAMR)

adjusting for 40 patient baseline factors.[12] A total of 22,248 patients underwent TAVR at 318 sites. Because 30-day vital status was missing in 20% of patients, only hospital death (5.1%) was analyzed. Quality-of-life (QOL) assessment was not possible because the baseline KCCQ and 5-m walk test were missing in approximately 50% of patients. The annualized median number of TAVR cases performed in each hospital was only 19 (interquartile range, 7–31), meaning that half of the hospitals did not meet the CMS NCD-stipulated annual minimum volume threshold.[6] Reliability-adjusted RAMR estimates ranged from 3.4% to 7.7%. The odds of dying for an individual patient were 80% higher if treated in a hospital one standard deviation below the mean compared to a hospital one standard deviation above the mean (odds ratio = 1.8; 95% credible interval, 1.4%–2.2%). Carroll et al[13] studied 42,988 TAVR patients treated at 395 hospitals by 1,927 operators (2011–2015). The annual TAVR volume was low, the median cumulative number of TAVRs performed per site was 80 (roughly a median of 20 TAVR cases/year), and the 25th and 75th percentiles for TAVR volume were 39 and 154 over 4 years. Incremental TAVR volume was assessed using a successive quartile model that compared the earliest cases across all centers, but only 119 hospitals contributed to the highest volume quartile statistics. Higher procedure volume was associated with lower in-hospital risk-adjusted rates of mortality ($P < .02$), vascular complications ($P < .003$), and bleeding complications ($P < .001$), but not stroke. The rate of most adverse outcomes declined after a hospital had performed around 100 TAVR procedures.

WHAT IS DRIVING THIS TSUNAMI OF NEW TAVR CENTERS?

It is unlikely to be a financial motive because almost all American hospitals actually lose money on TAVR, no matter how streamlined or "minimalist" they make the process. Market forces—hoping to capitalize on a TAVR program attracting more surgical AVR volume—may have been relevant years ago, but are moot today. Is it physician ego and marketing hype? This explosion of low-volume TAVR centers certainly is not based on the collective desire to concentrate special expertise, experience, and skill sets that will translate into better clinical outcomes and more rigorous patient selection, all of which will make the economic incremental cost-effectiveness ratio (ICER) more favorable for society. Given the much higher costs of TAVR over AVR, Reynolds et al stated, "The cost effectiveness of TAVR from a societal perspective is strongly affected by the presence or absence of a mortality benefit with TAVR."[14] Unless there is a difference in life years or quality-adjusted life years (QALYs) gained after TAVR versus surgical AVR, which is exceedingly unlikely for intermediate- and low-risk AS patients, the ICER will never favor TAVR from the standpoint of "society's willingness to pay," especially in an era when the United States is spending an unsustainable 19% of its gross domestic product on health care.

Coexistent diseases, such as dialysis, ESRD, recent stroke, untreated coronary artery disease, severe pulmonary disease, severe pulmonary hypertension, severe mitral regurgitation, active neoplasms, endocarditis, etc., were exclusion criteria in the trials. Even excluding these sicker patients, the all-cause 5-year mortality rates of TAVR patients in the PARTNER IB and PARTNER IA trials were 72%[15] and 68%,[16] respectively. These extremely high attrition rates reflect how old and sick these individuals were, and raise the question of whether this expensive, disruptive intervention was futile in many cases. One can logically argue that the 20% to 30% of patients who died in the first year after TAVR in the trials actually were "cohort C" patients who should not have been offered TAVR.[16] We must learn from our mistakes. To quote John Webb, "It's becoming more and more our job not to do the patients we did earlier" (personal communication, London PCR Valves, 2011).

Indeed, an investigation of poor outcome (combined lack of functional benefit, poor QOL, or death) by Arnold et al was eye opening in showing that one-third of 2,137 patients in the PARTNER I trial population had a poor outcome by 6 months.[17] Among 2,830 patients in the CoreValve US Pivotal Extreme and High Risk trials, it was sobering to learn that 51% experienced a poor outcome at 1 year (death in 30%, poor QOL in 20%, and QOL decline in 1%).[18] In the German GARY registry in 2011,[11] improvement in QOL was modest, and a substantial minority of patients reported no subjective or symptomatic improvement. Carabello's editorial evinced strongly that we must be much more selective in offering TAVR to elderly patients with multiple medical problems and procedural denial should not be misconstrued as a personal defeat.[19] Finally, Arnold et al analyzed 45,564 TAVR patients enrolled in the 2011 to 2016 TAVR registry: one-third of the patients had an unfavorable outcome (death or not symptomatically improved) by 1 year.[20] Moreover, KCCQ was missing in 18% of patients at baseline, in 31% at 30 days, and in 56% at 1 year.

Therefore, the MDT must identify patients who are not going to benefit to avoid a futile TAVR, a very expensive end-of-life treatment that does not help patients and is not sustainable financially for society. Several specific diseases or conditions that portend markedly limited life expectancy and much lower likelihood of func-

tional benefit after TAVR have now been identified[9] and must be considered relative if not absolute contraindications to TAVR. These include dialysis, advanced lung disease (especially if oxygen dependent), slow ambulation (6 min walk time < 150 m), atrial fibrillation, poor left ventricular systolic function (LVEF < 30%, LVSVI ≤ 35 mL/m^2, no contractile reserve with dobutamine stress echocardiography), low aortic gradient, pulmonary hypertension, severe organic mitral regurgitation, and STS PROM score > 15%.[15] Advanced dementia and impaired cognitive ability, active cancer, marked musculoskeletal disability, debilitating frailty, and severe cachexia and sarcopenia are other conditions where not offering TAVR is the wisest option, as extending the lives of these patients would only prolong their suffering. As Hlatky has said, " … if transcatheter AVR merely prolonged a miserable existence, it would not be very beneficial to patients."[21] In these circumstances, TAVR should not be offered.

CONCLUSION

As more centers compete for suitable TAVR candidates, patient selection criteria may inappropriately drift both upward and downward. The worst example of this is when a very experienced TAVR institution turns down a "cohort C" patient based on multiple comorbidities that portend that this patient will not benefit from TAVR, and then the family turns to a new eager TAVR center nearby that goes ahead to increase their TAVR volume numbers. The patient does not benefit, and this is financially irresponsible and squanders society's finite resources. Only rigorous analysis of survival and QOL at 1 year or beyond by CMS will determine which patients, which centers, and which operators have outcomes that meet the acceptable quality metric, which should be translated strictly into reimbursement policy. Putting pecuniary and other selfish interests aside and advising "procedural denial" is the responsible and most judicious course of action out of respect for the individual's dignity in many patients. "We have to figure out who is dying from their aortic stenosis and who is dying with aortic stenosis" (Michael Mack, personal communication, London PCR Valves, 2011). Just because TAVR can be done does not mean it should be done; given the unsustainable escalation of health care costs, we physicians must remain responsible stewards of society's limited resources. Not every patient with severe AS needs a TAVR before they die. Restricting reimbursement for TAVR to a smaller number of United States sites to ensure the most stringent patient selection criteria are applied and the best technical expertise is available represents the most rational, sensible, financially responsible, and prudent path forward. ■

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To understand this concept, one must look back to how TAVR was introduced to the United States market, which in the opinion of some, is a case study in success at many levels. It was an introduction that involved the collaboration of physicians, regulators, industry, and insurers. Industry was the biggest stakeholder as careful stewardship was required of billion-dollar corporate investments in the face of a competitive and highly regulated United States medical device market. Industry not only needed to introduce a new technology in an evolving market, but also had to ensure success by demonstrating excellent outcomes in FDA-adjudicated multi-institutional clinical trials. To do this, systems were set up for physician education and training. A dedicated team of physician-proctors imputed experience with intra-procedural coaching, thus leveling out the foreboding learning curve for new procedures. Industry also trained and mobilized a small army of well-educated and trained product representatives to provide technical support at every implantation and ensure proper use of their devices. Industry also made the unprecedented commitment of evaluating the anatomy of every patient undergoing valve replacement to ensure proper valve sizing, evaluating for possible implant complications, such as coronary artery occlusion, and suggested vascular access sites to optimize procedural success. In addition, guidance on optimizing imaging angles used during valve implantation facilitated efficient flow of the procedure.

The results of this approach were nothing short of astounding. In a short period of time, not only was the use of TAVR proven safe and effective for many patient populations in the most rigorously designed clinical trials to date, but government regulators, who were true partners with industry in this intensive scrutiny of TAVR, gave their blessing by ultimately approving commercial TAVR for three large cohorts of patients in the United States: inoperable, high-risk, and intermediate-risk patients.[1]

Not unsurprisingly, when the CMS developed institutional and operator requirements for TAVR reimbursement, they basically mirrored the site-participation requirements of the major clinical trials.[1] This ensured that as commercial TAVR sites developed, this operational variable would be consistent between the study sites and commercial sites. For its part, industry maintained a rigorous support system for TAVR as new programs opened, including intensive training of hospital personnel, physician proctoring, case review, and individual case support by industry representatives—a support system that remains to this day. This resulted in a dramatic increase in United States sites where TAVR was offered as a therapeutic option. One study demonstrated that early after CMS approval of the procedure, nearly four of five Michigan residents lived within 30 miles of TAVR services.[2] However, even though the study did not evaluate or address outcomes of the procedure, and without supporting data, the authors concluded, "Given procedural volume tends to relate positively with outcomes, increased access to TAVR might have negative effects on patient outcomes." The reason for the shift in emphasis of the paper was related to a concern that TAVR should only be performed at designated centers of excellence, volume being the surrogate for quality. An analysis of actual outcomes in the national TVT Registry of 43,000 patients undergoing TAVR at nearly 400 hospitals demonstrated a statistically significant association between procedure volume and mortality (ie, performing a higher volume of TAVR procedures was associated with a lower death rate).[3] The analysis included hospitals performing only a handful of procedures, to more than 600 cases at the highest volume centers, the median number of cases per center being 80. The study had significant limitations, including imperfect adjustments for differences in patient characteristics, the introduction of new technologies, and the "early learning curve" of the TAVR community in general. The early learning curve could not be separated out from the subsequent procedure period, which is commonly used to study volume-outcome relationships. In discussing the findings, the author stated, "Although procedure volume is important, volume is not a direct measure of quality."[4] He went on to state that, "The bottom line is not volume, but the actual outcomes achieved at a center. In general, outcomes at United States centers are excellent. Furthermore, there are some lower-volume centers that have excellent outcomes and some higher-volume centers that do not have the best outcomes."[4] Further stirring the muddy waters of TAVR outcomes and volume was the article by Panaich et al looking at the influence of hospital volume on outcomes of adult structural heart procedures.[5] The authors stated that hospital volume is significantly predictive of lower in-hospital mortality after TAVR. However, in their analysis, the authors arbitrarily divided their quartiles as annual hospital volumes being less than five TAVR procedures per year (first quartile),[5] TAVR procedures per year (second quartile), 11 to 20 TAVR cases per year (third quartile), and more than 20 TAVR cases per year (fourth quartile). Keep in mind that in the study presented by Carroll et al referenced previously, the median number of cases per center in the TVT Registry was 80.[3]

The conclusion in relation to volume is that high volume is good if your outcomes are good, and that a low volume is not necessarily bad if you have good outcomes. While the political and economic interests of high-volume centers will necessarily shape their policy positions on TAVR (and secondarily impact our Society Consensus Statements on TAVR because of their disproportionate representation in leadership), what will ultimately determine the dissemination of TAVR to a greater community presence will be center-specific outcomes. Which brings us back to the role of industry in this equation. Industry still has an enormous stake in ensuring excellent outcomes with their TAVR devices. With intense and growing competition in the marketplace and the presence of mandatory institutional database participation and reporting requirements, comparison of outcomes between different commercial devices is relatively easy, and excellent outcomes with a product will generally translate to increasing market share. Thus, the same platform that industry established to launch successful trial sites is now being utilized to establish and ensure success of community TAVR programs.

During this dissemination of TAVR from academic medical centers to community programs, the procedure itself is also undergoing an evolution. Smaller devices enable safe transfemoral delivery in the majority of cases.[6] High-resolution CT analysis ensures accurate valve sizing and the avoidance of intraprocedure complications, such as valve embolization, paravalvular leakage, annulus or root rupture, and coronary artery occlusion.[7] The ability to reposition some devices can mitigate the impact of malpositioning during valve placement.[8] With the evolution of TAVR to a purely catheter-based, low-risk procedure, the necessity of a cardiac surgeon as a co-operator will also be eliminated. Just as cardiac surgical backup for PCI has evolved from the formal surgical standby in the 1980s to an informal arrangement of first-available operating room today, TAVR will evolve and allow better utilization of hospital and physician resources. In addition, as with PCI, which can now be performed safely at institutions with offsite surgical backup when emergency transport is available, one can envision a time when TAVR might be performed in hospitals without a cardiac surgery team. In a study of TAVR programs in Germany from the beginning of 2013 to the end of 2014, 1,332 patients underwent TAVR at hospitals without onsite cardiac surgical services.[9] Even though patients undergoing TAVR at noncardiac surgery hospitals were older and had more comorbidities than patients at cardiac surgical centers, total procedural complications were lower in the noncardiac surgical centers (8.4% vs 11%; $P = .004$), whereas catastrophic complications, including annular rupture, aortic dissection, and device embolization, were similarly rare (all < 1%). In this study, in-hospital mortality was very high for all patients requiring emergent cardiac surgery for TAVR complications (50% for patients initially treated at noncardiac surgery hospitals and 62.5% for patients treated at hospitals with onsite cardiac surgery).[9]

Although TAVR has matured to a level where it is ready to be expanded to many more United States sites, as is already happening, there will continue to be debate at our national meetings about who should perform TAVR and about institutional requirements for the procedure. And, like the well-meaning physician carefully examining the vital signs of the diver just emergently pulled from the deep, all of the conclusions based on what is now seen are irrelevant. A process is set in motion that cannot be stopped, and TAVR will be coming to a hospital near you. ■

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