

Transcatheter Aortic Valve Implantation. Balancing Enthusiasm and Caution

John G. Webb

Director, Cardiac Catheterization, St. Paul's Hospital, McLeod professor of heart valve intervention, University of British Columbia, Vancouver, Canada.

Initial reports of transcatheter aortic valve implantation (TAVI) were met with a mixture of wonder and skepticism: Wonder that functional valve replacement could be accomplished without thoracotomy and cardiopulmonary bypass, and skepticism as to whether this initial experience would be reproducible and significant clinical benefit could truly be achieved. Early experience consisted of dramatic successes, but also unexpected problems. Nevertheless, TAVI has evolved rapidly into a reproducible procedure with convincing clinical benefits.¹⁻⁴ With the desire of patients for a less invasive option, and of physicians and medical device manufacturers to provide it, dissemination of this technology has been rapid. To date over 10 000 TAVI procedures have been performed, the majority in Europe.

The initial Spanish experience with TAVI has been reported by García et al⁵ and Moreno et al⁶ utilizing the Edwards Lifesciences SAPIEN device, and now by Avanzas et al utilizing the CoreValve device.⁷ These groups are to be congratulated for providing useful

insight into their real world experience. Both the balloon-expandable SAPIEN and the self-expanding CoreValve device have been documented to offer excellent functional results. Until now, SAPIEN valve has required larger femoral arteries than the lower profile CoreValve. However, a newer low-profile SAPIEN XT system is just now becoming available and an apical option may offer other advantages. The CoreValve system has a higher incidence of heart block requiring pacemaker implantation. There are many advantages and disadvantages to each system and the debate as to which system is better rages on. Regardless, both systems are evolving and new valve systems are coming. It is unlikely that either technology will retain the lead for long.

Avanzas et al report that their hospital mortality of 7.4% was “lower than the result obtained by applying the algorithm of the EuroSCORE (average 17%).”⁷ While this mortality rate is very encouraging, it is still important to acknowledge that good surgical centers may achieve mortality rates one third those predicted by logistic EuroSCORE estimates.⁸

Although EuroSCORE modeling may overestimate surgical risk in many patients, in some patients it may greatly underestimate risk.⁹ For instance, a 60-year-old patient with severe aortic stenosis, severe mitral and tricuspid regurgitation, chest irradiation, a calcified and atheromatous ascending aorta, malignancy and coagulopathy can plausibly have a logistic EuroSCORE of 2.2%, and yet might well be considered “inoperable.”

Other risk algorithms, such as the Society of Thoracic Surgeons (STS), may be more accurate risk predictors but all suffer from significant limitations.⁹ At the end of the day, an experienced surgeon is often the best predictor of surgical risk. Early data also shows that these surgical risk predictors bear little relevance to the risk associated with TAVI.^{10,11} New tools to evaluate transcatheter risk are needed. Moreover, the potential for reduced morbidity with a less invasive procedure may be more important to many elderly patients than the risk of mortality.

To provide perspective, 30-day mortality fell dramatically from 12.3% in the first half to 3.6%

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Disclosure: Dr Webb is a consultant to Edwards Lifesciences.

Correspondence: Dr J. G. Webb,
McLeod professor of heart valve intervention, St. Paul's Hospital, 1081
Burrard Street, Vancouver, BC, Canada V6Z 1Y6
E-mail: webb@providencehealth.bc.ca

in the second half of our early transarterial single center experience in high risk patients with aortic stenosis.¹¹ This compares with a mortality estimate of 25% with logistic EuroSCORE and 9% with STS had these patients undergone surgery instead. In the recently SOURCE EU post-marketing registry 463 patients underwent transarterial TAVI with a 30 day mortality of 6.3% (logistic EuroSCORE, 25.7%).¹² Similar results have been reported with the CoreValve registry.¹³

Beyond anecdotal reports and prospective, registries, randomized comparisons will be needed to understand the appropriate place of this new technology. The Placement of Aortic Transcatheter Valves (PARTNER) trial is a randomized comparison of TAVI versus the clinically available alternative, whether conventional surgery or medical management. Enrolment is now complete, with randomization of over 1000 high risk patients from 24 North American centers. While this study will suffer from the limitations of a first generation device and a steep learning curve, it will likely influence the availability and funding of TAVI for some time. Although the primary endpoint will be all-cause mortality at one year, the standards of surgical valve replacement will require much longer follow-up to document durable benefit.

Although durability remains to be proven, the valve-in-valve option may offer a reassuring strategy should transcatheter valves fail. Early experience with transcatheter valve implantation within failed surgical (and transcatheter) valves has now been accomplished in the aortic, mitral, pulmonary and even the tricuspid position.¹⁴ There are limitations in that the internal diameter of many surgical prostheses may be too small for full expansion of transcatheter heart valves. Moreover, current valves are not optimized for this application and their function and durability will be compromised. However, initial results are very encouraging and the appeal of a transcatheter procedure in preference to redo surgery may prove compelling. We may already be seeing a trend towards surgical selection of tissue, as opposed to mechanical, prostheses in anticipation of future valve-in-valve implants should late problems develop.

What then is the future of TAVI? It is likely that the profile of transarterial systems will fall to 14 from 16 French faster than many imagine. Routine percutaneous procedures will become the norm. Technical and procedural improvements will offer the potential for further improved outcomes. Physicians may anticipate TAVI systems that markedly facilitate accurate positioning and, if necessary, repositioning or removal. With time, TAVI may prove competitive with surgery even in low risk patients. An alternative scenario sees TAVI applied inappropriately and

poorly. TAVI holds considerable promise, but requires considerable caution.

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