EuroIntervention

Transcatheter aortic valve replacement: a surgeon's perspective

Allan S. Stewart[1]*, MD; Craig R. Smith[1], MD

1. Columbia University Medical Center, New York, New York, USA

Aortic valve replacement (AVR) is the only effective treatment in adults with symptomatic aortic stenosis. The operation unequivocally extends life and relieves symptoms[1]. The operative mortality for isolated AVR in the Society of Thoracic Surgeons (STS) National Database, as well as in the New York State database, is 3%. Even lower operative mortality has been reported from centres of excellence[2]. Additionally, surgical AVR is a durable procedure, with currently available bioprosthetic valves demonstrating improved freedom from structural valve disease[3]. Despite these data, many patients with severe aortic stenosis are never referred for surgical consultation, due to perceived prohibitive operative risk, or the presence of serious comorbidities thought to overwhelm any cardiac benefits of successful operation. Medical therapy in this patient cohort remains poor. While balloon valvuloplasty (BAV) may offer effective palliation its benefit is transient, with significant procedural mortality (8-14%) and discouraging one-year survival (54-75%)[4].

As surgeons, it is tempting to quote the low mortality for conventional AVR represented in large databases to all patients seeking surgical consultation. In truth, there is a high-risk population that should not be quoted such a favourable perioperative mortality, or more importantly, be assured freedom from significant morbidity. These patients are not well represented in the large databases, because they have not traditionally been offered AVR. Small numbers of such patients are clustered at the steep ends of the risk curves where discrimination is greatly reduced. In the STS database, for example, estimated operative risk that is only double the average mortality represents less than 10% of the database population. As a consequence, predictions of mortality, morbidity, and post-operative quality of life in these patients are poorly data-driven, and are usually based on the clinical instincts of surgeons and referring cardiologists. Regardless of the metric applied, there are patients for whom alternatives to conventional AVR might offer a much more favourable risk-benefit profile.

Surgeons have been reluctant to embrace non-surgical alternatives for AVR, in part because conventional AVR is safe and reproducible in experienced hands. It is also possible, since AVR represents an increasing fraction of cardiac surgical practice due to a declining CABG market, that unflattering market-share-preservation motives are playing a role.

As reluctant as surgeons may be, ageing demographics continue to expand the number of patients presenting with symptomatic AS. It is likely that those not conforming to classical risk expectations are disproportionately represented. Given that good alternative palliative medical treatments (including BAV) are not available, the search for a minimally invasive alternative has heightened in recent years. Early experience with transcatheter implantation of a prosthetic valve (TCAVR) by two access routes (transfemoral/retrograde and transapical/antegrade), suggests that TCAVR is technically feasible, reasonably safe, and possibly beneficial to survival[5,6].

While it is tempting to extrapolate the success in the feasibility trial to all patients with symptomatic AS, many challenges remain, and TCAVR is not yet appropriate for all patients currently receiving conventional AVR. As experience with percutaneous coronary interventions (PCI) clearly demonstrates, any procedure that avoids heart surgery is easily sold to patients even if the long-term results are unproven or frankly inferior. This creates an obligation for gatekeepers in the referral stream to keep all options in proper perspective. The storm of controversy swirling around drug-eluting stents is a cautionary tale. This is not to say that surgeons are immune to similar pressures, as overstatement of the benefits of small incisions

* *Corresponding author: Division of Cardiothoracic Surgery, Columbia University Medical Center, 177 Fort Washington Ave., MHB 7-GN, New York, N.Y. 10032, USA*

E-mail: as2276@columbia.edu

illustrates. The success of TCAVR will be intimately related to its appropriate utilisation. It must be remembered that durability of transcatheter valves is still unknown, with only standard accelerated wear testing available to predict longevity of the valve until clinical data is established. Serious device-related complications continue to occur, including major vascular injury, device embolisation, coronary ostial impingement, and aortic dissection. As long as these issues remain, average risk patients are clearly better served by surgical aortic valve replacement. Spirited debate continues, however, as to what constitutes high risk. Upcoming, randomised pivotal clinical trials are likely to focus on high-risk patients, such as those with an operative mortality of > 15% as determined by a cardiac surgeon, or those considered inoperable. The control group will be "best medical management" which will include medical therapy, balloon valvuloplasty, and surgical AVR. Limiting the study to a high risk population will allow for a useful comparison in those patients for whom the device is currently intended. Examples of such patients include those with severely compromised respiratory status, severe immunosuppressive disease, prior chest wall radiation therapy, porcelain aorta, and multiple previous operations combined with advanced multi-system dysfunction. There will probably be some institutional variability in exactly which combination of features justifies a high risk designation. Nonetheless, careful and methodical assessment of risk is necessary to protect our patients from inappropriate application of a fledgling technology, and to protect the technology from unfair comparison to results obtainable in average risk patients.

Once a patient is deemed appropriate for a transcatheter valve, a choice is made between the retrograde/transfemoral and transapical options. Both require a small incision. In its current iteration, the transfemoral delivery is not reproducibly percutaneous, although size reductions in the next generation may facilitate usage of closure devices. The true percutaneous delivery system via transseptal delivery from the femoral vein has been abandoned, given the lack of reproducibility and safety hazards. The size of retrograde delivery devices (19-24 Fr) excludes the transfemoral/retrograde approach in patients whose femoral and iliac arteries are not sufficiently large to safely accommodate the catheters. Calcium score and vessel tortuosity may indicate unacceptable risk of vascular injury with the retrograde approach. Extensive aortic arch calcification or mobile plaque increase embolic risk with a retrograde approach. In all such patients the transapical approach is more desirable. Conversely, the transapical approach is unattractive in patients who have had ventricular remodelling operations, or multiple previous operations, and in some patients who have had major chest wall radiation. In some patients only one method of delivery will be suitable, but most will be equally well served by both approaches. There is an understandable tendency to consider the transfemoral approach as belonging to interventional cardiology, even though it is currently not percutaneous, and an equal tendency to view the transapical approach as belonging to cardiac surgeons, even though it requires sophisticated catheter skills. Particularly if practitioners promote the transfemoral version as analogous to PCI, the temptation to indulge in unseemly inter-specialty conflict may be too great for some to resist. TCAVR is uniquely dependent on genuine cooperation between interventional cardiology and cardiac surgery, both in the conduct of the procedure, and in appropriately triaging between conventional AVR, the two methods of TCAVR, and medical treatment. As the device becomes more readily available, we will be doing a disservice to our patients if cooperation devolves into conflict.

Transcatheter aortic valve replacement is a reality. There is no question that it will expand treatment options in a group of patients currently not offered intervention. As the device is refined, and as the learning curve is mastered, it will have an expanded role in the treatment of patients currently receiving conventional AVR. This may reduce morbidity and mortality associated with conventional AVR, as high-risk patients are removed from the surgical population. It is also likely that fewer mechanical valves will be implanted, because TCAVR seems likely to offer an excellent option for patients with degenerated bioprostheses. Finally, the distinction between the cardiac surgeon and the interventional cardiologist will blur as surgeons are cross-trained in transcatheter valve therapy. Specialty-related bias should be diminished in the process, and such practitioners may become the ideal gatekeepers in the treatment of aortic stenosis. It is an exciting time in structural heart valve disease. New devices, improved skill sets, and heterogeneous treatment teams will evolve to benefit our patients and expand the treatment paradigm for symptomatic aortic stenosis.

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