The Evolving Treatment of Aortic Stenosis
Do New Procedures Provide New Treatment Options for the Highest-Risk Patients?

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The percutaneous treatment of valvular heart disease is rapidly progressing through clinical trials. For one valvular lesion, critical aortic stenosis, recent advances in technology and percutaneous techniques may potentially change the way in which we manage this disease in the most frail and elderly patients. Some of these new techniques blur the distinction between surgical and nonsurgical treatments. In this issue of Circulation, Lichtenstein and colleagues report the first series of patients to have an aortic valve implanted via a thoracotomy to expose the left ventricular apex, for subsequent sheath insertion, over-the-wire delivery system advancement, and image-guided implantation of a stent mounted equine crimped on a delivery balloon.1 This article is seminal in defining 2 major emerging issues: valvular heart disease treatments that are hybrids of surgical and catheter-based techniques and the challenges inherent in determining what treatment modalities are best in the growing problem of aortic stenosis in mature, ie, elderly, adults. This report adds to the recently published report from the St. Paul’s Hospital group in Vancouver using the retrograde percutaneous aortic valve (PAV) implantation technique.2

Which patients will be appropriate for these new approaches to the treatment of aortic stenosis in the mature adult population? Timely assessment of the efficacy and safety of these techniques will be critical for patients, care providers, regulatory agencies, and insurers to evaluate for patient-specific decision making and healthcare policy.

The Critical Data Needed in Apical and Percutaneous Aortic Valve Implantation

• Safety. The present small study had a 1-month mortality of 14%. One additional death would have made the mortalty much closer to the predicted surgical aortic valve replacement mortality. Therefore, the mortality results from multicenter studies of larger patient populations will be critical in documenting that this approach is safer. On the other hand, the apical approach has a safety advantage over the percutaneous delivery method in that it avoids the major complications that may occur with the large femoral sheath and delivery system (ie, 24 French) that must navigate the often diseased and tortuous iliofemoral arterial system.

• Burden of the treatment. Both the percutaneous and apical aortic valve implantation techniques require general anesthesia, a surgical incision (femoral artery cut-down or thoracotomy), and a postprocedural stay lasting close to a week. Refinements in the technology and technique should minimize the burden of the treatment by moving it closer to other percutaneous therapies.

• Durability of the prosthesis. These 2 approaches to prosthetic aortic valve implantation could potentially extend into traditional surgical patients if the prosthesis is durable and the unseeded aortic valve leaflets have no important negative consequence.

• Benefit. In the present report, “6 of the 7 patients were alive and well at 1 month” (italics added). The multiple comorbidities of the patients treated by Lichtenstein and colleagues may limit functional and quality-of-life improvements, alleviation of symptoms, and reduction of mortality, despite a hemodynamically effective treatment of aortic stenosis. The durable benefit of apical and percutaneous prosthetic AV implantation at 1 to 3 years must be carefully and objectively defined (see below). Indeed, parameters to measure recovery times and more comprehensive functional status after these procedures should be included in the data collection.

• Patient selection. The patients whom this treatment will truly help must be carefully defined and the benefits comprehensively presented. The report by Lichtenstein and colleagues, as well as that of Webb, had a predominance of men.1,2 Because women are underrepresented in the studies, the results of the apical approach and PAV remain to be defined for women, who often have a smaller femoral artery, a smaller annulus, and a smaller and hyperdynamic ventricle with accompanying higher risk for prosthetic-patient mismatch and operative mortality.3–6

• The learning curve. The ability of teams in other medical centers to achieve the same or better results as the Vancouver group without early learning curves marked by high mortality must be shown. These new procedures for valve implantation build on existing interventional and surgical skill sets but also involve major new techniques and knowledge, as well as the performance of novel tasks that, if performed incorrectly, could have dire consequences in a.

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patient population with minimal ability to tolerate operator error.

**The New Cardiac Surgery–Interventional Cardiology Interface**

The group of clinical investigators from St. Paul’s Hospital in Vancouver is representative of the type of clinical teams that will be needed to deliver the apical approach to prosthetic aortic valve implantation. Unlike the interactions of cardiologists and cardiac surgeons in the past, which have typically involved separate delivery of surgical and catheter-based treatments for coronary artery disease, the apical prosthetic valve implantation approach requires the presence of the entire team in a dedicated operating room–interventional suite. The closest current analogy in cardiovascular medicine is abdominal stent graft placement. Early in its development, this procedure was performed almost exclusively by multidisciplinary teams, but with time individuals from each specialty acquired the skills of the other group. The apical approach may be the first clear pathway for cardiac surgeons to acquire and use catheter-based and image-guidance skills, especially if the procedure starts to replace traditional surgical valve replacement in higher risk patients.

**Medical Decision Making in Mature Adults**

Aortic stenosis is a problem that is increasingly common now that more adults are living past the seventh decade of life. The recently released guidelines address the traditional issues of assessment of hemodynamic severity, the proper use of diagnostic testing, and indications for surgical valve replacement, currently the sole durable treatment option. These guidelines do not fully address the major dilemmas facing clinicians caring for mature adults with severe aortic stenosis and a variety of comorbidities. Furthermore, the percutaneous technique and the hybrid approach reported by Lichtenstein provide treatments that may significantly expand the patient population eligible for prosthetic valve implantation as well as patients currently undergoing surgical valve replacement, but at substantial operative risks who may soon have a less invasive option.

The complexity and heterogeneity of the health status of mature adults for whom these treatments are intended cannot be minimized. Should these treatments for valvular heart disease emerge, they will require clinical guidelines that address the new decision-making challenges they will pose. Patient-centered care plans will be very different for patients with similar degrees of aortic stenosis but marked differences in their medical status on the continuum from frail to robust.

Four issues stand out as important for decision making relevant to the apical and percutaneous techniques of valve implantation, assuming clinical trials successfully deliver the critical data needed for their approval and incorporation into clinical practice: the known rapid and progressive mortality associated with untreated aortic stenosis, the assessment of surgical risk, the assessment of the patient’s health status and potential to benefit from the procedure, and the role of patient treatment preferences.

The potential to help the patient escape both impending death and the severe limitations from symptoms of aortic stenosis with these new approaches to prosthetic valve implantation are the central facts of medical decision making in this population. The patients being enrolled in trials such as those presented by Lichtenstein and Webb would otherwise die from the aortic stenosis at a rate >2% per month, and the rate would probably be considerably higher in this population owing to comorbidities. These patients have moved past the inflection point on the famous Braunwald-Ross curve relating the onset of aortic stenosis symptoms to mortality. The progression of aortic stenosis is faster in those >50 years of age, those with CAD, and those with heavy valvular calcification. Thus the management of aortic stenosis in the senior population has a degree of urgency for each individual patient owing to the relatively rapid worsening of symptoms toward death and to the lack of medical treatment options. Indeed, the need to complete larger trials, review the data, and approve products in a timely fashion is great given the large number of patients who currently have no treatment options.

Surgical risk indexes have been developed to predict the mortality risk associated with cardiac surgery. The Society of Thoracic Surgeons database report on surgical risks in valve surgery identifies factors relevant to aortic stenosis in older adults, including age, female sex, and a variety of comorbidities. Another cardiac surgery risk scoring system, developed after a meeting of the European Association for Cardio-Thoracic Surgery, can be accessed on the Web by clinicians and patients for a rapid assessment of surgical risk using a multivariate analysis.

Other prognostic indices have also been developed to predict patient mortality based on comorbid conditions and functional parameters. The 4-year mortality in an 80-year-old patient increases from 16% to 80% as the number of comorbidities increases and functional status declines. These tools were developed to help clinicians advise patients on appropriate medical care decisions, including the decision to forego preventive measures when life expectancy is short. Primary care physicians, cardiologists, and cardiac surgeons must become skilled in adapting this form of prognostication to choose appropriately between implanting a new valve, when some improvement in longevity and quality of life can be expected, and providing palliative care, when aortic stenosis is one factor among many in a prognosis of impending death.

In this mature adult population, clinicians are confronted with a heterogeneous group of individuals in terms of life expectancy, presence of comorbidities, and degree of disability. These mature adults are also heterogeneous in their willingness to undergo treatments that impose a burden, in terms of diagnostic testing and treatment planning, need for hospitalization, and degree of invasiveness. The burden of treatment and the potential uncertainty of outcome influence treatment preferences in this population of hospitalized older adults.

Will valve implantation decrease mortality from critical aortic stenosis, and leave more elderly patients living, but with significant cognitive and functional disability from other chronic diseases? In the United States, there have been population-wide decreases in the disability of older adults despite the number of chronic diseases these individuals
have. Age-specific mortality is decreasing by 1% a year, while age-specific disability rates are declining by 2% a year. The role of improvements in medical care in contributing to this important trend remains undefined.

Will percutaneous and apical prosthetic aortic valve insertion join hip replacement, cataract surgery, and hearing aids in the armamentarium of techniques and technologies directed at prolonging the life and maintaining the functional status of mature adults? These new techniques in the treatment of severe aortic stenosis represent a significant breakthrough in the treatment options that clinicians may be able to offer to a large number of patients currently sent home to die. Determining whether these technologies should become an established part of our armamentarium of care will require gathering and analyzing the critical data defined above, wisdom in making decisions, and an informed consent process that is careful to define the patient’s preferences and values.

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