N. Kleiman, M.D.

INTRODUCTION TO TRANSCATHETER AORTIC VALVE IMPLANTATION

Neal Kleiman, M.D.

Methodist DeBakey Heart & Vascular Center, The Methodist Hospital, Houston, Texas

Medical scientists and cardiologists in particular have always been excited about breakthrough technologies that offer new modalities for treating common diseases. In cardiac surgery, the advent of the heart-lung machine led to groundbreaking procedures such as valve repair and replacement, coronary artery bypass, and heart transplantation. Interventional cardiology as a field began in 1977 when Andreas Gruntzig first began the practice of balloon coronary angioplasty. Coronary stent placement in the 1990s and drug-eluting stent implantation in the 2000s took center stage in this field — and in cardiology in general. As complication rates declined precipitously and the indications for stent placement narrowed somewhat, interventional cardiologists searched elsewhere for new frontiers. The refinement of new imaging modalities such as echocardiography and magnetic resonance imaging focused attention on structural abnormalities of the heart. At the same time, an aging population made degenerative aortic stenosis a prime target for further therapeutic advances.

In an often-cited statement in his 1931 textbook of cardiology, Paul Dudley White wrote: "There is no treatment for aortic stenosis." In an autopsy study of narrowed aortic valves, McGinn and White noted that the average duration between the onset of symptoms and death was approximately 1 year.[1] However, surgical replacement of aortic valves in the 1960s altered the paradigm for management of this disease and led to nearly normal survival for postoperative patients after aortic valve replacement. By far, the most common etiology of aortic stenosis in patients older than 75 years is degenerative calcification of the valve.[2] However, the major caveat of an open surgical approach is that to benefit from surgical aortic valve replacement, the patient must first survive the surgery. The issue of perioperative mortality and morbidity is particularly important in patients with degenerative aortic stenosis, as the frequency of the disease is age-dependent, ranging from about 2.4%, in patients between the ages of 75 and 84, to 7%, in men aged 85 or older.[3] Obviously, the risk associated with open-heart surgery is higher in these patients than in those who are younger. Consequently, a substantial proportion of elderly patients with degenerative aortic stenosis do not undergo surgical valve replacement

The advent of balloon aortic valvuloplasty in the 1980s led to novel thinking about catheter-based management of aortic valve disease. Originally derived from balloon dilation of the pulmonic valve in pediatric patients, this technique initially offered moderate symptom relief in patients who were not candidates for surgery. However, the results proved to be short lived, subsequent survival was dismal (< 25% at three years),[4] and enthusiasm for the procedure waned. The advent of percutaneous valve replacement by Cribier[5] — inspired by pulmonic valve implantations in late survivors of Tetralogy of Fallot corrections and first performed in a 57-year-old patient with a congenitally bicuspid aortic valve — led to the gradual development of more user-friendly valves and broader application of their use.

In 2010, the PARTNER cohort B study treated 358 otherwise inoperable patients suffering from critical aortic stenosis with transcatheter valve replacement (TAVR). Compared with medical therapy, TAVR saved one life at the end of a year for every five patients treated. By the end of the second year, the number needed to treat had fallen to four. These findings ignited enthusiasm for this procedure and assured it of a place in the mainstream of modern cardiac interventions.[6] One valve is currently approved in the United States for use in this population (Edwards SAPIEN), another valve is undergoing clinical trials (Medtronic CoreValve®), and two more are about to enter clinical trials. In Europe, three different valves are approved for clinical use. Investigators and regulatory authorities are currently evaluating expansion of the TAVR population to include patients in lower-risk categories who might otherwise undergo surgical aortic valve replacement albeit at higher-than-average risk.

This issue of the *Methodist DeBakey Cardiovascular Journal* includes contributions from a variety of internationally renowned experts who collectively have considerable experience in the historical development of TAVR and its evaluation and practice. Although the field has developed very rapidly and the use of TAVR has become accepted in extremely high-risk patients, there are hurdles that have yet to be surmounted before its use becomes more widespread. The learning curve for valve implantation is very steep. A recent report indicates that technical indicators of procedural success start to show improvement after about 30 procedures have been completed.[7] Even among experienced practitioners, multiple sources indicate that residual aortic insufficiency occurs in a substantial proportion of patients and is associated with a high mortality.[8] In addition, the single randomized trial comparing TAVR with surgical aortic valve replacement indicates a risk of stroke that is slightly higher in patients undergoing TAVR.[9] Thus, the technique remains considerably more complicated than intracoronary stent placement and, although performed percutaneously, should still be regarded as a form of cardiac surgery.

In this issue of the *Methodist DeBakey Cardiovascular Journal*, we highlight the background, benefits, and economics of the TAVR/TAVI procedure and use both terms interchangeably depending on the author's preference. The articles herein offer an overview for practitioners who are beginning or considering whether to begin a TAVR program.

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