Percutaneous Valve Implantation: A New Era in Cardiology

Basil S. Lewis MD FRCP FACC FESC and David A. Halon MB ChB FACC FESC

Department of Cardiovascular Medicine, The Heart Hospital at Lady Davis Carmel Medical Center, and Rappaport Faculty of Medicine, Technion-Israel Institute of Technology, Haifa, Israel

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Almost 50 years after valve replacement surgery so dramatically changed the management and prognosis of patients with valvular heart disease [1,2], we stand on the threshold of a new era in cardiology, where percutaneous valve implantation has the potential to change again the therapeutic possibilities for these patients. The immediate relevance is for the rapidly growing elderly population with aortic stenosis, in whom the prognosis following successful surgical valve replacement may be good but co-morbid conditions often negate the possibility of surgery [3].

In this issue of the journal, Danenberg et al. [4] report the first 55 patients undergoing percutaneous trans-catheter aortic valve implantation with one of the two devices currently available for clinical use in Israel. Following TAVI, mean trans-valvular aortic pressure gradient decreased from 51 ± 13 to 9 ± 3 mmHg and significant symptomatic improvement was evident in the vast majority of patients. The rate of procedural success was 98% and all-cause 30 day mortality 5.5%, remarkable results indeed considering that the patients were deemed too ill to undergo conventional cardiac surgery. The device used in this series (CoreValve, Medtronic, Luxembourg) was a self-expanding catheter-based bioprosthetic valve introduced via a percutaneous puncture of the femoral artery and implanted retrogradely in the aortic outflow tract. The device is rather bulky at 18F (soon to be available in a 16F version), but slightly smaller than the alternative balloon-expandable Edwards-Sapien valve (Edwards LifeSciences, Irvine, CA, USA) (currently 23F, soon to be 18F). When necessary, the CoreValve can be delivered through the subclavian artery using local surgical access. The Edwards device, on the other hand, has the option of antegrade trans-apical delivery using a local limited thoracic surgical approach and left ventriculotomy – all this for patients in whom small, narrowed or tortuous femoral arteries do not allow retrograde trans-femoral passage of the device. Since percutaneous valves are still in an early stage of clinical development, methods of delivery of these and other newer devices are likely to undergo frequent modification in the coming years.

TAVI = trans-catheter aortic valve implantation

Experience with TAVI is expanding rapidly, with more than 10,000 patients treated worldwide and well over 200 in an increasing number of medical centers in Israel. The results are in keeping with the experience in larger European [5-7] and Canadian series [8]. A major advantage of the percutaneous method is the immediate functioning of the bioprosthesis, with almost instantaneous elimination of the pressure gradient across the valve. A degree of minor perivalvular aortic insufficiency is acceptable, but sudden-onset moderate to severe regurgitation may cause heart failure and increase morbidity, emphasizing the importance of careful patient selection. This would exclude patients in whom the aorta and aortic annulus are too large (or too small) for currently available valves [9].

Complications in Danenberg's series were encouragingly few, the most common being heart block which prompted permanent pacemaker implantation in more than 30% of patients (similar to worldwide experience) [10,11]. The need for pacemaker implantation following CoreValve implantation may be related to pressure on the upper interventricular septum by self-expansion of the valve frame, the lower portion of which is positioned in the left ventricular outflow tract, and may continue for hours to days following implantation. In contrast, the more compact Edwards-Sapien valve is usually positioned a little higher in the outflow tract. The reported rate of pacemaker implantation (5.7%) has been lower and similar to surgical series [3,12]. Atrioventricular conduction disturbances are relatively common in the elderly, particularly in patients with aortic stenosis. It is possible that operator awareness following TAVI with the CoreValve influences clinical decision-making towards earlier implantation of a pacemaker that would be required at a later stage.

Notwithstanding the quite remarkable remedial results of TAVI, a number of issues need to be addressed. The crucial question is to what extent TAVI may replace surgery in patients in whom a regular surgical procedure is feasible and presently indeed advisable. While the advantages of the percutaneous approach are clear and attractive, surgically implanted valves have the advantage of many years of experience with excellent anticipated long-term durability. We need (and are rapidly accumulating) more experience and longer-term follow-up before recommending TAVI to the general population

of patients with aortic stenosis. We need assurance that no unrecognized complications develop. Surgery may remain preferable in patients who require correction of additional cardiac disease that is presently not treatable by a percutaneous approach [13,14]. We also need better equipment that will allow easier implantation in patients with vascular disease. Peripheral vascular problems are frequently the reason for *a priori* exclusion of the trans-femoral approach. The alternative trans-apical approach is feasible but is a form of minimally invasive surgery rather than a percutaneous procedure, and generally carries greater morbidity and mortality [15].

Lastly, we need to consider the possibilities offered by the percutaneous approach for patients with a broader spectrum of valve disease. This includes patients with mixed aortic valve disease and patients with the very common problem of mitral regurgitation and its varying etiologies. Larger valve sizes and designs may, in the future, enable treatment of patients with a given degree of aortic regurgitation but we will need the technology to implant and anchor these valves in the aortic outflow tract. Mitral disease is more challenging, but several approaches are presently in development or in clinical trials. These include annular modification using a ring implanted in the coronary sinus, or a clip to simulate the Alfieri surgical procedure, where clipping the anterior to posterior leaflet essentially creates two parallel but smaller mitral valve orifices and significantly reduces mitral regurgitation [16]. The EVEREST II trial [17] yielded results that were not inferior to open heart surgery in high risk surgical candidates. However, the technical challenge of stapling mitral leaflets percutaneously in the beating heart is not trivial. Possibilities of mitral valve implantation need to take into account the far greater complexity of the anatomic approach to the valve and the more complex structure of the atrioventricular as opposed to semilunar valves.

In summary, percutaneous aortic valve implantation is a giant leap forward to improving the prognosis of selected patients with aortic stenosis. We have scarcely begun percutaneous treatment of valve disease. We look forward to advances in technology that may allow percutaneous or minimally invasive procedures for an increasingly wider spectrum of valve disease.

Corresponding author:
Dr. B.S. Lewis
Dept. of Cardiovascular Medicine, The Heart Hospital at Lady Davis Carmel Medical Center, Haifa 34362, Israel
Phone: (972-4) 825-0457
Fax: (972-4) 834-3755
email: lewis@tx.technion.ac.il

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