HEART OF THE MATTER

On Transcatheter Aortic Valves

The natural history and pathology of aortic stenosis has been well described since the mid-18th century by John Baptist Morgagni. Its latency period usually runs 6-7 decades before expressing its classic symptoms. Once the symptoms of heart failure, angina, and syncope occur, the life span of patients is measured in 1-2 years.

Because of the increased number of octogenarians around these days, aortic stenosis has become a larger therapeutic problem to cardiologists. Unfortunately, when octogenarians come to the doctor with the symptoms of aortic stenosis, they usually bring a number of other comorbidities, such as coronary artery disease, diabetes, pulmonary insufficiency, and renal dysfunction, just to name a few. Surgical intervention in these patients carries high risk and both the patient and surgeon are reluctant to proceed with high-risk surgery in such a complex medical environment.

SIDNEY GOLDSTEIN, M.D.

The recent development of a percutaneous aortic valve that can be implanted either transvenously or transapically has provided interesting options for these elderly patients. Several transcatheter aortic valves are now available in Europe, but until the last few months there have been no randomized clinical trials evaluating there efficacy.

The two most recent trials, the PARTNER trials, using a SAPIEN heart valve system (Edwards Lifesciences) have provided an opportunity to consider the potential benefits of transcatheter aortic-valve replacement (TAVR). The first reported trial compared TAVR to standard medical therapy in patients with severe aortic stenosis deemed inoperable for traditional aortic valve replacement (AVR). A second group of patient with severe aortic stenosis was randomized to either TAVR or AVR. Both studies have provided optimism that these percutaneous devices can provided significant benefit.

The initial PARTNER study randomized 358 stenosis patients who were considered to be inoperable, to either TAVR or standard medical therapy including in some case balloon aortic valvulotomy (N. Engl. J. Med. 2010; 363:1597-607). That trial reported a 30-day mortality of 5.0% and 2.8% and a 1-year mortality of 30.7% and 50.7% in the TAVR and standard medical therapy groups, respectively. Associated with this improvement in mortality, there was both symptomatic improvement and decrease in hospitalization in the TAVR treated patients. There was, however, an increase occurrence of major strokes, at 5.0% in the TAVR patients compared with 1.1% in the medical patients.

The most recent PARTNER trial reported at the annual meeting of the American Cardiology compared TAVR to standard surgical AVR in patients with severe aortic stenosis. In that trial, 699 patients with mean aortic valve area of 0.6-0.7 cm^2, most of whom were in New York Heart Association functional class III-IV, the 30-day mortality was 3.4% vs. 6.5% and the 1-year mortality was 24.2% vs. 26.8% in the TAVR compared to AVR respectively. There was, however, an increase in all strokes in the TAVR patients compared to AVR, 4.6 % compared to 2.4%. Although most of the SAPIEN valves were implanted by the transfemoral approach, approximately one-third required the transapical approach because of poor femoral artery access.

The device used in PARTNER is currently approved for use in Europe and soon to be available in the United States. Several other transcatheter valve systems are currently in development by device companies, and one, the CoreValve (Medtronics) is currently undergoing clinical trials in the United States. The devices included in the early trials have been improved upon and investigators using the Edwards Lifesciences device are currently testing the fourth generation of that valve, which is smaller and easier to pass through the femoral artery.

In addition, protection devices are being developed to deal with the observed increased stroke morbidity. Although stroke remains a problem, emboli have not been limited to the brain but some reports suggest that, there is evidence for intracoronary embolism.

The development of these valves are obviously on the fast track but unfortunately little is known about their long-term durability. There are some follow-up data from Europe where the valve has been in use for about 2 years. When weighed against the years of experience and the excellent durability of the current AVR there should be some reticence to the application of these valves in patients at better surgical risks.

Although the operative risks for either TAVR or AVR are acceptable, considering the natural history of the disease, unfortunately the long-term risks of the elderly patients with aortic stenosis remains high even after successful valve replacement. ■

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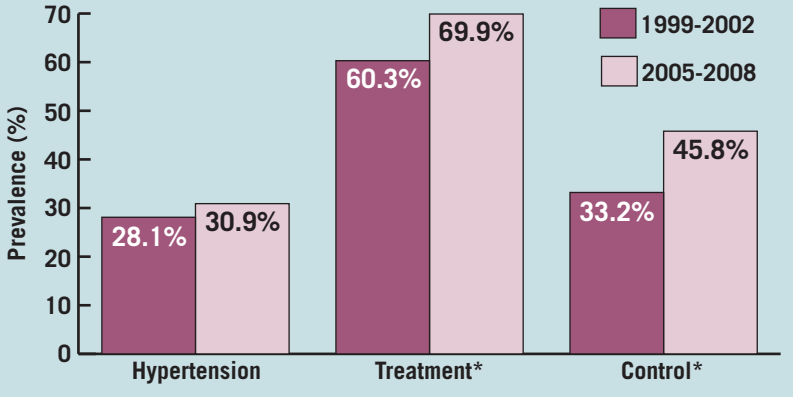
Hypertension Treatment and Control Increased Significantly From 1999-2002 to 2005-2008



*Among those with hypertension.
Note: Based on data from the National Health and Nutrition Examination Survey.
Source: Morbidity and Mortality Weekly Report 2011;60:103-8

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