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Aortic valve replacement: Options, improvements, and costs

HOW AORTIC VALVE DISEASE IS MANAGED continues to evolve, with novel approaches for both aortic valve stenosis and regurgitation.¹⁻⁸ Indeed, because of the spectrum of procedures, a multispecialty committee was formed to provide a detailed guideline to help physicians work through the various options.⁴

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The paper by Aksoy and colleagues in this issue of the *Journal* gives further insight into the complexities of decision-making.

As a rule, the indications for a procedure to treat aortic valvular disease continue to be based on whether the patient develops certain symptoms (fatigue, exertional dyspnea, shortness of breath, syncope, chest pain), myocardial deterioration, reduced ejection fraction, or ventricular dilatation.⁴ Furthermore, the options depend on whether the patient has comorbid disease and is a candidate for surgical aortic valve replacement.

■ OPEN SURGERY: THE MAINSTAY OF TREATMENT

Open surgery—including in recent years minimally invasive J-incision “keyhole” repair or replacement—has been the mainstay of treatment. The results of surgical aortic valve repair have been excellent, so that 10 years after surgery 95% of patients who have undergone a modified David reimplantation operation

have not needed a repeat operation.³ The results are comparable for repair of bicuspid aortic valves.^{2,3}

Furthermore, surgical aortic valve replacement has become very safe. At Cleveland Clinic in 2011, only 3 (0.6%) of 479 patients died during isolated aortic valve replacement, and in 2012 the mortality rate was even better, with only 1 death (0.2%) among 495 patients as of November 2012.

■ GOOD RESULTS WITH TRANSCATHETER AORTIC VALVE REPLACEMENT

For a new valve procedure to be accepted into practice, it must be easy to do, safe, and consistently good in performance measures such as producing low gradients, eliminating aortic regurgitation, and leading to high rates of long-term freedom from reoperation and of survival. To see if percutaneous aortic valve replacement meets these criteria, it was evaluated by both us at Cleveland Clinic and our colleagues at other institutions in the laboratory and also in feasibility trials in the United States.

The subsequent Placement of Transcatheter Aortic Valves (PARTNER) trial established the benefit of this procedure in terms of superior survival for patients who could not undergo surgery.⁸ Hence, the transcatheter device was approved for patients who cannot undergo surgery who meet certain criteria (valve area < 0.8 cm²; mean gradient > 40 mm Hg or peak gradient > 64 mm Hg). Of note, the cost per procedure was \$78,000, or approximately \$50,000 per year of life saved.

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The PARTNER A trial showed that the risk of death after transcatheter aortic valve replacement was as low as after open surgery, although the risk of stroke or transient ischemic attack risk was higher—indeed, with the transfemoral approach it was 3 times higher (4.6% vs 1.4%, $P < .05$).^{9,10} Furthermore, half the patients had perivalvular leakage after the new procedure, and even mild leakage reduced the survival rate at 2 years.¹¹

Nevertheless, we have now done nearly 400 transcatheter aortic valve replacement procedures in patients who could not undergo open surgery or who would have been at extreme risk during surgery. With the transfemoral approach, in 267 patients, 1 patient died (0.4%), and 2 had strokes (0.7%). (In the rest of the patients, we used alternatives to the transfemoral approach, such as the transaortic, transapical, and transaxillary approaches, also with good results.)

Thus, transcatheter aortic valve replacement in properly selected patients can meet the above criteria.

COSTS AND THE FUTURE

Based on the PARTNER trial results, the Centers for Medicare and Medicaid Services (CMS) agreed to pay for this procedure at the same rate as for surgical aortic valve replacement for patients who cannot or should not undergo surgery, with the approval of two surgeons and within the context of a national registry.¹⁰

The reimbursement is adjusted for geographic area. In the United States, for exam-

ple, hospitals on the East Coast or West Coast receive \$88,000 to \$94,000 per case, while most other areas receive \$32,000 to \$62,000.

The surgeon and cardiologist share the professional fee of approximately \$2,500, although typically we have a team of eight to 10 physicians (representing the fields of anesthesia, echocardiography, surgery, and cardiology) in the operating room for every procedure, in addition to nursing and technical staff. The challenge for institutions and providers, however, is that the device costs \$32,500, and CMS reimbursement does not cover the cost of both the valve and the procedure in many localities. This may affect how widely the valve is eventually used.

While many more options are available now for management of aortic valve disease (minimally invasive repair or replacement, and newer devices), the future usage of transcatheter aortic valve replacement may become dependent on costs, newer devices, cheaper iterations, competition, and CMS reimbursement.

There are now two additional trials, SURTAVI and PARTNER A2, evaluating transcatheter vs open aortic valve replacement in lower-risk patients. The issues that will have to be addressed with new iterations are the risk of stroke and transient ischemic attack, perivalvular leakage, and the costs of the devices.

Newer reports would suggest that the results with transcatheter aortic valve replacement in inoperable and high-risk patients continue to improve as experience evolves. ■

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