For patients with symptomatic critical aortic stenosis, aortic valve replacement improves survival. However, the risks of open heart surgery have prompted investigation of alternative therapies, including balloon aortic valvuloplasty and transcatheter aortic valve implantation (tAVI).

Past
At centers participating in the Society of Thoracic Surgery national database, the 30-day operative mortality in patients undergoing isolated aortic valve replacement is now <4%. This often-quoted risk, which includes young patients and those with bicuspid valves but excludes morbidity, may therefore represent only the floor of risk. In an older, but more inclusive, study from the National Medicare Database of patients ≥65 years of age, the average mortality was 8.8% and was as high as 13.0% in some centers. The risk of aortic valve replacement increases with age and other comorbidities, including emergency and prior cardiac surgery, lung and renal disease, small body surface area, history of stroke, atrial fibrillation, heart failure, and the need for associated coronary revascularization. Some patients may be truly inoperable or denied surgery because of the presence of a porcelain aorta, prior radiation, cirrhosis, generalized frailty, or physician or patient preference. A nonsurgical alternative for these patients is both welcome and needed.

In the past, high-risk and inoperable patients were offered balloon aortic valvuloplasty. This procedure remains an important palliative option but does not alter the natural history of aortic stenosis nor provide an improvement in survival. The current era of transcatheter aortic valve implantation built on this procedure and began with the first demonstration of feasibility in 2002.

Present
Two tAVI systems (CoreValve Revalving prosthesis, CoreValve Inc; and Edwards Sapien prosthesis, Edwards LifeSciences Inc) have CE Mark approval and are in widespread use in Europe. The present investigation describes a large, single-center experience of 136 consecutive CoreValve transfemoral implants. The findings from this series demonstrate a marked improvement in patients’ short-term hemodynamics and functional status. Technical improvements in device engineering reduced its size from a 25-French first-generation device to the current 18-French device, with an increase in acute procedural success from 70% to 91%. Operator experience and procedural learning resulted in better outcomes, with a reduction in 30-day major adverse events from 40% to 15%.

The patients in this study were elderly (mean age, 81.5 years), had critical aortic stenosis (mean aortic valve area, 0.7 cm²), and had multiple comorbidities, as reflected in the logistic EuroSCORE mortality estimate of 23.1%. The procedural mortality in the last group of 102 patients was a remarkable 0%, with a 30-day mortality of 10.8% and an estimated 1-year survival of 84%. In this group, other in-hospital major adverse events included stroke (2.9%), an increase in paravalvular aortic insufficiency (26%), and the need for a permanent pacemaker (33%). Importantly, the procedure has evolved from one requiring hemodynamic support, with cardiopulmonary bypass, general anesthesia, and surgical cutdown on the femoral artery, to one that can reliably be performed without bypass and with a true percutaneous approach under conscious sedation.

The CoreValve prosthesis is a trileaflet porcine pericardial tissue valve sutured in a self-expanding nitinol stent frame. In contrast, the Edwards Sapien prosthesis is a bovine pericardial tissue valve sutured in a balloon-expandable stainless steel stent. No head-to-head comparisons of these devices have been performed to date, but general conclusions from separate series suggest that the current-generation CoreValve prosthesis may be associated with a lower rate of vascular injury (because of its smaller profile), a lower incidence of associated aortic insufficiency, and a higher rate of postprocedure pacemaker implantation than the current-generation Edwards Sapien prosthesis. However, rapid technological improvements in device design, the availability of larger valves, and the development of a transapical insertion technique may mitigate some of these differences. Long-term durability is not yet available, but early structural failures have not been reported with either device in the first few years of use.

Future
The interpretation of this and other current reports of tAVI are complicated by rapidly changing technologies and procedural methods, inconsistent end-point definitions, and variable use of core laboratory assessment of outcomes and complications.
The learning curves for vascular access, management of complications, and appropriate patient selection are steep. The need for randomized trials that compare devices with surgeries is clear. In this regard, the North American PARTNER (Placement of Aortic Transcatheter Valves) trial, which is randomizing high-risk patients to surgery or tAVI and inoperable patients to medical management (including balloon aortic valvuloplasty) or tAVI with a 1-year mortality end point, will be a landmark development in the emerging field of transcatheter valve therapies.

New devices are already entering first-in-man feasibility evaluation. Advances in profile will reduce the risk for vascular complications. Some will be repositionable to allow more precise placement. Clever device improvements are likely to result in better sealing against the native annulus to reduce paravalvular regurgitation, new methods to protect the cerebral circulation from embolization, and ways to close large femoral access sites without surgery.

In the future, we will also need to solve training issues and evaluate our outcomes, with additional assessments of cost effectiveness and quality of life. Although there remains much to do, these early results suggest that the future of tAVI holds great promise and benefit for our patients with aortic valve disease.

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References

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