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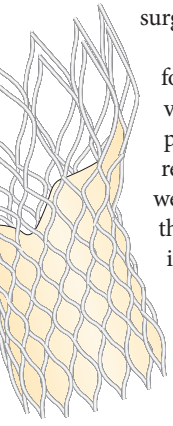
VALVULAR DISEASE

Transcatheter aortic valve replacement trials presented at the 2014 ACC Scientific Sessions

Two high-profile trials of transcatheter aortic valve replacement (TAVR) were presented at the 2014 ACC Scientific Sessions in Washington, DC, USA and published online in late March. Both the CoreValve US Pivotal High-Risk Trial and the CHOICE trial have been the foci of much discussion.

Findings from the CoreValve US Pivotal High-Risk Trial showed that TAVR using the self-expanding CoreValve® (Medtronic CV, Luxembourg) was not only noninferior to surgical aortic valve replacement (SAVR) in patients with severe aortic stenosis deemed to be high-risk surgical candidates, but that this intervention was associated with lower mortality than surgery in this patient group. The CoreValve study was a randomized, noninferiority trial performed at 45 centres in the USA, and funded and designed by Medtronic. The 795 enrolled patients (mean age 83 years) had severe symptomatic aortic stenosis.

The primary end point of 1 year all-cause death occurred in 14.2% and 19.1% of the groups treated with TAVR and SAVR, resepectively ($P<0.001$ for noninferiority; $P=0.04$ for superiority). Dr David Adams, who presented the findings at the ACC meeting, pointed out that "the low mortality rates with conventional surgery far exceeded the predicted mortality according to the Society of Thoracic Surgeons predictive model ... to pass a superiority threshold, transcatheter treatment with the CoreValve device had to exceed excellent surgical outcomes."



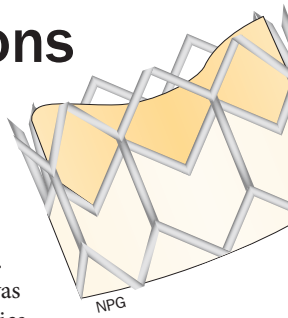
Procedure-related outcomes varied for the two treatment strategies. Major vascular complications, permanent pacemaker implantations, paravalvular regurgitation, and cardiac perforation were more common in the TAVR group than in the SAVR group. Acute kidney injury, new-onset or worsening atrial fibrillation, and bleeding were more common in the SAVR group than in the TAVR group.

Notably, stroke rates were similar for the TAVR and SAVR groups (4.9% vs 6.2% at 30 days, $P=0.46$; 8.8% vs 12.6% at 1 year, $P=0.10$). This finding contrasts with that of PARTNER A, the randomized trial in which the balloon-expandable SAPIEN® valve (Edwards Lifesciences, USA) was assessed in patients deemed to be high-risk surgical candidates. Dr Adams highlighted, however, that the stroke rates in the SAVR group of the CoreValve study were higher than those of PARTNER A, and the stroke rates in the TAVR groups in the two trials were similar. "I think the difference may be that we picked up more stroke rates for the surgery arm, because we looked for them more carefully," he commented. Strokes were adjudicated retrospectively in PARTNER A, but stroke assessment was prospectively scheduled in the CoreValve study.

In line with Dr Adams' theory are findings from a prospective observational cohort study of patients (≥65 years) who underwent SAVR between 2008 and 2012, which were published the day after the end of the ACC congress. In the DeNOVO study, in which neurologists carefully assessed 196 patients both preoperatively and postoperatively, clinical strokes and silent cerebral infarctions after SAVR were found to occur considerably more often than has been reported previously.

In CHOICE, TAVR using the self-expanding CoreValve® was prospectively compared with TAVR using the balloon-expandable SAPIEN XT® valve. This study is the first randomized trial in which the two prostheses commonly used in TAVR have been compared. Of 241 patients (mean age 81 years) with severe symptomatic aortic stenosis, who were enrolled at five centres in Germany, 121 were randomly assigned to receive the SAPIEN XT® valve and 120 to the CoreValve® group.

The primary end point of the trial was device success, defined as: successful access, delivery, and deployment of the valve, as well as successful retrieval of the delivery system; correct positioning of the valve; intended performance of the valve; and the need for only one valve to be implanted. The SAPIEN XT® valve was associated with better device success than the CoreValve® (95.9% vs 77.5%; $P<0.001$), mainly owing to a lower incidence of more-than-mild paravalvular aortic regurgitation. Rates of death, stroke, vascular complications, and bleeding by 30 days did not differ between the two groups. Fewer permanent pacemakers were implanted after deployment of the SAPIEN XT® valve than after intervention using the self-expandable prosthesis. The CHOICE investigators conclude that "long-term follow-up of the CHOICE population should be awaited to determine whether differences in device success will translate into a clinically relevant overall benefit for the balloon-expandable valve."



At the ACC meeting, Dr Roxana Mehran pointed out that the CHOICE study was designed with the aim of determining whether the SAPIEN XT® valve would be associated with device success superior to that of the CoreValve®. "So, to some degree, there is some bias in that, in choosing the sort of patients who would go into a study like this." She went on to say that "it's very important to have these types of studies, but also more important to know that both of these valves are extremely valuable for patients, because one size does not fit all."

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Original articles Adams, D. H. *et al.* Transcatheter aortic-valve replacement with a self-expanding prosthesis. *N. Engl. J. Med.* doi:10.1056/NEJMoa1400590 | Messé, S. R. *et al.* Stroke after aortic valve surgery: results froma prospective cohort. *Circulation* doi:10.1161/CIRCULATIONAHA.113.005084 | Abdel-Wahab, M. *et al.* Comparison of balloon-expandable vs self-expandable valves in patients undergoing transcatheter aortic valve replacement: the CHOICE randomized clinical trial. *JAMA* doi:10.1001/jama.2014.3316