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RAPID-DEPLOYMENT AORTIC VALVE SYSTEMS: THE SURGEONS' ALTERNATIVE TO TRANSCATHETER AORTIC VALVE IMPLANTATION?

To the Editor:

The search for innovative solutions to achieve better outcomes for patients with aortic stenosis still continues in the setting of aortic valve replacement performed under cardiopulmonary bypass and aortic crossclamping (XCL). In their report on the TRANSFORM (Multicenter Experience With Rapid Deployment Edwards INTUITY Valve System for Aortic Valve Replacement) trial, Barnhart and colleagues¹ noted that the trial evaluated the performance of the INTUITY rapid-deployment system (Edwards Lifesciences Corporation, Irvine, Calif) out to 1-year follow-up. Barnhart and colleagues¹ emphasized the importance of the meaningful reductions in cardiopulmonary bypass and XCL obtained with the INTUITY valve, although no control group was available for comparison of clinical outcomes (cerebral microembolism, paravalvular leak, etc). Surgical times, however, were reported to compare favorably with those of the Society of Thoracic Surgeons database; in other words, trained surgeons with expertise in the INTUITY valve system were compared with the rest of the US surgeons, including residents. Moreover, as a further indirect comparison term, implantation times (XCL time of 49 minutes for full sternotomy) were more than double those with the Perceval sutureless aortic valve (LivaNova PLC, London, United Kingdom), which had an XCL time of 18 minutes.²

It would have been interesting to have information on the explantation technique; it could be challenging. At our institution, explantation of the INTUITY valve resulted in a tear at the base of the anterior mitral leaflet in 1 patient. This necessitated transaortic aortomitral

junction reconstruction, which was performed successfully through a ministernotomy, with good clinical and echocardiographic outcomes.

High rates of postoperative permanent pacemaker implantation were reported in this trial.¹ The presence of preoperative right bundle branch block may partially account for this finding, as also reported in a previous study with the Perceval sutureless aortic valve.³ Several technical precautions have been implemented in sutureless aortic valve replacement, however, leading to significantly lower rates of postoperative pacemaker implantation.⁴

In our opinion, rapid-deployment aortic valve prostheses have the potential to shorten surgical time. Future research will determine whether this advantage translates into better outcomes for patients at high risk.

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Reply to the Editor:

The authors appreciate the comments and the opportunity to respond. Like other rapid-deployment aortic valve replacement premarket studies, TRANSFORM (Multicenter Experience With Rapid Deployment Edwards INTUITY Valve System for Aortic Valve Replacement)¹ was a single-armed, observational study approved by the Food and Drug Administration. As we noted in our manuscript, the randomized trial by Borger and colleagues²

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