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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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RAPID DEPLOYMENT AORTIC VALVE SYSTEMS: THE

SURGEONS' ALTERNATIVE TO TRANSCATHETER AORTIC VALVE IMPLANTATION?

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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Glenn R. Barnhart is a Consultant and Principal Investigator for the TRANSFORM Trial. Eugene A. Grossi is a Developer and receives IP royalties from Edwards Lifesciences. W. Randolph Chitwood, Jr, is Principal Investigator for the TRANSFORM Trial.

demonstrated a 24% reduction in clamp time with the use of the INTUITY valve compared with a conventionally implanted bioprosthetic group.

With regard to the explantation technique, we advocate first cutting the previously placed guiding sutures. Blunt dissection can then be performed with a flat instrument, separating the cloth-covered frame from the annular and left ventricular outflow tract tissue. In chronic animal explants, we found it helpful to place a nerve hook through the valve and pull the deployed subannular metal skirt radially into the center of the left ventricular outflow tract. However, the use of this technique has not been applied in the rare TRANSFORM study valve explants reported where, after blunt dissection, the valve was removed easily without damage to the annulus.

The need for a permanent pacemaker after rapid-deployment valves requires further study. In the European Triton study³ of the INTUITY valve, the 30-day incidence of pacemaker implantation was 6.9%. This is in contrast to a Canadian Percival multicenter study, which revealed a 17% pacemaker implant rate during the index hospitalization alone.⁴ Why North American studies have such a high observed pacemaker incidence is unclear. Currently, a detailed analysis of pacemaker usage in TRANSFORM is underway and suggests differences in pacemaker rates by implanters and centers.

We agree with the author that reduced surgical times may translate into better patient outcomes, especially in

those who are high risk; this technology may facilitate minimally invasive approaches for aortic valve replacement. We also concur that surgeons are still learning best practices to employ these new rapid-deployment devices, including surgical techniques as well as timing of pacemaker implantation.

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