How do we follow up our patients? Reporting outcomes without complete follow-up data renders us on the weak side

Carlos A. Mestres, MD, PhD, FETCS, and Alberto Weber, MD, FETCS

From the Department of Cardiovascular Surgery, University Hospital Zürich, Zürich, Switzerland.

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Address for reprints: Carlos A. Mestres, MD, PhD, FETCS, Department of Cardiovascular Surgery, University Hospital Zürich, CH-8091 Zürich, Switzerland (E-mail: Carlos.Mestres@usz.ch).

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Alberto Weber, MD, FETCS (left), and Carlos A. Mestres, MD, PhD, FETCS (right)

Central Message

Rapid deployment aortic valve replacement is gaining popularity. Follow-up data are critical to understand outcomes and perform comparisons and must be complete.

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The goals of rapid deployment aortic valve replacement include facilitation of minimally invasive surgery and reduced aortic crossclamp time, as stated by Young and colleagues¹ in their article in this issue of the *Journal*. They report the 1-year outcomes of the FOUNDATION registry, assessing the performance of a specific rapid deployment aortic valve replacement system in the era of ongoing restrictions for standard aortic valve replacement arising from increased use of the transcatheter aortic valve implantation strategy. In this study, 493 patients were enrolled in a 2-year period in 3 different surgical access groups (full sternotomy, mini upper sternotomy, and right anterior thoracotomy). Mean group crossclamp times were 47.3, 52.0, and 73.3 minutes, respectively. Mean follow-up is 1.8 years. Hemodynamics seemed appropriate, with increase in valve area and decrease of gradients. Pacemaker implantation peaked at 6.1% within 30 days, perivalvular leak stayed at 1.0%, and 9.8% exhibited severe prosthesis-patient mismatch at 1 year. The conclusion of Young and colleagues¹ is that their data support the safety and performance of this test valve system at 1 year.

This is new information on rapid deployment aortic valve replacement. Results of this registry are consistent with those of other studies.²⁻⁴ The average reader understands the message conveyed by Young and colleagues.¹ There are, however, some issues to consider. If reduced aortic crossclamp time and facilitation of minimally invasive surgery are the main goals, completeness of follow-up is critical. One also wonders whether specific populations were preferably addressed, because the enrollment rate per center was around 10 patients/year, and 42% had 19- and 21-mm valves implanted, which is consistent with specific populations with small body size, such as in the Mediterranean basin or Japan, where patients on average are smaller than in areas such as Northern Europe.⁵ This means that almost half of the patients undergoing implantation probably had at least 10% likelihood of development of severe prosthesis-patient mismatch, a matter of discussion for decades⁶ that continues to be an unsolved problem when it comes to

severity.⁷ Whether this new technique is going to impact such a population is still unknown, and comparisons with same-size stented bioprostheses would be appropriate, because the latter have demonstrated performances.⁸ Young and colleagues¹ report 79% 1-year follow-up and 76% 2-year follow-up. Some echocardiographic information is therefore missing in around one-fourth of the cases. The readership understands that if completeness of follow-up is an issue, there may be missing data for at least one-fourth of the patients with regard to such key aspects as perivalvular leak, late pacemaker implantation, and severe prosthesis-patient mismatch. Current surgical guidelines as used by Young and colleagues¹ are a standard for consistency in reporting and must be followed for the sake of increasing surgical credibility in the already established transcatheter era. Journals seek at least 95% completeness of follow-up in longitudinal studies. This raises some questions regarding how much impact the information should have if incomplete follow-up is produced and reinforces the critical role of complete follow-up in the clinical arena, especially in the analysis of new technologies, approaches, and strategies. Additional issues with respect to structural valve deterioration will need further elucidation.

Young and colleagues¹ are to be commended for commenting on a real-life study, aiming at setting the role of newer devices with as good as possible outcomes on the horizon. Past experiences with the test device seemed

appropriate in a controlled environment, such as in randomized studies¹; however, the more accurate the information on each investigational variable, the more the patients will benefit. The “grey zones,” as well defined by D’Onofrio and colleagues,² will be better understood, especially when it comes to comparisons with lesser access options such as transcatheter aortic valve implantation.⁹

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