CoreValve Aortic Bioprosthesis

Repositioning Techniques

In a recent issue of *JACC: Cardiovascular Interventions*, Latib et al. (1) presented images of a technique for repositioning a just-implanted CoreValve (Medtronic, Minneapolis, Minnesota) aortic bioprosthesis with a snare.

The “Snare” technique is a bail-out method, which has been described in detail by Vavouranakis et al. (2). This technique may be applied when the aortic prosthesis is initially positioned too low. A low deployment of the prosthesis would result in an angiographically significant aortic insufficiency (AI). In fact, an AI observed during implantation procedure could as well be attributed to an incomplete deployment of the valve. If this were the case, post-implantation balloon inflation would fully expand the frame of the prosthesis and the “skirt” of the prosthesis would effectively seal any perivalvular leaks. However, in the case of a truly low valve positioning, post-implantation inflation(s) would not improve the observed AI. In this case, the snaring and pulling technique might be used.

A critical point, regarding the “Snare” repositioning technique, is that the operator, when trying to capture the loop of the prosthesis with the snare, should be aiming at the loop that corrects the deep valve positioning. Of course, there are certain limitations to the possibility of full retraction of the valve in a correct position.

In addition to the presented technique, 1 more repositioning technique is available (2). This is the “Removing and Repositioning” technique, which may be used in the case of too-high initial positioning of the prosthesis. However, it can be performed only if the prosthesis is still semi-deployed. In this procedure, the prosthesis is: 1) retrieved within the housing sheath; 2) removed from the body and inspected; and 3) re-inserted and successfully implanted.

In conclusion, it should be noted that the CoreValve (Medtronic) was not primarily designed to be repositioned and the manufacturer does not promote it, so the described repositioning techniques should be used as bail-out techniques.

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Reply

We thank Dr. Vavuranakis and colleagues for their interest in our report of “Post-implantation repositioning of the CoreValve percutaneous aortic valve” (1) and for the opportunity to discuss our experience with repositioning techniques of the CoreValve prosthesis (Medtronic Inc., Minneapolis, Minnesota), which was beyond the scope of an Image in Intervention article. At the outset, we would like to state that the best repositioning technique for the CoreValve bioprosthesis is to aim at implanting the valve correctly the first time without having to reposition the valve later. In their letter, Dr. Vavuranakis et al. allude to an important point about implantation of the CoreValve bioprosthesis, which in our opinion is not sufficiently stressed. It has now become routine practice in our institution to post-dilate all CoreValve prostheses that have more than trivial (>1+) aortic regurgitation. In the majority of cases, this additional post-dilation optimizes expansion of the nitinol stent and reduces the severity of aortic regurgitation, unless the prosthesis was truly implanted very low. Snaring and repositioning the CoreValve is a “bail-out” technique that should be attempted with caution due to the risk of embolization. A potential risk of snaring the CoreValve is that the valve moves up and the skirt covers the coronary ostium; in this event, the valve should be pulled back a little more. If the valve embolizes during this maneuver, a second valve can be implanted in the correct position.

In our experience with implantation of the CoreValve in 72 patients to date, we have only performed the “snare” repositioning technique in the patient we published. Finally, the refolding and reinsertion technique is well described and is considered by some an advantage of the CoreValve Revolving System. We have used this technique successfully in 8 patients but would like to again stress that it is not without risk. Pulling the partially deployed valve back into the sheath can result in the stent struts scraping the aorta and atheroembolization. Indeed, in 1 of these 8 patients, we observed evidence of microembolization in multiple arterial beds immediately after this maneuver.

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Percutaneous Revascularization for Stable Coronary Artery Disease

Temporal Trends and Impact of Drug-Eluting Stents

We read with great interest the paper by Hilliard et al. (1) in JACC: Cardiovascular Interventions and congratulate the investigators on a very well-done and important analysis. Many of those who have criticized the COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) study as not being “generalizable” to contemporary clinical practice (e.g., only 6% of screened patients were randomized, percutaneous coronary intervention [PCI] was substandard, too many patients enrolled from Veterans Affairs and Canada, very low rate of drug-eluting stent usage, adherence to optimal medical therapy was not achievable in the real world) should be reassured by the Mayo Clinic data. The Mayo data indicate that procedural success and technical proficiency continue to evolve and improve, in-hospital mortality and target vessel revascularization continue to decline, and results achievable in the real world might even be better if more robust optimal medical therapy were more widely embraced and used.

The fact that the rates of death, death/myocardial infarction (MI), and revascularization in COURAGE at 4.6 years are virtually identical to the rates reported from Mayo at 4 years supports the concept suggested by the results of COURAGE that these late events (and need for subsequent revascularization) are not being driven by the stenoses that are initially “being fixed,” but rather by new plaque ruptures in non-flow-limiting vessels. Moreover, we note that the patient population undergoing PCI at Mayo between 1997 and 2003 was remarkably similar to patients enrolled in COURAGE during the same time period. Table 4 of Hilliard et al. (1) cites certain baseline characteristics of the Mayo population that were higher risk than those of the COURAGE population, but the investigators do not comment on the higher rates of diabetes (32% vs. 24%), multivessel coronary artery disease (69% vs. 51%), and left anterior descending coronary artery disease (68% vs. 47%) in the COURAGE PCI cohort as compared with the Mayo patients (2,3). Additionally, in their Table 1 (1), only 13% of patients in the Mayo Clinic cohort had a positive stress test as the predominant indication for PCI, whereas in COURAGE, all patients had objective evidence of myocardial ischemia (2,3). Thus, when a more comprehensive list of characteristics is analyzed it appears the Mayo and COURAGE PCI cohorts were indeed very comparable populations of North American stable angina patients. This is underscored further by the performance and outcomes of the PCI procedures that were very comparable in both studies and similar to contemporary practice in the National Cardiovascular Data Registry (4). The difference in procedural success noted in Table 4 (89% vs. 94%) of Hilliard et al. (1) is likely due to differing definitions (COURAGE excluded all periprocedural MIs whereas Mayo only excluded Q-wave MIs).

Based on these important observational data from a center widely acknowledged for excellence in PCI and which serves to validate the quality of PCI in COURAGE, there can no longer be any debate that optimal medical therapy is the cornerstone of management for all patients with stable coronary artery disease and should be the initial management strategy as concluded by the COURAGE study. We also enthusiastically concur with Hilliard et al. (1) that contemporary PCI is even safer and more efficacious than in the bare-metal stent era and is an important complement to optimal medical therapy for symptom relief in patients with angina that cannot be controlled by medications. Despite these advances, it is also noteworthy to emphasize that there has been no change in the unadjusted rates of mortality or the combined end point of death or MI in the drug-eluting stent era (2003 to 2006) as compared with the bare-metal stent era (1997 to 2003) in the Mayo observational experience. Lastly, the hypothesis that coronary revascularization improves prognosis in patients with severe ischemia is intriguing, but remains unproven, and must be evaluated in a rigorously designed and performed randomized clinical trial.

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REFERENCES


Reply

We thank Drs. Sedlis and Boden for their interest in our article in JACC: Cardiovascular Interventions (1). Although we agree that our study suggests that “COURAGE-like” results are being achieved in clinical practice, the analysis was not intended to investigate the generalizability of the trial (1,2). It is reasonable to propose that