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EDITORIAL COMMENT

Could a "Simplified" Transcatheter Aortic Valve Replacement Procedure Eliminate Post-Operative Delirium?*

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Since the first human implants over a decade ago, transcatheter aortic valve replacement (TAVR) has evolved as the new standard of care for both inoperable and carefully selected high-risk patients with severe symptomatic aortic valve stenosis. Initial concerns with the rates of vascular injury, stroke, and residual paravalvular regurgitation have decreased. Current data suggest that device refinements and rigorous patient screening may further reduce some of these recognized complications with mid-term durability that is similar to surgically implanted valves.

Post-operative delirium (POD) is a significant cause of cardiovascular morbidity and mortality after cardiac surgery with an incidence >30% in patients age >70 years (1-3). Compared with surgical revascularization alone, TAVR is associated with an added risk of POD (4-6). POD after cardiac surgery has been associated with prolonged mechanical ventilation (7,8), prolonged hospital length of stay, and increased short- and long-term mortality (8-11). Multiple non-pharmacological measures to predict and prevent POD have been documented in the published surgical data (12). Although few reports on the incidence and consequences of POD following TAVR are available (2,4,13), there is increasing interest in the potential ancillary benefits of a "simplified" transfemoral TAVR procedure with early mobilization and streamlined post-operative care (14-18).

In this issue of *JACC: Cardiovascular Interventions*, Abawi et al. (19) present a retrospective, single-center, observational cohort study examining the incidence of in-hospital POD after TAVR (average age 80 ± 7 years, logistic EuroSCORE 18 ± 9%). Over a

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3-year period, the incidence of in-hospital POD was 13.4% (36 of 268 patients undergoing TAVR). However, the rate of POD was 5-fold higher with alternative access (18 of 40, 45%) versus transfemoral (18 of 240, 8%) TAVR. POD was associated with a prolonged in-hospital length of stay regardless of complications. At a median follow-up of 16 months (6 to 27 months), POD was an independent predictor of mortality in patients undergoing transfemoral TAVR (hazard ratio: 2.81; 95% confidence interval: 1.16 to 6.83). Consistent with similar prior small studies (2,4,13), alternative access was the strongest predictor of POD, with an incidence similar to that observed in elderly patients after SAVR (1-3). The authors stressed that although general anesthesia was associated with POD, its independent effect could not be assessed because of multicollinearity with alternative access TAVR. In this retrospective study, all alternative access patients (40 of 40) but only 5% of transfemoral patients (12 of 240) received general anesthetic. All of the remaining transfemoral TAVR patients were treated with conscious sedation and were administered propofol and remifentanil.

Abawi et al. (19) should be commended for focusing our attention on the incidence, predictors, and effect of POD after TAVR. They utilized a delirium observational score, and a trained geriatrician was consulted to establish the diagnosis of delirium using Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, criteria when the score was ≥3. Unfortunately, frailty was subjectively assessed using the informal "eyeball test" and was evident in 24%

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of patients (63 of 268). Interestingly, the incidence of frailty was similar between those that developed POD (9 of 36, 25%) versus those that did not develop POD (54 of 232, 23%; p = 0.82).

Obvious questions arise: can delirium be significantly decreased or even eliminated in high-risk patients undergoing contemporary transfemoral TAVR? Can a fully awake procedure with objective anatomical and functional screening criteria reduce most complications, including POD, in elderly patients with multiple comorbidities? The 3M TAVR (Multidisciplinary, Multimodality, but Minimalist Approach to Transfemoral Transcatheter Aortic Valve Replacement) study (13 North American sites, n = 800) is currently prospectively enrolling elective transfemoral TAVR patients considered to be at increased surgical risk by their respective heart teams (NCT02287662). In contrast to Abawi et al. (19), the default strategy is a fully awake patient, with a prespecified conscious sedation protocol only if required. The Vancouver Clinical Pathway, utilized in the 3M TAVR study, also includes a simplified transfemoral procedure with early mobilization and next-day discharge. The coprimary outcomes comprise all-cause mortality and major stroke (modified Rankin Scale of 2 or more) by 30 days as well as the proportion of patients who can be safely discharged the next day. Multiple secondary endpoints include short- and long-term quality of life and health economic metrics, readmission rates, and POD with rigorous outpatient follow-up. The preliminary results are encouraging.

While we await the results of multicenter studies, avoiding alternative access and general anesthesia where possible will likely reduce the incidence of POD in high-risk patients. TAVR warrants a clinical pathway tailored to the unique procedure and patient requirements that optimizes opportunities for reducing risk and facilitates early recovery. A fully awake transfemoral procedure with early mobilization and next-day discharge may result in significant cost savings and early improvements in quality of life; furthermore, as highlighted by Abawi et al. (19), a significant ancillary benefit may be its ability to reduce or even eliminate POD.

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