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EDITORIAL COMMENT

The Relationship of Dialysis Risk and Transcatheter Aortic Valve Replacement From the UK TAVI Registry

Study Findings: Some Expected, Some Provocative*

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The rapid development and clinical implementation of transcatheter aortic valve implantation (outside the United States) or replacement (TAVR) (in the United States) has been remarkable. The robust body of evidence supporting the clinical benefit, derived from large randomized controlled trials, is relatively unique for modern cardiovascular devices. As with any new technology, determining individual patient benefit of TAVR versus harm outside a clinical trial can be challenging. This uncertainty is at the forefront when dealing with patients with aortic stenosis (AS) and concomitant chronic kidney disease (CKD). The prevalence of CKD in patients with AS is not trivial and renal function plays a key additive role in the Society of Thoracic Surgery (STS) and EuroSCORE calculations of surgical aortic valve replacement risk. In our experience in San Antonio for example, with a large diabetic and CKD population, renal dysfunction is often the primary clinical variable, which drives the heart team decision in favor of TAVR over surgical aortic valve replacement.

Numerous clinical and potentially ethical concerns remain with respect to TAVR in CKD patients. Acute procedural outcomes with respect to nonrenal complications, acute kidney injury (AKI) during the case, and valve longevity have been active areas of investigation in this population. Furthermore, the net benefit in patients with advanced CKD remains uncertain. Trading symptomatic AS for life-long hemodialysis warrants a discussion, not only from a clinical standpoint, but also from a resource utilization perspective. Of even greater ambiguity with respect to these issues is TAVR use in patients already on hemodialysis, a group not included in the pivotal clinical trials.

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With registry data—such as those presented by Ferro et al. (1) from the United Kingdom in this issue of *JACC: Cardiovascular Interventions*, we may begin to shed light on many of the questions in this context. The authors set out to evaluate the incidence, risk factors and outcomes following TAVR from the UK TAVI registry. The study evaluated patients who underwent TAVR procedure within the United Kingdom since the start of the registry, 2007, up until the year 2014. Data were collected on 6,464 patients with a median-follow up of 625 days. What did the authors find? Over the study period, 202 (3.1%) patients required dialysis for the first time after the TAVR procedure, with a reduction from 6.1% in 2007 to 2008 to 2.1% in 2014. Perhaps unsurprisingly, classic variables that predict AKI following cardiovascular procedures were identified in the present cohort and included baseline renal function, a left ventricular ejection fraction <30%, and diabetes mellitus. Of more specific interest with respect to TAVR, use of an Edwards Lifesciences (Irvine, California) valve versus a Medtronic (Saint Paul, Minnesota) valve,

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non-transfemoral approach, and conversion to open surgery were all associated with need for dialysis. Despite multivariable adjustments, it is likely that patients with inadequate femoral anatomy requiring alternative access represented a sicker population. The same may be said for patients who require emergent open thoracotomy, a situation that is fortunately rare in experienced centers. In reference to mortality, 2,486 (37%) of patients died during the follow-up period of 625 days, and 314 (4.9%) of those deaths occurred during the index hospital admission. Kaplan-Meier analysis revealed nearly a 6-fold increase in mortality in patients requiring dialysis after procedure than those without dialysis.

As the authors admit, an unexpected finding was that the type of valve—self-expanding (Medtronic) versus balloon expandable (Edwards Lifesciences)—appeared to be related to worsening renal function requiring dialysis. This data point will no doubt be provocative and stir much discussion. Even after adjusting for route of access, use of the Edwards valve (odds ratio: 1.85, 95% confidence interval: 1.09 to 3.14; $p = 0.006$) remained significantly associated with adverse renal outcomes. We can only speculate as to the reason for this difference. The need for greater pacing runs (not well captured by the present registry) often needed with balloon expandable valves, with episodes of hypotension or differences in systemic embolization remain possibilities to be tested. Recent study of embolic capture device use in TAVR has demonstrated that debris is captured in the majority (nearly 90%) of cases (2). Furthermore, larger tissue fragments may be more commonly embolized in balloon-expandable valves versus self-expanding valves. The lack of specific biomarkers or clinically validated imaging techniques for renal distal embolization may make exploration of this topic challenging. The present study findings do raise the question of whether direct embolic protection of the kidneys may improve renal outcomes (1).

Perhaps the biggest limitation is the lack of data within the registry with respect to contrast type and volume. It is difficult to reconcile the clinical variables with respect to worsening renal function without understanding the impact of contrast dye. Moreover, the repetitive exposure to contrast agents during the pre-TAVR workup are often overlooked. Computed tomography scans with contrast are frequently used to size the valve structures and iliac/femoral vessels. Coronary angiography with or without percutaneous coronary interventions often precedes the actual TAVR procedure. On the day of implantation, bolus injections of contrast are administered for valve placement.

So what are the takeaways from the present study? Given the marked increase in mortality in patients who end up on dialysis post-TAVR, there needs to be a greater urgency and focus on the role of CKD in these patients. Given the established role of contrast dye as a nephrotoxic agent and the growing evidence that both the route of valve delivery and perhaps the valve type may influence renal outcomes, future registries should be sufficiently granular in their data extraction to capture variables related to these factors. Although the role of embolic protection remains of interest in preventing stroke during TAVR, we should also look further down the aorta to the renal arteries as another vascular bed worthy of protection.

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