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Key Words: NOAC, anticoagulation, bioprosthetic valve

Discussion

Dr Thomas Schwann *(Springfield, Mass)*. I appreciate the opportunity to discuss your presentation, and this is yet another thought-provoking presentation from our colleagues at the Virginia Cardiac Surgical Quality Initiative. As with any good project, it provides interesting information and forces us to pause and reevaluate the basis of what perhaps has become dogma as to how we take care of patients after cardiac surgery who need anticoagulation in the perioperative period.

NOACs have been approved for the prevention of venous thromboembolism in orthopedic procedures and in preventing systemic thromboembolic phenomenon in patients with nonvalvular atrial fibrillation. I think as you already pointed out and I need to reemphasize, as of 2019, despite a documented increase in the use of NOACs, there are no data to support their safety or efficacy in observational or prospective studies in cardiac surgery as an alternative to warfarin.

So aside from demonstrating a shift in practice of Virginia surgeons away from warfarin in favor of NOACs, what are the take-home messages from your study? I believe that the first take-home message is that we as cardiac surgeons don't incorporate practice guidelines into our clinical activities as evidenced here by the low rates of anticoagulation, especially of bioprosthetic aortic valves, an approach that contradicts the 2017 American College of Cardiology/American Heart Association focused update of the 2014 management of patients with valvular disease. The skepticism about warfarin efficacy in patients receiving bioprostheses noted here has been corroborated by Brennan and colleagues, who found only 35% of patients who received bAVRs were discharged on warfarin. Vinod Thourani, in a single institutional study, and our group from an analysis of the National STS Database found that only 55% to 58% of patients undergoing bMVR received warfarin at discharge. Compared with those patients discharged on warfarin, none of these patients showed any increased evidence of perioperative risk of thromboembolic phenomenon or bleeding.

Given the well-known shortcomings of warfarin that have been articulated, including the need for close monitoring, its extensive interaction with multiple foods and medications, and the difficulty of maintaining therapeutic anticoagulation with out-of-range international normalized ratio being reported as high as 70%, it is no wonder that surgeons look for circumstantial data to support alternative clinical practices, such as avoiding anticoagulation entirely or resorting to NOACs. Despite the guidelines, the current knowledge gap does not permit us to definitively state whether bioprosthetic recipients should be discharged on no anticoagulation, warfarin, or NOACs.

The second take-home message is that surgeon dissatisfaction with the current standard of care incorporated into clinical guidelines is a driving force for innovation in clinical medicine. Clearly, warfarin-based anticoagulation is neither patient- nor provider-friendly. There is a precedent for clinician dissatisfaction with the standard of care leading to innovative alternatives, such as the development of percutaneous coronary intervention, multi-arterial CABG, and, more recently, transcatheter aortic valve replacement. I suspect that given the shortcomings of warfarin therapy, it is only a matter of time before NOACs supplement warfarin therapy for patients who present in atrial fibrillation after cardiac surgery, given their increased superiority in efficacy, improved safety profile, and provider and patient-user friendliness, which has been documented in the general population with atrial fibrillation in the RE-LY study, the ROCKET AF study, and particularly in the ARISTOTLE trials, in which NOACs had an improved impact on mortality in patients with atrial fibrillation.

Surgical innovators have the responsibility to ensure each individual patient's safety and interests. We need to be thoughtful and circumspect in how we approach innovation. We all need to be innovators, but we cannot be cowboys. Center-to-center variability in practice based on reasonable and logical extension of available data to similar but not identical circumstances should serve as a basis for such innovation. But if we choose to be involved in innovation in off-label applications of medications and procedures, we must be meticulous in our follow-up and data analysis to ensure that we comply with the most basic mantra of health care, which is primum non nocere.

Given these controversies, I would ask you 2 questions. What is your recommendation for anticoagulation management in patients undergoing bAVR and bMVR? And what is your recommendation for anticoagulation management in patients who develop new-onset postoperative atrial fibrillation?

Dr Robert B. Hawkins *(Charlottesville, Va)*. You picked the 2 controversial aspects of anticoagulation in cardiac surgery. I do think that the main point of this study and some of the others that we have looked at within VCSQI is that cardiac surgeons and guidelines don't necessarily agree. In this case, we see that that dissatisfaction with guidelines is leading to off-label use of NOACs. The point of this study was to see if that's safe, at least with the data that we have available, and all the data that we have available, which is limited, seem to show that that's the case.

In terms of recommendations for bAVR use, I think that multiple studies have demonstrated a small but consistent risk for thromboembolic complications. I don't think that we have the data yet to make strong and clear recommendations, and so the point of this study was to try to demonstrate some level of equipoise to where we can get to that point.

I firmly believe, particularly with the data coming out of ARISTOTLE, that certain agents are going to have clear benefits in terms of reducing that risk after bioprosthetic implantation with better safety profiles. I think with a better safety profile, they will lead to a more rigorous recommendation after implantation.

In terms of postoperative atrial fibrillation, it is a process we don't fully understand, we can't really consistently provide prophylaxis for, and we really don't have a firm understanding of who should get anticoagulation. We don't understand what duration of postoperative atrial fibrillation is needed to trigger the risk/benefit ratio, and again, the same points here, where a better safety profile would lower that threshold for anticoagulation.

So with some degree of short-term equipoise, a trial looking at NOAC use with detailed information about duration and type of arrhythmia postoperatively, other bleeding risks for risk adjustment, and comparison among all 3 arms, for VKA, NOAC, and nonanticoagulation use would be beneficial to really derive a true recommendation. So, those aren't really answers, but they are recommendations.