

## Letter by Secemsky et al Regarding Article, “Relationship Between Femoral Vascular Closure Devices and Short-Term Mortality From 271 845 Percutaneous Coronary Intervention Procedures Performed in the United Kingdom Between 2006 and 2011: A Propensity Score–Corrected Analysis From the British Cardiovascular Intervention Society”

To the Editor:

As interventional cardiologists, we often decide at the end of a procedure whether to close the femoral arterial access site with a vascular closure device (VCD). We make this decision based on a multitude of factors, including the extent of calcification of the femoral artery, the location and quality of the arterial puncture site, and whether the patient requires continued arterial pressure monitoring because of a tenuous condition, or conversely, might benefit from earlier ambulation with a VCD to facilitate same day discharge.

As clinical investigators, we have learned that the inability to capture the clinical nuances that govern treatment decisions create the preconditions for confounding of observational studies, particularly when these variables may themselves be associated with better or worse outcomes. We, therefore, read with both interest and skepticism the study by Farooq et al<sup>1</sup> in *Circulation: Cardiovascular Interventions*, which found that VCDs were associated with a lower risk of mortality among more than 270 000 patients undergoing percutaneous coronary intervention using femoral arterial access, after propensity score adjustment. As the authors acknowledge in their conclusions, “the potential for residual confounding factors impacting on short-term mortality cannot be excluded, despite the study having measured and balanced all recorded confounder factors.” In this case, we believe residual confounding to be not the potential explanation, but in fact, the most likely explanation for the findings.

We have previously advocated for the use of alternative observational study designs, such as those using instrumental variables or falsification end points, as an attempt to overcome the limitations of propensity score methodologies in the setting of unmeasured confounding.<sup>2</sup> In fact, we applied such methods to examine this question in this same journal this year,<sup>3</sup> concluding that VCDs were associated with only a modest benefit in terms of reducing vascular complications and bleeding, and had no impact on in-hospital mortality. Analysis of our data using a propensity score approach would have found a greater reduction in bleeding and a significant decrease in mortality with VCD use, but, also, implausibly, a reduction in nonaccess site bleeding, a strong indication that this method would have been insufficient to overcome confounding. If feasible, we would encourage Farooq et al<sup>1</sup> to perform an instrumental variable study to see if their results change, or, perhaps more simply, to examine propensity score–adjusted rates of nonaccess site bleeding as a falsification end point to test for confounding. Although these methods are not a panacea,<sup>4</sup> we believe they deserve stronger consideration in such circumstances, when clinically credible confounders may completely invalidate a study’s primary conclusions.

More broadly, however, we believe that the publication of such diverging studies without an attempt to reconcile their differences does a disservice to both the research and clinical communities. Perfunctory acknowledgments of the potential for unmeasured confounding now appear in nearly every observational study, but confounding does not affect all studies or approaches equally. It is imperative that investigators, peer reviewers, and journals work together to create, evaluate, and disseminate research in a manner that helps us discern the difference.

## Disclosures

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