Correspondence


To the Editor:

The study by Sanborn et al is a post hoc analysis in which multiple statistical tests have been made in an exploratory manner to examine the possible differences in access-site bleeding (ASB) with or without a vascular closure device (VCD). If $P$ values <0.05 are used for statistical significance, a high false discovery rate for significant differences is to be expected.

Patients with a major ASB were allotted to 7 end-point subgroups, but the sum of the patients in the subgroups is greater than the total number with major ASB. Therefore, many patients have been allotted to several subgroups and included in several analyses.

The only end-point subgroup comparison showing a significant difference was the ≥5-cm-diameter hematoma end point, inconsequential concerning the need for intervention or surgical correction. The difference between the VCD and the no-VCD groups concerning requirement for interventional or surgical correction of ASB, with a $P$ value of 0.048, may be because of chance.

Patients who did not receive a VCD may have been more prone to develop an ASB because of a higher rate of hypertension and renal insufficiency. They may have received more intense platelet inhibition because of a higher rate of elevated biomarkers, and their higher rate of anemia may have increased the likelihood of intervention because of hemorrhage.

VCD complications can result in permanent tissue malfunction or loss and severe infections. There is no proof to support the belief of the authors that contemporary VCD complication rates are decreasing. A realistic VCD complication rate on the order of 1:275 among the 4307 patients would result in 16 complications, most of them far more serious than the 16 ASBs in their study, requiring interventional, presumably transfusions, or surgical correction. In addition, late undetected complications may occur.

The use of a VCD has not been demonstrated to improve survival. In contrary, their use has been followed by serious complications. Although bleeding is a predictor of 30-day mortality in invasively managed patients, the implied assumption that VCD use can reduce the mortality is presently unfounded.

Some of the authors may have a vested interest in the performance of firms producing VCDs.

Disclosures

None.

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References


Letter by Dregelid Regarding Article, "Impact of Femoral Vascular Closure Devices and Antithrombotic Therapy on Access Site Bleeding in Acute Coronary Syndromes: The Acute Catheterization and Urgent Intervention Triage Strategy (ACUITY) Trial"

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