analysis. Of these, 465 (1.3%) developed significant pericardial complications. Patients with significant pericardial complications were more likely to develop in-hospital complications including all-cause mortality. Female [OR 2.29, 95% CI 1.46−3.6; p <0.001] and coagulopathy [OR 1.6, 95% CI 1.05−2.46; p = 0.031] were associated with higher rates of significant pericardial complications, while a history of coronary artery bypass grafting (CABG) [OR 0.39, 95% CI 0.16−0.92; p = 0.033] or cardiovascular implantable electronic device (CIED) implantation [OR 0.32, 95% CI 0.11 −0.88; p = 0.028] was associated with a lower odds for significant pericardial complications. Significant pericardial complications were also independently associated with >7-fold higher odds for mortality [OR 4.91, 95% CI 2.56−9.43, p <0.001].

In both females and the elderly, it has been suggested that a thinner myocardial wall leaves these patients more vulnerable to pericardial injury.[5,4,5] In contrast, a history of CABG has been reported to be associated with lower incidence of significant pericardial complications in patients who underwent noncoronary procedures such as device implantation.[3,5] This is likely due to pericardial inflammation and subsequent fibrosis, postcardiotomy.[3,5] This study also reports an association of CIED in situ with a lower incidence of significant pericardial complications in a TAVR cohort. Rapid pacing with implanted CIEDs is not currently routine practice, therefore, it does not follow that CIEDs are in any way cardio-protective, but rather that many significant pericardial complications may be due to requisite temporary pacemaker insertion. Nonetheless, operators should pay particularly close attention during insertion or manipulation of temporary pacemaker wires during TAVR procedures.

The National Inpatient Sample (NIS) database includes limitations inherent to retrospective database analysis. The inability to review procedural details limits our ability to ascertain exact clinical circumstances in any single case. We exercised due diligence to exclude patients who may have suffered significant pericardial complications from other causes, and present only patients who most likely developed significant pericardial complications due to their TAVR procedure. Our results do not extend to patients who experienced major procedural complication resulting in surgical aortic valve replacement or those who required permanent pacemaker implantation (Table).

In this observational study describing characteristics and predictors of significant pericardial complications in patients who underwent TAVR, we found that (1) significant pericardial complications were not uncommon, ranging 1.2% −1.5% in the 3 years studied. (2) These complications were associated with markedly increased morbidity and mortality. (3) Presence of CIED and a history of CABG were associated with lower odds for these complications while female and a history of coagulopathy were associated with higher odds.

Disclosures

The authors have no conflicts of interest to disclose.

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Prognosis is Different than Treatment Effect

We have concerns with the publication, "Relation of Obesity to Outcomes of Hospitalizations for Atrial Fibrillation"[1] (AF). We found it to be another example in which the rules of logic are ignored to produce findings that appear paradoxical and surprising, but are really predictable and mundane. This analysis and others like it misinterpret associations seen in observational evidence, and ultimately serve as a source of confusion to those aiming to practice evidence-based medicine.

Agarwal et al[1] analyzed a nationwide sample of patients who were hospitalized with AF and found that those who were obese had better outcomes than those who were not obese. Because obesity is a known risk factor for AF, the authors convey a sense of surprise in the findings, describing them as "paradoxical." The findings are not paradoxical. There are many things that cause AF. Obesity is just one cause. Patients included in this study who were not obese must have had another cause for the condition. And those who have non−obesity-related causes for AF (e.g., systolic and diastolic heart failure, valvular heart disease, uncontrolled hypertension, chronic obstructive lung disease, aging-related frailty, and so on) did worse. Thus, in relative terms, patients who had the condition caused merely by obesity appear to do better.

Prognosis (i.e., prediction) is different than treatment effect. A clinician can see a patient drive up to the clinic in a new $75,000 Tesla and predict that the patient will live longer than another patient who arrives to clinic through less wealthy means. It does not

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mean that the Tesla causes a longer life. We use this obvious example to emphasize the need to think about the reasons for associations.

Like most papers reporting the so-called "obesity paradox," the authors hedge on the implications of their findings. For instance, they state that "... favorable survival outcomes in obese AF-patients do not assume causation ..." If they would stop there, they would not be wrong. But, they also write in the first line of the abstract that the "*impact* of presence of obesity on outcomes of hospitalizations for AF has not been investigated." This statement clearly suggests that the purpose of their study was to evaluate the causal implications (i.e., impact) of obesity. They further cloud the situation in the discussion section with this sentence: "To the best of our knowledge, our study is the first to report the paradoxical *protective effect* of obesity on in-hospital outcomes in AF hospitalization at a large, nationwide level." (Emphasis ours.) There is no way to interpret the previous sentence other than as a statement of the effect of obesity.

Furthermore, in this particular study, the authors seem to misunderstand their research methods, stating that this was "an unselected cohort." In fact, this was a highly selected cohort in that it included patients who were (1) hospitalized and (2) hospitalized for AF. Researchers should consider what might cause a person to be enrolled into a study. In this study, included patients who were not obese had to have AF and be ill enough to require hospitalization. In the United States, there are approximately 3 to 6 million patients with AF,[2] and most are not in the hospital. When observing the effect of something, such as obesity, that causes inclusion into the study, here, AF and hospitalization, then there is often selection bias before study onset.[3] This was not an unselected cohort.

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