Anticoagulation medications show no gender-based variations in outcomes for TAVR patients

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A study on the impact of using different anticoagulation medications on men and women who have undergone a transcatheter aortic valve replacement (TAVR) found no difference in early vascular complications or mortality. The BRAVO 3 results were presented today as a late-breaking clinical trial at the Society for Cardiovascular Angiography and Interventions (SCAI) 2016 Scientific Sessions in Orlando, Fla.

BRAVO 3 assessed contemporary TAVR procedures administered through the leg, or transfemoral procedures, and compared the use of two anticoagulation medications, bivalirudin and unfractionated heparin (UFH). The study was a randomized multicenter trial with 31 centers participating (n = 802). The primary endpoint was major bleeding occurring within 48 hours. Major bleeding was defined as Bleeding Academic Research Consortium (BARC) type 3b, which is overt bleeding with a significant drop in hemoglobin or that requires surgical intervention and/or IV vasoactive agents to control.

"Prior evidence has shown that while women have a higher rate of survival post TAVR, they are at a greater risk of complications from bleeding soon after a procedure," said Anita W. Asgar, MD, the paper's lead author. "BRAVO 3 was designed to look at whether different anticoagulation medications could reduce the early risk in women."

The study was comprised of 49 percent women (n = 391, 195 received bivalirudin and 196 received UFH) and 51 percent men (n = 411, 209 received bivalirudin and 202 received UFH). Women were older than men and had fewer comorbidities, such as coronary artery disease, atrial fibrillation and diabetes. While women had a lower EuroSCORE I— a predictor of operative mortality in patients undergoing cardiac surgery— all patients were considered high-risk for TAVR.

Compared with men, at 30 days, women demonstrated similar survival (19 men vs. 19 women, p = 0.87), major adverse cardiac event (34 men vs. 29 women, p = 0.65) and vascular complications (32 men vs. 43 women, p = 0.12).

"The good news is that we found early outcomes for women were comparable to those of men," said Dr. Asgar. "That being said, the BRAVO 3 study only looked at outcomes over 30 days, so the next step would be to see long-term results for post-TAVR procedures."

BRAVO 3 did find a trend—although not statistically significant—that women who were given bivalirudin experienced less mortality. Dr. Asgar noted this indication could warrant further studies, with a larger population, on using bivalirudin over UFH for women.

More information: Dr. Asgar presented "Sex-Based Differences in Outcomes with Bivalirudin or Unfractionated Heparin for Transcatheter Aortic Valve Replacement: Results from the BRAVO 3 Randomized Trial" on Friday, May 6, 2016 at 9:45 a.m. ET.
For more information about the SCAI 2016 Scientific Sessions, visit www.SCAI.org/SCAI2016.

Provided by Society for Cardiovascular Angiography and Interventions