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Bravo-3 clinical trial shows strong safety profile for Proglide suture device

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Results from an analysis of a large randomized trial shows ProGlide vascular closure device (VCD) was associated with lower rates of vascular complications, lower rates of acute kidney injury (AKI) and shorter hospitalizations after transcatheter aortic valve replacement (TAVR) when compared with Prostar XL. Both ProGlide and Prostar XL are leading VCDs in interventional cardiology, and the study examined the impact of these devices on vascular bleeding complications after TAVR. The study is scheduled to be presented on Wednesday, May 22 at the Society for Cardiovascular Angiography and Interventions (SCAI) 2019 Scientific Sessions.

More than five million Americans are diagnosed with heart valve disease each year (AHA). TAVR is a procedure used for high-risk patients with severe narrowing of the aortic vessel where a prosthetic valve is implanted and the damaged valve is replaced. VCDs are used during TAVR to close the artery after the procedure to prevent blood loss. Although VCD failure is rare, when it does fail, a patient's risk for severe vascular complications increases dramatically.

The BRAVO-3 randomized trial analyzed 802 patients undergoing transfemoral TAVR. Patients were stratified according to type of VCD used and the 30-day incidence of major or minor vascular complications, including bleeding, AKI, myocardial infarction, stroke and death were analyzed. Associations between device type and outcomes were assessed via multivariate logistical regression analysis.

In total, 746 (93 percent) patients were treated with either ProGlide (n= 394, 53 percent) or Prostar XL (n= 352, 47 percent) VCDs, without significant differences in successful deployment rate (ProGlide 94.2 percent vs Prostar XL 91.2 percent). ProGlide was associated with a significantly lower incidence of major or minor vascular complications compared to Prostar XL (ProGlide 15 percent vs Prostar XL 24 percent). Rates of AKI were lower with ProGlide with only 17 percent of patients versus 25 percent of patients post-TAVR procedure. Patients treated with ProGlide had a shorter length of hospital stay compared to patients treated with Prostar XL (7.3 days versus 9.2 days), however there were no significant differences between major bleeding, Major Adverse Cardiovascular and Cerebrovascular Event (MACCE) and death.

"Patients undergoing TAVR are very frail and vulnerable to begin with, so significant blood loss, a kidney injury or spending extra days in the hospital may truly take a toll on their outcomes," said lead author David Power, MD, MBBCh, Icahn School of Medicine at Mount Sinai in New York, NY. "Our trial is the first using highly adjudicated randomized trial data to showcase how the ProGlide device may lower rates of vascular complications, lower rates of kidney injury and shorten hospitalization time when compared to ProStar XL. The results show that this device has the potential to serve as the safer, more effective option."

Moving forward, the authors of the study would hope to refine these devices to be able to use smaller sheaths allowing better access to the artery during TAVR. Additionally, future randomized control studies would aim to solidify ProGlide as the leading VCD for TAVR procedures.

More information: "Featured Clinical Science, Part II: "Vascular Closure Device Type Impacts Bleeding and Vascular Complications

After TAVR: Results from the BRAVO 3 Randomized Trial" [May 22, 2019, 11:55 a.m. - 12:05 p.m. PDT, Belmont Ballroom 4]

Provided by Society for Cardiovascular Angiography and Interventions