Article Summary
Vascular Closure Devices

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Impact of Percutaneous Closure Device Type On Vascular and Bleeding Complications After TAVR: A Post Hoc Analysis From the BRAVO-3 Randomized Trial

Power, David et al. Catheter and Cardiovasc Interv. 2019 Jun 1;93(7):1374-1381.

PURPOSE

- To investigate the impact of vascular closure devices (VCD) on vascular and bleeding complications after transfemoral TAVR in the large Bivalirudin Versus Heparin Anticoagulation in Transcatheter Aortic Valve Replacement (BRAVO-3) randomized trial population.

METHODS

- A post hoc analysis of the BRAVO-3 trial included stratification of patients based on the type of VCD used. Out of 802 patients, 746 received a VCD:
  - Prostar™ XL: N = 352 (47%)
  - ProGlide™: N = 394 (53%)
- Examined the 30-day incidence of the following:
  - Major or minor vascular complications
  - Major bleeding (BARC ≥ 3b)
  - Acute Kidney Injury (AKI)
  - Major Adverse Cardiac and Cerebrovascular Events (MACCE; death, myocardial infarction or stroke)

RESULTS

- The Prostar system was associated with an increased incidence of major or minor vascular complications when compared to the ProGlide system (adjusted OR: 0.54, 95% CI, $p < .01$).
- The overall incidence of major or minor vascular complications was 24% with Prostar and 15% with ProGlide. The incidence of major bleeding (BARC ≥ 3b) was 11% and 8% respectively.
- Incidence of Acute Kidney Injury was lower with the ProGlide system as well.
- There was no significant difference between the two VCDs in bleeding, MACCE, and death.

AUTHOR CONCLUSIONS

- Compared to Prostar, the ProGlide VCD was associated with a lower rate of major or minor vascular complications and lower rates of AKI after transfemoral TAVR.
- Operators should be aware of the impact percutaneous VCDs have on vascular and bleeding complications.

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30-DAY CLINICAL OUTCOMES

	PROSTAR™ XL N = 352	PROGLIDE™ N = 394
MAJOR OR MINOR VASCULAR COMPLICATIONS	86 (24%)	61 (15%)
MAJOR BLEEDING (BARC ≥ 3B)	39 (11%)	33 (8%)
ANY BARC BLEEDING	167 (47%)	194 (49%)
ACUTE KIDNEY INJURY	70 (25%)	57 (17%)
MACCE	28 (8%)	32 (8%)
DEATH	21 (6%)	16 (4%)

KEY POINTS

- Although there was no significant difference between ProGlide and Prostar, bleeding complications after transfemoral TAVR occurred frequently in patients with either VCD (9.5% major bleeding BARC ≥ 3b).
- Preventative and bleeding avoidance strategies, such as the early detection of bleeding events, can reduce the risk of bleeding in a high-risk TAVR patient population.