Article Summary
Vascular Closure Devices

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Real-world Experience of Suture-based Closure Devices: Insights From The FDA Manufacturer and User Facility Device Experience

Case BC, Kumar S, Yerasi C, et al. *Catheter Cardiovasc Interv. 2021;1–6.*

PURPOSE

- To understand the most commonly reported complications associated with suture-based vascular closure devices (VCDs) in real-world experience.
- To understand the mechanisms of failure from suture-based vascular closure devices.

METHODS

- Retrospective analysis of post-marketing surveillance data from the U.S. FDA MAUDE database for suture-based VCD.
- The MAUDE database includes reports of adverse events involving medical devices submitted to the FDA by both mandatory and voluntary reporters.
- Perclose ProGlide™ (Abbott) and Prostar™ XL (Abbott) reports of device-related death, vessel injuries, and modes of device failure.

RESULTS

- Of 703 reports of major complications with the Perclose ProGlide system, 404 involved injury and 1 involved death.
- Of 153 reports of major complications involving the Prostar XL system, 94 involved injury and 1 involved death.
- Vessel injury resulting in bleeding was the most common complication reported followed by groin hematoma and occlusion.
- Interventions included surgical repair, manual compression, and percutaneous covered stent.
- The most common mode of failure for the Perclose ProGlide system was a suture-related malfunction or a missing suture.
- The most common mode of failure for the Prostar XL device was failed deployment followed by a suture- related malfunction.

AUTHOR CONCLUSIONS

- Real-world use of these devices report major vascular complications such as bleeding, thrombus, pseudoaneurysms, and death.
- Operators should be aware of the mehcanisms of failure for both devices and the related complications, especially in a high-risk patient population.

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(Continued)

Summary of MAUDE Reports on Suture-Based VCDs*

	Perclose ProGlide™ N = 827	Prostar™ XL N = 175
Patient-Related Complications	n = 405 (48.97%)	n = 95 (54.29%)
Death	1 (0.12%)	1 (0.57%)
Injury	404 (48.85%)	94 (53.71%)
Vessel injury	**384 (46.43%)**	**87 (49.71%)**
Hematoma	**10 (1.21%)**	**3 (1.71%)**
Thrombus	5 (0.60%)	1 (0.57%)
Vessel occlusion	2 (0.24%)	-
Pseudoaneurysm	2 (0.24%)	1 (0.57%)
Not specified	15 (1.81%)	2 (1.14%)

Most common adverse events from suture-based VCDs are vessel injuries resulting in bleeding and hematomas.

KEY POINTS

- Bleeding from vessel injury was the most common complication described with both suture-based VCDs, followed by hematoma and occlusion.
- Preventative and bleeding avoidance strategies, such as the early detection of bleeding events, can reduce the risk of bleeding from VCD malfunction, especially in a high-risk patient population.

* Percentages represent the proportion of total MAUDE reports and not true incidence rates of each complication

Indications for Use. The Early Bird is indicated for the introduction of catheters, catheter balloons, and other diagnostic and interventional devices into the femoral artery or femoral vein while maintaining hemostasis during diagnostic and interventional endovascular procedures.
Contraindications. There are no known contraindications for Early Bird.