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Editorial Commentary

The "Pro-Seal" Large-Bore Arterial Access Closure Technique: Making the Best of What Is Available

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The number of patients undergoing transcatheter aortic valve replacement (TAVR) and other percutaneous procedures for structural heart disease has risen in recent years and will likely continue to increase. Despite iterative improvements in delivery systems resulting in smaller sizes and entry profiles, large-bore vascular access will continue to be needed. Cardiovascular interventionalists are tasked with performing TAVR procedures as safely as possible while maintaining a low incidence of bleeding and ischemic access site complications—all while using commercially available vascular closure equipment.

Multiple large-bore vascular closure devices are currently used in clinical practice; one of the most commonly employed is the suture-based Perclose ProGlide system (Abbott Vascular, Inc). Even though its versatility and effectiveness are acceptable, the Perclose ProGlide device does occasionally fail. How best to achieve complete hemostasis when a failure occurs remains to be determined.

In this issue of the *Journal*, Cakal et al[1] report their experience using an ANGIO-SEAL device (Terumo Medical Corporation) in patients for whom Perclose ProGlide device deployment did not result in complete hemostasis. The authors performed a retrospective review of 185 patients who underwent TAVR in their center. In all individuals, vascular closure was performed using 2 Perclose ProGlide devices; in 46 of these patients, an 8F ANGIO-SEAL device was added as a "bailout" when the Perclose ProGlide device failed and persistent vascular bleeding was noted. The auxiliary ANGIO-SEAL device was deemed successful in all cases. No statistically significant differences in vascular complications were noted, although a higher incidence of hematoma formation was found in the ANGIO-SEAL bailout group.

The findings from Cakal et al[1] support the safety and feasibility of using an ANGIO-SEAL device as bailout when use of 2 Perclose ProGlide devices fails to achieve hemostasis in large-bore arterial closure—an approach that has come to be referred to as the "Pro-Seal" technique. These are welcome data because they inform current practice and broaden the operators' options in complex patients. Nonetheless, it is worth noting a particular limitation of this study and its proposed approach (beyond its limited number of patients and retrospective nature). Deciding when hemostasis is suboptimal remains a significantly subjective endeavor. It is unclear whether manual compression after Perclose ProGlide closure might have successfully controlled bleeding in some of these patients, thereby avoiding the use of an additional device that could cause further complications. Clarifying this point is especially important because the operators suggest a Perclose ProGlide failure rate exceeding 20%, which is significantly higher than expected. Fortunately, given the authors' experience, the downside of adding an ANGIO-SEAL device appears to be minimal.

Even though a surgeon with experience in open vascular repair may be profoundly dissatisfied with the macroscopic and microscopic appearance of 2 Perclose ProGlide devices and 1 ANGIO-SEAL device in the arteriotomy site, the Pro-Seal technique appears to be an acceptable solution for completing the procedure safely and efficiently. This strategy is effective not only as bailout in case of bleeding but also as a planned strategy from the outset, as demonstrated in a large retrospective study.[2] As

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expected, additional data confirming the utility, safety, and effectiveness of the Pro-Seal approach are needed, as is the development of newer and better closure devices designed from inception to be used specifically for large-bore access closure.

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