CLOSURE

MYNX® Utility for Both Arterial and Venous Access Sites

An overview of the clinical outcomes and safety and efficacy profile of the MYNX® VCD.

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Vascular closure devices (VCDs) can provide mechanical closure and employ a sealant to achieve hemostasis at the access site after percutaneous interventions. VCDs can help reduce bleeding complications, facilitate earlier ambulation, and offer patients a shorter and less painful alternative to manual compression. The data to support these findings for systematic utilization of VCDs are emerging, although cost-effectiveness data are still lacking. Of the VCDs on the market, MYNX® VCD (Cordis, a Cardinal Health company) has become a popular choice among interventional cardiologists, as it is labeled for closure of both arterial and venous femoral access sites.

The MYNX® VCD uses a polyethylene glycol material as a sealant that grips to the vessel wall and facilitates clot formation. The sealant is bioresorbable within 30 days, which may help avoid issues seen with other VCDs that leave hardware behind at the access sites. In multiple studies, MYNX® has demonstrated safety and efficacy for its indicated uses compared with other VCDs and manual compression.[1-5]

ARTERIAL CLOSURE

A European multicenter prospective single-arm study by Scheinert et al evaluated the hemostatic safety and efficacy of Grip® sealant.[1] The MYNX® VCD was evaluated in patients following diagnostic or interventional endovascular procedures performed through 5-, 6-, or 7-F introducer sheaths in the common femoral artery. The study reported a high procedural success rate, absence of major complications, and relatively infrequent minor complications. Mean times to hemostasis and ambulation were 1.3 ± 2.3 minutes and 2.6 ± 2.6 hours, respectively. The investigators pointed to the MYNX® VCD as a "new approach, away from the mechanical reliance, toward a physiologic solution" due to the effectiveness of the device's sealant after cardiac catheterization and percutaneous coronary intervention (PCI).[1]

MYNX® COMPARED WITH OTHER VCDs

Baker et al compared the prevalence of complications and failure rates between the most commonly used "active" anchoring VCD, Angio-Seal™ (Terumo Interventional Systems), and "passive" anchoring VCD, MYNX®, in contemporary practice in a total of 4,074 patients undergoing PCI.[2] Although the two VCDs differ in their application of the sealants—the Angio-Seal™ sealant is designed to be intra-arterial, whereas MYNX® sealant helps facilitate natural external thrombosis and healing—the authors reported a similar safety and efficacy profile for both devices. However, the investigators noted the potential theoretical advantage of the MYNX® VCD, "as no intra-arterial anchor remains upon device removal."[2]

MYNX®and Angio-Seal™ were also previously evaluated in a study by Noor et al that focused on emergent surgery for access site complications after femoral catheterization.[3] In the retrospective review, the authors compared the rates of surgeries needed between those who received MYNX®, Angio-Seal™, and manual compression and found a significant reduction in surgeries in the MYNX® and Angio-Seal™ patients.

In contrast, Resnic et al reported a higher risk of any vascular complication with the MYNX® VCD than with alternative VCDs in their study.[4] This prospective, active surveillance of a national clinical registry monitored the safety of the MYNX® VCD in 73,124 patients who received the device after PCI. Relative risks were greater in patients with diabetes, those who were 70 years or older, and women. However, in centers that were experienced in the use of the MYNX® VCD, the rates of complications were lower, which suggests a need for sufficient operator experience when utilizing closure devices. This observation was also true for other VCDs. The investigators of the study cautioned against overinterpretation of their results due to potential confounders that could not be matched between MYNX® and the alternative VCDs.

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VENOUS CLOSURE

In 2014, the FDA granted approval for the use of MYNX® for femoral veins. The venous indication could help interventional health care providers increase the efficiency of their labs and minimize potential complications associated with venous closure by replacing the need for manual compression. The MYNX® VCD is intended to reduce times to hemostasis and ambulation, thereby potentially shortening postprocedure recovery times.

Indeed, the MYNX® VCD was shown to be effective at achieving hemostasis of transfemoral venous access sites in a study by Srivatsa et al.[5] In this study, the authors compared manual compression against closure with MYNX® after having deployed 7-F sheaths in the femoral veins of swine. In both the manual compression control group and the MYNX® group, hemostasis was achieved in all cases without groin complications or device failures. The authors concluded that venous closure with the MYNX® VCD is safe and reliable, noting that there were no differences in histological responses between access sites in both groups.

Similarly, a randomized study by Ben-Dor et al compared MYNXGRIP® with manual compression after procedures using femoral venous access.[6] This was a multicenter, randomized, prospective study of 206 patients who underwent either diagnostic or interventional procedures. Patients were randomized 1:1 to receive venous hemostasis achieved using the MYNXGRIP® VCD versus manual compression for 5-, 6-, or 7-F sheaths placed in the common femoral vein. Patients were followed through hospital discharge to assess the primary safety outcome of deep vein thrombotic and/or bleeding/vascular injury-related complications from the target venous closure site. MYNXGRIP® was shown to be safe and effective when compared to manual compression. The study investigators reported no closure device failures or complications related to venous access closure, as well as significantly shorter hemostasis time with MYNXGRIP® compared to manual compression when removing 5- to 7-F venous sheaths.

CONCLUSION

MYNX® has demonstrated its value as a VCD with advantages for patients who have undergone procedures with percutaneous access. Clinical data on the device have reported satisfactory performance for both femoral arterial and venous closure with regard to its safety and effectiveness profile. When compared with manual compression, the MYNX® VCD shortens the time to hemostasis, which can provide comfort to the patient and efficiency to the catheterization lab. ■

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