

Real-world Evidence for VASCADE MVP

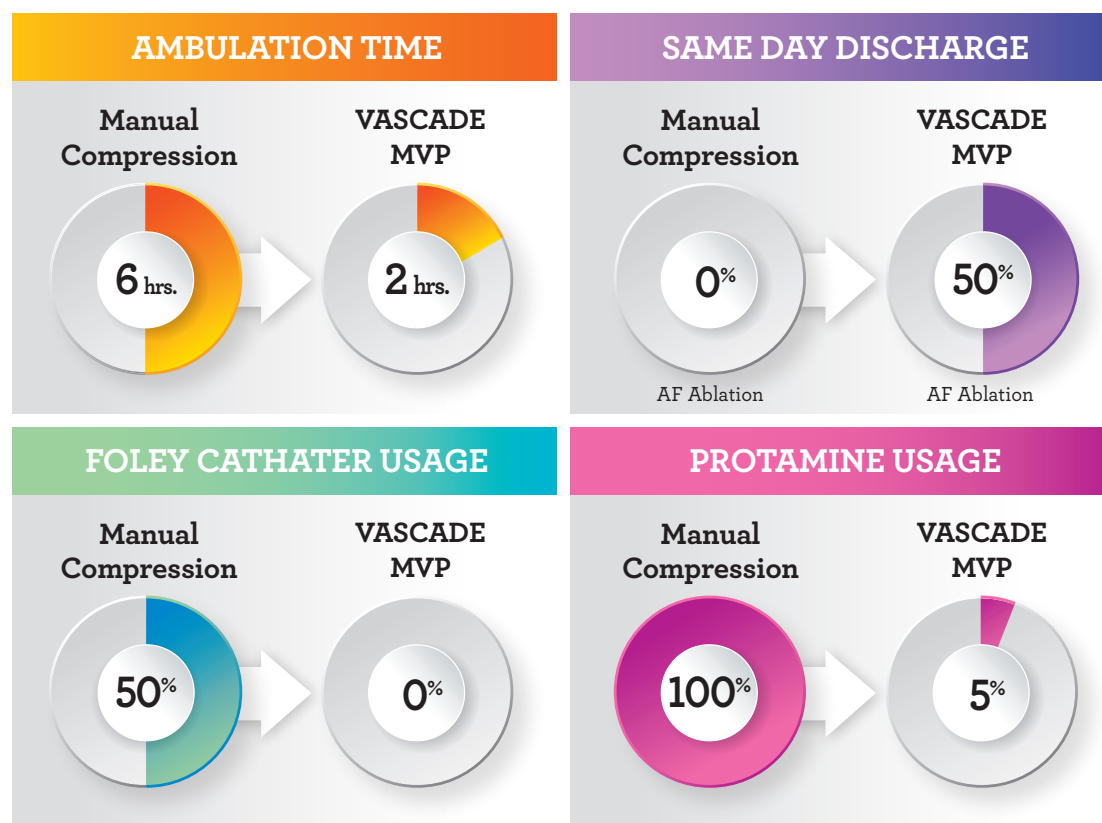
About the EP Program

- Consultants in Cardiology & Electrophysiology is a Chicago based group offering a comprehensive range of cardiac diagnostic and interventional services.
- The group has 3 EPs who perform procedures in the 2 EP labs at nearby Advocate Christ Medical Center.
- They are actively involved with many new technologies including left atrial appendage occlusion and transcatheter pacing. They were one of thirteen investigator sites for the VASCADE MVP AMBULATE PMA clinical trial.



William Spear, MD, FACC, FHRS
Photo courtesy Community Healthcare System®.

Benefits for Patients with VASCADE MVP at Advocate Christ Medical Center



By taking away the worst part of the procedure for patients, VASCADE MVP has dramatically changed the whole patient experience for AF ablation.

Discussion with Dr. Spear

Q: How has VASCADE MVP affected the patient experience, especially for patients who have had a previous ablation?

A: The patient experience is much more positive now. Patients who had a previous ablation with manual compression and subsequently a procedure with VASCADE MVP closure have been pleasantly surprised. Patients who had a prior ablation are dreading going back for another ablation because they remember the post-procedure recovery time – the manual compression, the pull of the sheath, the 6-hour bedrest and the associated pain and discomfort. A lot of patients bring that up in the office when we discuss going back for

another ablation. When I let them know that we have access to a new closure device, and they will be up and around within ~2 hours, they are much more willing to have the additional procedure.

Q: From your staff's perspective, what has been the impact of using VASCADE MVP?

A: Our teams have seen benefits both in the lab and in the recovery area. In the lab, we've developed a more efficient process with anesthesia after the procedure; as our patients are lightly waking up, we are closing the groin. By the time the lab has been broken down, our patients are fully awake and ready to be taken to recovery.

Additionally, our new post-procedure protocols really simplify things in the recovery area. Since patients have a stable groin when they reach the recovery area, they are required to spend significantly less time there. Now, our recovery staff has come to expect that there is a closure device and instead of managing sheaths and checking ACTs, they are able to focus more on the patients.

Q: How does VASCADE MVP compare to other closure techniques you have used?

A: VASCADE MVP is a much more sophisticated way to close the veins. Other closure systems are complicated and have a steep learning curve. VASCADE MVP is very simple and easy to learn.

Some people are adding a 3-way stopcock to a figure-of-eight (fo8) stitch so that they can tighten or loosen the stitch as needed. To me, that feels like a step backwards. The fo8 stitch definitely helps with hemostasis, but it does not shorten the time to ambulation, and it is painful for patients. It is really nice to be able to use VASCADE MVP instead of the fo8 stitch.

Q: How often are you currently using VASCADE MVP in your practice and were there cost concerns about adding it to your procedures?

A: Initially, we used VASCADE MVP only with our AF ablation cases. Now we use it in all procedures with groin access based on the substantial increases in patient satisfaction and lab efficiency.

Regarding cost, our partners in the cath labs have demonstrated the value of closure over many years. As a result, everyone already understood that the benefits outweigh any additional costs.

Q: Finally, how significant are the VASCADE MVP post-procedure protocol changes in the world of EP?

A: This is one of the biggest things that has happened for AF ablation in the last decade. We have had improvements in ablation technologies but have seen little to no innovation to the patient experience. By being able to walk patients 2 hours after the procedure, VASCADE MVP has changed the whole dynamic of AF ablation. I see it as a hugely positive effect to the procedure itself.

We have been able to shorten AF ablation procedure time yet we were having patients lay flat for 6 hours after a 1-2 hour procedure – 3-4 times the length of the procedure itself! Now, by shortening that period of time, it gives us the opportunity to take the experience from an all-day affair down to a few hours. This change has enabled same-day discharge for many of our AF ablation patients, and with COVID-19, same-day discharge is even more important.

All of these things have dramatically changed the patient experience in a very positive way.

Dr. Spear is not financially compensated by Cardiva Medical for this publication, and the content is an accurate presentation of his personal opinion of the VASCADE MVP device. Refer to the product IFU before use for important safety information.

Early Ambulation. Simple. Proven.

Introducing VASCADE[®] MVP VASCULAR CLOSURE FOR EP¹ PROCEDURES

VASCADE MVP was evaluated in the AMBULATE pivotal trial.

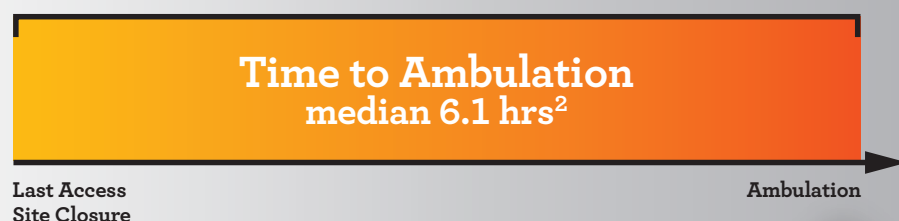
- Multicenter
- 204 patients
- 1:1 randomization VASCADE MVP or manual compression



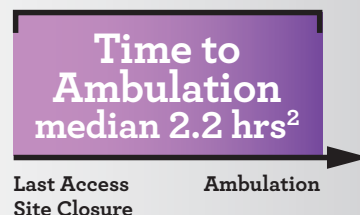
1. Electrophysiology (EP)
 2. Difference in median time to ambulation as reported in the IFU.
 3. As demonstrated in the AMBULATE Pivotal study. Attribute was unspecified, but actual results imply superiority.

Patient Satisfaction with Duration of Bedrest

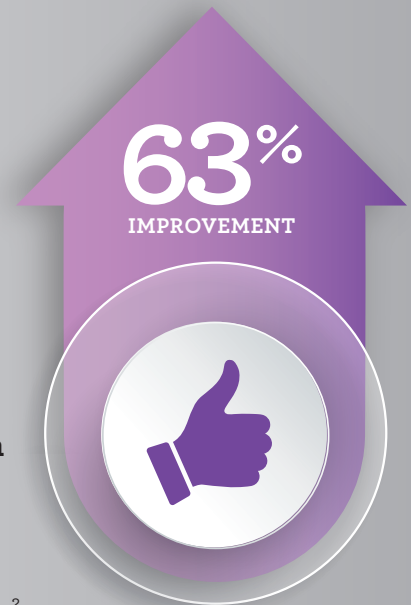
Manual Compression



VASCADE MVP



-3.9 hrs.



Patient Satisfaction with Duration of Bedrest

Manual Comp = 5.1 vs. VASCADE MVP = 8.3 mean²