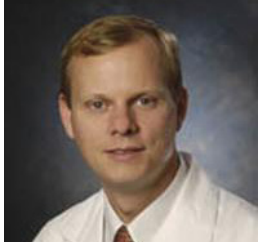


UAB Real World Experience: Same Day Discharge Program for AF Ablation Using VASCADE MVP®



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UAB is an international leader in cardiovascular care, including ongoing arrhythmia research and participation in several electrophysiology clinical trials. We have an experienced team of five electrophysiologists who treat a range of complex arrhythmias, including atrial fibrillation (AF). We perform approximately 800 ablations per year, including 500+ for AF.

In 2019, we implemented early ambulation following AF ablation using VASCADE MVP® and have been studying early ambulation and same day discharge as part of the AMBULATE Same Day Discharge Clinical Studies² where we have been a top enrolling site in the two prospective studies.

Our Vascular Closure Journey

We initially used manual compression (MC) to achieve hemostasis. Historically, MC of the femoral venous access site/s post-AF ablation has been the most common method for achieving hemostasis; however MC is uncomfortable for patients, usually requiring 4-6 hours of lying flat to keep the limb/s immobilized, and often including the use of a urinary catheter. Manual compression also creates workflow challenges for clinicians and nursing staff, requiring dedicated resources to manage patients post procedure for several hours.

“At UAB, reducing our time to ambulation from 6 hours to 2 hours has made for a better patient experience, and the improved workflow has allowed us to send approximately 90% of our AF ablation patients home the same day.”

— Tom McElderry, MD

Moving away from MC, we used a Figure of Eight suture (FO8) to hasten time to hemostasis and lessen the staffing burdens inherent with MC. While FO8 is effective at attaining initial hemostasis and is inexpensive from a cost and purchasing perspective, our patients found this approach quite painful. Patients were dissatisfied with having a FO8 suture in place during post-procedure care and it did not hasten time to ambulation at our center.

We searched for a closure approach that would be better for patients – and this is what led us to implementing an early ambulation program using VASCADE MVP.

Adopting Early Ambulation, Improving Patient Satisfaction

We began using the VASCADE MVP Venous Vascular Closure System (Cardiva Medical, now part of Haemonetics) in 2019, following the FDA approval in November 2018 based on the AMBULATE Pivotal Trial,¹ a prospective, multicenter trial where VASCADE MVP was randomized 1:1 to MC. The study’s primary endpoints were time to ambulation and major access site complications, with additional data reported on patient satisfaction and use of opioids post procedure.

VASCADE MVP is used with 6F-12F inner diameter (15F maximum outer diameter) procedural sheaths, including for use in

AMBULATE Same Day Discharge Clinical Studies^{2,5}

Prospective and retrospective multicenter studies of same day discharge in AF ablation patients

1st & Only

VASCADE MVP® is the first and only vascular closure device FDA-approved for same day discharge following cardiac ablations^{3,4}

90%

of VASCADE MVP® patients in the prospective study² were successfully discharged the same day

2,143



Access Sites

99%

of VASCADE MVP patients in both the prospective and retrospective studies^{2,5} who were successfully discharged the same day did not require intervention during the follow-up period⁶

648



Patients

27



Investigators

0%

ZERO (0) major complications in both the prospective and retrospective studies⁷

8



US Centers

- Natale A, et al. Venous vascular closure system versus manual compression following multiple access electrophysiology procedures: THE AMBULATE Trial. JACC Clin Electrophysiol October 2019. DOI: 10.1016/j.jacep.2019.08.013. **NCT03193021**
- AMBULATE Same Day Discharge Registry Prospective Studies: **NCT04203329**. **Paroxysmal AF data included in this article. Persistent AF data not yet publicly available.**
- IFUs of commercially available venous vascular closure devices: VASCADE MVP®, MYNXGRIP®, Perclose ProGlide™ and Perclose ProStyle™. As of 13 Sep 2021.
- Catheter-based cardiac ablations requiring two or more venous access sites within the same limb. See VASCADE MVP IFU 3972 Indications for Use.
- AMBULATE Same Day Discharge Registry Retrospective Study: **NCT04538781**
- For venous access site closure-related complications through 15-day follow up or standard of care follow up, and for procedure related complications the next day.
- Major venous access site closure related complications through the follow-up period.

RF and cryoablation, as well as left atrial appendage closure (LAAC) procedures. VASCADE MVP can be used in single or multiple access sites, in one or both limbs.

Similar to the overall conclusions reported in the AMBULATE Trial, our patient satisfaction at UAB has improved with the use of VASCADE MVP; patients have felt more relaxed and comfortable during their post-operative care, reported less pain, and reduced their use of post-ablation pain medications.

We also experienced improved workflow in our lab, as well as economic value to hospital administration, which was of particular importance as the COVID-19 pandemic grew.

Same Day Discharge for AF Ablation is Our New Standard

Our team at UAB continues to participate in the evaluation of same day discharge post AF ablation as part of the AMBULATE Same Day Discharge Clinical Studies.

VASCADE MVP is the first and only vascular closure device FDA-approved for same day discharge following cardiac ablations.^{3,4} In the AMBULATE Same Day Discharge retrospective⁵ and prospective² multicenter studies studying 648 patients at 8 US centers, it was found that 99% of VASCADE MVP patients who were successfully discharged the same day did not require intervention during the follow-up period.⁶ There were zero (0%) major complications reported.^{2,5}

Same Day Discharge for AF Ablation Patients Using VASCADE MVP® at UAB



At UAB, reducing our time to ambulation from 6 hours to 2 hours has made for a better patient experience, and the improved workflow has allowed us to send approximately 90% of our AF ablation patients home the same day.

Every patient is assessed to determine if they are a good candidate for same day discharge. However, there are some patients who would ultimately benefit from an overnight stay, whether for clinical or social reasons, including:

- Medical comorbidities
- Need for diuresis
- Anesthesia-related complications
- Distance to travel from hospital, no caregiver/support at home
- Cases that finish in the evening: some patients might be discharged but will spend the night at a hotel connected to the hospital, and will receive follow-up from our clinical care coordinators before going home

Value vs. Cost

Value-based healthcare is a central tenet in any hospital service line, and at UAB, we recognized the importance of understanding the clinical and economic

At UAB, our same day discharge program for AF ablation patients provides an estimated average per-patient savings of ~\$2,900 (including the cost of VASCADE MVP devices).

value of our same day discharge program. In reviewing our EP lab workflow and associated costs before and after the program was implemented, we found an average per-patient savings of ~\$2,900, which includes the cost of the VASCADE MVP devices.

Though there is a small incremental cost per procedure when using any vascular closure device, the same day discharge program using VASCADE MVP creates the potential for significant annualized savings to the hospital.

The value of same day discharge following AF ablation is realized by all stakeholders: patients, physicians and administration.

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VASCADE MVP®
VENOUS VASCULAR CLOSURE SYSTEM