Putting Our Patients First is a Win for Everyone: Same Day Discharge for AF Ablation using VASCADE MVP®

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Texas Cardiac Arrhythmia has 24 Electrophysiologists with full-time offices in Austin, Dallas, Houston, and El Paso, in addition to other outreach locations. Working with Dr. Javier Sanchez, Dr. Senthil Thambodorai and Dr. Kamala Tamarisa, I practice in the greater Dallas-Fort Worth region. My electrophysiology (EP) lab staff and I treat patients at locations in North Richland Hills, TX and Arlington, TX, where we provide a full spectrum of diagnostic and interventional solutions to treat complex cardiac arrhythmias.

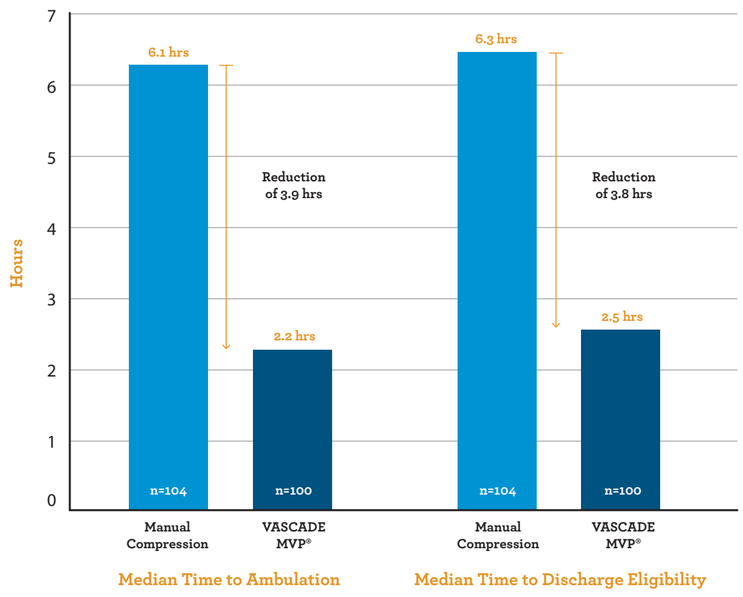
Our Vascular Closure Journey

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.

Our protocol for post-AF ablation care was to pull sheaths outside the EP lab, and conduct MC in the post-anesthesia care unit (PACU). Patients would typically be on bedrest for approximately 6 hours, after which they were ambulated.

Previously, we also used Figure of Eight (FO8) stitch to achieve post-ablation hemostasis. At first glance, FO8 is a straightforward approach that adds minimal cost to patient care; however our patients told us that FO8 can be painful during bedrest, and we found that it could create some late bleeding which resulted in more follow-up for nursing staff and physicians.

AMBULATE Trial[1]



1. 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
2. VASCADE MVP demonstrated median Time to Discharge Eligibility of 2.5 hours in the AMBULATE Clinical Trial.
3. Catheter-based cardiac ablations requiring two or more venous access sites within the same limb. See VASCADE MVP IFU 3972

> ***"There are very few EP interventions that improve satisfaction for patients, physicians, lab staff and hospital administration – same day discharge for AF ablation is one of them."***
> — William Nesbitt, MD

Why We Needed a New Solution

We required an approach that would bring satisfaction to our patients, while also alleviating logjams in our PACU. We were also concerned about the incidence of groin hematoma and post-procedure bleeding, and knew that any new program we introduced would have to meet our institution's expectations for high-quality care.

Holding compression at the vascular access sites was quite painful for our patients; we wanted to provide them with the best possible post-procedure care while increasing their comfort and satisfaction, as well as improving our workflow and EP lab efficiencies.

Our administrators requested that we gather some data to illustrate the costs and economic benefits of using early ambulation with VASCADE MVP® at two centers. We successfully demonstrated that, despite adding costs from the closure devices, the overall financial value to both hospitals was favorable.

Same Day Discharge Through Early Ambulation[2]

VASCADE MVP® is the only FDA-approved closure device for use following cardiac ablations.[3] Designed for EP procedures, VASCADE MVP is used with 6F-12F inner diameter (15F maximum outer diameter) procedural sheaths, including for use in radiofrequency 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.

VASCADE MVP was randomized 1:1 to MC in the prospective, multicenter AMBULATE Trial. The study's primary endpoints were time to ambulation and major access site complications, with secondary endpoints of time to hemostasis, total post-procedure time, time to discharge and discharge eligibility, time to closure eligibility, procedure and device success and minor access site complications. Additional data were reported on patient satisfaction and use of opioids post procedure.

COVID-19 Created Greater Urgency for Same Day Discharge

As our hospitals began resuming elective procedures, we were confident in our ability to enact a comprehensive SDD program. Our experience with early ambulation and SDD using VASCADE MVP enabled us to approach our hospital administration with a scalable plan to resume AF ablations. In addition, we worked closely with each patient to educate them on the SDD process and ensured they felt comfortable going home the same day.

95% Same Day Discharge Transforms Post-Ablation Workflow

We are now discharging 95% of AF ablation patients the same day. This is significant when considering that prior to implementing our SDD program, we had 0% of AF patients going home the same day. We were able to significantly improve our SDD rate through the adoption of an early ambulation program using VASCADE MVP.

The small percentage of patients kept overnight is typically due to patient preference or for social reasons; for example, if a patient lives a long distance from the hospital or does not feel they have adequate caregiver support at home.

SDD has wide-reaching improvements in workflow, lab and staff efficiencies, and hospital resource utilization including:

Reduction in Use of Protamine Sulfate – Historically we used protamine in almost all of our AF ablation patients but after reviewing our AF ablation workflow closely, we realized that use of a 50 mg bolus of protamine added 5-10 minutes of anesthesiologist time as they monitored for any drop in blood pressure.

Decreased Logjams in PACU – Our ability to discharge AF ablation patients the same calendar day streamlined our workflow in the PACU, where delays and bottlenecks were common and resulted in increased frustration for patients and nursing staff.

Freeing up Beds – Previously, any patients that finished from about noon to 3 pm would be moved to the cardiovascular ICU or telemetry. With a successful SDD program, we can have a direct impact in freeing up beds for critical patients, including those diagnosed with COVID-19.

Fewer Physician Calls for Bleeding or Oozing – Prior to adopting an early ambulation and SDD program, these calls could take up significant time for me, as well as my staff. We have observed a reduction in these follow-up activities with SDD.

Same Day Discharge Benefits All Stakeholders

There are very few EP interventions that improve satisfaction for patients, physicians, lab staff and hospital administration – same day discharge for AF ablation is one of them.

Same Day Discharge for AF Ablation Patients Using VASCADE MVP® at Texas Cardiac Arrhythmia

Delivering high-quality care to patients isalways our first priority and we are proud to hear how satisfied our patients have been with SDD.

Putting our patients first provides additional benefits for everyone: our physicians, staff and hospital administration.

Patient Perspective: Mike's Story

When discussing with Dr. Nesbitt his first post-ablation experience using traditional manual compression closure methods, Mike simply asked, "There has got to be something better than lying on my back for 4-6 hours, with people pressing on my groin and causing me all that pain."

When Mike met with Dr. Nesbitt to discuss his recent procedure, he was told that he may require femoral venous access in both legs, and this gave him great concern based on previous experience. The pain from manual compression was challenging enough with one limb and having to lay flat for 4-6 hours was excruciating, now he was facing double the impact; Mike wanted to make sure he talked about his post-ablation care.

Dr. Nesbitt explained that they would be using the VASCADE MVP® device, which would typically allow him to get up and walking 2 hours after his ablation – without the need for manual compression.

Mike's reply was, "by all means use it." And as Mike can now attest, "it worked like a charm." With the use of VASCADE MVP, Mike was able to ambulate at 2 hours and did not have the pain and bruising from manual compression.

Mike believes that all ablation patients should talk to their EP about post-ablation care. He understands that most patients will be more concerned about the procedure itself, but once they realize that there is a device that can improve their recovery, it can provide added peace of mind.

Dr. Nesbitt was not financially compensated by Cardiva Medical for this publication, and the content is an accurate presentation of their personal opinions. Refer to the product IFU before use for important safety information.

VASCADE MVP®
VENOUS VASCULAR CLOSURE SYSTEM

LIT 5384 Rev A

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