

Real-world Evidence for VASCADE MVP®

Discussion with Dr. Javier Sanchez

Q: Tell me about your practice and the EP Program at Medical City Heart Hospital?

A: Texas Cardiac Arrhythmia has 24 Electrophysiologists with fulltime offices in Austin, Dallas, Houston, and El Paso in addition to other outreach locations. Dr. Bill Nesbitt, Dr. Senthil Thambodorai, Dr. Kamala Tamarisa and I work full-time at Medical City Dallas and the greater DFW area. Opening in 2019, Medical City Heart Hospital is a state-of-the-art facility offering highly specialized, advanced cardiovascular care. We work with colleagues in other groups including Dr. Jodie Hurwitz who is the director of our EP lab. Medical City Heart Hospital has:

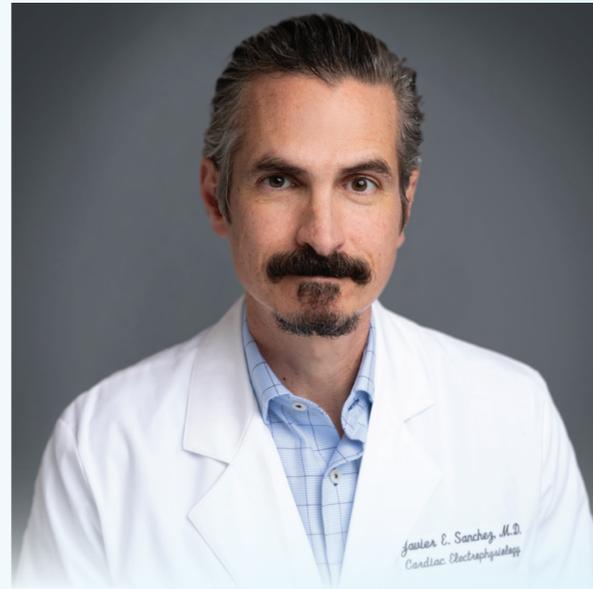
- 63 private patient rooms
- The only dedicated cardiac emergency room in Dallas, Texas
- 1,000+ Ablation and EP procedures
- Dr. Sanchez is an investigator in the Same Day Discharge Registry for AF ablation patients

Q: What was your initial impression of VASCADE MVP versus historic methods of closing with Figure of 8, or manual compression?

A: Technically, the device is elegantly simple and easy to use. For other methods of closing the venotomy after a procedure, our talented EP lab staff would be required to hold manual pressure, or I would close with a surgical stitch. Both methods required significantly more time than the VASCADE MVP and often resulted in decreased patient satisfaction. With suture mediated closure, I've had the concern of potentially creating a complication that may require acute surgical intervention, which seems to me is very unlikely with the VASCADE MVP and in fact, that has been our experience.

Q: How has VASCADE MVP helped with your workflow and the patient experience post-ablation?

A: Our method of closing with VASCADE MVP has helped by providing a more secure and pain-free method of closure for our patients. This enables us to control the patient experience more efficiently and effectively when they leave the lab. The patients are thrilled to know they can sit up after 1.5 to 2 hours (for normal BMI patients) and in my experience, very often they have less pain and discomfort than with manual compression or figure-of-eight suture. The AMBULATE trial documented a pretty dramatic reduction on the use of post-op pain medications. This has also enabled us to reliably and consistently discharge more of our ablation patients the same day than we did in the past.



Dr. Javier Sanchez, M.D., FACC, FHRS

Q: What are some considerations you use to evaluate a patient's ability to be sent home the same day as their procedure?

A: It is important to us that the patient and family do not feel rushed, and that we are not in a hurry. Additionally, we work through the following considerations for each patient.

Same-Day Discharge Considerations	
Time of Procedure	▪ Daytime
Social	▪ Adequate Support at Home ▪ Desire to Go Home
Education	▪ Fully Complete
Functional	▪ Ambulatory ▪ Eating on Own ▪ Bathroom on Own
Intracardiac Echocardiogram (pre/post procedure)	▪ No Pericardial Effusion
Total Ablation Time	▪ Extensive Procedures May Stay Overnight
Left Atrial Pressure	▪ May Require Diuresis

SAME-DAY DISCHARGE FOR DR. SANCHEZ'S ABLATION PROCEDURES



>90% of all VASCADE MVP patients go home the same day.

Q: Can you share what has changed in your workflow after you started utilizing VASCADE MVP?

A: Previously, we used Foley catheters and Protamine 100% of the time and we pulled sheaths in the lab. Our patients would go to the PACU and ambulate after 4–6 hours and then stay overnight.

With VASCADE MVP, we no longer need routine Foley catheters, or Protamine and our standard protocol is to ambulate patients after two hours. We then determine whether to send patients home same day by asking why they shouldn't be able to go home versus why they should be able to go home. This is a change from our previous thought process and our patients are thrilled to be able to get up earlier and go home sooner. This is especially true as we safely work through the challenges associated with COVID-19.

Q: You work very closely with Medical City administration to increase quality of care while being fiscally responsible. How has your administration responded to the improvements in post procedural process while balancing cost of the VASCADE MVP?

A: Initially, our value analysis committee reviewed the cost versus value of introducing a new product and process to be sure it met our key criteria of patient satisfaction, improving quality and of course, safety. Early on, we were not sending patients home same-day and the benefit was early ambulation. However, as we began to reliably and consistently send more patients home same-day, this allowed for a more efficient use of lab and staff resources. When we considered the Ambulate trial data, patient satisfaction, reduction of Opioid use as well as the staff satisfaction, the costs versus benefits are very favorable.

ADMINISTRATION PERSPECTIVE

Interview with Josh Kempf, Chief Operating Officer
Medical City Heart Hospital, Dallas, Texas

How has COVID-19 forced you to make changes?

With COVID-19, we really needed to free up beds for COVID-potential and future COVID patients. Elective procedures were restricted or shut down and our non-COVID-19 patients needed care. With same-day discharge, we were able to open additional telemetry beds for EP and CV Surgery, decrease time waiting for sheaths to be pulled, decrease time in PACU and in ARU, make more efficient use of all personnel, free up pre- and post-beds and relieve log jams. Additionally, we had fewer groin complications, no re-bleeds, earlier ambulation and same-day discharge!

How has VASCADE MVP affected your ability to predict patient flow?

Our staff plan and anticipate our lab schedule 5–7 days in advance based on patient procedures and workflow. The more accurately we can predict scheduled start, end, and recovery times, the better. Also, if we can allow our patients to remain in an outpatient setting and not take up inpatient beds, we have more flexibility to care for COVID patients as needed. For example, when we saw an increase in ECMO patients with COVID, we were able handle the acute challenge. The improvement in predictability of patient workflow and same day discharge also improves staff and patient satisfaction. We are able to predict and adhere to our schedules and reduce variability. Staff and patients have improved experiences without unexpected delays. Globally, our goal is to reduce the amount of time patients are required spend in the hospital, reduce the costs associated with the utilization of resources and improve patient satisfaction. Improved ability to predict patient flow helps with each of these goals.

Dr. Sanchez and Mr. Kempf are not financially compensated by Cardiva Medical for this publication, and the content is an accurate presentation of their personal opinions of the VASCADE MVP device. Refer to the product IFU before use for important safety information.

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