The Economics of Vascular Closure for Interventional Cardiology and EP:

How Early Ambulation and Same-Day Discharge Help both Patients and Practices

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Faculty Disclosures

- **Barry Bertolet, MD**: Advisory Board—Medtronic; Speaker—Medtronic, Shockwave
- **T. Jared Bunch, MD** has disclosed no relevant financial relationship with any ineligible company (commercial interest)
- **Zayd Eldadah, MD, PhD**: Speaker's Bureau—AtriCure

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Program Information

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Learning Objectives

- Review the landscape of vascular closure for EP and IC procedures
- Understand the benefits of early ambulation and same day discharge for the patients
- Identify economic benefits to your healthcare practice because of same day discharge and early ambulation

EP = electrophysiology; IC = interventional cardiology.

Introduction and Update on Vascular Closure in PCI/Coronary

Barry Bertolet, MD

PCI = percutaneous coronary intervention.

Barry Bertolet, MD

Dr. Bertolet graduated from the University of Mississippi School of Medicine and completed his residency at Shands Hospital at the University of Florida. Dr. Bertolet has been in practice for over 30 years—he is the former Cardiac Catheterization lab director and current Program Director for the Cardiovascular Fellowship Program at North Mississippi Medical Center in Tupelo, MS and current VP of the Mississippi Health Care Alliance.

Pressures on Hospital Based and ASC Cath Labs

- Throughput/access
- Transition to ambulatory care
- Cost per procedure
- Maintain high patient satisfaction

ASC = ambulatory surgery center.

COMPARISON OF FEMORAL AND RADIAL ACCESS FOR CARDIAC CATHETERIZATION		
Feature	**Femoral**	**Radial**
* Access site bleeding	3%–4%	0%–0.6%
Artery complications	Pseudoaneurysm, retroperitoneal bleed	Rare local arteriovenous fistula, painful hematoma irritation, pulse loss 3%–9%
Patient comfort	Acceptable	Great
* Ambulation	2–4 h	Immediate
* Extra costs	Closure device	Band, Sheaths, Catheters
Procedure time*	Perceived shorter	Perceived longer
Estimated radiation exposure*	Perceived shorter	Perceived longer
Access to left internal mammary artery	Easy	Difficult from right radial artery
Use of artery for CABG	N/A	Unknown
Learning curve	Short	Longer
> 8-F guide catheters	No problem	Maximum 7 F (in men)
Peripheral vascular disease, obese	Problematic	No problem

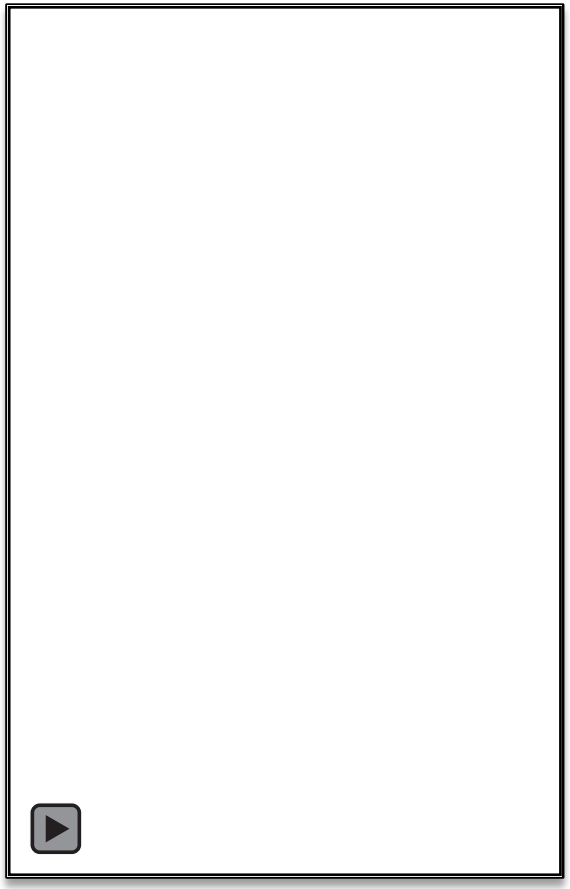
***Operator dependent.**
Modified with permission from: Kern MJ, et al. *Cath Lab Digest*. 2009;17:4-5.

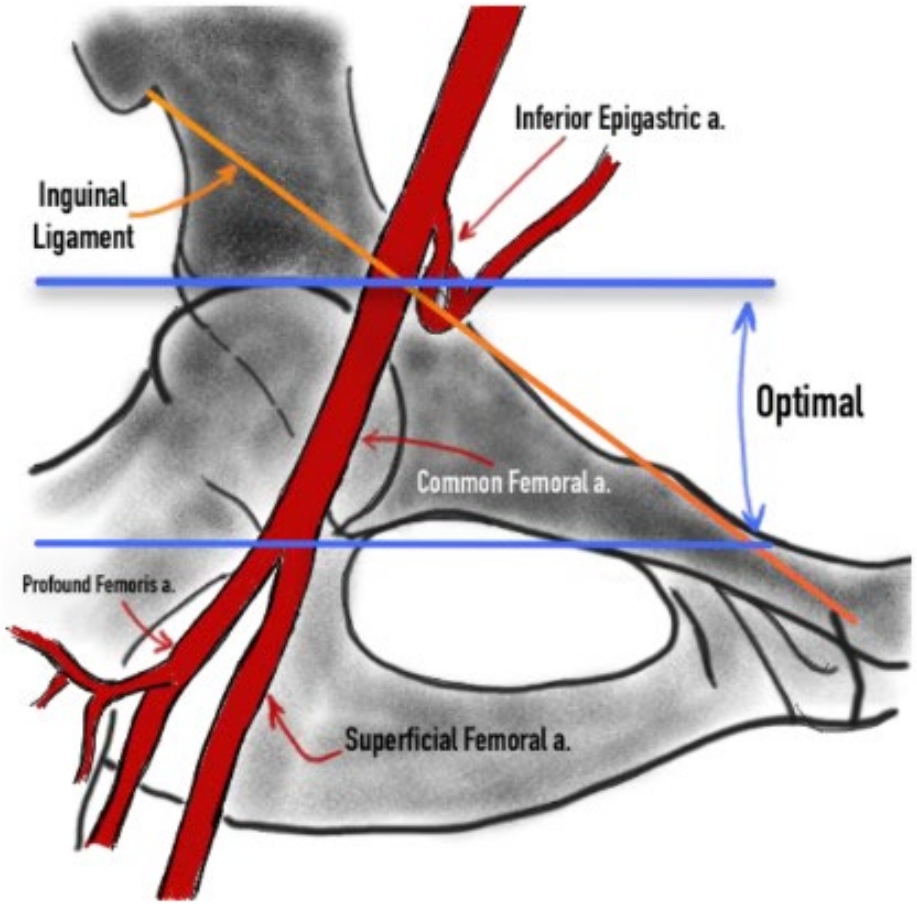
Femoral Access Is Still Needed!

- Small or tortuous radial arteries
- Graft cases
- Right and left heart cath
- Peripheral interventions
- Structural heart cases

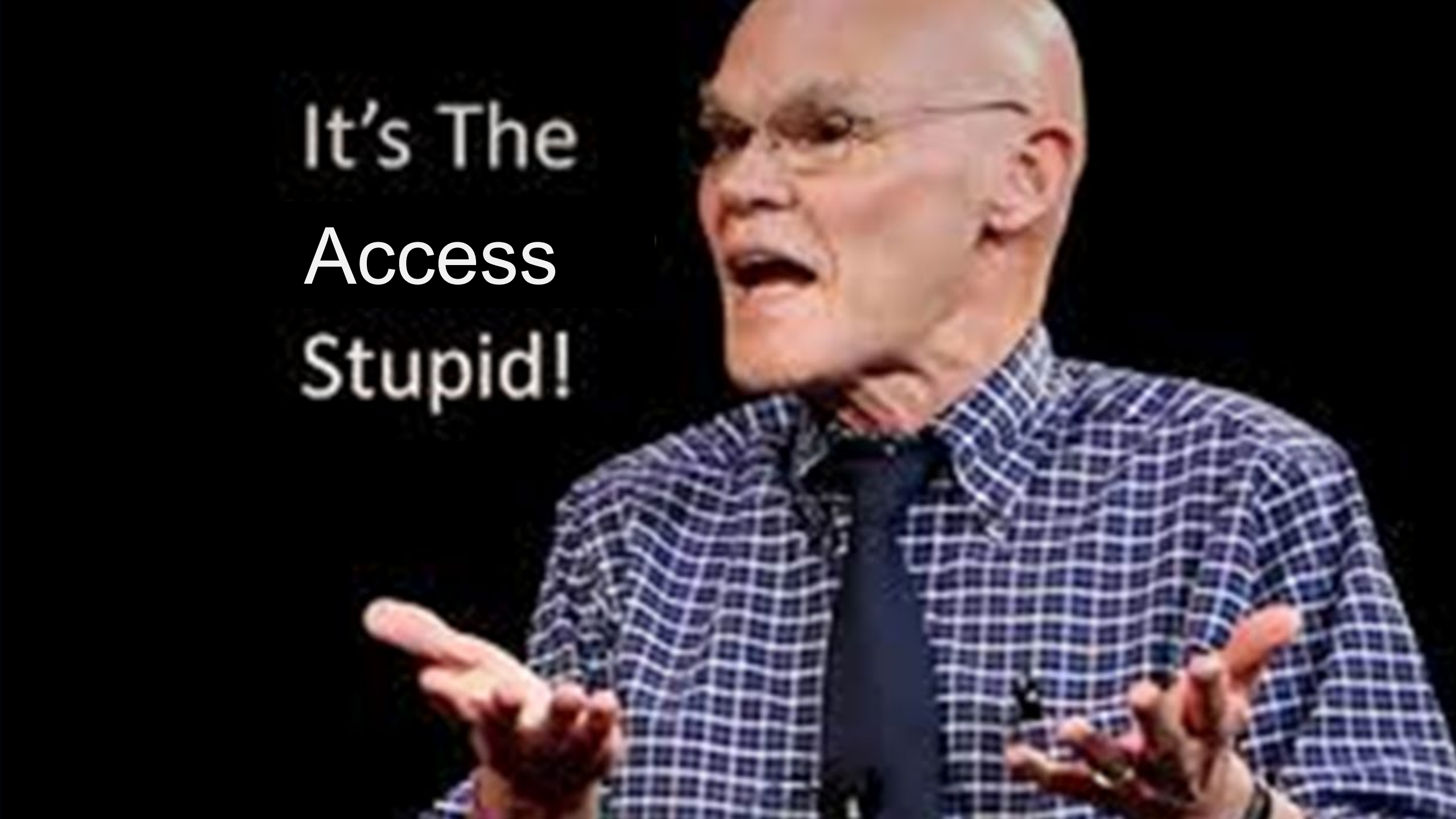
Successful Closure Begins with Proper Access

The access site is what the patient will remember you by!



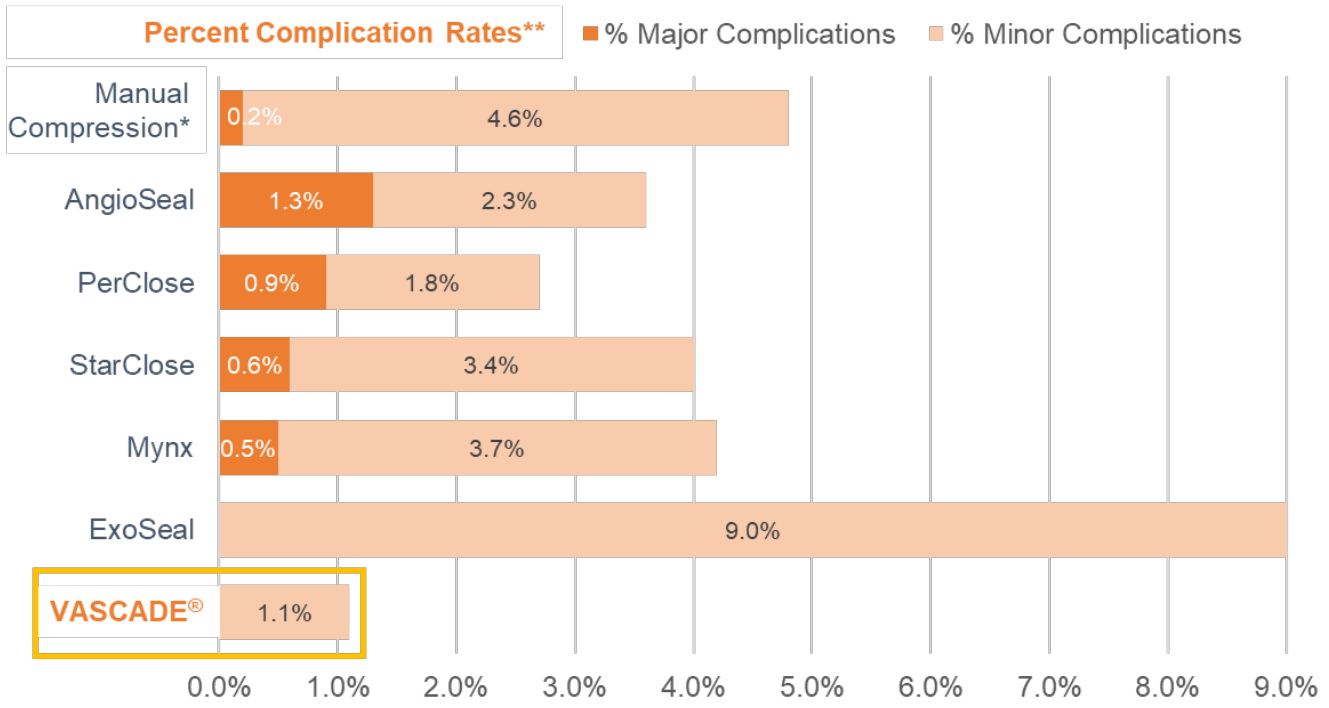


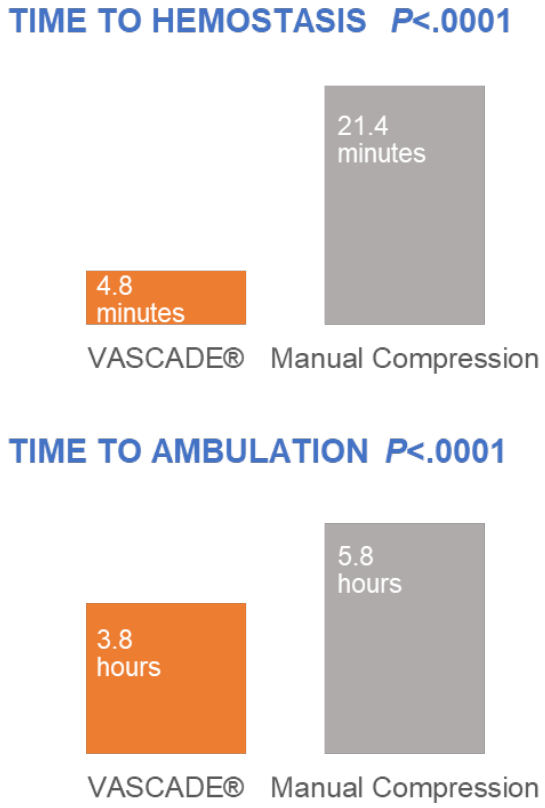
Taming the SRU. March 3, 2018. Accessed November 11, 2024. https://www.tamingthesru.com/blog/procedural-education/the-anatomy-of-femoral-vascular-access.


It's The
Access
Stupid!

VASCADE® Clinical Validation: RESPECT Trial

Comparison of Vascular Closure Devices in Arterial Pivotal Trials





***Complication rates for manual compression presented are based on the composite of manual compression complication rates included in the IFUs of the devices presented; **Data for the chart is from U.S. FDA SSED and IFU's and includes both Interventional and Diagnostic treatment arms. All Intention To Treat patients and events are included in the chart. As complication rate data are based on a cross-trial comparison and not head-to-head clinical trials, the data may not be directly comparable due to differences in study protocols, conditions and patient populations.**

Hermiller JB, et al. *J Invasive Cardiol*. 2015;27(3):129-136. NIH. Accessed November 11, 2024. https://clinicaltrials.gov/study/NCT01297322.

VASCADE® vs Manual Compression

- Time-to-hemostasis was 3.0 minutes for VASCADE® vs 20.0 minutes for manual compression
  - **This means on the table hemostasis vs going to a holding room/delayed room turnover**
- Time-to-ambulation/discharge was 3.2/3.6 hours, respectively for VASCADE® vs 5.2/5.7 hours for manual compression
  - **This means early discharge and better bed utilization**
- VASCADE® is the **ONLY** marketed closure device **proven to reduce complications and improve workflow** compared to MC in a RCT

MC = manual compression; RCT = randomized clinical trial.
Hermiller JB, et al. *J Invasive Cardiol*. 2015;27(3):129-136.

ANTEGRADE-PVD Registry

Comparison of Antegrade Closure Studies

	VASCADE® VCS	AngioSeal™	ExoSeal™	Mynx™
Literature	**ANTEGRADE-PVD Study**	Cicuto, et al (2013)	Schmelter, et al (2013)	Pruski, et al (2017)
Study Type	**Prospective Multi-Center (US)**	Retrospective Single Center (US)	Prospective Single Center (OUS)	Prospective Single Center (OUS)
Number of Patients	**52**	50	93	66
Procedure Success	**98%**	-	96%	-
Device Success	**98%**	98%	96%	94%
Minor Complications	**1.9% (1)**	8% (4)	7.5% (7)	7.6% (5)
Major Complications	**1.9% (1)**	2% (1)	3.2% (3)	0% (0)
Patients that were Complication-Free	**96.2%**	90%	89%	92%

VASCADE® demonstrated safe and effective performance when used in antegrade femoral access.

OUS = outside of the United States.

Walker C, et al. *Vasc Disease Manag*. 2018;15(9):E102-E107. Cicuto K, et al. *J Vasc Intervent Radiol*. 2013;24(4):S118. Schmelter C, et al. *Cardiovasc Intervent Radiol*. 2013;36(3):659-668. Pruski MJ, et al. *Vasc Endovasc Surg*. 2017;51(2):67-71. NIH. Accessed November 11, 2024. https://clinicaltrials.gov/study/NCT02948257.

VASCADE® Performance Guarantee Study

- 104 US centers
- All-comers
- Sites were financially incented to report complications
- 71,700 units used
- 62 complications reported
- **<0.1% access site complications in the real world**

Bertolet B, et al. *Vasc Disease Manag*. 2020;17(12):E221-E226.

The Bottom Line $

- In our institution, we recognized a 3% absolute risk reduction in major femoral access adverse events AND a mean 3-hour reduction in LOS in the outpatient cath lab observation unit
- For every 100 patients, this would result in a $18,000 reduction in vascular access complication costs and an observation area cost reduction of $45,000

LOS = length of stay.

In My Experience, Vascade Can Be Used Where Other VCDs Are Discouraged

- In antegrade common femoral access
- In vessels with >50% stenosis
- In calcified vessels
- In small common femoral vessels
- In bifurcation, profunda, and proximal SFA sticks
- In vessels which have been stented (deploy under fluoroscopy)

VCD = vascular closure device.

VASCADE MVP® vs Manual Compression: AMBULATE

Venous Access

Study Design

- Multi-center: 204 patients, 13 sites
- Prospective, randomized, controlled
- Electrophysiologic ablation procedures
- 6-12 French access

Study Outcomes

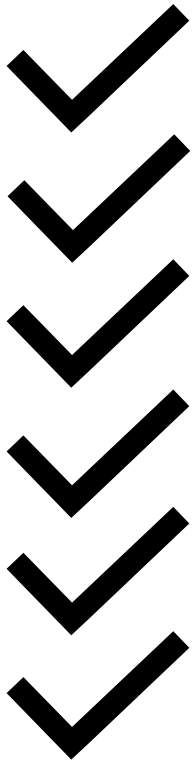
- Compared with MC, VASCADE® resulted in an approximately 3.3-hour (54%) decrease in time-to-ambulation
- **Opioid use was reduced by 58%**
- **Patient satisfaction scores with duration of and comfort during bedrest were 63% and 36% higher in device group**

Any site complication: VASCADE® 1.0% vs manual compression 2.4%

Natale A, et al. *JACC Clin Electrophysiol*. 2020;6(1):111-124. NIH. Accessed November 11, 2024. https://clinicaltrials.gov/study/NCT04538781.

VASCADE® Femoral Closure

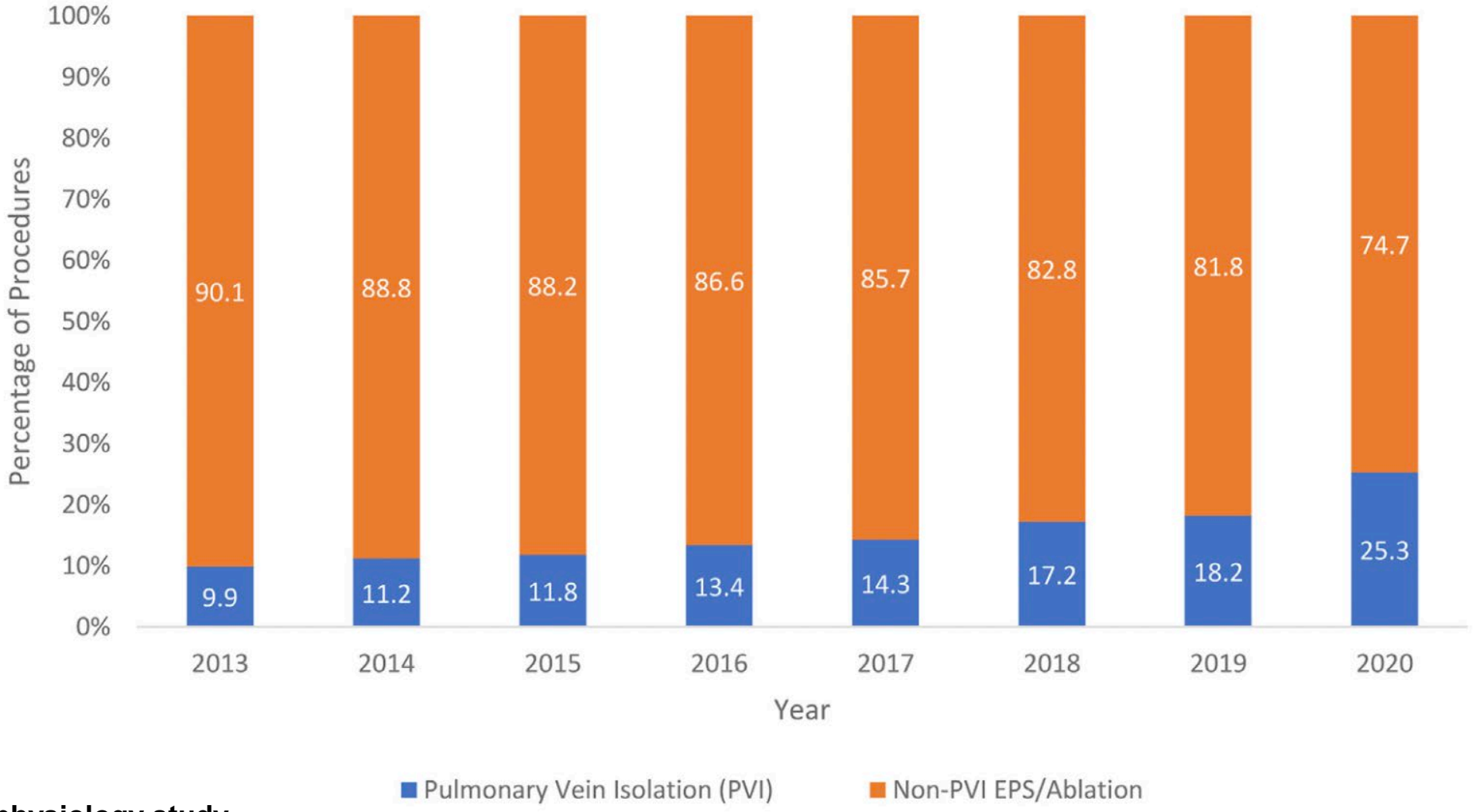
- Decrease major vascular complications
- Decrease incidence of major bleeding complications
- Decrease time-to-ambulation
- Increased patient movement and comfort
- Allows early discharge policy
- May decrease cost



Update on Vascular Closure in EP and Review of Publications Supporting Early Ambulation and Same Day Discharge

T. Jared Bunch, MD

PVI vs Non-PVI Procedures: 2013-2020



EPS = electrophysiology study.

Scott M, et al. *Heart Rhythm O2*. 2022;4(3):193-199.

Major Drivers of Healthcare System Costs and Cost Variability for Routine AF Ablation

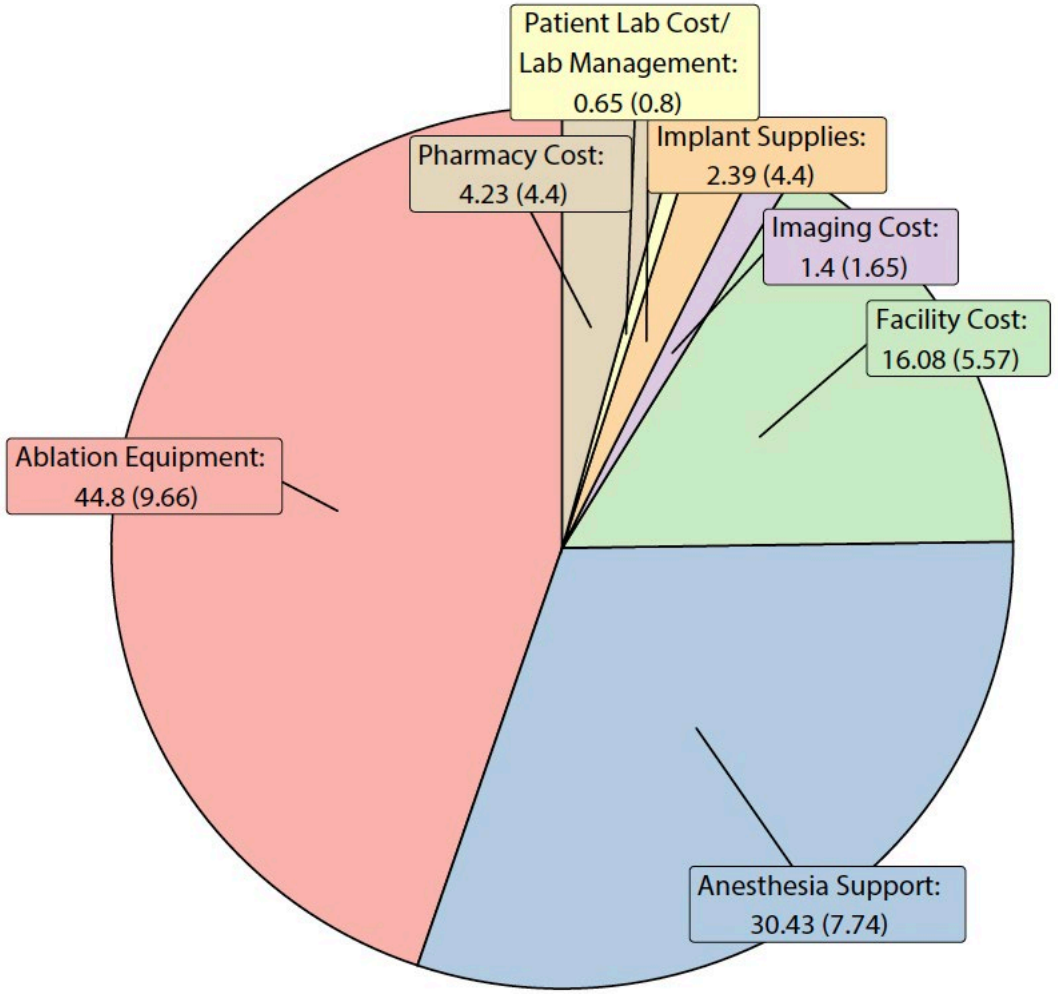


Table 2 Factors associated with variability in overall ablation cost to the healthcare system, expressed as average percent difference in overall cost

Variable	% Difference	95% CI
Age	−0.009	−0.112 to 0.094
Male	−1.296	−3.432 to 0.886
White	2.671	−1.679 to 7.215
Operator 1	11.961	6.033 to 18.219
Operator 2	8.647	4.336 to 13.135
Operator 3	8.026	2.708 to 13.621
Operator 4	0.166	−3.084 to 3.524
Operator 5	11.558	7.497 to 15.773
Operator 6	10.685	6.319 to 15.23
Beta-blocker	0.654	−1.506 to 2.862
Calcium-channel blocker	−0.7	−2.875 to 1.523
Prior ablation	−0.499	−2.535 to 1.579
Anticoagulation	−1.509	−5.146 to 2.267
Antiarrhythmic drugs	−0.401	−2.508 to 1.75
CHA_2DS_2-VASc score	−0.342	−1.008 to 0.328
Prior Cardioversion	1.477	−0.649 to 3.65
Left ventricular ejection fraction value	−0.021	−0.111 to 0.069

CHA_2DS_2-VASc = congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, prior stroke or transient ischemic attack or thromboembolism, vascular disease, age 65-74 years, sex category; CI = confidence interval.

AF = atrial fibrillation.

Zenger B, et al. *Heart Rhythm O2*. 2023;4(4):251-257.

Pulsed field ablation: A promise with future broad-based applicability or a pause needing further analysis—Is catheter ablation at a crossroads? A critical appraisal of the new challenger—pulsed field ablation

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KEYWORDS PFA; Appraisal; Efficacy; Safety; Efficiency; Fiscal

Introduction

Recent scientific data have positioned pulsed field ablation (PFA) as a possible replacement for traditional atrial fibrillation (AF) ablation approaches delivering radiofrequency or cryoablation thermal energy. PFA uses nonthermal, high-voltage electrical fields applied to cardiac tissue to create nanopores in the cellular membrane that disrupt cellular integrity, resulting in cellular necrosis and irreversible electroporation.

Whereas PFA represents a significant advance, there are relevant scientific, clinical, operational, and fiscal challenges that must be considered before cardiac electrophysiologists rush to jump on the band wagon of this "Brave New World."

Efficacy and safety

Multiple nonrandomized clinical trials and registries have demonstrated that this new technology is associated with excellent acute and durable pulmonary vein isolation and a high degree of freedom from recurrent atrial arrhythmias.[1–4] However, the outcome efficacy results in these pivotal, nonrandomized studies, compared with similar nonrandomized comparison publications employing standard AF ablation approaches, have not demonstrated any significant incremental efficacy for PFA.[5,6] Furthermore, in the prospective, randomized ADVENT trial, there was no difference in the primary efficacy end point between thermal and PFA approaches.[7] Accordingly, the existing data allow us to cautiously assume similar efficacy but not superiority.

The PFA mechanism of action and the ability of this approach to selectively target myocardial tissue posit a possible improved safety profile for PFA compared with conventional energy sources. Experienced investigators in the initial, nonrandomized studies generated transmural lesions while avoiding collateral damage to adjacent structures, resulting in an overall low complication rate.[2–4]

In a meta-analysis, the overall PFA complication rate was low (2.23%), with most of the adverse events having limited clinical significance.[8] However, there are existing concerns that must be addressed before we can automatically assume that PFA is associated with better safety outcomes. A similarly low but concerning slightly higher complication rate was observed in the real-world MANIFEST registry.[9] In the ADVENT trial, the primary safety end point was not statistically different between the PFA (2.1%) and the thermal ablation (1.5%) groups.[7] Furthermore, when PFA has been used in broader ablation locations, not just in performing pulmonary vein isolation, there have been reports of coronary artery spasm when energy is delivered adjacent to a coronary artery,[10–12] reports of temporary PFA-related phrenic nerve paralysis that was both dose dependent and proportional to the catheter proximity to the ablation site,[13] and reports of other untoward outcomes. Accordingly, the off-label use of PFA in additional sites should be avoided pending additional research.

It is reassuring that the operators at experienced institutions participating in the pivotal PFA trials were able to

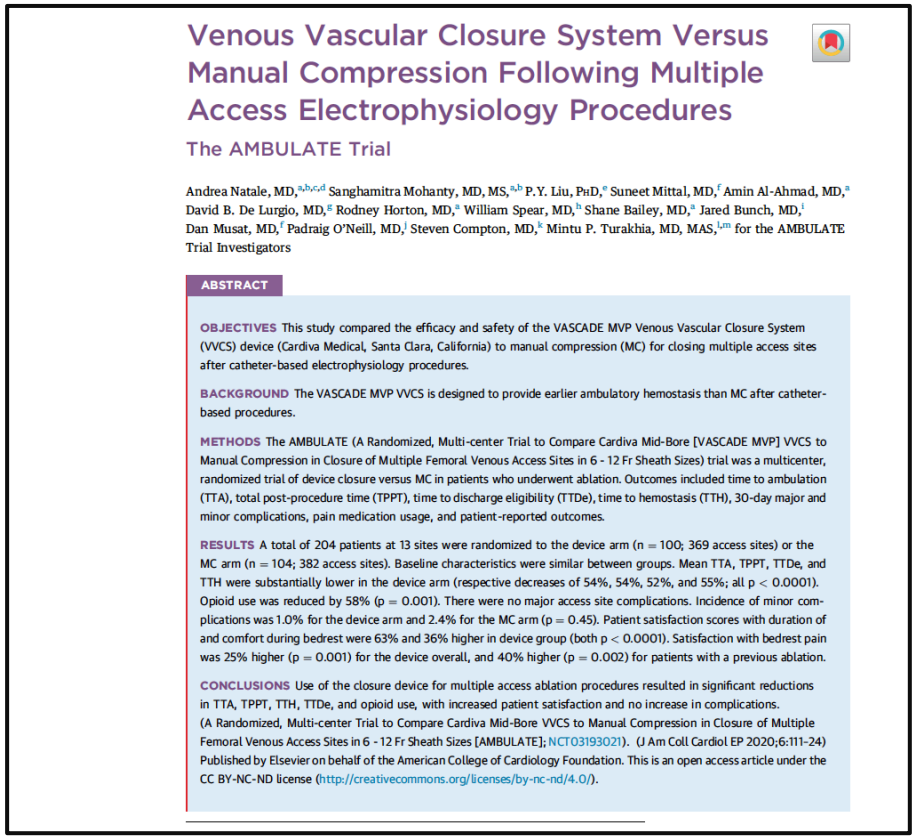
"The possibility of achieving significantly shorter total case time with PFA in general clinical practice has much potential to produce an important clinical and financial benefit… The potential reduction in the catheter use time is likely to represent a minimal alteration in the total case time when one includes turnover times… the creation of meaningful economic and operational impact will necessitate that any time saved by employing PFA translates into an ability to perform additional procedures."

PFA = pulsed field ablation.
Deering TF, et al. *Heart Rhythm*. 2024;21(8):1242-1244.

Evolution of AF Ablation Workflow

PAST:

Manual Compression



Venous Vascular Closure System Versus Manual Compression Following Multiple Access Electrophysiology Procedures

The AMBULATE Trial

Andrea Natale, MD,[a,b,c,d] Sanghamitra Mohanty, MD, MS,[a,b] P.Y. Liu, PhD,[e] Suneet Mittal, MD,[f] Amin Al-Ahmad, MD,[a] David B. De Lurgio, MD,[g] Rodney Horton, MD,[a] William Spear, MD,[h] Shane Bailey, MD,[a] Jared Bunch, MD,[i] Dan Musat, MD,[f] Padraig O'Neill, MD,[j] Steven Compton, MD,[k] Mintu P. Turakhia, MD, MAS,[l,m] for the AMBULATE Trial Investigators

ABSTRACT

OBJECTIVES This study compared the efficacy and safety of the VASCADE MVP Venous Vascular Closure System (VVCS) device (Cardiva Medical, Santa Clara, California) to manual compression (MC) for closing multiple access sites after catheter-based electrophysiology procedures.

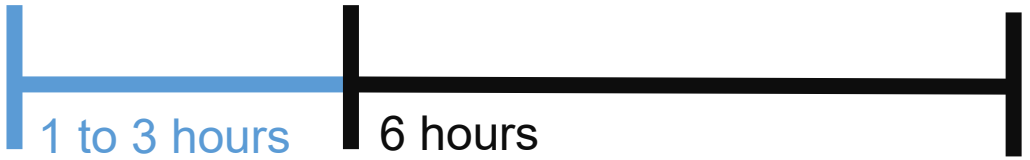
BACKGROUND The VASCADE MVP VVCS is designed to provide earlier ambulatory hemostasis than MC after catheter-based procedures.

METHODS The AMBULATE (A Randomized, Multi-center Trial to Compare Cardiva Mid-Bore [VASCADE MVP] VVCS to Manual Compression in Closure of Multiple Femoral Venous Access Sites in 6 - 12 Fr Sheath Sizes) trial was a multicenter, randomized trial of device closure versus MC in patients who underwent ablation. Outcomes included time to ambulation (TTA), total post-procedure time (TPPT), time to discharge eligibility (TTDe), time to hemostasis (TTH), 30-day major and minor complications, pain medication usage, and patient-reported outcomes.

RESULTS A total of 204 patients at 13 sites were randomized to the device arm (n = 100; 369 access sites) or the MC arm (n = 104; 382 access sites). Baseline characteristics were similar between groups. Mean TTA, TPPT, TTDe, and TTH were substantially lower in the device arm (respective decreases of 54%, 54%, 52%, and 55%; all $p < 0.0001$). Opioid use was reduced by 58% ($p = 0.001$). There were no major access site complications. Incidence of minor complications was 1.0% for the device arm and 2.4% for the MC arm ($p = 0.45$). Patient satisfaction scores with duration of and comfort during bedrest were 63% and 36% higher in device group (both $p < 0.0001$). Satisfaction with bedrest pain was 25% higher ($p = 0.001$) for the device overall, and 40% higher ($p = 0.002$) for patients with a previous ablation.

CONCLUSIONS Use of the closure device for multiple access ablation procedures resulted in significant reductions in TTA, TPPT, TTH, TTDe, and opioid use, with increased patient satisfaction and no increase in complications.

(A Randomized, Multi-center Trial to Compare Cardiva Mid-Bore VVCS to Manual Compression in Closure of Multiple Femoral Venous Access Sites in 6 - 12 Fr Sheath Sizes [AMBULATE]; NCT03193021). (J Am Coll Cardiol EP 2020;6:111-24) Published by Elsevier on behalf of the American College of Cardiology Foundation.



- Lower patient satisfaction
- Higher use of opioids/pain meds

- Shorter time to hemostasis
- Shorter time to ambulation
- Higher patient satisfaction
- Lower use of opioids/pain meds
- Potential for same day discharge

Natale A, et al. *JACC Clin Electrophysiol*. 2020;6(1):111-124.

Evolution of Venous Vascular Closure

1) Manual Compression

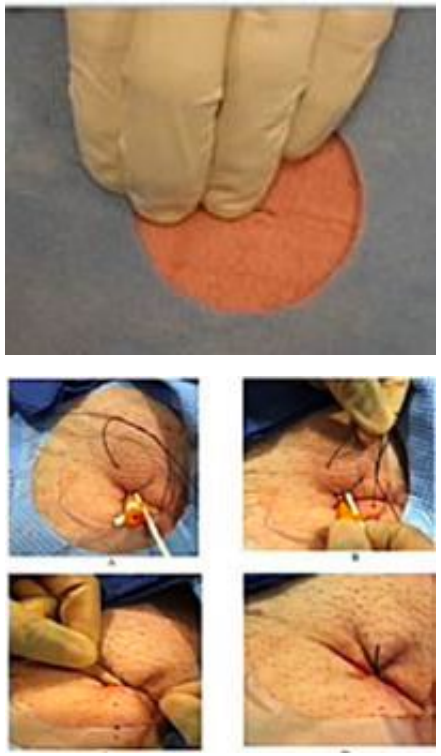
- Current standard of care
- Requires long bedrest (6 hours) often resulting in back pain, patient discomfort and use of pain meds
- Limits ability to discharge same day and requires the use of Foley catheter in many cases

2) Figure-of-8 Suture (FO8)

- Achieves hemostasis
- Has not been evaluated for time to ambulation in multicenter EP clinical studies
- No data published on patient satisfaction post-procedure
- Requires removal prior to discharge

3) Perclose ProGlide™

- Indicated for venous closure, 5F-24F
- For sheath sizes greater than 8F, at least two devices and pre-close technique are required by labeling
- Non-resorbable, permanent sutures
- Not indicated for same day discharge, or multi-access site closure required for EP Ablation procedure
- Closing multiple access sites requires 30 steps



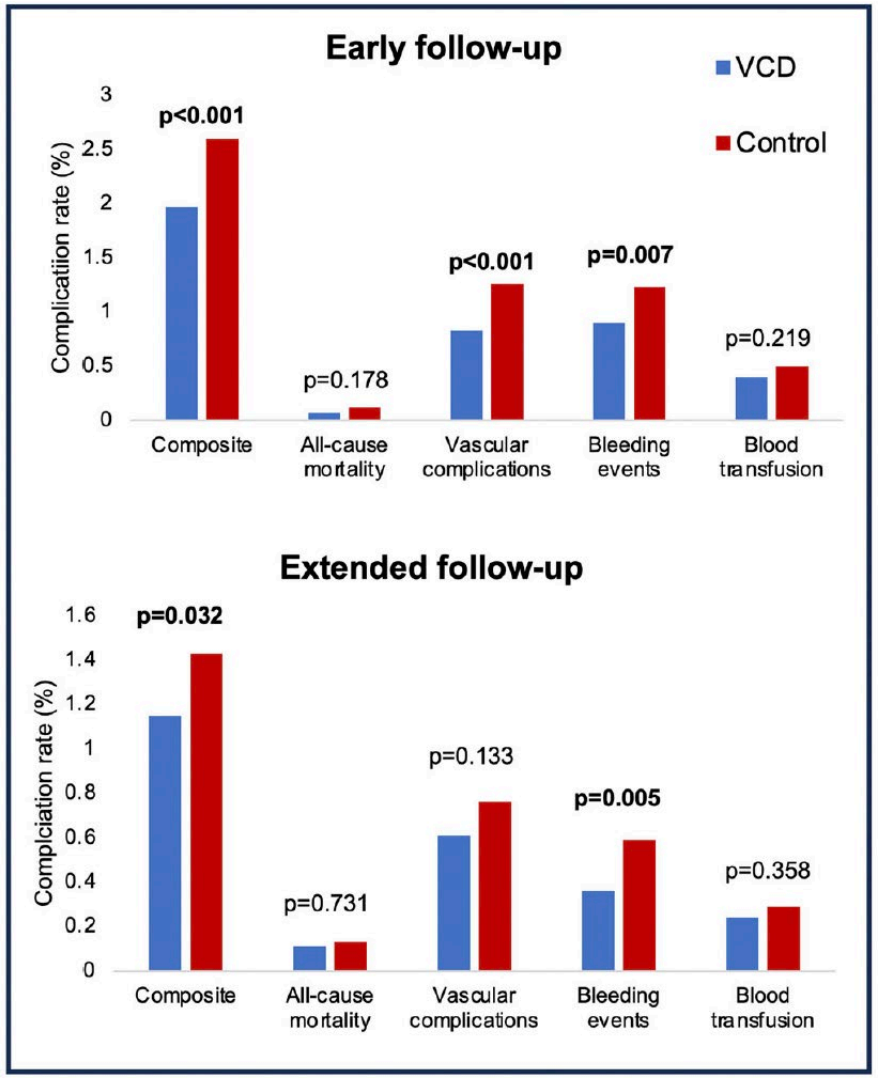
Lakshmanadoss U, et al. *Indian Pacing Electrophysiol J*. 2017;17(5):134-139. FDA. Accessed November 21, 2024. https://www.accessdata.fda.gov/cdrh_docs/pdf/P960043S118C.pdf.

Vascular Closure as a Concept for AF Ablation

- Retrospective study of 36 healthcare organizations using a global federated research network (TriNetX): those receiving a VCD for femoral hemostasis, and those not receiving a VCD
- A 1:1 propensity score matching (PSM) model

Perclose ProGlide™ (Abbott)	VASCADE® (Cardiva)	MYNX CONTROL™ (AccessClosure)
		

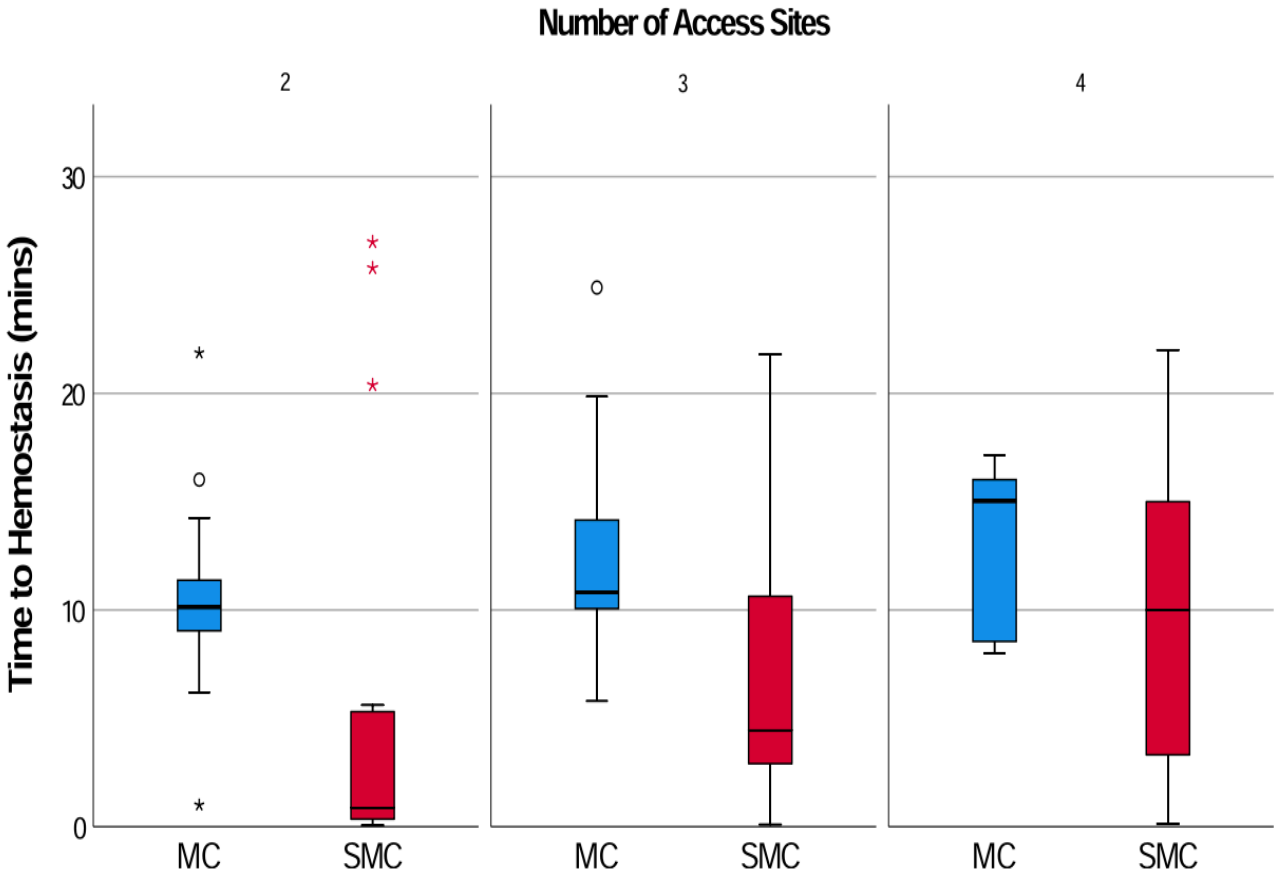
28,872 patients were included (14,436 in each cohort)



Mills MT, et al. *J Cardiovasc Electrophysiol*. 2024;35(8):1656-1662.

Figure of 8 Closure vs Manual Compression

1:1 randomized trial comparing suture closure versus manual compression following AF ablation (107 patients: 53 in the Suture group and 54 in the MC group)



Time to successful ambulation
Lower in the Suture group compared to the MC group (2.2 hr vs 4.2 hr, *P*<.0001).

Delays from planned time of discharge
High in the MC group compared to the Suture group (31.5% vs 11.3%, *P*=.0144)

Kiani S, et al. *J Cardiovasc Electrophysiol*. 2024 [Epub ahead of print].

Figure of 8 Closure vs Manual Compression

TABLE 4 Results of the patient satisfaction questionnaire.

	Discharge			Follow Up		
Question	**MC**	**SMC**	***p* level**	**MC**	**SMC**	***p* level**
Pain in your groin	0.72 (1.14)	1.13 (1.455)	0.102	0.25 (0.845)	0.59 (1.206)	0.137
Tenderness around your groin	0.65 (1.067)	1.21 (1.405)	0.015	0.49 (1.084)	0.84 (1.546)	0.413
Numbness in your groin area	0.3 (0.743)	0.42 (0.719)	0.143	0.08 (0.392)	0.29 (0.764)	0.090
Bruising around your groin area	0.52 (1.077)	0.7 (1.249)	0.247	0.84 (1.488)	0.73 (1.44)	0.437
Problems in groin where catheter was inserted	0.37 (0.938)	0.49 (0.869)	0.147	0.37 (0.937)	0.29 (0.913)	0.352
The appearance of your bruise	0.41 (0.962)	0.64 (1.128)	0.070	0.92 (1.719)	0.8 (1.581)	0.825
Sum of scores	2.96 (4.813)	4.58 (4.99)	0.010	2.96 (5.048)	3.53 (5.892)	0.819
Questions at discharge only						
Pain in your back	0.89 (1.55)	0.66 (1.27)	0.588	N/A	N/A	--
Discomfort from bedrest	0.87 (1.401)	1.04 (1.441)	0.429	N/A	N/A	--

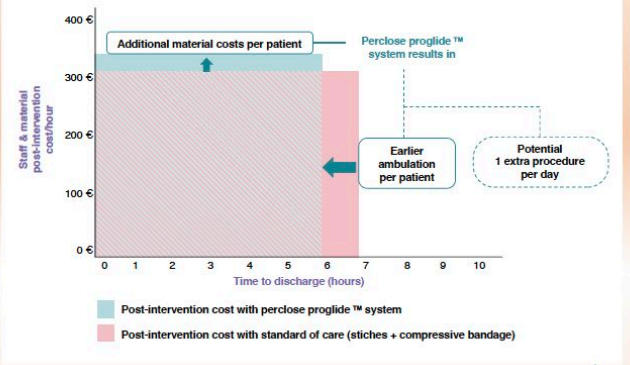
SMC = suture-mediated percutaneous closure.
Kiani S, et al. *J Cardiovasc Electrophysiol*. 2024 [Epub ahead of print].

Perclose Closure for AF Ablation (PRO-PVI Study)

50 patients admitted for PVI + Perclose Proglide™ suture-mediated vascular closure

Feasibility	% of pts with early discharge
Safety	Incidence of vascular complications
Efficacy	time to haemostasis time to ambulate time to discharge
Satisfaction	Patients questionnaire
Cost analysis	Analysis of direct and indirect costs

96% (48/50) pts with early discharge



No major vascular complications

Cost neutral impact on overall hospital budget

Time to haemostasis: within 1 minute for 60% of pts.
Median time to ambulate was 3 hours and 11 minutes (1:26-6:23)
Median time for discharge was 5 hours and 51 minutes (3:38-7:57).

0 = Completely Disappointed — 10 = Completely Satisfied

0 1 2 3 4 5 6 7 8 9 10

4,5 → Appreciation of the length of time spent in supine position, if it was 2-3 hours longer (SD: 2.8)
4,3 → Discomfort tolerance after PVI, if laying position was 2-3 hours longer (SD: 2.7)
4,7 → Pain tolerance after PVI, if laying position was 2-3 hours longer (SD: 2.9)

8,0 → Appreciation of the length of time spent in supine position. (SD: 2.2)
7,9 → Evaluation of the discomfort in laying position after PVI (SD: 2.1)
7,8 → Evaluation of the pain after PVI (SD: 2.2)

Fabbricatore D, et al. *Europace*. 2023; 25(4):1361-1368.

AMBULATE Pivotal Trial

A Prospective, Multi-Center, Randomized 1:1 Clinical Trial

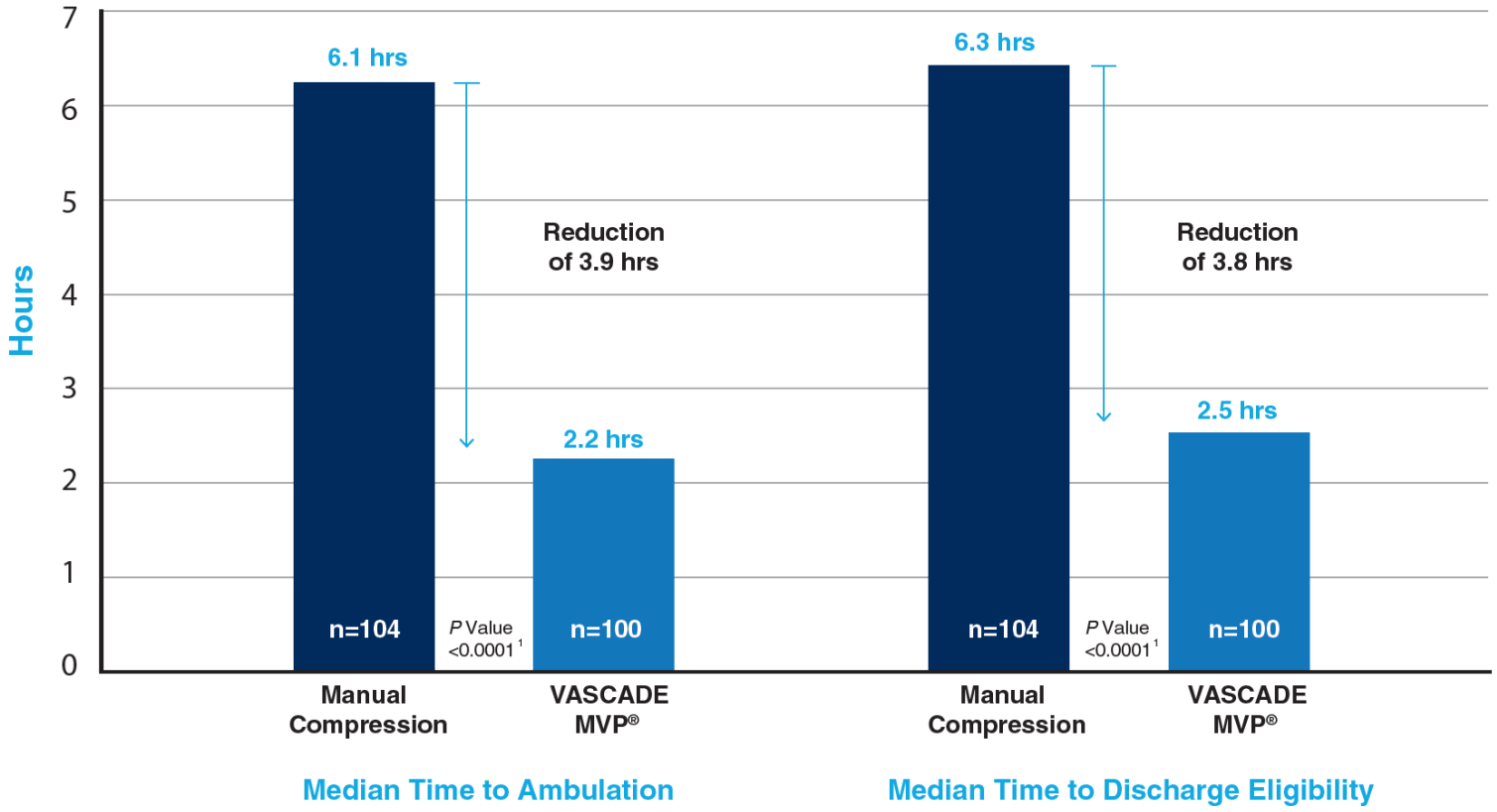
Study Overview

- **Randomized clinical trial:** 204 patients, 13 sites, 28 physicians, randomized 1:1 against manual compression
- **Primary endpoints:** time to ambulation, major access site complications
- **Secondary endpoints:** time to hemostasis, total post-procedure time, time to discharge eligibility, time to discharge, time to closure eligibility, procedure success, device success, minor access site complications
- **Additional data:** patient satisfaction, pain meds

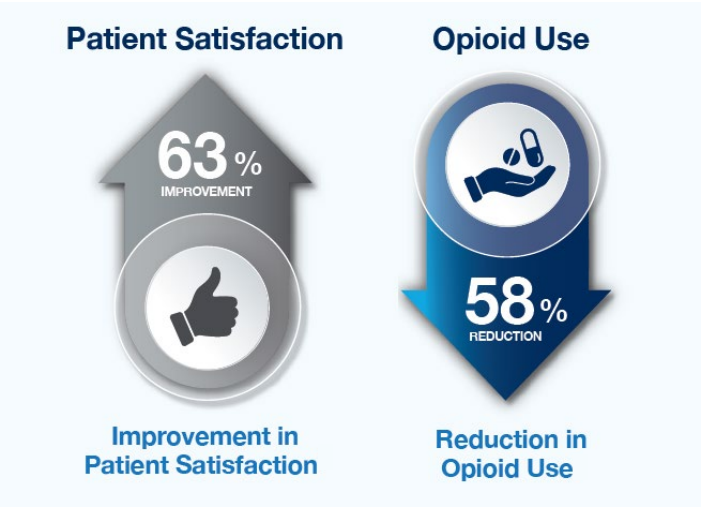
Natale A, et al. *JACC Clin Electrophysiol*. 2020;6(1):111-124. NIH. Accessed November 11, 2024. https://clinicaltrials.gov/study/NCT03193021.

AMBULATE Pivotal Trial

VASCADE MVP® System Compared to Manual Compression



SAFETY ENDPOINT	VASCADE MVP® n=199 limbs	Manual Compression n=209 limbs	*P* Value
Major complications	0%	0%	–
Minor complications	1.0%	2.4%	0.45 [2]



[1]P-values from 2-sided Wilcoxon rank-sum test for medians, unadjusted for stratification factor; [2]P-value by 2-sided Fisher's exact test;
*Patient satisfaction surveys administered prior to discharge. Rated on sale of 0-10, with 10 being very satisfied.

Natale A, et al. *JACC Clin Electrophysiol.* 2020;6(1):111-124. NIH. Accessed November 11, 2024. https://clinicaltrials.gov/study/NCT03193021.

AMBULATE Pivotal Trial

	VASCADE MVP® n=100 patients	Manual Compression n=104 patients	P Value
Median Time to Ambulation (TTA)	2.2 hours	6.1 hours	<.0001[1]
Median Time to Discharge Eligibility (TTDE)	2.5 hours	6.3 hours	<.0001[1]
	VASCADE MVP® n=199 limbs	Manual Compression n=209 limbs	P Value
Major Complication Rate	0%	0%	-
Minor Complication Rate	1.0%	2.4%	.45[2]
	VASCADE MVP® n=100 patients	Manual Compression n=102 patients	Nominal P Value
Patient Bed Rest Duration Satisfaction*	8.3±2.4	5.1±3.4	<.0001
63% increase in patient satisfaction with bed rest duration with VASCADE MVP®			
	VASCADE MVP® n=100 patients	Manual Compression n=104 patients	Nominal P Value
Opioid Use - Yes	15 (15%)	37 (36%)	.001
58% reduction in opioid use with VASCADE MVP®			

[1]P-values from 2-sided Wilcoxon rank-sum test for medians, unadjusted for stratification factor; [2]P-value by 2-sided Fisher's exact test;
*Patient satisfaction surveys administered prior to discharge. Rated on sale of 0-10, with 10 being very satisfied.

Natale A, et al. *JACC Clin Electrophysiol.* 2020;6(1):111-124. NIH. Accessed November 11, 2024. https://clinicaltrials.gov/study/NCT03193021.

Patient-Reported Outcomes

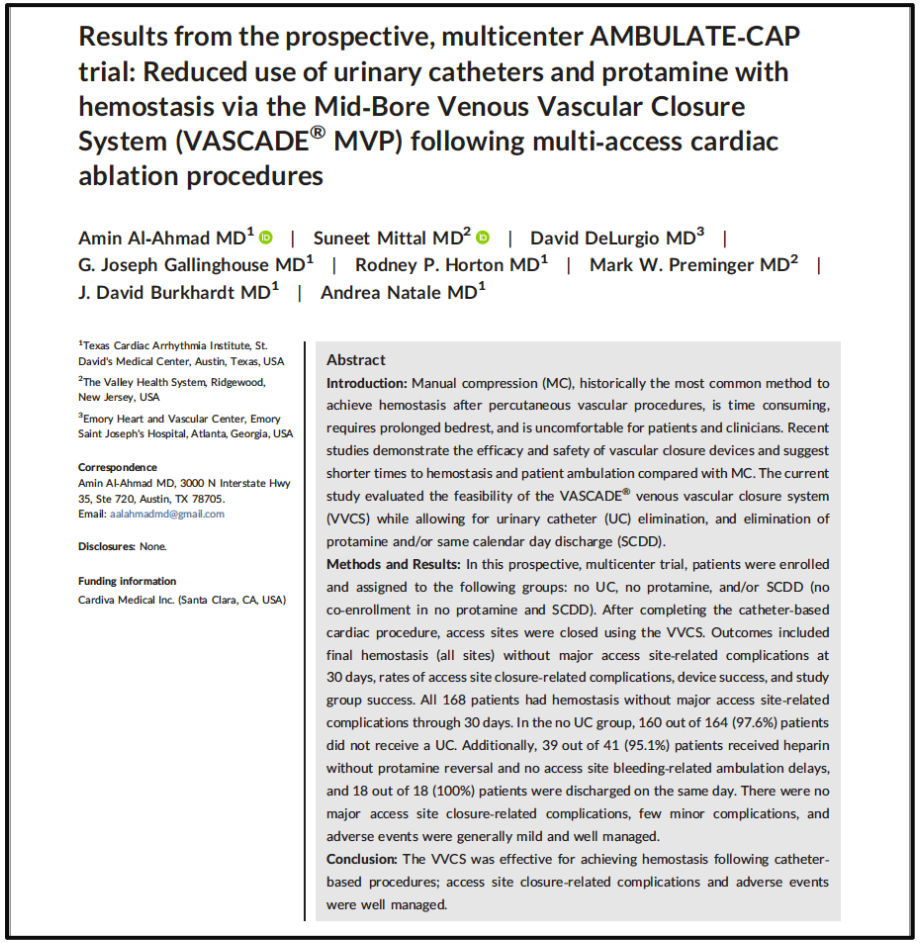
Additional Patient Data		VASCADE MVP® n=100	Manual Compression n=102	Nominal P-Value[1]
Patient-Reported Satisfaction*	ALL PATIENTS – DE NOVO			
	Duration, current episode	8.3±2.4	5.1±3.4	<.0001
	Discomfort, current episode	7.2±3.1	5.3±3.1	<.0001
	Pain, current episode	7.5±3.2	6.0±3.4	.001
	REPEAT CARDIAC ABLATION PATIENTS	n=30	n=39	
	Duration, compared to previous	7.9±2.3	5.6±3.0	.001
	Discomfort, compared to previous	7.5±2.1	5.4±2.8	.001
	Pain, compared to previous	7.7±2.8	5.5±2.9 (n=38)	.002

[1]P-value by 2-sided Fisher's exact test; *Patient satisfaction surveys administered prior to discharge. Rated on sale of 0-10, with 10 being very satisfied.

Natale A, et al. *JACC Clin Electrophysiol.* 2020;6(1):111-124. NIH. Accessed November 11, 2024. https://clinicaltrials.gov/study/NCT03193021.

AMBULATE CAP Study

- Prospective, multi-center, single-arm study
- n=168 patients, 325 limbs
- 3 sites: Texas Cardiac Arrhythmia, Valley Heart & Vascular, and Emory St. Joseph's
- **98%** of patients did not receive a urinary catheter through successful ambulation
- **95%** of patients did not receive protamine reversal, and had no delays in ambulation due to bleeding
- **98%** of attempted access sites (n=622) successfully achieved hemostasis using VASCADE MVP®
- **100%** of patients in the same day discharge group went home the same day with no further access site complications or rehospitalization
- Zero major complications, 2.2% minor complications (per-limb basis)



Results from the prospective, multicenter AMBULATE-CAP trial: Reduced use of urinary catheters and protamine with hemostasis via the Mid-Bore Venous Vascular Closure System (VASCADE® MVP) following multi-access cardiac ablation procedures

Amin Al-Ahmad MD[1] | Suneet Mittal MD[2] | David DeLurgio MD[3] | G. Joseph Gallinghouse MD[1] | Rodney P. Horton MD[1] | Mark W. Preminger MD[2] | J. David Burkhardt MD[1] | Andrea Natale MD[1]

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Disclosures: None.

Funding information
Cardiva Medical Inc. (Santa Clara, CA, USA)

Abstract

Introduction: Manual compression (MC), historically the most common method to achieve hemostasis after percutaneous vascular procedures, is time consuming, requires prolonged bedrest, and is uncomfortable for patients and clinicians. Recent studies demonstrate the efficacy and safety of vascular closure devices and suggest shorter times to hemostasis and patient ambulation compared with MC. The current study evaluated the feasibility of the VASCADE® venous vascular closure system (VVCS) while allowing for urinary catheter (UC) elimination, and elimination of protamine and/or same calendar day discharge (SCDD).

Methods and Results: In this prospective, multicenter trial, patients were enrolled and assigned to the following groups: no UC, no protamine, and/or SCDD (no co-enrollment in no protamine and SCDD). After completing the catheter-based cardiac procedure, access sites were closed using the VVCS. Outcomes included final hemostasis (all sites) without major access site-related complications at 30 days, rates of access site closure-related complications, device success, and study group success. All 168 patients had hemostasis without major access site-related complications through 30 days. In the no UC group, 160 out of 164 (97.6%) patients did not receive a UC. Additionally, 39 out of 41 (95.1%) patients received heparin without protamine reversal and no access site bleeding-related ambulation delays, and 18 out of 18 (100%) patients were discharged on the same day. There were no major access site closure-related complications, few minor complications, and adverse events were generally mild and well managed.

Conclusion: The VVCS was effective for achieving hemostasis following catheter-based procedures; access site closure-related complications and adverse events were well managed.

Al-Ahmad A, et al. *J Cardiovasc Electrophysiol.* 2021;32(2):191-199. NIH. Accessed November 12, 2024. https://clinicaltrials.gov/study/NCT03573206.

Patient-Reported Outcomes and Costs

Patient-reported outcomes and costs associated with vascular closure and same-day discharge following atrial fibrillation ablation

Benjamin A. Steinberg MD, MHS[1] | Shannon Woolley[1] | Haojia Li MS[2] | Candice Crawford[3] | Christopher A. Groh MD[1] | Leenhapong Navaravong MD[1] | Ravi Ranjan MD, PhD[1] | Brian Zenger PhD[1] | Yue Zhang PhD[2] | T. Jared Bunch MD[1]

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Funding information
Cardiva Medical; National Heart, Lung, and Blood Institute

Abstract

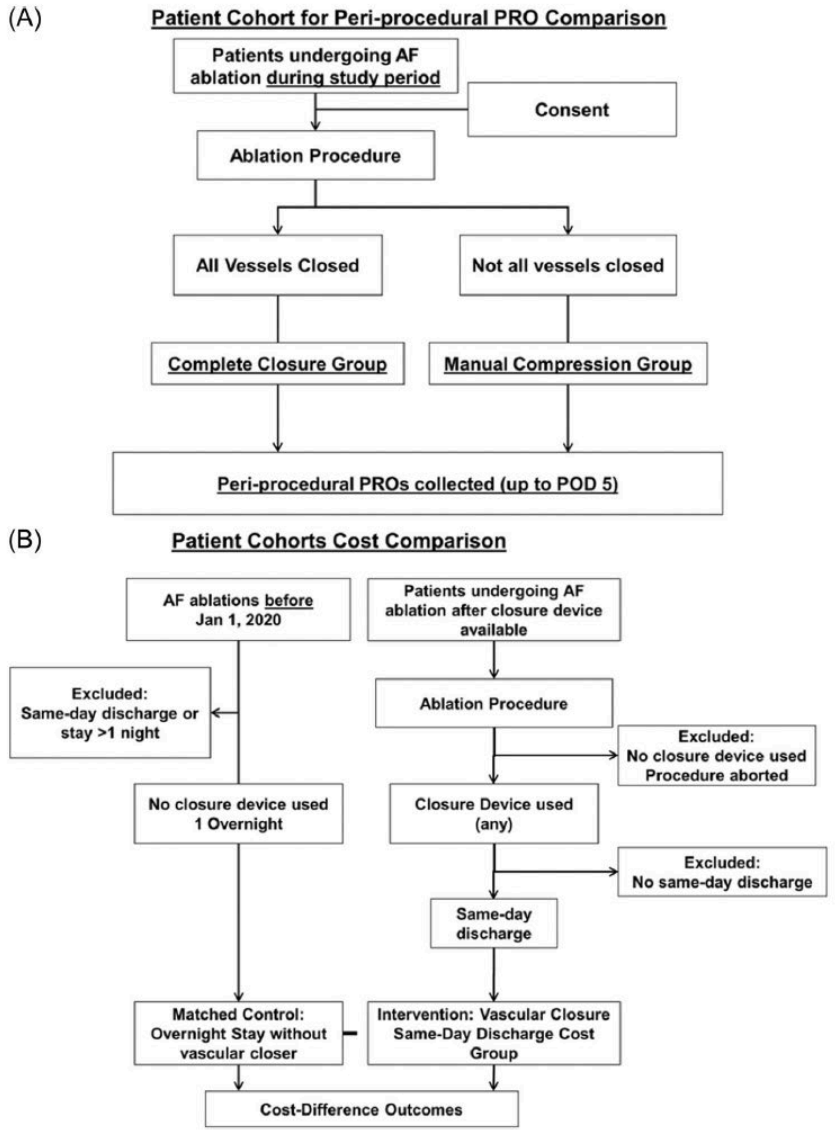
Background: We aimed to measure patient-reported outcomes (PROs) and costs associated with same-day discharge (SDD) for atrial fibrillation (AF) ablation and vascular closure device implantation in clinical practice.

Methods: PROs were prospectively measured in 50 AF ablation patients, comparing complete vascular device closure ($n = 25$) versus manual compression hemostasis ($n = 25$). Health-system costs for SDD patients receiving vascular device closure were compared to matched controls with one-night stays who did not receive any closure device.

Results: Prospectively enrolled patients receiving vascular device closure for AF ablation had a mean age of 65 years, 17% were female, with a mean CHA_2DS_2-VASc score of 3. The mean number of venous sheaths was higher among patients receiving vascular device closure (3.8 vs. 3.1, $p < 0.001$), and there was one case of rebleeding in a patient receiving a vascular closure device (no other complications). Same-day discharge rates (76% vs. 8.3%, $p < 0.001$), patient satisfaction with bedrest time (8.5 vs. 6, $p = 0.004$) and with pain (8 vs. 5.1, $p = 0.009$) were significantly better among patients receiving vascular closure. In matched analyses of health-system costs, patients with vascular closure had mean age 66, 32% were female, and the mean CHA_2DS_2-VASc score was 2 (p = NS vs. controls). SDD with vascular closure was associated with the significantly lower facility, pharmacy, and disposable costs, but higher implant costs. Overall costs for ablation were not significantly different (mean difference 1.10%, 95% confidence interval [CI] −3.03 to 5.42).

Conclusions: Vascular closure for AF ablation improves patient experience in routine care. The use of vascular closure and SDD after AF ablation reduces several components of healthcare system costs, without an overall increase.

KEYWORDS
ablation, atrial fibrillation, costs, patient reported outcomes, value driven healthcare

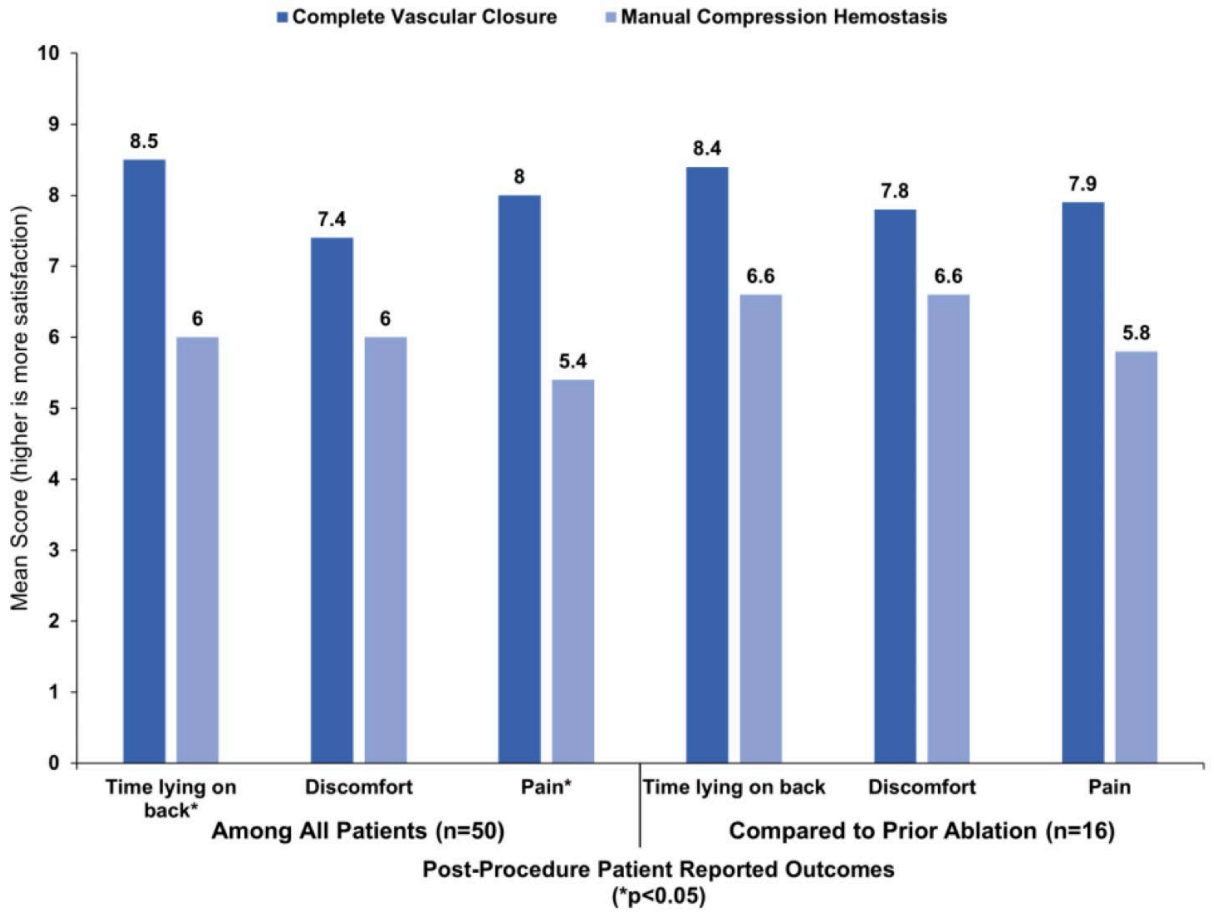


PRO = patient-reported outcome; POD = postoperative delirium.

Steinberg BA, et al. *J Cardiovasc Electrophysiol.* 2022;33(8):1737-1744.

Complete Vascular Closure vs Manual Compression Homeostasis

	Complete Vascular Closure (n=25)	Manual Compression Hemostasis (n=25)	p
Age, years	65.16 (12.10)	65.68 (10.75)	0.873
Female Sex	6 (24.0)	7 (28.0)	1.000
Hypertension	11 (44.0)	8 (32.0)	0.560
Diabetes mellitus	4 (16.0)	8 (32.0)	0.321
Sleep apnea	10 (40.0)	12 (48.0)	0.776
Chronic kidney disease	5 (20.0)	5 (20.0)	1.000
Congestive heart failure	8 (32.0)	11 (44.0)	0.560
Coronary artery disease	12 (48.0)	13 (52.0)	1.000
Prior MI	8 (32.0)	8 (32.0)	1.000
Peripheral arterial disease	7 (28.0)	4 (16.0)	0.495
Prior stroke or TIA	3 (12.0)	3 (12.0)	1.000
Prior catheter ablation (any)	8(32%)	8(32%)	>0.99
$CHADS_2$-VA_2Sc score	2.60 (1.89)	2.80 (1.66)	0.693
Body mass index (kg/m^2)	30.75 (6.48)	30.17 (5.55)	0.736
Left-ventricular ejection fraction	54.22 (7.38)	57.36 (12.10)	0.505
Relevant medications prior to ablation			
Non-steroidal anti-inflammatory drugs	4(16%)	3(12%)	>0.99
Aspirin	0(0%)	1(4%)	>0.99
Clopidogrel	2 (8%)	2 (8%)	>0.99
Anticoagulation			0.316
Warfarin	3 (12%)	4 (16%)	
Dabigatran	0 (0%)	1 (4%)	
Rivaroxaban	4 (16%)	7 (28%)	
Apixaban	18 (72%)	12 (48%)	
None	0 (0%)	1 (4%)	

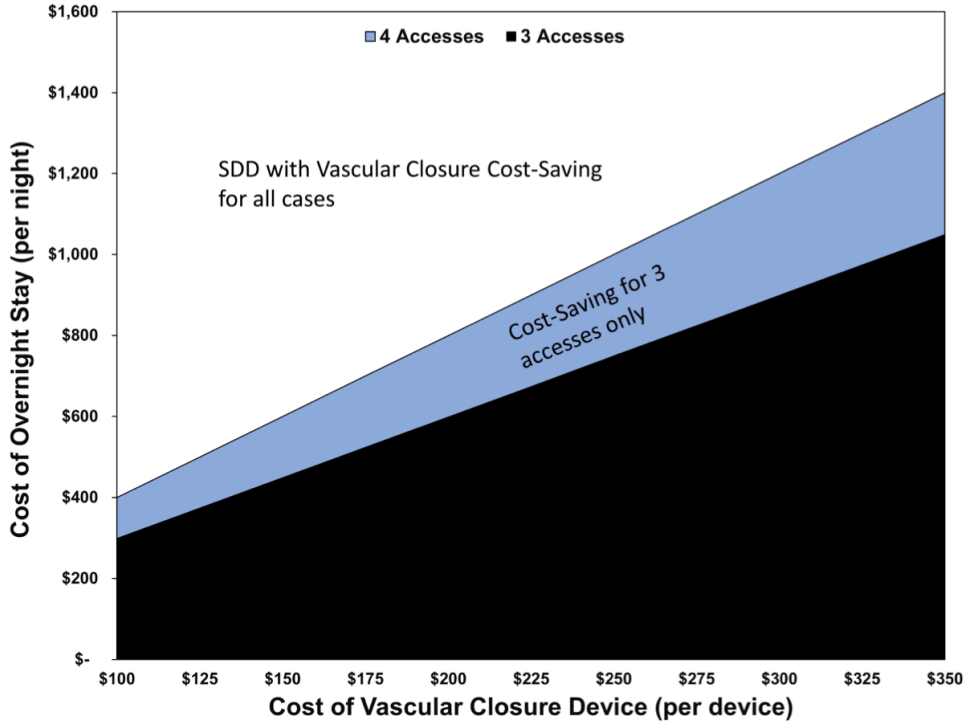


MI = myocardial infarction; TIA = transient ischemic attack; $CHADS_2$-VA_2-Sc = congestive heart failure, hypertension, age 75 or older (doubled), diabetes, stroke or transient ischemic attack (doubled), vascular disease, sex category.

Steinberg BA, et al. *J Cardiovasc Electrophysiol.* 2022;33(8):1737-1744.

Cost of Overnight Stay vs Cost of VCD

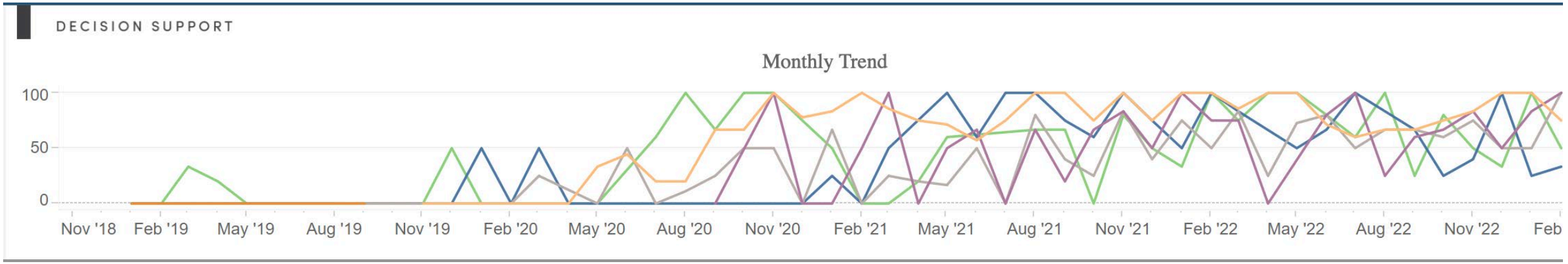
	Cost Difference* (%)	Lower Bound (2.5%)	Upper Bound (97.5%)
Total cost	1.10	-3.03	5.42
Supply cost	-7.14	-11.13	-4.22
Pharmacy cost	-70.69	-87.14	-20.82
Other services	0.1	-7.11	13.19
Facility utilization	-89.1	-91.77	-83.29
Implant supplies	447.62	367.54	495.82



SDD = same day discharge.

Steinberg BA, et al. *J Cardiovasc Electrophysiol.* 2022;33(8):1737-1744.

Trends in SDD Use at the University of Utah



AMBULATE SDD Registry

Same-day discharge following catheter ablation and venous closure with VASCADE MVP: A postmarket registry

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Abstract

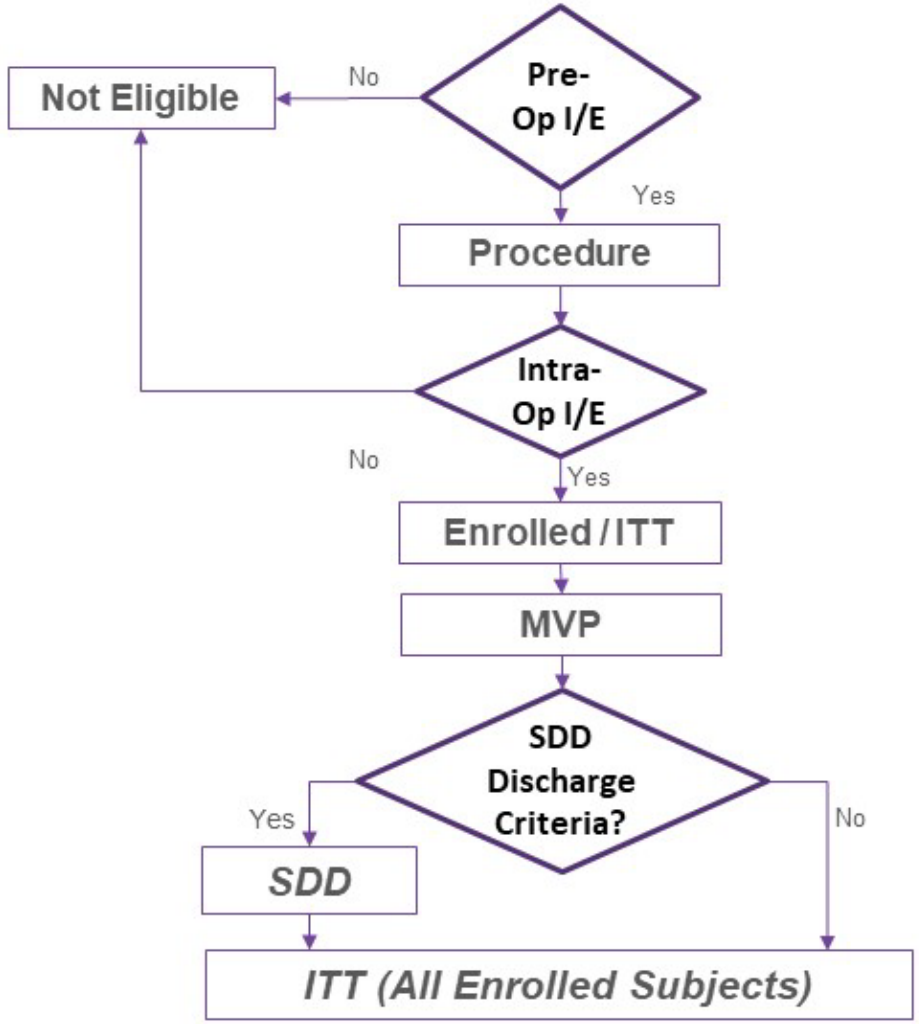
Introduction: Early and safe ambulation can facilitate same-day discharge (SDD) following catheter ablation, which can reduce resource utilization and healthcare costs and improve patient satisfaction. This study evaluated procedure success and safety of the VASCADE MVP venous vascular closure system in patients with atrial fibrillation (AF).

Methods: The AMBULATE SDD Registry is a two-stage series of postmarket studies in patients with paroxysmal or persistent AF undergoing catheter ablation followed by femoral venous access-site closure with VASCADE MVP. Efficacy endpoints included SDD success, defined as the proportion of patients discharged the same day who did not require next-day hospital intervention for procedure/access site–related complications, and access site sustained success within 15 days of the procedure.

Results: Overall, 354 patients were included in the pooled study population, 151 (42.7%) treated for paroxysmal AF and 203 (57.3%) for persistent AF. SDD was achieved in 323 patients (91.2%) and, of these, 320 (99.1%) did not require subsequent hospital intervention based on all study performance outcomes. Nearly all patients (350 of 354; 98.9%) achieved total study success, with no subsequent hospital intervention required. No major access-site complications were recorded. Patients who had SDD were more likely to report procedure satisfaction than patients who stayed overnight.

Conclusion: In this study, 99.7% of patients achieving SDD required no additional hospital intervention for access site–related complications during follow-up. SDD appears feasible and safe for eligible patients after catheter ablation for paroxysmal or persistent AF in which the VASCADE MVP is used for venous access-site closure.

KEYWORDS
atrial fibrillation, catheter ablation, patient-reported outcomes, same-day discharge, VASCADE MVP



I/E = inclusion/exclusion; ITT = intention-to-treat.

Eldadah ZA, et al. *J Cardiovasc Electrophysiol.* 2023;34:348-355. NIH. Accessed November 12, 2024. https://clinicaltrials.gov/study/NCT04538781.

SDD Following Catheter Ablation and Venous Closure with VASCADE MVP®: A Post-Market Registry

	SDD (n=323)	Non-SDD (n=31)	Total ITT (N=354)	P-Value
Age, mean (SD), years	64.5 (10.6)	66.6 (11.1)	64.7 (10.7)	.29
Male, no. (%)	231 (71.5)	22 (71.0)	253 (71.5)	1.00
Body mass index, mean (SD), kg/m^2	30.4 (6.5)	31.0 (5.6)	30.4 (6.4)	.62
Comorbidities, no. (%)				
Hypertension	215 (66.6)	28 (90.3)	242 (68.4)	.0073
Hypercholesterolemia	201 (62.2)	19 (61.3)	220 (62.1)	1.00
Diabetes mellitus	70 (21.7)	7 (22.6)	77 (21.8)	1.00
Congestive heart failure	73 (22.6)	10 (32.3)	83 (23.4)	0.27
History of stroke/transient ischemic attack	21 (6.5)	5 (16.1)	26 (7.3)	.06
History of myocardial infarction	21 (6.5)	1 (3.2)	22 (6.2)	.71
Peripheral arterial disease	5 (1.5)	0 (0.0)	5 (1.4)	1.00
Sleep apnea	103 (31.9)	9 (29.0)	112 (31.6)	1.00
CHA_2DS_2-VASc risk scale, mean (SD)	2.3 (1.5)	3.1 (1.7)	2.4 (1.5)	.005
Previous cardiac ablation, no. (%)	104 (32.3)	6 (19.4)	110 (31.1)	.16
Persistent AF, no. (%)	185 (57.3)	18 (58.1)	203 (57.3)	1.00

SD = standard deviation.

Eldadah ZA, et al. *J Cardiovasc Electrophysiol.* 2023;34:348-355.

Performance and Safety Outcomes, Pooled Analysis

	Performance		Safety	
Population	Total success	Device success	Access-site closure-related complications	
			Major	Minor
SDD	99.1% (320/323)	99.2% (1097/1106)	0.0% (0/465)	0.9% (4/465)
SDD/ITT	90.4% (320/354)			
ITT	98.9% (350/354)			

Eldadah ZA, et al. *J Cardiovasc Electrophysiol.* 2023;34:348-355.

Patient-Reported Outcomes

	SDD (n=321)	Non-SDD (n=30)	Total (ITT) (N=351)
Access site (groin) discomfort, mean (SD) (scale 1-10; no discomfort to very painful)	1.7 (1.2)	2.3 (1.7)	1.8 (1.3)
Bed rest experience, no. (%)			
Just right	290 (90.3)	20 (66.7)	310 (88.3)
Too long	14 (4.4)	7 (23.3)	21 (6.0)
Too short	17 (5.3)	3 (10.0)	20 (5.7)

Eldadah ZA, et al. *J Cardiovasc Electrophysiol.* 2023;34:348-355.

Conclusions

- AF ablation is increasingly being performed compared to other EP procedure
- Evolving ablation technologies significantly augment procedural costs and need to be associated with other measures to lower hospital costs to realize their potential value
- Vascular closure after AF ablation improves patient experience and allows for earlier discharge compared to standard of care in randomized and observational trials
- Vascular closure is successful in >99% of patients
- Same day discharge offsets costs of vascular closure and can be performed in most patients that undergo an AF ablation

Patient Flow Improvements, Patient Satisfaction, and Economic Benefits of Early Ambulation and Same Day Discharge

Zayd Eldadah, MD, PhD

History of Vascular Closure Post-Ablation

- Historically, manual compression (MC) has been the most common method for achieving hemostasis
  - Often uncomfortable for patients and usually requires four to six hours of bedrest, might need urinary catheter
- A figure-of-eight suture technique (FO8) has been shown to reduce the time to hemostasis compared to MC
- Suture mediated closure (SMC) more recently have been used in electrophysiology (EP) procedures
  - The SMC device places permanent sutures to close the venous access site

Natale A, et al. *JACC Clin Electrophysiol*. 2020;6(1):111-124. Atti V, et al. *J Interv Card Electrophysiol*. 2020;57(3):379-385. Castro-Urda V, et al. *Pacing Clin Electrophysiol*. 2023;46(7):598-606. Fabbricatore D, et. al. *Europace*. 2023;25(4):1361-1368. Kiani S, et al. *JACC Clin Electrophysiol*. 2022; 8(6):803-805

Same Day Discharge Evidence in PAF and PsAF Ablation

AMBULATE SDD Retrospective

- Multicenter, single arm study on procedural outcomes in SDD for AF ablation patients
- 497 patients at 4 U.S. centers
- 99.8% of patients had no minor access site closure-related complications
- 0% major access site closure-related complications

AMBULATE Same Day Discharge Clinical Studies

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

Using the VASCADE MVP® System

1,106 Access Sites	91.2% Discharged the Same day (SDD)
354 Patients	99.7% SDD Success with no access site complications[1]
45 Investigators	0% ZERO (0) major complications[2]
14 US Centers	

[1]Did not require intervention for access site complications the next day through 15-day follow up; [2]Major venous access site closure-related complications through 15-day follow up.

Eldadah ZA, et al. *J Cardiovasc Electrophysiol.* 2023;34:348-355. NIH. Accessed November 20, 2024. https://clinicaltrials.gov/study/NCT04538781.

Five EP Clinical Studies

3,788  **Access Sites**

1,223  **Patients**

111  **Investigators**

41  **U.S. Centers**

0%

Major Complications

Natale A, et al. *JACC Clin Electrophysiol*. 2020;6(1):111-124. Al-Ahmad A, et al. *J Cardiovasc Electrophysiol.* 2021;32(2):191-199. Eldadah ZA, et al. *J Cardiovasc Electrophysiol.* 2023;34:348-355. NIH. Accessed November 20, 2024. https://clinicaltrials.gov/study/NCT04538781.

FO8 Challenges Can Impact Patients, Staff, and Physicians

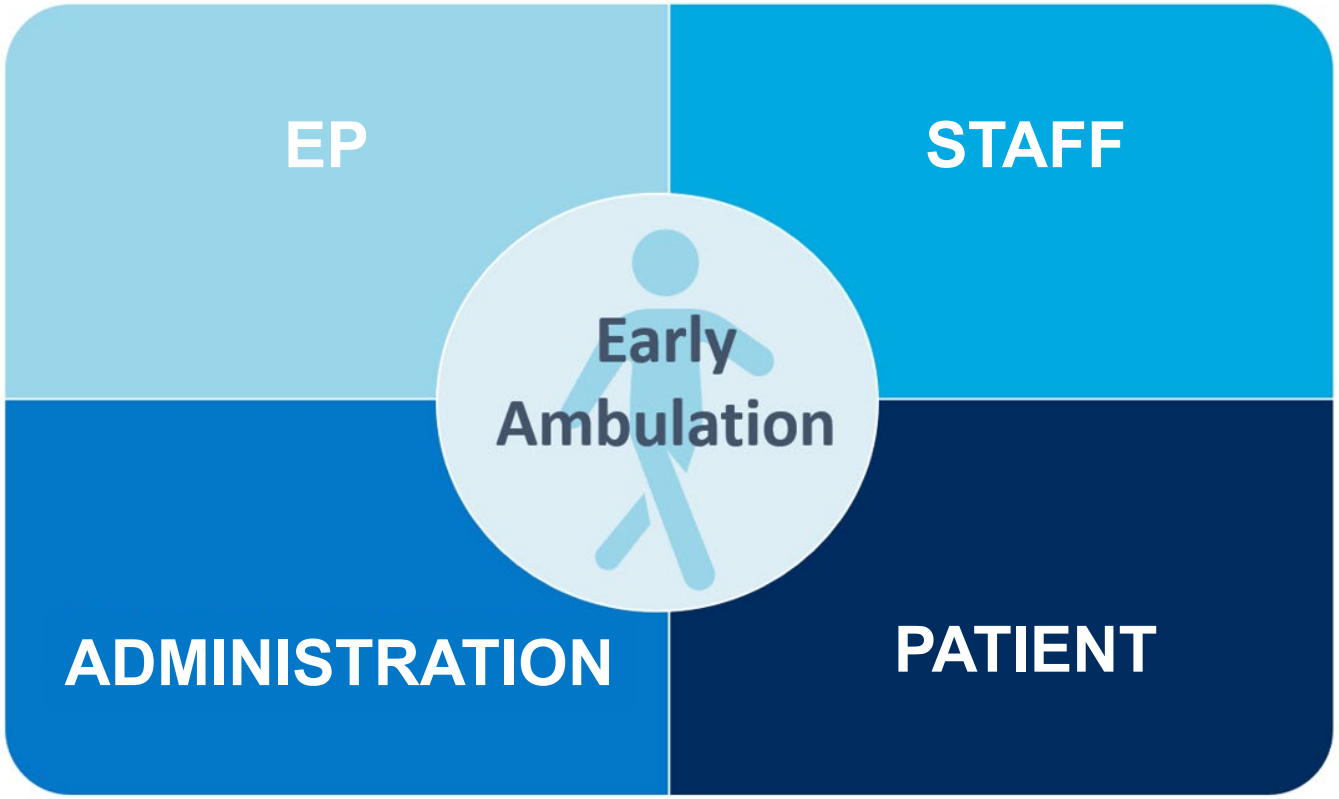
- Patients lie flat with the stitch in place
- FO8 has been shown to reduce time to ambulation compared to MC
- In my experience, some patients can find the FO8 technique to be painful
- There was no significant difference in patient satisfaction or analgesic use for FO8 compared to MC and SMC

Mohammed M, et al. *J Interv Card Electrophysiol*. 2022;64(2):301-310. Lakshmanadoss U, et al. *Indian Pacing Electrophysiol J*. 2017;17(5):134-139.

FO8 Challenges Can Impact Patients, Staff, and Physicians

- FO8 post-procedure workflow requires staff to clip and remove the suture on the floor prior to discharge
- In my experience, sometimes patients can inadvertently be sent home with the suture still in place, mandating a return office visit
- Sutures could loosen, potentially requiring additional attention from staff
- In placing a stitch with a needle, there is a risk of inadvertently nicking an artery

Impact of Early Ambulation using VASCADE MVP® System

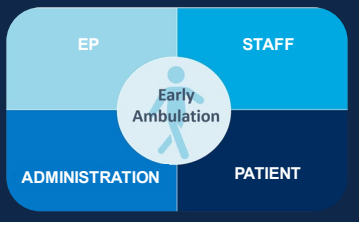


Early Ambulation Potential Goals and Objectives

- Same day discharge
- Patient satisfaction
- Reduce opioids
- No/low foley & UTI
- Additional cases
- No/low protamine
- Greater throughput
- Manage limited bed space
- Faster lab turnover
- Lower overall costs
- Address staff shortages

Natale A, et al. *JACC Clin Electrophysiol*. 2020;6(1):111-124. Al-Ahmad A, et al. *J Cardiovasc Electrophysiol.* 2021;32(2):191-199. Eldadah ZA, et al. *J Cardiovasc Electrophysiol.* 2023;34:348-355. NIH. Accessed November 20, 2024. https://clinicaltrials.gov/study/NCT04538781.

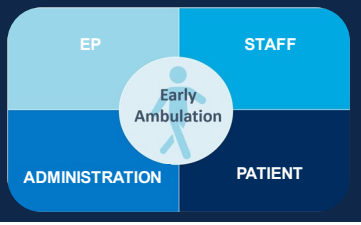
Benefits to EPs



- Early ambulation with VASCADE MVP® is reproducible compared to manual compression
- The system is simple and easy to use, which enables our PAs and Fellows to perform vascular closure
- It has demonstrated 0% major complications in 1223 patients in 5 EP clinical studies
- Potential for low rates of urinary catheter use
- It demonstrated a 63% improvement in patient satisfaction for bedrest duration compared to manual compression
- Same day discharge—no need to round the next day

Natale A, et al. *JACC Clin Electrophysiol*. 2020;6(1):111-124. Al-Ahmad A, et al. *J Cardiovasc Electrophysiol.* 2021;32(2):191-199. Eldadah ZA, et al. *J Cardiovasc Electrophysiol.* 2023;34:348-355. NIH. Accessed November 20, 2024. https://clinicaltrials.gov/study/NCT04538781.

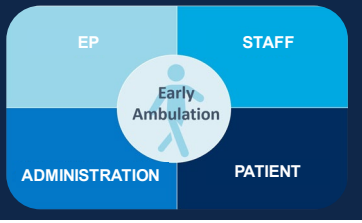
Benefits to Staff at St. David's Hospital



- Early ambulation improves post-procedure workflow
- Free up and streamline bed and lab space before, during, and after the procedure
- More efficiency in our lab turnover
- Nurses can be leveraged for higher value clinical care vs managing sheaths

Natale A, et al. *JACC Clin Electrophysiol*. 2020;6(1):111-124.

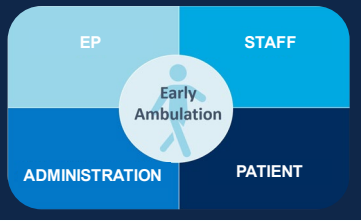
Benefits to Administration



- Improved workflow has the potential to enable better throughput, which can lead to more cases
- Comprehensive clinical evidence in same day discharge for AF ablation
- Early ambulation and SDD have the potential to generate healthcare cost savings
- Improved patient satisfaction scores compared to manual compression in AMBULATE pivotal study

Eldadah ZA, et al. *J Cardiovasc Electrophysiol.* 2023;34:348-355. Steinberg BA, et al. *J Cardiovasc Electrophysiol*. 2022;33(8):1737-1744. Natale A, et al. *JACC Clin Electrophysiol*. 2020;6(1):111-124.

Benefits to Patients



- Patients are ambulating in a median 2.2 hours and may be eligible to go home the same day
- VASCADE MVP® System improved patient satisfaction by 63% compared to manual compression
- Reduced opioid use compared to manual compression, by 58%
- Nothing permanent left behind
- No sutures
- Resorbable, thrombogenic collagen plug
- Allows for re-access at the same site after 30 days—may be beneficial for repeat ablation patients

AMBULATE PIVOTAL TRIAL	VASCADE MVP n=100 patients	Manual Compression n=104 patients	Nominal *P* Value
Patient Bed Rest Duration Satisfaction*	8.3±2.4	5.1±3.4	<0.0001**
63% increase in patient satisfaction with bed rest duration with VASCADE MVP			
AMBULATE PIVOTAL TRIAL	**VASCADE MVP n=100 patients**	**Manual Compression n=104 patients**	**Nominal *P* Value**
Opioid Use – Yes	15 (15%)	37 (36%)	0.001**
58% reduction in opioid use with VASCADE MVP			

***Patient satisfaction surveys administered prior to discharge. Rated on sale of 0-10, with 10 being very satisfied; **Nominal p-value by two-sided Fisher's exact test.**

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Improved Patient Satisfaction from AMBULATE for De Novo and Repeat Ablation Patients

Additional Patient Data		VASCADE MVP® System n=100	Manual Compression n=102	Nominal P-value**	Summary
Patient-Reported Satisfaction*	**ALL PATIENTS – DE NOVO AND REPEAT ABLATION PATIENTS**				
	Duration, current episode	8.3±2.4	5.1±3.4	<0.0001	**Scores 63% higher for MVP**
	Discomfort, current episode	7.2±3.1	5.3±3.1	<0.0001	**Scores 36% higher for MVP**
	Pain, current episode	7.5±3.2	6.0±3.4	0.001	**Scores 25% higher for MVP**
	REPEAT CARDIAC ABLATION PATIENTS	**n=30**	**n=39**		
	Duration, compared to previous	7.9±2.3	5.6±3.0	0.001	**Scores 41% higher for MVP**
	Discomfort, compared to previous	7.5±2.1	5.4±2.8	0.001	**Scores 39% higher for MVP**
	Pain, compared to previous	7.7±2.8	5.5±2.9 (N=38)	0.002	**Scores 40% higher for MVP**

***Patient satisfaction surveys administered prior to discharge. Rated on sale of 0-10, with 10 being very satisfied; **Nominal p-value by two-sided Fisher's exact test.**

Natale A, et al. *JACC Clin Electrophysiol*. 2020;6(1):111-124.

Conclusions

- 0% major complications in 5 EP clinical studies means no added time needed for managing patients with these complications
- Same day discharge with VASCADE MVP® has proven to be feasible after AF ablation, as demonstrated in the AMBULATE SDD clinical studies
- Figure-of-Eight suture has not been well-studied in large, multi-center, prospective, randomized trials
- Early ambulation enables stakeholders to achieve their goals and objectives—patients, physicians, staff, and hospital
- VASCADE MVP® has potential per-patient cost savings post-ablation, based on workflow improvements compared to MC
- FO8 has shown limited data to date on patient satisfaction and analgesic use

Natale A, et al. *JACC Clin Electrophysiol*. 2020;6(1):111-124. Eldadah ZA, et al. *J Cardiovasc Electrophysiol.* 2023;34:348-355.

Discussion