CardioVascular Learning Network | CME

Coagulation Management in EP Procedures

Faculty

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Faculty Disclosures

- **Suneet Mittal, MD**: Consultant—Boston Scientific, Haemonetics Corporation, Medtronic
- **David DeLurgio, MD, FACC, FHRS**: Consultant—Haemonetics Corporation, Abbott Medical, Atricure Inc, Boston Scientific, Medtronic

Program Information

- This program is provided by HMP Education, an HMP Global company
- Supported by an educational grant from Haemonetics Corporation

Learning Objectives

- **Assess anticoagulation strategies in EP procedures** by interpreting current measurement tools (eg, ACTs) and understanding their clinical relevance to peri-interventional stroke and bleeding risk
- **Apply patient-specific risk stratification models** in atrial fibrillation to optimize management of anticoagulation and minimize complications such as thromboembolism and bleeding
- **Evaluate emerging technologies and closure strategies** that address anticoagulation-related risks and procedural complications, incorporating evidence-based approaches into clinical practice

EP = electrophysiology; ACTs = activated clotting procedures.

CardioVascular Learning Network | CME

Optimizing Anticoagulation in AF Ablation:
Risk, Tools, and Targets

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Case Presentation

ESC European Society of Cardiology
Europace (2024) **26**, 1–107
https://doi.org/10.1093/europace/euae043
EHRA DOCUMENT
EHRA European Heart Rhythm Association

2024 European Heart Rhythm Association/ Heart Rhythm Society/Asia Pacific Heart Rhythm Society/Latin American Heart Rhythm Society expert consensus statement on catheter and surgical ablation of atrial fibrillation

Stylianos Tzeis [1]* (EHRA Chair), Edward P. Gerstenfeld[2] (HRS Co-Chair), Jonathan Kalman [3,4] (APHRS Co-Chair), Eduardo B. Saad [5,6] (LAHRS Co-Chair), Alireza Sepehri Shamloo [7] (Writing Group Coordinator), Jason G. Andrade [8], Chirag R. Barbhaiya [9], Tina Baykaner[10], Serge Boveda [11,12], Hugh Calkins [13], Ngai-Yin Chan [14], Minglong Chen [15], Shih-Ann Chen[16], Nikolaos Dagres [17], Ralph J. Damiano[18], Tom De Potter [19], Isabel Deisenhofer [20], Nicolas Derval [21], Luigi Di Biase [22], Mattias Duytschaever [23], Katia Dyrda [24], Gerhard Hindricks [17], Meleze Hocini [21], Young-Hoon Kim[25], Mark la Meir [26], Jose Luis Merino [27,28], Gregory F. Michaud[29], Andrea Natale [30,31,32,33], Isabelle Nault [34], Santiago Nava [35], Takashi Nitta [36], Mark O'Neill [37], Hui-Nam Pak [38], Jonathan P. Piccini [39], Helmut Pürerfellner [40], Tobias Reichlin [41], Luis Carlos Saenz [42], Prashanthan Sanders [43], Richard Schilling [44], Boris Schmidt [45], Gregory E. Supple [46], Kevin L. Thomas [39], Claudio Tondo [47,48], Atul Verma [49], and Elaine Y. Wan [50]

Tzeis S, et al. *Europace*. 2024;26(4):euae043.

Pre-Ablation Anticoagulation Management

- Based on currently used stroke risk assessment that guides decision-making on eligibility for antithrombotic treatment, patients with AF and stroke risk factor(s) (CHA2DS2-VASc score ≥1 in males and ≥2 in females) who are scheduled for AF catheter ablation should receive oral anticoagulation therapeutically for at least 3 weeks prior to ablation
- A minimum of 3-week therapeutic anticoagulation before AF catheter ablation is also beneficial in patients with the lowest CHA2DS2-VASc score (0 in males and 1 in females) if they are considered to have increased risk of thrombus due to persistent AF type or specific underlying heart disease (HCM, rheumatic heart disease, and cardiac amyloidosis)

AF = atrial fibrillation; HCM = hypertrophic cardiomyopathy.

Tzeis S, et al. *Europace*. 2024;26(4):euae043.

Pre-Ablation Anticoagulation Management

Catheter ablation of AF without interruption of anticoagulation is beneficial in patients who have been therapeutically anticoagulated with either vitamin K antagonists or direct oral anticoagulants (DOACs)

For patients anticoagulated with a DOAC prior to AF catheter ablation, it is reasonable to hold one dose prior to AF catheter ablation with early reinitiation post-ablation

Tzeis S, et al. *Europace*. 2024;26(4):euae043.

Anticoagulation during AF Ablation

Procedural management and techniques	Category of advice	Type of evidence
Heparin should be administered during AF catheter ablation and adjusted to achieve and maintain an ACT of at least 300 seconds	Advice TO DO	OBS
Administration of initial heparin bolus before transseptal puncture is reasonable, especially when performed under echocardiographic guidance	May be appropriate TO DO	OBS

ACT = activated clotting time; OBS = observational studies or registries.
Tzeis S, et al. *Europace*. 2024;26(4):euae043.

Anticoagulation during AF Ablation

ACT >300 seconds

(2/3 of writing group)

ACT >350 seconds

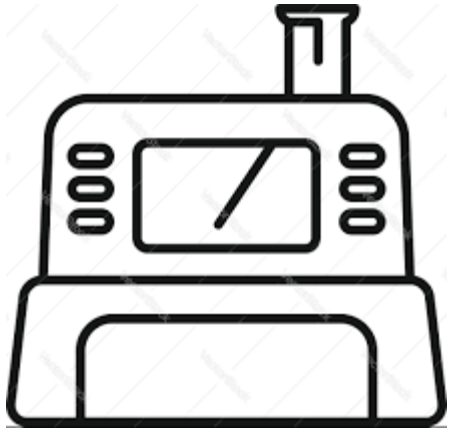
(1/3 of writing group)

Tzeis S, et al. *Europace*. 2024;26(4):euae043.

Measuring an ACT

Whole Blood Sample

0.4–2 mL



ACT Cartridge

Activator
Optical or magnetic detector

Clot Formation

The time from blood activation to detected clot formation is the ACT, reported in seconds

Variables

Heparin dose and timing
Hemodilution
Low platelet count
Use of direct thrombin inhibitors
Device-to-device variability

Device-to-Device Variability

Original Research Article

Activated Clotting Time Requires Adaptation Across Altered Measurement Devices: Determination of Appropriate Range During Atrial Fibrillation Ablation

Clinical and Applied Thrombosis/Hemostasis
Volume 31: 1-9
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DOI: 10.1177/10760296251332938
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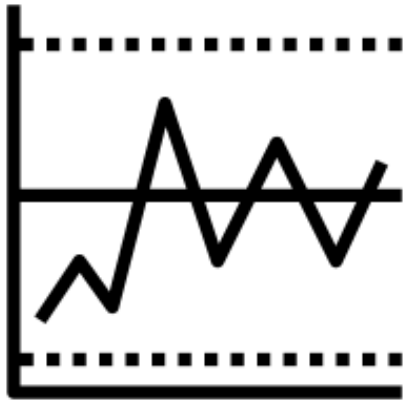


Haruna Sakanoue, RN[1], Hirosuke Yamaji, MD[2], Sayaka Okamoto, RN[1], Kumi Okano, RN[1], Yuka Fujita, RN[1], Shunichi Higashiya, MD[2], Takashi Murakami, MD[2], Satoshi Hirohata, MD[3] and Shozo Kusachi, MD[2,3]

Sakanoue H, et al. Clin Appl Thrombosis Hemostasis. 2025;31:1-9.

Thromboembolism during AF Ablation

Incidence Rate
0.15–0.50%

How to Prevent

ACT >300 seconds during ablation

Avoid pre-ablation OAC interruption

Heparin bolus before TSP

Ice monitoring for thrombus

Preprocedural thrombus exclusion

Sheath and catheter management

OAC = oral anticoagulant.

Tzeis S, et al. *Europace*. 2024;26(4):euae043.

PFA vs Thermal AF Ablation

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Pulsed Field or Conventional Thermal Ablation for Paroxysmal Atrial Fibrillation

Vivek Y. Reddy, M.D., Edward P. Gerstenfeld, M.D., Andrea Natale, M.D., William Whang, M.D., Frank A. Cuoco, M.D., Chinmay Patel, M.D., Stavros E. Mountantonakis, M.D., Douglas N. Gibson, M.D., John D. Harding, M.D., Christopher R. Ellis, M.D., Kenneth A. Ellenbogen, M.D., David B. DeLurgio, M.D., Jose Osorio, M.D., Anitha B. Achyutha, M.Tech., M.S.E., Christopher W. Schneider, M.Eng., Andrew S. Mugglin, Ph.D., Elizabeth M. Albrecht, Ph.D., Kenneth M. Stein, M.D., John W. Lehmann, M.D., M.P.H., and Moussa Mansour, M.D., for the ADVENT Investigators*

Reddy VY, et al. *N Engl J Med*. 2023;389(18):1660-1671.

PFA vs Thermal AF Ablation

HeartRhythm

The Official Journal of the Heart Rhythm Society, The Cardiac Electrophysiology Society, and The Pediatric & Congenital Electrophysiology Society

Heart Rhythm Society SM

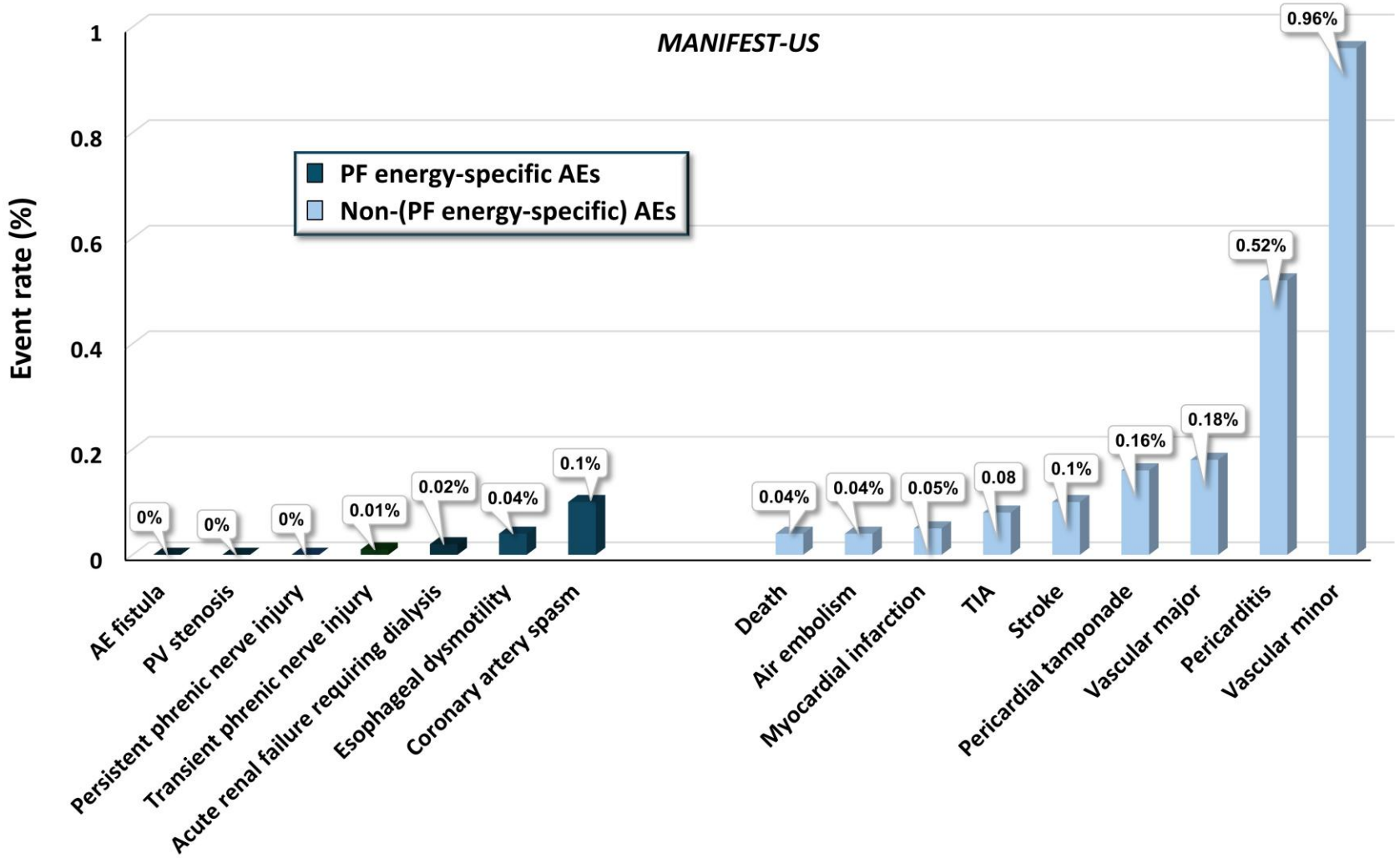
Check for updates

Comparison of cerebral safety after atrial fibrillation using pulsed field and thermal ablation: Results of the neurological assessment subgroup in the ADVENT trial

Chinmay Patel, MD,[1] Edward P. Gerstenfeld, MD, FHRS,[2] Sanjaya K. Gupta, MD, FHRS,[3] Jeffrey Winterfield, MD, FHRS,[4] Christopher Woods, MD, PhD, FHRS,[5] Andrea Natale, MD, FHRS,[6] Christopher W. Schneider, MEng,[7] Anitha B. Achyutha, MTech, MSE,[7] Scott K. Holland, PhD,[8] Elizabeth Richards, MS,[7] Elizabeth M. Albrecht, PhD,[7] John W. Lehmann, MD, MPH,[9] Moussa Mansour, MD, FHRS,[10] Vivek Y. Reddy, MD[11]

Patel C, et al. *Heart Rhythm*. 2024;21(11):2103-2109.

MANIFEST-US: 42,000 Patients



PF = pulsed field; AE = adverse event; PV = pulmonary vein; TIA = transient ischemic attack.

Turagam MK, et al. Presented at: AHA Scientific Sessions 2025; November 7-10, 2025; New Orleans, Louisiana.

AF Ablation in the Modern Era

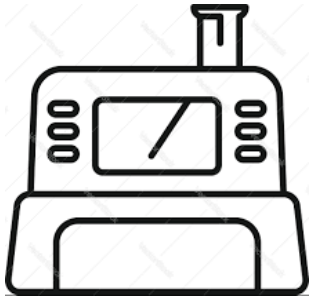
Durations (minutes)	PFA Subjects (N = 305)	Thermal Subjects (N = 302)	Difference (95% BCI)
Procedure time	105.8 ± 29.4	123.1 ± 42.1	-17.3 (-23.1, -11.5)
Left atrial dwell time	59.4 ± 18.3	83.7 ± 30.3	-24.3 (-28.3, -20.3)
Total ablation time	29.2 ± 14.3	50.0 ± 24.6	-20.8 (-24.0, -17.6)
Pre-ablation mapping time	3.8 ± 6.0	6.2 ± 5.4	-2.4 (-3.4, -1.5)
Fluoroscopy time	21.1 ± 11.0	13.9 ± 12.8	7.1 (5.2, 9.1)

Procedure Times

Same-Day Discharge

Reddy VY, et al. *N Engl J Med*. 2023;389(18):1660-1671.

Vascular Access Complications



Higher ACTs

Larger Sheaths

Protamine

Vascular Closure

Patient-Specific Factors

Post-Ablation Anticoagulation Management

- Anticoagulation is recommended for at least 2 months following catheter ablation for all patients, regardless of CHA2DS2-VASc score in prior guidelines and consensus documents
  - This is due to endothelial damage, an inflammatory state, and potential stunning of atrial myocardium following ablation and/or cardioversion
- The management of anticoagulation beyond the early postprocedural period after AF ablation remains controversial
- Prior guidelines have recommended continuing anticoagulation based on the patient's stroke risk profile rather than the presumed success or failure of the ablation

Tzeis S, et al. *Europace*. 2024;26(4):euae043.

Post-Ablation Anticoagulation Management

Low-risk patients (CHA2DS2-VASc 0 in males and 1 in females)

- Anticoagulation should be discontinued 2 months after ablation, regardless of the ablation outcome

Intermediate-risk patients (CHA2DS2-VASc 1 in males and 2 in females)

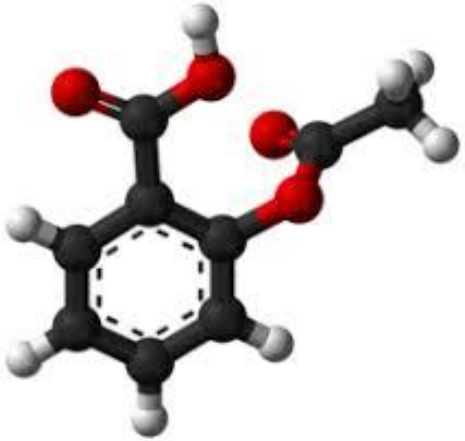
- Discontinuation of anticoagulation may be considered 12 months following catheter ablation in the absence of clinical symptoms or electrocardiographically documented AF recurrence
  - A proposed prerequisite to maximize safety after discontinuation of anticoagulation is that both patients and their physicians are committed to long-term rhythm monitoring (daily pulse or ECG monitoring, digital heart rhythm devices, or invasive monitoring) to screen for AF recurrence and guide the reinitiation of anticoagulant treatment

Higher risk patients (CHA2DS2-VASc ≥2 in males and ≥3 in females)

- Anticoagulation should not be discontinued

Tzeis S, et al. *Europace*. 2024;26(4):euae043.

Anticoagulation Discontinuation



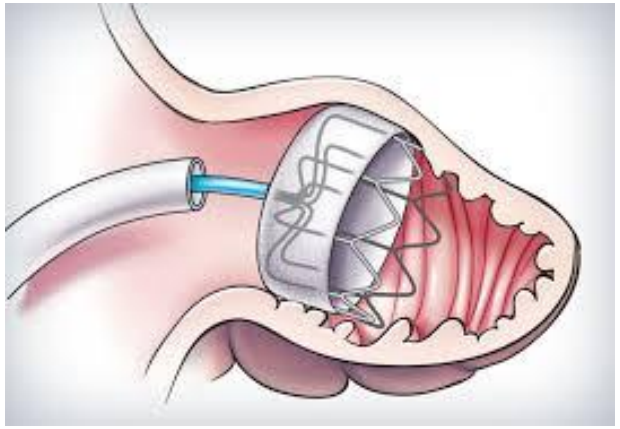
Aspirin (acetylsalicylic acid)

OCEAN

Smart Watch

REACT-AF

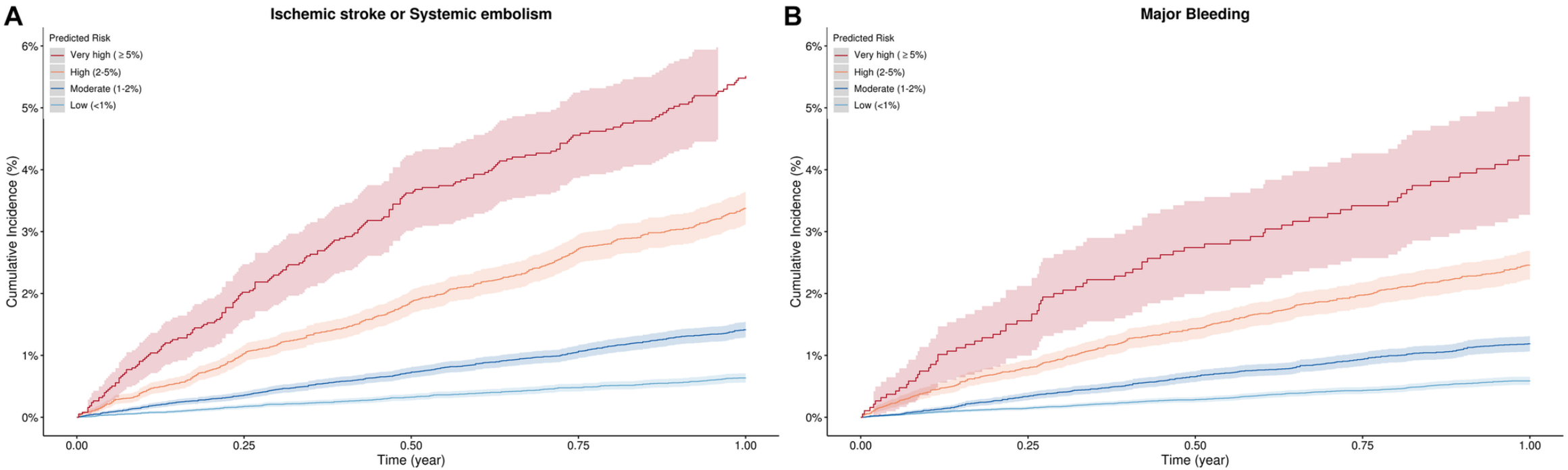
Loop Recorder



LAA Closure

OPTION

Dynamic Risk of TE and Bleeding



Dynamic prediction models incorporating time-dependent variables, such as DOAC adherence, were developed to estimate the 1-year thromboembolic and major bleeding risks over a 2-year period following DOAC initiation

TE = thromboembolism.

Heo KN, et al. *J Am Heart Assoc.* 2025;14:e043979

Thromboelastography (TEG)

- TEG evaluates the entire clotting process in real time, including
  - Clot initiation (enzymatic activity, coagulation factors)
  - Clot kinetics and amplification (fibrin formation and cross-linking)
  - Clot strength (platelet–fibrin interaction)
  - Clot stability and fibrinolysis
- Unlike ACT, TEG is a whole blood viscoelastic assay, capturing the contribution of
  - Platelets
  - Coagulation factors
  - Fibrinogen
  - Clot architecture
  - Fibrinolysis
- This makes it particularly useful in procedural settings with bleeding/thrombosis risk, such as EP procedures

Shaydakov ME, et al. Thromboelastography. StatPearls [Internet]; 2023.

Key TEG Parameters and Clinical Interpretation

Parameter	Represents	Clinical Meaning
R time (reaction time)	Time to initial fibrin formation	↑R = coagulation factor deficiency or anticoagulation (heparin, DOAC effect)
K time	Speed to achieve a certain clot strength	↑K = low fibrinogen or impaired clot kinetics
α-angle	Rate of clot formation	Low angle = impaired fibrin build-up (low fibrinogen)
MA (maximum amplitude)	Overall clot strength	↓MA = platelet dysfunction or low fibrinogen; ↑MA = hypercoagulability
LY30	Fibrinolysis 30 min after MA	↑LY30 = hyperfibrinolysis; 0% = suppressed fibrinolysis (post-TXA, trauma, etc.)

TXA = tranexamic acid.

Shaydakov ME, et al. Thromboelastography. StatPearls [Internet]; 2023.

Peri-Procedural Anticoagulation

TEG can help

- Identify residual DOAC or heparin activity when ACT is equivocal
- Understand patient-specific coagulation profiles prior to transseptal puncture
- Assess hypercoagulability in high-risk AF patients
- Evaluate bleeding risk post-ablation (especially with multiple access sites)

Shaydakov ME, et al. Thromboelastography. StatPearls [Internet]; 2023.

Conclusions

“There are known knowns; there are things we know we know.

We also know there are known unknowns; that is to say, we know there are some things we do not know.

But there are also unknown unknowns—the ones we don’t know we don’t know.”

– Donald Rumsfeld, February 12, 2002

CardioVascular Learning Network | CME

Evolving Strategies for Hemostasis and Vascular Safety in EP Procedures

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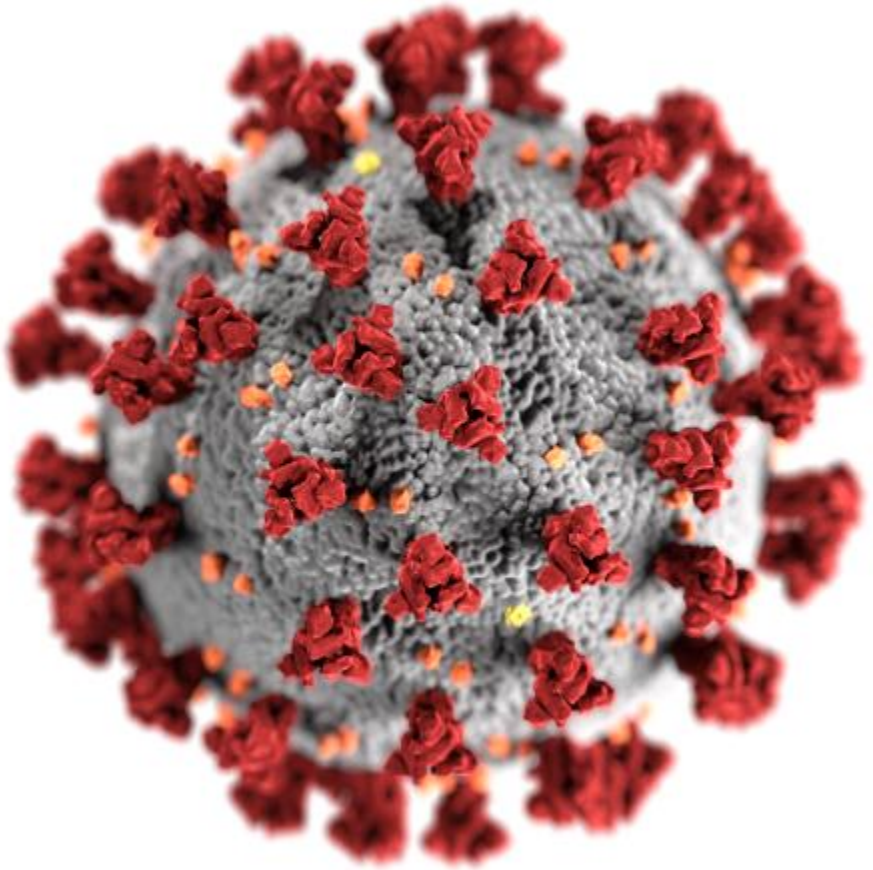
Atlanta, Georgia

Disruptor Number 1



Eckert A and Higgins D. Public Health Image Library. 2020. Accessed November 11, 2024. https://phil.cdc.gov/Details.aspx?pid=23312.

Disruptor Number 2

LIFETIME RISK for AF
1 in 3 individuals

Catheter ablation or medical therapy to delay progression of atrial fibrillation: the randomized controlled atrial fibrillation [illegible] (ATTEST)

Karl-Heinz Kuck [1]*, Dmitry S. Lebedev [2], Ev[illegible]
Alexander Romanov[3], László Gellér[4], Oskars Kal[illegible]
Karapet Davtyan [7], Young Keun On[8], Sergey P[illegible]
Michael Schlüter [11], Stephan Willems[12], and F[illegible]

Comparative risk of dementia among patient[illegible] with atrial fibrillation treated with catheter ablation versus anti-arrhythmic drugs

Emily P. Zeitler, MD, MHS[a], T. Jared Bunch, MD[b], Rahul Khanna, BPharm, MBA, PhD[c], Xiaozh[illegible]
Maximiliano Iglesias, MBA[d], and Andrea M. Russo, MD[c] *Lebanon, NH; Salt Lake City, UT; New [illegible] Irvine, CA; Camden, NJ*

2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation: A Report of the American College of Cardiology/[illegible]ee on

Society

[illegible], FAHA, FHRS;
[illegible]RS;
[illegible], MD;
[illegible], FAHA, FHRS;
[illegible]MD, FAHA;

Jonathan P. Piccini, MD, MHS, FACC, FAHA, FHRS; Andrea M. Russo, MD, FACC, FAHA, FHRS¶; Prashanthan Sanders, MBBS, PhD, FAHA, FHRS; Megan M. Streur, PhD, MN, ARNP; Kevin L. Thomas, MD, FACC, FHRS; Sabrina Times, DHSC, MPH#; James E. Tisdale, PharmD, FACC, FAHA, FCCP; Anne Marie Valente, MD, FACC, FAHA**; David R. Van Wagoner, PhD, FAHA, FHRS

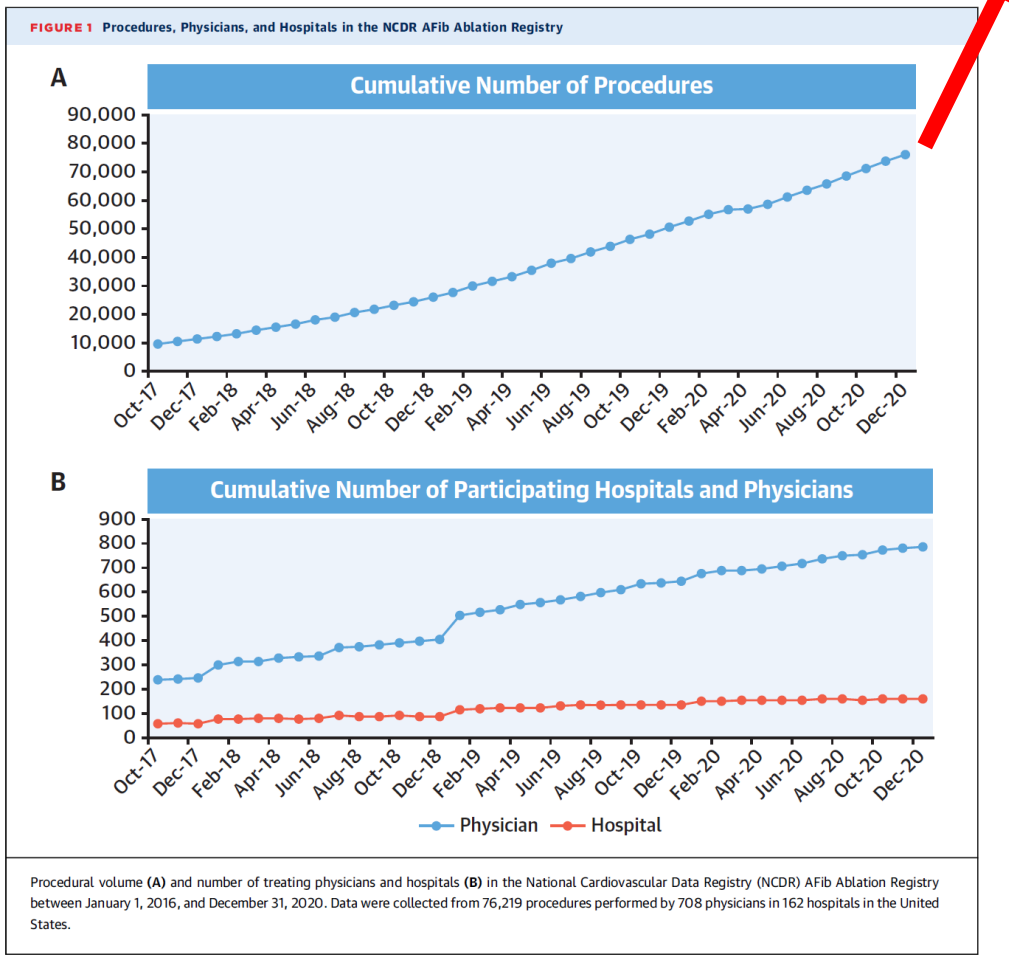
Left Atrial Appendage Closure after Ablation for Atrial Fibrillation

O.M. Wazni,[1] W.I. Saliba,[1] D.G. Nair,[2] E. Marijon,[3] B. Schmidt,[4] T. Hounshell,[5] H. Ebelt,[6] C. Skurk,[7] S. Oza,[8] C. Patel,[9] A. Kanagasundram,[10] A. Sadhu,[11] S. Sundaram,[12] J. Osorio,[13] G. Mark,[14] M. Gupta,[15] D.B. DeLurgio,[16] J. Olson,[17] J.E. Nielsen-Kudsk,[18] L.V.A. Boersma,[19,20] J.S. Healey,[21] K.P. Phillips,[22] F.M. Asch,[23] K. Wolski,[1] K. Roy,[24] T. Christen,[24] B.S. Sutton,[24] K.M. Stein,[24] and V.Y. Reddy,[25] for the OPTION Trial Investigators*

Effect of Catheter Ablation vs Antiarrhythmic Drug Therapy on Mortality, Stroke, Bleeding, and Cardiac Arrest Among Patients With Atrial Fibrillation
The CABANA Randomized Clinical Trial

Kuck KH, et al. *Europace.* 2021;23(3):362-369. Zeitler EP, et al. *Am Heart J.* 2022;254:194-202. Joglar JA, et al. *Circulation.* 2024;149(1):e1-e156. NIH. Accessed November 12, 2024. https://clinicaltrials.gov/study/NCT00578617. Wazni OM, et al. *N Engl J Med.* 2025;392(13):1277-1287.

Overview of Challenge: Performing Increasing Numbers of AF Ablations



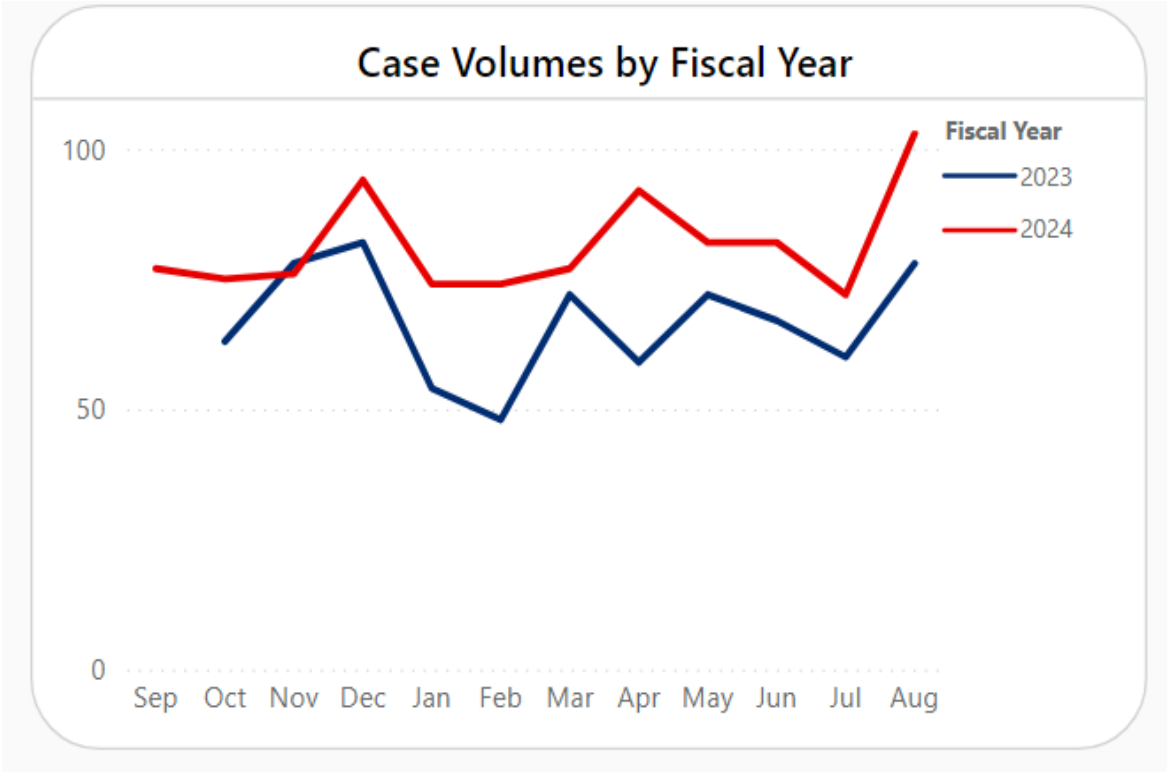
ACC National Cardiovascular Data AFIB Ablation Registry (NCDR): 2016–2020

Since 2020 we have seen revised guidelines, introduction of PFA, and introduction of concomitant ablation and LAAC

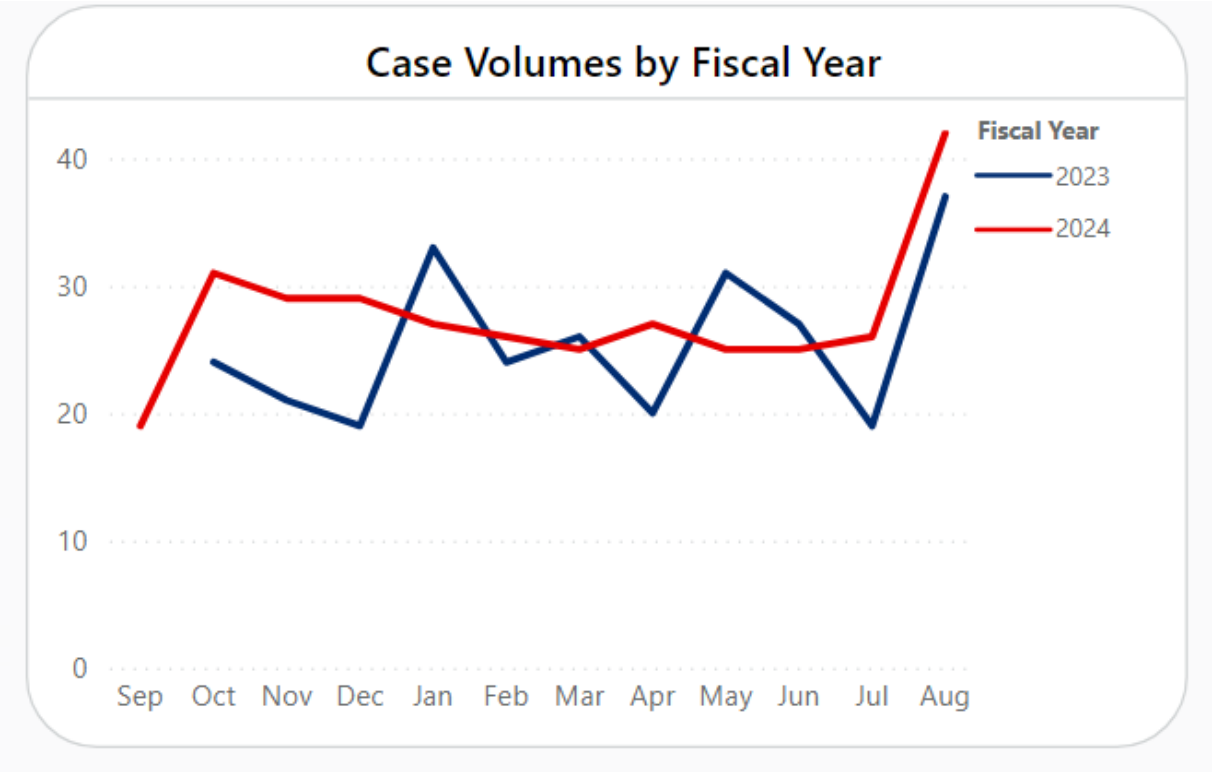
Hsu JC, et al. *J Am Coll Cardiol.* 2023;81(9):867-878.

AFIB vs LAAC Case Volumes: Emory St. Joseph's Hospital

AFIB Ablation Volume



LAAC Volume



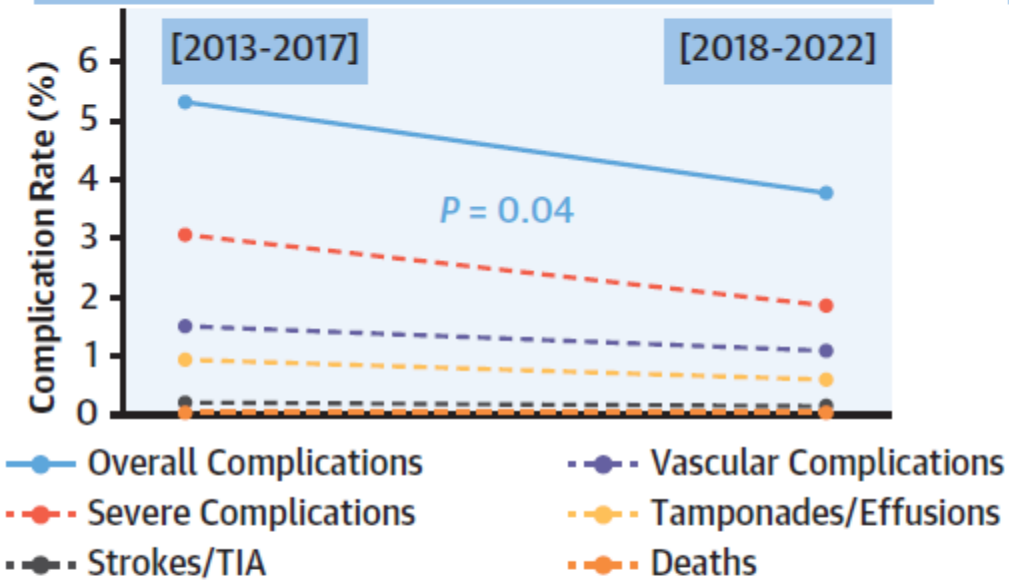
LAAC = left atrial appendage closure.

Proce
Cathe

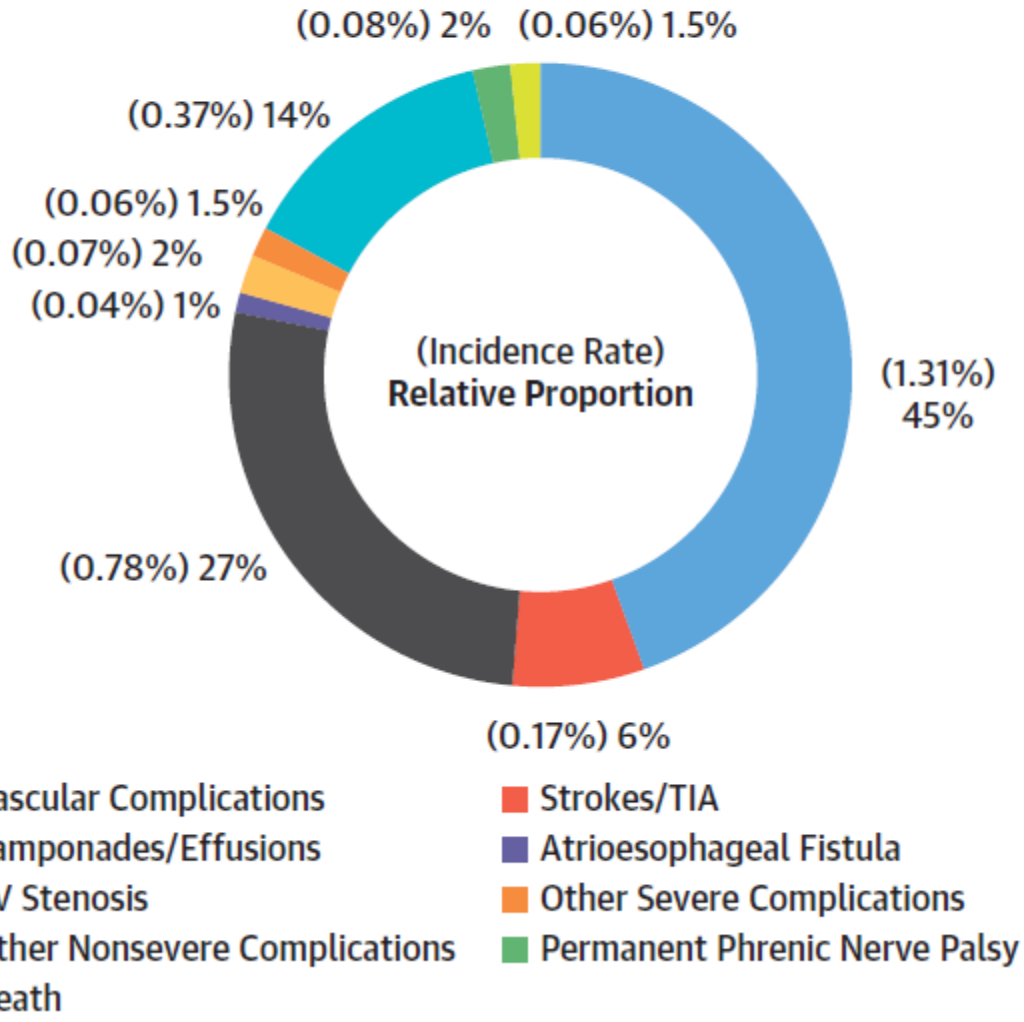
Karim Benali, M
Antoine Da Cos

89 RCTs Published Between 2013 and 2022, 15,701 Patients Undergoing a First CA Procedure for AF

Temporal Trend in Complications



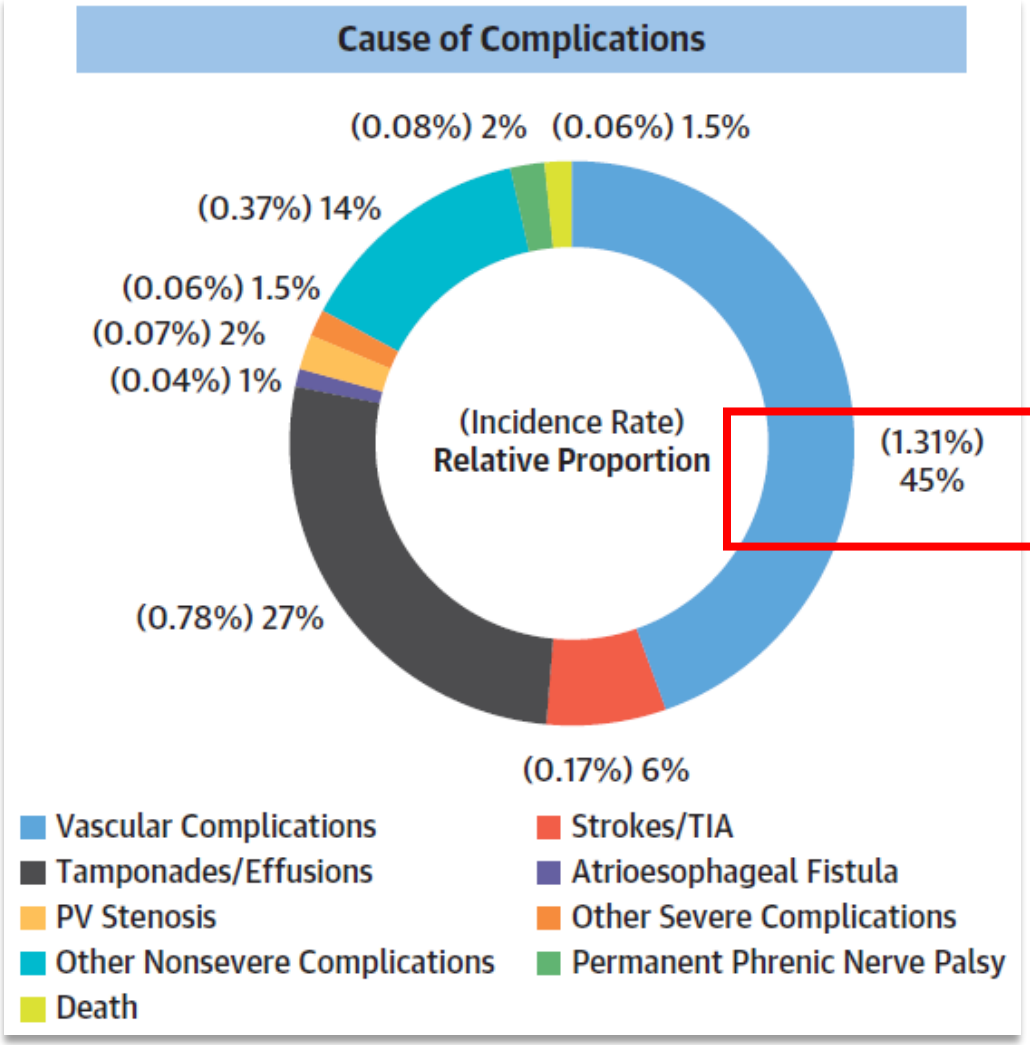
Cause of Complications

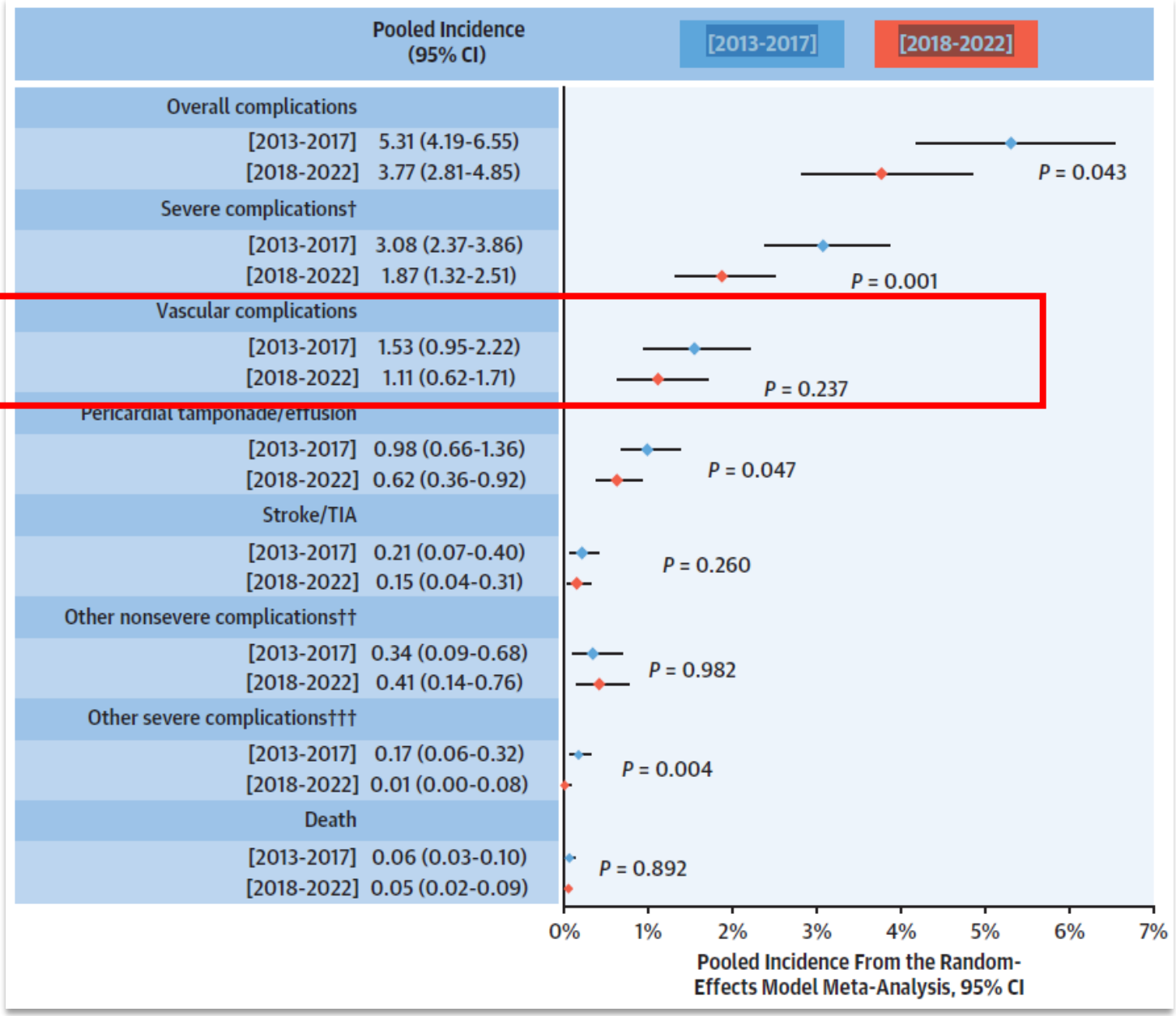


Procedure-Related Complications [2018-2022]

3.8%	1.9%	0.05%
Overall complications	Serious complications	Mortality

Belai K, et al. *J Am Coll Cardiol*. 2023;81(21):2089-2099.





Belai K, et al. *J Am Coll Cardiol*. 2023;81(21):2089-2099.

Overview of Challenge: Major Drivers of Healthcare System Costs for AF Ablation

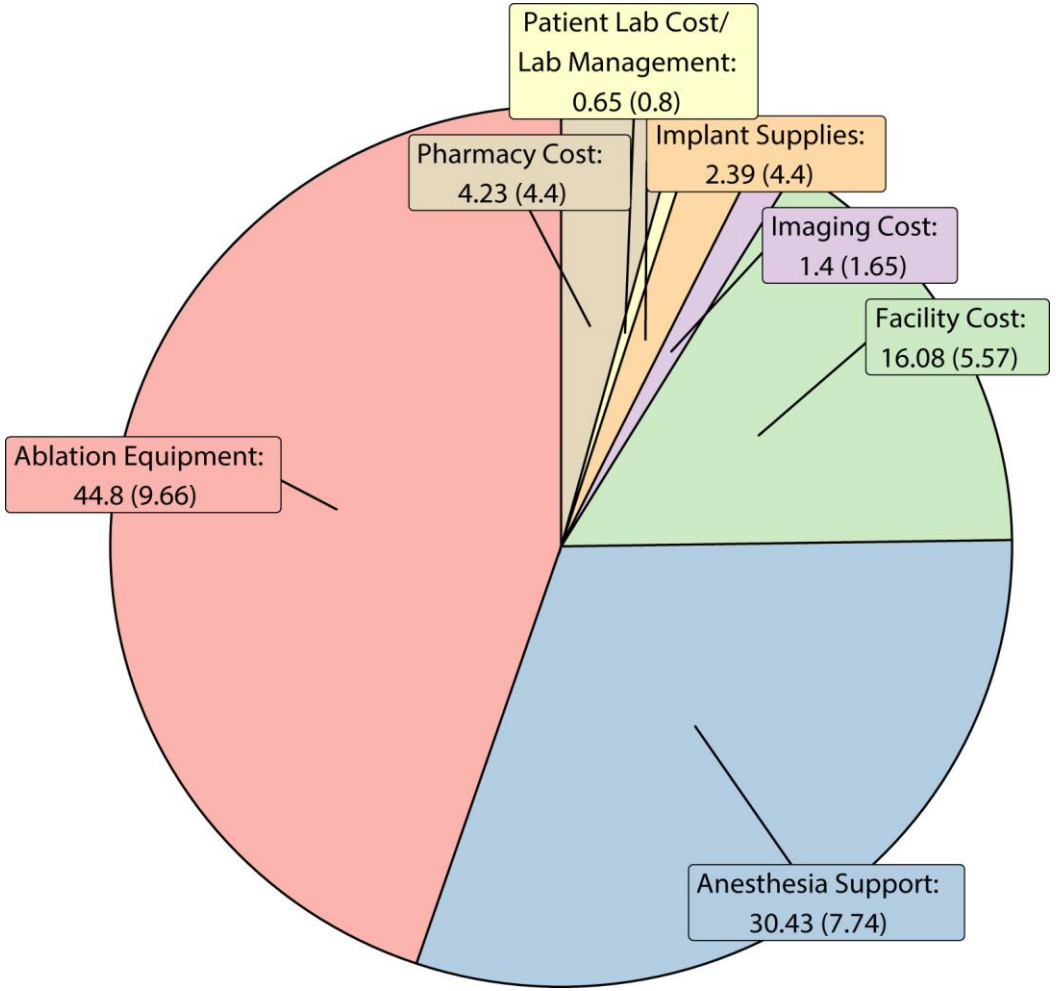


Table 1 Baseline patient characteristics of patients included in this study (N = 910)

Age, y	
Mean ± SD	65.2 ± 11.33
Median (IQR)	67 (58.25, 73.00)
Range	24–92
Female	302 (33%)
White	860 (95%)
BMI, kg/m^2	30.8 ± 6.7
Hypertension	469 (52%)
Diabetes mellitus	202 (22%)
Myocardial infarction	222 (24%)
Congestive heart failure	299 (33%)
Chronic kidney disease	108 (12%)
Peripheral vascular disease	278 (31%)
Pulmonary disease	278 (21%)
History of stroke	91 (10%)
CHA_2DS_2-VASc score	
Mean ± SD	2.83 ± 1.94
Median (IQR)	3 (1, 4)
Range	0–9
Prior cardioversion	349 (38%)
Prior ablation	204 (22%)
Anticoagulation	859 (94%)
Beta-blocker	587 (65%)
Calcium-channel blocker	266 (29%)
Antiarrhythmic drugs	638 (70%)
Left ventricular ejection fraction, %	
Mean ± SD	56.55 ± 11.32
Median (IQR)	60 (52.5, 63)
Range	15–80

Values are n (%) or mean ± SD, unless otherwise indicated.

Where are the cost savings opportunities?

SD = standard deviation; IQR = interquartile range; BMI = body-mass index.

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

Overview of Challenge: Nursing and Staffing Shortages

Importance of Addressing Staff Efficiencies in EP


LETTER FROM THE EDITOR

Hospital Staffing Shortages Will Hold Back Growth in Cardiac Electrophysiology Procedures in 2023

Bradley P Knight, MD, FACC, FHRS, Editor-in-Chief, EP Lab Digest

January 2023
EP Lab Digest. 2023;23(1):6.

- Approximately 18% of healthcare workers have quit since the COVID-19 pandemic
- Hospitals rely on contract travel nurses with salaries that are typically 3x higher
- Hospital administrators are unable/unwilling to pay for added staffing—even for EP programs with potential for revenue growth
- ***"The volume of hospital-based rhythm procedures, such as AF ablation and LAAC procedures, will not be able to grow unless hospital and electrophysiology lab staffing shortages improve."***


BECKER'S HOSPITAL REVIEW

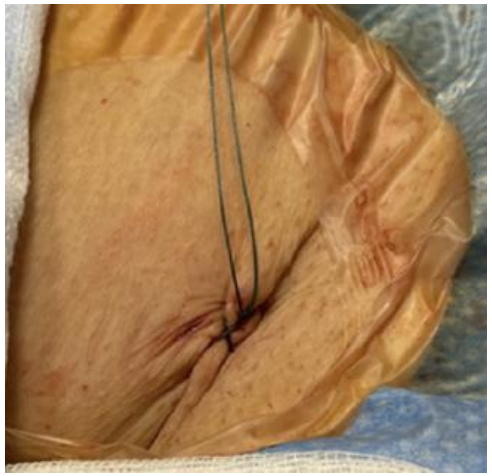
Leadership & Management

The No. 1 problem keeping hospital CEOs up at night

- Workforce challenges are ranked the highest for concern among healthcare executives

Knight BP. *EP Lab Dig*. 2023;23(1):6. Becker's Hospital Review 2024. Accessed February 14, 2025. https://www.beckershospitalreview.com/hospital-management-administration/the-no-1-problem-still-keeping-hospital-ceos-up-at-night.html.

VCDs Have Gained Traction, and Several Options Are Available



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

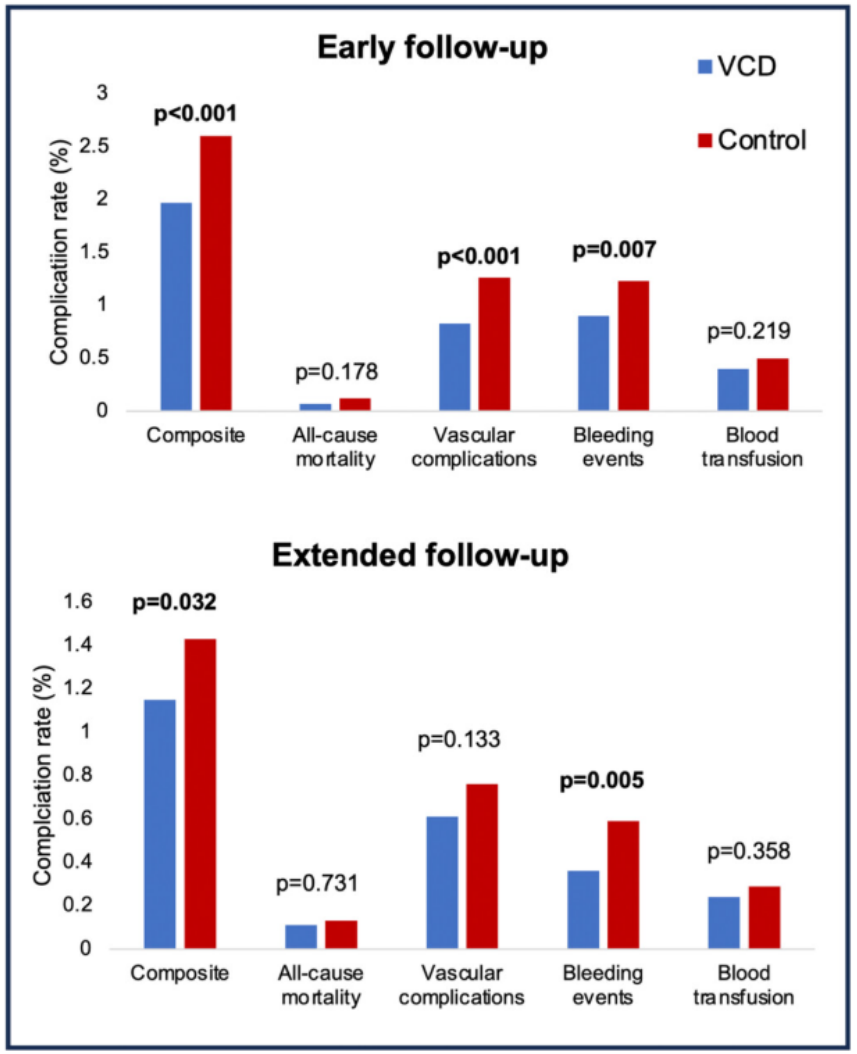
VCD = vascular closure device.

Use of VCDs for Femoral Hemostasis in AF Ablation Demonstrate Reduced Complications

- 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
- VCD group includes the following VCDs

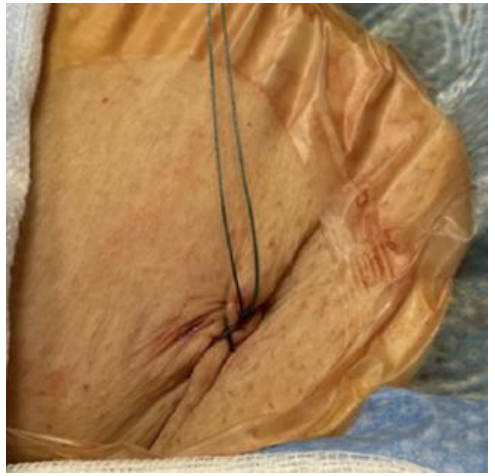
Perclose ProGlide™ (Abbott)	VASCADE® (Cardiva)	MYNX CONTROL™ (AccessClosure)
		

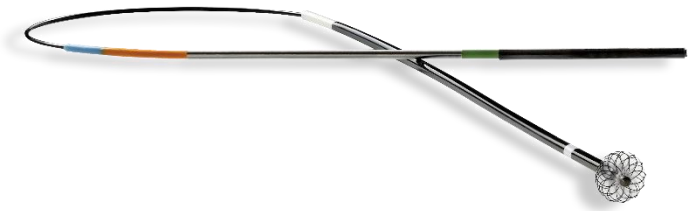
- Control group includes patients receiving manual compression and suture-mediated hemostasis with or without three-way stopcock
- 28,872 patients were included (14,436 in each cohort)



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

Why Have We Used Different Approaches to Vascular Closure?





<u>Manual compression (MC)</u>
Historical gold standard
Long time lying flat
Nursing sources to hold pressure

<u>Figure of eight suture (FO8)</u>
Low supply cost
Achieves hemostasis
Reduces TTA compared to MC

<u>VASCADE MVP® System</u>
Simple, easy to use
Improved patient satisfaction*
Reduced opioids*
Reduced pain meds*

***Compared to manual compression.**
TTA = time to ambulation.

Tilz RR, et al. *EP Europace*. 2024;26(5):euae105. Mohammed M, et al. *J Interv Card Electrophysiol*. 2022;64(2):301-310. Lakshmanadoss U, et al. *Indian Pacing and Electrophysiol J.* 2017;17(5):134-139. Natale A, et al. . *JACC Clin Electrophysiol* 2020;6(1):111-124.

Advantages to using a Venous Vascular Closure System

- Excellent operational success rate
- Low rate of vascular and puncture site complications
- Reduced patient time to ambulation
- Increase patient comfort and satisfaction
- In addition, ultrasound-guided manoeuvres contribute to improving safety when using vascular closure devices

Ease of use

- Single operator
- No sutures, no materials left in the vessel

Two mechanisms of action

- Mechanical
- Physiological

Resorbable and thrombogenic collagen plug

- Expands to fill tissue tract

Extravascular Design

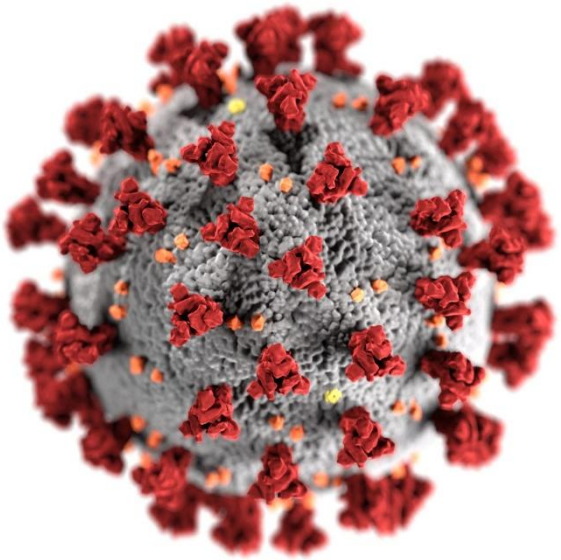
- No permanent or intraluminal implants
- Simple deployment
- Multiple access site closure
- Allows for re-access*, for repeat ablation procedures
- Workflow enhancements and quicker time to ambulation compared to manual compression

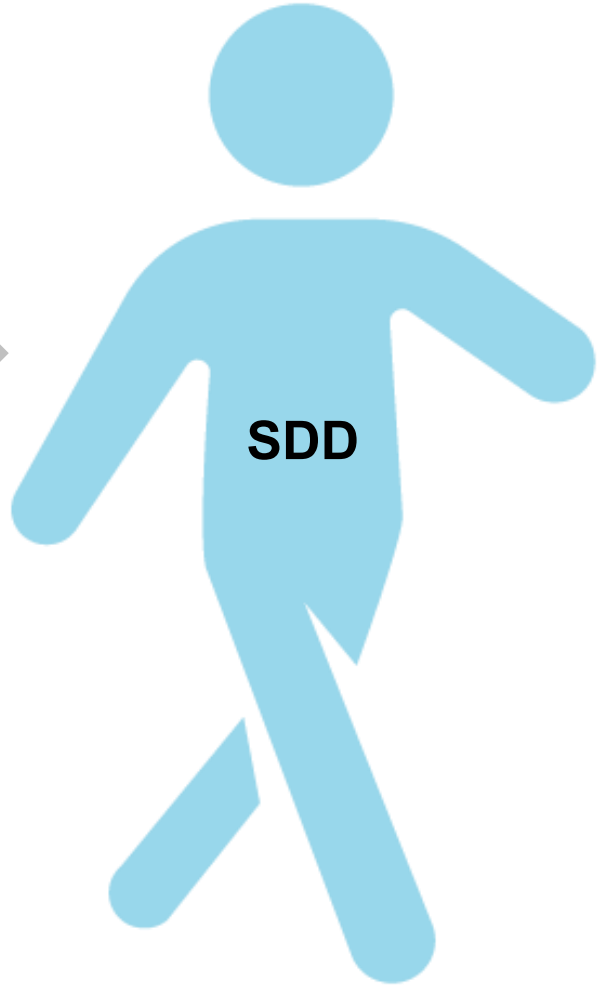
***After 30 days.**

Ding W, et al. *Med Sci Monit.* 2024;30:e944884.

Why We Adopted Venous Vascular Closure Systems at Emory St. Joseph's Hospital

- Interest in new VCDs
- AMBULATE Trial Investigator
- Managing hospital administration pushback





SDD = same day discharge.

Why We Adopted Venous Vascular Closure Systems at Emory St. Joseph's Hospital

A New Approach Post-COVID

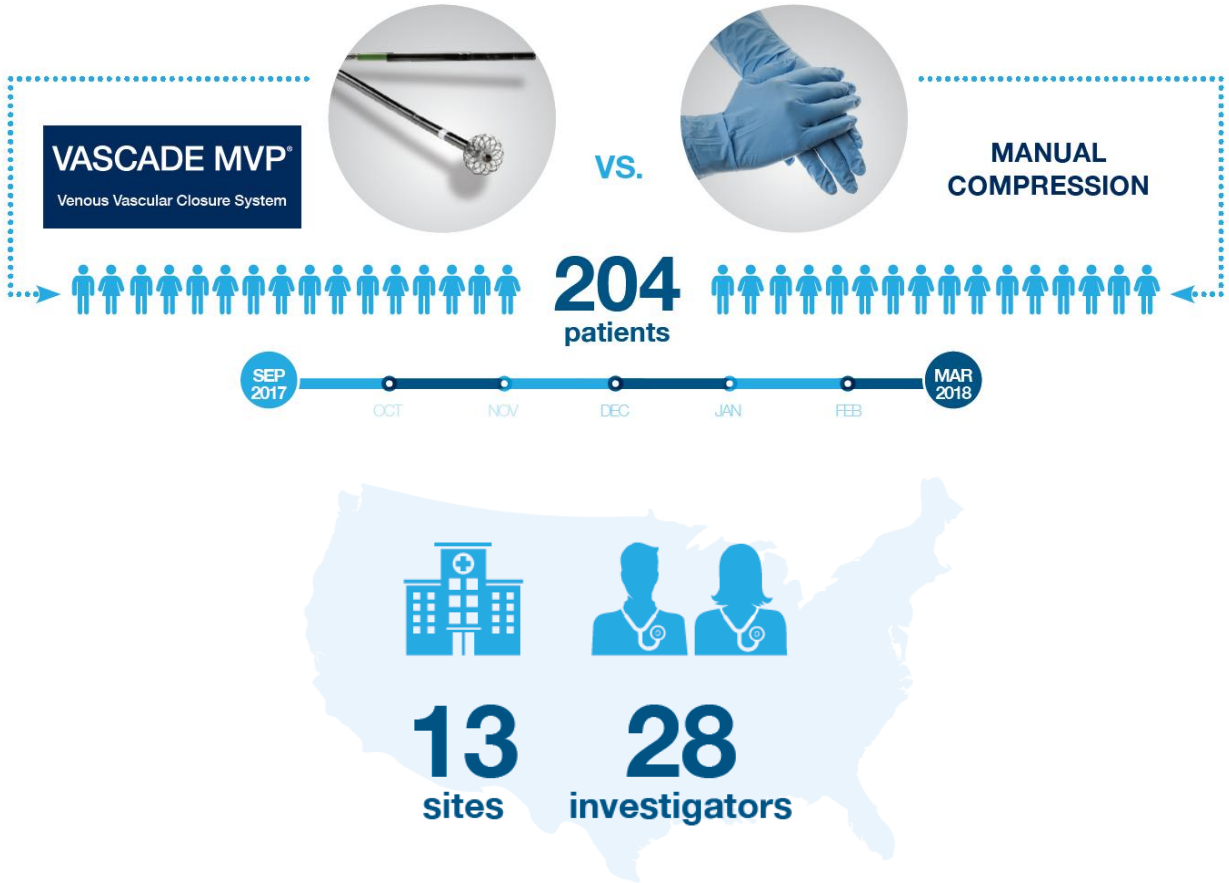
Workflow	Before	Using Venous Vascular Closure Device n=700 AF patients
Pull Sheaths	Recovery	EP Lab
Closure Methods	Manual Compression	Venous Vascular Closure Device
Time to Ambulation	4 hours	2 hours
SDD for AF Patients	0%	95%

Our Paradigm Flipped → Same Day Discharge for all AF ablation patients except for travel issues or a specific medical reason

AMBULATE Pivotal Trial

Prospective, Multicenter, Randomized 1:1 Clinical Trial

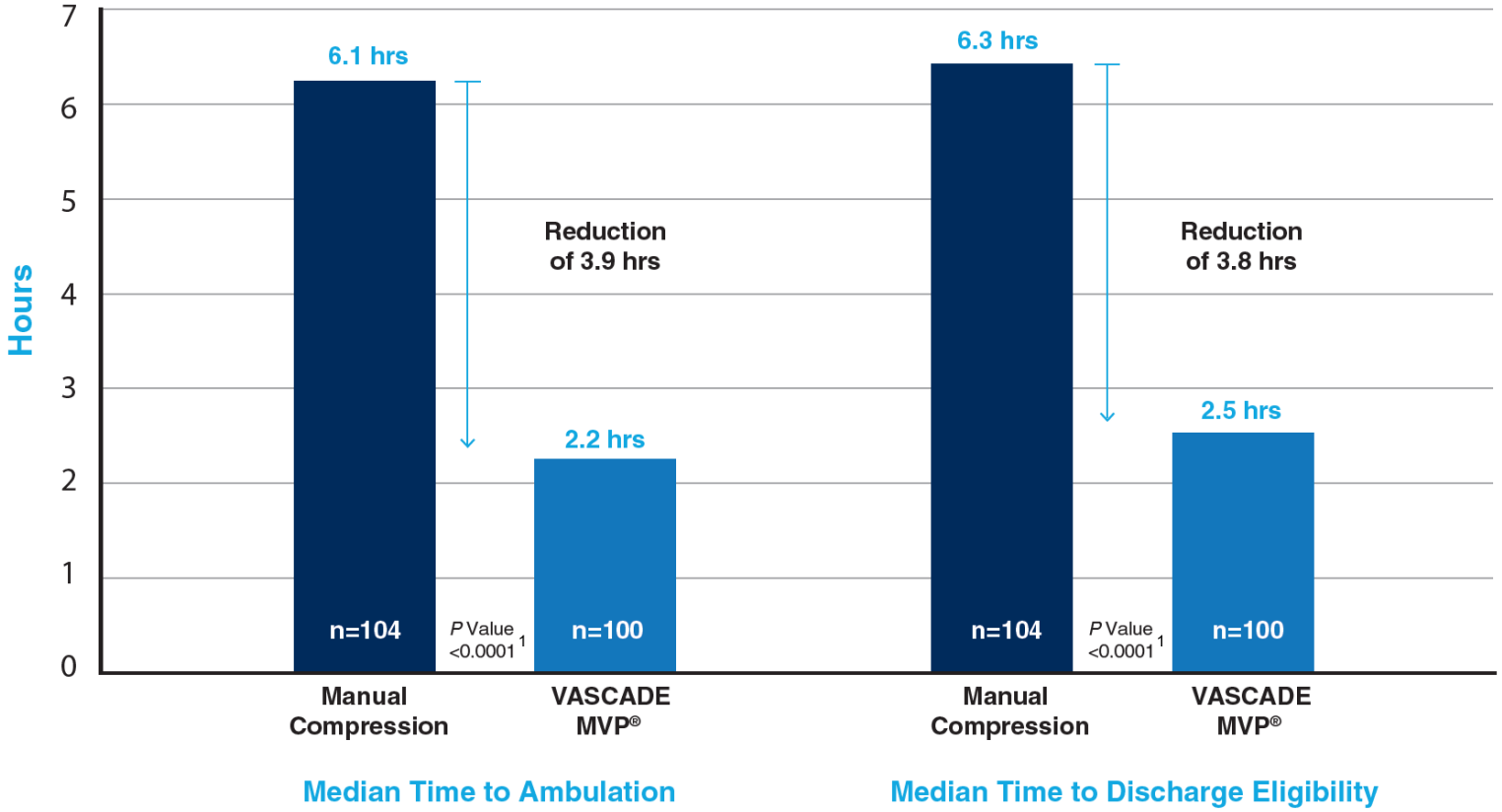
- **Randomized clinical trial:** 204 patients, 13 sites, 28 physicians, randomized 1:1 against manual compression
- **Primary endpoints:** Time to ambulation, major access site complications
- **Secondary endpoints:** Time to hemostasis, total post-procedure time, time to discharge eligibility, time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



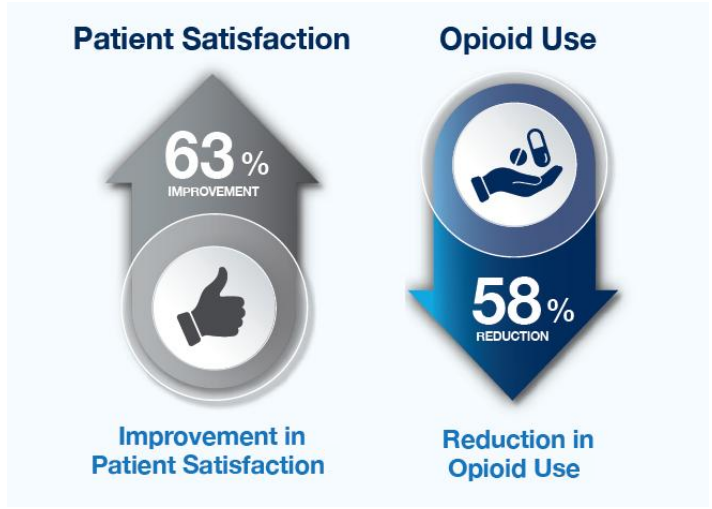
Natale A, et al. *JACC Clin Electrophysiol.* 2020;6(1):111-124.

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[3]	0%	0%	–
Minor complications[3]	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 two-sided Fisher's exact test; [3]Venous access site closure-related complications per limb through follow-up period; *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

Portfolio of Studies

AMBULATE
Pivotal Trial

- Randomized clinical trial: 204 subjects, 13 sites, 28 enrolling physicians
- Pivotal for FDA approval
- JACC EP: Natale et al, Oct 2019

AMBULATE CAP
Continued Access Protocol

- Single arm venous closure in EP cases; 3 sites,168 patients
- Endpoints: same calendar day discharge, Foley use, protamine usage, complications
- JCE: Al-Ahmad et al, Jan 2021

AMBULATE
Same Day Discharge Clinical Studies

- Retrospective SDD
- Prospective SDD 1
- Prospective SDD 2
- JCE: Eldadah et al, Nov 2022

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(2):348-355. NIH. Accessed November 12, 2024. https://clinicaltrials.gov/study/NCT03193021; NCT03573206; NCT04538781; NCT04203329.

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
354	Patients
45	Investigators
14	US Centers

91.2%
Discharged the Same day (SDD)

99.7%
SDD Success with no access site complications *

0%
ZERO (0) major complications **

***Did not require intervention for access site complications the next day through 15-day follow-up. **Major venous access site closure-related complications through 15-day follow-up.**
PAF = paroxysmal atrial fibrillation; PsAF = persistent atrial fibrillation.
Eldadah ZA, et al. *J Cardiovasc Electrophysiol*. 2023;34(2):348-355. NIH. Accessed December 1, 2025. https://clinicaltrials.gov/study/NCT04538781.

5 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. NIH. Accessed December 1, 2025. https://clinicaltrials.gov/study/NCT04538781. Eldadah ZA, et al. *J Cardiovasc Electrophysiol*. 2023;34(2):348-355.

Clinical Evaluation of Large Bore Collagen Plug VCD at Emory and Nationally

- 58% more collagen
- Larger disc

Dry, uncompressed collagen comparisons

VASCADE MVP® XL System

Features	VASCADE MVP® System	VASCADE MVP® XL System	Increase
Collagen	12mg ± 3 mg	19mg ± 3 mg	58%
Disc Size	23F	25F	9%
Sheath Size Compatibility	6-12F ID (15F OD)	10-12F ID (15F OD)	None

Vascular access site closure with the new vascular closure device (VASCADE-XL) versus the earlier VASCADE-MVP in patients undergoing electrophysiology procedures: A single-center experience on efficacy and complications

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Texas Cardiac Arrhythmia Institute
St David's Medical Center

Background

- Vascular closure devices, used for the percutaneous closure of the femoral venous access sites following electrophysiology (EP) procedures, are known to require shorter time to hemostasis compared to manual compression.
- The new **VASCADE-MVP XL** (Haemonetics Corp., USA) was designed for procedures utilizing large procedural sheaths, with a resorbable patch with 58% higher collagen content than the earlier VASCADE-MVP system, for better efficacy (FIGURE 1).

Objective

We aimed to **compare the safety and efficacy of VASCADE MVP-XL and VASCADE MVP** in consecutive patients with atrial fibrillation (AF) undergoing procedures utilizing large sheaths (i.e. Farapulse pulsed-field ablation and left atrial appendage closure procedure)

Methods

- Based on the device used to achieve access-site hemostasis, AF patients undergoing EP procedures were classified into,
  - Group 1: MVP-XL (n=151)
  - Group 2: MVP (n=423)
- The closure device was deployed under fluoroscopic guidance and included 2-4 minutes of gentle compression followed by approximately 2 hours of bedrest
- All procedures were performed under uninterrupted anticoagulation
- The access-sites were examined immediately after the procedure, after the 2-hour bed-rest and before discharge

Results

TABLE 1A:	MVP XL: July 2024-OCT. 2024	Vascade MVP: Sept 2021- June 2024	P-value
	N = 151	N = 423	
Baseline Demographics and Clinical Characteristics			
Age, yrs	67.88 ± 10.34	67.12 ± 10.21	0.434
Body mass index, kg/m2	26.90 ± 2.31	27.14 ± 2.42	0.29
Male	100 (66.2%)	287 (67.8%)	0.715
Hypercholesterolemia	59 (39.1%)	132 (31.2%)	0.078
Hypertension	47 (31.1%)	159 (37.5%)	0.155
Diabetes mellitus	23 (15.2%)	57 (15.2%)	0.593
TIA/Stroke	6 (4.0%)	15 (3.5%)	0.81
COPD	18 (11.9%)	44 (10.4%)	0.606
CAD	36 (23.8%)	72 (17.0%)	0.066
DVT	8 (5.3%)	12 (2.8%)	0.157
Procedure type			
AF	81 (53.6%)	263 (62.2%)	0.066
AF+AFL	5 (3.3%)	28 (6.6%)	0.134
Watchman	65 (43.0%)	132 (31.2%)	0.009
TABLE 1B:			
Procedural Parameters			
	MVP XL (n=151)	Vascade MVP (n=423)	
Final sheath pull (time between administration of protamine to short sheath insertion) (Min)	10.78 ± 7.56	12.01 ± 06.98	0.069
Time to Hemostasis (time between device insertion and hemostasis) (Min)	5.01 ± 3.89	6.33 ± 3.19	**<0.001**
Time to ambulation (time between end of Anesthesia and ambulation) (Min)	123.01 ± 20.88	121.98 ± 37.01	0.746
Urinary catheter use	0 (0)	0 (0)	1
Time to Discharge (hrs)	24.02 ± 8.45	24.23 ± 10.67	0.827
Complications (access site bleeding)	0 (0)	13(3.1)	**0.029**
Sheath used (13 Fr)	86 (57.0%)	105 (24.8%)	<0.001
Sheath used (12Fr)	65 (43.0%)	132 (31.2%)	<0.001
Sheath used (8Fr)	0 (0)	186 (44.0%)	<0.001

Results

Figure 1:

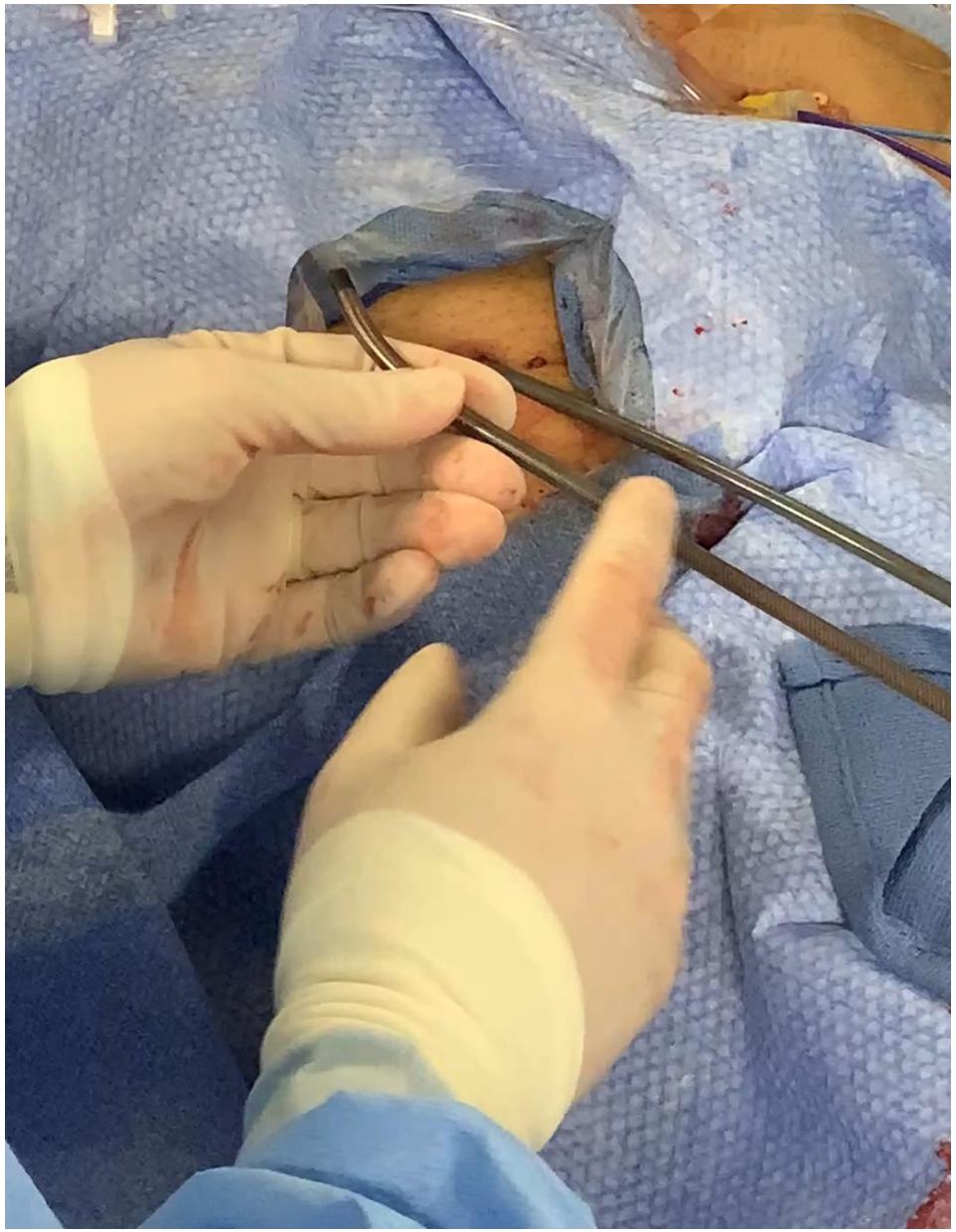
- Proper positioning and accurate deployment of the collagen patch was achieved under fluoroscopic guidance in all patients
- Baseline characteristics were comparable across groups except the procedure type (Watchman) and rivaroxaban use (Table 1 A)
- Time to final sheath pull, time to ambulation and time to discharge were similar between the groups (Table 1B).
- **Time to hemostasis was significantly shorter in the MVP-XL group** (Table 1B).
- **Access-site bleeding was observed in 13 (3.1%) of MVP group vs none (0%) in the MVP-XL population (p=0.029).**

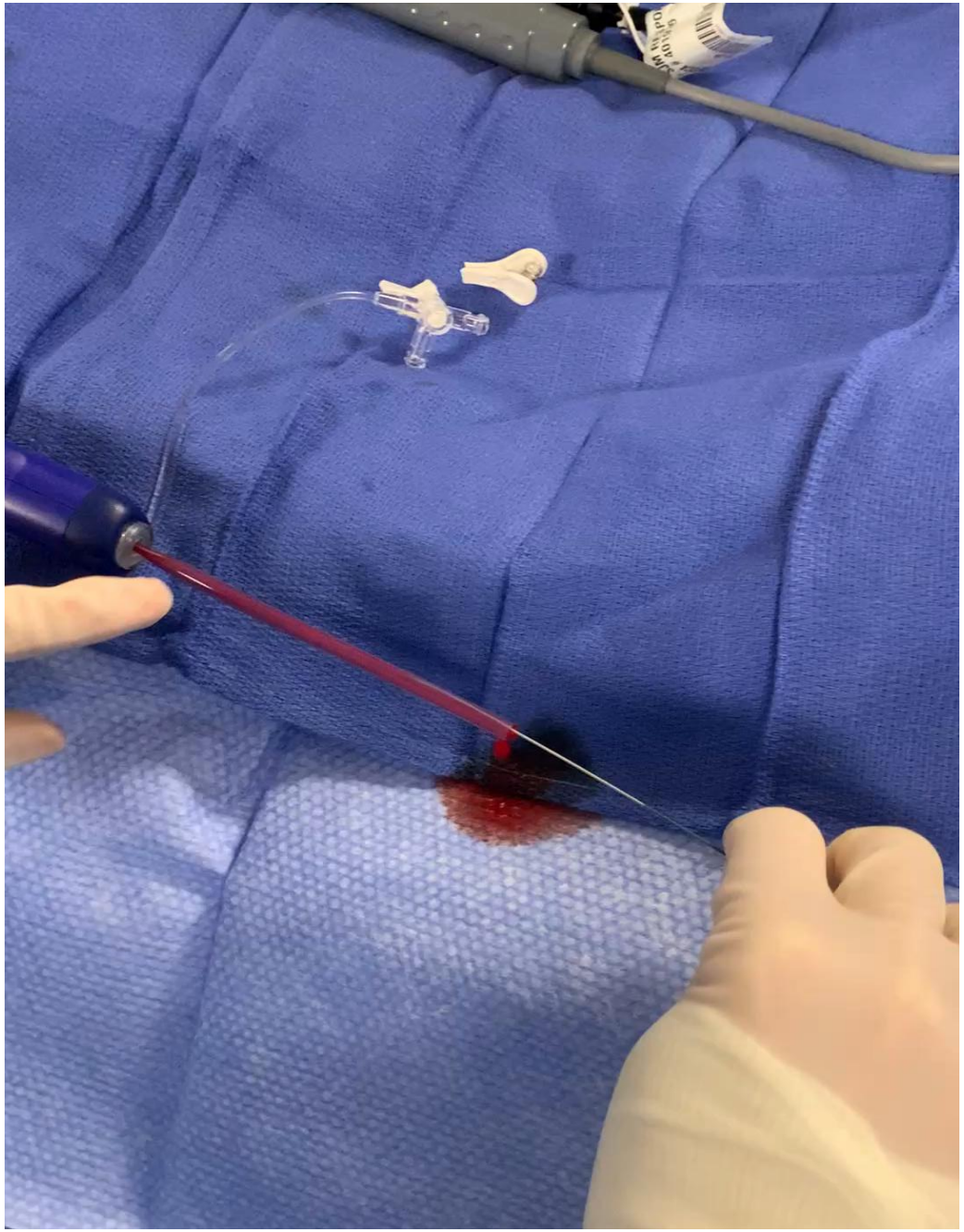
Conclusion

VASCADE-MVP XL has a better safety and efficacy profile compared to the VASCADE-MVP system, especially in procedures involving large sheaths

Disclosure

A.Natale: Consultant for Abbott, Biosense Webster, Biotronik, Boston Scientific , iRhythm and Medtronic





VASCADE MVP® XL EXPAND Clinical Study Overview

	The AMBULATE EXPAND Trial (VASCADE MVP XL Indication Expansion)
Study Design	Multi-center, Prospective, Single Arm, IDE trial
Primary Endpoints	• Safety: Major Access Site Closure-Related Complications • Effectiveness: Time to Ambulation (TTA)
Follow-Up	30 ± 7 days
Estimated Enrollment	102 =70 evaluable + 7 attrition + ~25 roll-ins Evaluable includes 25 subject ultrasound sub-study
Sites	8 sites (max 25% of subjects per site); U.S. only
Access Sites	Bilateral Access • Investigational (1 access site): 16-17F OD (current approved indication is up to 15F OD) • Non-Investigational (0-3 access sites): ≤15F OD, closed with commercial VASCADE device
Procedure Focus	EP • FARADRIVE Steerable Sheath • WATCHMAN TruSteer Access System • FlexCath Contour Steerable Sheath • POLARSHEATH Steerable Sheath • Amulet 14F Delivery Sheath
Timeline	• FPI anticipated CY2025Q1, enrollment anticipated <6 months • US Commercial Launch post-PMA approval, anticipated mid to late CY2026

NIH. Accessed December 1, 2025. https://clinicaltrials.gov/study/NCT06615154.

Summary

- Disruptors in AF management have required adaptation
  - Changing guidelines – early AF ablation, ablation in CHF
  - Limited hospital resources
  - Need for efficiencies
  - Pulsed field ablation
  - LAAC – standalone and concomitant
- Safe and effective large-bore vascular site closure has been a critical part of our response

CHF = congestive heart failure.

Q&A