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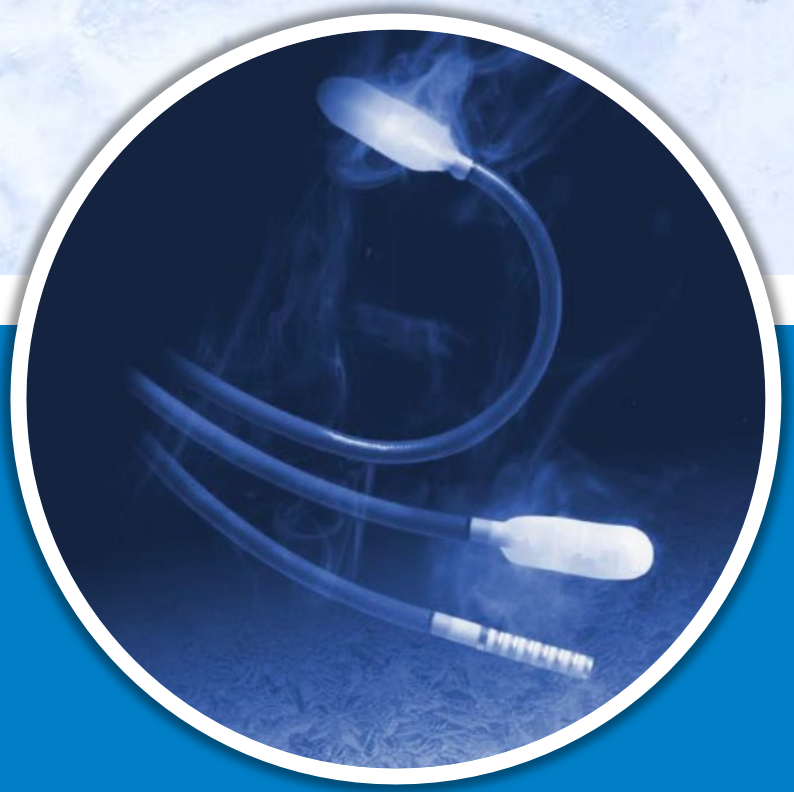

FULCRUM-VT Investor Event

Dr. Atul Verma • Dr. William Stevenson • Dr. Matthew Hakimi

April 27, 2026

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- CONFIDENTIAL -

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Heart Rhythm
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April 23-26, 2026 • Chicago, IL

EFFECTIVENESS AND SAFETY OF ULTRA-LOW TEMPERATURE ABLATION OF VENTRICULAR TACHYCARDIA IN PATIENTS WITH STRUCTURAL HEART DISEASE: OUTCOMES OF THE PIVOTAL **FULCRUM-VT** TRIAL

Atul Verma, MD, McGill University Health Centre
on behalf of FULCRUM-VT investigators

THANK YOU TO ALL CO-INVESTIGATORS!

April 26, 2026

Heart Rhythm Society℠

DISCLOSURES

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Dr. Atul Verma

Research Grants

Bayer, Biotronik, Biosense Webster, Medtronic, Abbott, Cardiofocus

Advisory Board

Cardiofocus, Adagio Medical, Lilly, Biosense Webster, Kardium, Medtronic, Medlumics, Abbott, Volta Medical

Clinical trials

Biosense Webster, Adagio Medical, Cardiofocus, Medtronic, Abbott

Dr. William Stevenson

Honoria

Abbott, Biotronik, Boston Scientific, Johnson & Johnson, Medtronic

Research Support

Adagio Medical, Varian, Medtronic, Thermedical

MOTIVATION

- RF lesions – insufficient depth for effective endocardial-only ablations in the ventricle
- Safe application of PFA to achieve deeper lesions in the ventricle is an open question
- Lack of universal approach (and approved devices) for ablations in both the ICM and NICM patients

RF=Radiofrequency; PFA=Pulsed Field Ablation; ICM=Ischemic Cardiomyopathy; NICM=Non Ischemic Cardiomyopathy

ULTA SYSTEM DESIGN

PURPOSE-BUILT FOR ENDOCARDIAL VENTRICULAR ABLATIONS

- Console + 9 Fr bi-deflectable catheter
- 15 mm long ablation element, -120 C
- 8 electrodes for EGM, EAM, pacing
- No irrigation

ABLATION PROTOCOL

(freeze – thaw - freeze cycle)

Freeze Duration (sec)	Lesion Depth Range (mm)[1]
30	< 4
60	4-6
120	7-9
180	≥ 10

[1] Adagio Medical, Inc. MKT-086 Rev B. Data on file

Fr=French; EGM=Electrocardiogram; EAM=Electroanatomical Mapping

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ULTRA-LOW TEMPERATURE ABLATION

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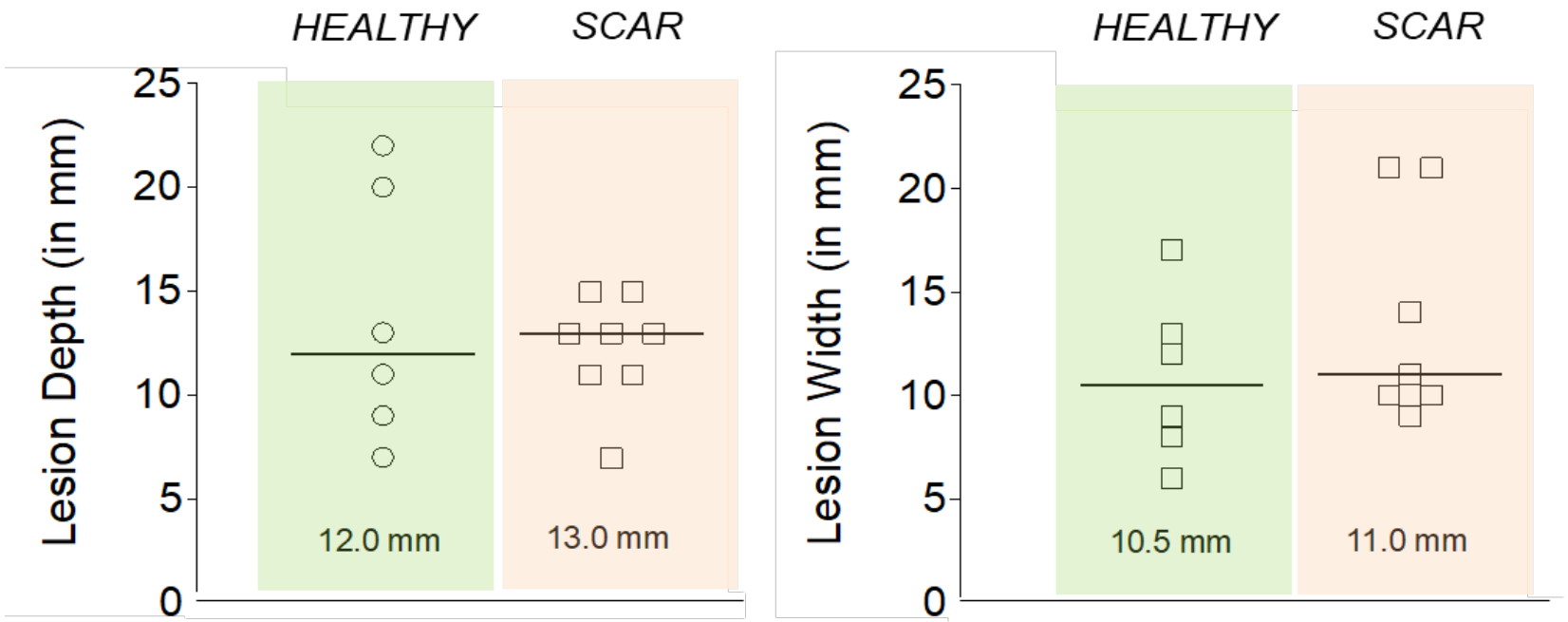
Ablative power to produce large footprint, depth-controlled endocardial lesions ≥10 mm, unaffected by the presence of the scar

PRE-CLINICAL LESIONS



Dewland T, et al. Ultra-low temperature cryoablation versus ultra-low temperature cryoablation combined with pulsed field ablation in a swine ventricular infarct model. JACC EP 2026

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FULCRUM-VT TRIAL DESIGN

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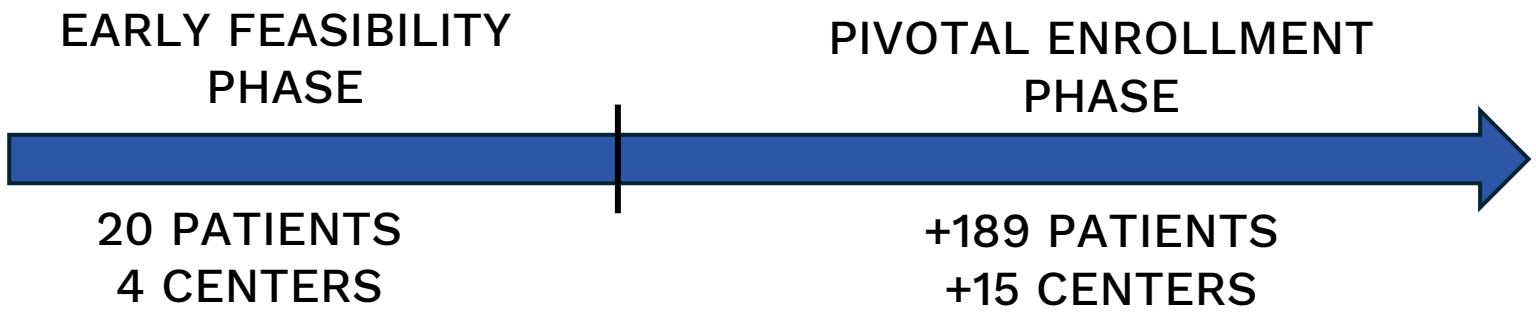
Study Design	Patient Population	Primary Endpoints
• Single arm • 209 patients • 19 sites • **Endocardial access only** (ablation or mapping)	• 20% ≤ LVEF ≤ 50% • **ICM** • **NICM**, incl. ARVC • ≤ 1 prior VT ablation in last 2 years	• Protocol-defined Major Adverse Events (MAEs) 0-7 days • Acute non-inducibility of VTs targeted for ablation • Freedom from sustained VT or appropriate ICD intervention without AAD escalation

THE FIRST IDE TRIAL OF A PURPOSE-BUILT VT ABLATION CATHETER



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ICD= implantable cardioverter defibrillator; AAD=anti-arrhythmic drug

PATIENT DEMOGRAPHICS

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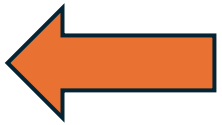
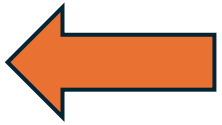
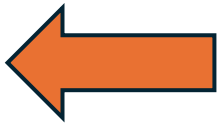
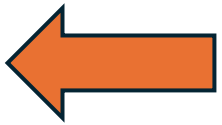
	All patients	ITT Cohort*
Number of Patients	209	157
Age	68 ± 11 y.o.	69 ± 10 y.o.
Male Sex	92.8%	94.3%)
BMI	30 ± 6	30 ± 6
Cardiomyopathy		
ICM	64.1%	65.6%
NICM	30.1%	28.0%
both ICM and NICM	5.7%	6.4%
LVEF	35% ± 10%	35% ± 10%
≤ 30%	38.3%	36.3%
31-40%	33.0%	35.0%
41-50%	23.9%	24.8%
>50%	4.8%	3.8%
Congestive Heart Failure	75.6%	78.3%
History of AADs	90.4%	91.7%
Amiodarone	69.4%	71.3%

*Intention to Treat (ITT) Cohort excluded Early Feasibility Study (EFS) and Roll-in patients

PROCEDURAL DETAIL

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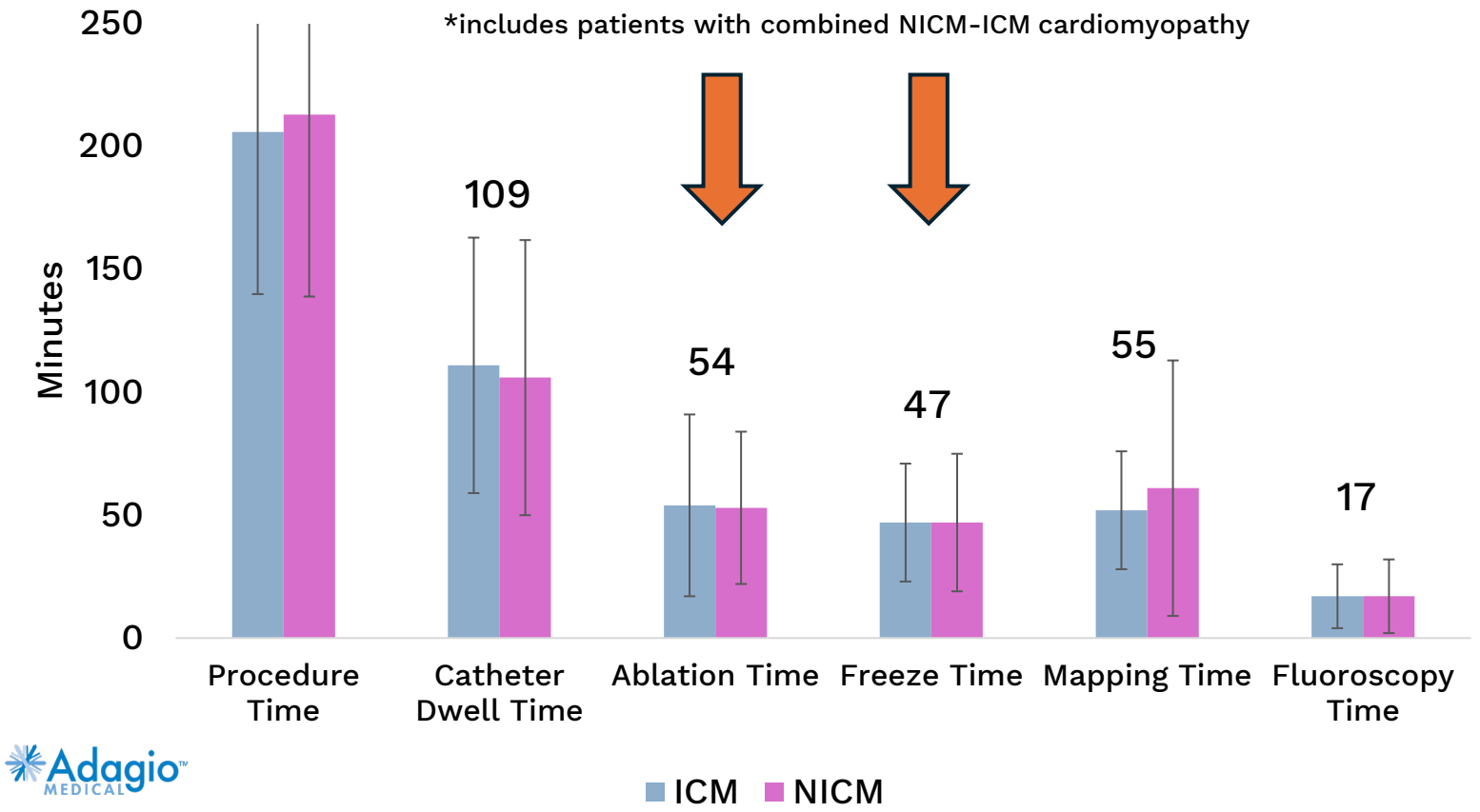
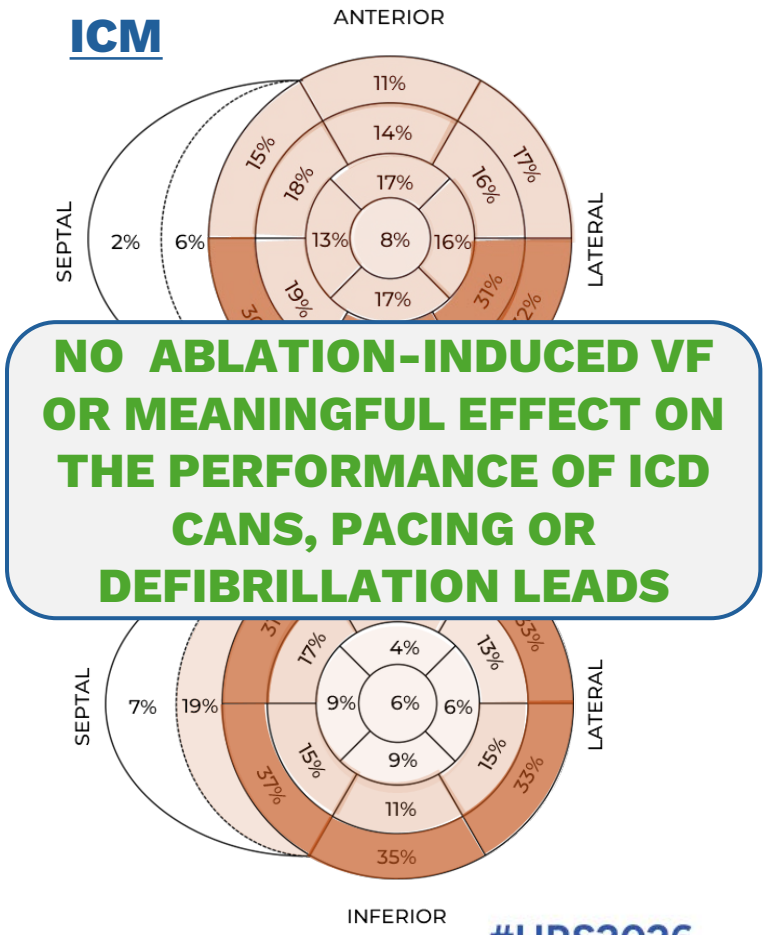
	ICM n=103	NICM* n=54
Lesions / patient	12 +/- 6	11 +/- 7
Total freeze time/lesion, min	4 +/- 1	4 +/- 1

*includes patients with combined NICM-ICM cardiomyopathy





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PRIMARY SAFETY

- **Primary Safety Endpoint: 2.4% (5/209)**
  - 2 (1.0%) device-related events
- 8% (17/209) rate of non-device, procedure-related events

MAJOR ADVERSE EVENTS

EVENT DESCRIPTION	# PATIENTS
Death	1 (0.5%)
Cardiac perforation/tamponade	2 (1.0%)
Cerebral infarct or systemic embolism	1 (0.5%)
Major bleeding requiring transfusion	1 (0.5%)

OTHER PROCEDURE-RELATED SERIOUS ADVERSE EVENTS*

EVENT DESCRIPTION	# EVENTS
Access site complications	2
Fluid overload (HF)	1
PEA arrest	1
Cardiogenic shock	4
Infection/sepsis	1
Pericardial effusion	2
Cardiac perforation	1
Respiratory Failure	4
Hemoptysis	1
Total	**17 (16 pts.)**

* None of these events was adjudicated as definitely or probably device-related

ACUTE EFFECTIVENESS

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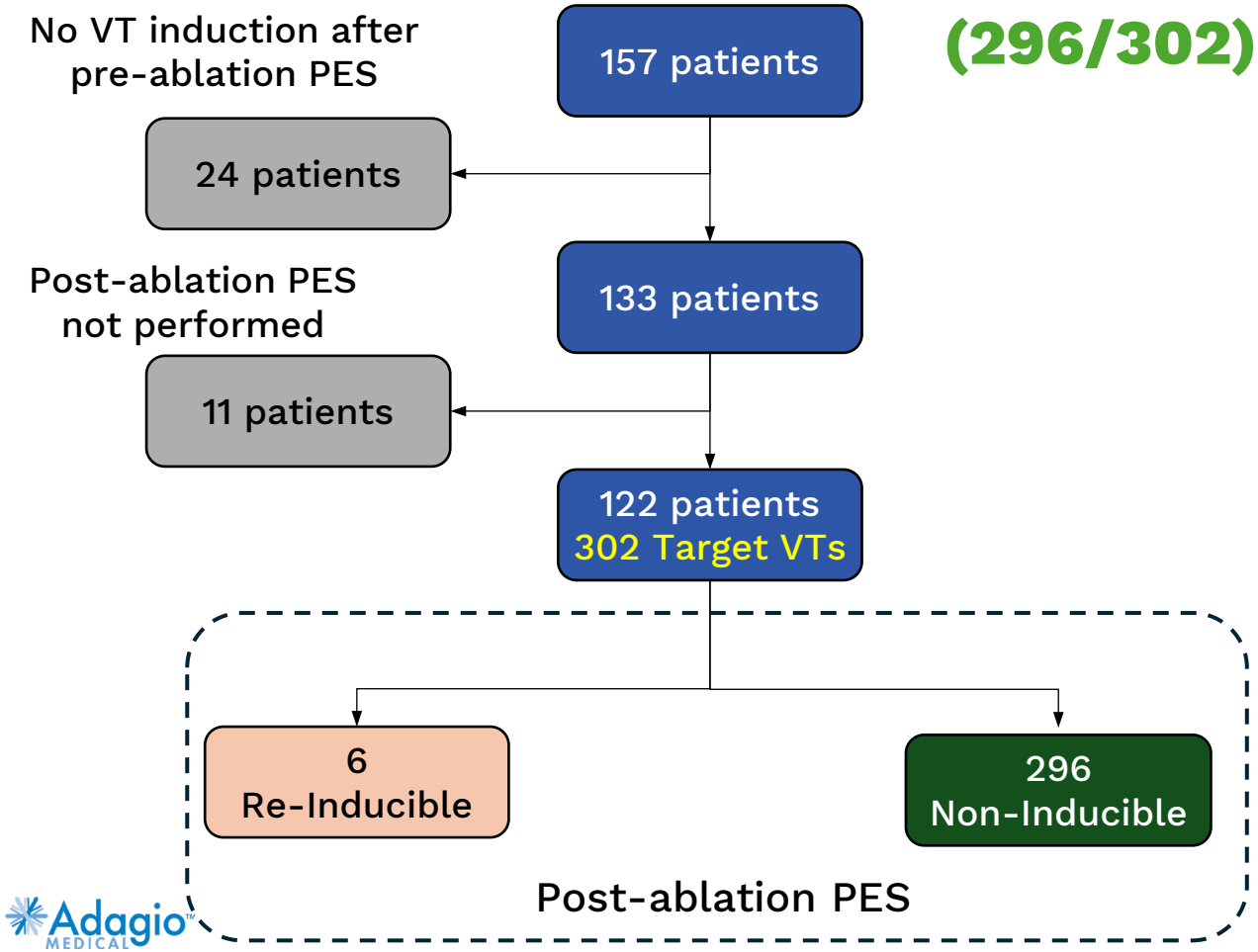
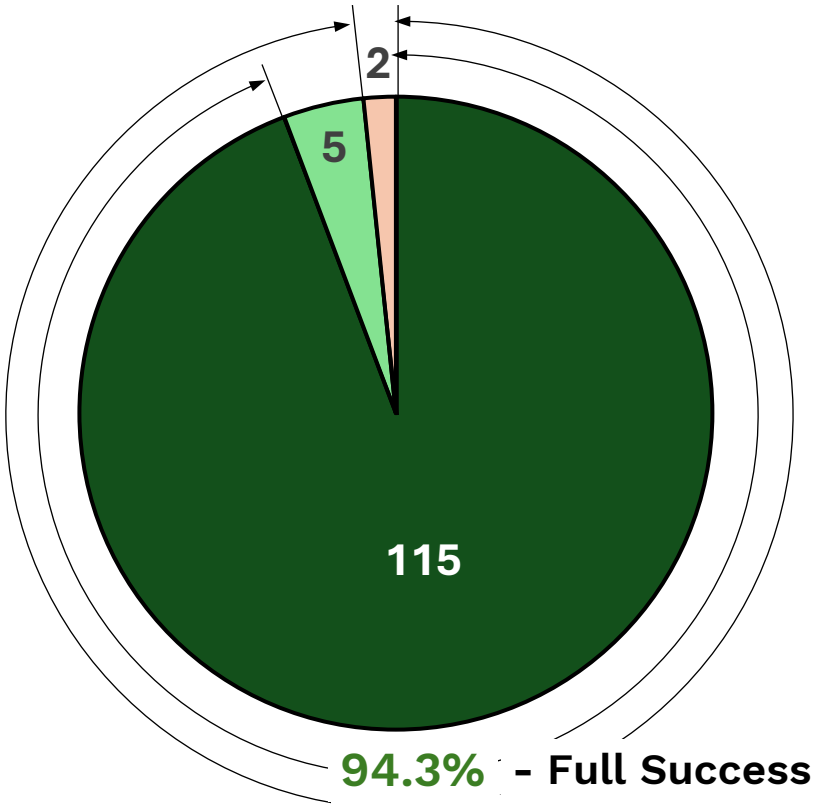
- Primary Acute Effectiveness: **98.0%**
  (296/302)



PATIENT-LEVEL ACUTE SUCCESS



94.3% - Full Success
98.4% - Clinical Success

- No VTs reinduced in post-ablation PES
- Non-clinical VTs after post-ablation PES
- Clinical VTs in post-ablation PES

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PRIMARY CHRONIC EFFECTIVENESS

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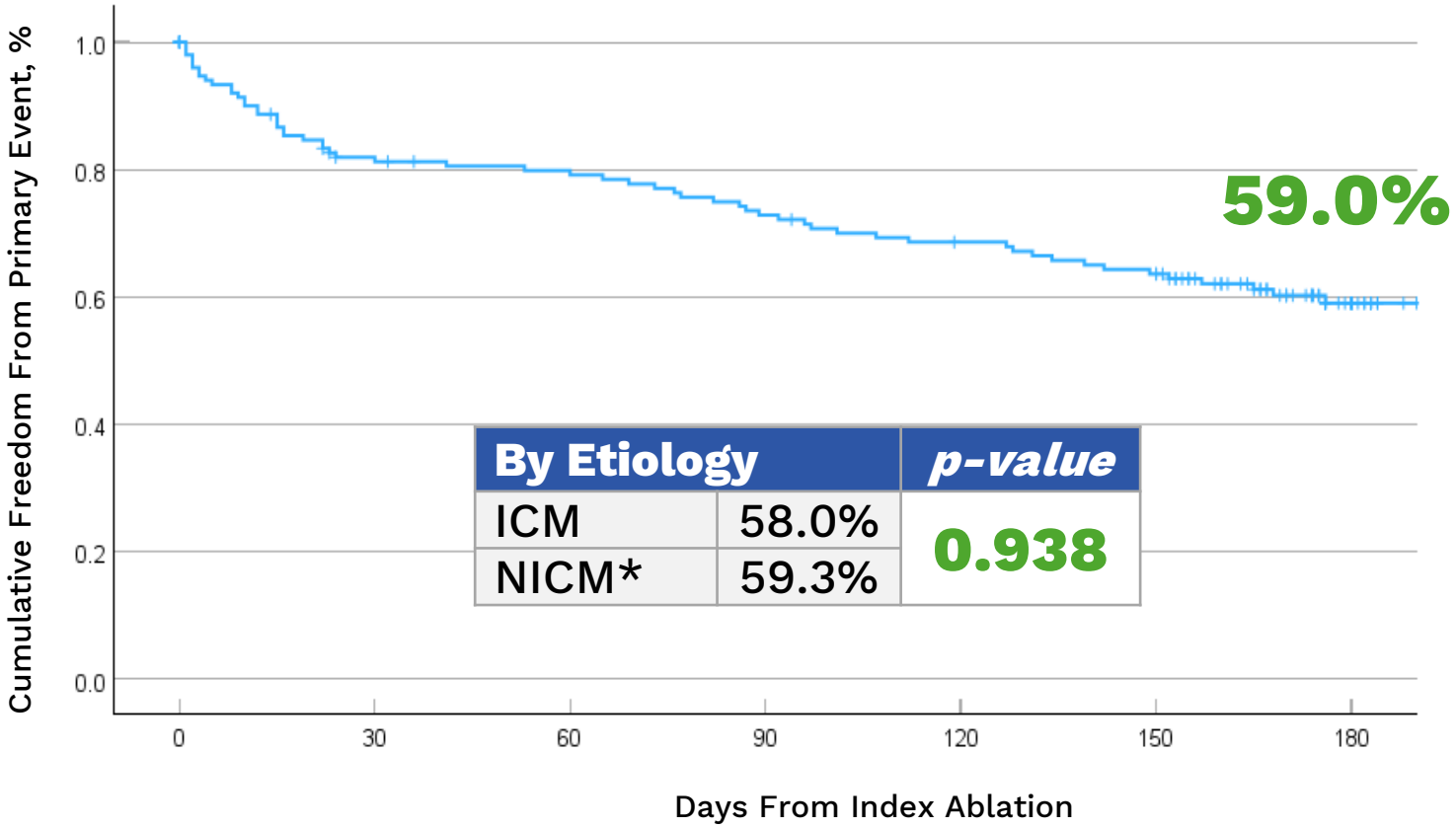
KAPLAN-MEIER FREEDOM FROM ANY VT RECURRENCE OR AAD ESCALATION



By Etiology		p-value
ICM	58.0%	0.938
NICM*	59.3%	

PRIMARY EVENTS, BY TYPE

Number of Events	n=58
ICD Therapy (ATP or Shock)	54
ATP Only	*32*
ICD Shock	*22*
Monitoring Zone VT > 30 sec	3
AAD Escalation	1

ATP=anti-tachycardia pacing

PRIMARY EFFECTIVENESS PERFORMANCE GOAL MET ✓

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*includes patients with combined NICM-ICM cardiomyopathy

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EFFECTIVENESS BY ETIOLOGY

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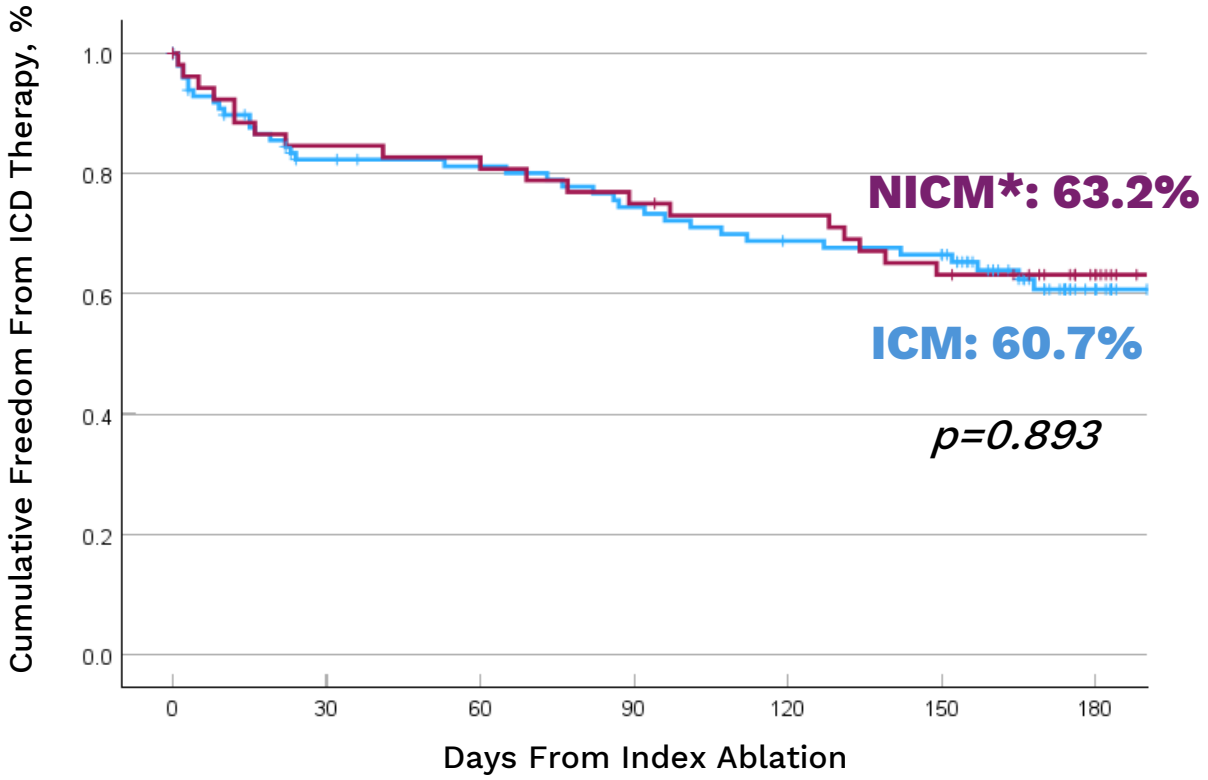
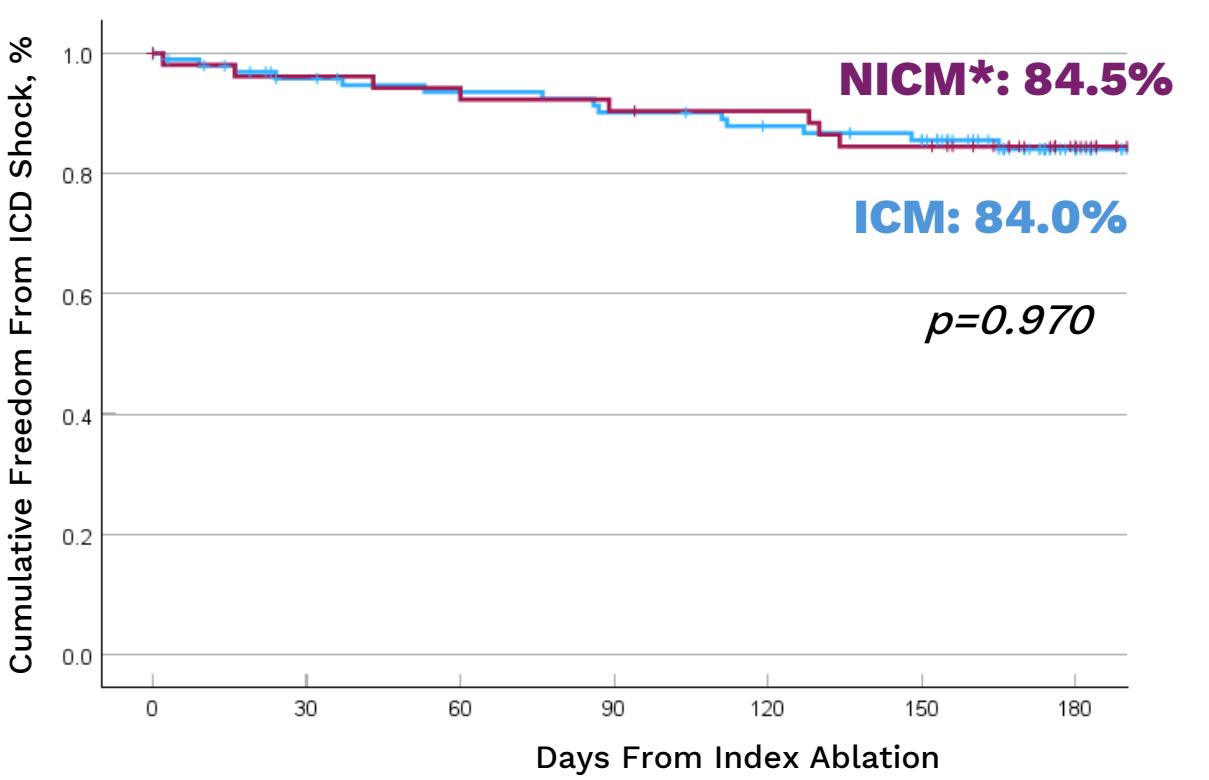
IDENTICAL EFFECTIVENESS for both ICM and NICM patients

K-M FREEDOM FROM ANY ICD THERAPY: 61.8%



K-M FREEDOM FROM ICD SHOCK: 84.3%



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REDUCTION IN VT BURDEN

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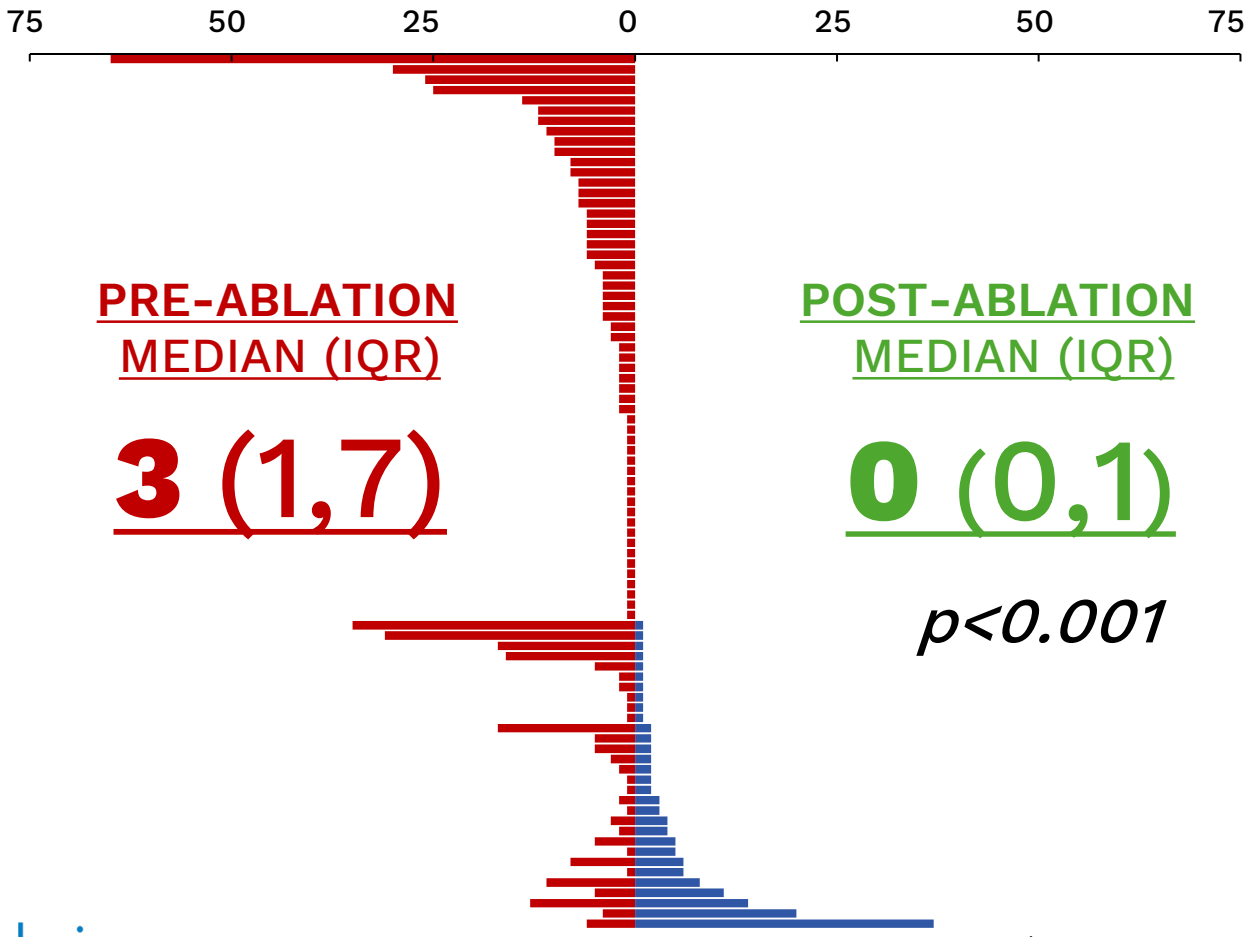
VT BURDEN PRE- AND POST-ABLATION*



PRE-ABLATION
MEDIAN (IQR)

3 (1,7)

POST-ABLATION
MEDIAN (IQR)

0 (0,1)

p<0.001

PATIENTS WITH ICD SHOCK* POST-ABLATION

ICM : 81% ⇩

NICM : 82% ⇩

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* 85 patients with > 150 days of ICD data in both pre- and post-ablation

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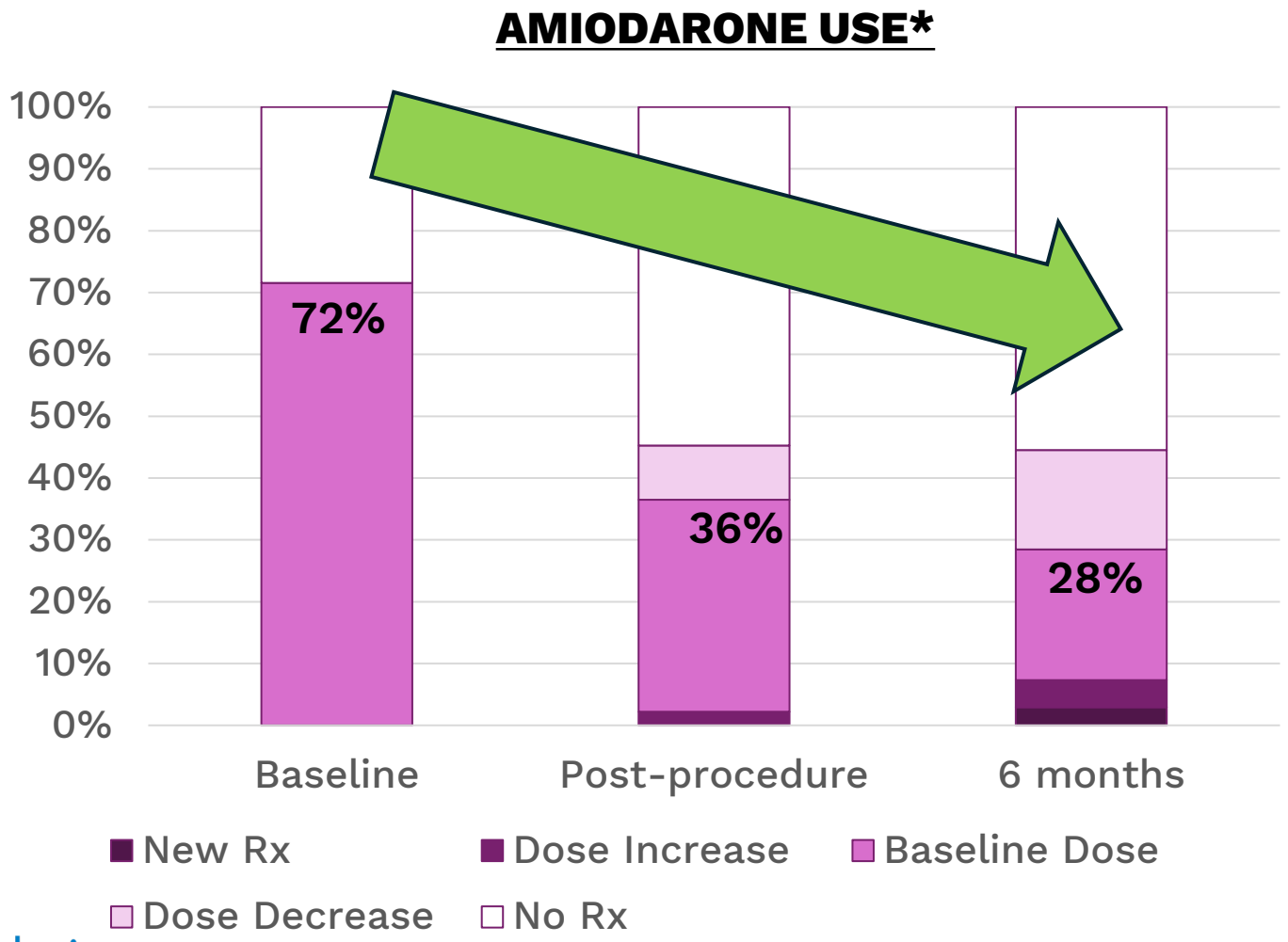
REDUCTION IN AAD USE



AT 6 MO

- **72%** of patients are free or on reduced dose of amiodarone
- **60%** relative reduction in amiodarone use

* 137 patients in study through 6 months follow-up

30-DAY RE-ADMISSIONS

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	Literature Reported[1,2]	FULCRUM-VT
VT	7-8%	**1.9%** (3/154)
HF	2-3%	**1.3%** (2/154)
All-cause	14-19%	**8.4%** (13/154)

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[1]Cheung et al. Circ Arrhythm Electrophysiol. 2018;11:e006754
[2]Tan MC et al. Journal of Interventional Cardiac Electrophysiology (2024) 67:513–521
HF=heart failure

FULCRUM-VT EXPANSION TRIAL

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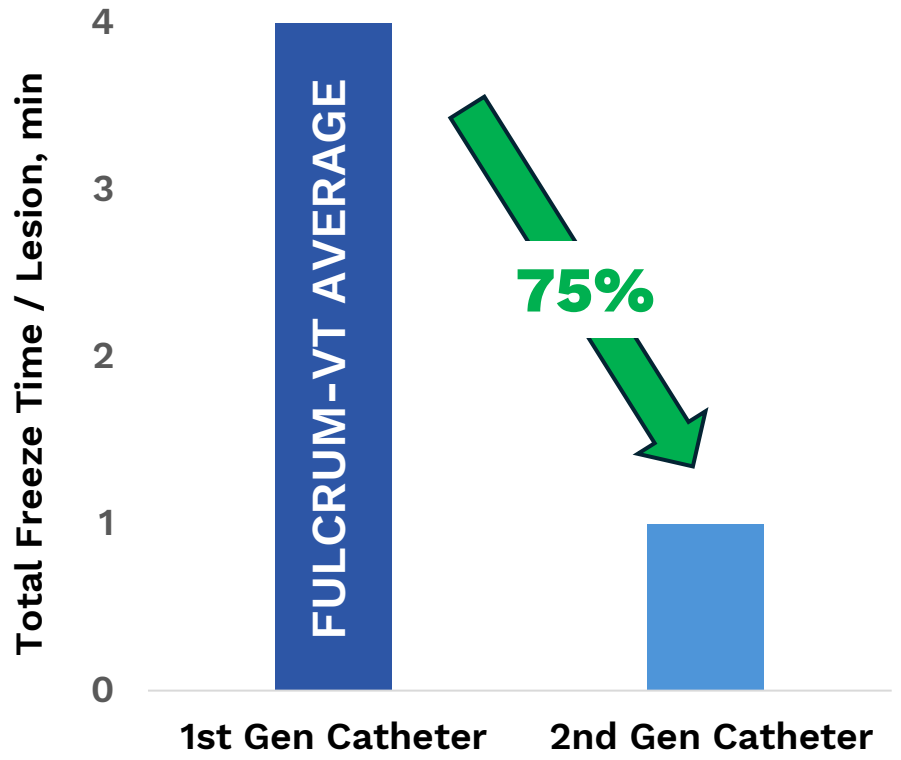
NOW ENROLLING

2nd vs 1st GENERATION OF ULTA CATHETER

	1st Gen	2nd Gen
Sheath compatibility	9 Fr	8.5 Fr
Shaft stiffness profile	Uniform	Variable
Bi-directional deflection	F/F	D/F
Ablation element length	15 mm	12 mm
Number of electrodes	8	6
# of freezes per lesion	2	1

FREEZE TIME PER LESION REDUCTION*



*K. Dyrda et al. Initial Pre-Clinical Evaluation of the Augmented Ultra-Low Temperature Cryoablation Catheter for Ventricular Ablations. J Cardiovasc Electrophysiol 2026

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CONCLUSIONS

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THE FIRST IDE FOR PURPOSE-BUILT VENTRICULAR CATHETER

- **Endocardial ablation** only, **one-third** non-ischemic CM
- **2.4%** primary safety event rate
- **59%** freedom from ANY VT recurrence or AAD escalation
- **84%** freedom from ICD shock
- **Equivalent outcomes** in ischemic and non-ischemic CM
- **Median burden 3 → 0** pre- to post-ablation
- **72%** free from or on reduced dose of amiodarone
- Objective standards to compare VT outcome trials

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Q & A