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EU 1st Faculty Meeting
Frankfurt, Germany
May 2022

Meeting Objectives

- To standardize training
  - of the Hybrid AF Convergent Therapy
  - and left atrial appendage management

- Review of Professional Education training support
  - Slide-deck template for faculty
  - Peer-to-peer webex conference call
  - On-site case observation
  - Hybrid AF Course with hands-on CADet/cadaver lab training
  - Proctor support for initial cases
  - Hospital staff education (to include OR and Post op nursing staff) by AtriCure for program implementation
  - Ongoing case support by AtriCure

- Consensus on Peri-operative clinical protocols for risk mitigation
  - Pre, Intra, Post-procedure
    - ✓ Anti-coagulation Therapy
    - ✓ Pain management
    - ✓ Esophageal protection (Esophageal temp monitoring, irrigation, PPI)
    - ✓ Diuretics
    - ✓ Effusion risk mitigation

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EU Indications

The EU Indications:

EpiSense
The EPi-Sense ® Guided Coagulation System with VisiTrax® is intended for the coagulation of cardiac tissue using Radiofrequency (RF) energy during cardiac surgery for the treatment of arrhythmias including Atrial Fibrillation (AFIB) or Atrial Flutter (AFL)

LARIAT
The LARIAT/LARIAT+/LARIAT RS Suture Delivery Device facilitates suture placement and knot tying for use in surgical applications where soft tissue, including the Left Atrial Appendage (LAA), are being approximated and/or ligated with a pre-tied polyester suture.

AtriClip PRO2 & PROV
The AtriClip™ LAA Exclusion System is indicated for open occlusion of the heart's left atrial appendage.

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Provide clinical evidence and rationale

- Why treat AF?
- What are the treatment options?
- Why does the Convergent procedure work?
- Why LAA epicardial exclusion should be part of a hybrid procedure?
- Who should be treated with a hybrid procedure?
- What are the procedural concerns?
- How do you mitigate adverse effects?
- How do you start a hybrid program?

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Why treat AF?

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AF: A Serious and Growing Problem

Atrial Fibrillation is an irregular heartbeat (or arrhythmia) that affects more than 33 million people worldwide.[1]

5x Risk of stroke[3]

>5x Higher risk of heart failure[4]

46% Greater risk of all-cause mortality[4,5]

> 3X Greater risk of dementia

More cardiac complications[6]

Approximately 1.2 million AF diagnoses annually in the US.[2]

Consequences of AF:

- Impact on QOL and normal daily activities
- Stroke, heart failure (structural remodeling), dementia

1 Rahman, F., et al. (2014). Global epidemiology of atrial fibrillation. *Nature Reviews Cardiology,* 11, 639-654, https://doi.org/10.1038/nrcardio.2014.118.
2 Braid-Forbes, M.J. Health Research, 2014 CMS SAF, August 2016. NIS for volume and Medicare to look back over 3 years and obtained diagnosis
3 Colilla, S. et al. (2013). Estimates of current and future incidence and prevalence of atrial fibrillation in the U.S. adult population. Am J Cardiol, 112(8):1142-7.
4 Odutayo, A. et al. (2016) Atrial fibrillation and risks of cardiovascular disease, renal disease, and death: systematic review and meta-analysis. BMJ; 354:i4482
5Boriani, G., & Proietti, M. (2017). Atrial fibrillation prevention: an appraisal of current evidence. Heart, 104(11):882-7.
6 Fukunaga, S. et al. (2008). Effect of surgery for atrial fibrillation associated with mitral valve disease. Ann of Thorac Surg, 86(4):1212-7. 7 Boriani, G., & Proietti, M. (2017). Atrial fibrillation prevention: an appraisal of current evidence. Heart, 104(11):882-7

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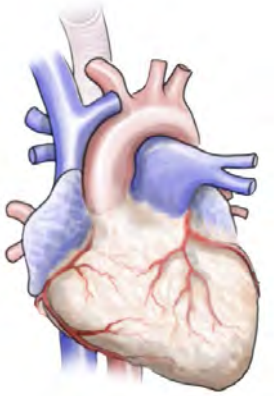
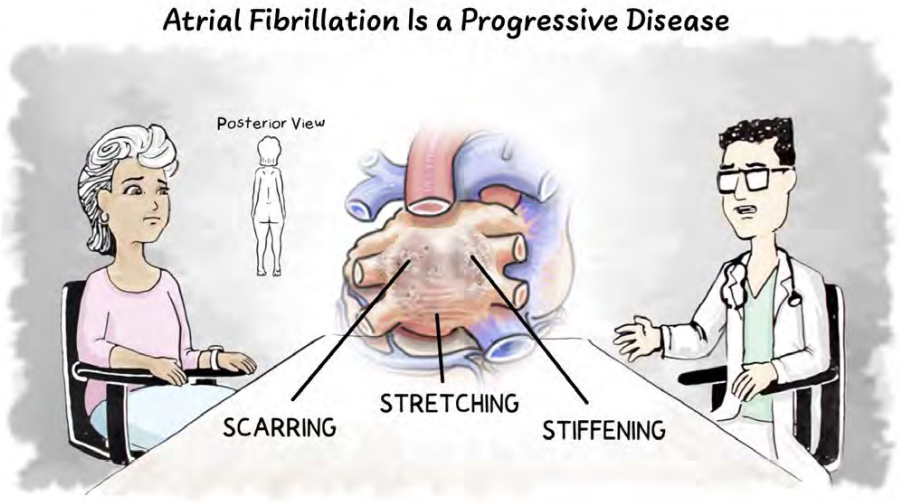
AF: Atrial Fibrillation Is Progressive[6]

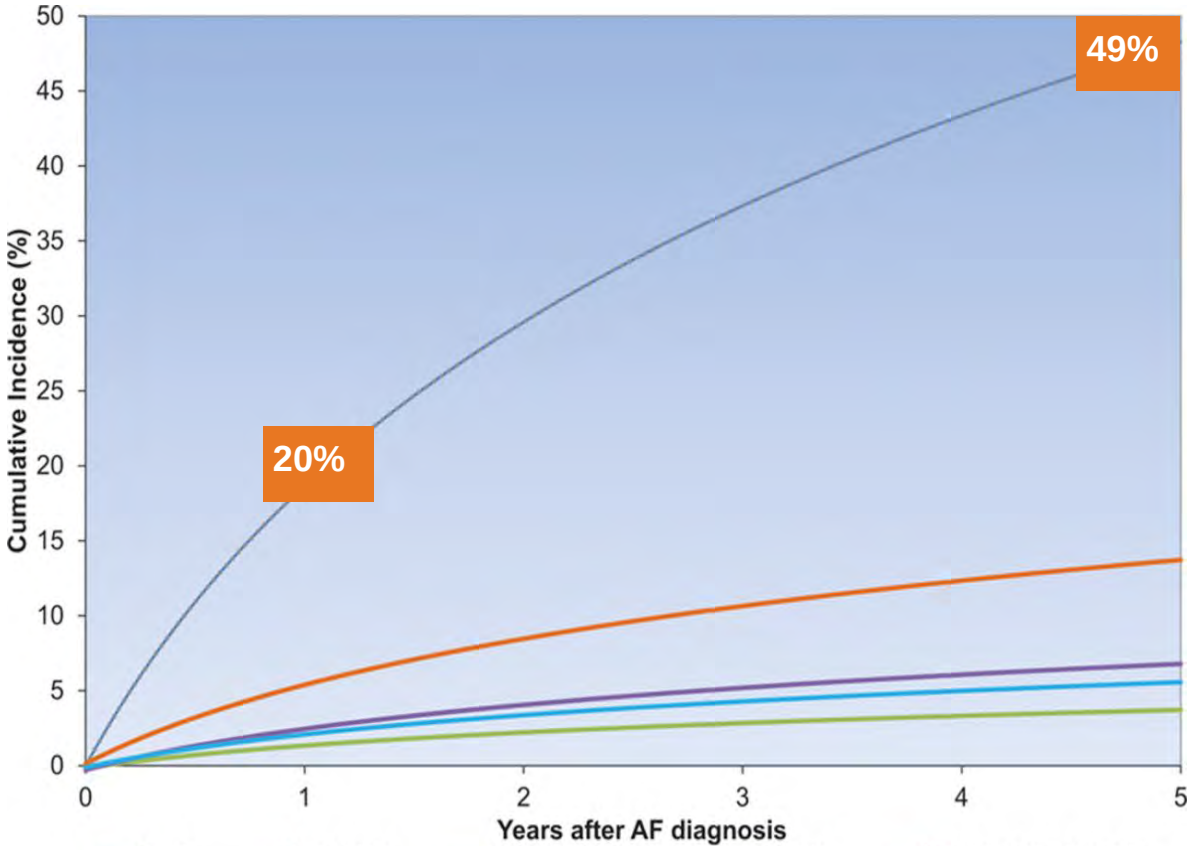


Healthy Heart



- AF burden is associated with atrial remodeling and development of atrial fibrosis
- Structural and functional atrial changes eventually lead to the development, maintenance, and progression of AF

Cumulative Incidence of Events in the 5 Years after Diagnosis of In-Hospital AF in Medicare Patients



Adapted from: Picini et al. Eur Heart J 2014;35:250-256 Mozaffarian et al. Circulation. 2015;131:e29-e322

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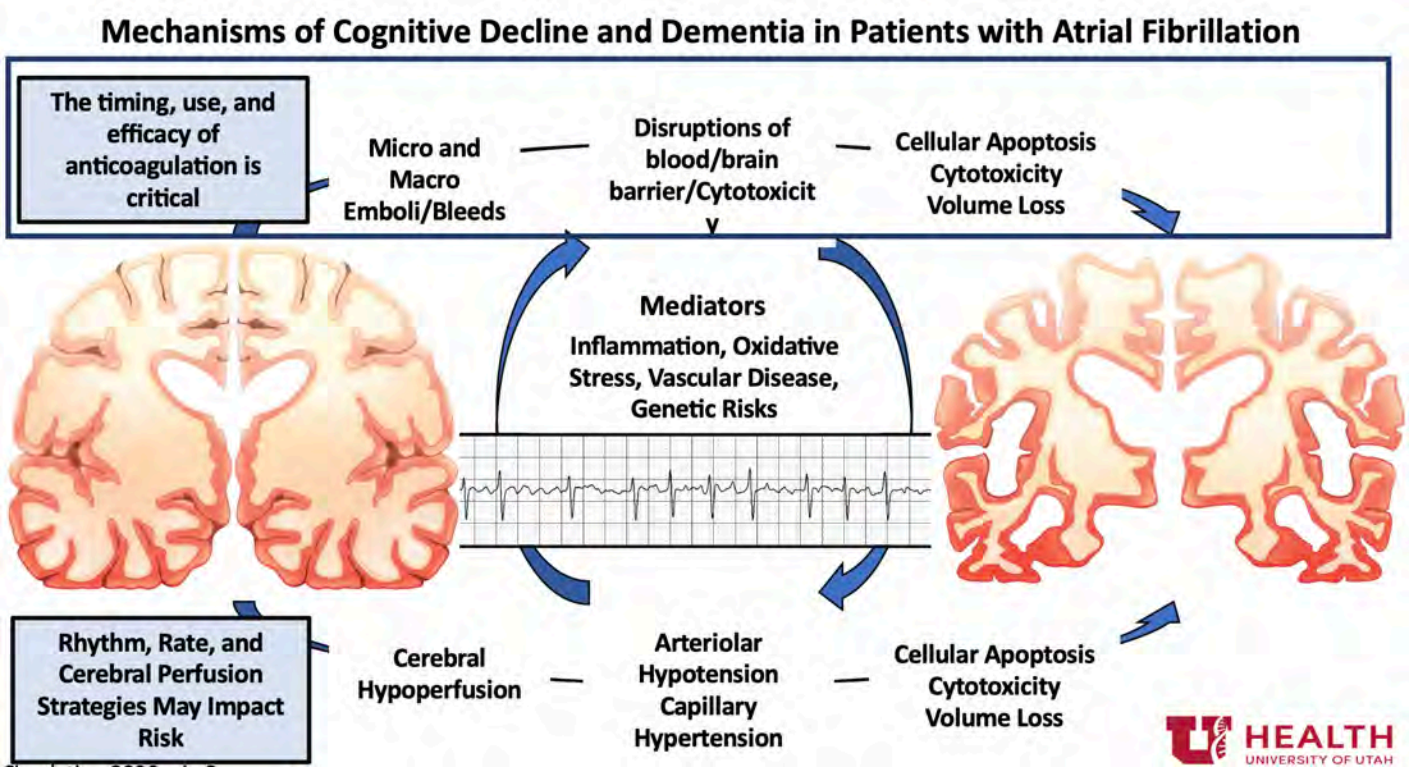
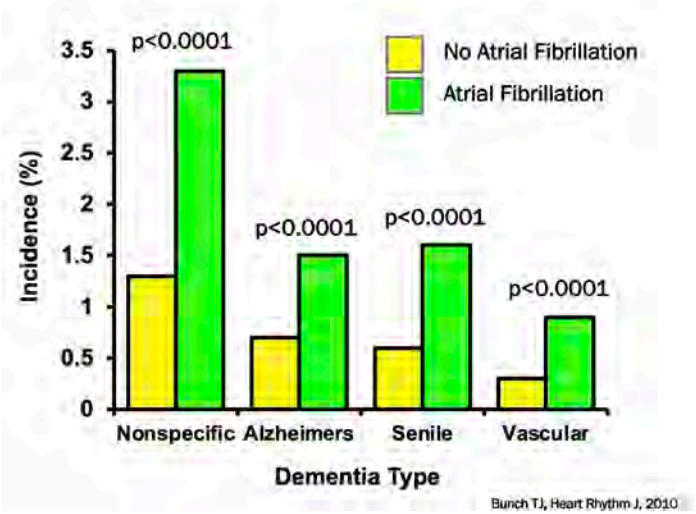
AF and Dementia



Bunch et at Circulation 2022 (In Press)



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How do we treat AF?

AF Treatment Strategies: Impact on CV Morbidity

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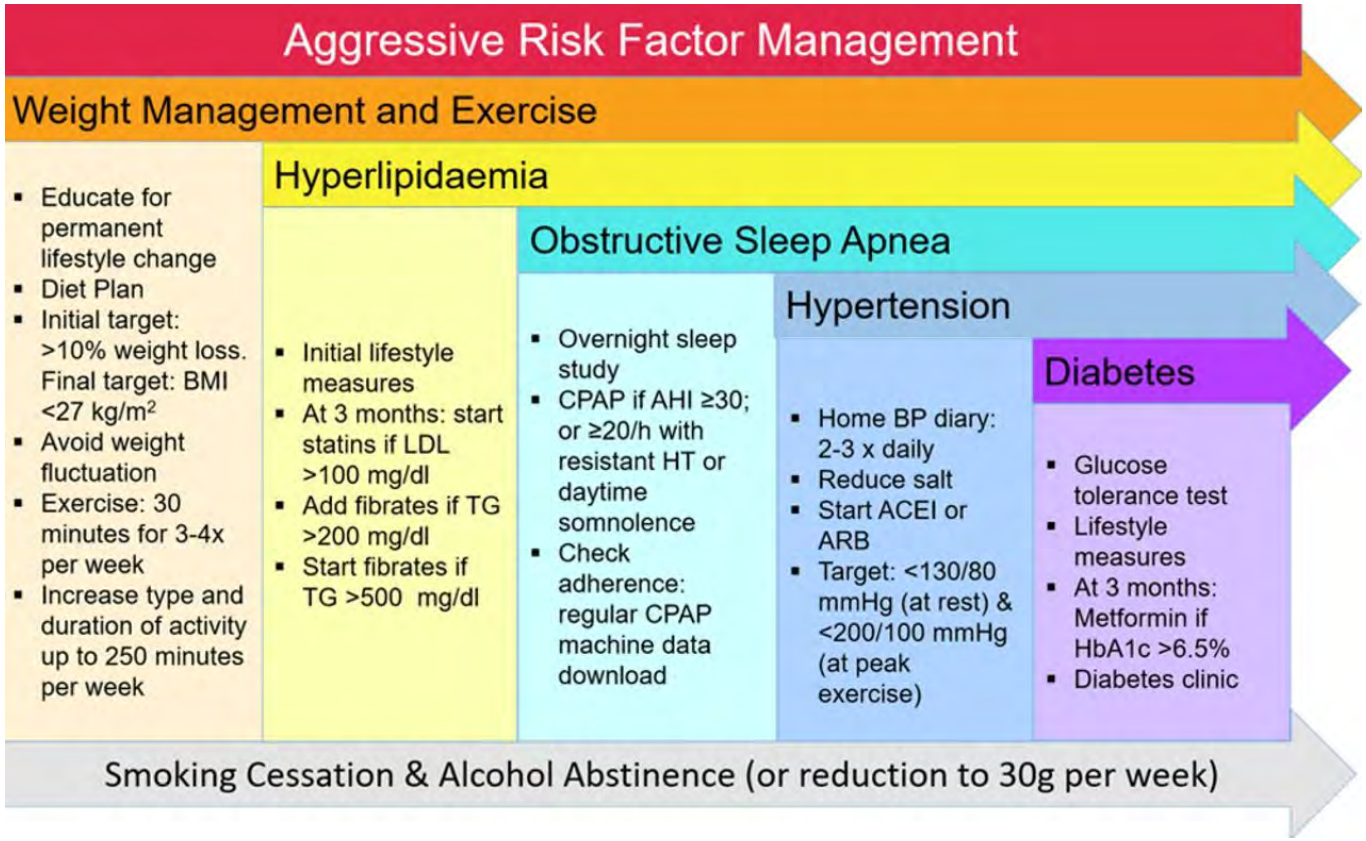
AF Risk Factor Modification

- HTN
- DM
- Obesity
- Sleep Apnea
- Alcohol
- Exercise



Lau et al. Circulation 2017;136:583–596

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The Real Debate

Drugs versus catheter ablation

Rate Control vs Rhythm Control

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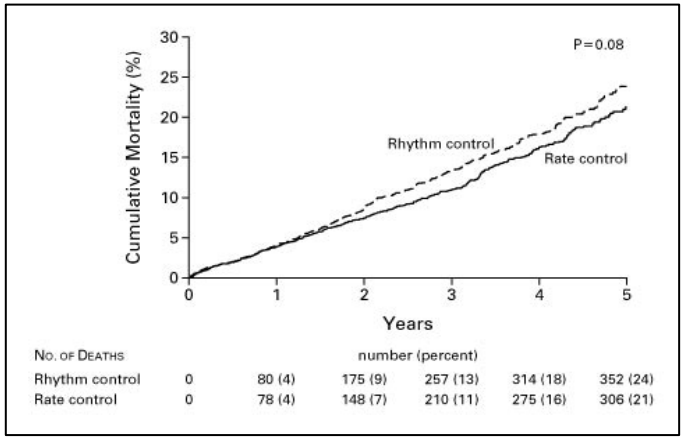
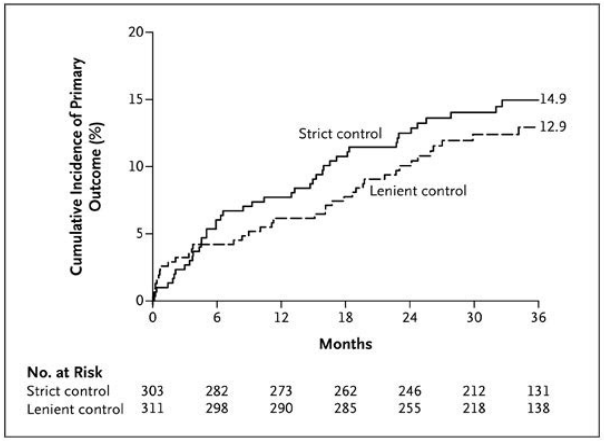
Rate vs Rhythm

AFIRM Trial



(AFFIRM) Investigators. N Engl J Med 2002;347:1825-1833

RACE-2 Trial

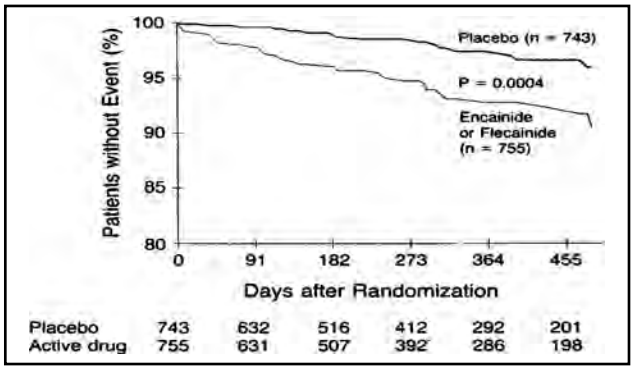


Van Gelder IC et al. N Engl J Med 2010;362:1363-1373

Positive benefit of rate control biased by increased side effects and mortality of AADs

Drug related mortality and morbidity

- Amiodarone
  - Toxicities: Lung, Thyroid, Cataracts, Skin, Neurological
- Class Ic (encainide, flecainide, propafenone)
  - Increase mortality in patients with ischemic heart disease
- Dofetilide/Sotalol
  - Torsade



Echt DS et al. N Engl J Med 1991;324:781-788

CAST trials demonstrated increased mortality in patients with CAD to Class 1c AADs

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Land-Mark Trials

CABANA

East-AF

CASTLE-AF

ATTEST

Shift from just relieving symptoms to include improving cardiovascular outcomes and mortality

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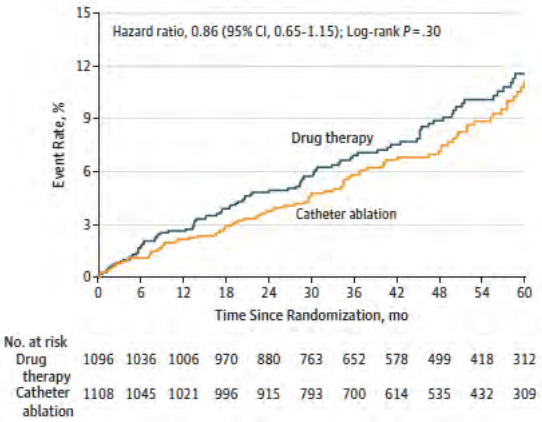
CABANA Results

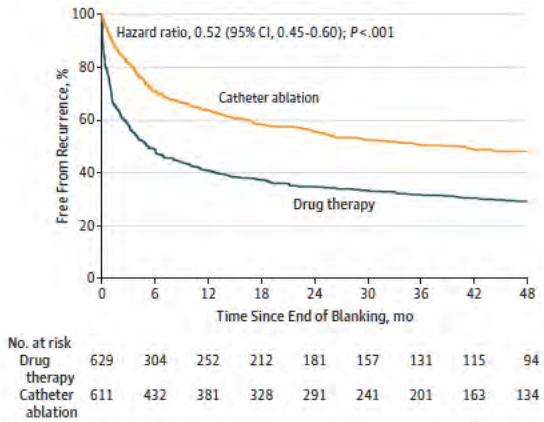
Catheter ablation vs conventional medical therapy

Primary End Point



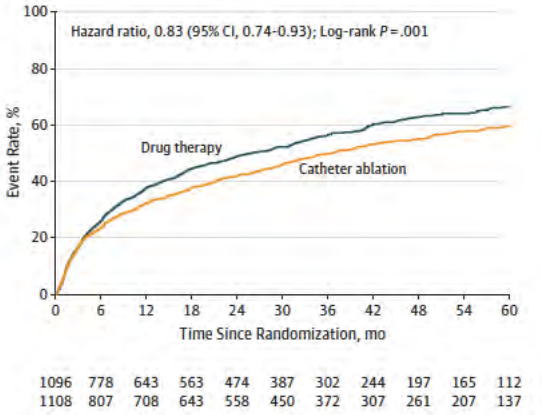
Composite of death, disabling stroke, serious bleeding, or cardiac arrest

Recurrent Atrial Fibrillation



After Blanking by Intention-to-Treat Analysis

Composite secondary end point



Death from any cause or CV hospitalization

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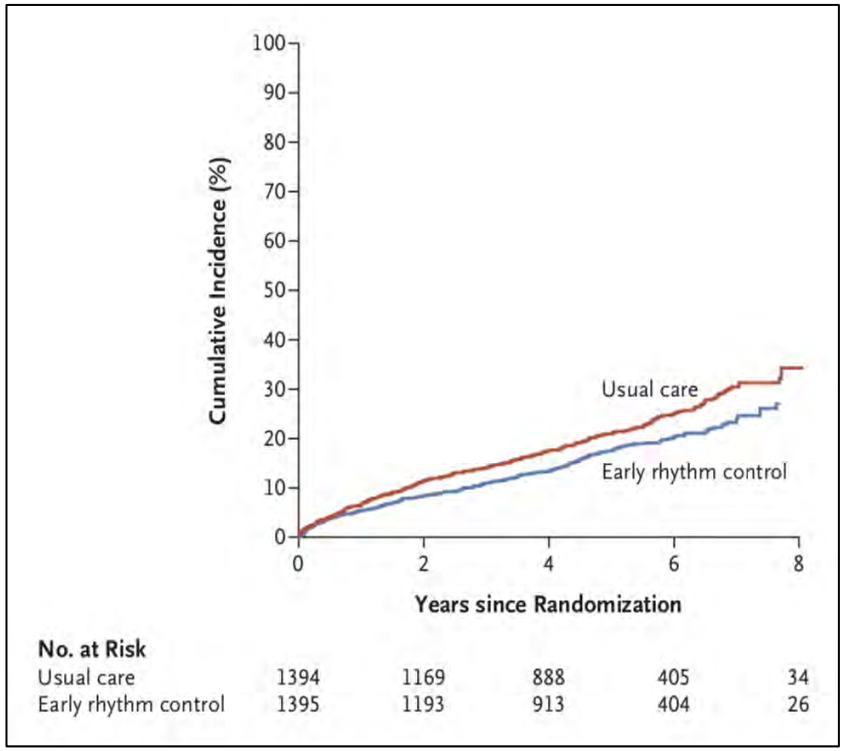
EAST-AFNET: Cumulative-Incidence Curves

- AF Population: Early AF patients (<1 year) with cardiovascular conditions. Most patients (>70%) were asymptomatic.
- Hypothesis: Test whether rhythm control versus usual care reduces the risk of cardiovascular complications
- Primary outcome: A composite of death from cardiovascular causes, stroke, or hospitalization with worsening of heart failure or acute coronary syndrome
- The trial was stopped for efficacy at the third interim analysis after a median of 5.1 years of follow-up per patient.
- Early rhythm-control therapy was associated with a lower risk of cardiovascular outcomes than usual care among patients with early atrial fibrillation and cardiovascular conditions.



Kirchhof et al. NEJM 2020

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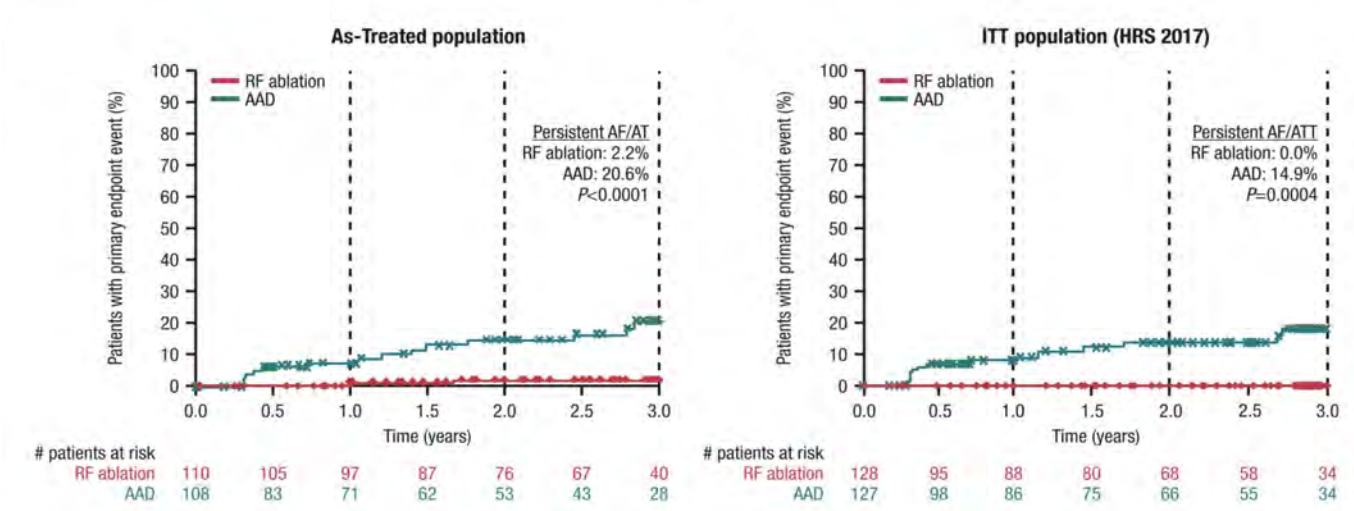
Catheter ablation or medical therapy to delay progression of atrial fibrillation (ATTEST study)

Evaluates whether RF catheter ablation delays the progression of AF compared with AAD treatment using current AF management guidelines



Radiofrequency ablation is superior to guideline-directed AAD therapy in delaying the progression from paroxysmal to persistent AF

Kuck et al. Europace (2021) 23, 362–369

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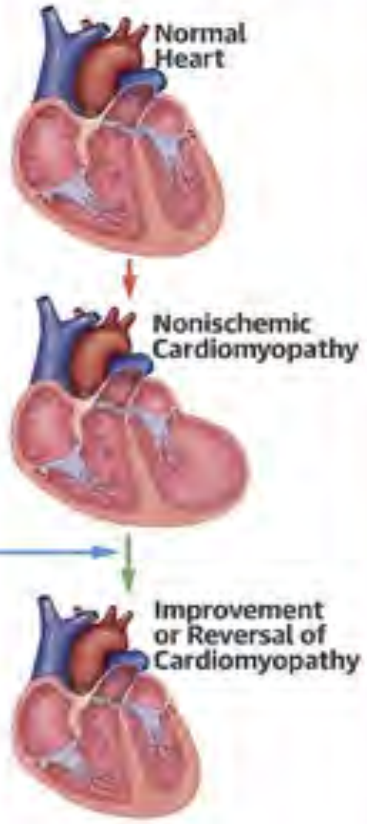
Arrhythmia-induced cardiomyopathy

CENTRAL ILLUSTRATION: Arrhythmia-Induced Cardiomyopathies: Possible Triggers, Mediators, Effect, and Recovery

	Tachycardia	Frequent PVCs	Atrial Fibrillation
Triggers	Increased HR	• LV dyssynchrony • AV dissociation • HR irregularity • Intermittent tachycardia • Sympathetic dysregulation • Post-extrasystolic potentation	• HR irregularity • Sympathetic dysregulation • Loss of atrial contraction
Mediators	• Ca^{2+} overload • Ca^{2+} mishandling	• Ca^{2+} overload • Ca^{2+} mishandling ???	• Ca^{2+} mishandling ???
Effect	• Fibrosis • Myocyte and electrical remodeling • Contractile dysfunction • Neurohormonal activation	• Myocyte and electricial remodeling • Contractile dysfunction ? Fibrosis	• Contractile dysfunction ???
Arrhythmia Suppression	Ablation / Antiarrhythmic drugs		
Recovery	• Normalized LVEF • Ventricular dilatation • Diastolic dysfunction • Reactive hypertrophy • Persistent fibrosis	• Normalized LVEF and dimensions	• Normalized LVEF ???



Huizar, J.F. et al. J Am Coll Cardiol. 2019;73(18):2328-44.

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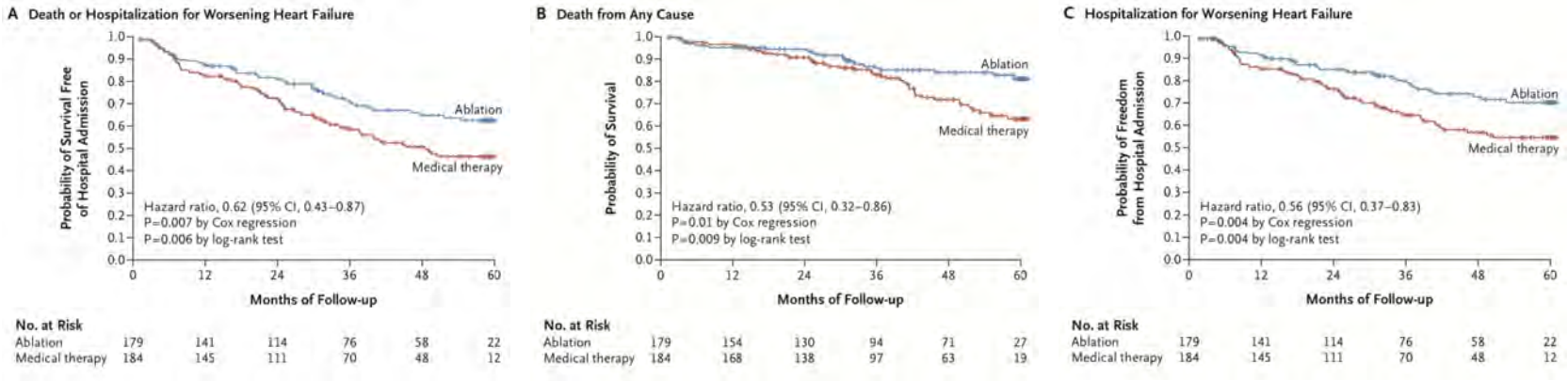
The CASTLE-AF Trial

Catheter Ablation versus Standard conventional **T**reatment in patients with **LE**ft ventricular dysfunction and **A**trial **F**ibrillation

Primary Endpoint
- All-cause mortality
- Worsening heart failure admissions



Catheter ablation for atrial fibrillation in patients with heart failure was associated with a significantly lower rate of a composite end point of death from any cause or hospitalization for worsening heart failure than was medical therapy.

Marrouche et al. NEJM 378:417-427, 2018

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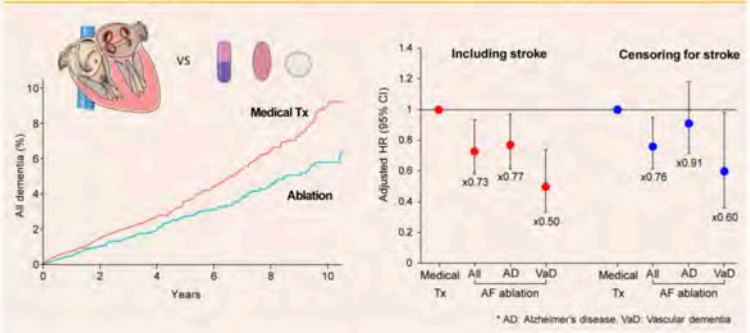
Sinus Rhythm decreases Dementia

Less dementia after catheter ablation for atrial fibrillation: a nationwide cohort study

Daehoon Kim[1†], Pil-Sung Yang[2†], Jung-Hoon Sung[2], Eunsun Jang[1], Hee Tae Yu[1], Tae-Hoon Kim[1], Jae-Sun Uhm[1], Jong-Youn Kim[1], Hui-Nam Pak[1], Moon-Hyoung Lee[1], Gregory Y.H. Lip[3*‡], and Boyoung Joung[1*‡]

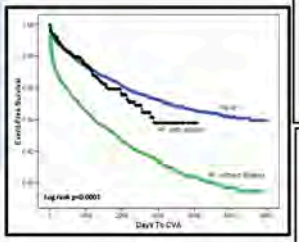
Variables	Before matching			After matching		
	Ablation (*N* = 9119)	Medical therapy (*N* = 17 978)	ASD	Ablation (*N* = 5863)	Medical therapy (*N* = 5863)	ASD
Concurrent medication[~]						
Aspirin	1757 (19.3)	3057 (17.0)	5.9%	1120 (19.1)	1107 (18.9)	0.6%
$P2Y_{12}$ inhibitor	875 (9.6)	1028 (5.7)	14.6%	469 (8.0)	462 (7.9)	0.4%
Warfarin	5079 (55.7)	12 590 (70.0)	30.0%	3609 (61.6)	3594 (61.3)	0.5%
NOAC	384 (4.2)	368 (2.0)	12.5%	186 (3.2)	200 (3.4)	1.3%

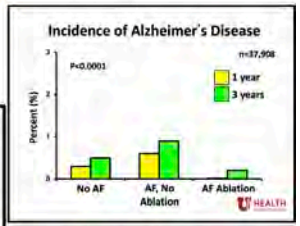


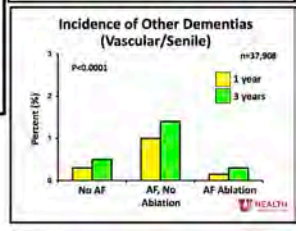
Impact of Atrial Fibrillation Ablation

Intermountain Experience

Characteristic	No AF (n=16,848)	AF, no ablation (n=16,848)	AF, ablation (n=4,212)	p-value
Age (years)	64.1±13.0	66.0±13.3	64.8±12.7	<0.0001
Sex (male)	60.8%	60.8%	60.8%	1.00
Diabetes	19.0%	21.1%	16.3%	<0.0001
Hypertension	41.2%	45.3%	47.8%	<0.0001
Hyperlipidemia	38.4%	37.3%	44.0%	<0.0001
CHF	14.5%	23.6%	29.5%	<0.0001
Renal Failure	5.6%	7.8%	7.5%	<0.0001
TIA History	4.0%	4.2%	4.6%	0.16
CVA History	4.4%	6.3%	4.5%	<0.0001





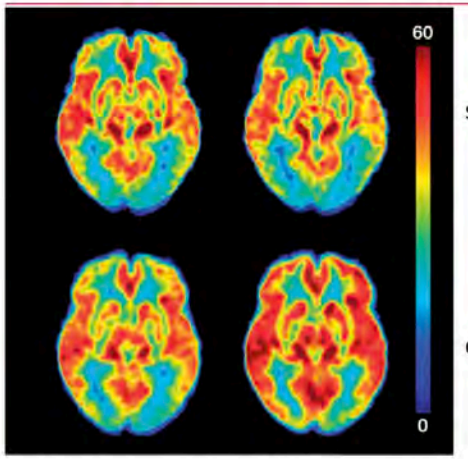


- 3 Year Success Rate (no antiarrhythmics, no AF recurrences): 64.4%
- Repeat procedure: 1,162 (27.6%)

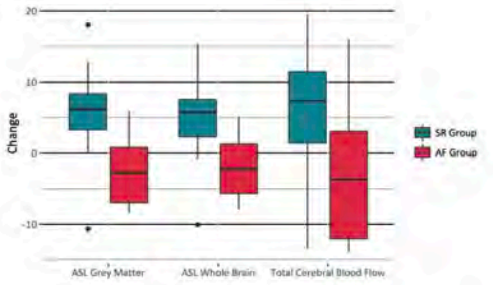
J Cardiovasc Electrophysiol. 2011; 22(8):839-45.

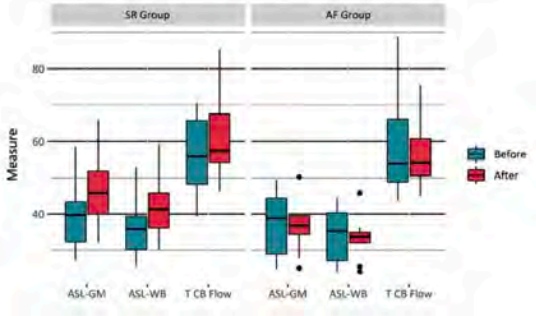
Improved brain perfusion after electrical cardioversion of atrial fibrillation

Marianna Gardarsdottir[1], Sigurdur Sigurdsson[2], Thor Aspelund[2,3], Valdis Anna Gardarsdottir[4], Lars Forsberg[2], Vilmundur Gudnason[2,3], and David O. Arnar[3,4*]



Before cardioversion After cardioversion





Treatment of AF

Shifted from just relieving symptoms to improving cardiovascular outcomes, mortality and dementia

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Why does the Convergent Procedure work?

Rationale for LA Posterior Wall Isolation and Hybrid Epi/Endo Ablation

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LA Posterior Wall as a target in non-paroxysmal AF

- Embryologically, anatomically, electrophysiologically an extension of the pulmonary veins
- Involved in initiating and sustaining atrial fibrillation
  - Non-PV trigger source up to 32% of time
  - Site of rotor activity
  - Adjacent to ganglionic plexi
- Isolation shown to be feasible, effective and safe in several studies

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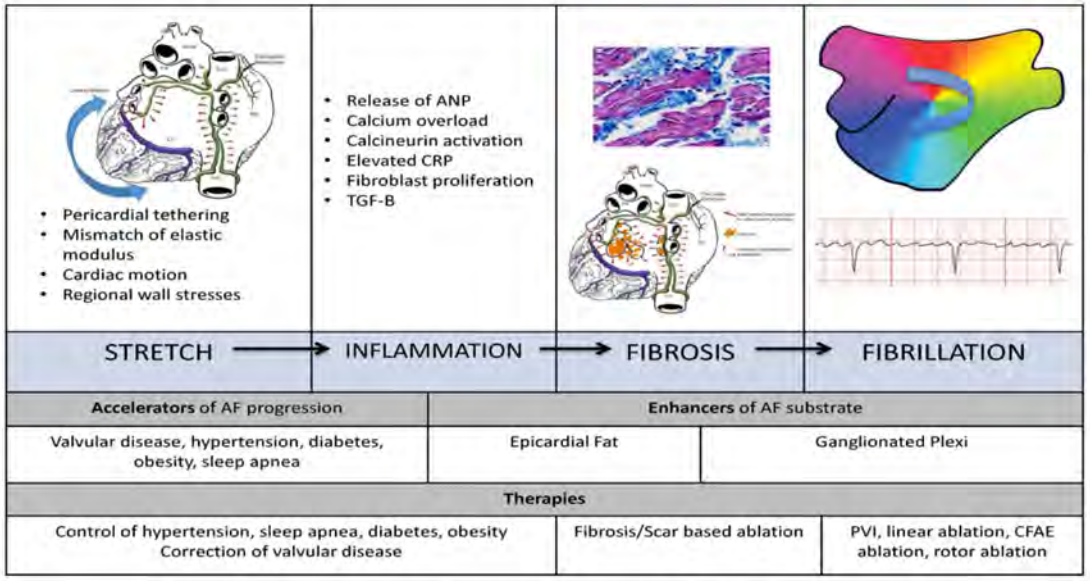
Advanced AF: Characterized by changes to LA substrate

- While PV triggers are predominant earlier in the development of AF, there is an increased involvement of the atrium as the disease progresses.
- Mechanical stress on the atrium due to pericardial tethers and cardiac motion causes stress induced inflammation and fibrosis, especially in posterior left atrium.
- Atrial fibrosis is a key factor in the genesis and/or perpetuation of AF.



Stretch-Inflammation-Fibrosis-Fibrillation (StIFF) Axis Progression

Addressing progressive nature of AF and fibrosis during ablation may yield improved outcomes.

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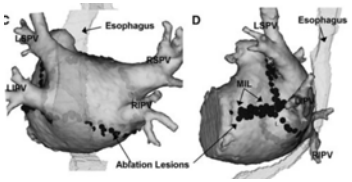
Yang et al. J Atr Fibrillation. 2017 Oct-Nov; 10(3): 1627

RCTs comparing PVI to endocardial PWI

Reported posterior wall isolation techniques



Lim 2012, Single ring isolation (SRI), & SRI + MI

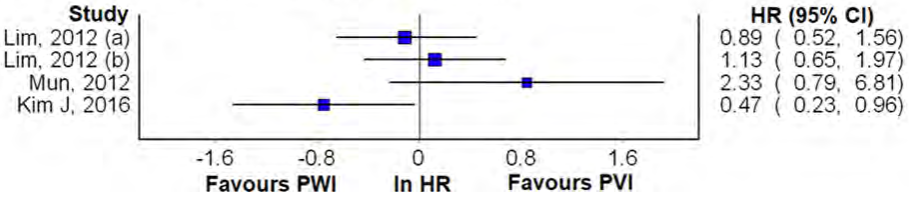
Mun 2012, Box

Kim 2015, BOX + Anterior mitral

A Summary of Studies Comparing PWI to PVI

Study	AF type	PWI Technique	Comparator	Ablation Time (mins)	Freedom from Atrial Arrhythmias
Lim, 2012	pAF / peAF	SRI SRI + MI	CPVI CPVI + MI	72.3±22.9 vs 72.4±20.9 (p=NS) 82.7±22.5 vs 86.7±21.3 (p=NS)	49% vs 46% at 2 years (p=NS) 55% vs 50% at 2 years (p=NS)
Mun, 2012	pAF	Box	CPVI	91.6±21.9vs 68.1±23.1 (p<0.001)	Recurrence rate: 19.4% vs 11.5% over 15.6±5.0 months (p=NS)
Kim J, 2015	peAF	Box + AM	CPVI+AM	128.9±37.9 vs 121.7±58.7 (p=0.42)	83.3% vs 63.3% at 12 months (p=0.02)

B Comparison of PWI vs PVI on Atrial Arrhythmia Recurrence



RCTs comparing the outcomes of endocardial posterior wall isolation to PVI on arrhythmia recurrence yielded conflicting results that could not be combined in a meaningful manner.

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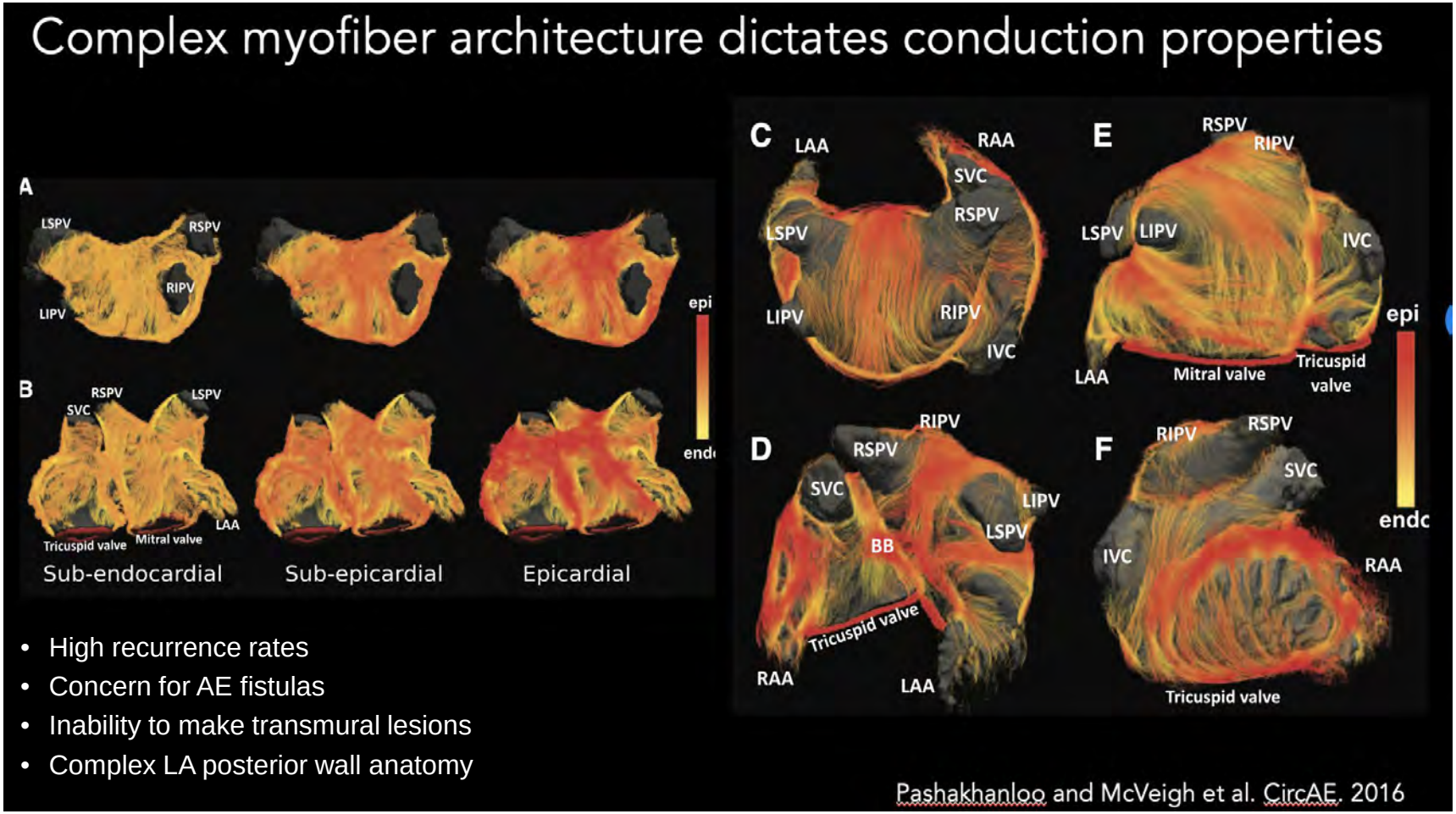
Limitations of endocardial LA PWI



- High recurrence rates
- Concern for AE fistulas
- Inability to make transmural lesions
- Complex LA posterior wall anatomy

Pashakhanloo and McVeigh et al. CircAE. 2016

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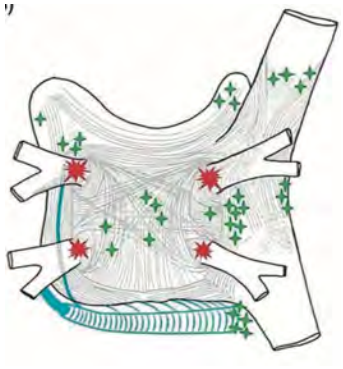
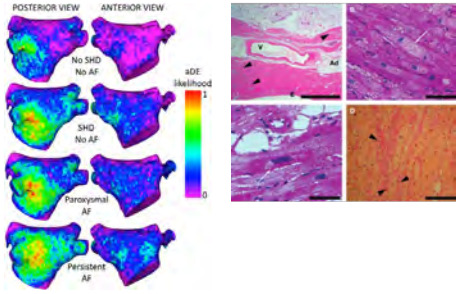
Factors Contributing to Endocardial Ablation Inconsistencies for Posterior LA in Non-PAF

Non-PV Triggers

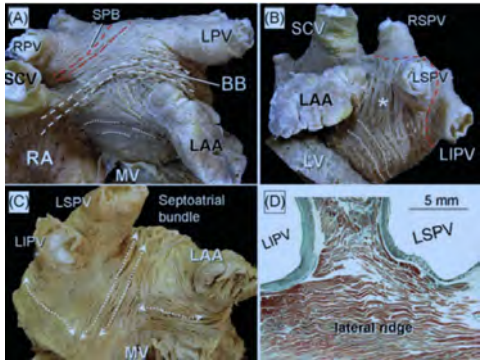


Substrate changes

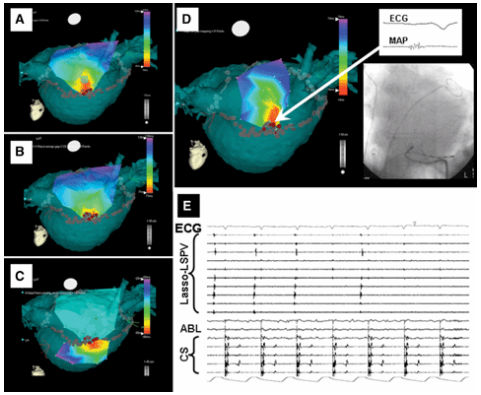


Cochet H, et al. JCE 26: 484-492, 2015

Epi/Endo Connections

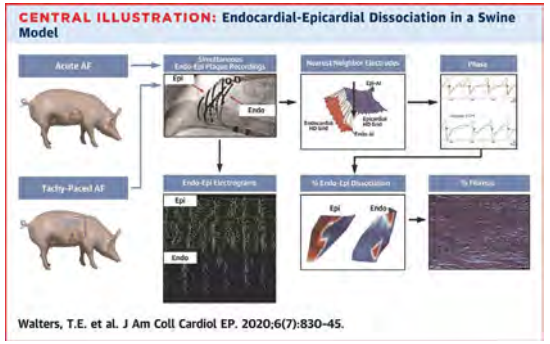


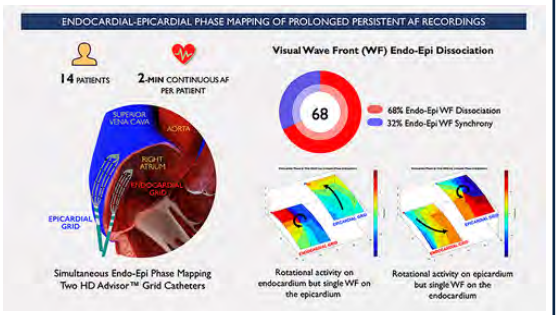
Cabrera et al. Eur Heart J. 29, 356–362, 2008



Reddy et al. JCE 19: 326-329, 2008

Epi/Endo Dissociation





Parameswaran et al. Circ AE 2020

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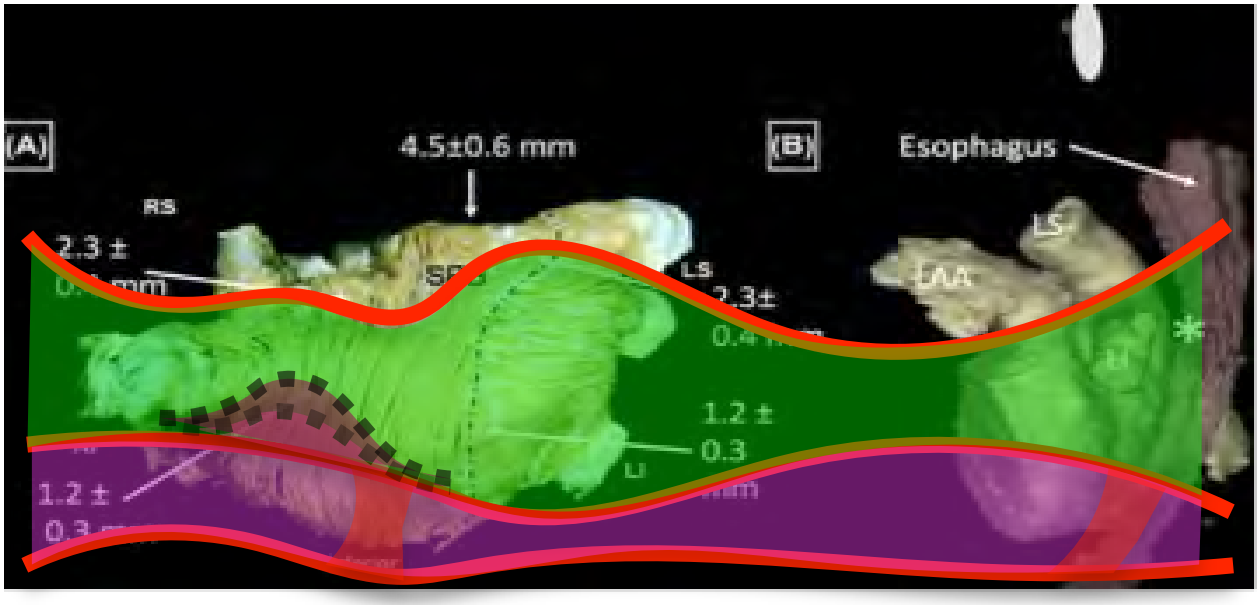
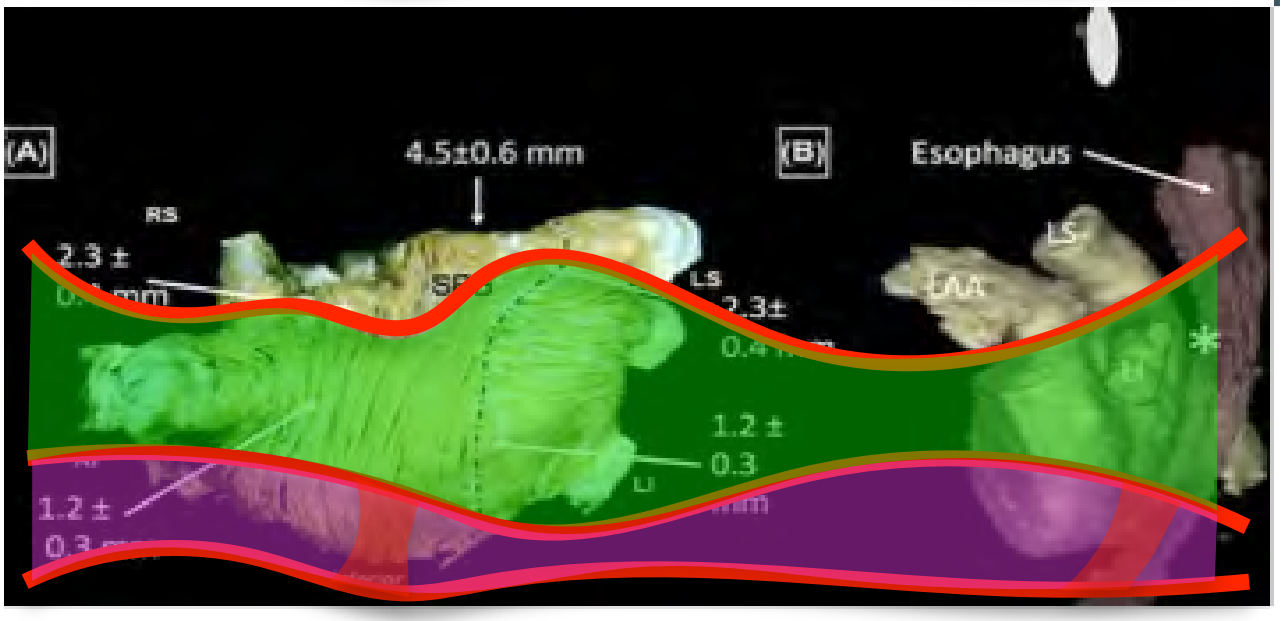
What is the True Posterior Wall?



Posterior

Infero-Posterior



Posterior

Infero-Posterior

JCardiovascElectrophysiol.2018;29:345–352.

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Conclusions:

Difficulties Associated with Endocardial Ablation of LAPW

- High recurrence rates
- Concern for AE fistulas
- Fibrosis and Fat bundles
- Unique epicardial structures impair the effectiveness of creating transmural lesions
- Dual layers
- Epi-Endo LA dissociation

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Why LAA exclusion should be part of a hybrid procedure?

Benefits of Epicardial Left Atrial Appendage (LAA) Exclusion

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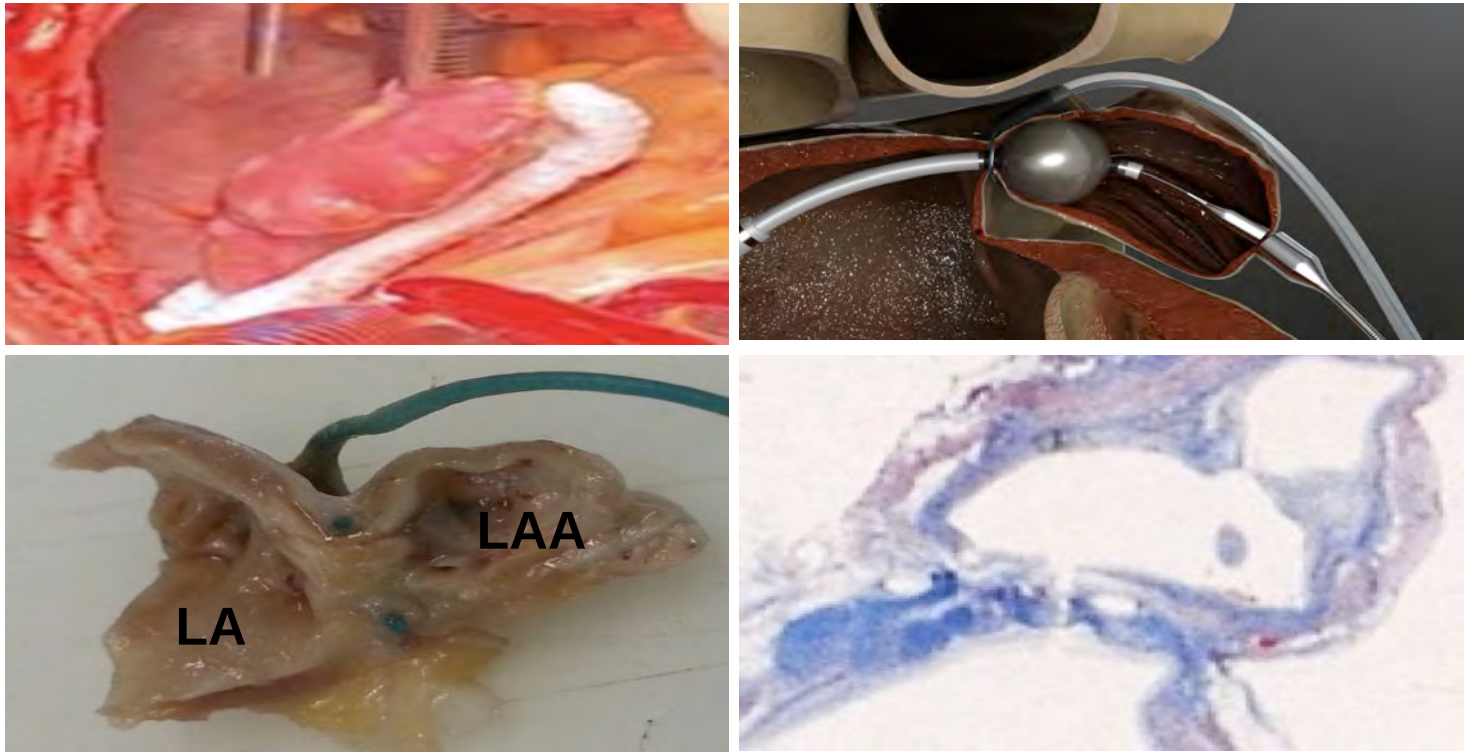
Epicardial LAA exclusion



Epicardial LAA exclusion results in an ischemic necrosis of the LAA with resorption and atrophy of the LAA

Bartus et al., Circ Arrhythmia 7:764-767, 2014

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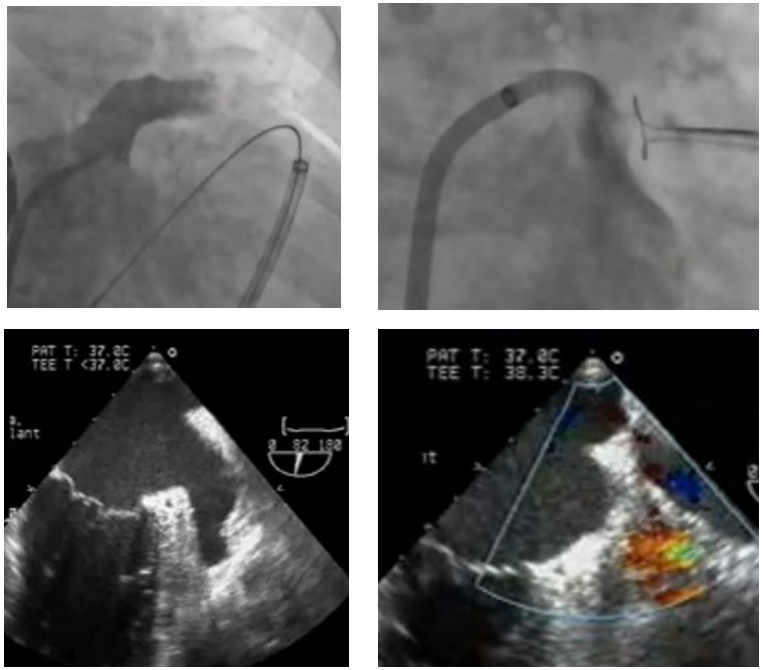
Potential Benefits of Epicardial LAA Exclusion

Eliminates LAA nidus for thrombus formation

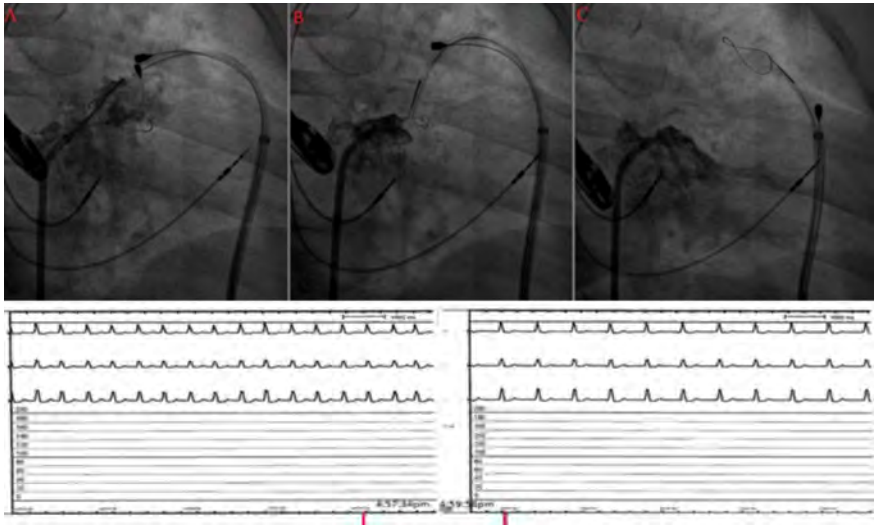


Bartus et al., JACC,2012

Anti-arrhythmic effects

- Eliminates ATs from the body of LAA distal to the ligation
- Reduces LA mass

Catheter ablation refractory AT termination by LAA suture ligation



Antoui et al., JAFIB 2015

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Left Atrial Appendage Occlusion Study (LAAOS III)

LAAO v. no LAAO in cardiac surgery patients with a history of AF

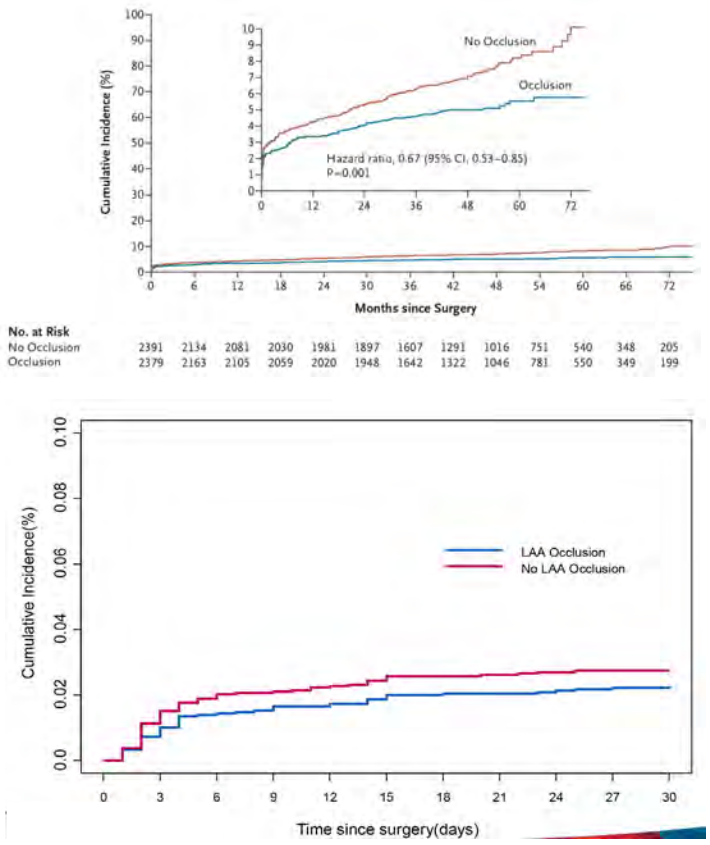
- N=4,811 patients
- 1:1 randomization
- Prospective
- Blinded at follow-up
- 3.8 years avg follow up duration

	Ischemic Stroke and Systemic Embolization		
	LAAO	No LAAO	Benefit of LAAO
3.8 years f/u overall	4.8%	7.0%	33% reduction (P=0.001)
>30 days only	2.7%	4.6%	42% reduction (HR 0.58; 95% CI)
No significant difference in: • Perioperative bleeding • Heart Failure • Death			

Conclusions:

- Surgical LAA exclusion reduces ischemic stroke by 33%
  - After the first 30 postoperative days, by 42%
- No evidence of adverse events
- The benefits are additive to oral anticoagulation


Left Atrial Appendage Occlusion during Cardiac Surgery to Prevent Stroke



LAAOS III did not compare LAAO vs OAC therapy, so surgical LAA exclusion is not a replacement for OAC therapy

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Prophylactic Left Atrial Appendance Exclusion in Patients Undergoing Cardiac Surgery: Results of the Prospective, Multi-center, Randomized ATLAS Trial

Marc W. Gerdisch, MD[1], H. Edward Garrett Jr., MD[2], Mubashir A. Mumtaz, MD[3], John Grehan, MD, PhD[4], Mario Castillo-Sang, MD[5], Jeffrey Miller, MD[6], George Zorn III, MD[7], Stanley Gall Jr., MD[8], John Johnkoski, MD[9], Basel Ramlawi MD[10]

[1]Franciscan Health Heart Center, Indianapolis, IN, [2] Cardiovascular Surgery Clinic, Memphis, TN, [3]Pinnacle Health Cardiovascular Institute, Harrisburg, PA, [4]Allina Health Clinic, St. Paul, MN, [5]The Christ Hospital, Cincinnati, OH; [6]Emory University Hospital, Atlanta, GA; [7]University of Kansas Hospital, Kansas City, KS; [8]Wellmont CVA Heart Institute, Kingsport, TN; [9]Aspirus Wausau Hospital, Wausau, WI; [10]Lankenau Heart Institute, Philadelphia, PA

BACKGROUND

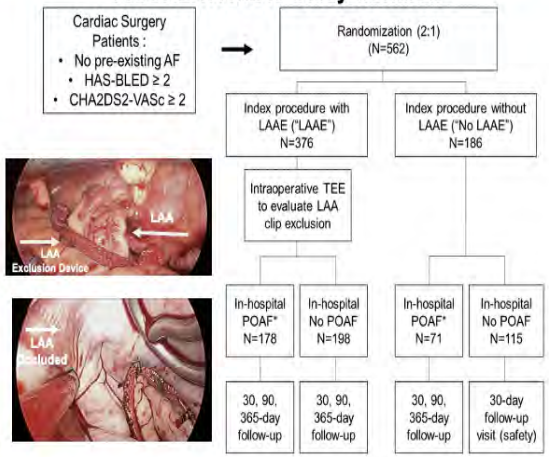
Post-operative atrial fibrillation (POAF) occurs in 30-40% of cardiac surgery patients. Routine care for POAF is variable. Oral anticoagulation (OAC) may be prescribed to prevent thromboembolic events (TEs) but has a bleeding risk. Since the left atrial appendage (LAA) is the primary site of thrombus formation with AF, prophylactic LAA exclusion (LAAE) during cardiac surgery may mitigate TE risk.

OBJECTIVE

The ATLAS prospective, randomized, multi-center feasibility trial evaluated TE and major bleeding rates with and without LAAE in cardiac surgery patients who developed POAF.

METHODS

FIGURE 1. ATLAS Study workflow



RESULTS

TABLE 1. Patient Characteristics

Parameter	LAAE (n=376)	No LAAE (N=186)	P-value
CHADS-VASc (Mean ± SD)	3.4 ± 1.18	3.14 ± 1.12	p=NS
HAS-BLED (Mean ± SD)	2.8 ± 0.68	2.9 ± 0.65	p=NS
POAF Detected, % (n/N)	47% (178/376)	38% (70/186)	P=0.047
Post-procedure OAC use	23.7% (89/376)	16.1% (30/186)	p=0.33

TABLE 2: Results of LAA Exclusion (n=376)

Successful LAAE device implantation	99.2% (373/376)[a]
LAAE success (stump ≤10 mm and no residual flow)	98.9% (366/370)[b]
Procedural Serious Adverse Event[c] (intraoperative torsion of heart)	0.3% (1/376)
Procedural Non-Serious Adverse Event[c] (post-pericardiotomy syndrome)	0.3% (1/376)
LAAE-related renal failures	0% (0/376)

[a]3 patients did not have device implantation due to inability to directly visualize the LAA, adhesion of LAA to heart, and surgeon decision due to concomitant procedure complication. [b]3 patients did not have complete TEE data available for assessment. [c]Events were resolved without sequelae.

TABLE 3. Thromboembolic events with prophylactic LAAE vs. No LAAE in high-risk patients who developed POAF after cardiac surgery through 1 year

Parameter	LAAE (N=178)	No-LAAE (N=71)
Ischemic strokes	1.7% (3)	2.8% (2)
Transient ischemic attack	0% (0)	2.8% (2)*
Peripheral ischemia	1.7% (3)	1.4% (1)
Total events	3.4%	7.0%

Percentage reflects total events/patients; p=0.40 between LAAE and no LAAE for total events

*Two events in one patient

KEY POINTS

- Intra-operative LAAE was successful in **99%**
- Procedural Serious Adverse Event rate was **0.3%**
- No significant difference in mortality between LAAE and No LAAE at 30 days and 1 year
- There was a trend towards reduced thromboembolic event with LAAE compared to no LAAE: **51% reduction** in TE rate

DISCLOSURES

To be added for MG and BR

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Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION
American Heart Association.
Learn and Live.

Left Atrial Appendage

An Underrecognized Trigger Site of Atrial Fibrillation

Luigi Di Biase, J. David Burkhardt, Prasant Mohanty, Javier Sanchez, Sanghamitra Mohanty, Rodney Horton, G. Joseph Gallinghouse, Shane M. Bailey, Jason D. Zagrodzky, … See all authors

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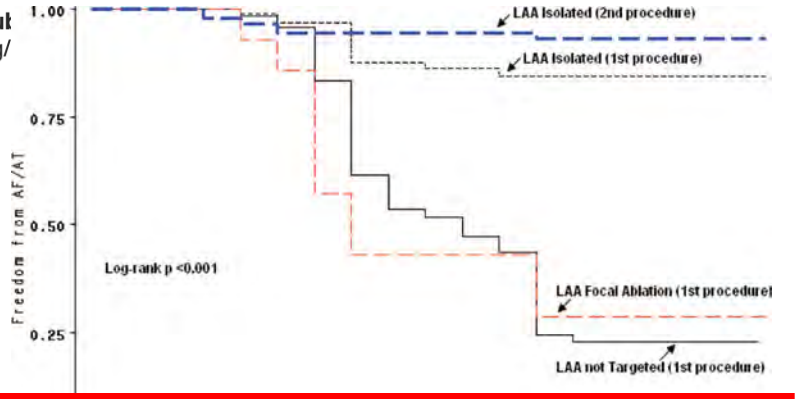
https://doi.org/



LAA Firing Observed in 27% of Redo Procedures

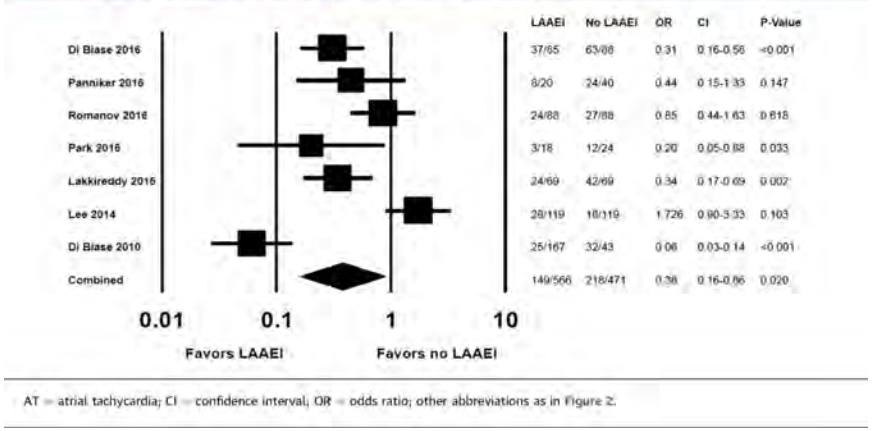
Paroxysmal AF (18%)
Persistent AF (23%)
Long Standing Persistent AF (58%)

Di Biase et al., Circulation. 2010;122:109-118

Left Atrial Appendage Electrical Isolation for Treatment of Recurrent Atrial Fibrillation

A Meta-Analysis

Daniel J. Friedman, MD,[a,b] Eric W. Black-Maier, MD,[a] Adam S. Barnett, MD,[a] Sean D. Pokorney, MD, MBA,[a,b] Sana M. Al-Khatib, MD, MHS,[a,b] Kevin P. Jackson, MD,[a] Tristram D. Bahnson, MD,[a,b] Christopher R. Ellis, MD,[c] Brett D. Atwater, MD,[a] Robert K. Lewis, MD, PhD,[a] Jonathan P. Piccini, MD, MHS[a,b]



AT = atrial tachycardia; CI = confidence interval; OR = odds ratio; other abbreviations as in Figure 2.

Freidman et al. J Am Coll Cardiol EP 2018;4:112–20

Cohort studies suggests that LAA isolation improves the outcome of AF ablation in patients undergoing redo ablation for persistent AF.

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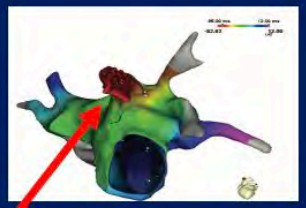
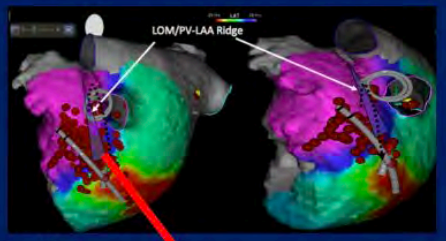
Arrhythmogenesis of LAA and Associated Structures

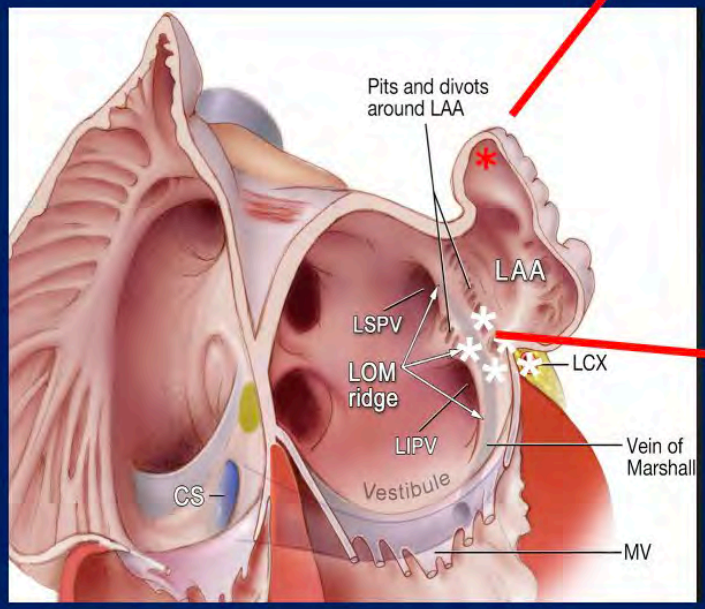
Triggers from the LAA body
2%



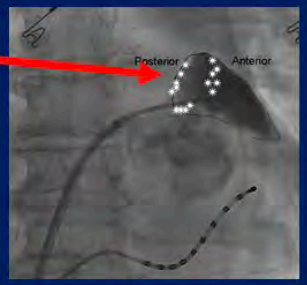


Ligament of Marshall
11%

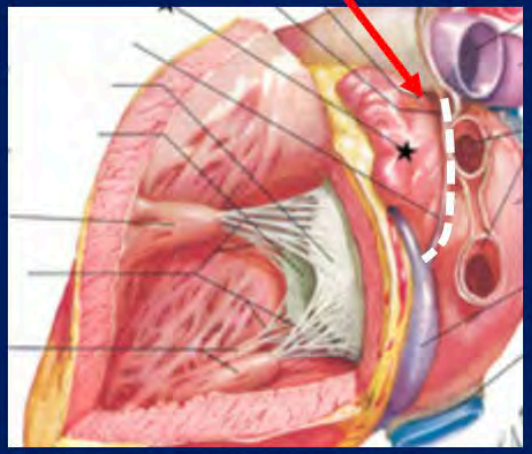
Chick et al., PACE 2014
Valderrabano et al JAMA, 2020



Triggers from the base of the LAA
27% in recurrent AF



Hocini et al. Heart Rhythm 2011



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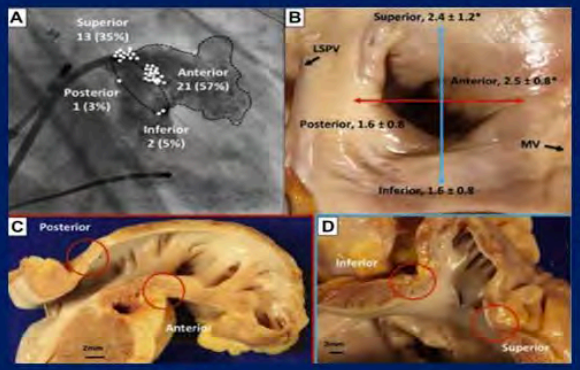
Approaches for Targeting the LAA

Cather based LAA isolation

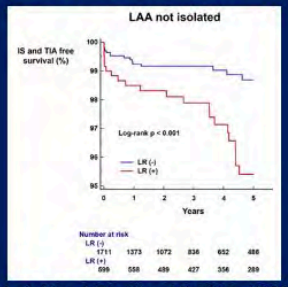


Romero et al. Heart Rhythm 15: 1577-1582, 2018

- High recurrence rate (>30%)
- LAA perforation
- Phrenic nerve injury
- Injury to L. circumflex A.
- Thrombus formation (>22%)

Rillig et al. Circ Arrhythm Electrophysiol., 2016

Ischemic Stroke/TIA



Kim et al. Heart Rhythm 15:1746–1753, 2018

Epicardial LAA exclusion

Epicardial LAA exclusion results in an ischemic necrosis of the LAA with resorption and atrophy of the LAA

Bartus et al., Circ Arrhythmia 7:764-767, 2014

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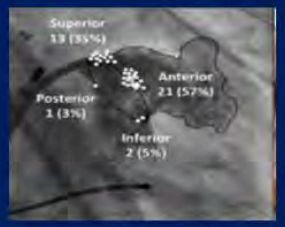
Majority of Triggers Originate from the Base of the LAA

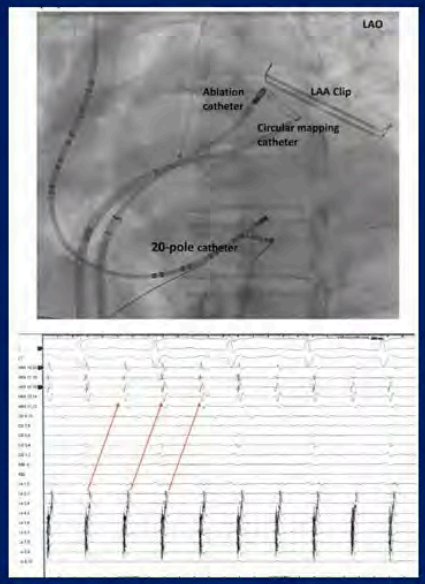
Yamada T et al. *Heart Rhythm* 2007

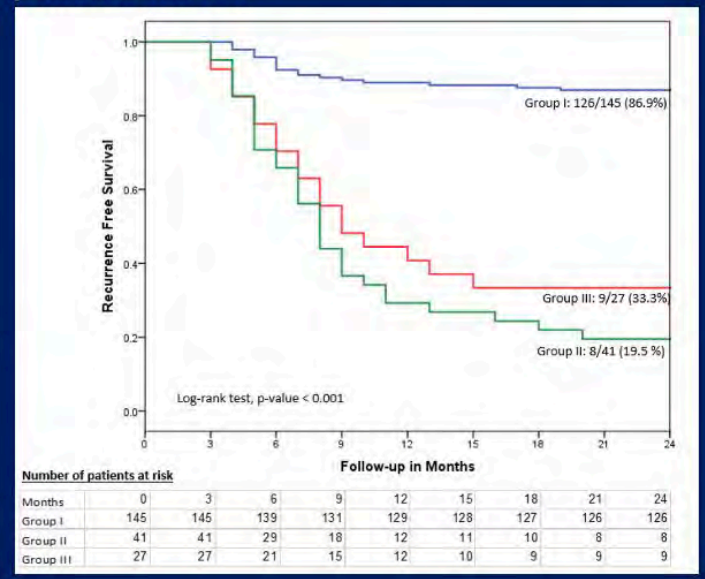
Hocini et al. Heart Rhythm 2011



Romero et al. Heart Rhythm 2018

Arrhythmogenecity and thrombogenicity of the residual left atrial appendage stump following surgical exclusion of the appendage in patients with AF





Number of patients at risk

Months	0	3	6	9	12	15	18	21	24
Group I	145	145	139	131	129	128	127	126	126
Group II	41	41	29	18	12	11	10	8	8
Group III	27	27	21	15	12	10	9	9	9

LAA stump is arrhythmogenic and electrical isolation improves clinical outcome. TE events are rare following epicardial exclusion of the LAA

Mohanty et al. JCE 2019;30:339–347.

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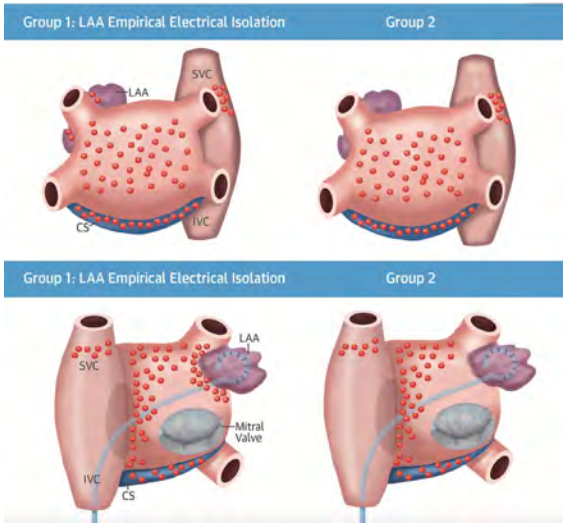
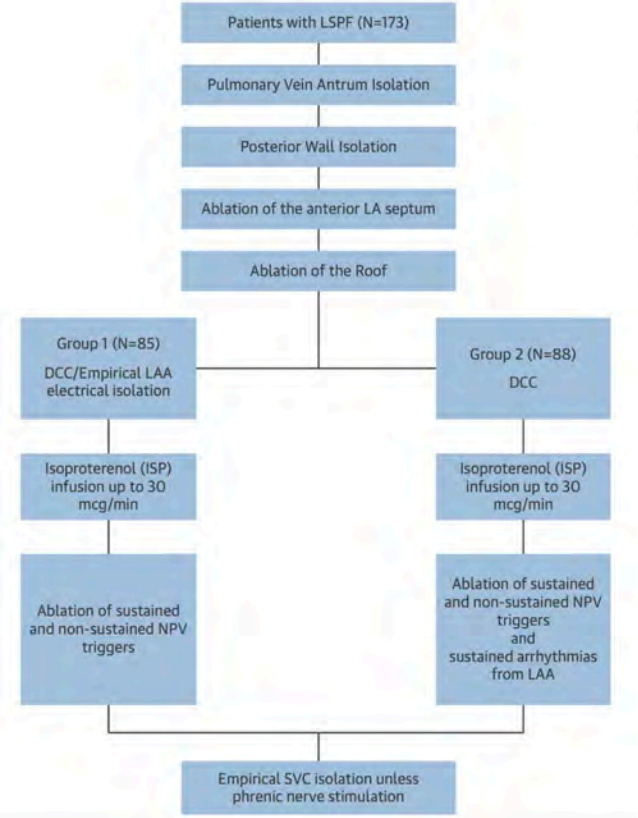
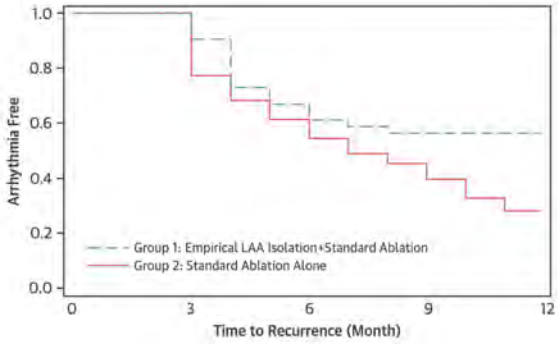
Left Atrial Appendage Isolation in Patients With Longstanding Persistent AF Undergoing Catheter Ablation

BELIEF Trial

Luigi Di Biase, MD, PhD,[a,b,c,d] J. David Burkhardt, MD,[a] Prasant Mohanty, MD,[a] Javier E. Sanchez, MD,[a] Chintan Trivedi, MD, MPH,[a] Mahmut Güneş, MD,[a] Rodney P. Horton, MD,[a] Sakis Themistoclakis, MD,[e] G. Joseph Gallinghouse, MD,[a] Jason D. Zagrodzky, MD,[a] Richard H. Hongo, MD,[f] Salwa Beheiry, MD,[a] Michela Casella, MD,[g] Antonio Dello Russo, MD,[g] Amin Al-Ahmad, MD,[a] Dhanunjaya Lakkireddy, MD,[h] Claudio Tondo, MD,[g] Andrea Natale, MD[a]







Empirical electrical isolation of the LAA improved long-term freedom from atrial arrhythmias without increasing complications.

Di Biase JACC 2026

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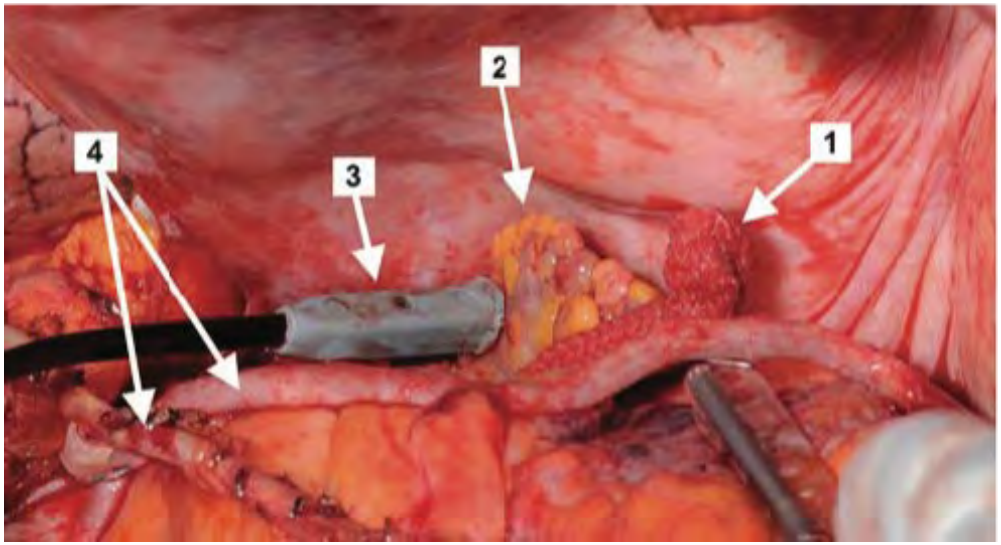
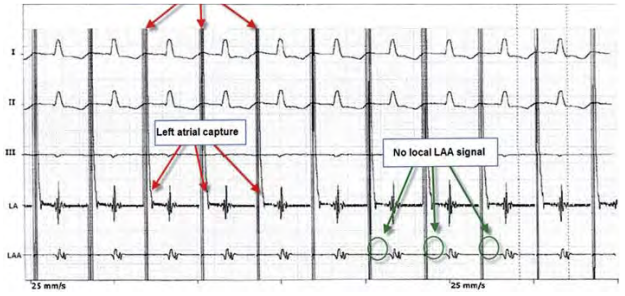
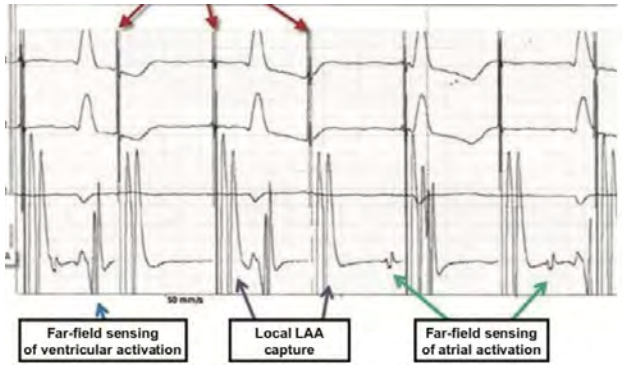
Epicardial left atrial appendage clip exclusion provides electrical isolation of the left atrial appendage



LA pacing demonstrating LAA entrance block



LAA pacing demonstrating LAA exit block



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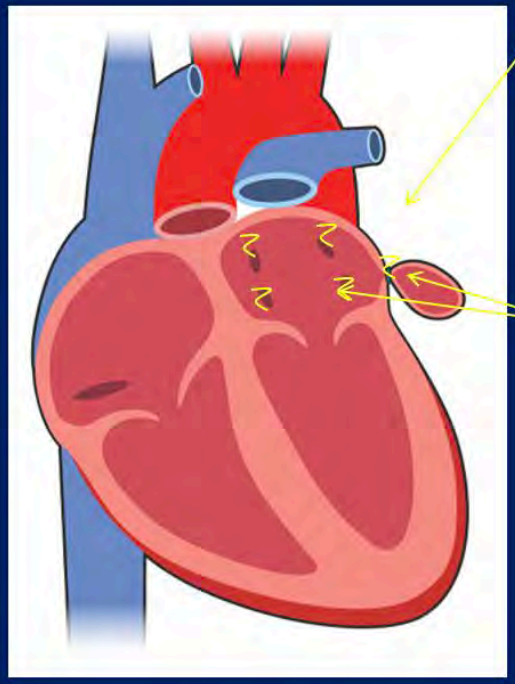
Stark et al Interact Cardiovasc Thorac Surg. 2012; 15(3): 416–8

amaze



Close the LAA

- LAA permanently disappears and no longer a source of thrombus

Electrically Isolate the LAA
LAA Debulking

Hypothesis

- The LAA is a critical structure in the maintenance of persistent and longstanding persistent AF; and LAA ligation will decrease the recurrence of AF in patients with persistent and longstanding persistent AF.

Clinicaltrials.gov Identifier: NCT02517397

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aMAZE Trial Design

Design & Patient Population

Prospective, multicenter, randomized (2:1) controlled trial (NCT#02517397)

53 active U.S. sites
610 total randomized

Symptomatic persistent and longstanding persistent AF subjects (> 7 days and < 3 years continuous AF), failed AAD therapy, planned for initial catheter ablation

Bayesian Adaptive, Superiority Design (400 – 600 subjects)

Primary endpoint analyses performed in the modified intent to treat (mITT) population
mITT: randomized subjects who undergo an attempt at the assigned procedure (LARIAT or PVAI).

Endpoints

Primary Effectiveness Endpoint
Freedom from documented atrial arrythmias (AA) at 12M post PVAI with no new or increased dosage of Class I or III AAD

AA defined as atrial fibrillation, atrial flutter or atrial tachycardia lasting > 30 seconds

Rhythm evaluation: 24-hr Holter and symptomatic event monitoring

Primary Safety Endpoint
Composite of predefined 30-day post LARIAT serious adverse events compared to a performance goal (PG)

Technical Success
Successful LARIAT placement to achieve effective LAA ligation (≤1 ± 1mm diameter residual communication)

Trial design and endpoint definitions consistent with HRS 2012 Consensus Guidelines

Trial Oversight & Monitoring

National Co-Principal Investigators
David Wilber, MD
DJ Lakkireddy, MD

Executive Committee
Oversight of trial conduct

Independent Core Laboratories
Validated rhythm monitoring outcomes and CT/TEE imaging data
Cardiovascular Research Foundation
BioTel Research (Cardiocore)

Independent CEC and DMC
Adjudicated safety events, monitored safety, performance endpoints and integrity

Clinical Research Organization
Database, data analysis, CEC and DMC
Avania

Sponsor remained **blinded** to aggregate data and results throughout the trial

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Summary of Primary Results

The LARIAT System appears to be safe, and successfully excludes the LAA in this first prospective, rigorous and independently monitored clinical trial evaluating LARIAT LAA ligation.

- 30-day post LARIAT **primary safety endpoint rate was 3.4%** (<10% PG); 95% Bayesian CI: 2.0, 5.0
- High LAA closure rates with LARIAT (85 – 99%) at 12 months post PVAI

Residual Communication (mm diameter) [1]	Post LARIAT Ligation [2]	30-Days Post LARIAT	12-Months Post PVAI
0 mm (100% Closure)	80%	75%	84%
≤ 1 ± 1 mm [3]	87%	81%	85%
≤ 3 mm	94%	89%	93%
≤ 5 mm	99%	99%	99%

- Freedom from AA at 12-months post PVAI was **64.3%** in the LARIAT + PVAI group compared to **59.9%** for PVAI only (difference of 4.3%); 95% Bayesian CI: -4.2, 13.2
- Adjunctive LAA ligation was not superior to PVAI alone in reducing recurrent atrial arrhythmias in the overall persistent AF population undergoing initial AF ablation
- Initial, pre-specified exploratory analysis suggested that in the subgroup with early persistent AF and larger LA volumes, adjunctive LAA ligation may provide improved rhythm control

Wilber LBCT AHA 2022

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Impact of Left Atrial Volume On Outcomes Of Adjunctive Left Atrial Appendage Ligation Compared To Pulmonary Vein Antral Isolation Alone

Deeper Insights From The aMAZE Trial

DJ Lakkireddy, MD, MBBS, Kansas City Heart Institute
David J. Wilber, MD, Loyola University Chicago
Randall J Lee, MD, PhD, University of California, San Francisco
For the aMAZE Trial Investigators

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May 1, 2022

Heart Rhythm Society

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Who might benefit from a hybrid procedure?

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Atrial Fibrillation Is Progressive

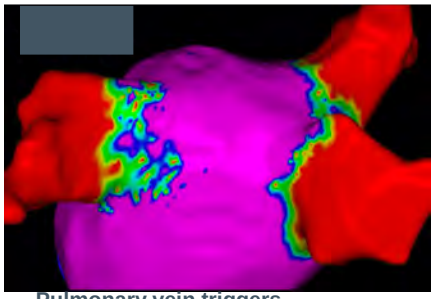
← PAF → ← Non-PAF →

Paroxsymal	Persistent	Long-standing Persistent	Permanent
< 1 week	> 1 week to < 1 year	> 1 year	Decision has been made not to pursue restoration of sinus rhythm

Non-PV Triggers
Substrate Remodeling
Sustained by Drivers

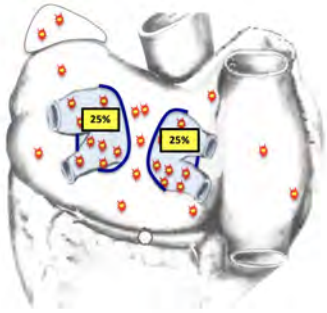
PV Triggers

PVI



Pulmonary vein triggers
Haissaguerre, *NEJM 1998*

Non-PVI



PVI
Isolates
< 50% of
Triggers

PVI
Interrupts
0% of
Drivers

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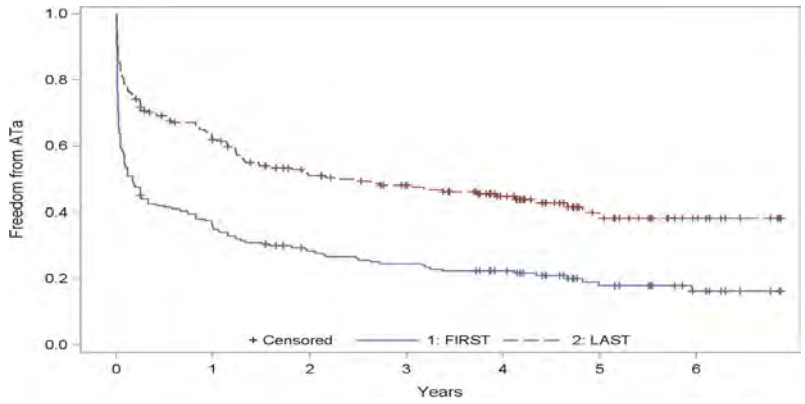
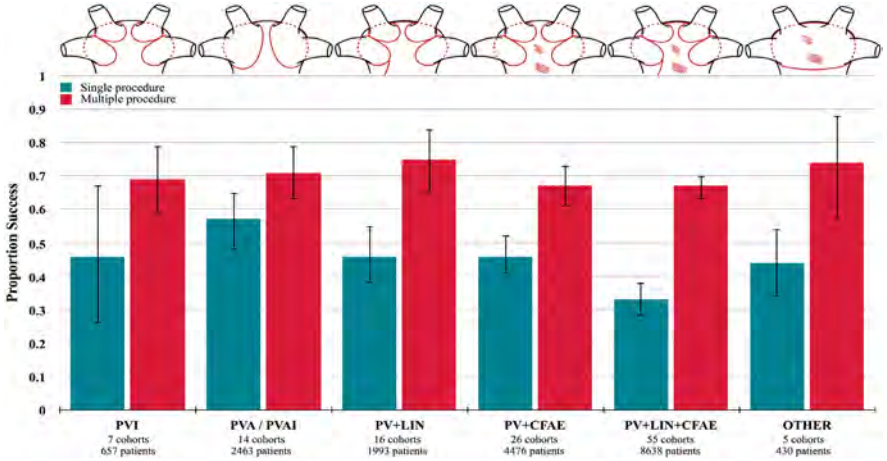
Advanced AF: Not easily addressed by endocardial ablation alone

Catheter ablation of long-standing persistent atrial fibrillation: 5-year outcomes of the Hamburg Sequential Ablation Strategy



12-mo single-procedure success : 35.6%

Outcomes of persistent and long-standing persistent atrial fibrillation ablation: a systematic review and meta-analysis



Single-procedure success : 43% (95% CI; 39–47%)

Lack of a standardized lesion set, challenges of achieving transmural lesions, and the phenomenon of endocardial-epicardial dissociation in AF together contribute to limited effectiveness of endocardial ablation alone

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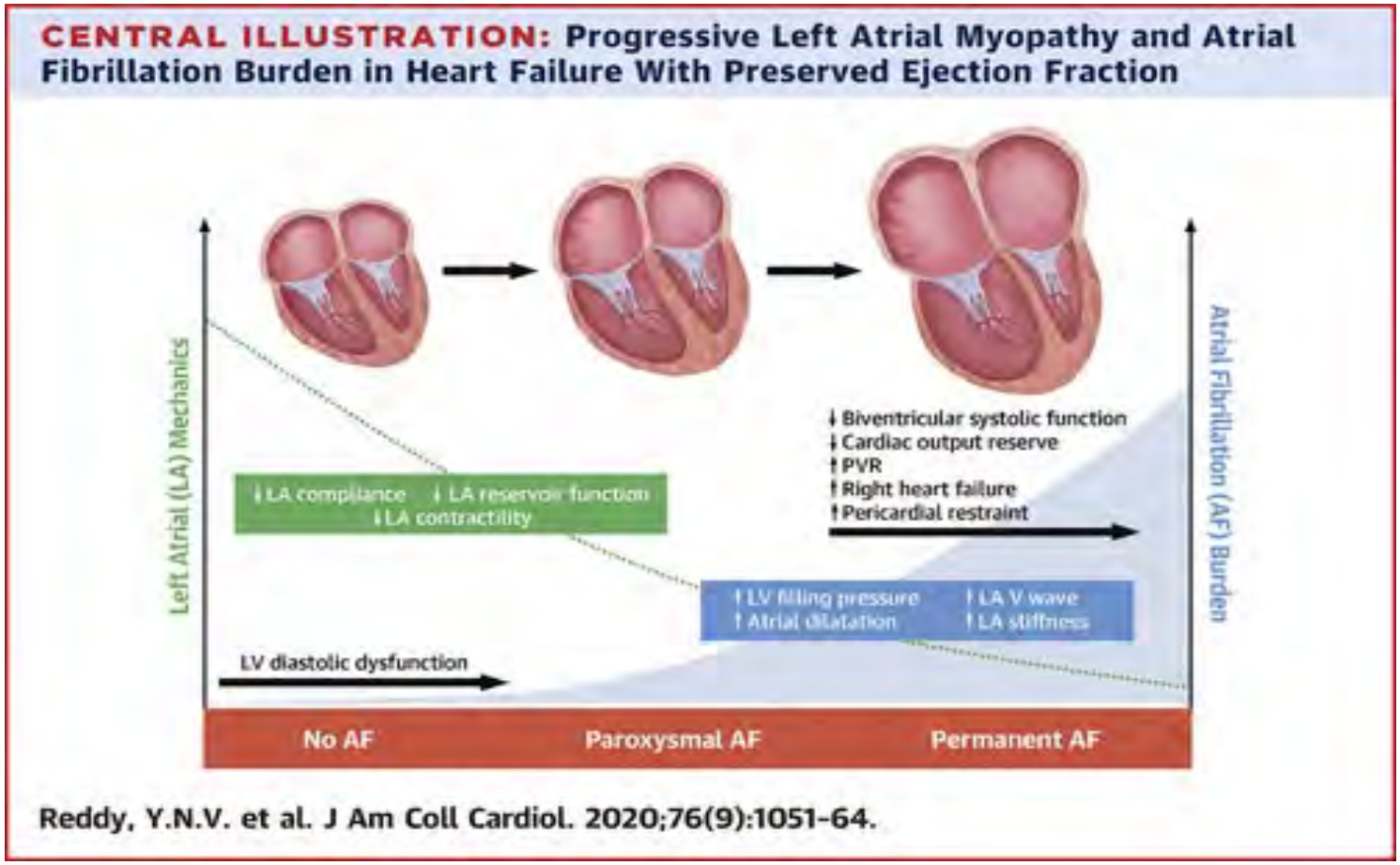
Tilz et al JACC 2012

Progression of AF



JACC
JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY

Yogesh N.V. Reddy et al. J Am Coll Cardiol 2020; 76:1051-1064.

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Potential patients who would benefit from a hybrid procedure with LAAM

- Non-paroxysmal patients
- PVI refractory patients
- Patients with large LA size
- Symptomatic AF patients with history of LAA thrombus or intolerant to long-term OAC therapy

VI. EPi-Sense™ Guided Coagulation

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EPi-Sense Guided Coagulation

First and Only FDA PMA Approved Minimally Invasive Catheter Ablation Therapy for Long-Standing Persistent AF Patients

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EPi-Sense Indication of Use

US Indication: The EPi-Sense Guided Coagulation System is intended for the treatment of symptomatic long-standing persistent atrial fibrillation (continuous atrial fibrillation greater than 12 months duration) when augmented in a hybrid procedure with an endocardial catheter listed in the instructions for use, in patients:

- Are refractory or intolerant to at least one Class I and/or III antiarrhythmic drug (AAD); and
- The expected benefit from rhythm control outweighs the potential known risks associated with a hybrid procedure such as delayed post-procedure inflammatory pericardial effusions.

EU Indication: The EPi-Sense ® Guided Coagulation System with VisiTrax® is intended for the coagulation of cardiac tissue using Radiofrequency (RF) energy during cardiac surgery for the treatment of arrhythmias including Atrial Fibrillation (AFIB) or Atrial Flutter (AFL)

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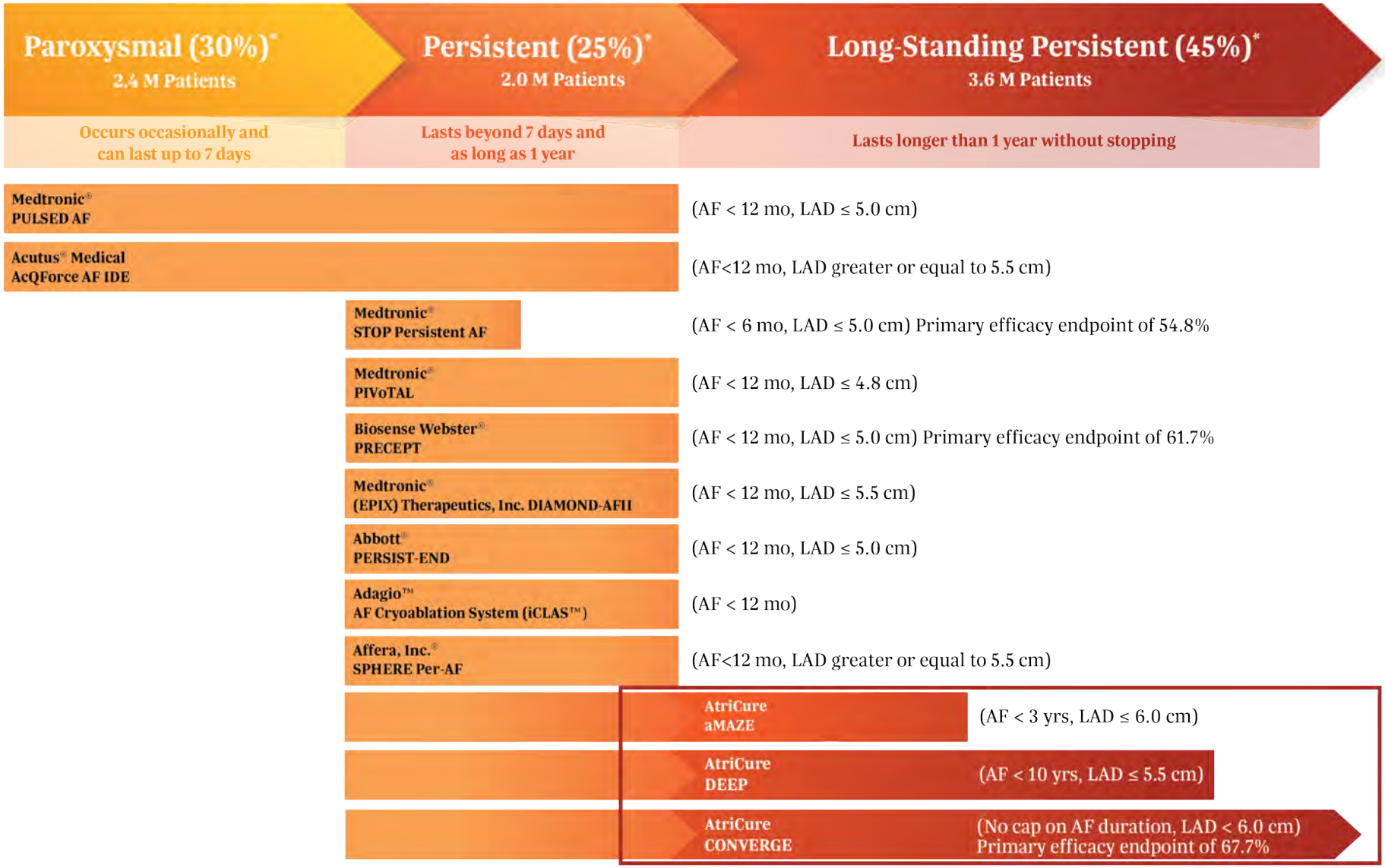
Persistent / Long-Standing Persistent AF Clinical Trial Patient Landscape



*Percentages reflect the percentage of diagnosed AF patients in each disease stage in the AF Progression

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How relevant is the data?

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CONVERGE Trial

Hybrid Convergent Procedure Vs Endocardial Catheter Ablation for the Treatment of Drug Refractory Persistent and Longstanding Persistent AF (CONVERGE Trial)

PROSPECTIVE RANDOMIZED CONTROLLED MULTICENTER TRIAL

27

US & UK Sites

153

Patients with drug refractory symptomatic persistent and longstanding persistent AF

LESION SET

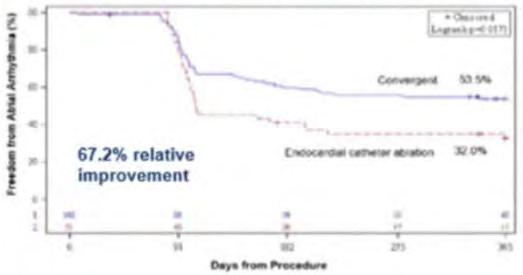
HYBRID CONVERGENT arm

2:1 randomization

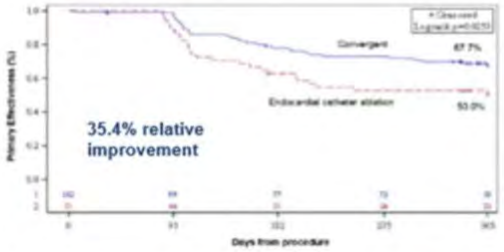
Endocardial catheter ablation arm

OUTCOMES THROUGH 12 MONTHS

21.5 % absolute improvement (P = 0.013) – Off AADs



17.7% absolute improvement (P = 0.036) off new/increased dose of failed AADs



Safety rate of 2.9% through 7days & 7.8% through 30 days

DeLurgio et al, *Circ Arrhythm Electrophysiol.* 2020

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Baseline Characteristics and Procedural Parameters LSP Patients

Parameter	Hybrid Convergent (N=38)	Endocardial Ablation alone (N=27)
Age (mean)	61.5 yrs	65.2 yrs
Male	82%	56%
BMI	32.7	35.4
Left atrial size (mean)	4.5 cm	4.3 cm
AF duration (mean)	6.0 yrs	5.9 yrs
Patients with cardioversion within previous 12 months	53%	59%
Epicardial ablation time (mean)	77 minutes	Not applicable
Endocardial ablation time (mean)	140 minutes	180 minutes

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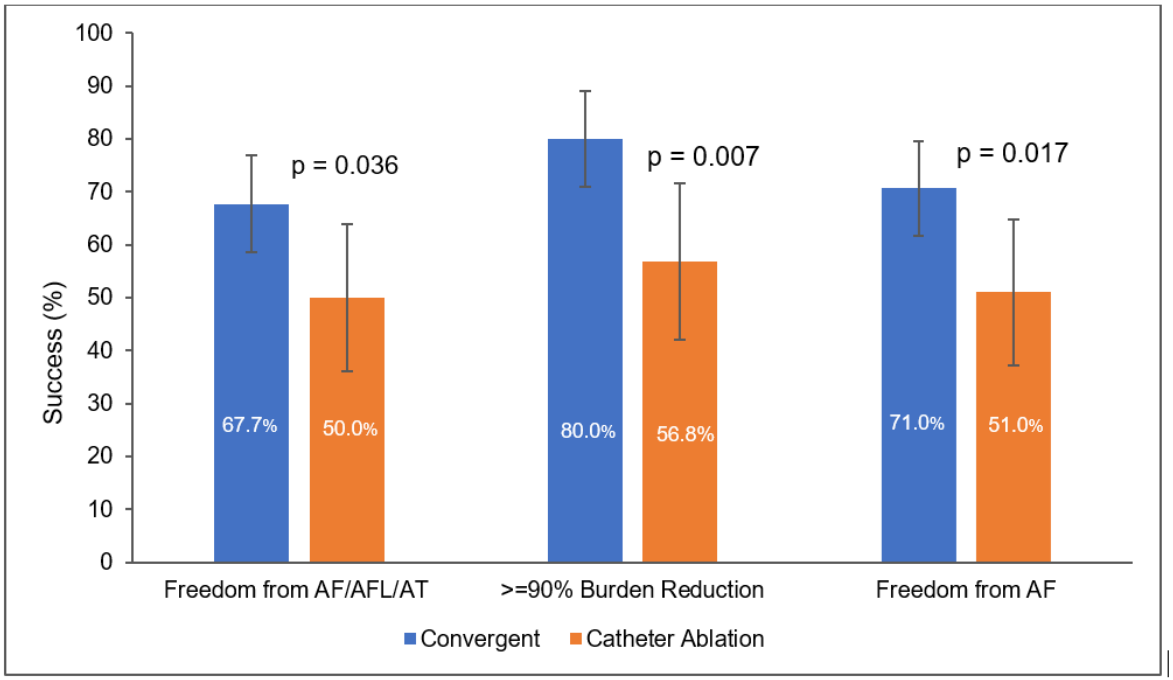
Primary and Secondary Effectiveness



Chi-squared p values

The superiority of the Hybrid Convergent procedure over Catheter ablation in achieving
a) ≥90% reduction in AF burden relative to baseline
b) Freedom from AF at 12 months was demonstrated

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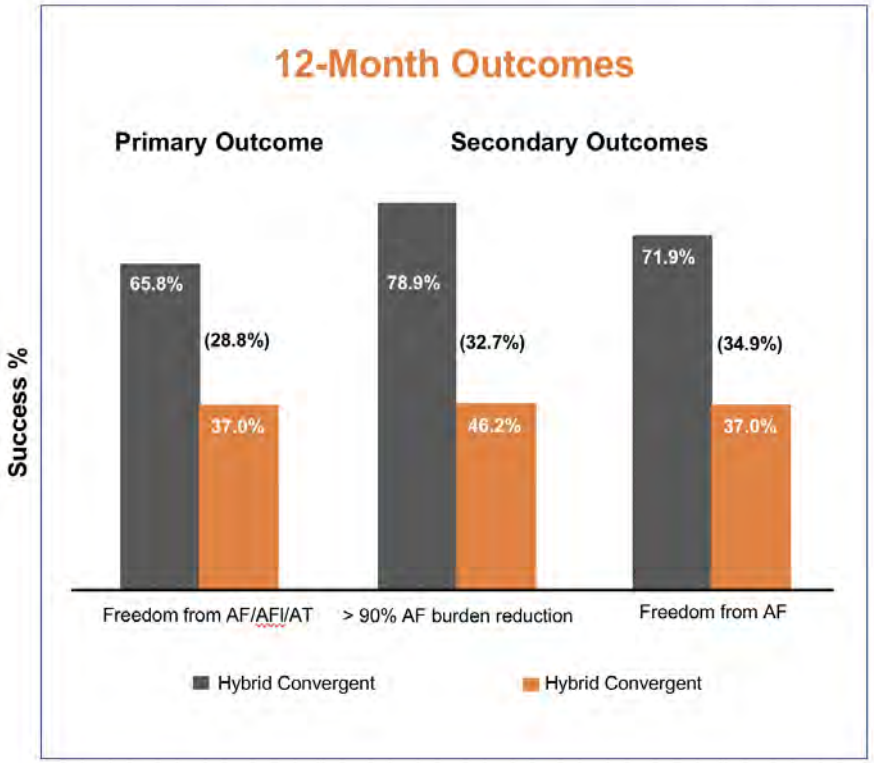
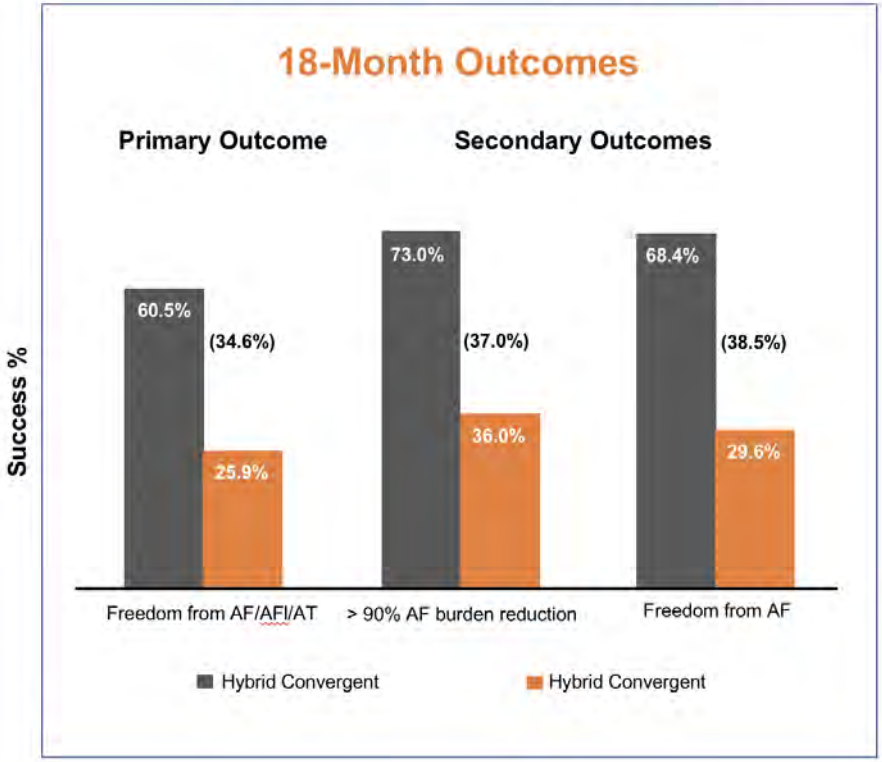
CONVERGE IDE Trial Results
LSP Patients

Long-Standing Persistent Outcomes



Long-Standing Persistent Outcomes



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Hybrid AF CONVERGE IDE: Outcomes
Primary Safety Data Summary

7 DAYS

Not Pre-Specified by Protocol in Line with Endocardial Studies

2.9%

30 DAYS

Pre-Specified CONVERGE Protocol

7.8%

CONVERGE Safety Events (Full Cohort):

No Deaths | No Cardiac Perforation | No AE Fistula

Safety Events:

- 1 Stroke (slightly slower left facial movement, did not have debilitating effect)
- 1 Phrenic nerve injury (PNI), resolved
- 1 Bleed
- 1 Bleed with late pericardial effusion
- 1 Transient ischemic attack (TIA)
- 4 Cardiac Tamponade

7-day safety rate is in-line with the rates reported with the endocardial catheters. Delayed pericardial effusion were due to inflammatory response, occurred between 1-3 wks post procedure and were treated successfully with timely recognition.

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IFU for EPi-Sense® Guided Coagulation System Data: PMA# P200002

Real World Data: Published Literature

Reference	Sample Size	Population	AF Duration	Previous catheter ablation	LA Diameter
Makati 2020 (TRAC-AF Registry)	226	PersAF & LSPersAF	5.08 ± 6.20	Not available	Not available
Larson 2020	113	PersAF & LSPersAF	5.1 ± 4.6 yrs	45%	4.8 ± 0.7
Maclean 2020	43	100 % LSPers AF	3.0 ± 2.5 yrs	34.8%	4.74 ± 0.63
Gulkarov 2019	31	PersAF and LSPers AF	2.0 yrs (Range: 0.8 – 4.0)	19.3%	4.3

Published literature on 413 patients with advanced AF i.e. long duration, larger left atrium was reviewed.

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1. Circ Arrhythm Electrophysiol. 2020 2. Circ Arrhythm Electrophysiol. 2020 3. Cardiovasc Electrophysiol. 2020 4. J Card Surg. 2019

Real World Data: Effectiveness Outcomes LSP AF Patients

Parameter	Sample size	Duration of follow up	Method of Monitoring	Effectiveness absent new AADs	Effectiveness regardless of AAD use
Makati 2020	109	16.8 ± 6.3 months	Implantable devices & ECGs	70%	Not reported
Maclean 2020 – Hybrid Convergent arm	43	12 months	72-hour holter at 3mo, 6mo and 12 mo	Not reported	60.5%
Maclean 2020 – Endocardial Ablation arm	43	12 months		Not reported	25.6% (p=0.002) **

Published literature demonstrates Hybrid Convergent procedure is effective and the results are consistent with the CONVERGE RCT results

***P-values for the difference in success rates between Hybrid Convergent and Catheter ablation.*

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Real World Data: Safety Rates

Study	Sample size (Safety rate)	AEF	Cardiac Perf.	Death	Pericardial Effusion	Severe PVS	Excessive Bleeding	MI	Stroke	TIA	Phrenic Nerve Injury
Makati 2020	226 (5.3%)	0	0	0	6 (2.6%)	0	3 (1.3%)	0	1[+++] (0.4%)	0	2 (0.9%)
Maclean 2020	43 (6.9%)	0	0	0	2 (4.6%)	0	0	0	0	0	1 (2.4%)
Gulkarov 2020	31 (12.9%)	0	0	0	2 (6.4%)	0	0	0	2[+] (6.4%)	0	0
Larson 2020	113 (4.4%)	0	0	0	3 (2.6%)	0	2[++] (1.7%)	0	0	0	0
Total	**413 (5.8%)**	**0**	**0**	**0**	**13 (3.1%)**	**0**	**5 (1.2%)**	**0**	**3 (0.7%)**	**0**	**3 (0.7%)**

Safety rate was 5.8% in 413 patients : No AEF, Cardiac Perforation or Death.

AEF: Atriesophageal fistula, PE: Pericardial effusions, PVS: Pulmonary Vein Stenosis, MI: Myocardial Infarction
[+] Minor CV accidents which resolved without any residual deficit
[++] One instance of right ventricular injury while device introduction requiring surgical repair. One instance of LAA injury with surgical repair
[+++] History of stroke, sleep apnea, BMI 39 and CHADS2 VASc score of 4.
The following other complications were reported but were not part of CONVERGE MAE list
**Vascular complication, volume overload, transient renal failure,*
***Inferior vena cava rupture requiring sternotomy*
**** Vascular complications (arteriovenous fistula), incisional hernia, liver injury, minor bleeding from abrasion treated intraoperatively.*

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Safety Rate Comparison
Hybrid AF ablation and Endocardial RF Catheter Only

Study	AEF	Death	Pericardial Effusion/ Tamponade	Severe PV Stenosis	Excessive Bleeding	Stroke / TIA	Phrenic Nerve Injury
Hybrid Convergent Procedure	0%	0%	3.1%	0%	1.2%	0.7%	0.7%
Endocardial RF Catheter Only**	0.02% - 0.11%	<0.1% - 0.4%	0.2% - 5%	<1%	0.2% - 1.5%*	0% - 2%	0% - 0.4%

Reported events were inline with incidence of complication with the AF ablation.

*AEF: Atriesophageal fistula, PE: Pericardial effusions, PVS: Pulmonary Vein Stenosis, MI: Myocardial Infarction *Vascular complication*
*** 2017 HRS Expert Consensus on Catheter and Surgical Ablation of Atrial Fibrillation*

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Conclusion

- First multicenter, randomized controlled clinical trial comparing the effectiveness of combined epicardial and endocardial ablation to endocardial catheter ablation alone for the treatment of persistent and longstanding persistent AF patients.
- The study demonstrates that the Hybrid Convergent procedure has an acceptable safety profile and superior effectiveness when compared to endocardial catheter ablation alone for the treatment of persistent AF.
- The study provides high-quality evidence supporting the addition of a transmural posterior wall ablation to pulmonary vein isolation.
- Lastly, the study emphasizes the value of a team-based approach where collaboration between the electrophysiologists and cardiac surgeons helps achieve improved outcomes for patients with persistent AF

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VII Hybrid AF Convergent Therapy

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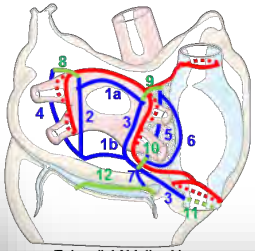
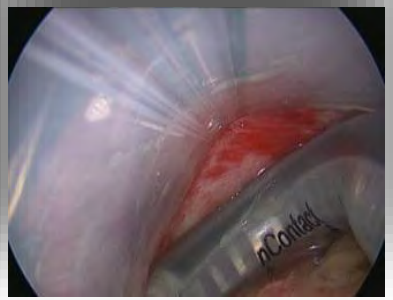
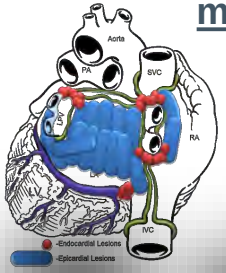
Evolution of Convergent Approach
Simplified & Standardized Epicardial & Endocardial Ablation

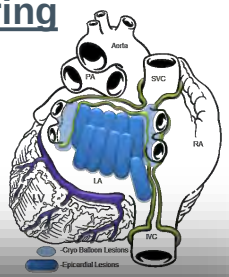
Hybrid EX-MAZE (2009 - 2011)
Box Posterior LA
Electrode Curved Along Guidewire



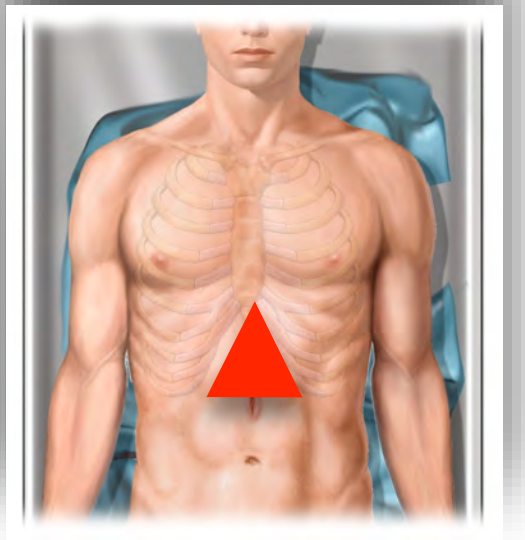


CONVERGE (2012 –2016)
Transdiaphragmatic Posterior Ablation
wire free EpiSense with **EGM monitoring**





CONVERGE (2016-Present)
Sub Xiphoid Posterior Ablation
Electrode Kept in Straight Configuration



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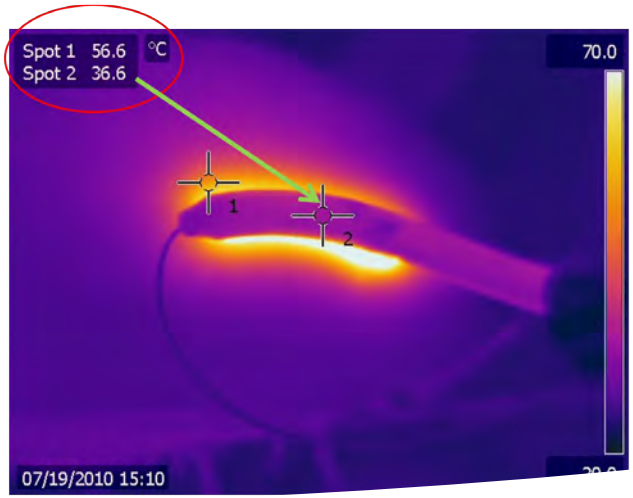
EPi-Sense Catheter



- **Contact**: Suction allows for consistent tissue contact
- **Electrode**: the continuous coiled electrode allows for power distribution along the length leveraging “the path of least resistance” analogy until there is a uniform ablation
- **Power Delivery Algorithm**: not a dose delivery .... adaptive power responding to impedance changes
- **Safety**
  - Controlled Irrigation - assured the ablation pod remains cooled
  - Algorithm - limits power to minimize risk of over delivery of RF energy
  - Direct Visualization

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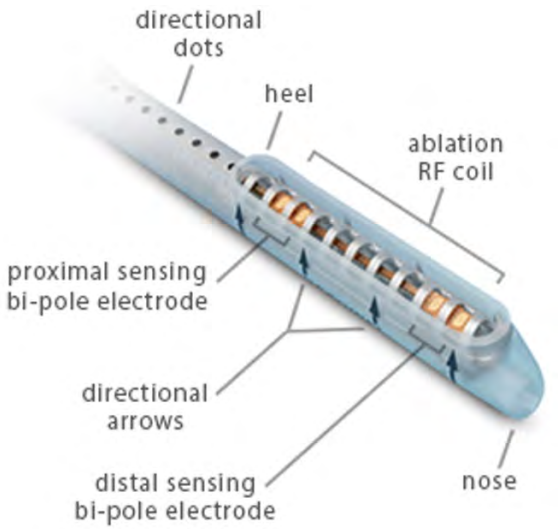
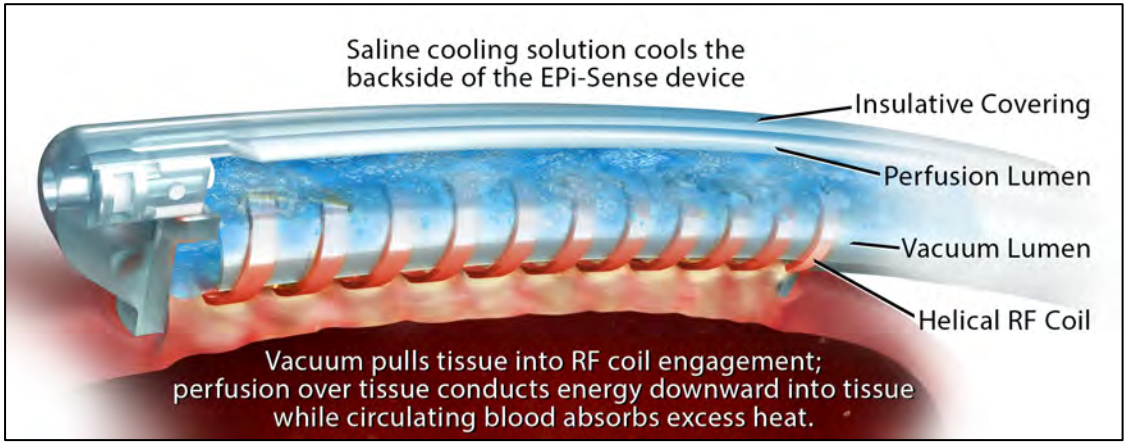
Consistent Tissue Contact with Consistent Energy Delivery Produces Reliable & Robust Lesions





- Integration of vacuum, perfusion, irrigation, and RF energy combine for robust lesions
- Vacuum creates consistent tissue contact to RF coil
- Perfusion cools device during energy delivery
- Directionality & irrigation prevent collateral damage
- Low profile enables endoscopic delivery

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Image Source: AtriCure Image Database

EPi-Sense Catheter

Arrows and black line indicate proper placement of ablation electrodes against cardiac tissue

Epi-Sense suction applied to the right atrium (seen from the endocardial side in a porcine model).

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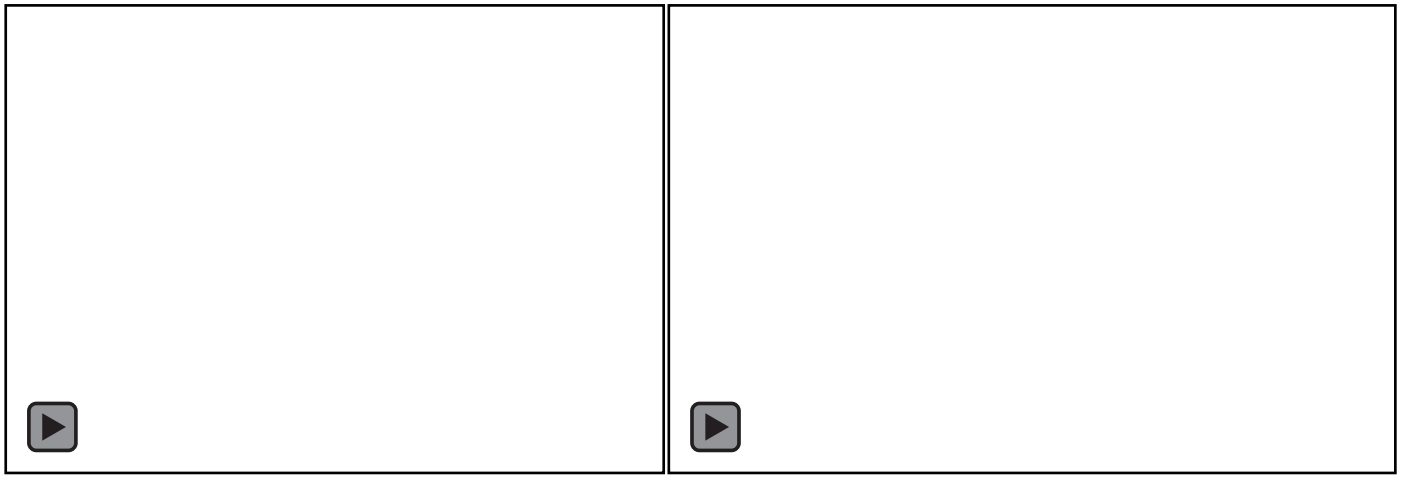
TEE:
Identifying Potential Thrombus in LAA



No Thrombus

Thrombus

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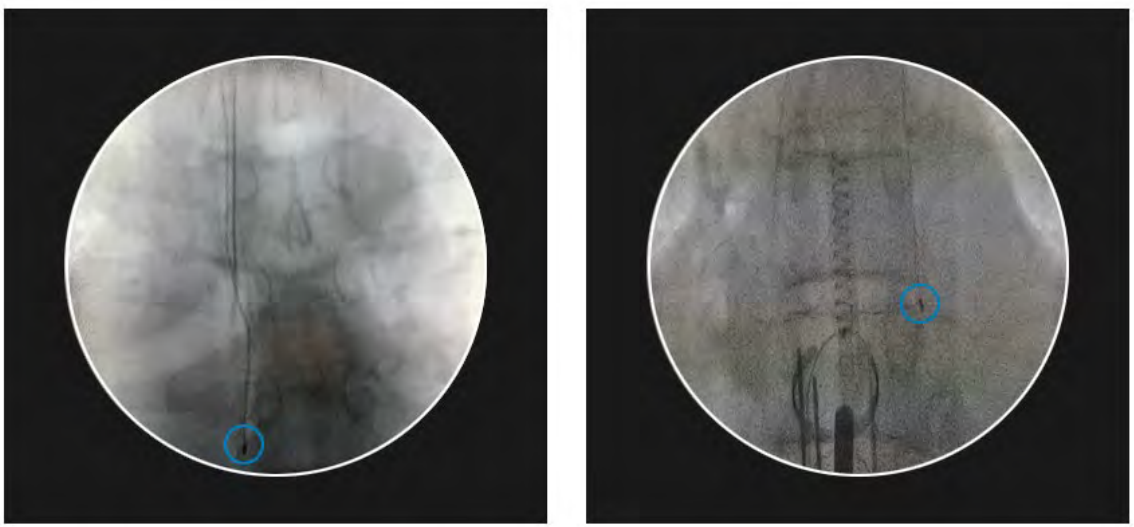
Video Source: AtriCure Multimedia Database

Esophageal Temperature Probe: Placement, Verification & Monitoring



Option One

Temp Probe Placed approximately 2 vertebral bodies below Carina and adjust to patient anatomy

Option Two

Temp Probe Placed at level of the Catheter & Cannula

Temperature in the esophagus should be measured throughout the ablation procedure.

- Fluoroscopy should be used to position the esophageal temperature probe behind the heart and adjacent to the left atrium.
- If esophageal temperature exceeds 38°C, or more than 0.5°C from the baseline temperature, RF energy delivery should be discontinued until the esophageal temperature returns to baseline.
- Saline (room temperature) should be injected through the cannula to reduce temperature in the pericardial space prophylactically and upon observation of esophageal temperature rise.

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Image Source: AtriCure Image Database

Anticoagulation regiment:

Prior to Ablation

- **Anticoagualtion therapy:**
  - If patient is on NOAC/DOAC, consider stopping 24-48 hours prior to procedure
  - If patient is on Warfarin, stop as per your protocol and bridge with Lovenox
  - If the decision is to stop all AC therapy more than 48 hours prior to procedure, consider bridging with Lovenox

During Ablation

- **Anticoagualtion therapy:**
  - Bolus and/or heparin drip to maintain ACT >250
  - Restart OAC therapy 4-6 hours after completion of epicardial ablation

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Important Considerations

- Be aware of Coronary Sinus (CS)
  - Do not ablate CS
  - Leave 1cm to 2cm buffer around CS

- Cardiac tissue ablation techniques
  - Most common is two rows (Superior & Inferior)
  - 50% overlap between Superior & Inferior rows
  - Revisit for gaps identified by visualization and/or sensing

- Pericardial reflections
  - Revisit & re-ablate Roof/Dome after completing Superior row
  - Pericardium will stretch allowing for better access of catheter

- EPi-Sense electrogram utilization
  - Sensing can identify gaps for re-ablation

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Real-Life Scenarios & Troubleshooting

- Hemodynamic changes
- Anterior left-atrium catheter placement
- Epicardial fat pads
- Power delivery: consider re-ablating low-power lesions
- Impedance changes: ideally a minimum 10%
- Suction fails
- Esophageal temp probe spikes
- Anatomical abnormalities – Spine, Vascular, & etc.
- Drain placement & incision closure
- Additional anatomical ablation targets (optional)
- Left atrial appendage management (optional)

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VIII. Peri-operative and Post-procedural Considerations

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Contraindications

- The EPi-Sense Guided Coagulation System is contraindicated for use in:
  - Patients with presence of left atrial thrombus
  - A systemic infection, active endocarditis, or another infection local to the surgical site at the time of surgery
  - Patients with Barrett's Esophagitis

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Procedural Precautions

Precautionary measures should be taken prior to considering treatment of patients:

- Deemed to be high risk and who may not tolerate a potential delayed post-procedure inflammatory pericardial effusion
- Who may not be compliant with needed follow-ups to identify potential safety risks
- Ensure patients undergoing treatment are well informed of the benefits, potential risks and procedural outcomes associated with the EPi-Sense Hybrid Convergent procedure. Physicians should document accordingly in the medical record.

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Key Risk Mitigation Areas

AE Fistula

Stroke

Postoperative Pericarditis

Delayed Pericardial Effusions

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Updated Warnings in US IFU

- Physicians should implement a comprehensive anti-coagulation protocol including pre-operative, intra-operative and post-operative anticoagulation management to prevent potential thrombo-emboli
- Physicians should use esophageal temperature monitoring as was conducted during the clinical investigation of the device to monitor for potential collateral tissue damage. Throughout the procedure ensure the probe is located directly behind the ablation probe to ensure an accurate reading
- Care should be taken to fill cannula with room temperature saline during ablation to avoid collateral tissue damage
- Care should be taken to ensure device is perfused during ablation to avoid unintentional tissue damage
- Physicians should consider post-operative anti-inflammatory medication to decrease the potential for post-operative pericarditis and/or delayed post-procedure inflammatory pericardial effusions
- Physicians should obtain post-procedural imaging (i.e1-3 weeks post-procedure) for detection of post-procedure inflammatory pericardial effusions

*** Changes pending EU MDR approval**

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Avoidance of AE Fistulas: Epicardial Lesion Creation

- Esophageal temperature monitoring should be utilized during epicardial and endocardial ablation. If esophageal temperature increases more than 0.5ºC during each ablation or above an absolute maximum of 38.0ºC, RF energy should be terminated until temperature reduces to baseline or under 37ºC

- Prior to creating any lesions, retract the TEE probe (if used) and the NG/OG tube (if used) to the upper third of the esophagus; between 18 – 23 cm from the incisors. At a minimum, retract the TEE probe relative to the esophagus, so that the probe is not near the atrium.

- Retract the cannula until the sensing and coagulation electrodes are distal to the cannula tip and in contact with the left atrium. This will allow the heart to better sit against the device.

- Always ensure proper orientation of the exposed ablation coil electrode under endoscopic visualization, utilizing the directional arrows and black stripe on back of device to confirm contact with atrial tissue only.

- Fill cannula with approximately 10 to 20 mL of room temperature saline. Saline may be administered via the cannula stopcock or directly through the cannula. See Cannula IFU for stopcock set-up.

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Acute vs. Delayed Pericardial Effusion

Parameter	Acute Pericardial Effusions (PEs) (Catheter Ablation)	Delayed Inflammatory PEs (Hybrid Ablation)
Type of Event	Immediate pericardial effusion Acute periprocedural injury to cardiac structure	Delayed pericardial effusion i.e., effusions take a period of time to develop, course of effusion accumulation is predictable
Severity	Emergent, **potentially fatal** complication	**Non emergent, easily monitored**
Cause	Trauma induced to cardiac structure, or steam pops	Inflammatory response due to pericardiotomy and ablation
Intervention	Urgent intervention required	Elective management Patients recover without sequelae

Catheter ablation pericardial effusion = emergent, potentially fatal complication

Surgical pericardial effusion = non-emergent, inflammatory response

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IFU Pericardial Effusion Mitigation Section

New section added to the US IFU

- **Drain management**
  - Leave pericardial drain in the pericardial space (until drainage is less than 50 mL, over at least 12 hours is preferable)
- **Prophylactic anti-inflammatory agents**
- A three (3) week duration is recommended
- **Use of diuretics**
  - As needed
- **Echocardiogram**
  - Should be performed between 1-3 weeks post-procedure and
  - Whenever there are suggestive symptoms or signs to screen for late onset pericardial effusion
- **Patient education on**
  - Symptoms of pericarditis, pericardial effusion and cardiac tamponade
  - Closely monitoring for suspected symptoms, which should be further evaluated with appropriate imaging tests
- **Follow-up**
  - Follow-up should be conducted at approximately 30 days post procedure to monitor for signs of delayed onset pericarditis or pericardial effusion

*** Changes pending EU MDR approval**

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