CMHC
Cardiometabolic Health Congress

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Foundations of Cardiometabolic Health Certification Course

Certified Cardiometabolic Health Professional (CCHP)

Overview of Cardiac Arrhythmias and Treatment Options

William H. Sauer, MD

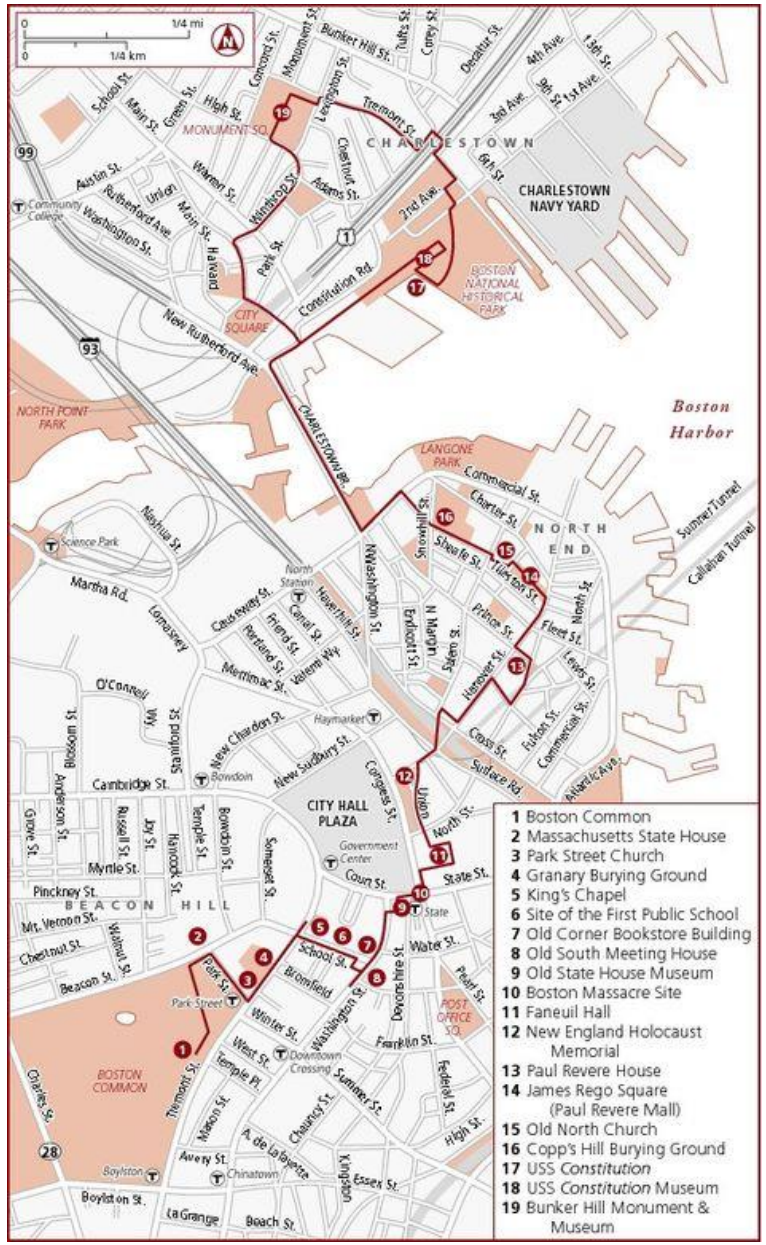
Chief, Cardiac Arrhythmia Services

Brigham and Women's Hospital

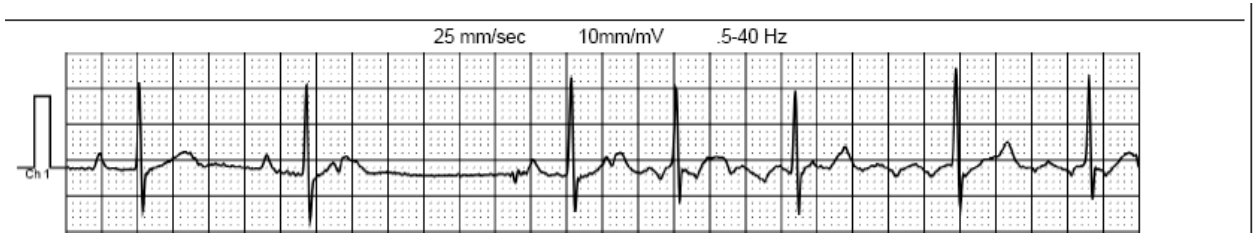
Harvard Medical School

Road Map

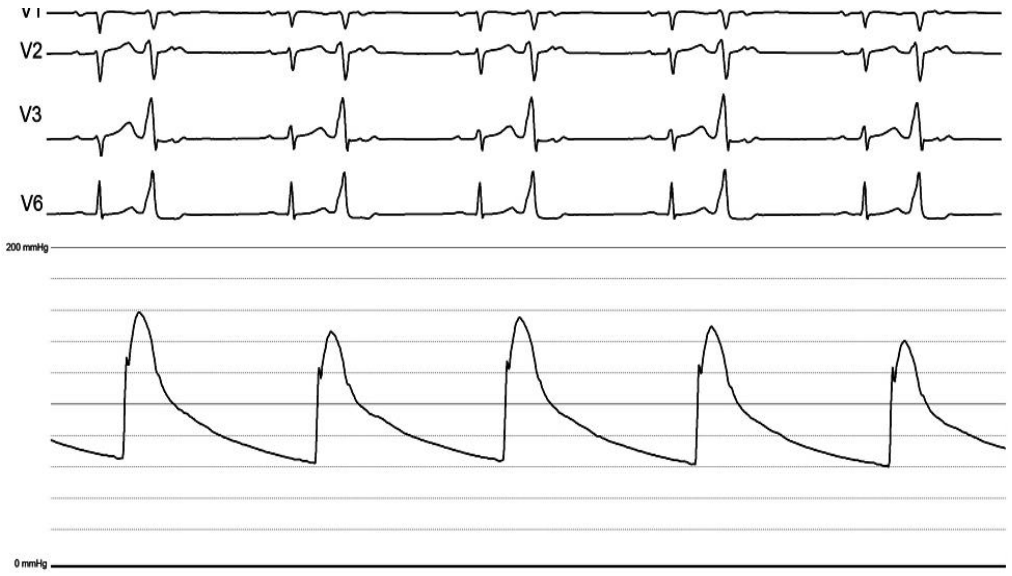
- Overview of Cardiac Arrhythmias and Treatment Options
  - Antiarrhythmic Medications
    - AFFIRM 1999
    - EAST AF 2019
  - Implantable Devices
    - SCD-HeFT 2005
  - Catheter Ablation
    - CABANA 2019
    - PAUSE-SCD 2021
- Summary



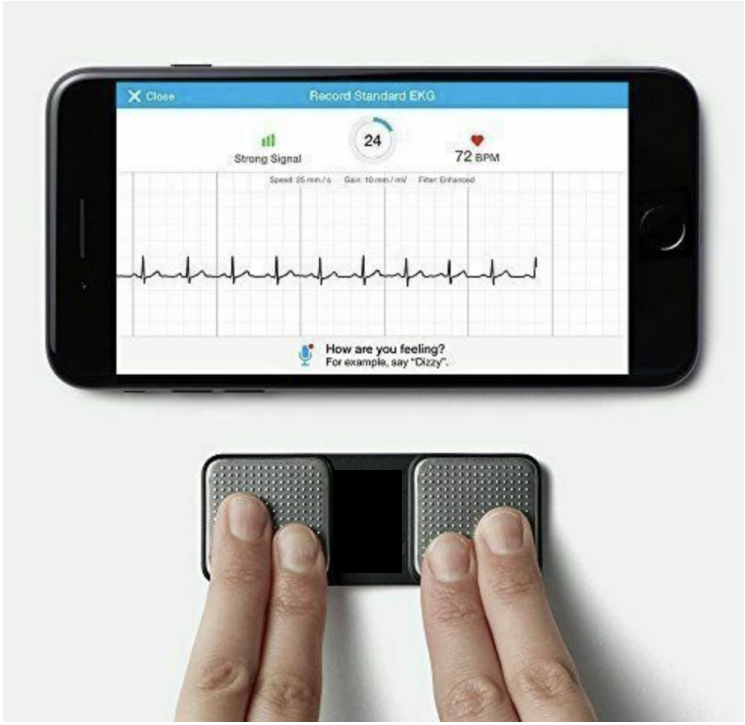
Cardiac Arrhythmias

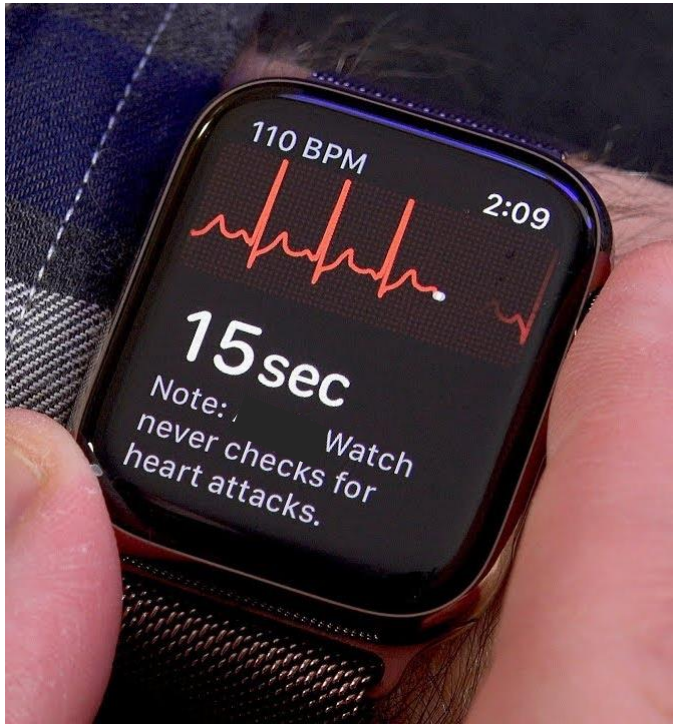


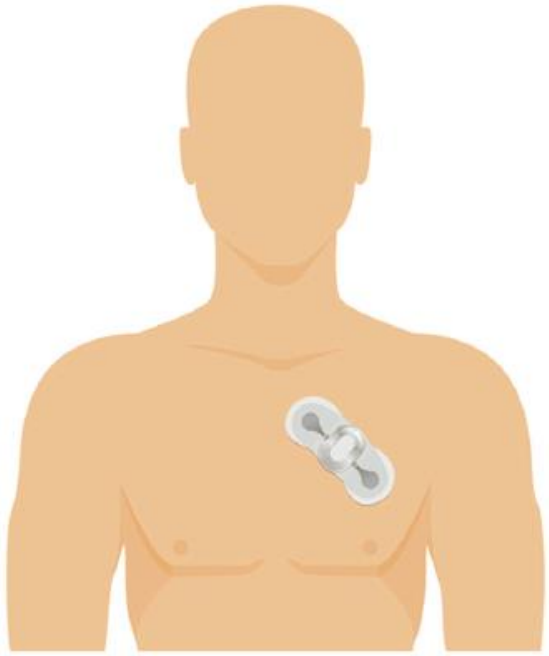
- Too Fast (Tachyarrhythmias)
  - Atrial Fibrillation and Atrial Flutter
  - Supraventricular Tachycardia (SVT)
  - Ventricular Tachycardia (VT) and Ventricular Fibrillation (VF)
- Too Slow (Bradyarrhythmias)
  - Sinus Node Dysfunction
  - Heart Block and Conduction System Disease
  - Premature Ventricular Contractions (PVCs)

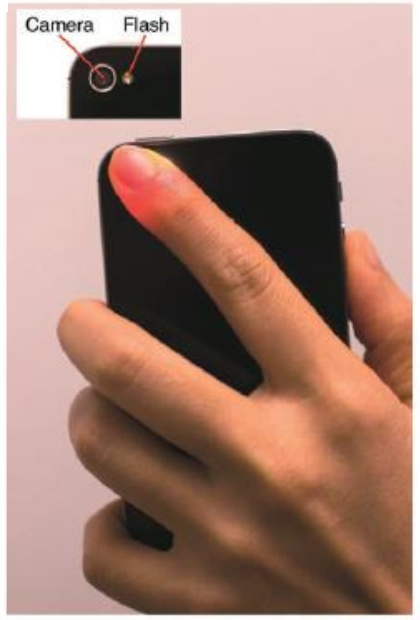


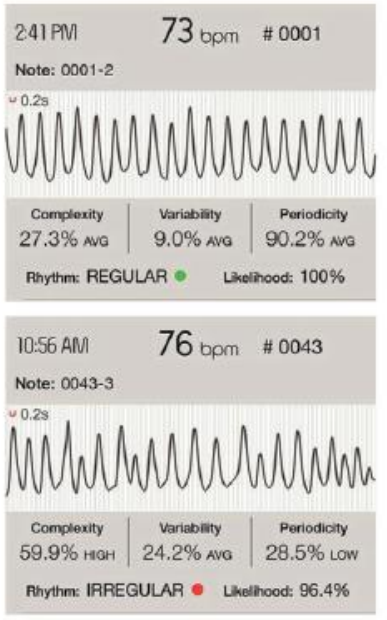

6-lead EKG recording with left ankle



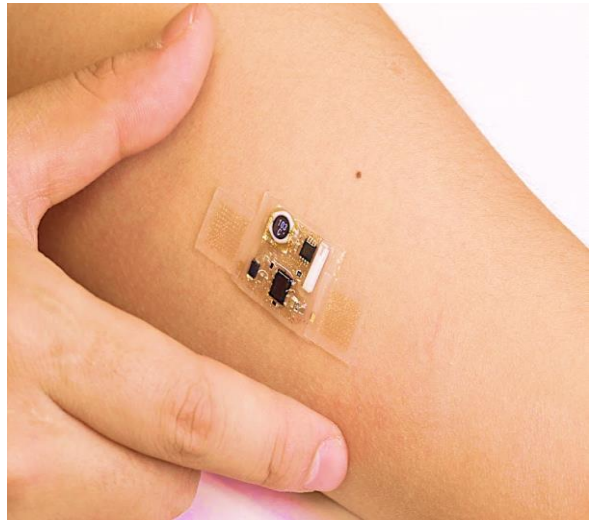








Norman J. Holter (1914 – 1983)
"Father" Of Ambulatory ECG
Monitoring First Holter 1947:
Weight **85 pounds**



Begin forwarded message:

From
Date: September 12, 2019 at 11:43:15 AM EDT
To: "wsauer@bwh.harvard.edu" <wsauer@bwh.harvard.edu>
Cc:
Subject:

External Email - Use Caution

Dr. Sauer:

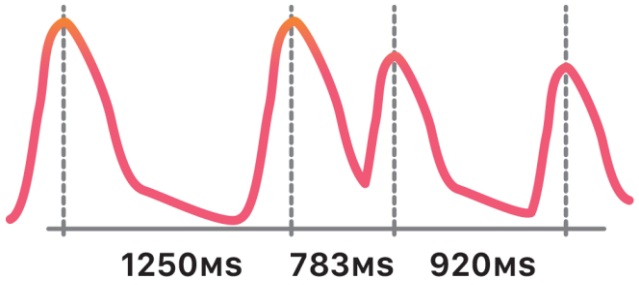
As you requested, attached is a copy of an ECG report I took today. I started to taking the apixaban yesterday. Can you please advise as respects to the Flecainide?

Patient: Brooks Martin, 5/4/62 (57yrs)
Recorded: 9 at 11:34:42 AM
Heart Rate: 68 BPM
Duration: 30s

Instant Analysis: Normal

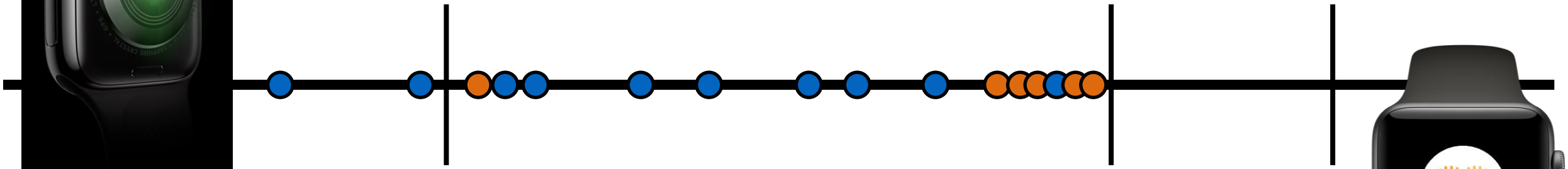
Enhanced Filter, Mains Frequency: 60Hz Scale: 25mm/s, 10mm/mV

Irregular Pulse Notification Algorithm



Algorithm results

- Regular pulse
- Suggestive of Afib



Tachogram = Periodic, opportunistic measurements

5 confirmations ⇒ notify user

Positive triggers frequent measurements

Not confirmed ⇒ return to usual sampling

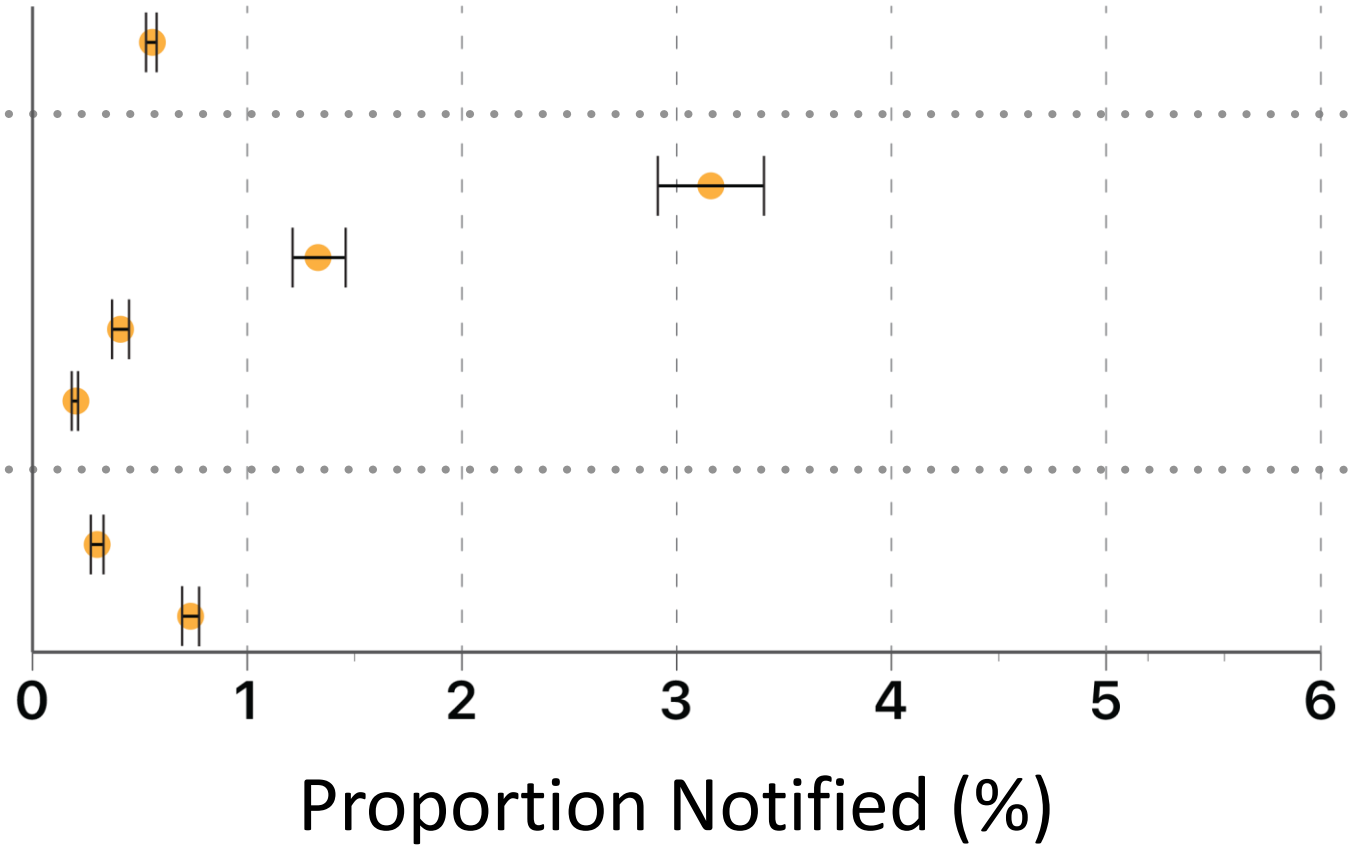
The algorithm does not use the watch ECG feature

Initial Irregular Pulse Notifications

Overall Cohort

~ 8 Months Monitoring

Grouping		Notified / Total	%
	Overall	2,161 / 419,297	0.52
Age	≥ 65	775 / 24,626	3.2
	55–64	556 / 42,633	1.3
	40–54	488 / 132,696	0.37
	22–39	341 / 219,179	0.16
Sex	Female	461 / 177,087	0.26
	Male	1,672 / 238,700	0.70



Perez, MV et al. NEJM 2019; 381.20: 1909-1917.

Date of Birth: Jun 6, 1988 (Age 30)

Recorded on Mar 9, 2019 at 3:09 PM

Heart Rate Over 120 — ♥ 200 BPM Average

This ECG was not checked for AFib because your heart rate was over 120 BPM.

If you repeatedly get this result or you're not feeling well, you should talk to your doctor.

Reported Symptoms

- Rapid, pounding, or fluttering heartbeat
- Chest tightness or pain
- Fainting

iOS 12.1.4, watchOS 5.1.3, Watch4,2

25 mm/s, 10 mm/mV, Lead I, 511Hz, iOS 12.1.4, watchOS 5.1.3, Watch4,2 — The waveform is similar to a Lead I ECG. For more information, see Instructions for Use.

Arrhythmia Treatment Options

- Medical Therapy
  - Antiarrhythmic Drug Therapy
  - Anticoagulation for Stroke Prevention
- Pacemakers
  - Conduction System Pacing
  - Cardiac Resynchronization
- Implantable Cardiac Defibrillators
  - Identification of high risk patients (primary prevention)
- Catheter Ablation

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Antiarrhythmic Medications

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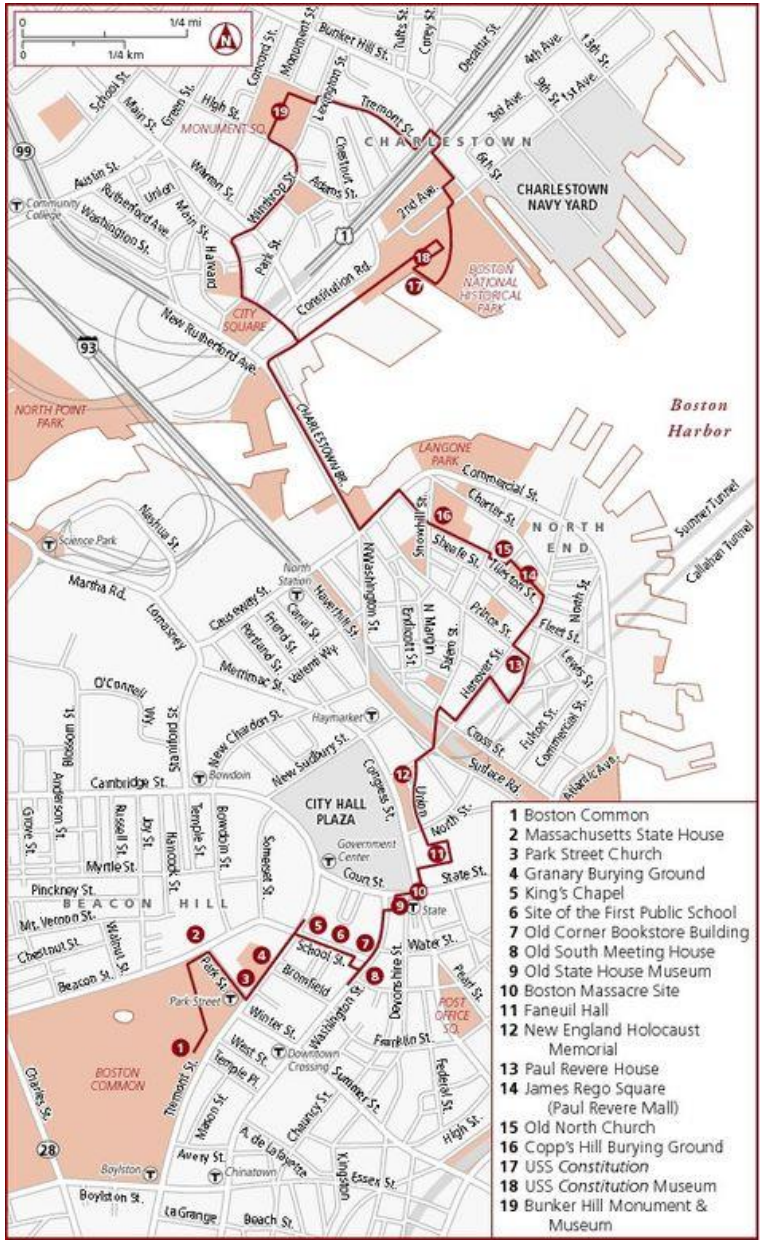


AFFIRM – Study Overview

- Randomized comparison of two treatment strategies
  - Rate control + anticoagulation
  - Rhythm control +/- anticoagulation
- Subjects without symptoms, but with risk factors for stroke
- Enrollment 1995 - 1999

The AFFIRM investigators. NEJM 2002; 347.23: 1825-1833.

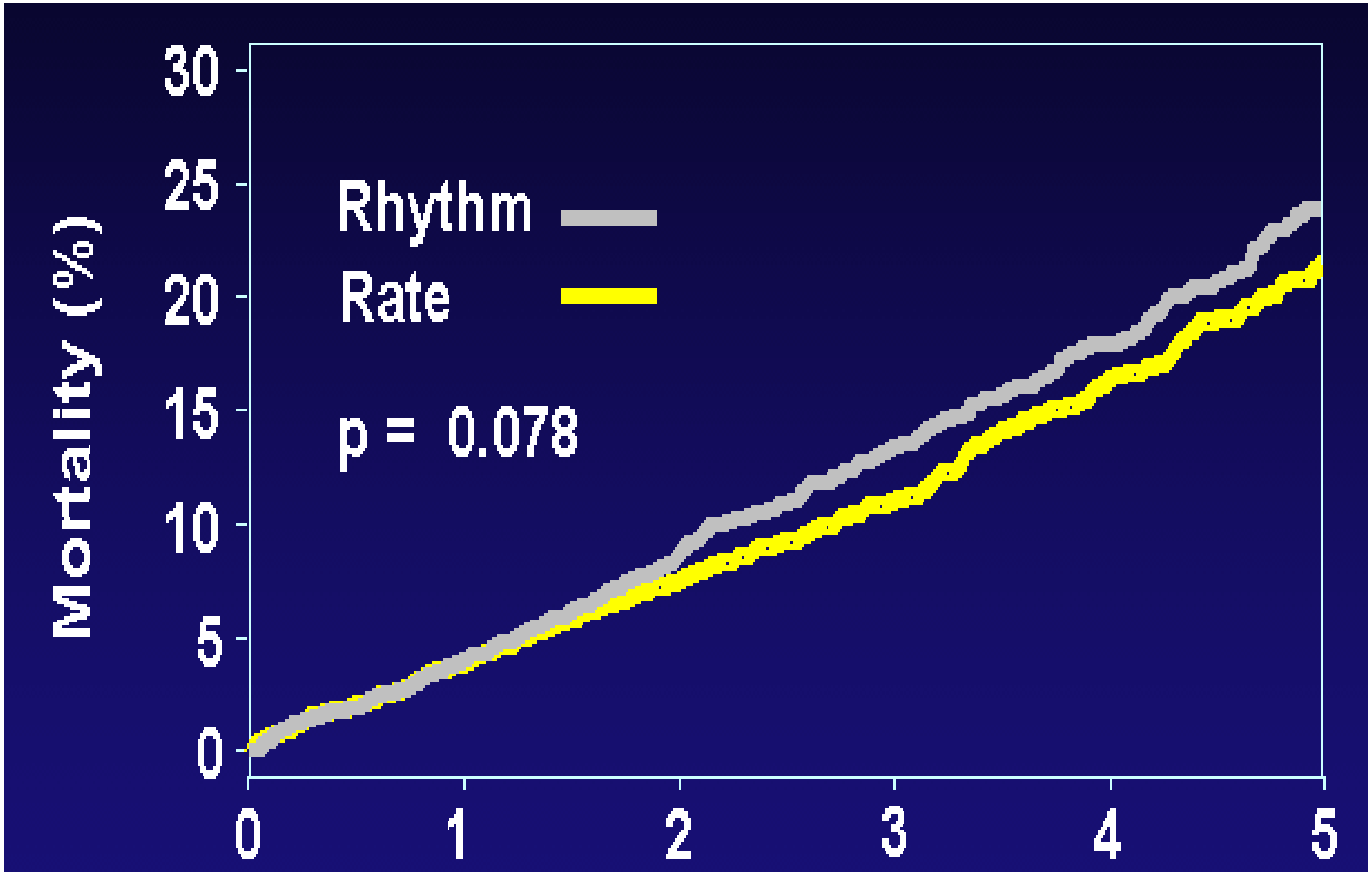
Patients

- Age = 69.7 +/- 9.0 years
- 39% Women
- Abnormal LV function: 26%
  - NYHA HF Class > 2: 9%
- HTN: 51%

- Rate Control
  - Digoxin: 48%
  - Beta-blockers: 47%
  - Ca++ blockers: 39%
- Rhythm Control
  - Amiodarone: 38%
  - Sotalol: 31%
  - Propafenone: 9%
  - Others (<5%): Flecainide, Disopyramide, Quinadine, Moricizine

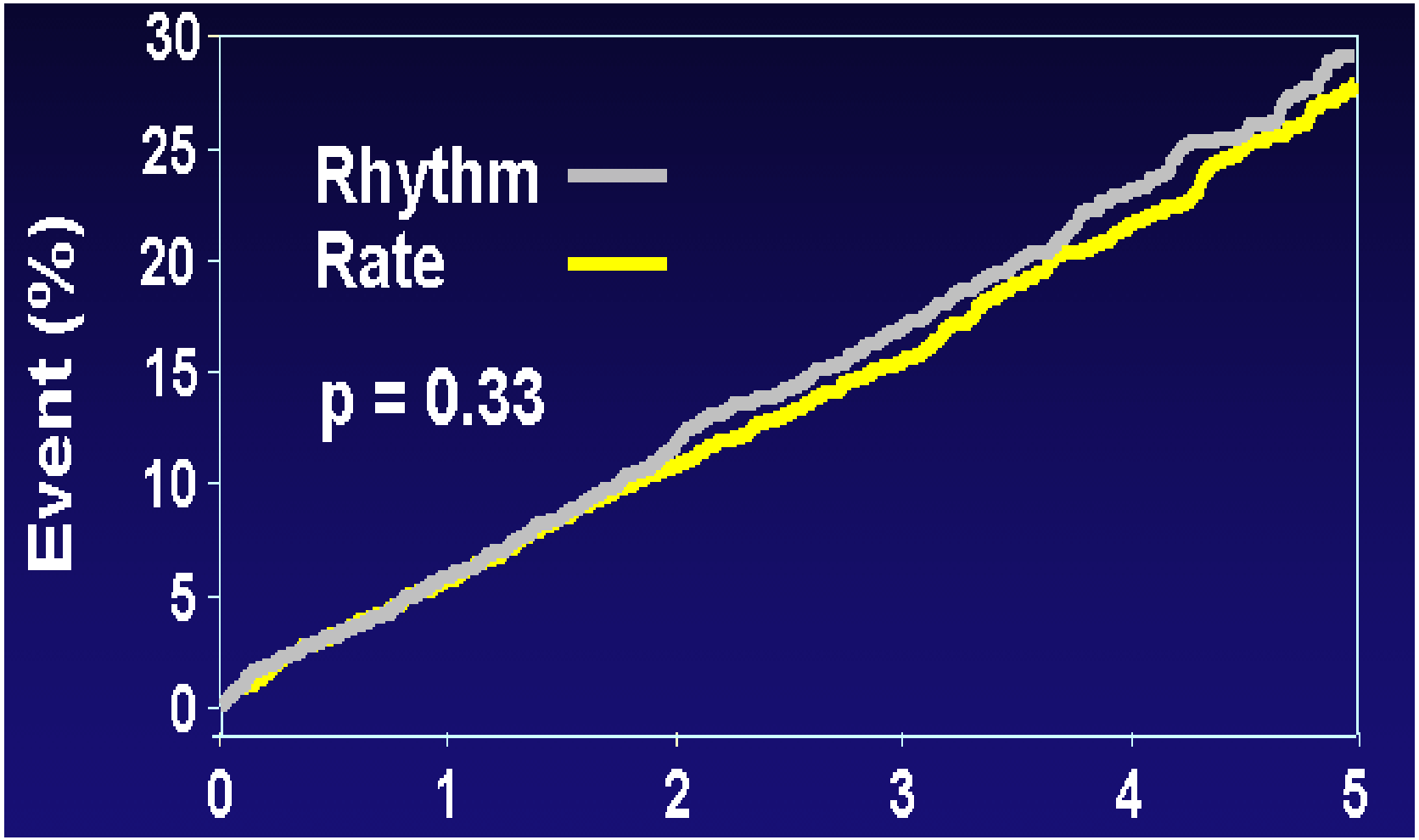
The AFFIRM investigators. NEJM 2002; 347.23: 1825-1833.

Primary Endpoint : All cause mortality



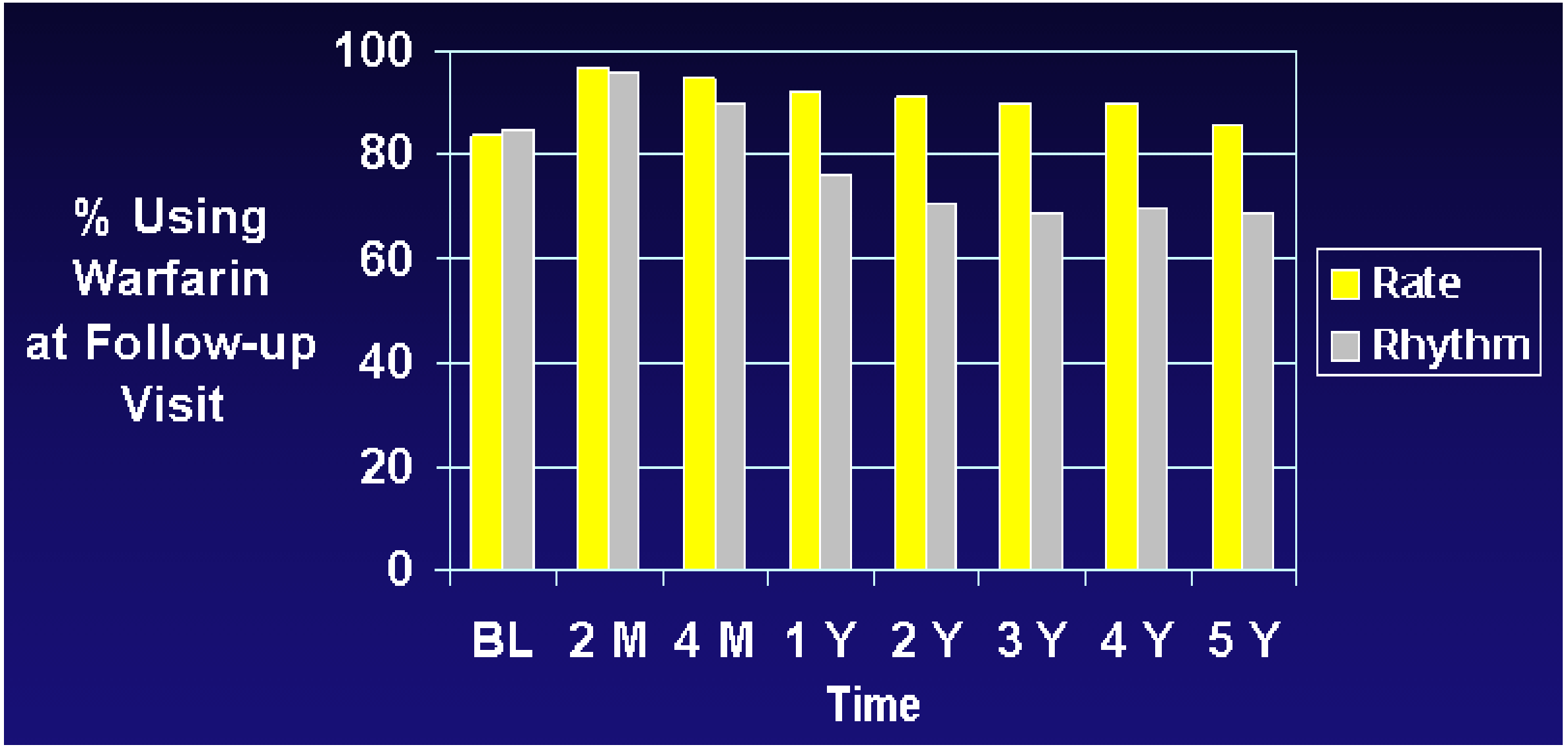
The AFFIRM investigators. NEJM 2002; 347.23: 1825-1833.

Secondary Endpoint-Death, Disabling Stroke or Anoxic Encephalopathy, Major Bleed, or Cardiac Arrest



The AFFIRM investigators. NEJM 2002; 347.23: 1825-1833.

Warfarin Use



Limitations of AFFIRM

- Patients with any symptoms of AF were not enrolled
- The mean follow-up of 3.5 years is not long-term.
  - AF begets AF – this makes cross-over to rhythm control difficult
  - AF symptoms could develop over time
- AFFIRM did not evaluate low risk patients
- AFFIRM did not evaluate patients with heart failure

The Case for Rhythm Control within AFFIRM

- Rhythm control arm was only successful at sinus rhythm maintenance 60% of the time
  - Not truly a comparison of strategies
  - Actually, there was significant survival benefit in those patients able to maintain sinus rhythm
- The apparent increase in stroke and mortality risk in the rhythm control arm is entirely explained by lack of anticoagulation

The AFFIRM investigators. Circulation 2004; 109: 1509-1513.

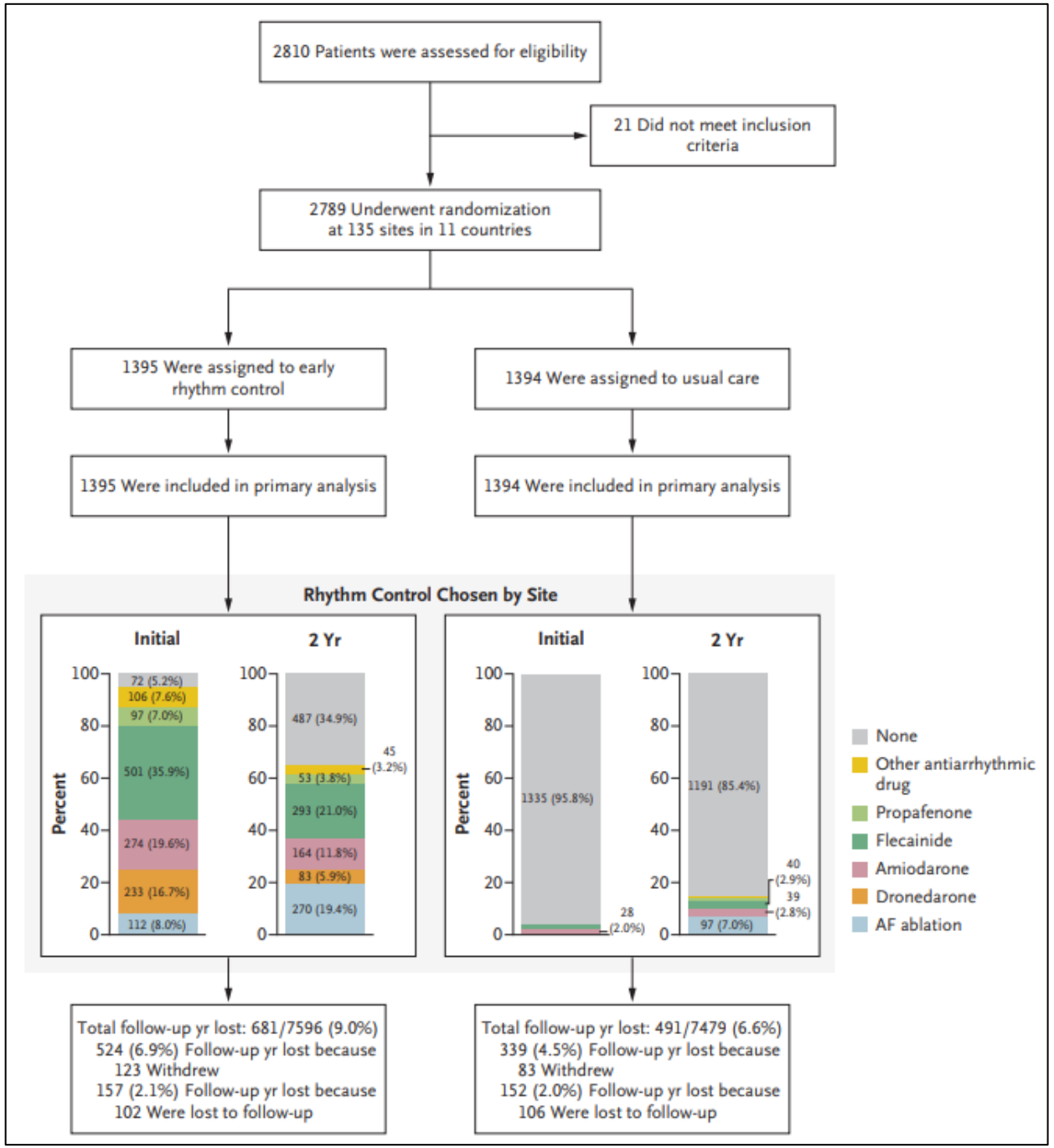
Summary of AFFIRM (as I see it)

- Rate control is an acceptable strategy for treatment of *asymptomatic* AF
- Rhythm control should be considered if there is a decent chance for long-term sinus rhythm maintenance
- Anticoagulation should be continued in patients with risk factors for stroke – even in those who appear to maintain sinus rhythm
- Patients with any symptoms attributable to AF should be treated with a rhythm control strategy

Fast forward 20 years to EAST-AF

EAST-AF

- Enrollment
  - Study population – key characteristics
    - Median age 70, ≥mild cognitive impairment 44%
    - First episode: 38%, paroxysmal: 36%; 26% persistent
    - 30% asymptomatic, 54% in NSR at enrollment
    - Median days since AF diagnosis: 36
    - CHA2DS2-VASc 3.4
    - CHF: 29%
    - 90% anticoagulated
    - 80% on beta blockade



Kirchhof P, et al. New England Journal of Medicine. 2020 Oct 1;383(14):1305-16.

- Outcomes
  - Enrollment stopped early due to efficacy of treatment arm, median followup 5.1 years.
  - Choice of rhythm control in treatment arm:
    - At enrollment: 36% flecainide, 20% amio, 8% ablation
    - After 5 years: 19% ablation
  - **Primary composite #1:** 3.9 vs. 5.0/100 person-years (P-Y) (hazard ratio [HR] 0.79, 95% confidence interval [CI] 0.66-0.94, (p 0.005)
  - **Primary composite #2:** LOS 5.1 vs. 5.8 days (p 0.23). AFFIRM and AF-CHF each reported increased LOS with rhythm control.

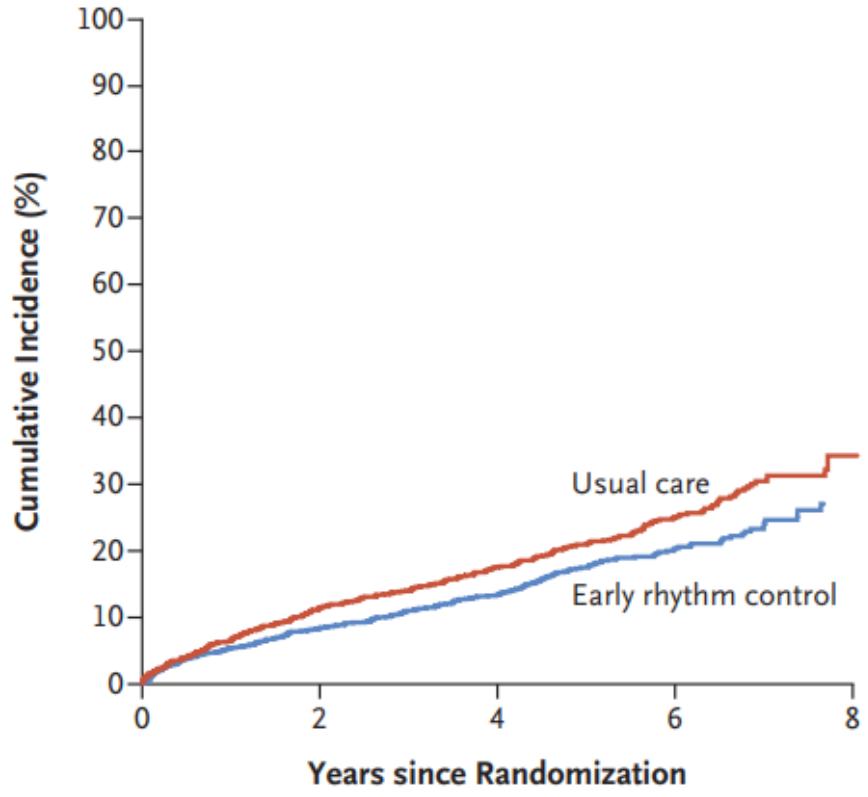


Figure 2. Aalen–Johansen Cumulative-Incidence Curves for the First Primary Outcome.

The first primary outcome was a composite of death from cardiovascular causes, stroke, or hospitalization with worsening of heart failure or acute coronary syndrome.

Kirchhof P, et al. New England Journal of Medicine. 2020 Oct 1;383(14):1305-16.

Table 2. Efficacy Outcomes.*

Outcome	Early Rhythm Control	Usual Care	Treatment Effect
First primary outcome — events/person-yr (incidence/ 100 person-yr)	249/6399 (3.9)	316/6332 (5.0)	0.79 (0.66 to 0.94)†
Components of first primary outcome — events/person-yr (incidence/100 person-yr)			
Death from cardiovascular causes	67/6915 (1.0)	94/6988 (1.3)	0.72 (0.52 to 0.98)‡
Stroke	40/6813 (0.6)	62/6856 (0.9)	0.65 (0.44 to 0.97)‡
Hospitalization with worsening of heart failure	139/6620 (2.1)	169/6558 (2.6)	0.81 (0.65 to 1.02)‡
Hospitalization with acute coronary syndrome	53/6762 (0.8)	65/6816 (1.0)	0.83 (0.58 to 1.19)‡
Second primary outcome — nights spent in hospital/yr	5.8±21.9	5.1±15.5	1.08 (0.92 to 1.28)§
Key secondary outcomes at 2 yr			
Change in left ventricular ejection fraction — %	1.5±9.8	0.8±9.8	0.23 (–0.46 to –0.91)¶
Change in EQ-5D score‖	–1.0±21.4	–2.7±22.3	1.07 (–0.68 to 2.82)¶
Change in SF-12 Mental Score**	0.7±10.6	1.6±10.1	–1.20 (–2.04 to –0.37)¶
Change in SF-12 Physical Score**	0.3±8.5	0.1±8.2	0.33 (–0.39 to 1.06)¶
Change in MoCA score	0.1±3.3	0.1±3.2	–0.14 (–0.39 to 0.12)¶
Sinus rhythm — no. of patients with feature/total no. (%)	921/1122 (82.1)	687/1135 (60.5)	3.13 (2.55 to 3.84)††
Asymptomatic — no. of patients with feature/total no. (%)‡‡	861/1159 (74.3)	850/1171 (72.6)	1.14 (0.93 to 1.40)††

Kirchhof P, et al. New England Journal of Medicine. 2020 Oct 1;383(14):1305-16.

AFFIRM and EAST-AFNET

- AFFIRM did not show superiority for rhythm control
  - Inconsistent Anticoagulation
  - Low efficacy of antiarrhythmic medications
- EAST-AF be viewed as a correction of the present-day problems with AFFIRM
  - Ablation included (~20% patients)
  - Improved anticoagulation adherence
  - Improved medical therapy for non-arrhythmic therapy

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Implantable Devices for Arrhythmias

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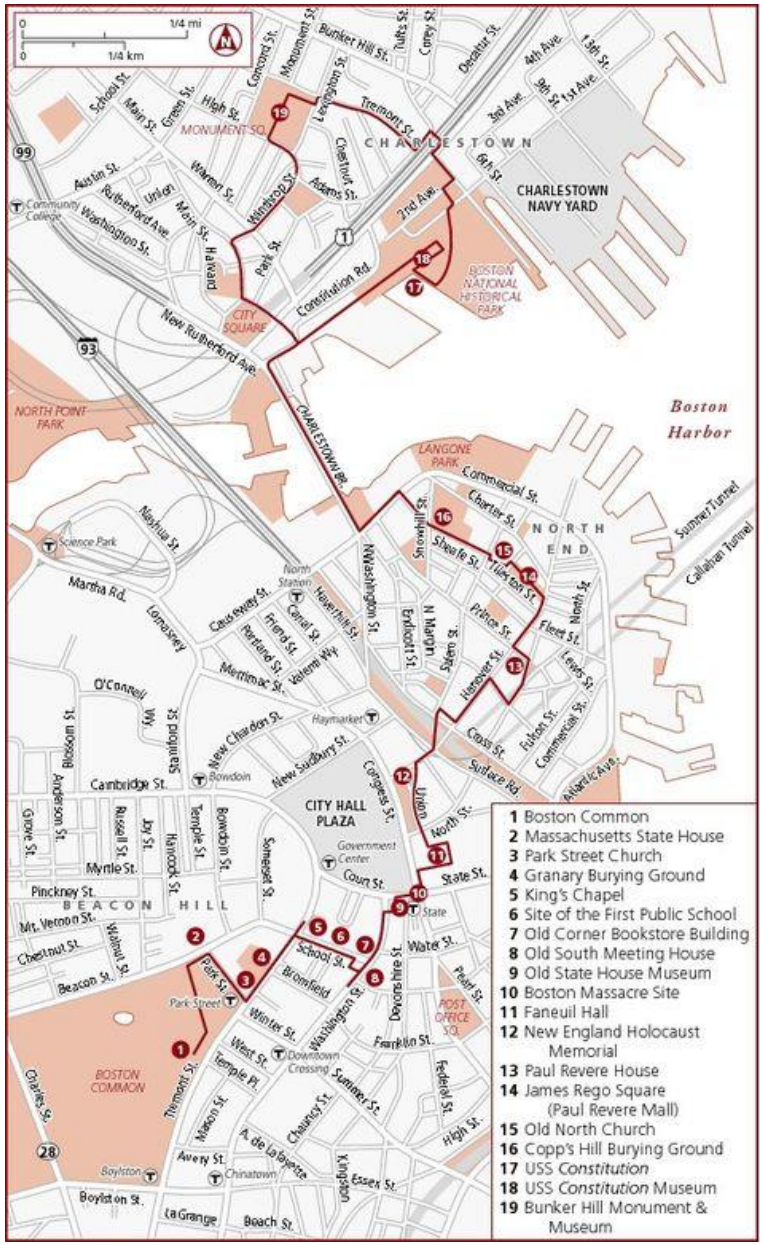
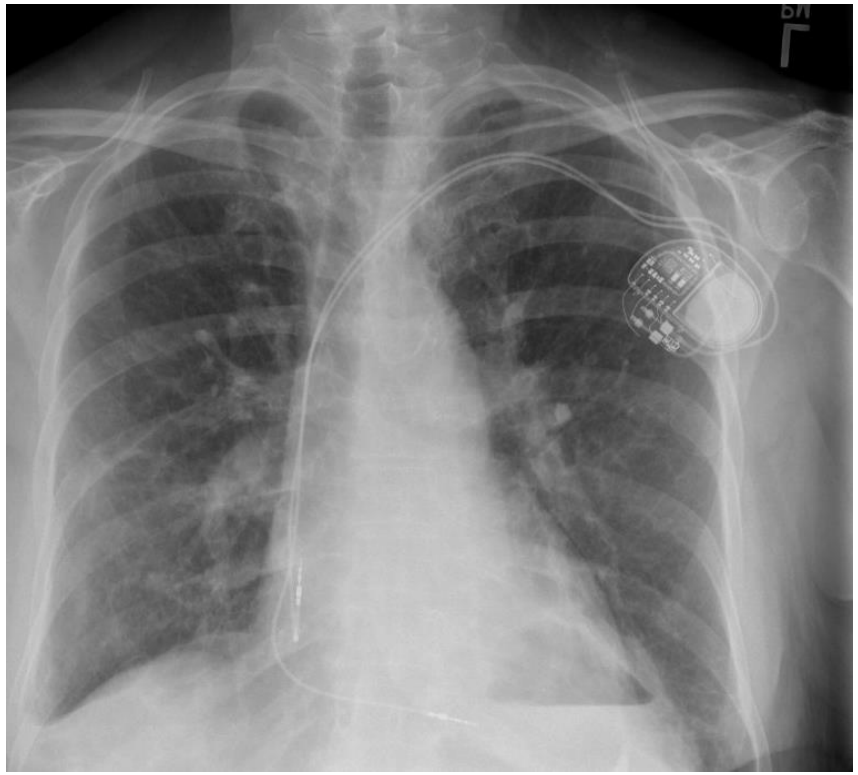
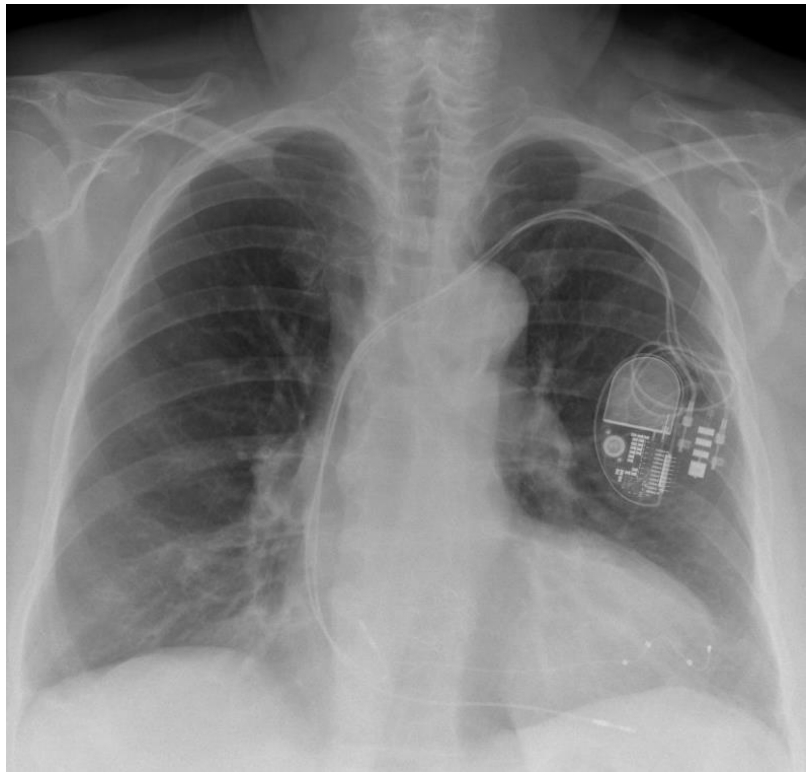


Implantable Cardiac Rhythm Devices - Pacing

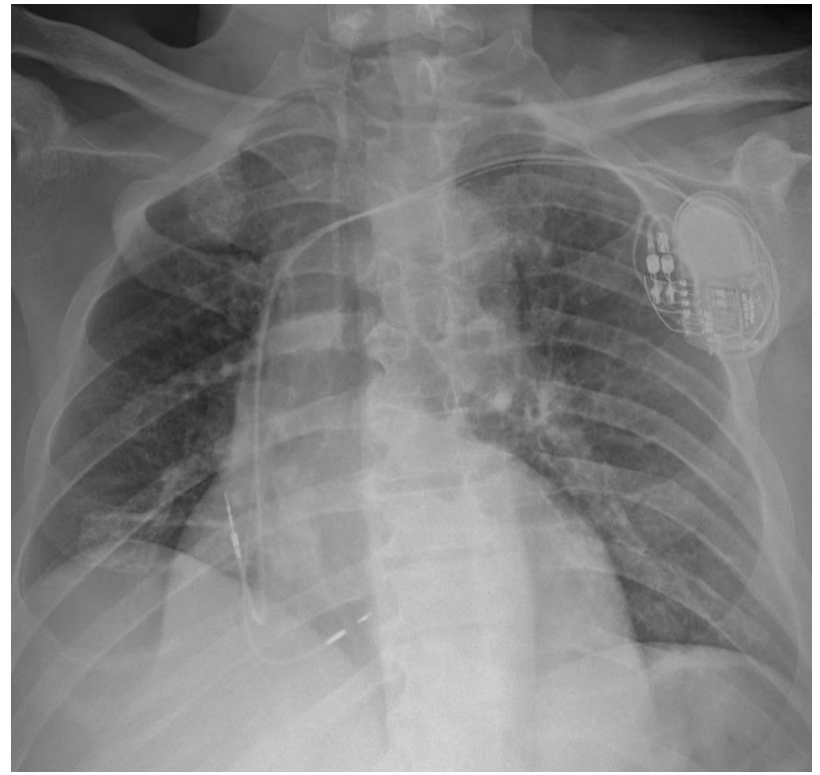
Options for Pacing



Dual Chamber Pacer



Biventricular Pacer



His Bundle Pacer

Historical perspective

1958 — First External Pacemaker

1960 — First Implantable Pacemaker

1970 — Pediatric Asynchronous Pulse Generator

1979

1986 — Rate response

1989 — Dual chamber rate response

1990 — Radically smaller size

1991

1995 — 1st Micro-processor-based, Mode switching

1998 — Rate response via activity & minute ventilation

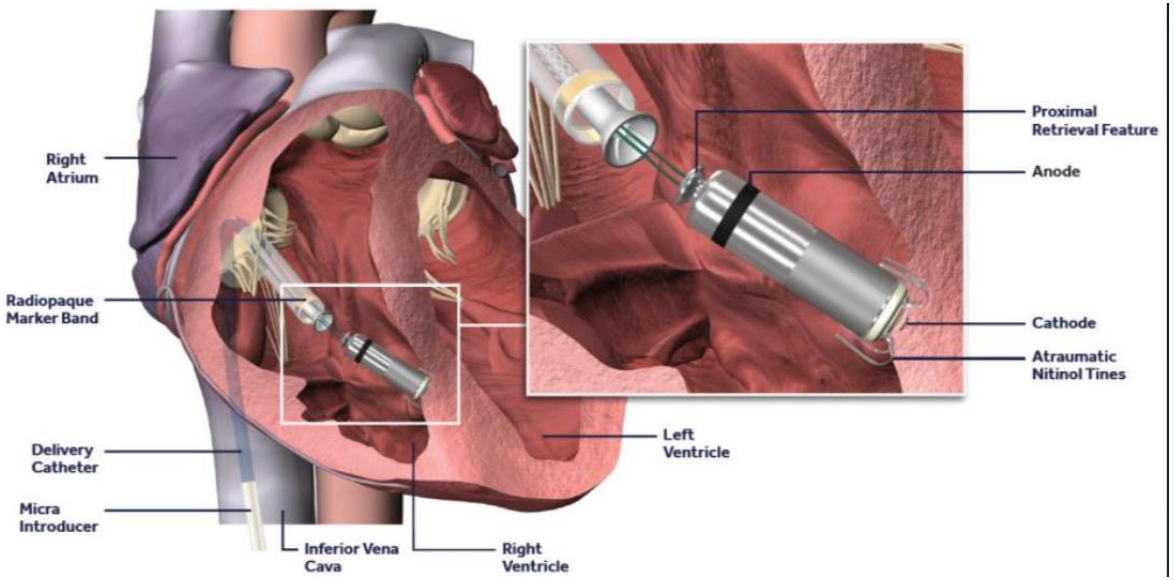
2004 — Full automaticity

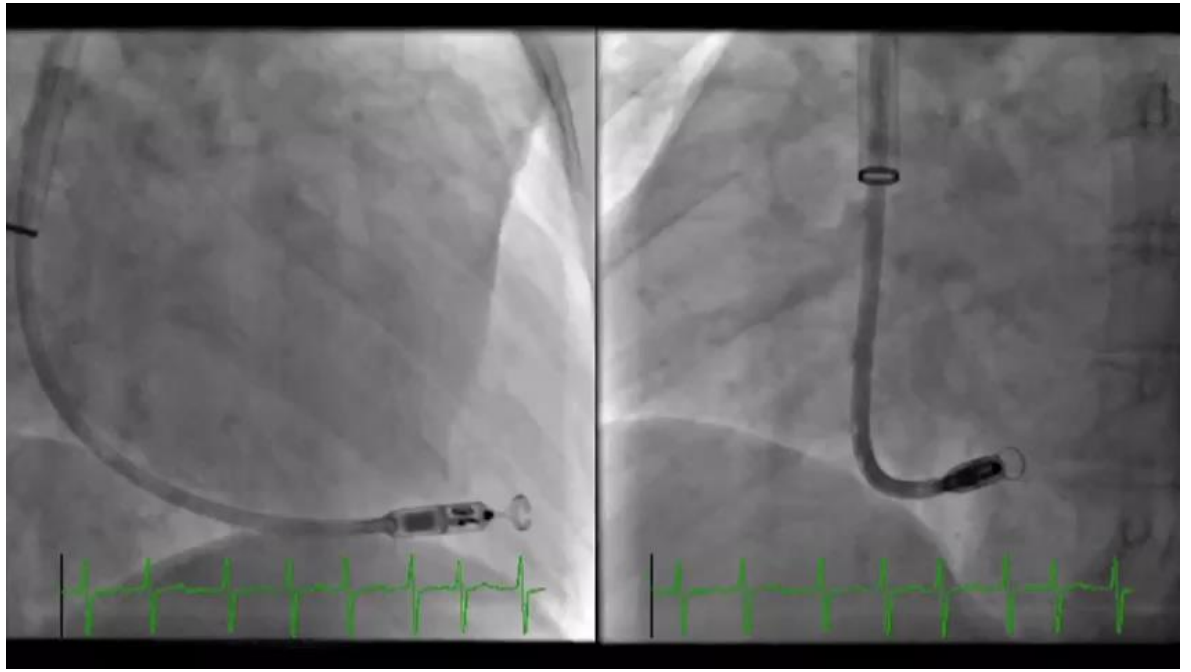
2006 — MVP™, Full automaticity

2011 — 1st MRI-Conditional

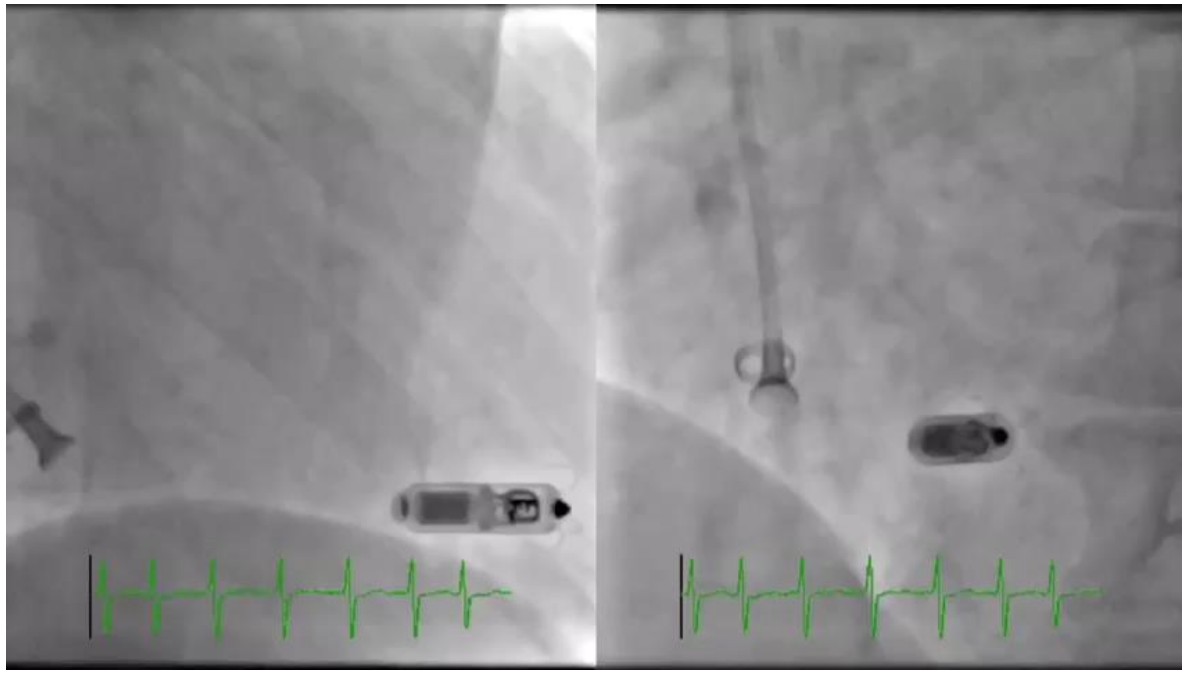
2013 — 2nd MRI-Conditional

2016 — **Transcatheter Pacing System**

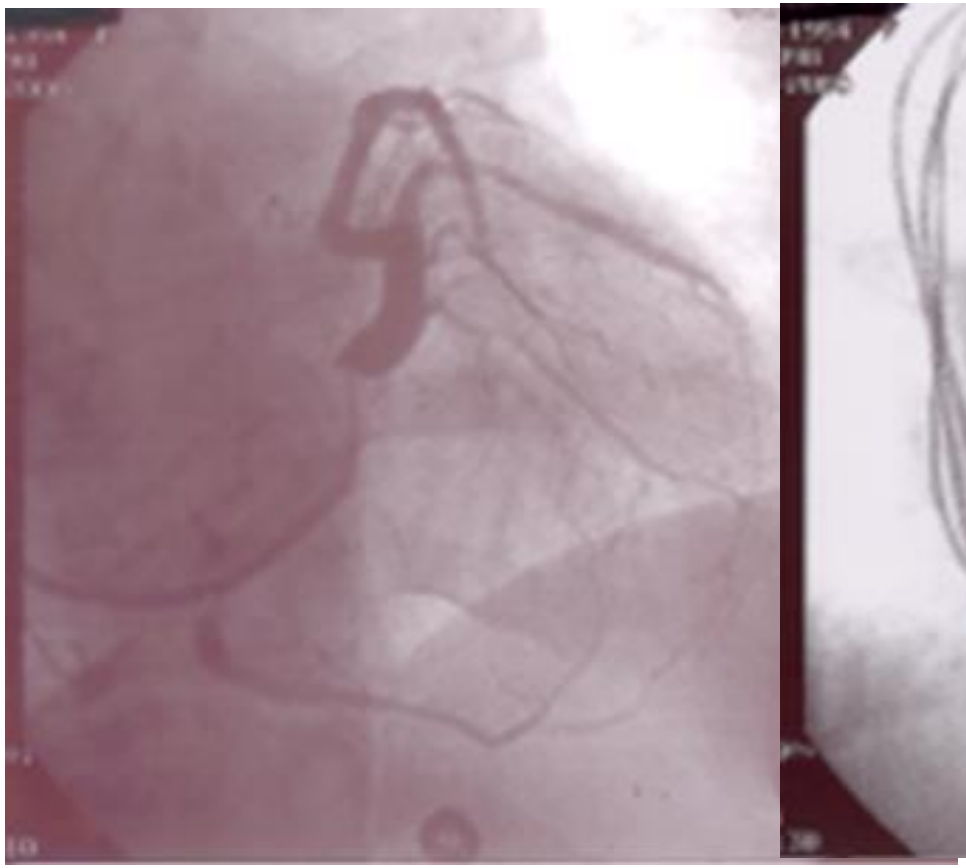

Right Atrium
Radiopaque Marker Band
Delivery Catheter
Micra Introducer
Inferior Vena Cava
Right Ventricle
Left Ventricle
Proximal Retrieval Feature
Anode
Cathode
Atraumatic Nitinol Tines

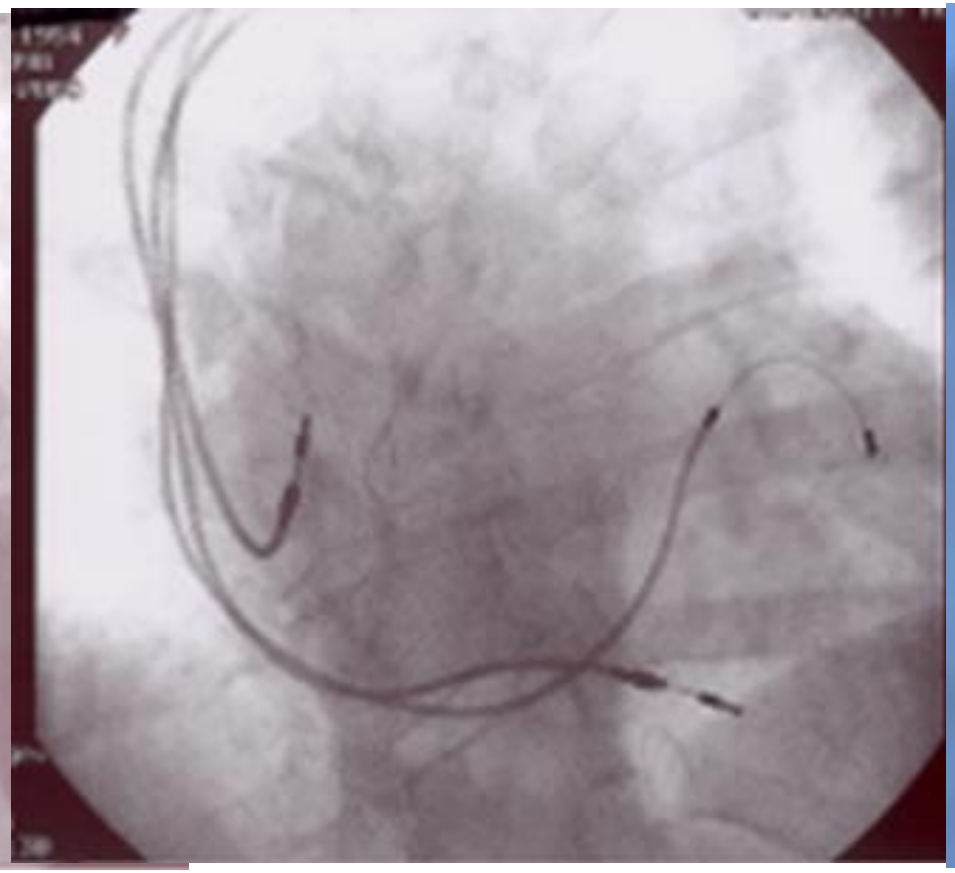


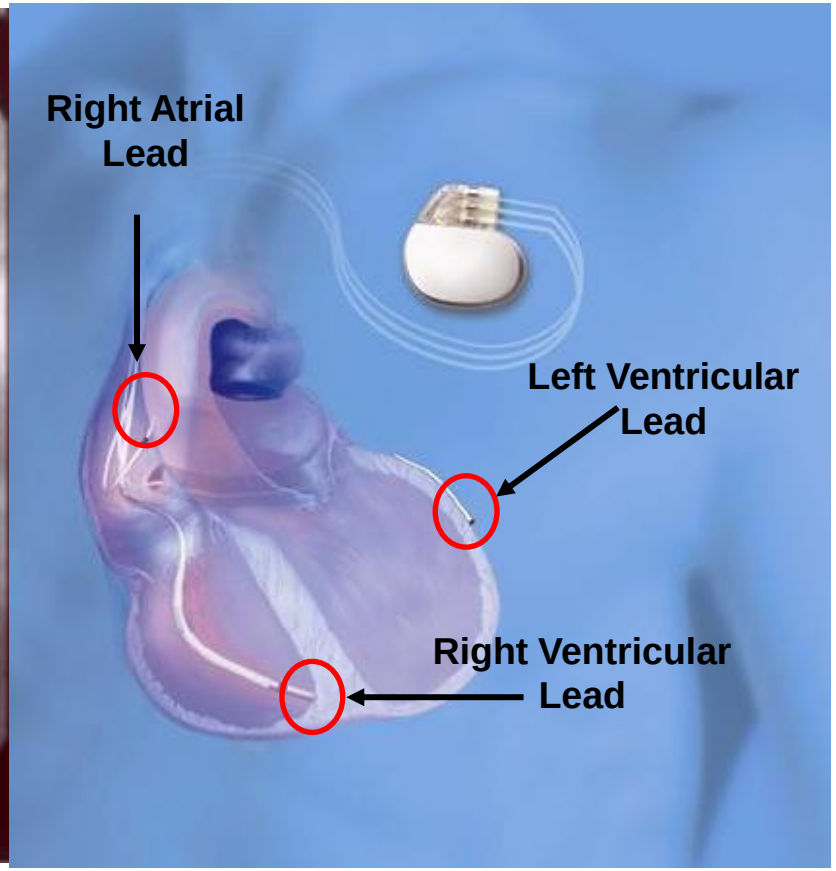

LIBERTY
1987

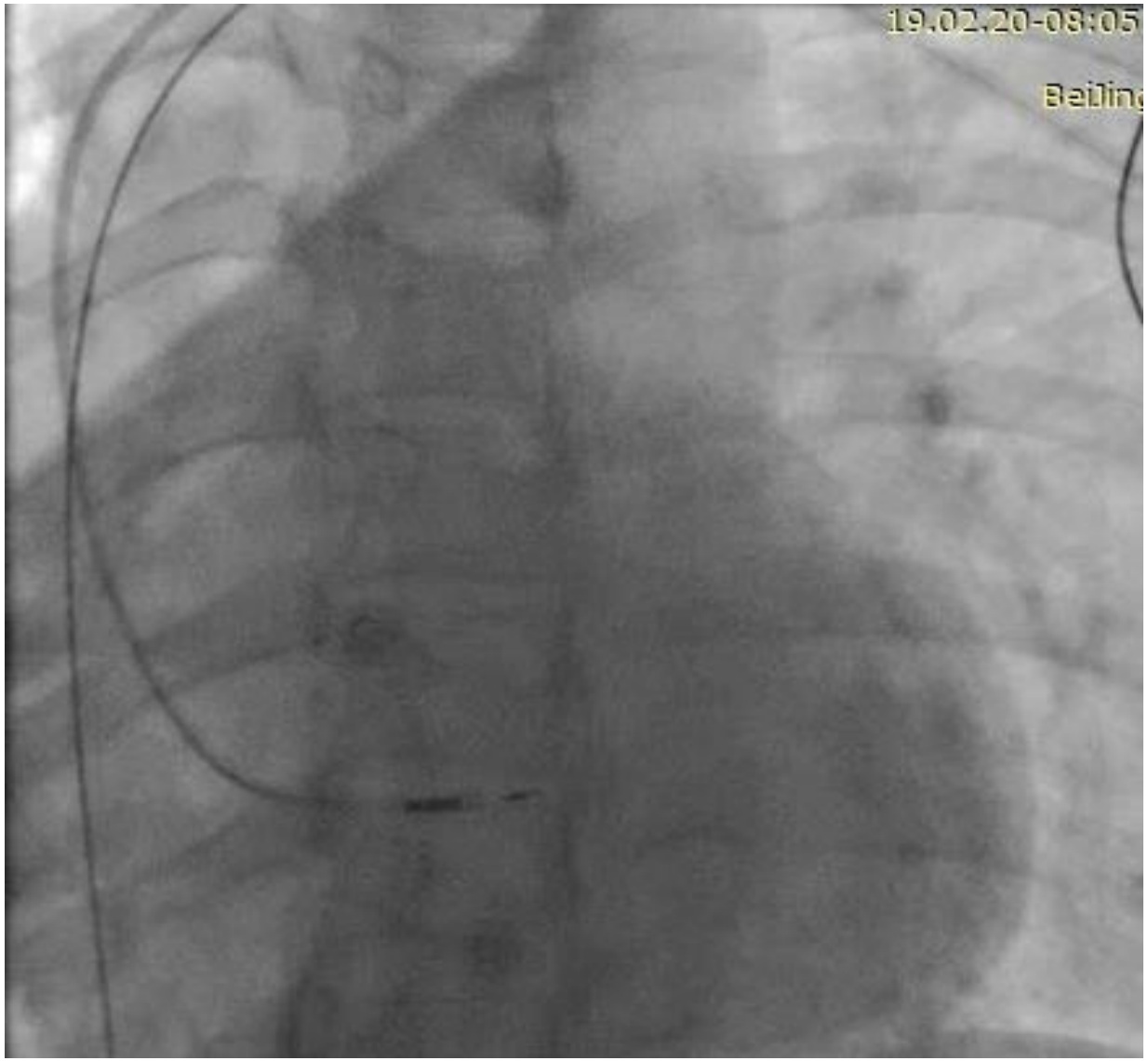


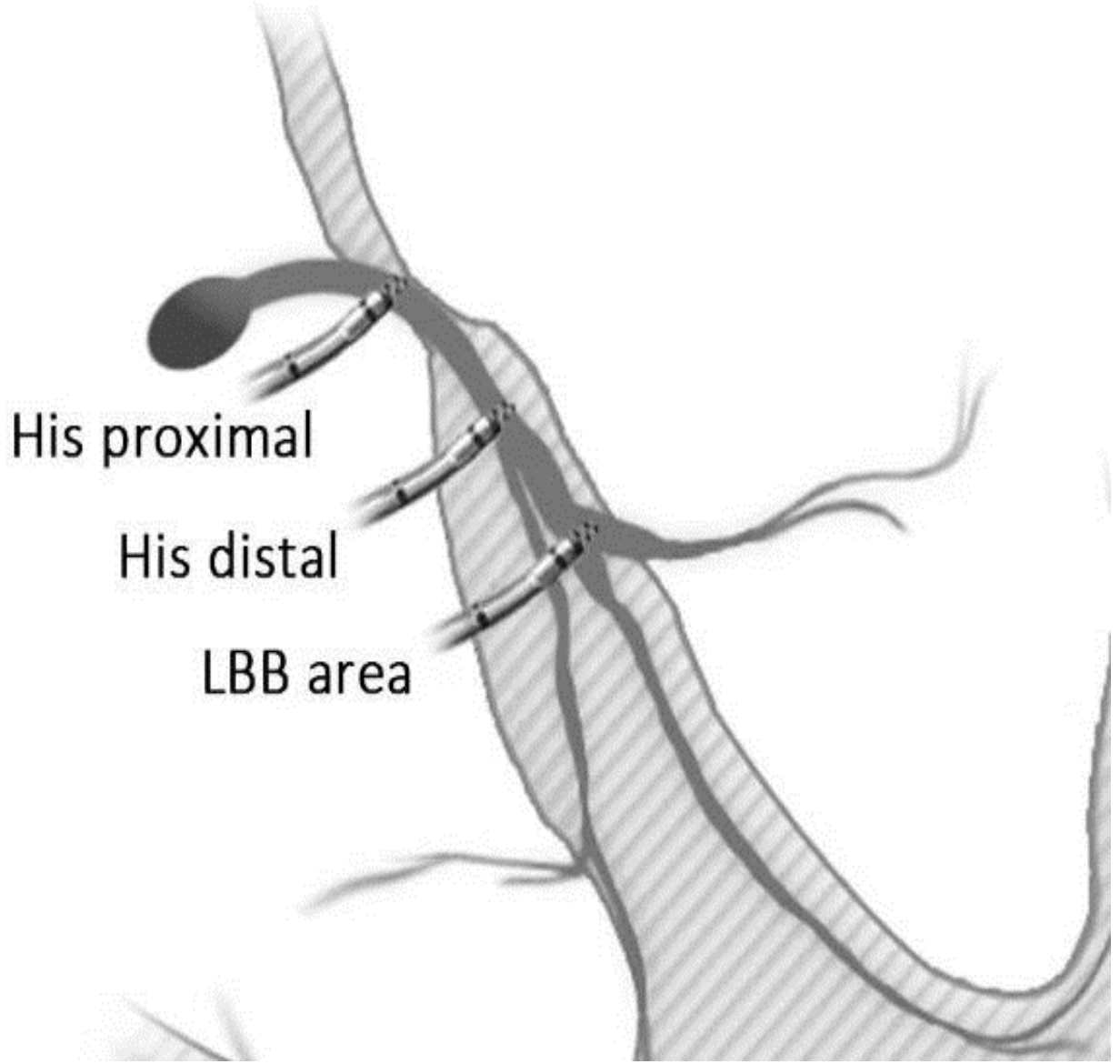
Cardiac Resynchronization Therapy (CRT)

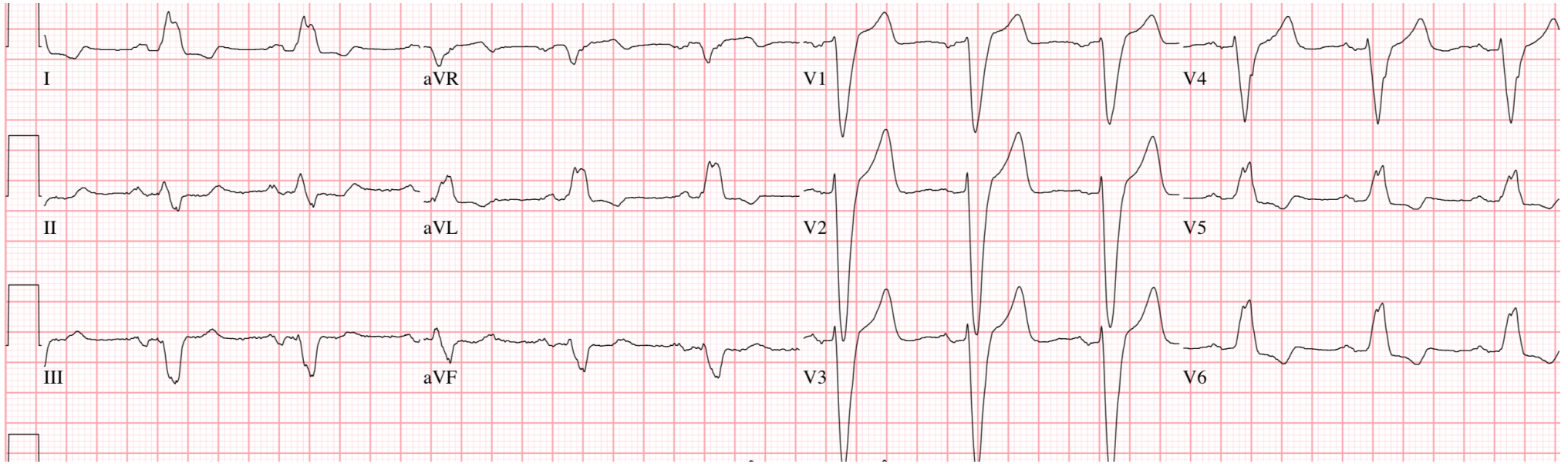




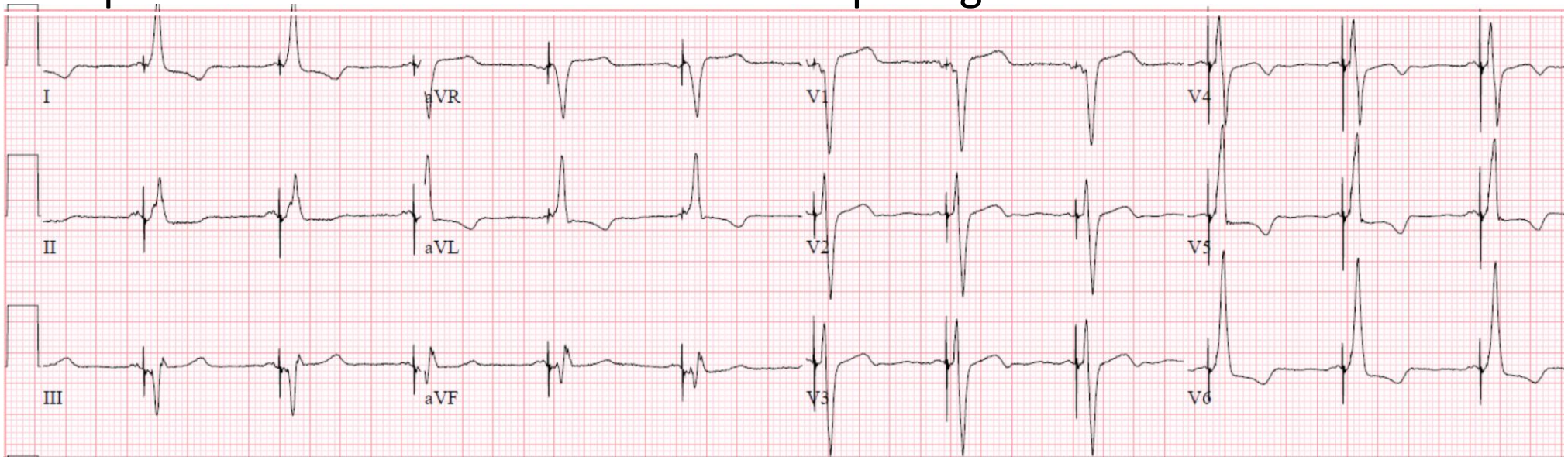



19.02.20-08:05
Beijing


His proximal
His distal
LBB area

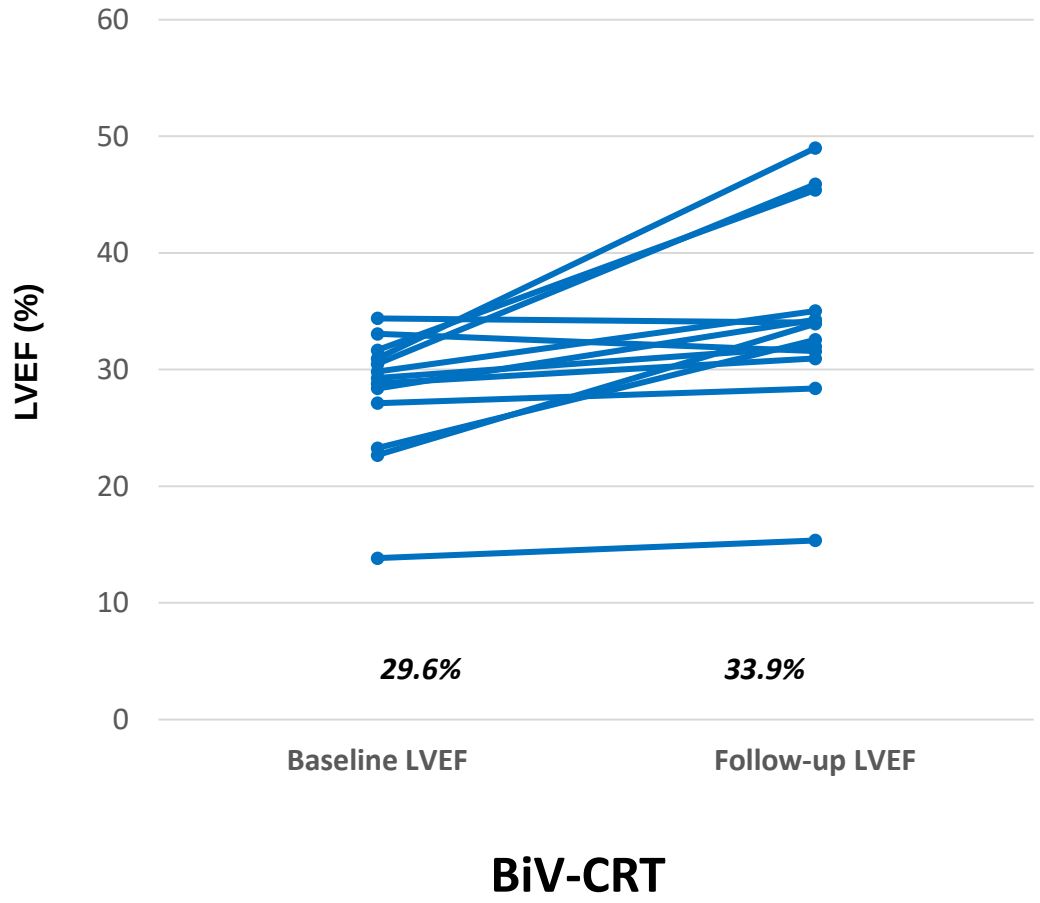


Typical LBBB pattern randomized to His corrective pacing

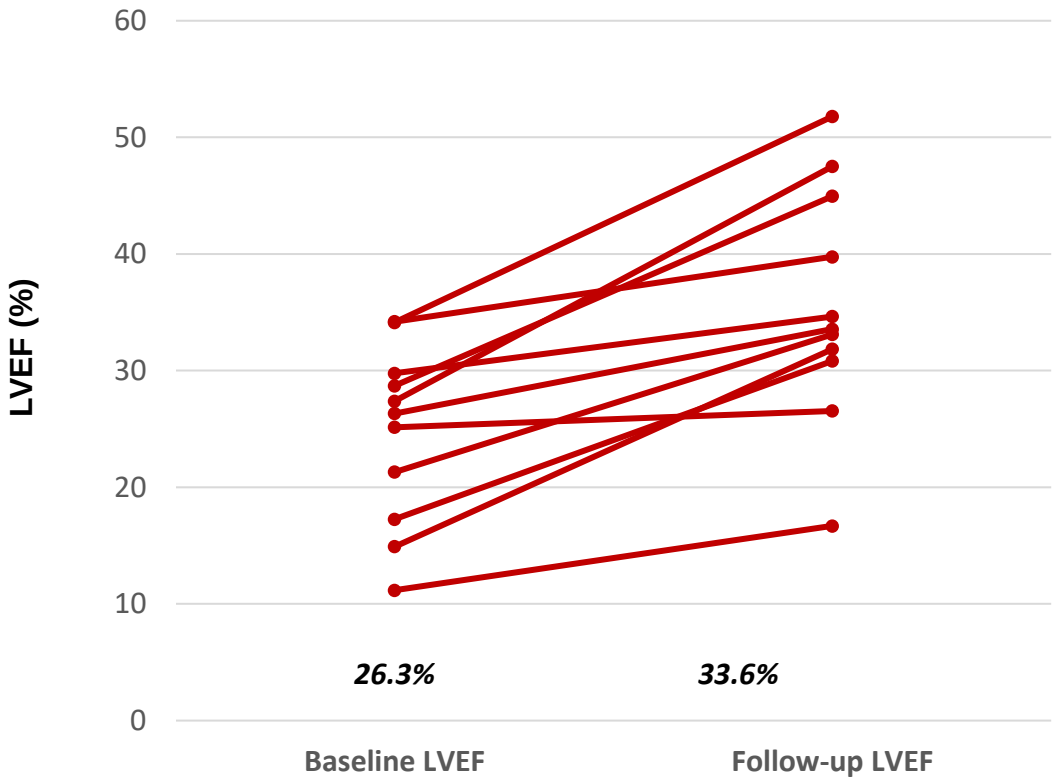


Tung, et al. JACC 2019 and LBCT HRS 2019

Results- *Per-Protocol Analysis*

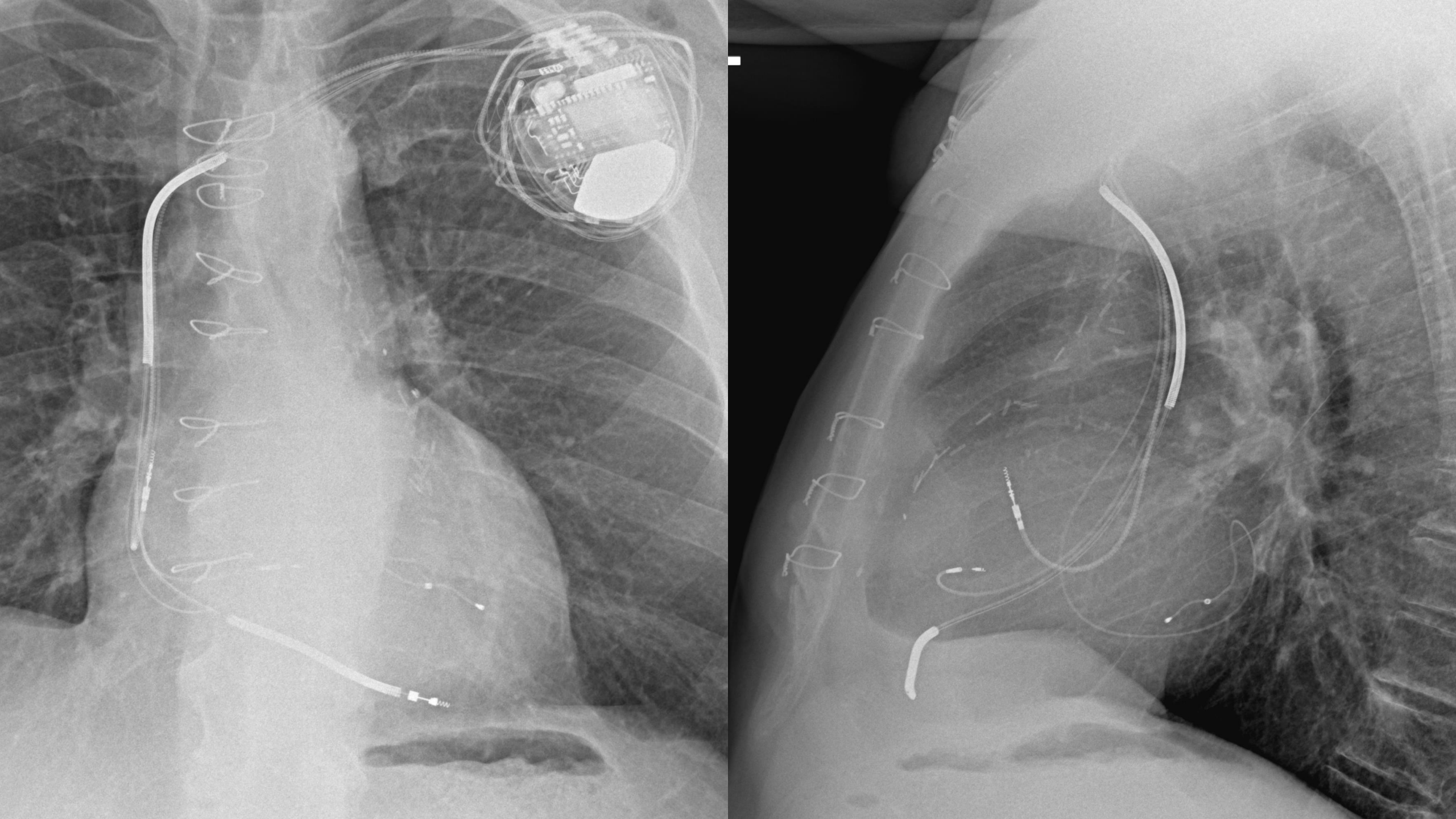


BiV-CRT

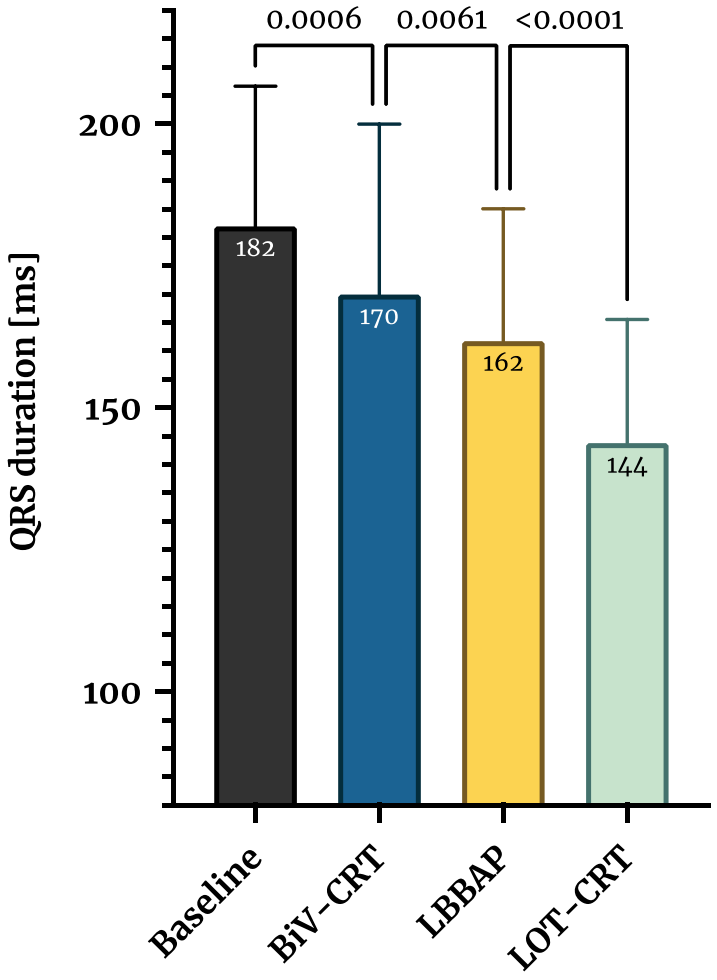


His-CRT

Tung, et al. JACC 2019 and LBCT HRS 2019

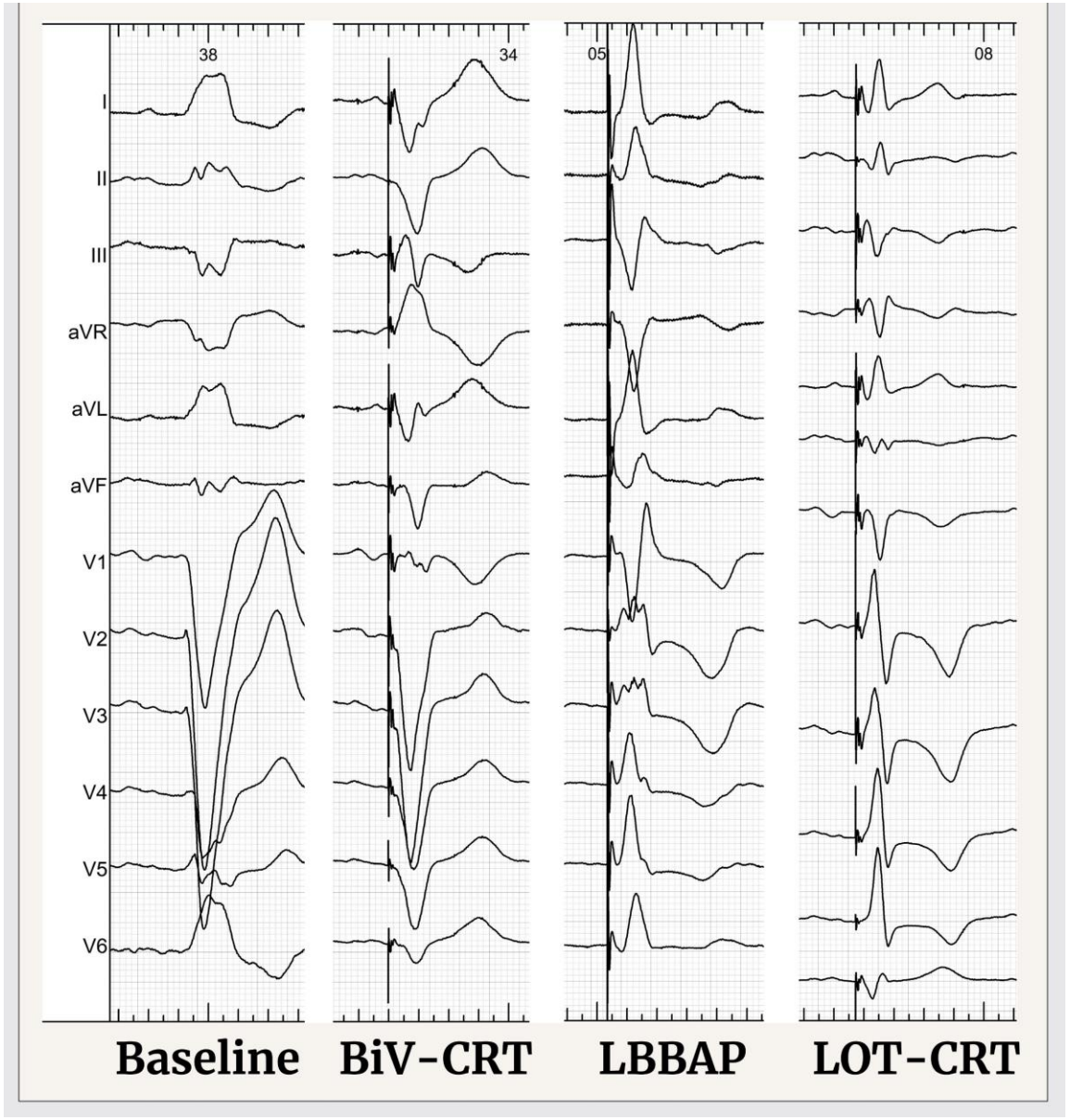


Electrocardiographic outcomes



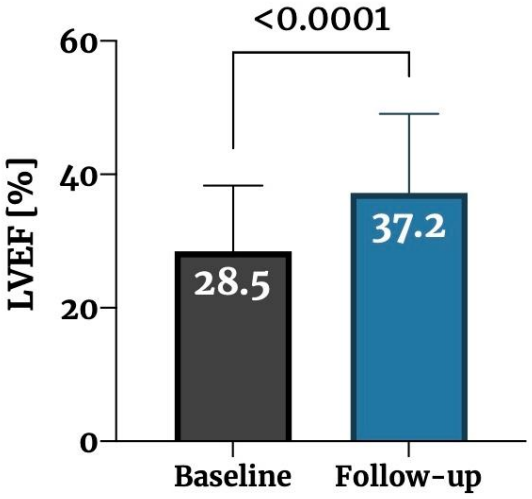
Lack of QRS narrowing during:

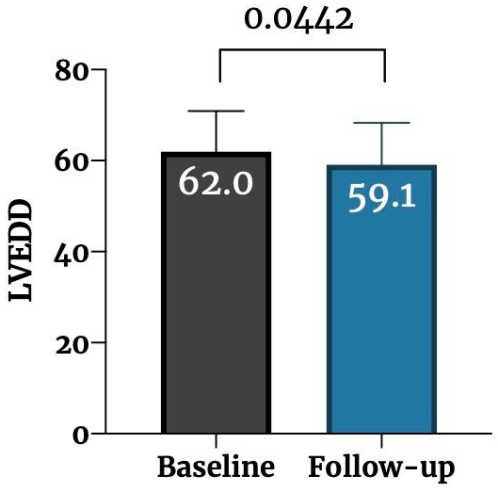
- BiV-CRT: 20.6%
- LOT-CRT: 3.3%

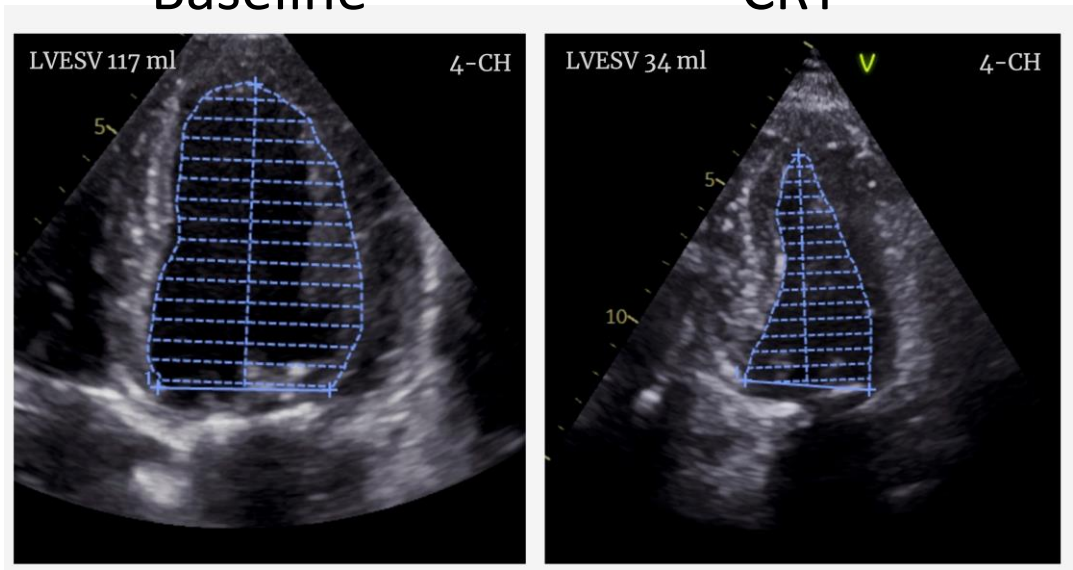


Jastrzębski, M et al. Heart Rhythm 2021

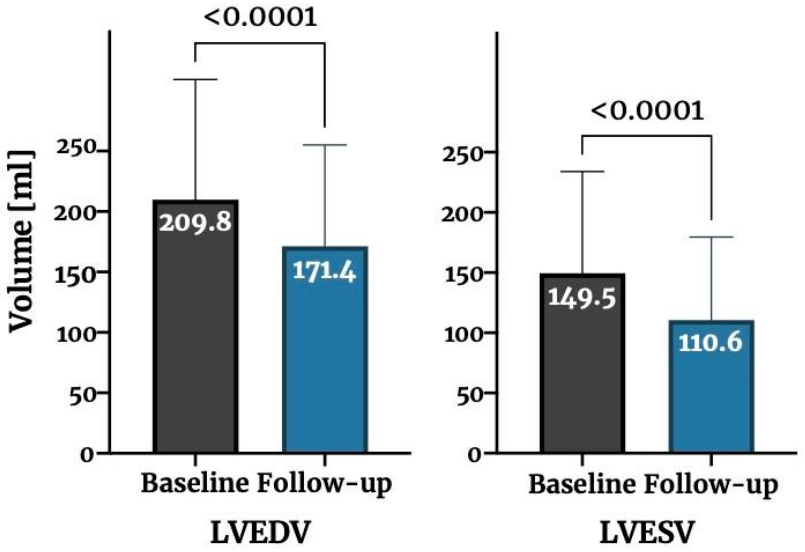
Echocardiographic outcomes





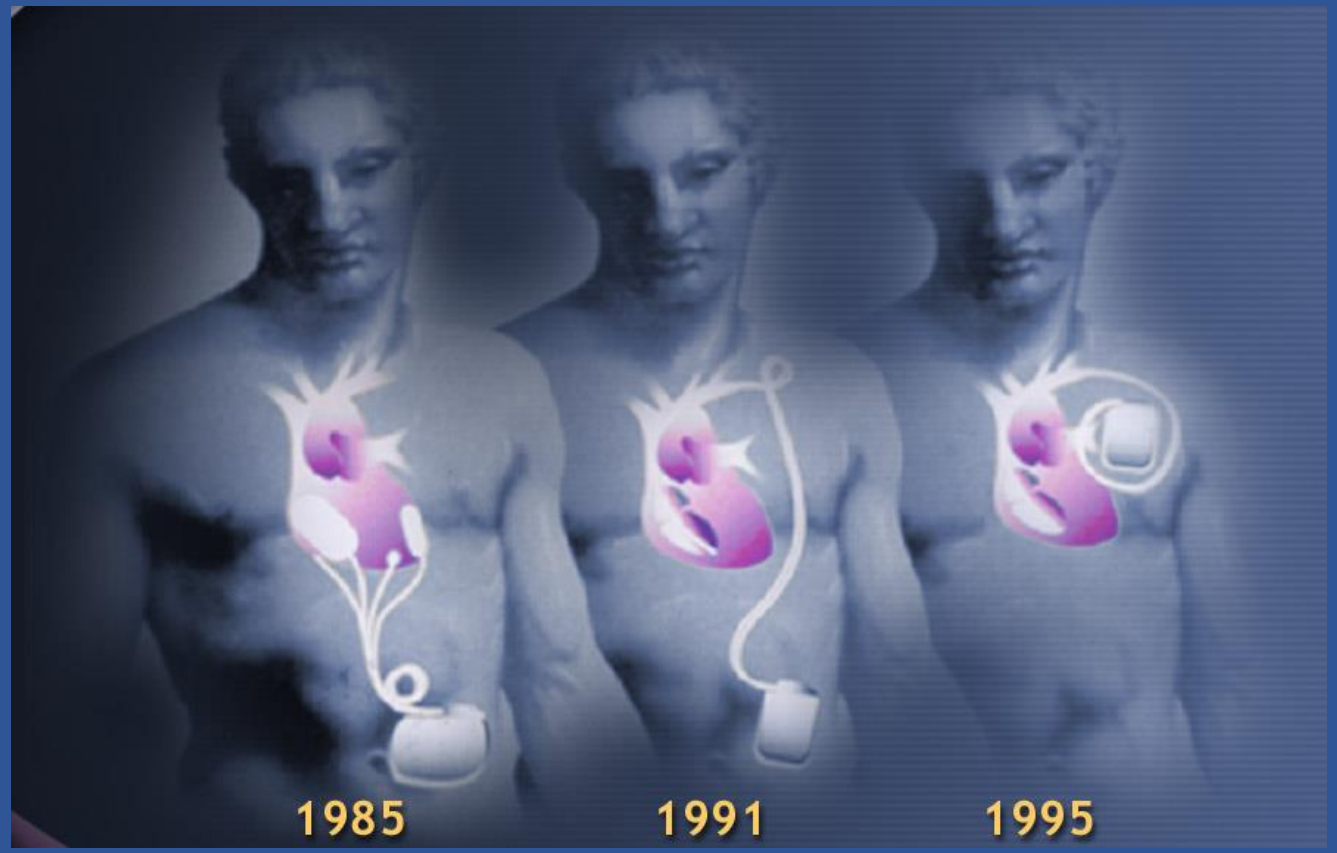


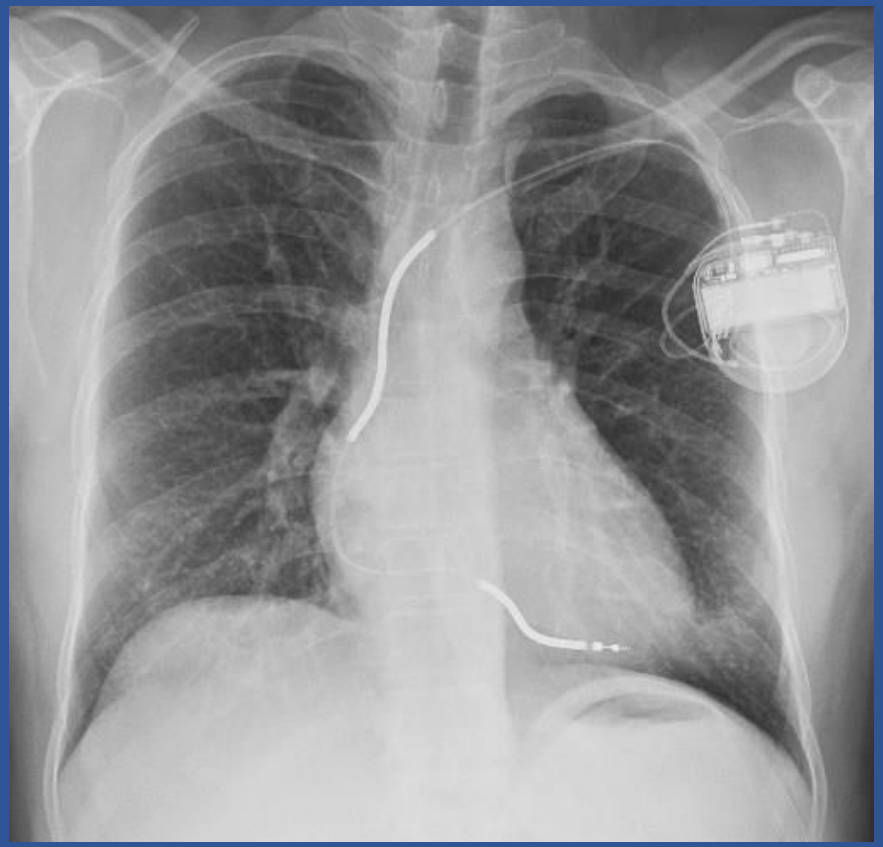
Super-response 24.4%



Jastrzębski, M et al. Heart Rhythm 2021

Treatment Options - ICDs


1985
1991
1995




209 cc
113 cc
80 cc
80 cc
72 cc
54 cc


49 cc
39.5 cc
39 cc
39.5 cc
39 cc
39.5 cc
36 cc

Hypothesis and Primary Endpoint

Sudden Cardiac Death
SCD-HeFT
Heart Failure Trial

- To determine, by intention-to-treat analysis, if amiodarone or a conservatively programmed shock-only single lead ICD reduces all-cause mortality compared to placebo* in patients with either ischemic or non-ischemic NYHA Class II and III CHF and EF $\leq$ 35%.

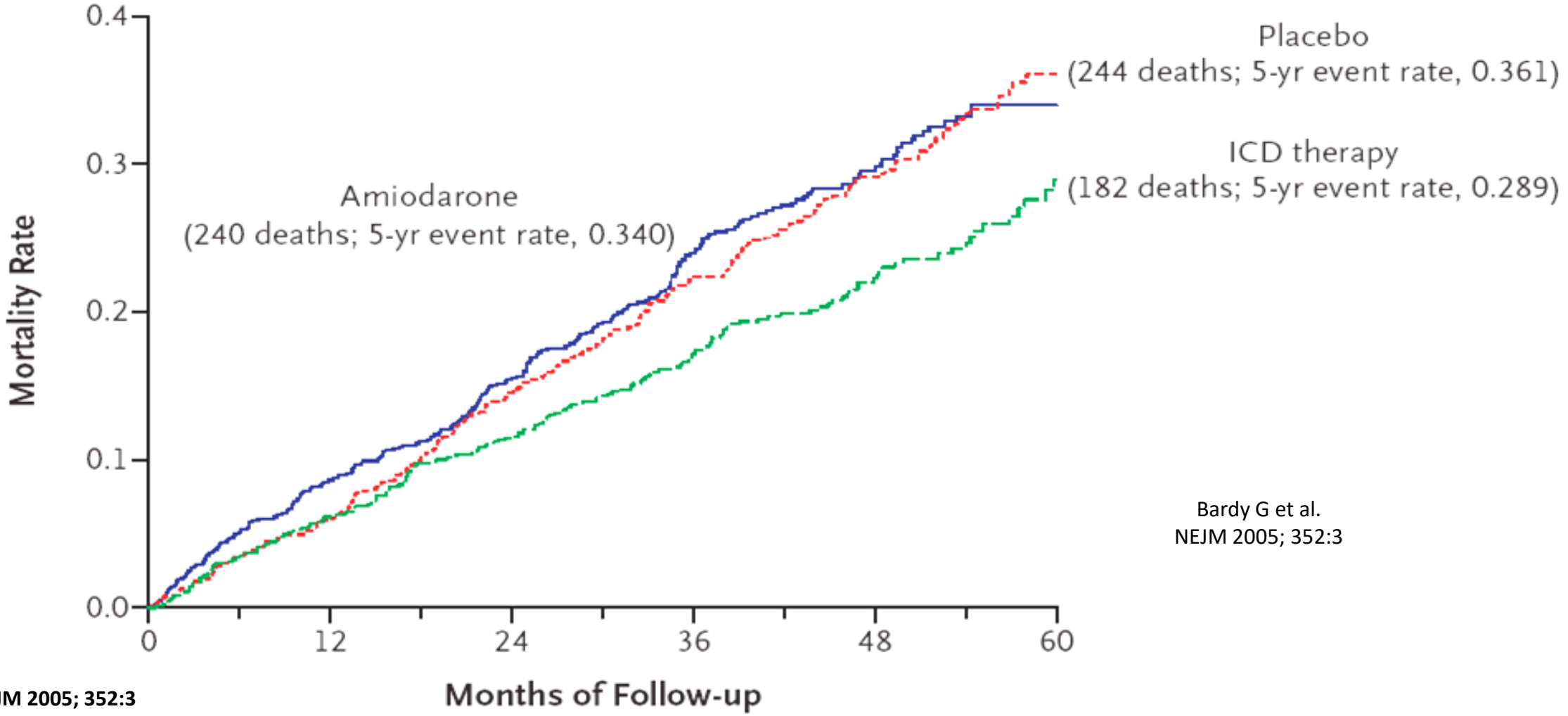
*Double-blind for drug therapy

Bardy G et al. NEJM 2005; 352:3

Kaplan-Meier Estimates of Death from Any Cause

Sudden Cardiac Death
SCD-HeFT
Heart Failure Trial

	Hazard Ratio (97.5% CI)	P Value
Amiodarone vs. placebo	1.06 (0.86–1.30)	0.53
ICD therapy vs. placebo	0.77 (0.62–0.96)	0.007

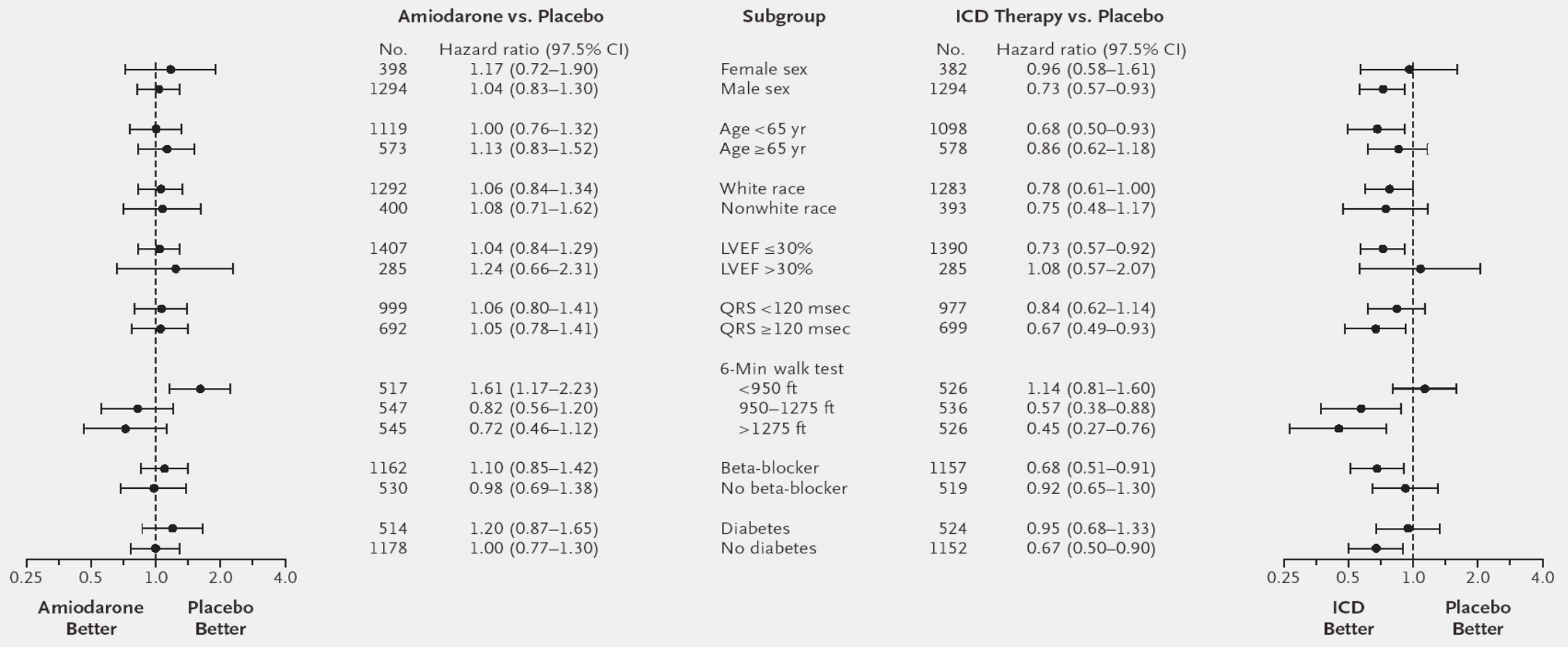


Bardy G et al.
NEJM 2005; 352:3

Bardy G et al. NEJM 2005; 352:3

Hazard Ratios for the Comparison of Amiodarone and ICD Therapy with Placebo

Sudden Cardiac Death
SCD-HeFT
Heart Failure Trial



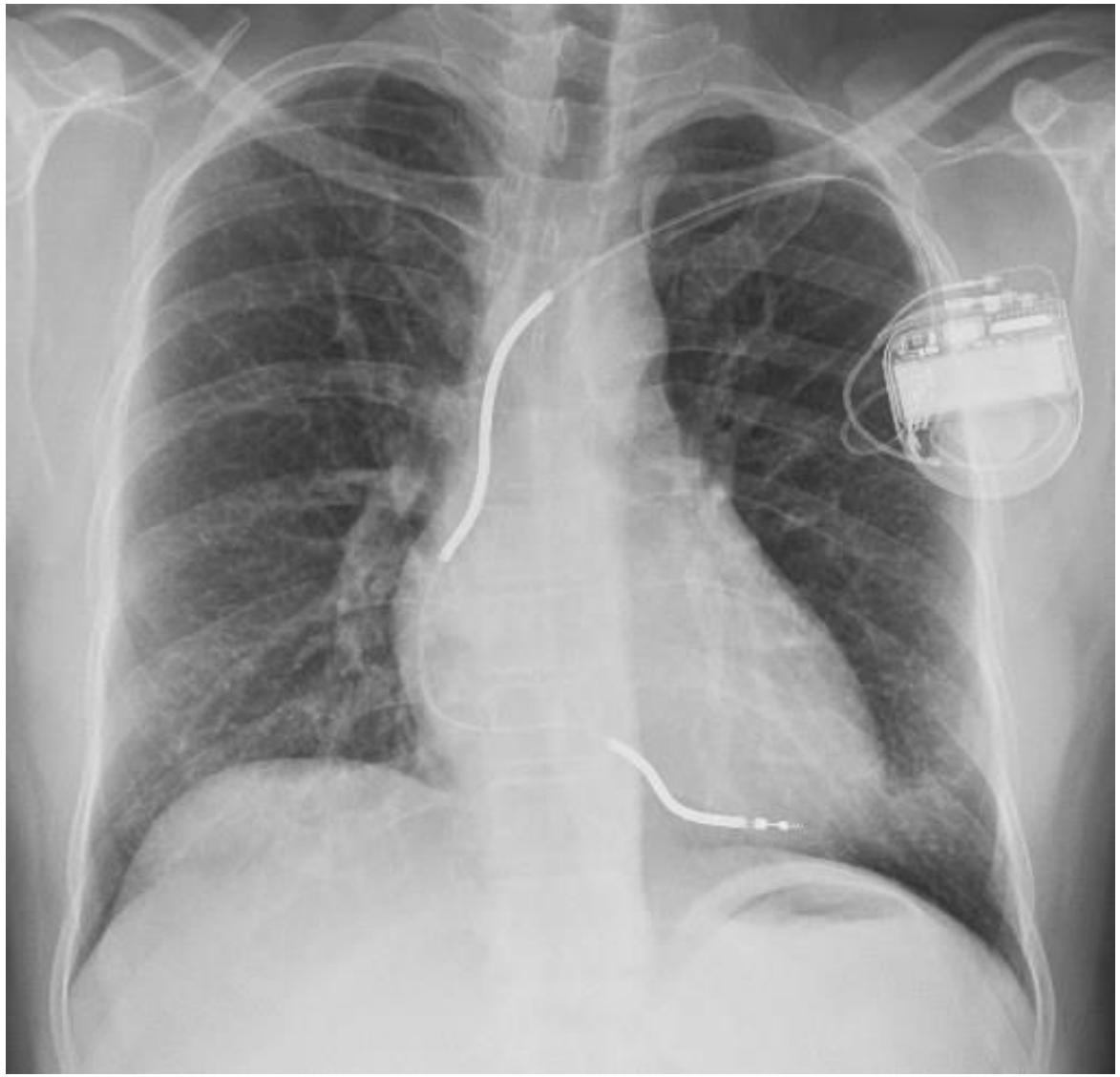
Bardy G et al. NEJM 2005; 352:3

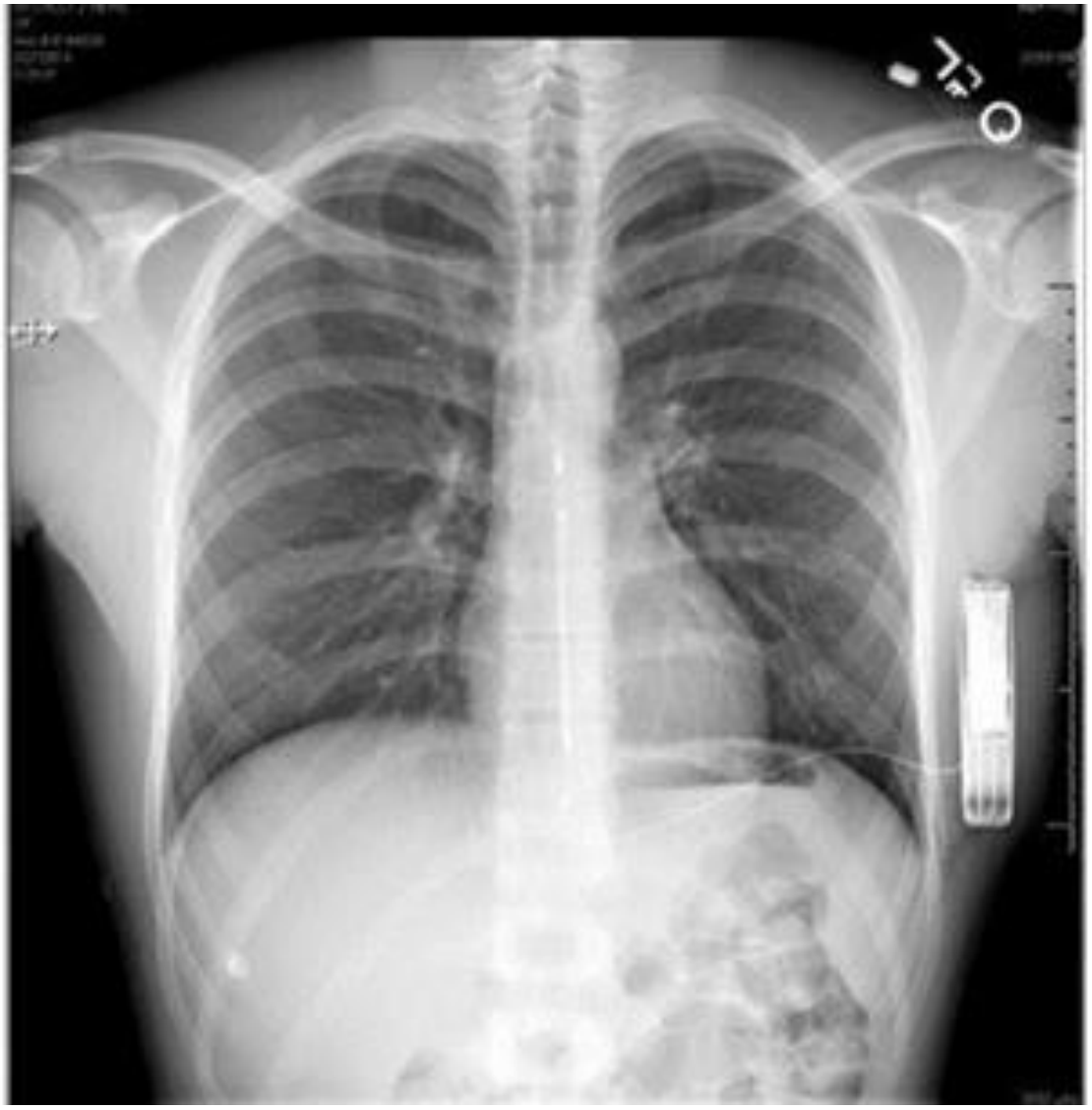
SCD-HeFT: Primary Conclusions

Sudden Cardiac Death
SCD-HeFT
Heart Failure Trial

- In class II or III CHF patients with EF < 35% on good background drug therapy, the mortality rate for placebo-controlled patients is 7.2% per year over 5 years
- Simple, single lead, shock-only ICDs decrease mortality by 23%
- Amiodarone, when used as a primary preventative agent, does not improve survival

Bardy G et al. NEJM 2005; 352:3





CMHC
Cardiometabolic Health Congress

www.cardiometabolichealth.org

Foundations of Cardiometabolic Health Certification Course

Certified Cardiometabolic Health Professional (CCHP)

Catheter Ablation

William H. Sauer, MD

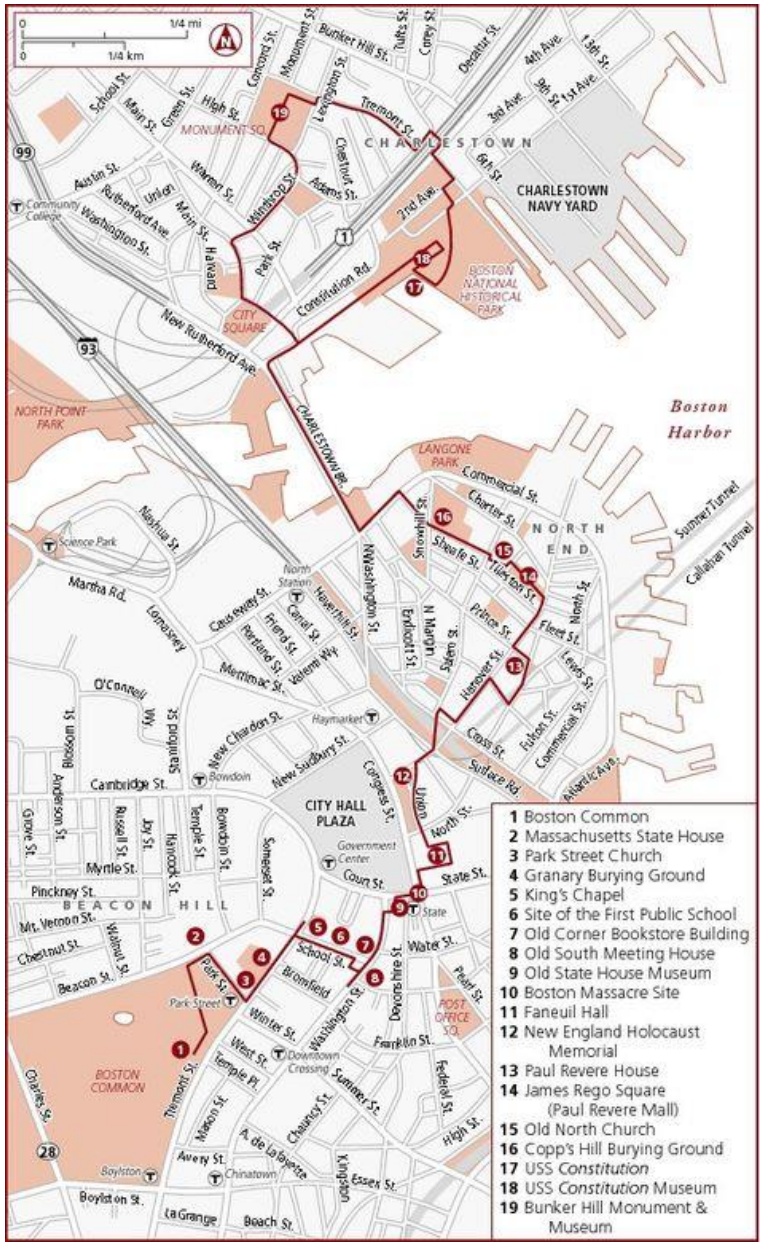
Chief, Cardiac Arrhythmia Services

Brigham and Women's Hospital

Harvard Medical School

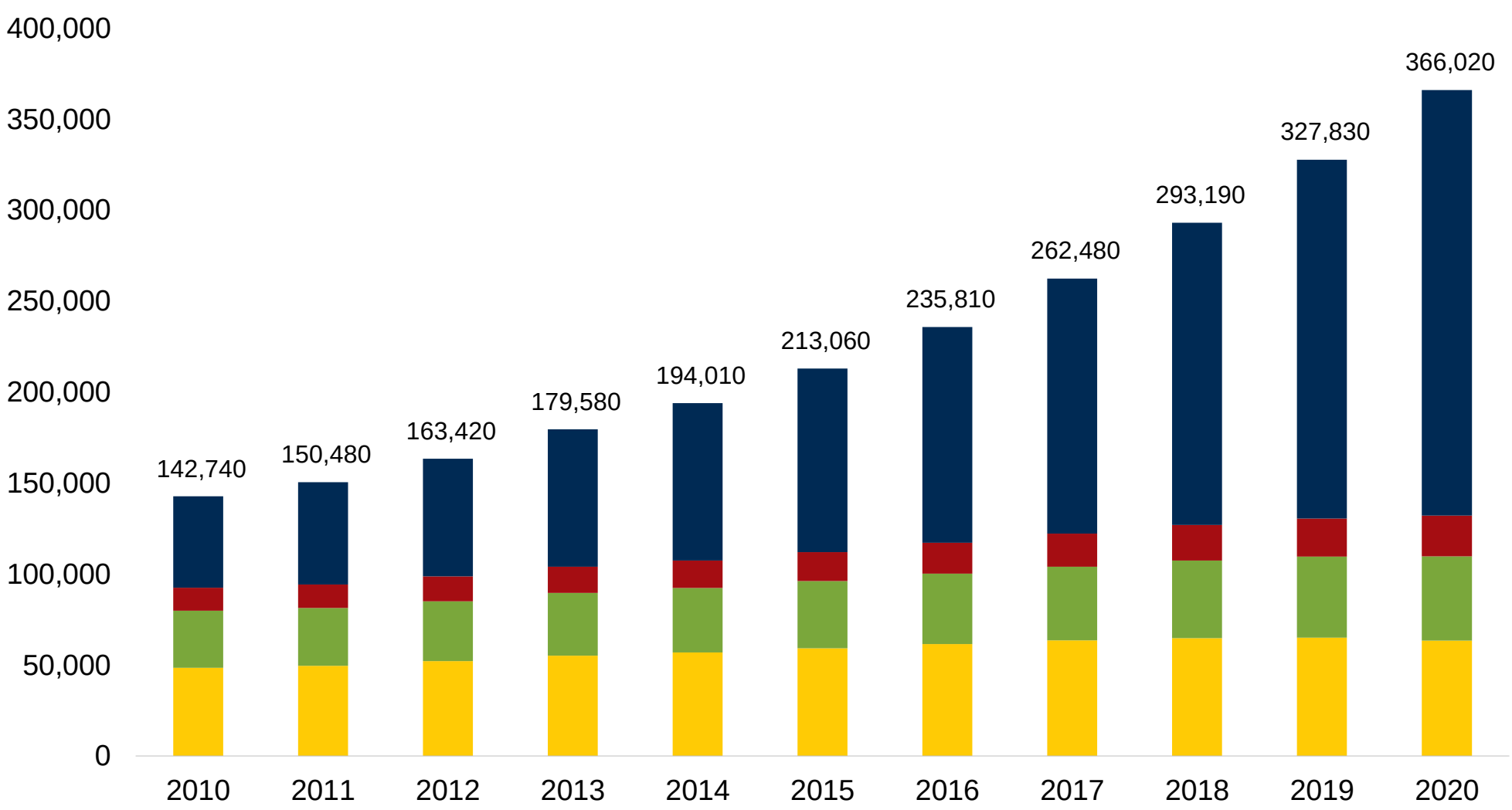
Road Map

- Overview of Cardiac Arrhythmias and Treatment Options
  - Antiarrhythmic Medications
    - AFFIRM 1999
    - EAST AF 2019
  - Implantable Devices
    - SCD-HeFT 2005
  - Catheter Ablation
    - CABANA 2019
    - PAUSE-SCD 2021
- Summary



Arrhythmia Treatment Options – Ablation

Cardiac Ablation Volume



CAGR 2010 – 2020	
AF	16.6%
VT	5.8%
AFL	3.9%
SVT	2.7%
ALL	9.8%

Consider the Alternative --Antiarrhythmic Drugs

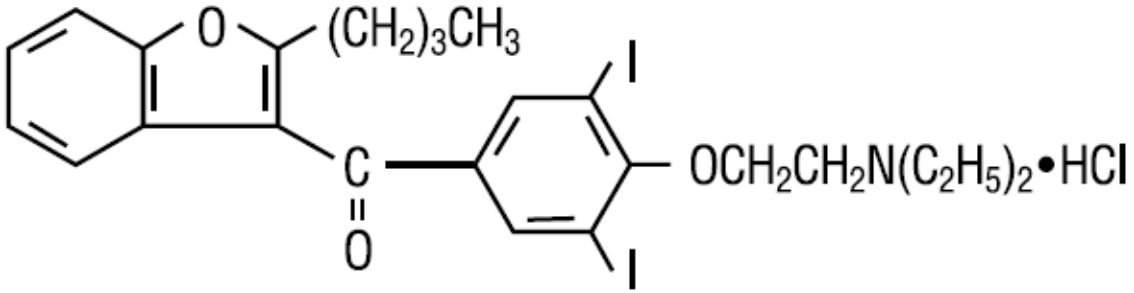
(Amiodarone HCl) Tablets

DESCRIPTION

(Amiodarone HCl) Tablets are a member of a new class of antiarrhythmic drugs with predominantly Class III (Vaughan Williams' classification) effects Tablets are available in three strengths, containing 100 mg, 200 mg, and 400 mg amiodarone hydrochloride, for oral administration. The 100 mg tablets are white tablets with the following inactive ingredients: anhydrous lactose, colloidal silicone dioxide, corn starch, magnesium stearate and povidone. The 200 mg tablets are pink, scored tablets with the following inactive ingredients: lactose monohydrate, magnesium stearate, povidone, pregelanitized corn starch, sodium starch glycolate, stearic acid, FD&C Red 40 and FD&C Yellow 6. The 400 mg tablets are light yellow, scored tablets with the following inactive ingredients: colloidal silicon dioxide, corn starch, lactose monohydrate, magnesium stearate, povidone and D&C Yellow 10 Aluminum Lake.

Amiodarone hydrochloride, the active ingredient in Tablets, is a benzofuran derivative: 2-butyl-3-benzofuranyl 4-[2-(diethylamino)-ethoxy]-3,5-diiodophenyl ketone hydrochloride. It is not chemically related to any other available antiarrhythmic drug.

The structural formula is as follows:



$C_{25}H_{29}I_2NO_3 \bullet HCl$

Molecular Weight: 681.8

https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=730039c2-0a32-4775-855d-98b2207e93e2

PRECAUTIONS

Impairment of Vision

Optic Neuropathy and/or Neuritis

Cases of optic neuropathy and optic neuritis have been reported (see "**WARNINGS**").

Corneal Microdeposits

Corneal microdeposits appear in the majority of adults treated with amiodarone. They are usually discernible only by slit-lamp examination, but give rise to symptoms such as visual halos or blurred vision in as many as 10% of patients. Corneal microdeposits are reversible upon reduction of dose or termination of treatment. Asymptomatic microdeposits alone are not a reason to reduce dose or discontinue treatment (see "**ADVERSE REACTIONS**").

Neurologic

Chronic administration of oral amiodarone in rare instances may lead to the development of peripheral neuropathy that may resolve when amiodarone is discontinued, but this resolution has been slow and incomplete.

Photosensitivity

Amiodarone has induced photosensitization in about 10% of patients; some protection may be afforded by the use of sun-barrier creams or protective clothing. During long-term treatment, a blue-gray discoloration of the exposed skin may occur. The risk may be increased in patients of fair complexion or those with excessive sun exposure, and may be related to cumulative dose and duration of therapy.

Thyroid Abnormalities

Amiodarone inhibits peripheral conversion of thyroxine (T_4) to triiodothyronine (T_3) and may cause increased thyroxine levels, decreased T_3 levels and increased levels of inactive reverse T_3 (rT_3) in clinically euthyroid patients. It is also a potential source of large amounts of inorganic iodine. Because of its release of inorganic iodine, or perhaps for other reasons, amiodarone can cause either hypothyroidism or hyperthyroidism. Thyroid function should be monitored prior to treatment and periodically thereafter, particularly in elderly patients, and in any patient with a history of thyroid nodules, goiter or other thyroid dysfunction. Because of the slow elimination of amiodarone and its metabolites, high plasma iodide levels, altered thyroid function and abnormal thyroid-function tests may persist for several weeks or even months following Pacerone® (Amiodarone HCl) Tablets withdrawal.

The following side-effect rates are based on a retrospective study of 241 patients treated for 2 to 1,515 days (mean 441.3 days).

The following side effects were each reported in 10 to 33% of patients:

Gastrointestinal: Nausea and vomiting.

The following side effects were each reported in 4 to 9% of patients:

Dermatologic: Solar dermatitis/photosensitivity.
Neurologic: Malaise and fatigue, tremor/abnormal involuntary movements, lack of coordination, abnormal gait/ataxia, dizziness, paresthesias.
Gastrointestinal: Constipation, anorexia.
Ophthalmologic: Visual disturbances.
Hepatic: Abnormal liver-function tests.
Respiratory: Pulmonary inflammation or fibrosis.

The following side effects were each reported in 1 to 3% of patients:

Thyroid: Hypothyroidism, hyperthyroidism.
Neurologic: Decreased libido, insomnia, headache, sleep disturbances.
Cardiovascular: Congestive heart failure, cardiac arrhythmias, SA node dysfunction.
Gastrointestinal: Abdominal pain.
Hepatic: Nonspecific hepatic disorders.
Other: Flushing, abnormal taste and smell, edema, abnormal salivation, coagulation abnormalities.

What is the most important information I should know about amiodarone Tablets?

Tablets can cause serious side effects that can lead to death including:

- **lung damage**
- **liver damage**
- **worse heartbeat problems**
- **thyroid problems**

Call your doctor or get medical help right away if you have any symptoms such as the following:

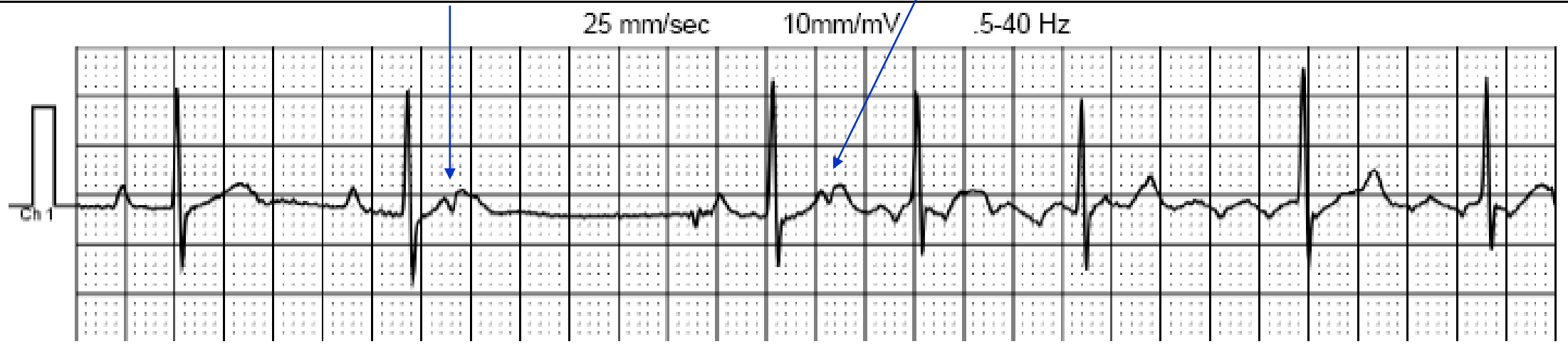
- shortness of breath, wheezing, or any other trouble breathing; coughing, chest pain, or spitting up of blood

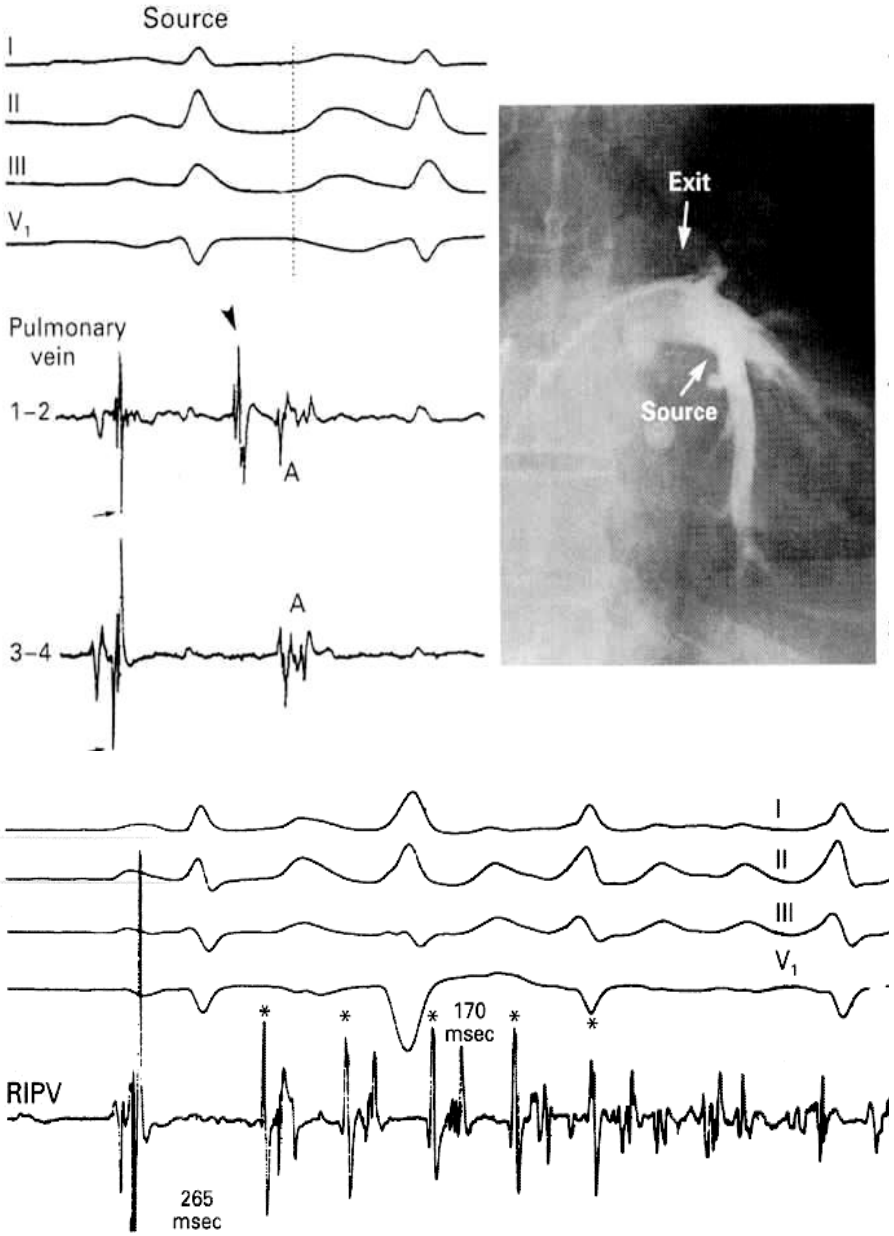
Catheter Ablation

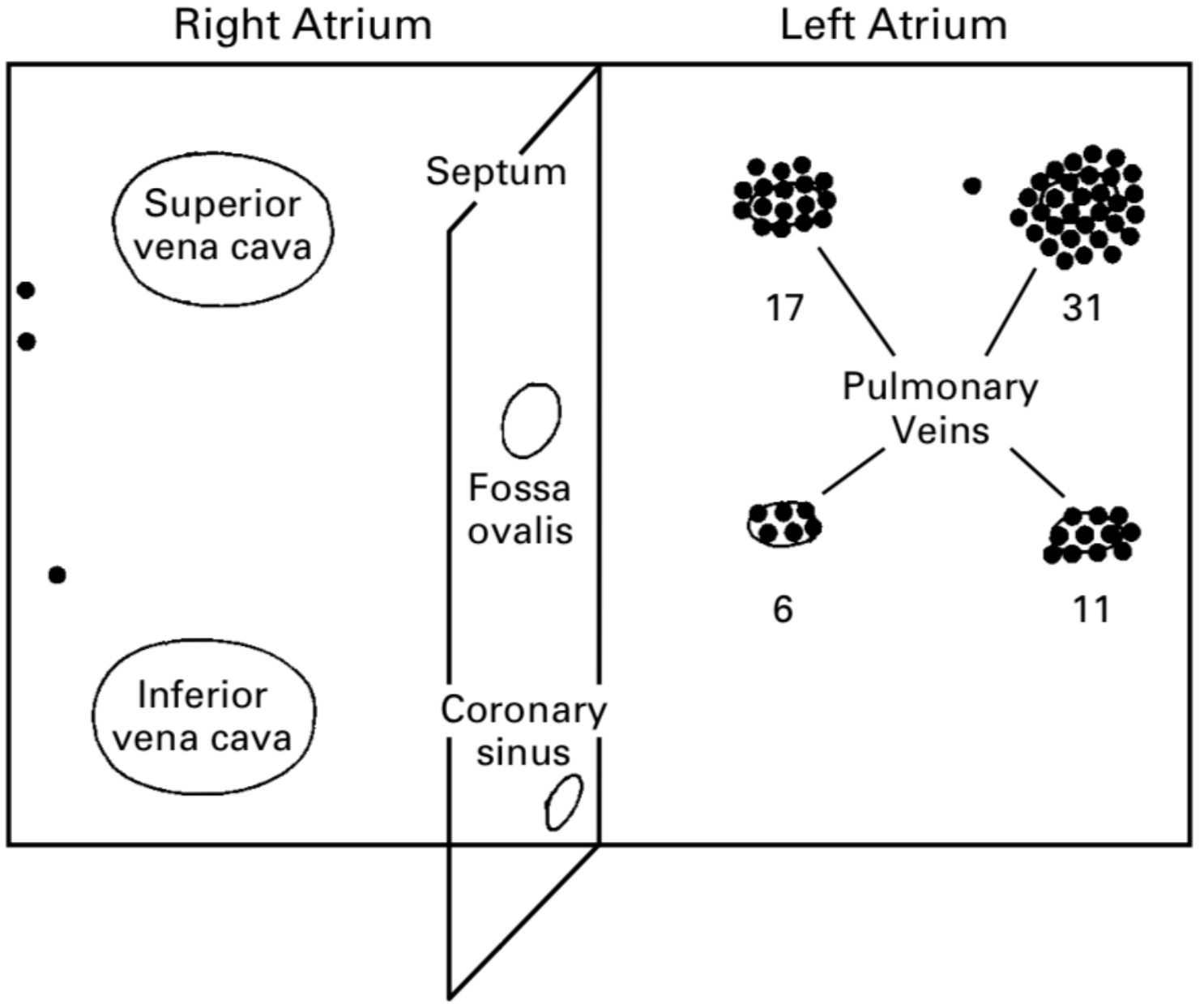
- Continued advancements with improved technology leading to improved outcomes
  - Electroanatomical mapping
  - Intracardiac echocardiography
  - Force sensing catheters
  - Automated signal processing
  - Introduction of varied energy sources

Identification of an AF trigger

Preliminary Findings	HR 64 bpm	Activities: None Indicated
Sinus Rhythm with 1st Degree AVB Blocked PAC and Atrial Fibrillation/Flutter Onset		Symptoms: None Indicated







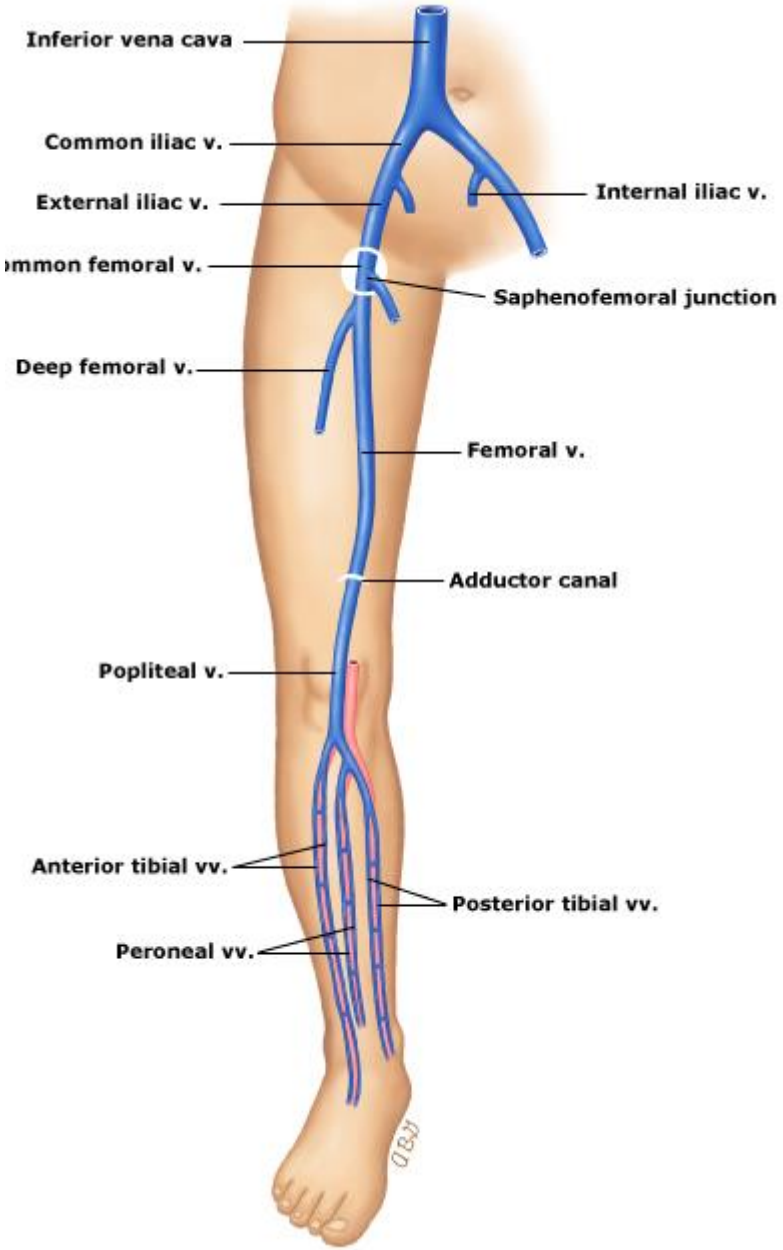
Haissaguerre M, et al. NEJM 1998

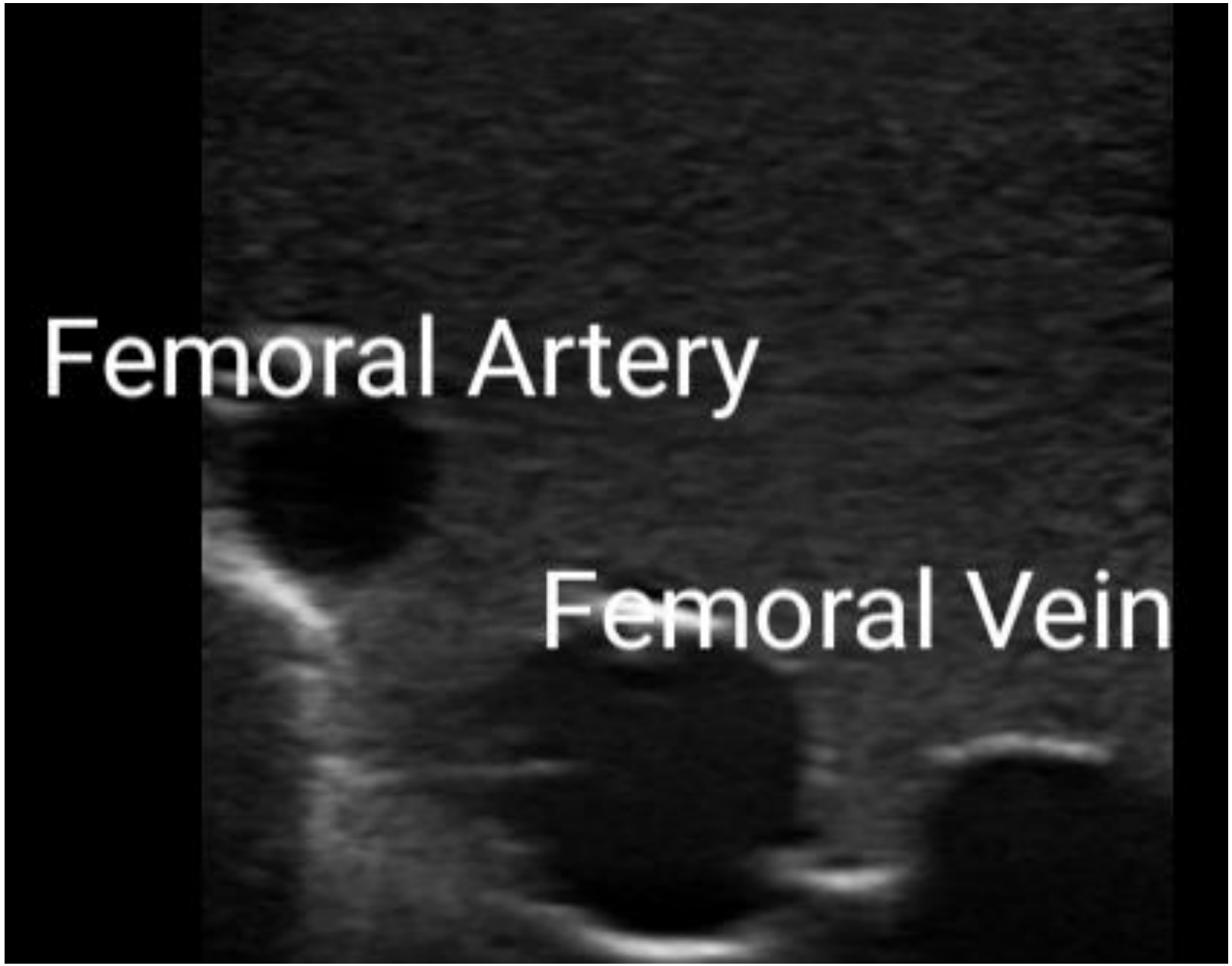
Equipment and Personnel in the Ablation

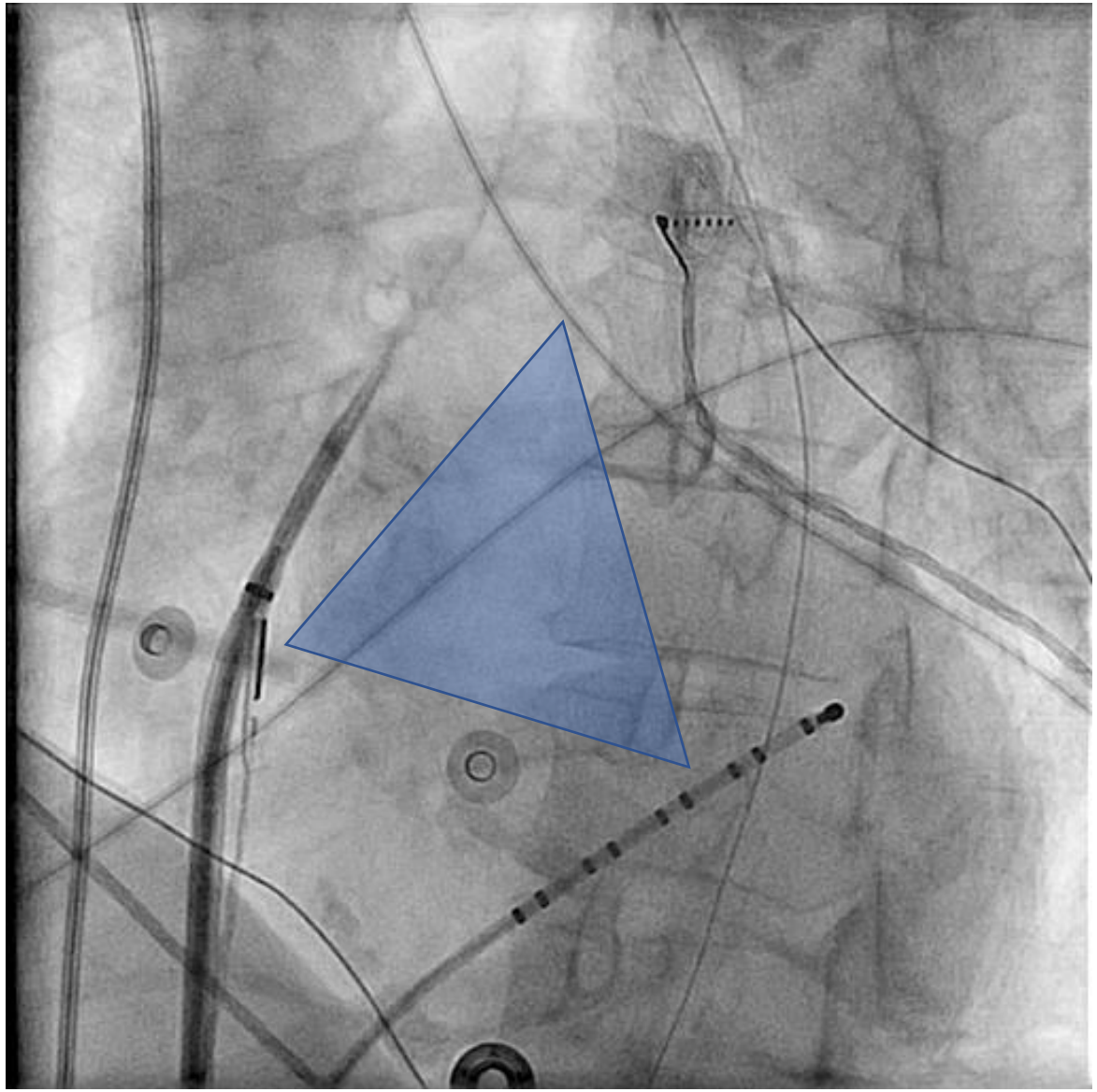
- Fluoroscopy
- Electroanatomical Mapping System

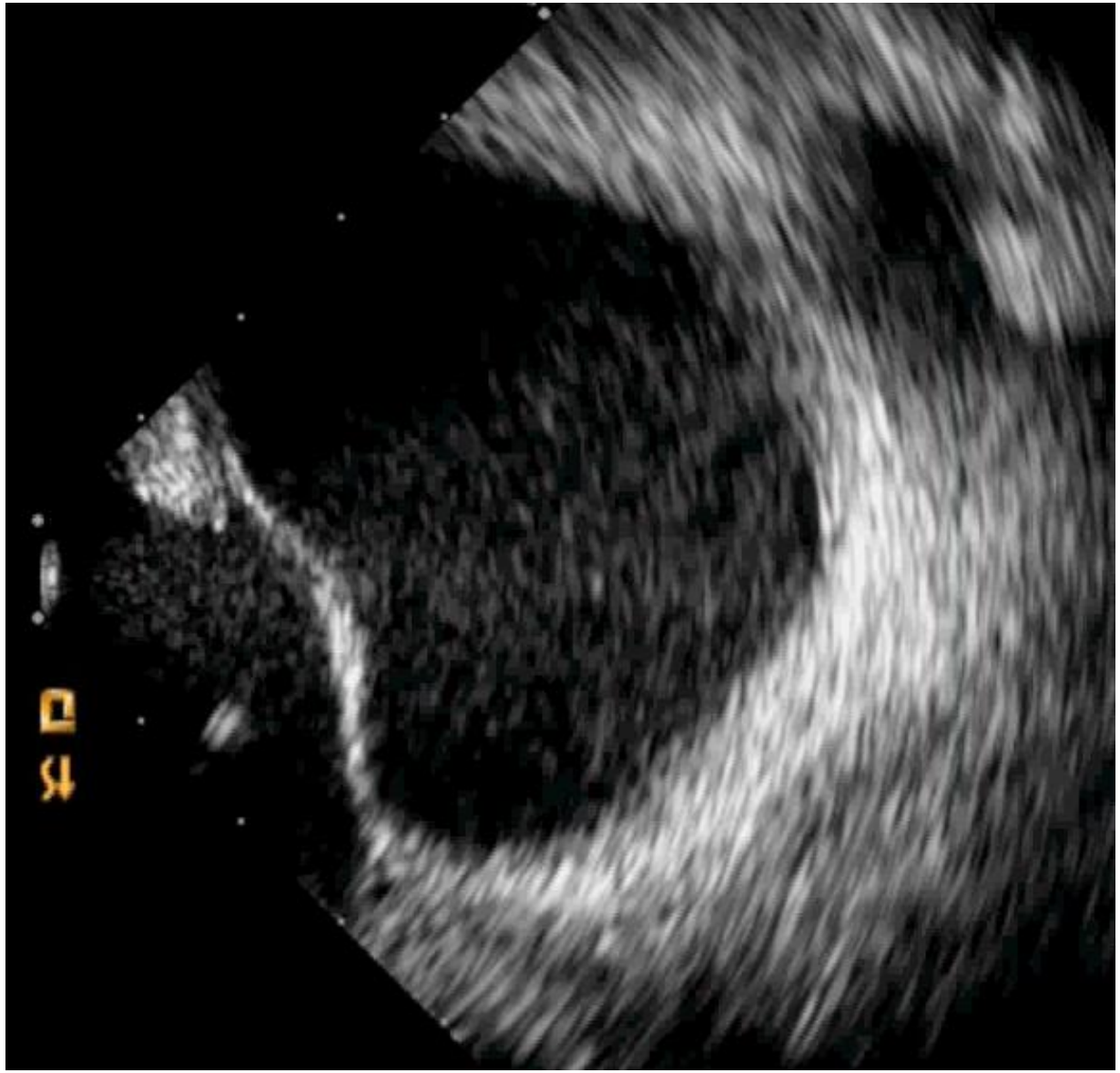
- Ultrasound catheter
- Ablation catheter
- Mapping catheter(s)

- MD Assistant
- Technicians
- Nurses
- Anesthesiologist
- Electrophysiologist

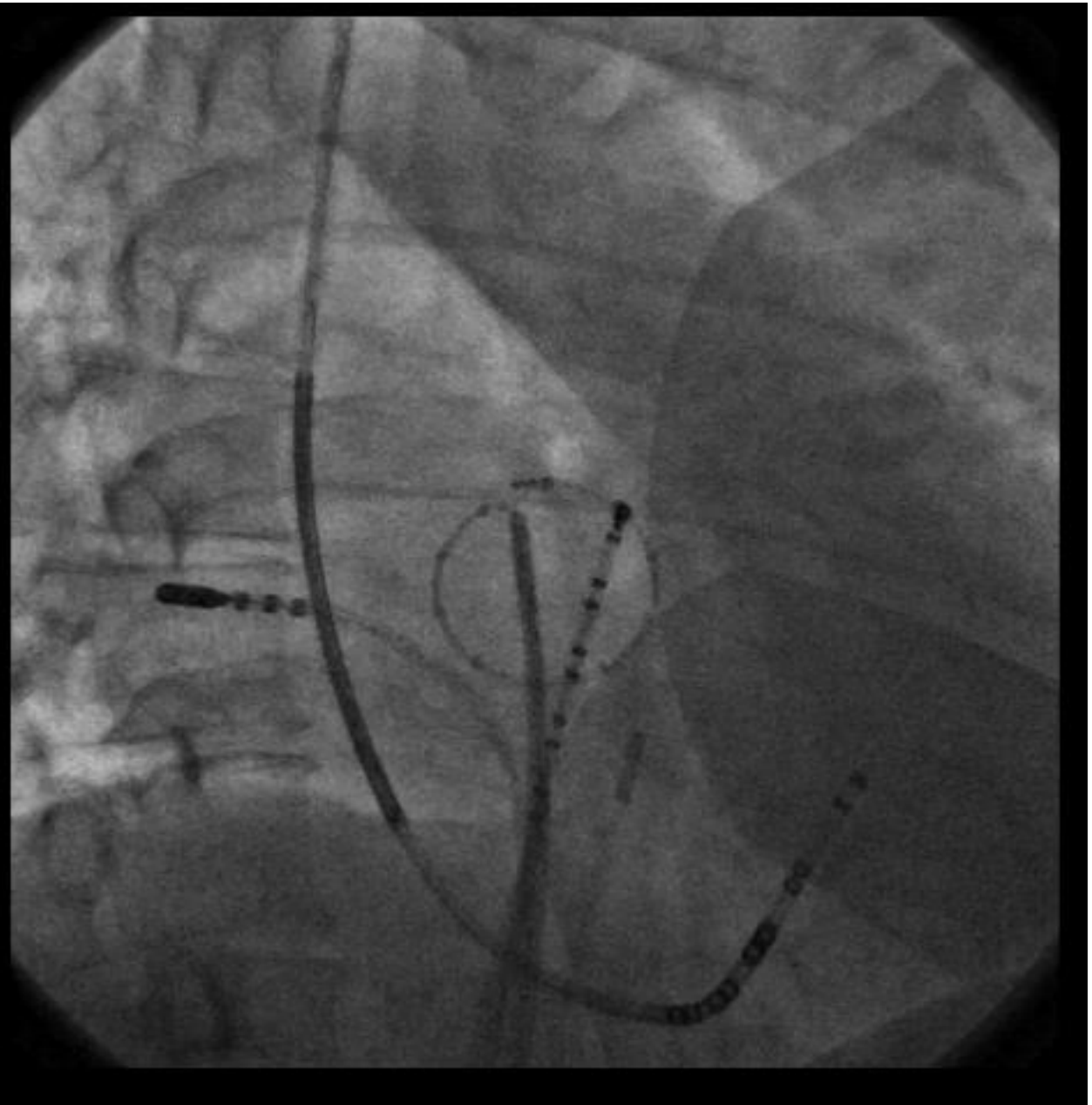

Inferior vena cava
Common iliac v.
External iliac v.
Internal iliac v.
ommon femoral v.
Saphenofemoral junction
Deep femoral v.
Femoral v.
Adductor canal
Popliteal v.
Anterior tibial vv.
Posterior tibial vv.
Peroneal vv.

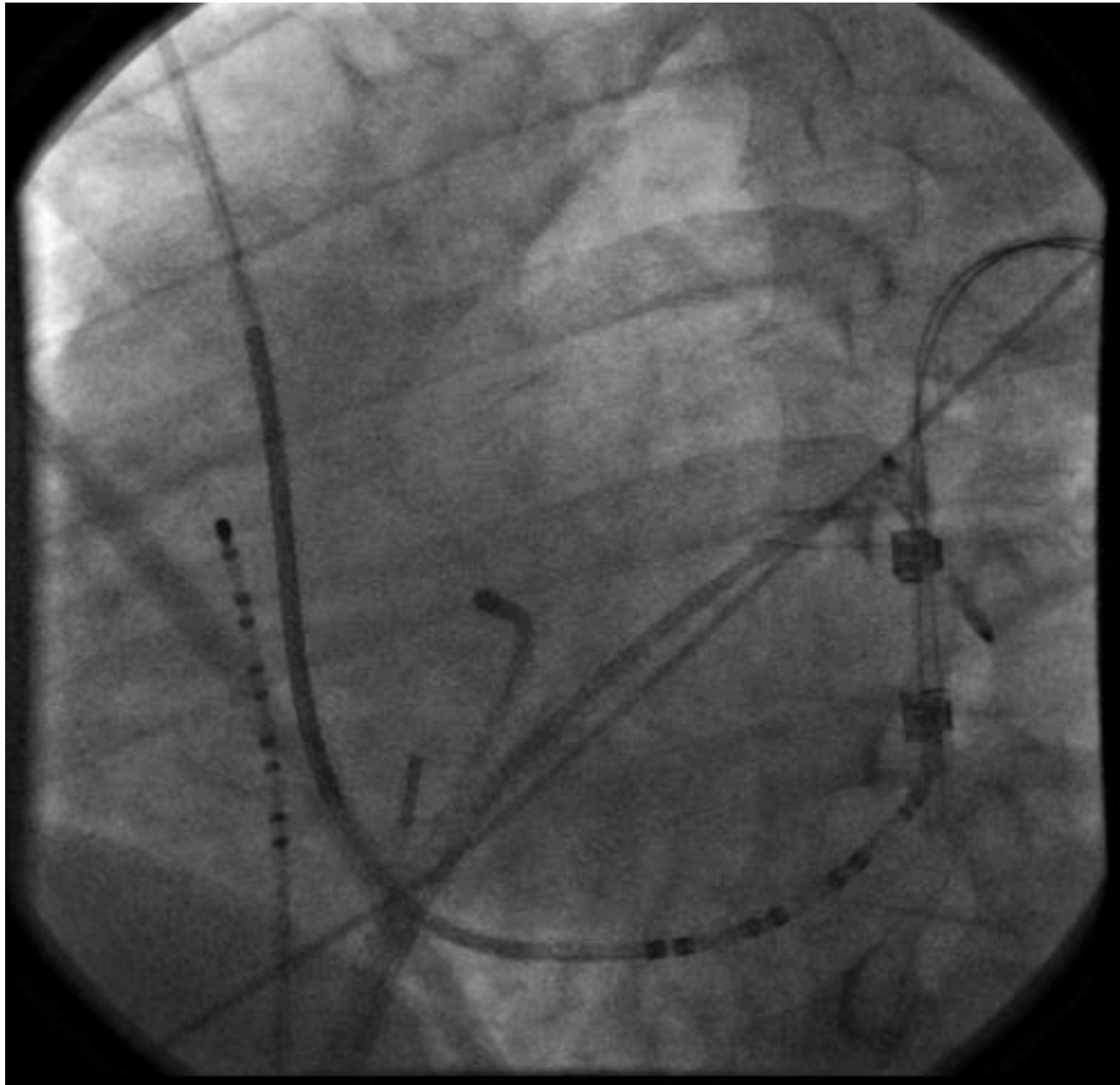

Femoral Artery
Femoral Vein



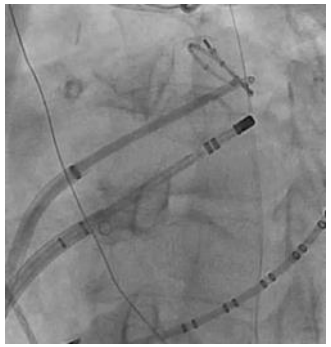


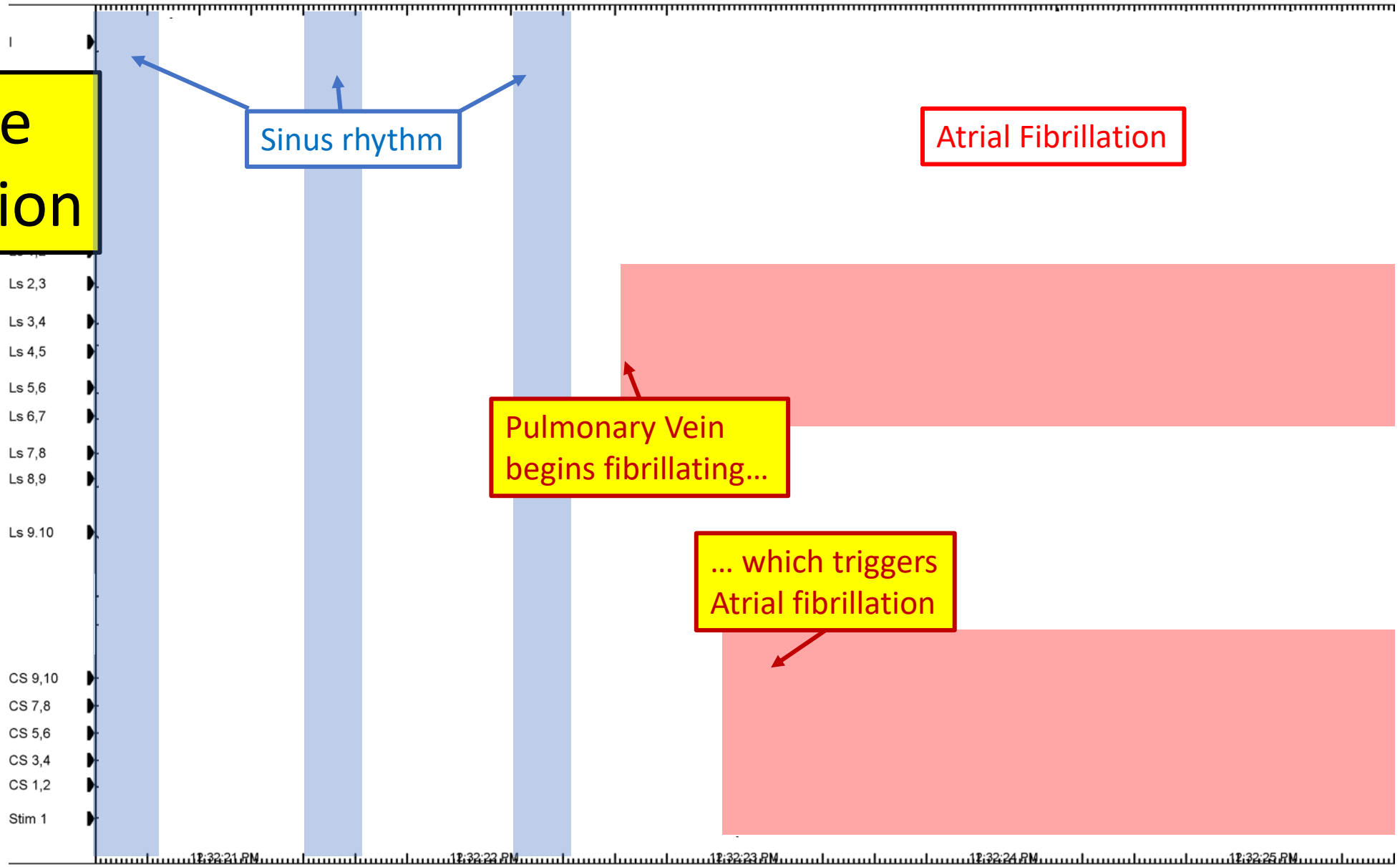
Catheter Positions for Identification of AF initiation



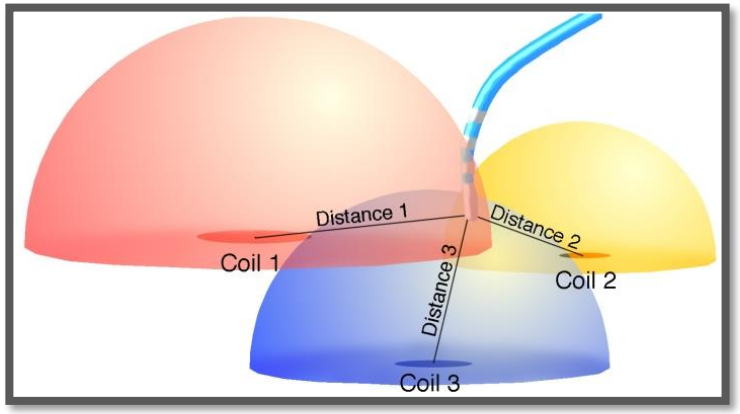


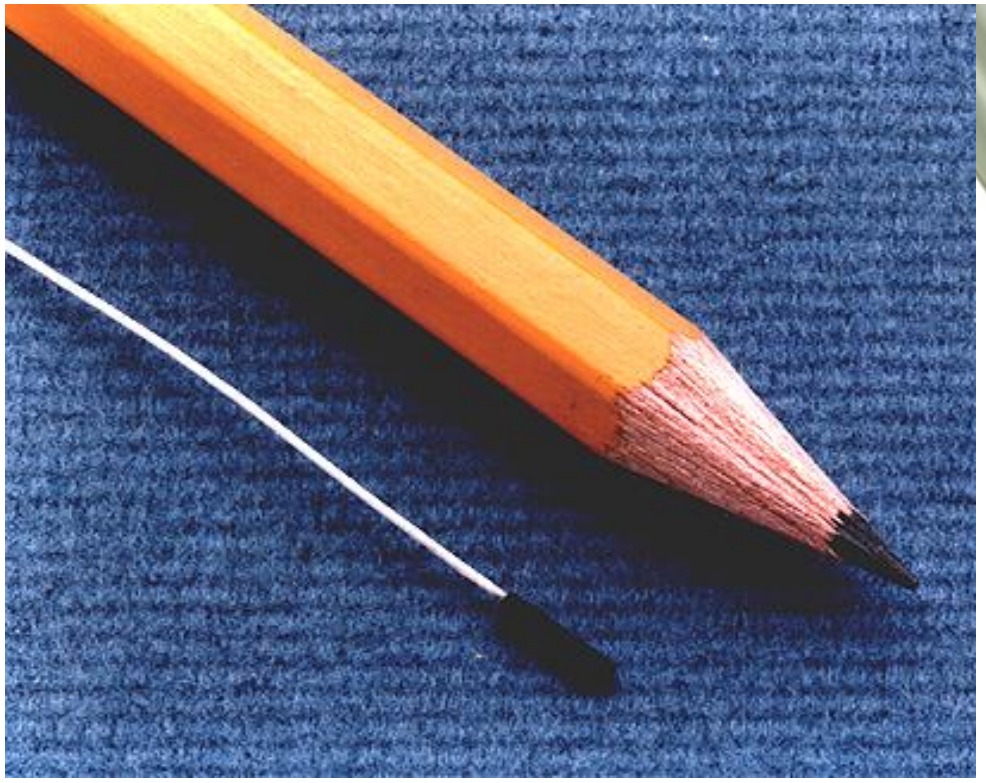
Before Ablation

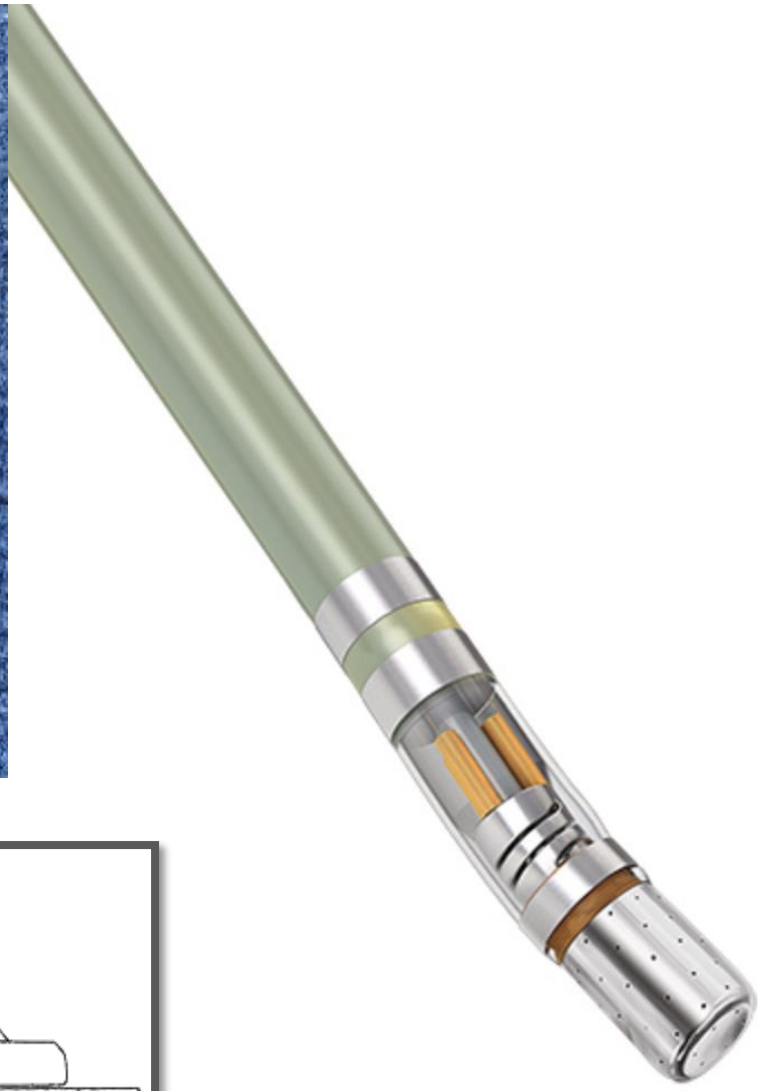


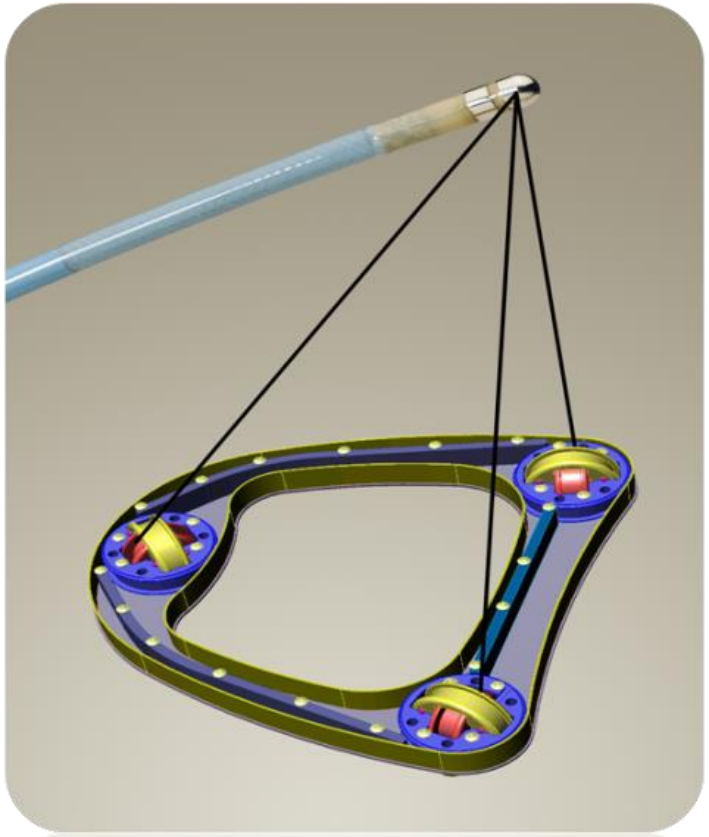


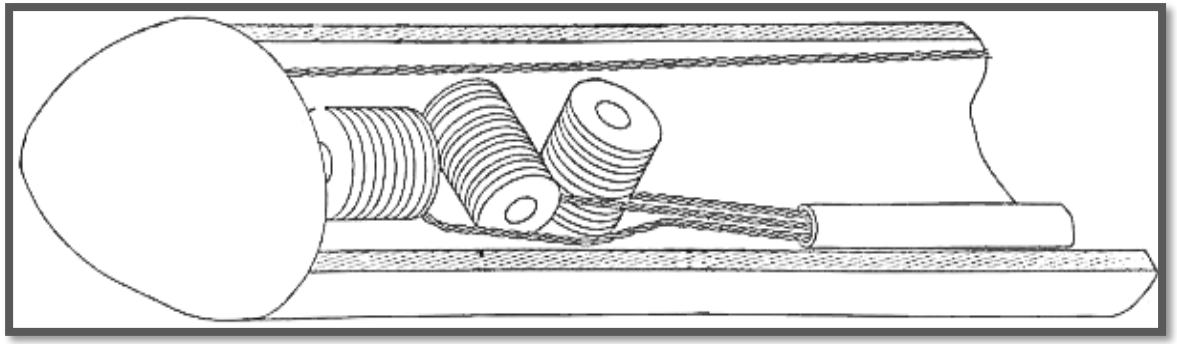
Electroanatomical Mapping

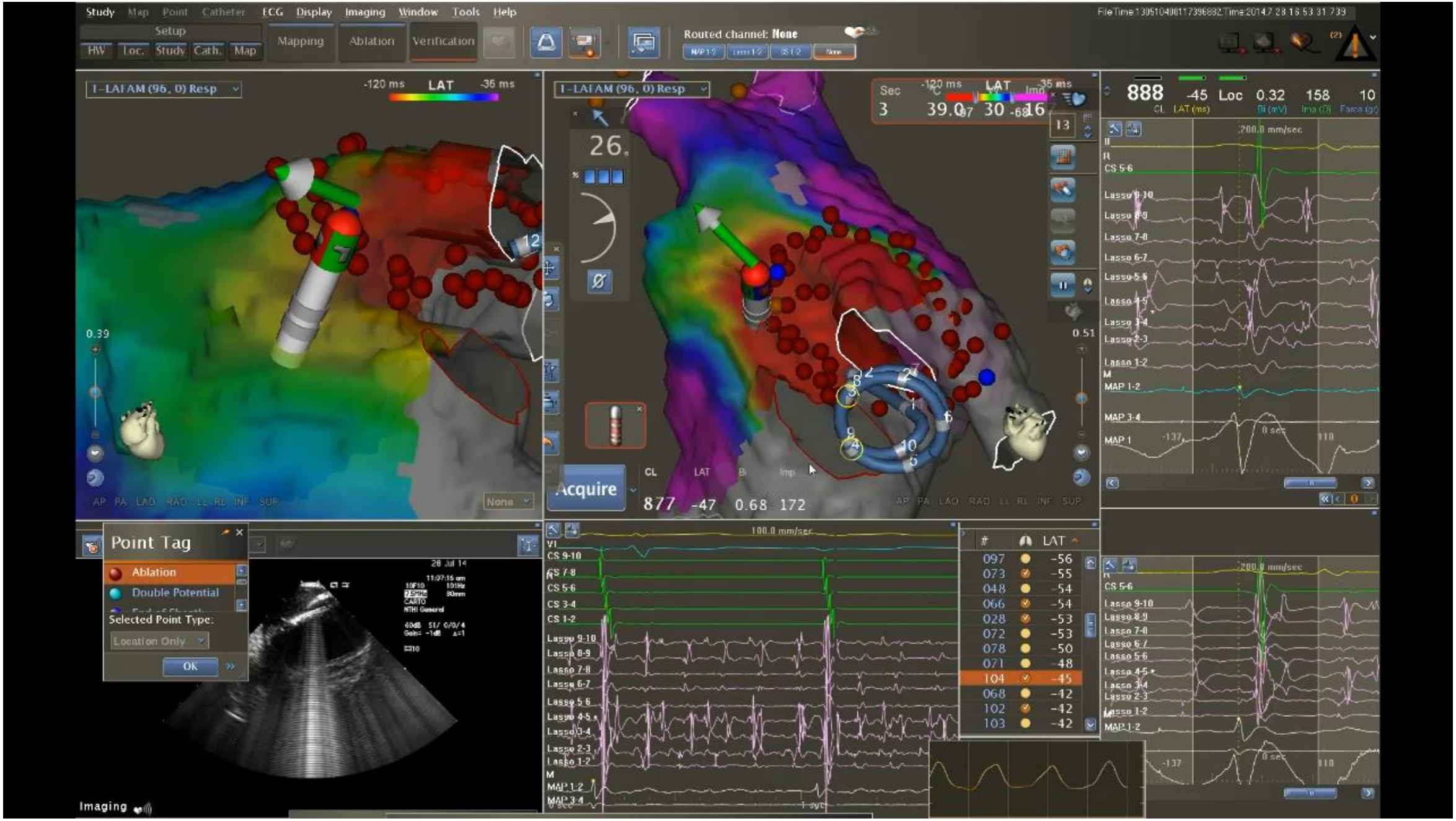











Study Map Point Catheter ECG Display Imaging Window Tools Help
Setup
HW Loc. Study Cath. Map
Mapping
Ablation
Verification
Routed channel: None
I-LATAM (96, 0) Resp
-120 ms LAT -35 ms
Acquire
CL LAT Bi Imp
877 -47 0.68 172
888 -45 Loc 0.32 158 10
Point Tag
Ablation
Double Potential
Selected Point Type:
Location Only
Ok
Imaging
LAT
097 -56
073 -55
048 -54
066 -54
028 -53
072 -53
078 -50
071 -48
104 -45
068 -42
102 -42
103 -42

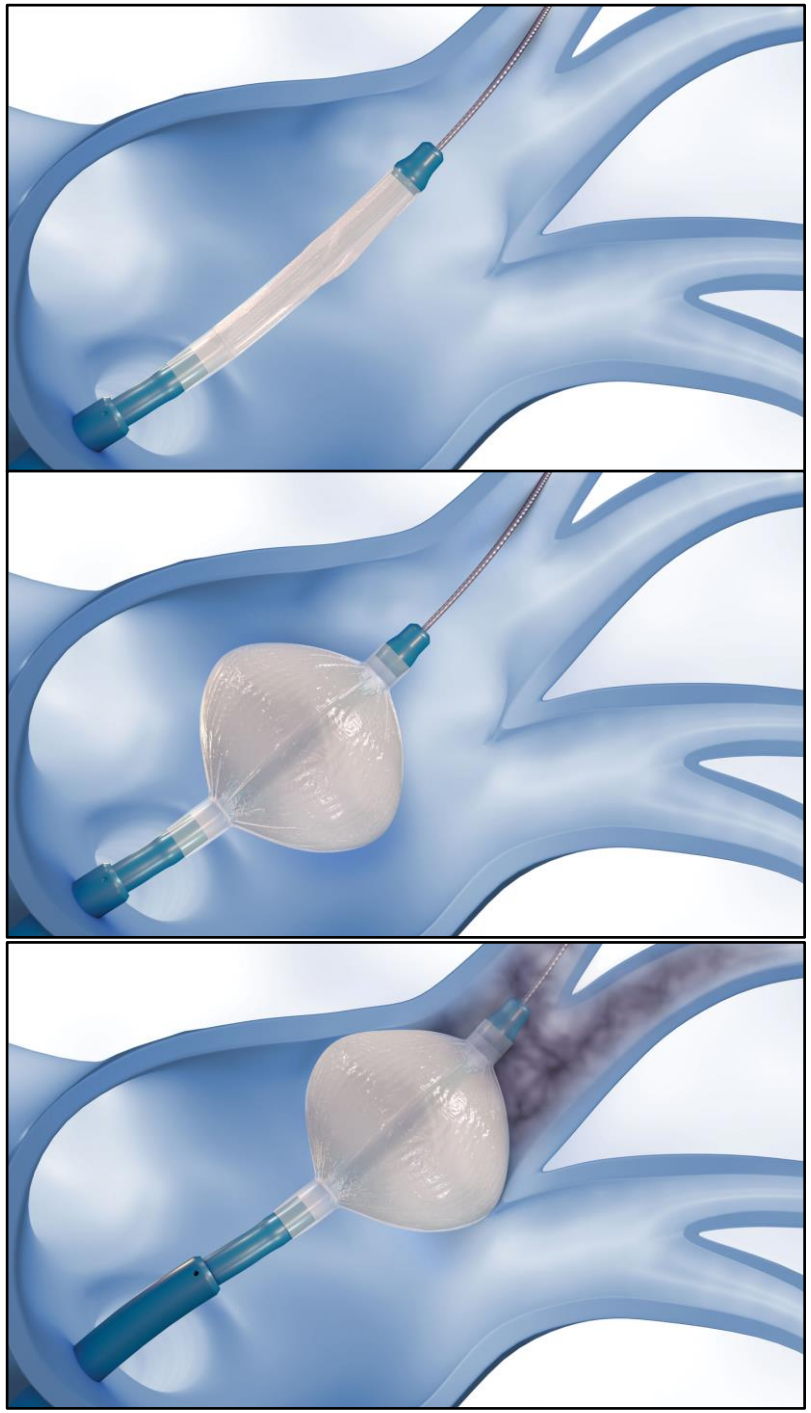

Study Map Point Catheter ECG Display Imaging Window Tools Help
Setup
HW Study Loc. Cath. Map
ultrasound Ablation mapping
Routed Channel None
4-1-Rel... (38, 0) Resp
0.10 mV Bi 0.50 mV
200 gs FTI 350 gs
Force
12
Bi
0.19
Imp
126
CL
829
LAT
88
0.51
0%
AP PA LAO RAO LL RL INF SUP
None
5-ra fam (3, 0) Resp
Bi
FTI
0.53
60%
AP PA LAO RAO LL RL INF SUP
Timeline
W 126Ω
50 W 200 Ω 150 g
40 30 20 10
54 48 42 36
170 140 110 80
150
0 12 24 36 48 60 Sec
Time Type ectrode Preset ommer
602 -62 Loc 189.7 N/A N/A 6
CL LAT (ms) Bi (mV) µBi (mV) Imp (Ω) Force (g)
2000 mm/sec
CS 9-10
CS 7-8
CS 5-6
CS 3-4
CS 1-2
Penta 1-2
Penta 3-4
Penta 5-6
Penta 7-8
Penta 9-10
Penta 11-12
Penta 13-14
Penta 15-16
Penta 17-18
Penta 19-20
MAP 1-2
MAP 3-4
MAP 1
MAP 2
-120
120
0sec
0s 1s 2s
Imag

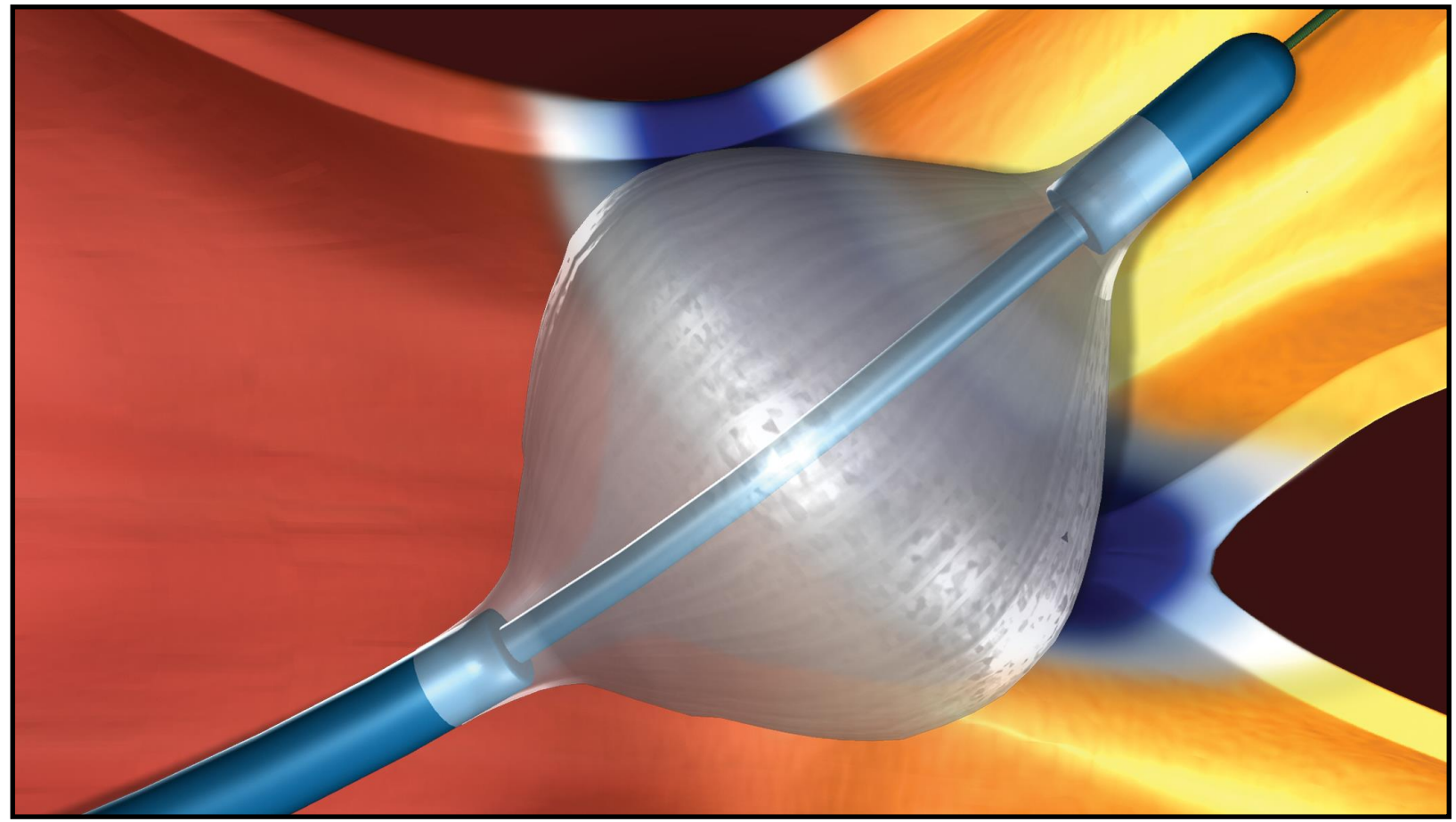
After Ablation

Sinus rhythm (on surface)

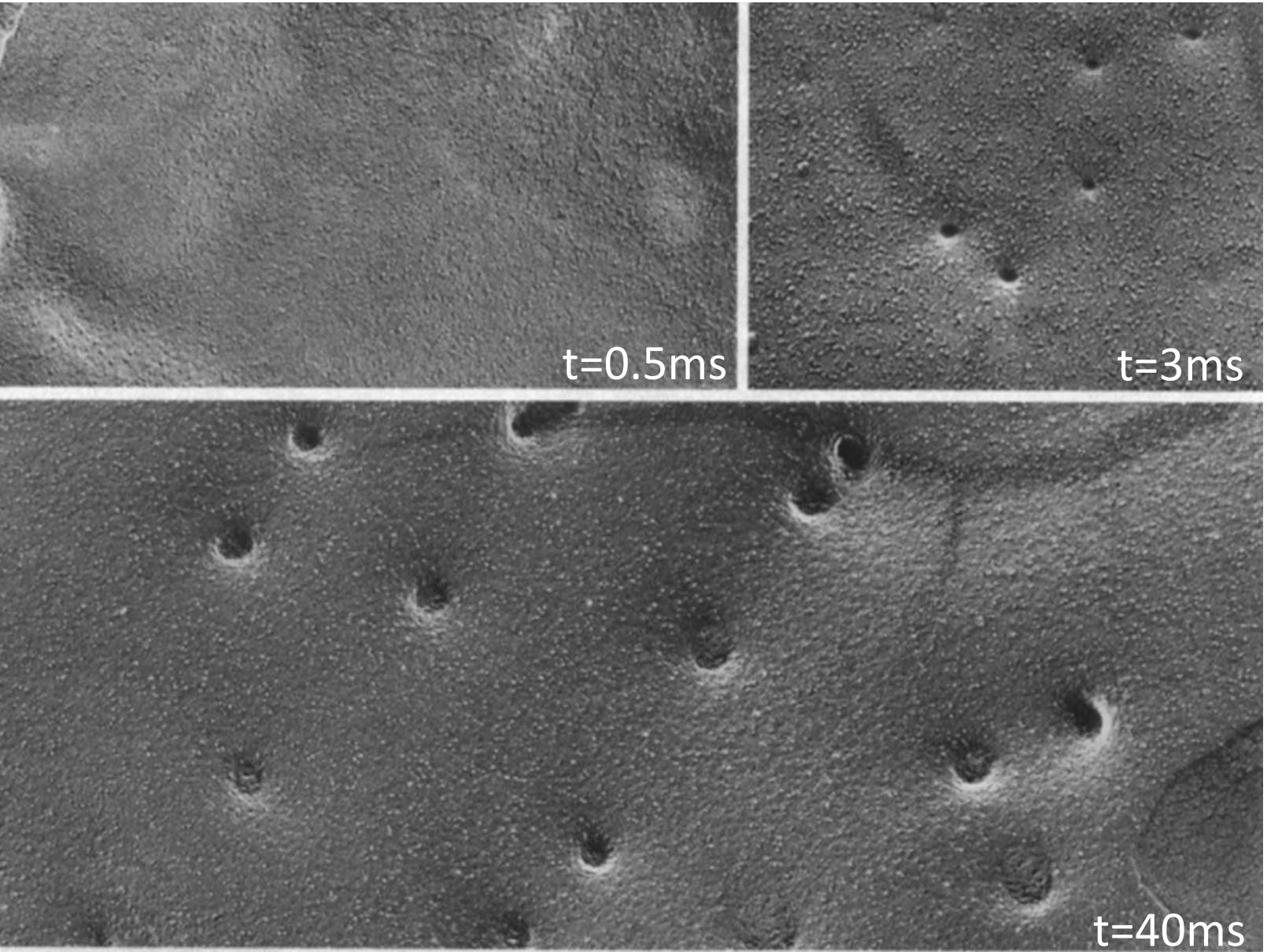
Left Superior PV Fibrillation (after isolation)

Atrium in Sinus Rhythm





Electroporation and Pulsed Field Ablation



JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY VOL. 74, NO. 3, 2019

Pulsed Field Ablation for Pulmonary Vein Isolation in Atrial Fibrillation

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ABSTRACT

BACKGROUND Catheter ablation of atrial fibrillation using thermal energies such as radiofrequency or cryothermy is associated with indiscriminate tissue destruction. During pulsed field ablation (PFA), subsecond electric fields create microscopic pores in cell membranes—a process called electroporation. Among cell types, cardiomyocytes have among the lowest thresholds to these fields, potentially permitting preferential myocardial ablation.

OBJECTIVES The purpose of these 2 trials was to determine whether PFA allows durable pulmonary vein (PV) isolation without damage to collateral structures.

METHODS Two trials were conducted to assess the safety and effectiveness of catheter-based PFA in paroxysmal atrial fibrillation. Ablation was performed using proprietary bipolar PFA waveforms: either monophasic with general anesthesia and paralytics to minimize muscle contraction, or biphasic with sedation because there was minimal muscular stimulation. No esophageal protection strategy was used. Invasive electrophysiological mapping was repeated after 3 months to assess the durability of PV isolation.

RESULTS In 81 patients, all PVs were acutely isolated by monophasic ($n = 15$) or biphasic ($n = 66$) PFA with ≤3 min elapsed delivery/patient, skin-to-skin procedure time of 92.2 ± 27.4 min, and fluoroscopy time of 13.1 ± 7.6 min. With successive waveform refinement, durability at 3 months improved from 18% to 100% of patients with all PVs isolated. Beyond 1 procedure-related pericardial tamponade, there were no additional primary adverse events over the 120-day median follow-up, including: stroke, phrenic nerve injury, PV stenosis, and esophageal injury. The 12-month Kaplan-Meier estimate of freedom from arrhythmia was 87.4 ± 5.6%.

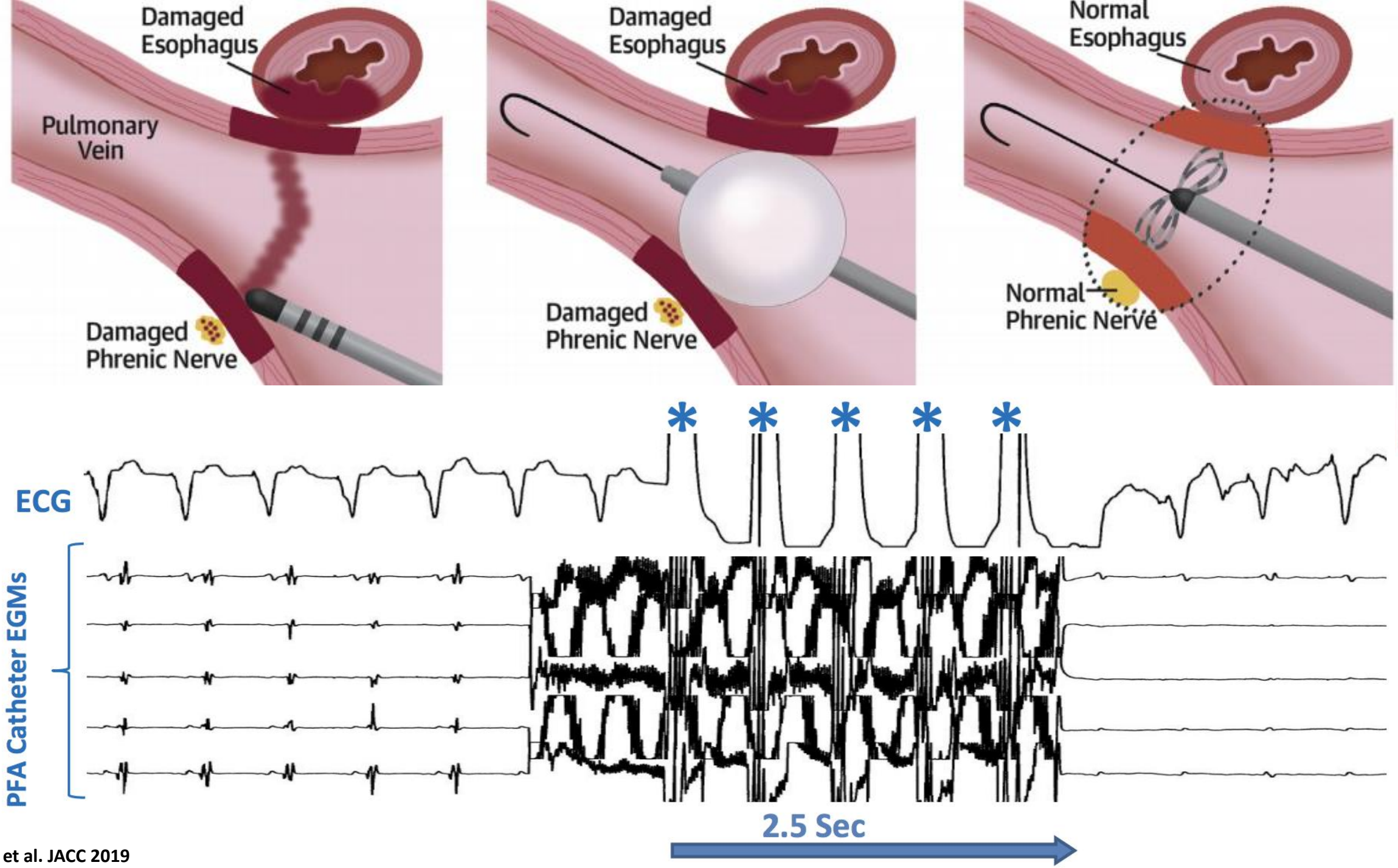
CONCLUSIONS In first-in-human trials, PFA preferentially affected myocardial tissue, allowing facile ultra-rapid PV isolation with excellent durability and chronic safety. (IMPULSE: A Safety and Feasibility Study of the IOWA Approach Endocardial Ablation System to Treat Atrial Fibrillation; NCT03700385; and PEFCAT: A Safety and Feasibility Study of the FARAPULSE Endocardial Ablation System to Treat Paroxysmal Atrial Fibrillation; NCT03714178)
(J Am Coll Cardiol 2019;74:315-26) © 2019 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Chang, Reese, Biophys J 1990

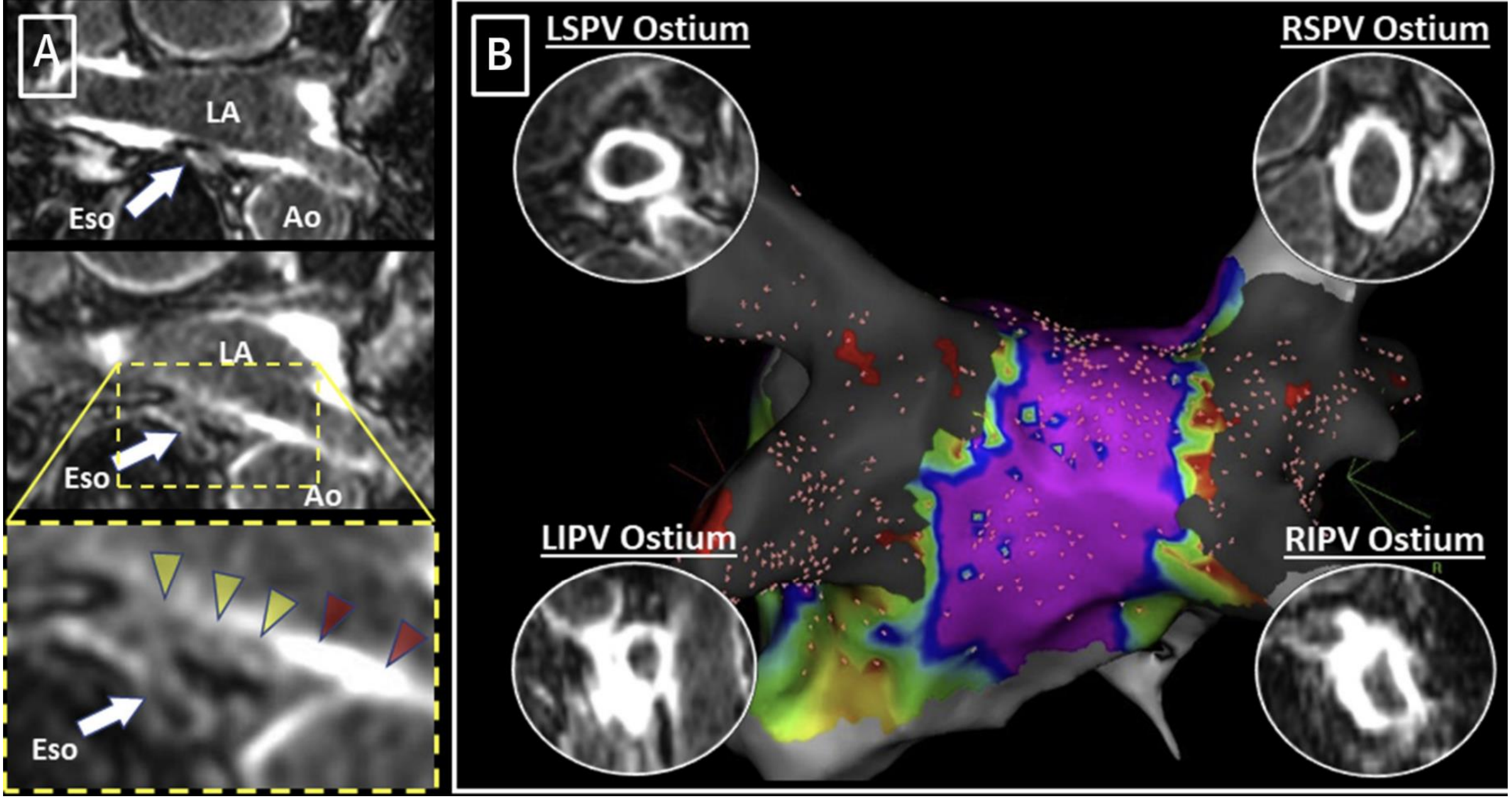
Electroporation: Tissue Specificity

Tissue Type	PEF Ablation Threshold (V/cm)
Nerve	3800
Vascular smooth muscle	1750
Red blood cell	1600
Myocardium	400

Adapted from Reddy et al., JACC EP 2018

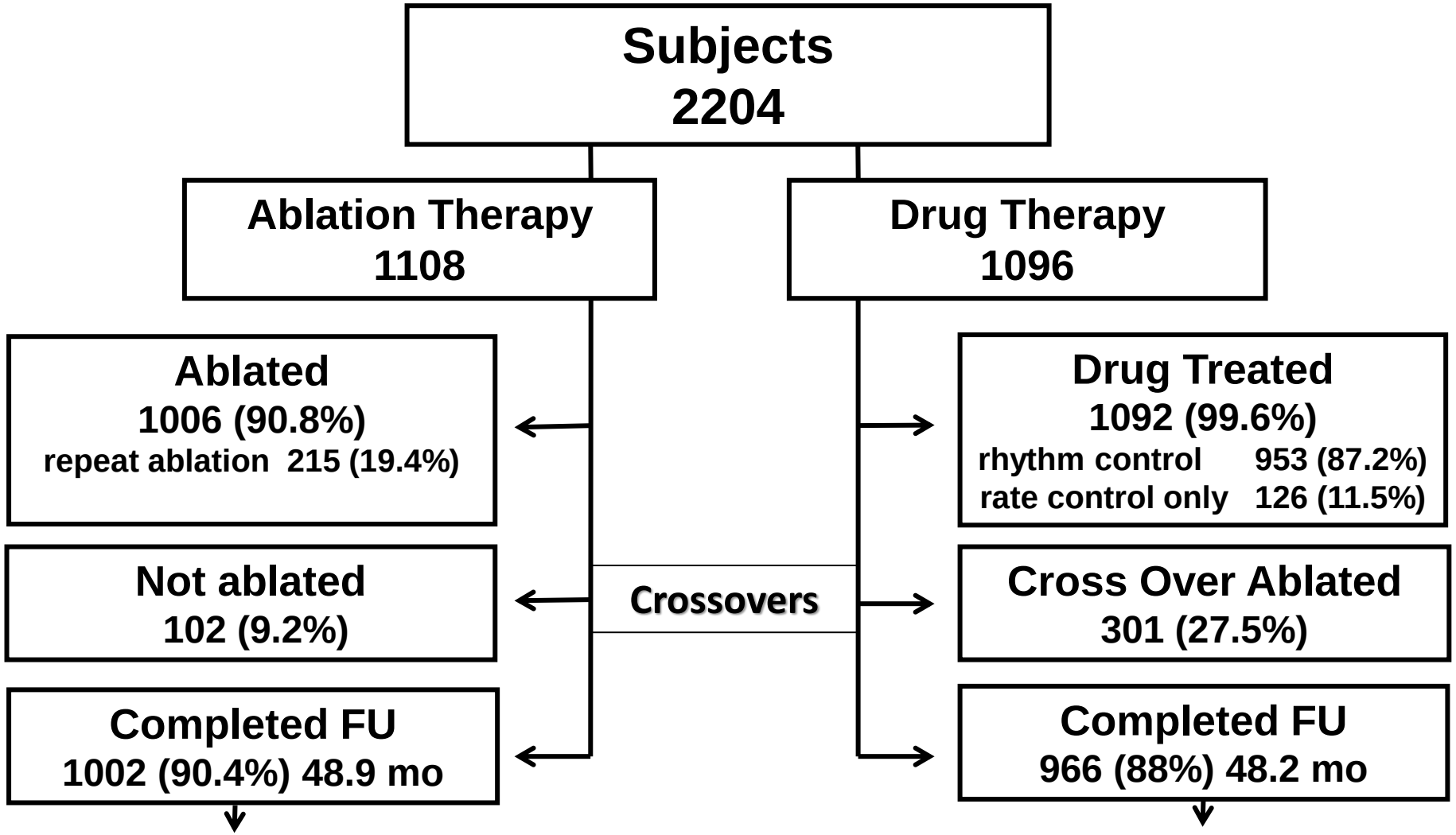


Reddy, Jais, et al. JACC 2019


A
LA
Eso
Ao
LA
Eso
Ao
Eso
B
LSPV Ostium
RSPV Ostium
LIPV Ostium
RIPV Ostium

How well does ablation work?

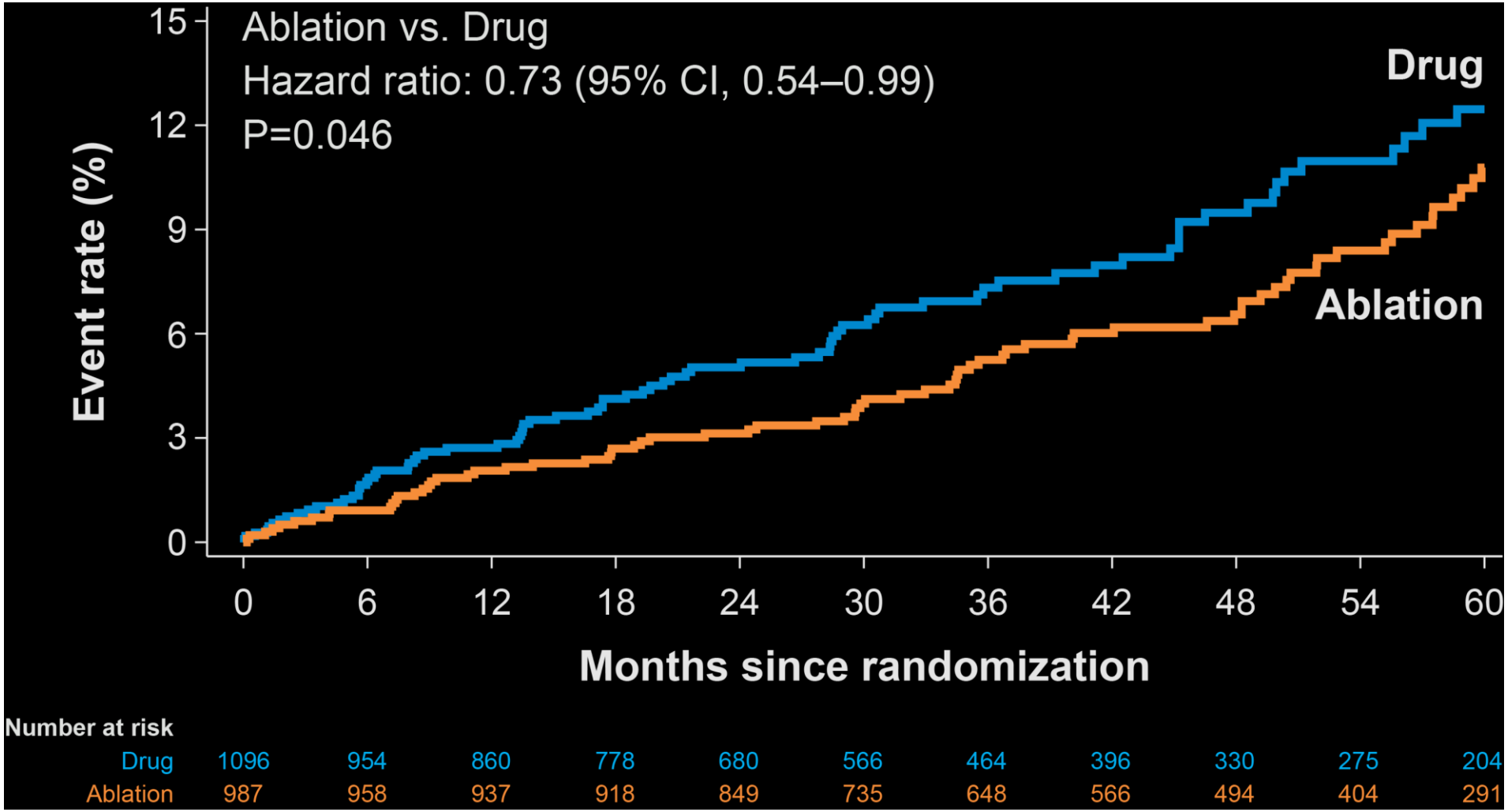
Patient Randomization



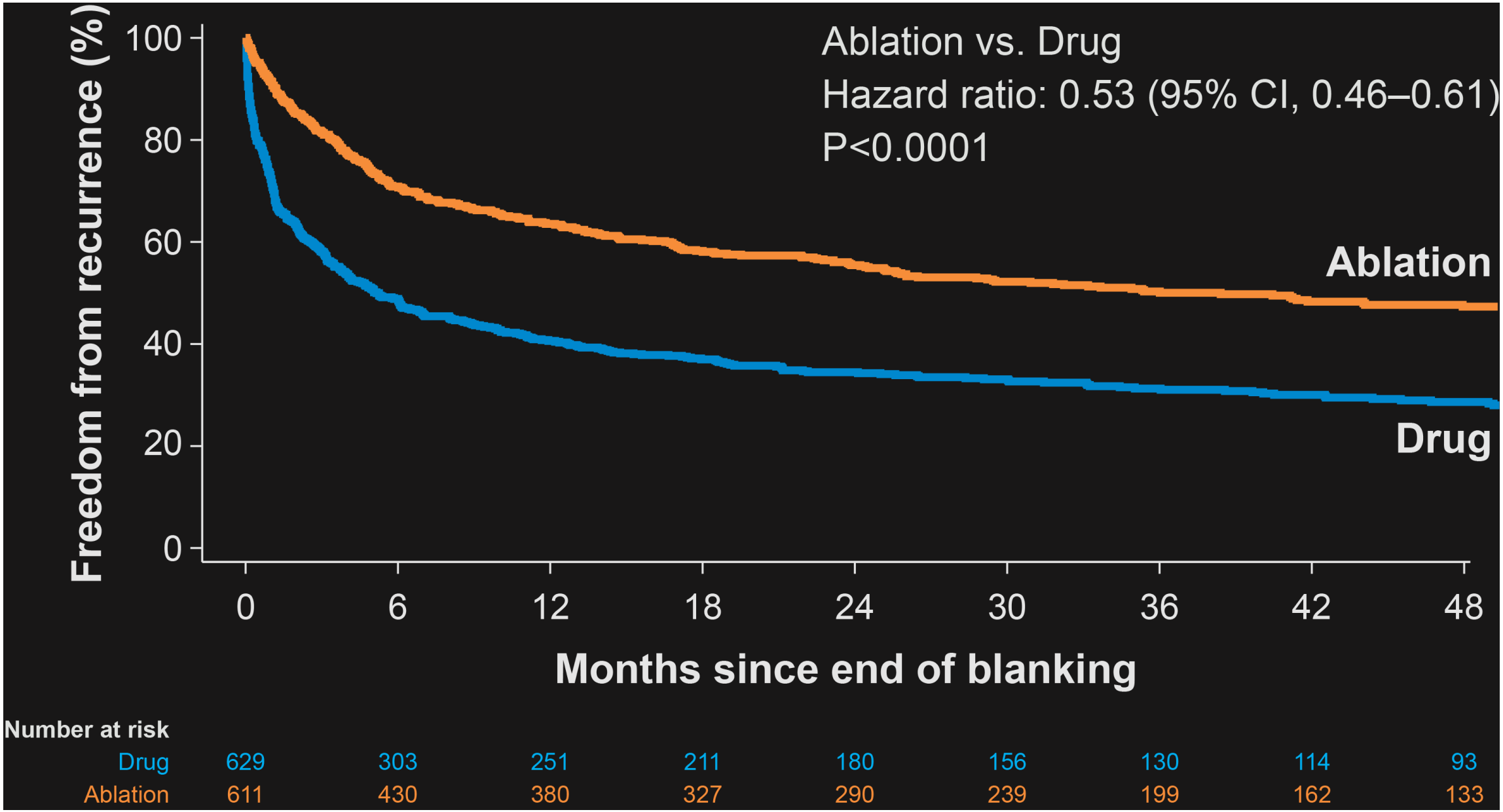
Packer DL et al CABANA. JAMA 2019

* Withdrew <3 years

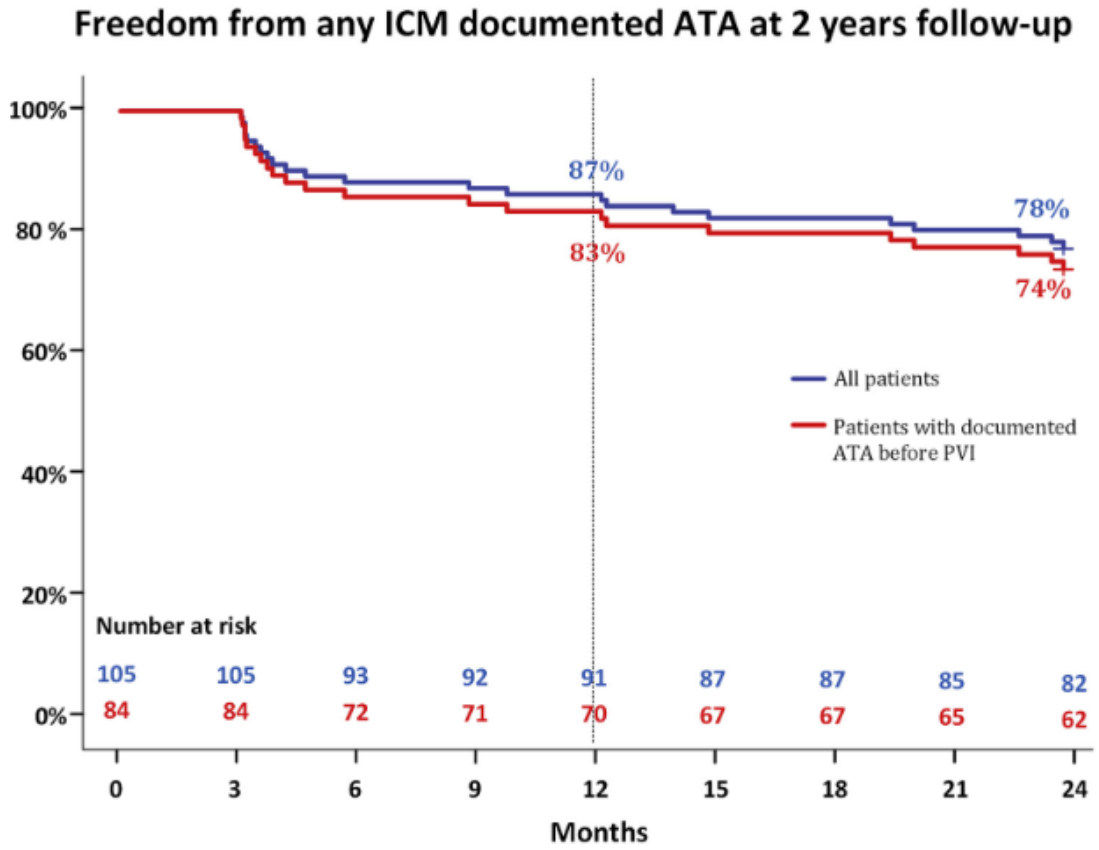
Primary Endpoint (Death, Disabling Stroke, Serious Bleeding, or Cardiac Arrest (Per Protocol)

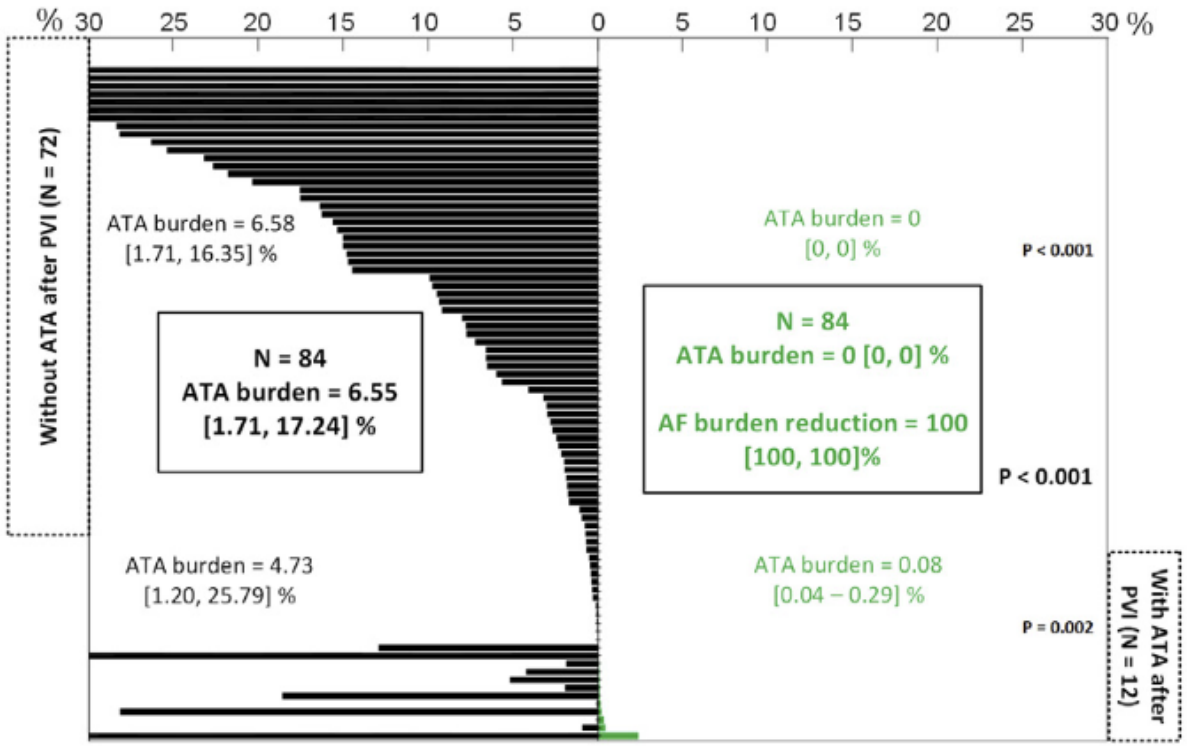


Packer DL et al CABANA. JAMA 2019



Packer DL et al CABANA. JAMA 2019

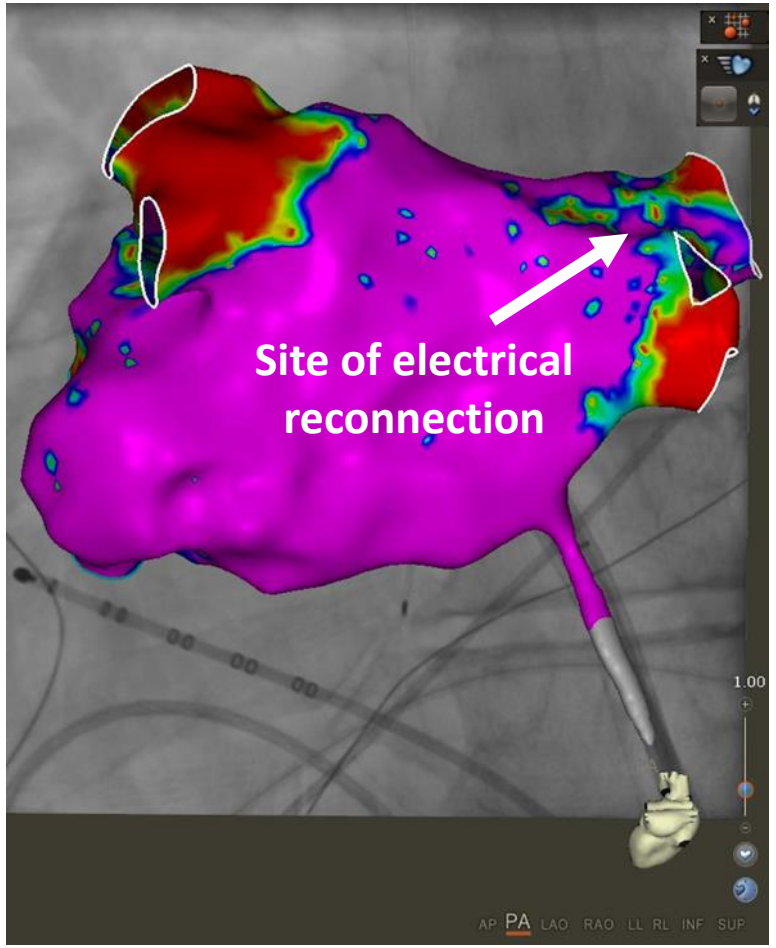




Duytschaever et al CLOSE to CURE Study. Heart Rhythm 2020

Catheter Ablation and 1 Year Freedom of AF

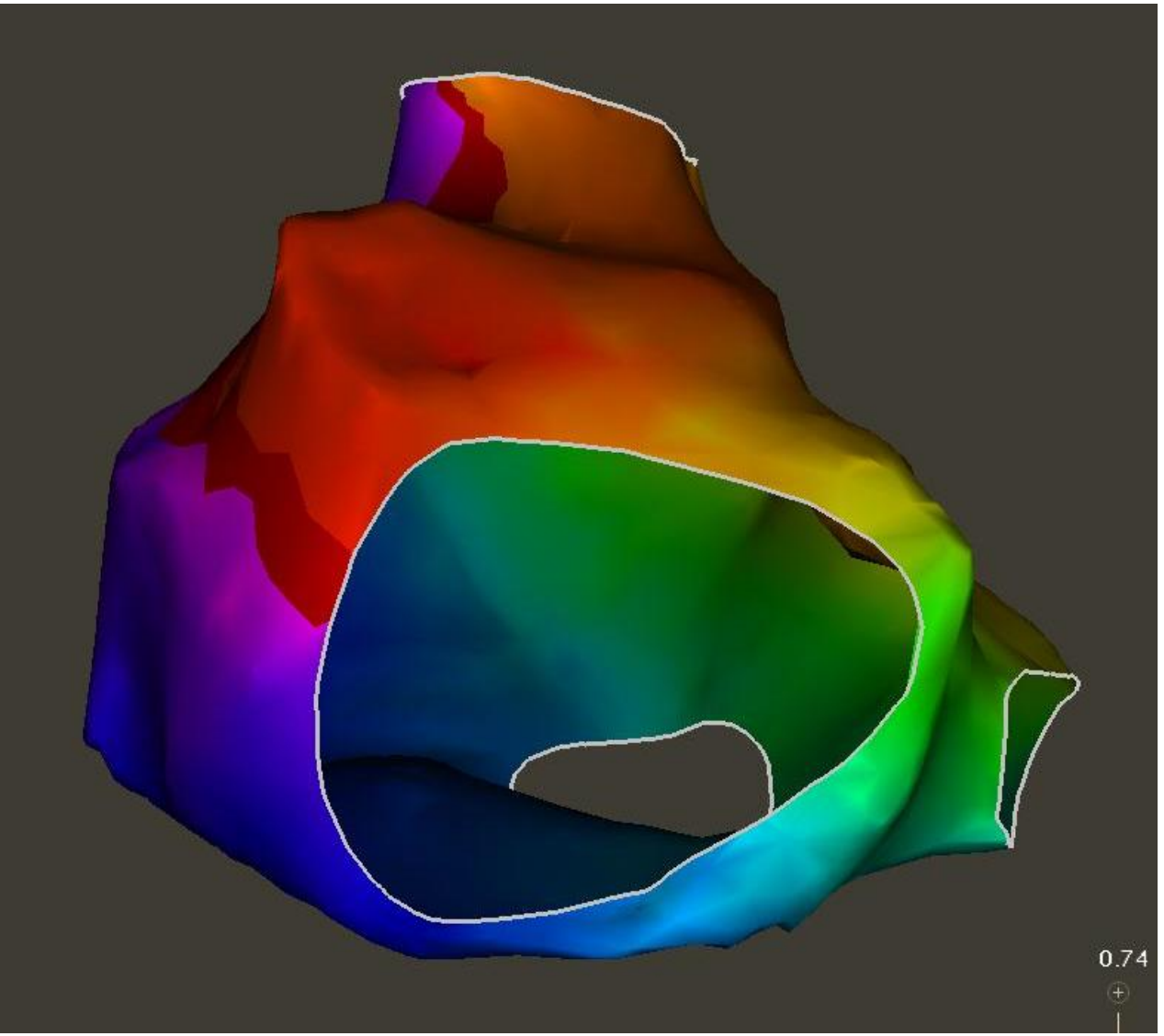
- Paroxysmal: ~85%
- Persistent: ~70%
- Longstanding Persistent: ~50%



Why not 100% ?

- Pulmonary veins can electrically “reconnect” (The heart can heal!)

- There can be other sources for AFib besides the pulmonary veins.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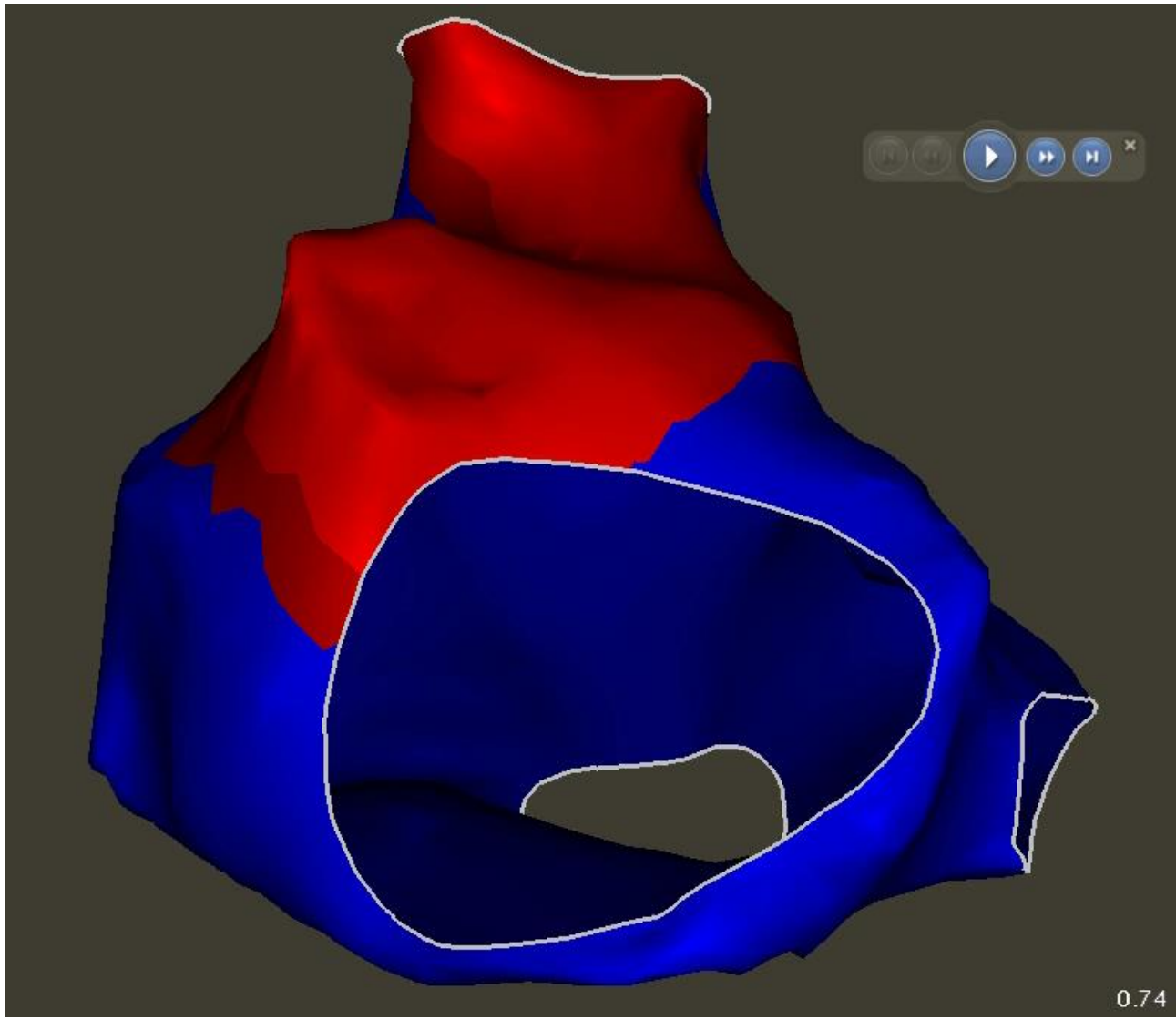
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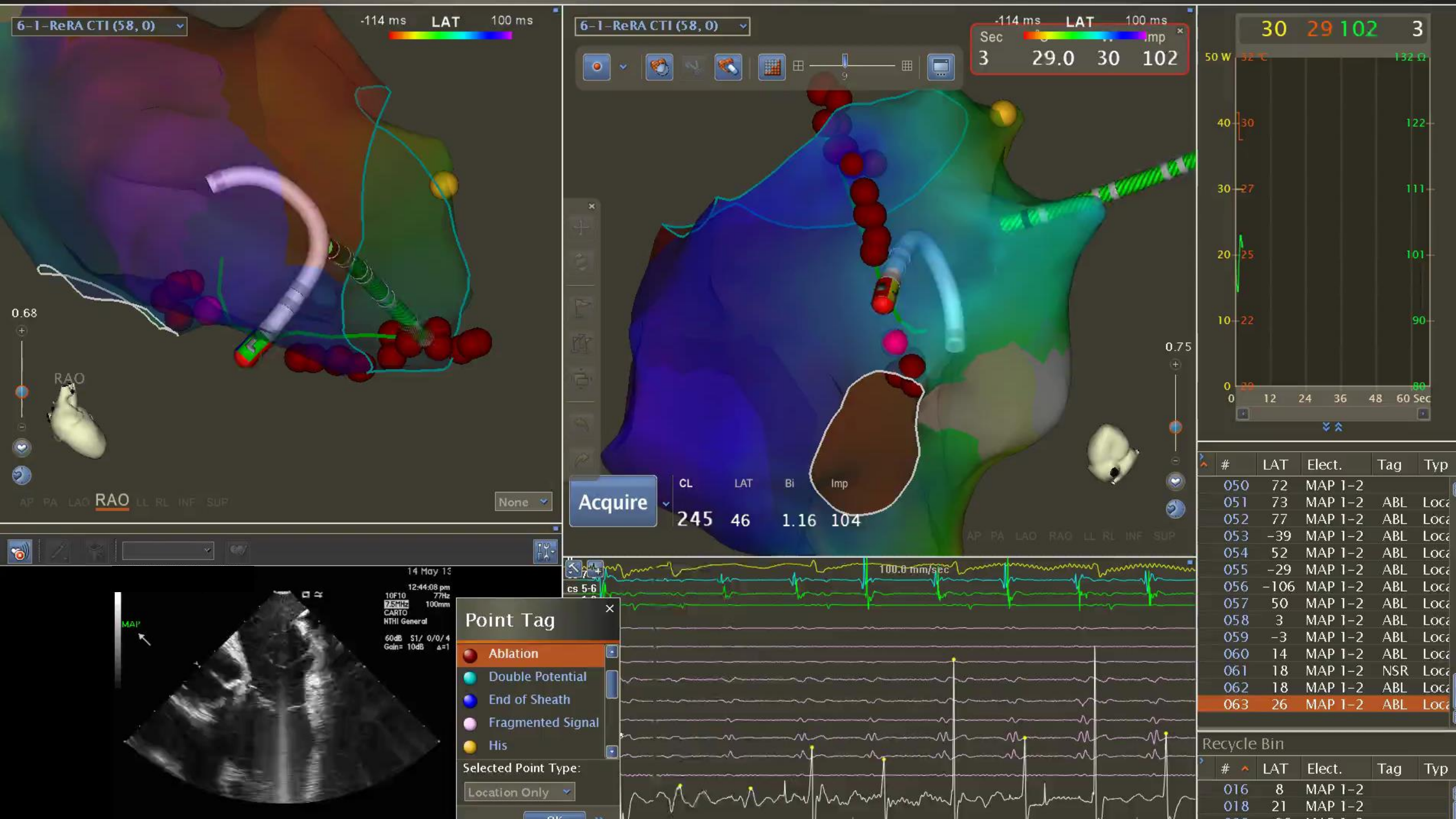
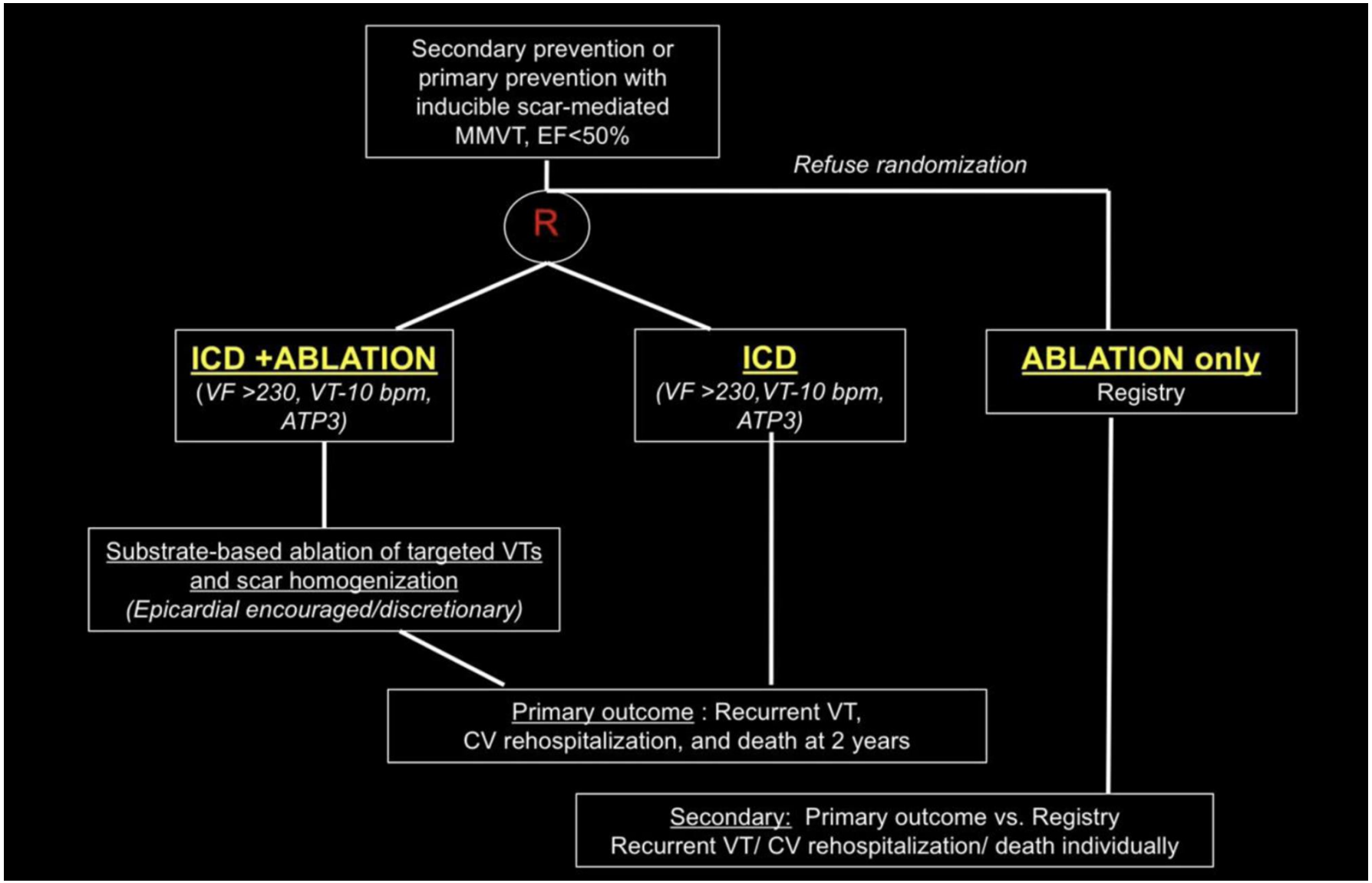

6-1-ReRA CTI (58, 0)
-114 ms
LAT
100 ms
0.68
RAO
AP PA LAO RAO LL RL INF SUP
None
6-1-ReRA CTI (58, 0)
-114 ms
LAT
100 ms
Sec
Imp
3
29.0
30
102
0.75
Acquire
CL
LAT
Bi
Imp
245
46
1.16
104
AP PA LAO RAO LL RL INF SUP
30
29
102
3
50 W
32 °C
132 Ω
40
30
122
30
27
111
20
25
101
10
22
90
0
20
80
0
12
24
36
48
60 Sec
14 May 13
12:44:08 pm
10F10
77Hz
7.5MHz
100mm
CARTO
NTHI General
60dB
Gain= 10dB
MAP
cs 5-6
100.0 mm/sec
Point Tag
Ablation
Double Potential
End of Sheath
Fragmented Signal
His
Selected Point Type:
Location Only
LAT Elect. Tag Typ
050 72 MAP 1-2
051 73 MAP 1-2 ABL Loca
052 77 MAP 1-2 ABL Loca
053 -39 MAP 1-2 ABL Loca
054 52 MAP 1-2 ABL Loca
055 -29 MAP 1-2 ABL Loca
056 -106 MAP 1-2 ABL Loca
057 50 MAP 1-2 ABL Loca
058 3 MAP 1-2 ABL Loca
059 -3 MAP 1-2 ABL Loca
060 14 MAP 1-2 ABL Loca
061 18 MAP 1-2 NSR Loca
062 18 MAP 1-2 ABL Loca
063 26 MAP 1-2 ABL Loca
Recycle Bin
LAT Elect. Tag Typ
016 8 MAP 1-2
018 21 MAP 1-2

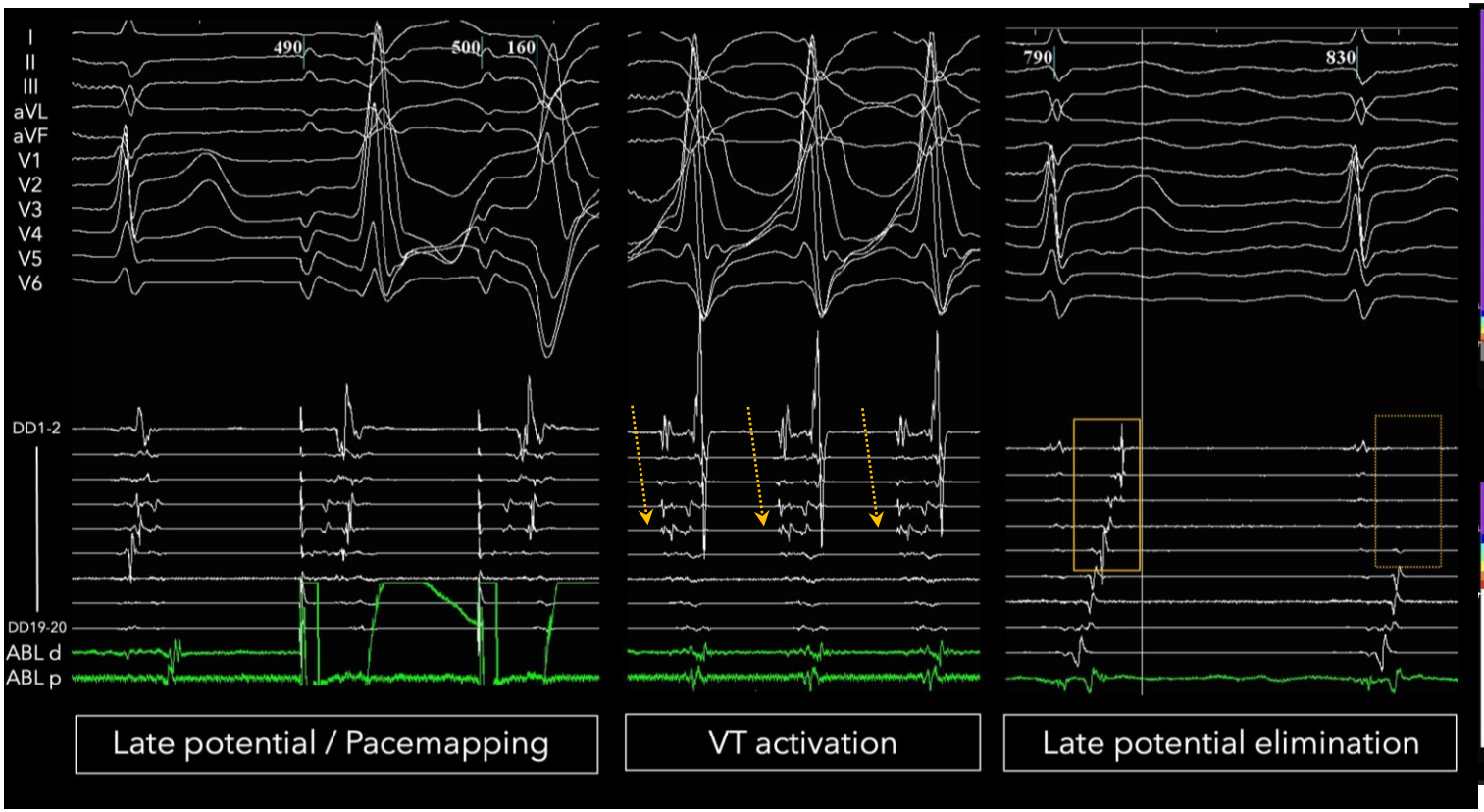
Study Design

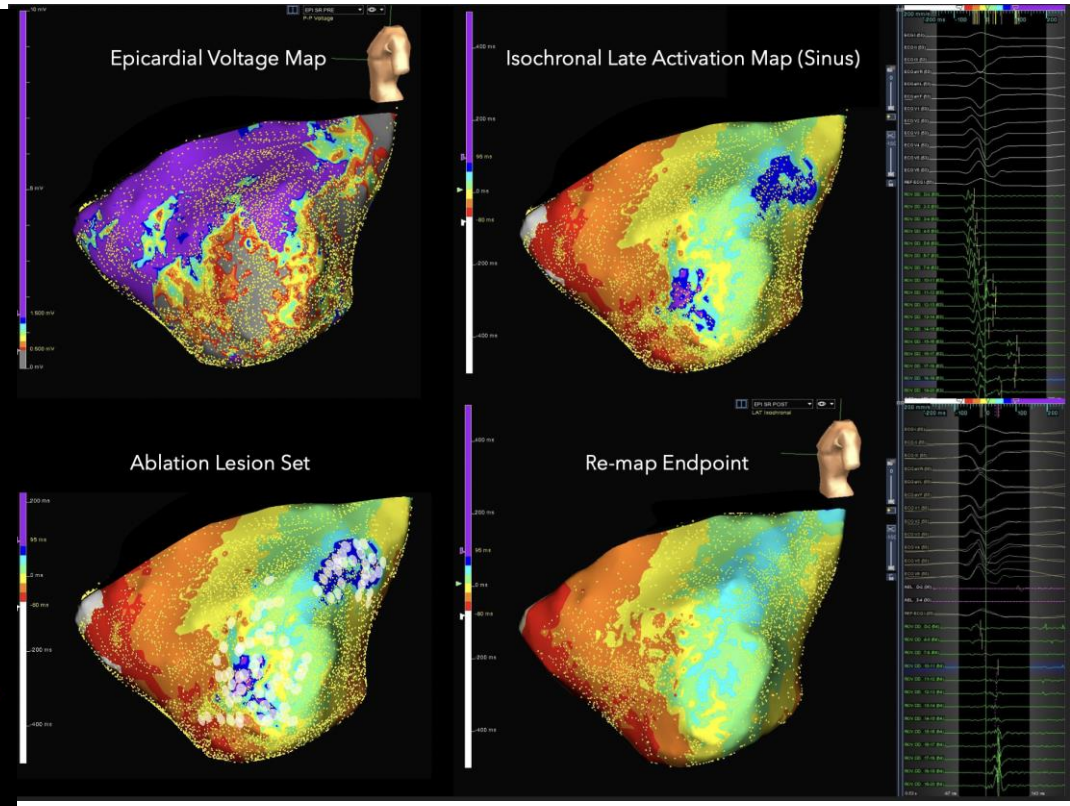


Chen M, Wu S…Tung R; PAUSE-SCD Investigators. *J Interv Card Electrophysiol*. 2019.

Results- *Ablation Techniques*

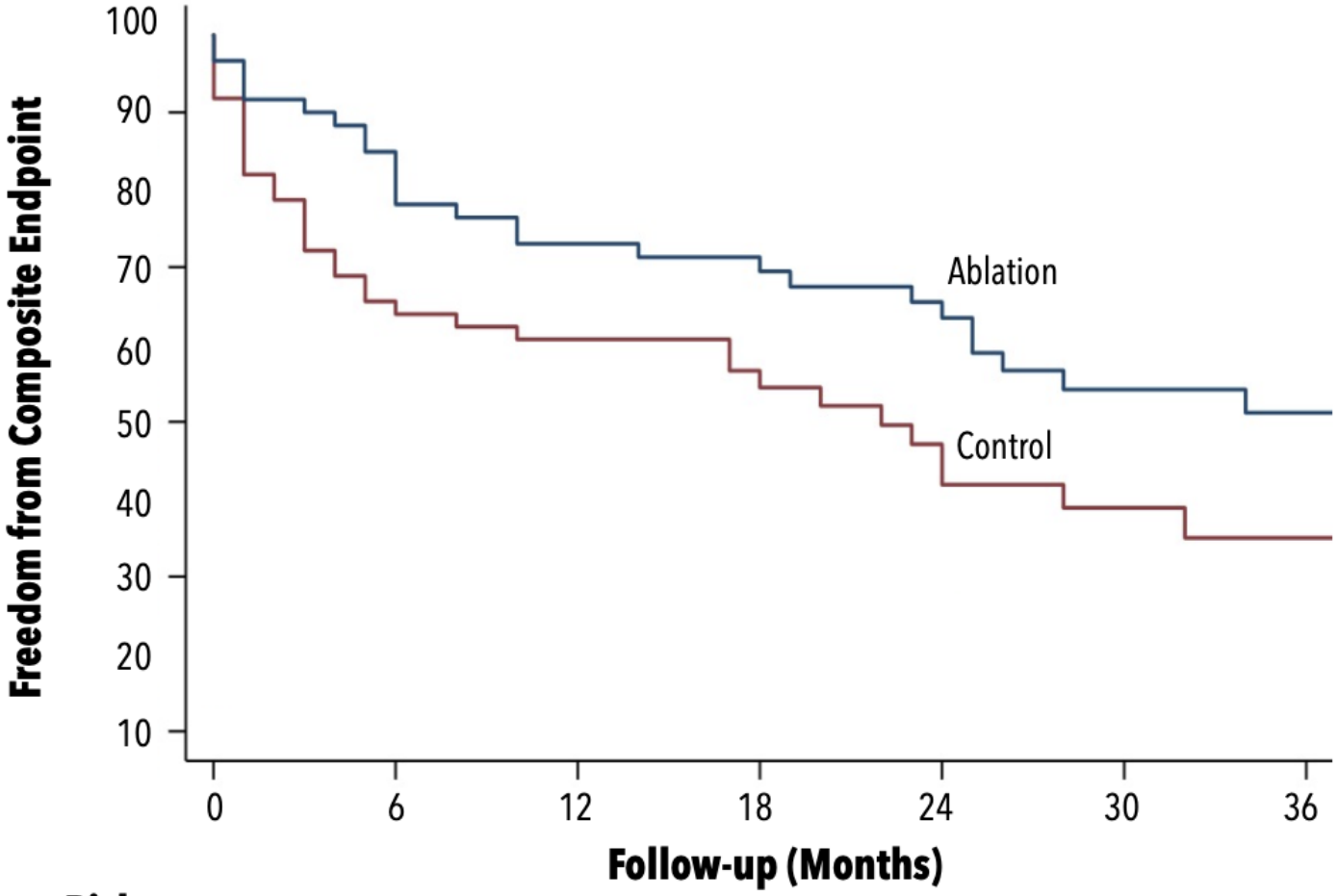
- Epicardial approach in 52%
- Multielectrode catheters in 88%





- Predominant strategies: Pacemapping 40% , ILAM 30%, VT activation 30%, entrainment 22%, LP elimination 67%
- Termination of at least 1 VT 59% of cases, noninducibility 80%
- Stable VTs in 41%, multiple 50%
- Median RF time: 45 min (30-60 min), procedural duration: 240 min (166-280 min)

Results- *Primary Outcome*



No. at Risk							
Control	61	40	36	26	18	11	8
Ablation	60	50	43	39	32	21	13

Tung R. et al. PAUSE-SCD 2021: 1623-1624.

CMHC
Cardiometabolic Health Congress

www.cardiometabolichealth.org

Foundations of Cardiometabolic Health Certification Course

Certified Cardiometabolic Health Professional (CCHP)

Cardiac Arrhythmias: Concluding Remarks

William H. Sauer, MD

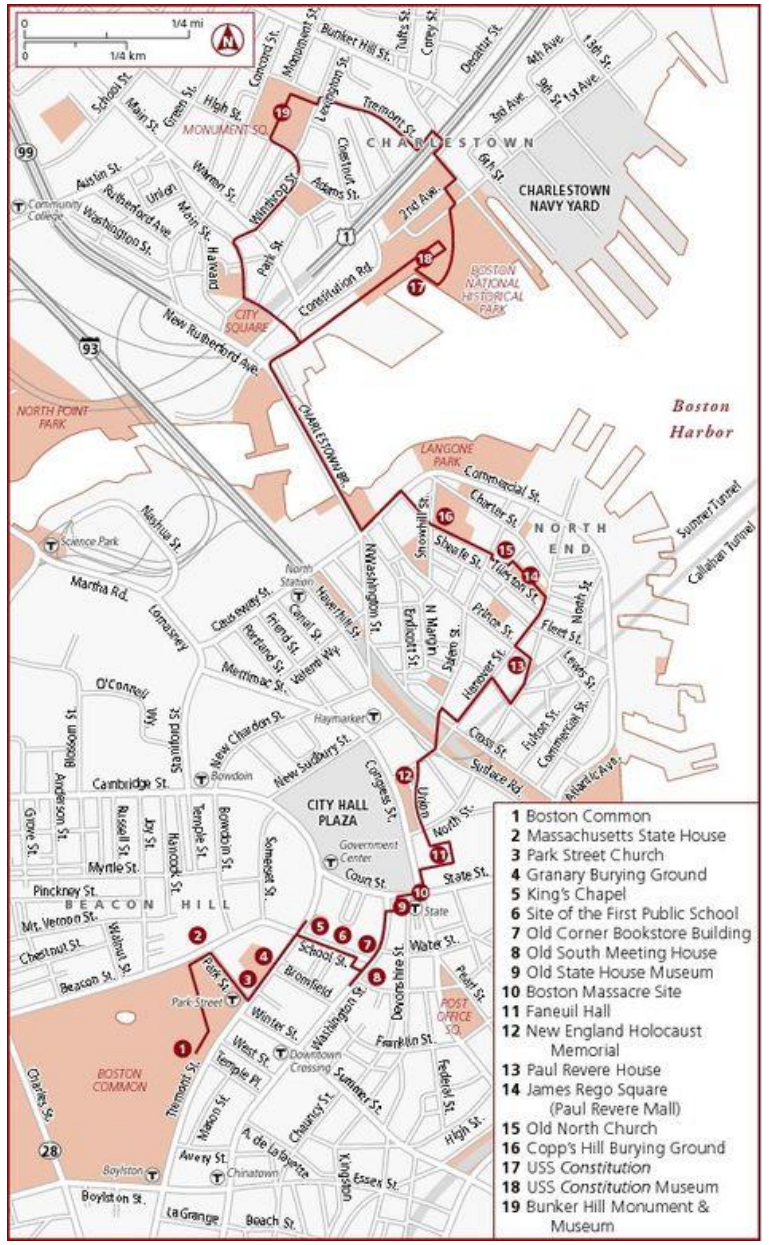
Chief, Cardiac Arrhythmia Services

Brigham and Women's Hospital

Harvard Medical School

Road Map

- Overview of Cardiac Arrhythmias and Treatment Options
  - Antiarrhythmic Medications
    - AFFIRM 1999
    - EAST AF 2019
  - Implantable Devices
    - SCD-HeFT 2005
  - Catheter Ablation
    - CABANA 2019
    - PAUSE-SCD 2021
- Summary



Summary

- Cardiac arrhythmias are increasingly being recognized by patients
- Treatment options continue to evolve
- Catheter ablation is superior to medications for controlling arrhythmias

Thank You

Thank You - Brigham and Women's Hospital Cardiac Arrhythmia Service

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