A New Job for the EP Community

Plumbing Electrical Dysfunction & Thromboembolism: Wireless "Boxes" and Protecting "Umbrellas"

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Mount Sinai *Heart*

Disclosures

- Grant support and/or Consultant:
  - Boston Scientific Inc, Coherex Inc, EBR Systems, Medtronic Inc, St Jude Medical Inc

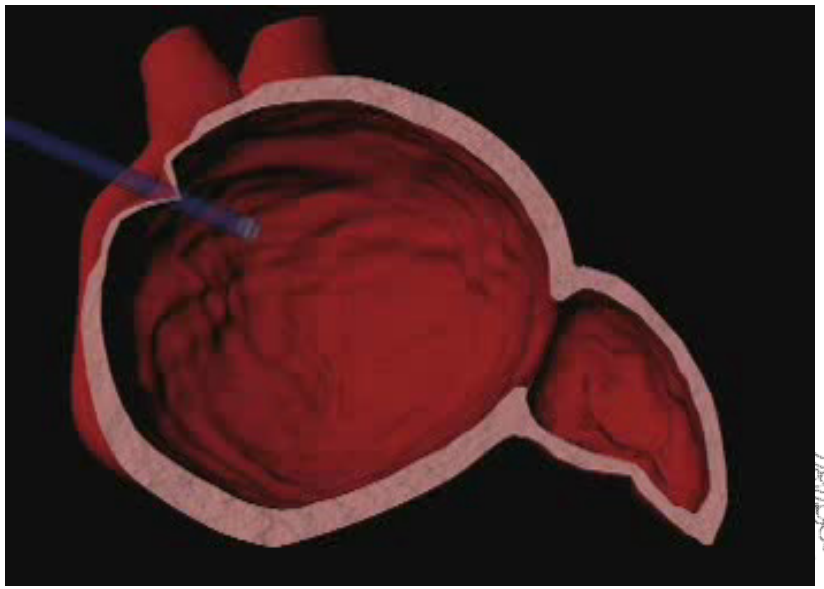
  (I have no equity interest in LAAC or leadless pacing)

- I will be discussing non-approved devices.

Stroke Risk in Atrial Fibrillation

FDA Labeling

- AF afflicts 5-7 million individuals in the U.S.
- Incidence of AF is increasing
- AF increases the risk of stroke by 6-fold
- Limitations to Oral Anticoagulants
- Led to Development of Mechanical LAA closure



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PROTECT AF

Superiority of Watchman over Warfarin

- RCT: Can the WATCHMAN device ***replace*** Warfarin

Non-Valvular AF
$CHADS_2 \geq 1$

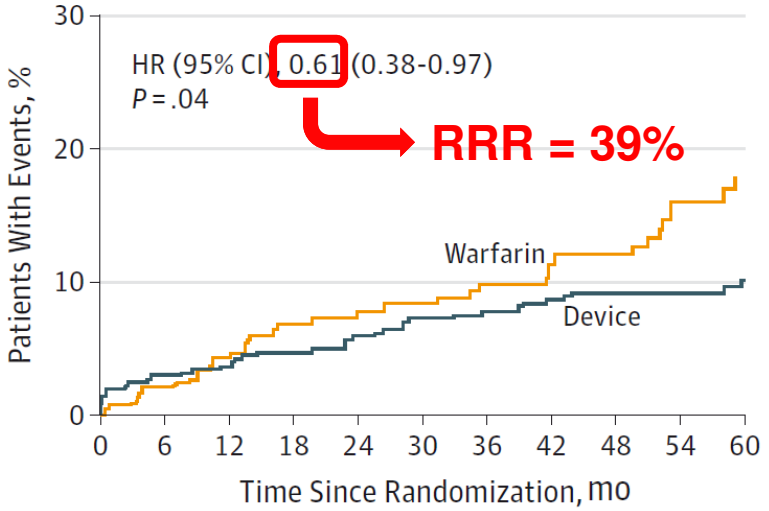
↓

Randomization (1:2)

↓

Anticoagulation Regimen
- **Implant to 6 weeks**
  - **Warfarin**
  - **Aspirin**
- **6 weeks to 6 months**
  - **Clopidogrel**
  - **Aspirin**
- **After 6 months**
  - **Aspirin**

Primary Endpoint
[Stroke / SE / CV Death]



No. of patients

Device	463	398	382	370	360	345	337	327	317	285	196
Warfarin	244	230	218	210	200	188	173	159	147	121	87

Hemorrhagic Stroke: 85%↓↓

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V.Reddy, H.Sievert, J.Halperin et al, *JAMA*, 312:1988 (2014)

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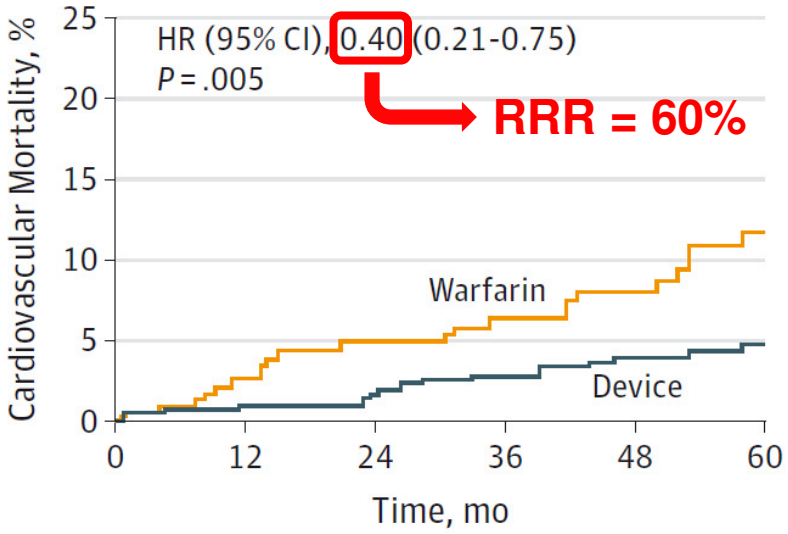
PROTECT AF: Watchman *vs* Warfarin

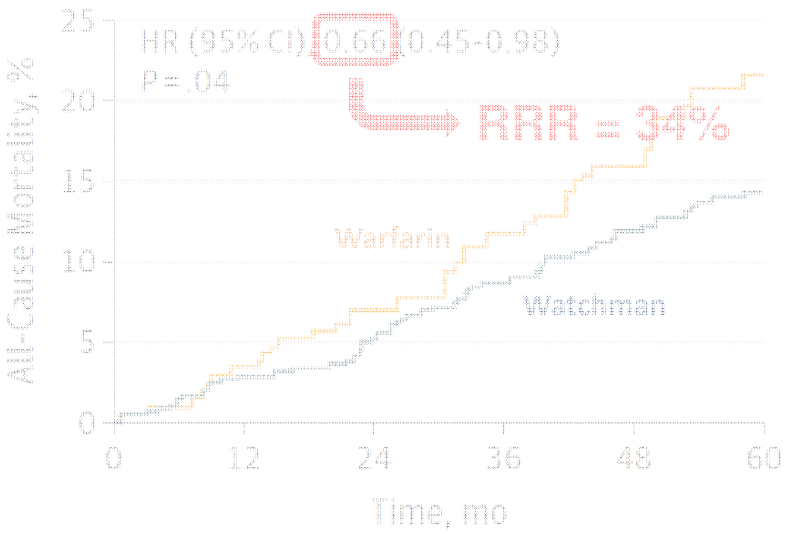
Mortality Benefit with Watchman

CV Death



463	389	372	351	328	165
244	222	204	176	147	69

All-Cause Mortality



463	389	373	352	330	202
244	222	204	177	150	92

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V.Reddy, H.Sievert, J.Halperin et al, *JAMA*, 312:1988 (2014)

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PROTECT-AF & PREVAIL

Combined Analysis

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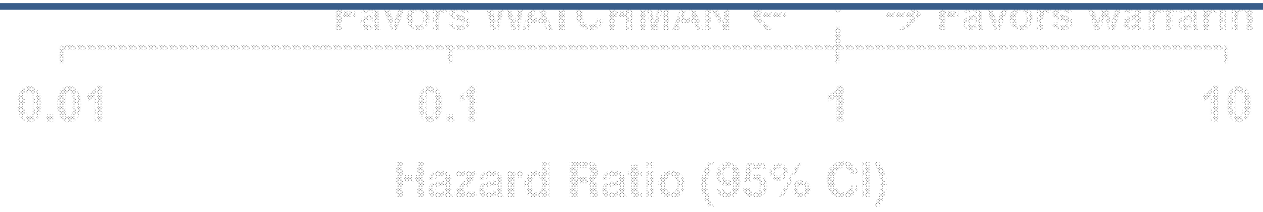
Left Atrial Appendage Closure as an Alternative to Warfarin for Stroke Prevention in Atrial Fibrillation

A Patient-Level Meta-Analysis

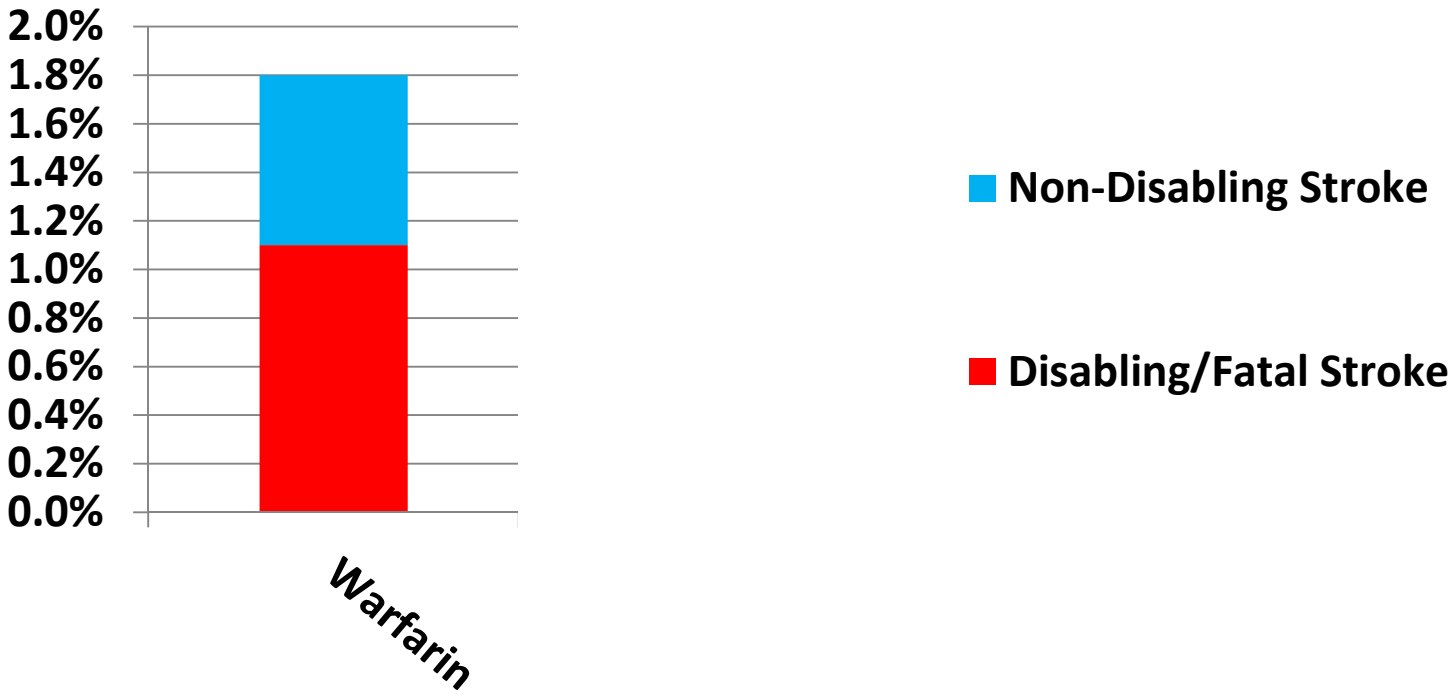
David R. Holmes, Jr, MD,* Shephal K. Doshi, MD,† Saibal Kar, MD,‡ Matthew J. Price, MD,§ Jose M. Sanchez, MD,‖ Horst Sievert, MD,¶ Miguel Valderrabano, MD,# Vivek Y. Reddy, MD**



D.Holmes / V.Reddy *JACC* 65:2614 (2015)

Stroke Severity in PROTECT AF/PREVAIL

Non-Disabling *vs* Disabling/Fatal



- Disabling stroke defined as MRS change of 2 or more or death
- Similar results if defined as absolute MRS > 2

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V.Reddy et al, *FDA Panel Presentation*, October 2014.

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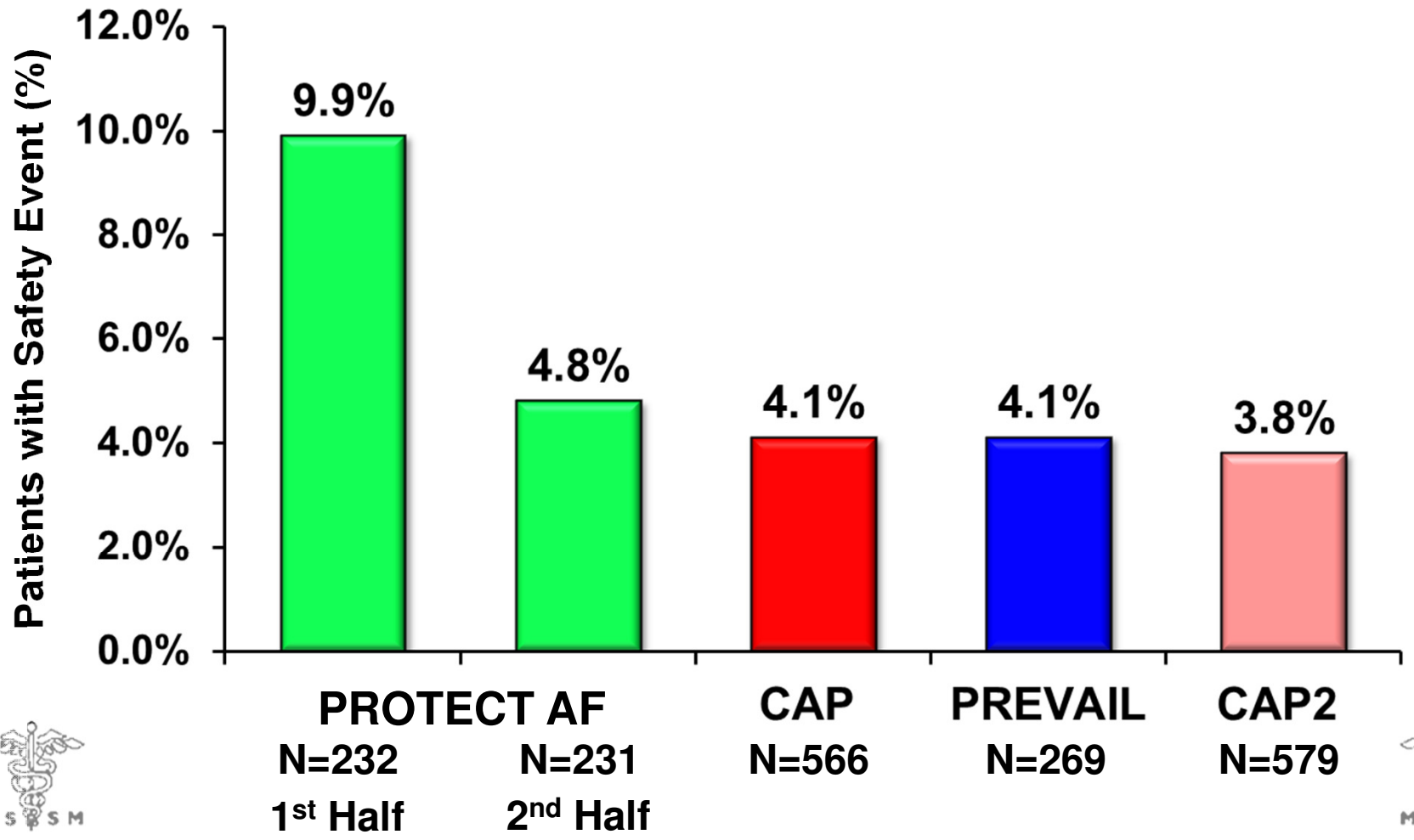
Safety Events Across Trials

PROTECT AF, CAP, PREVAIL & CAP-1



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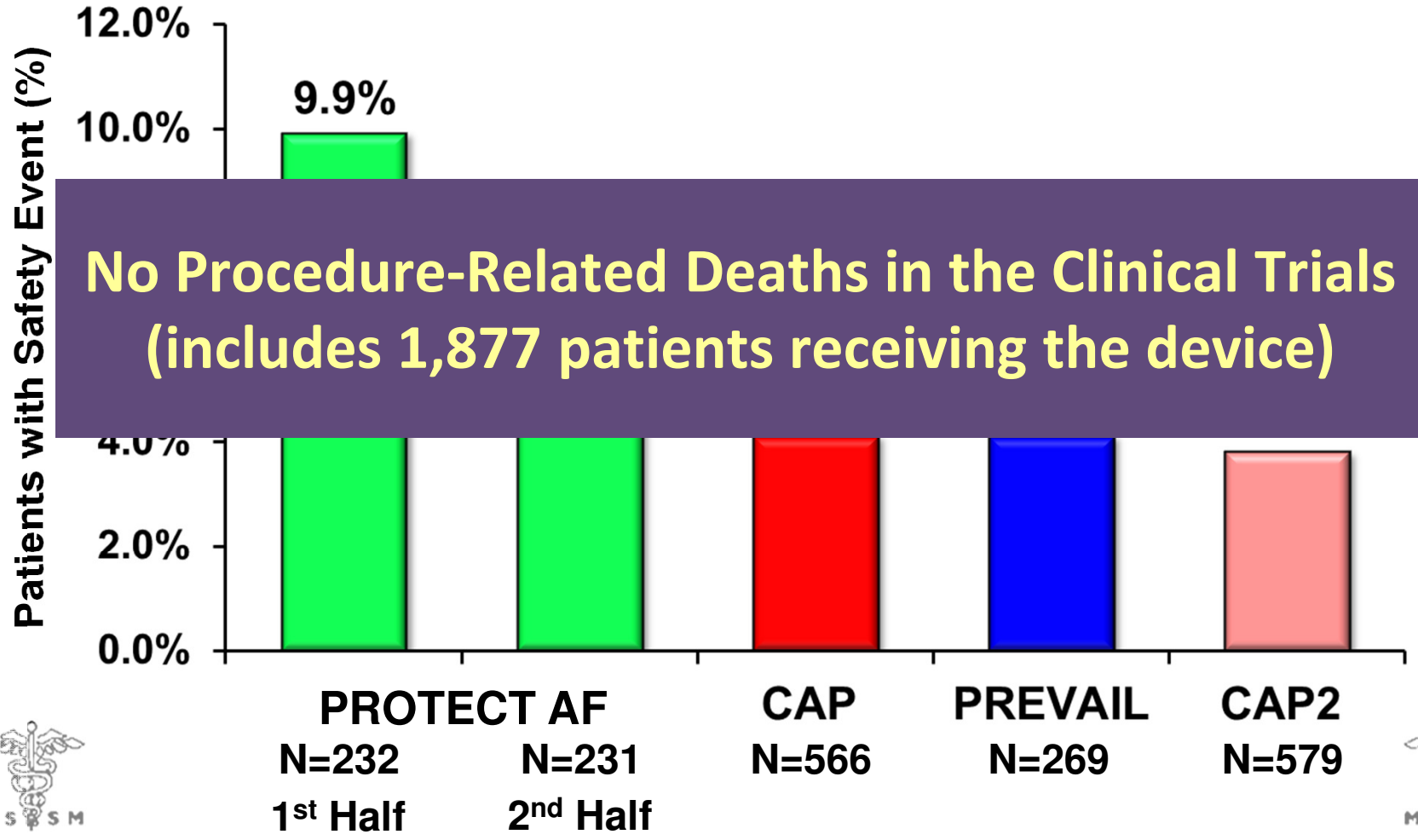
PROTECT AF, CAP, PREVAIL & CAP-1



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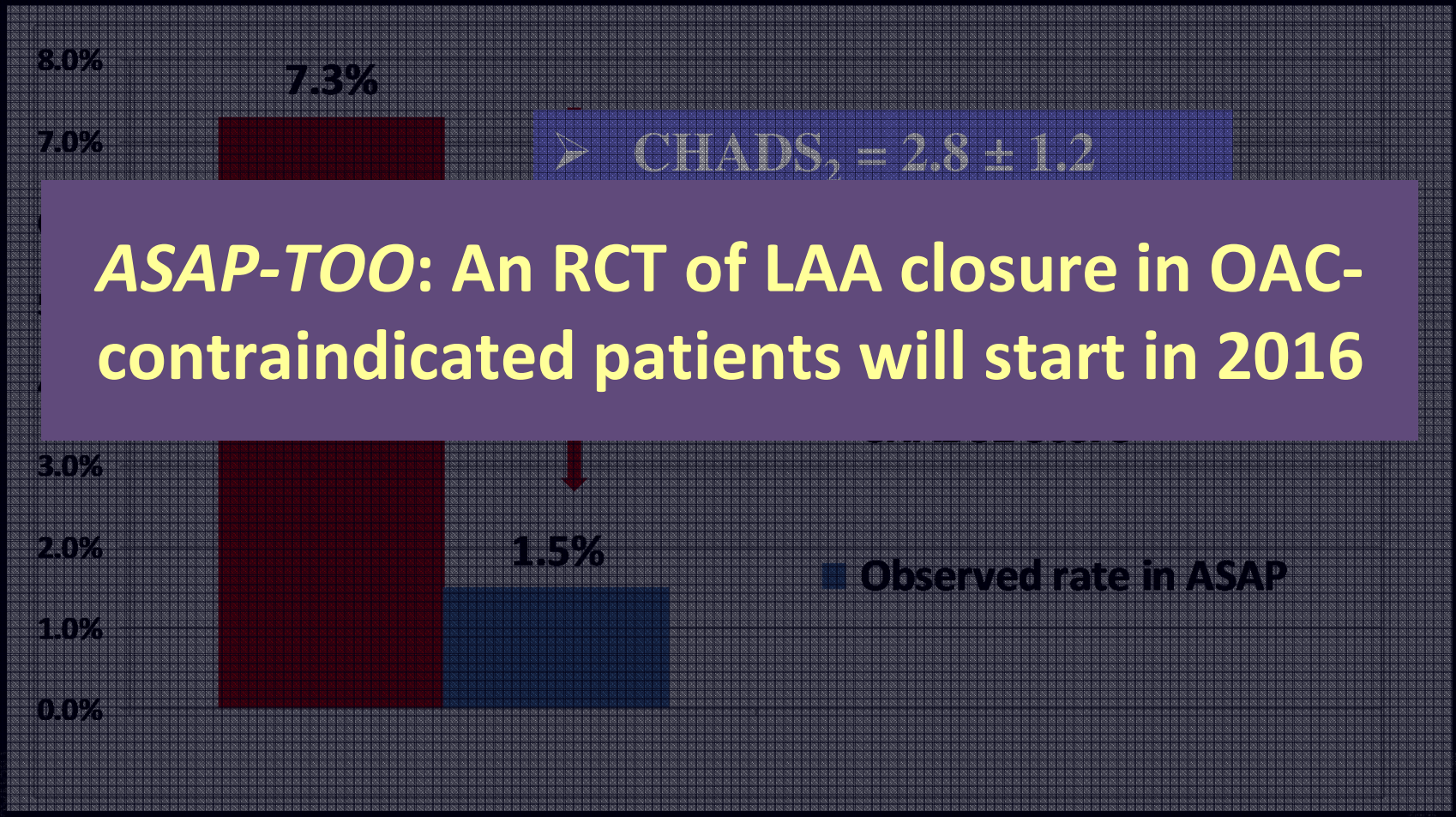
ASAP Registry

Contraindicated Pts (n=150): Watchman → ASA/Clop x 6 mo



***ASAP-TOO*: An RCT of LAA closure in OAC-contraindicated patients will start in 2016**

V.Reddy et al, *JACC* 61:2551 (2013)

What is Happening in the "Real World"?

EWOLUTION Registry

- Prospective, Multicenter (n=47), Non-randomized Registry
- Enrollment
  - Consecutive Watchman Patients
  - 47 sites: Europe, Russia, Middle East
  - From October 2013 – May 2015
  - Total Enrollment = 1021 pts
- Follow-Up:
  - Normally 1-3 months post-implant
  - Annually for at least 2 years
  - OAC Regimen: Physician preference

Characteristic	All Pts (N=1021)
History of TIA	10.7%
History of Ischemic Stroke	19.7%
Previous Hemorrhagic Stroke	15.0%
Prior Major or Predisposition Bleeding	38.7%
Labile INRs	17.0%
Concomitant Use of Drugs	27.8%
Alcohol Abuse	4.2%
$CHADS_2$	2.8 ± 1.3
CHA_2DS_2-VASC	4.5 ± 1.6
HAS-BLED	2.3 ± 1.2

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L.Boersma et al, *AHA LBCT - Orlando* (2015)

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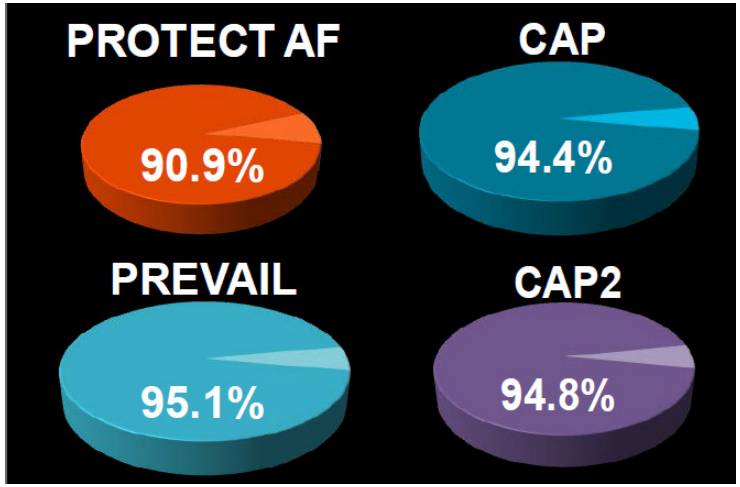
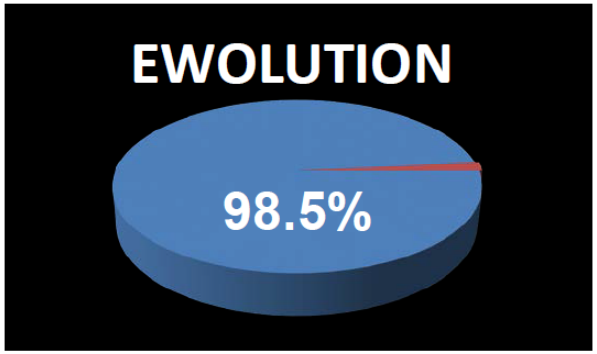
What is Happening in the "Real World"?

EWOLUTION Registry

What is implant success in the "real world"?





Comparison of proportions between all studies: p=<0.001

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L.Boersma et al, *AHA LBCT - Orlando* (2015)

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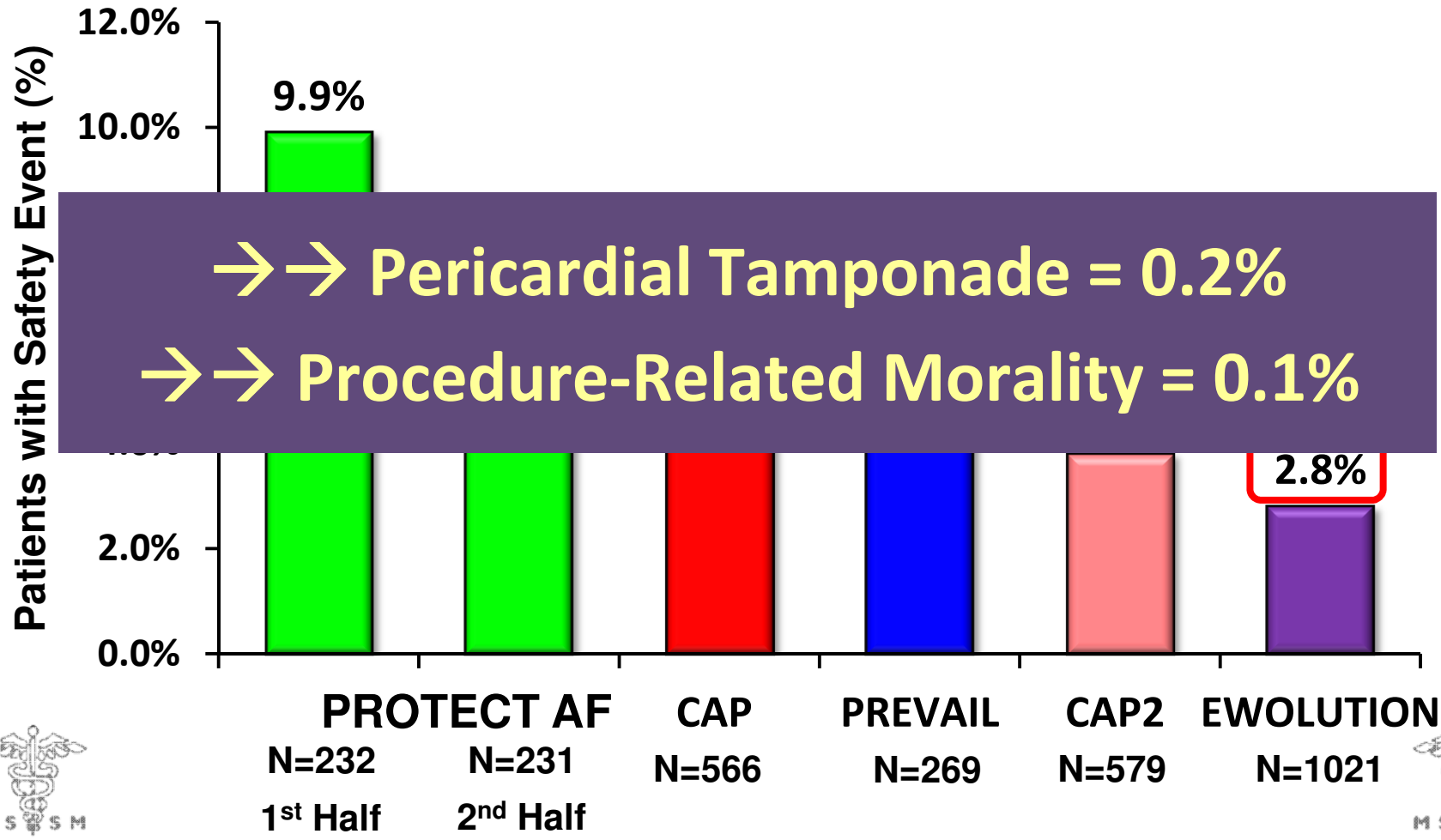
Safety Events Across Trials

FDA Trials *vs* EWOLUTION



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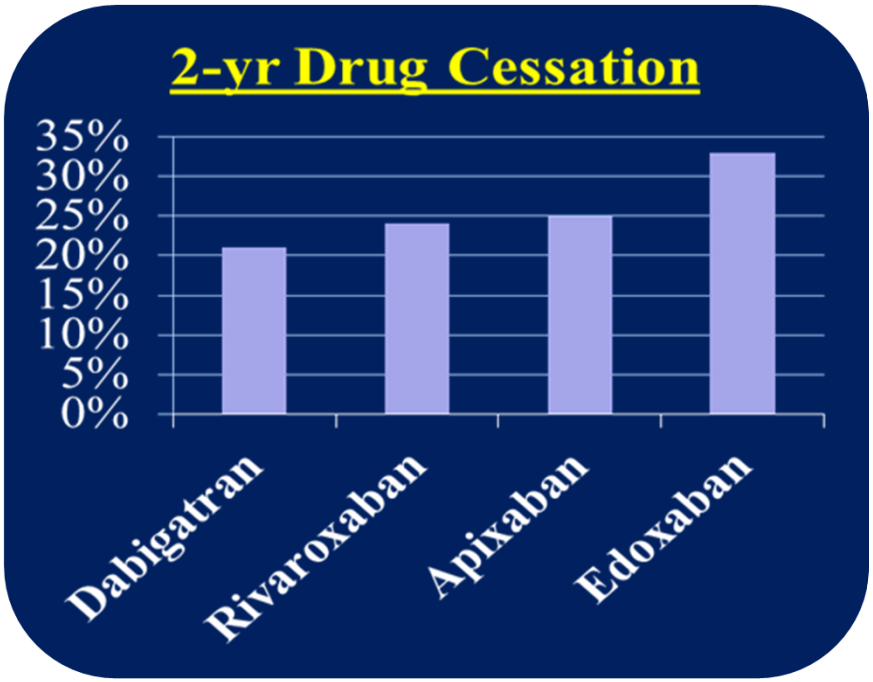
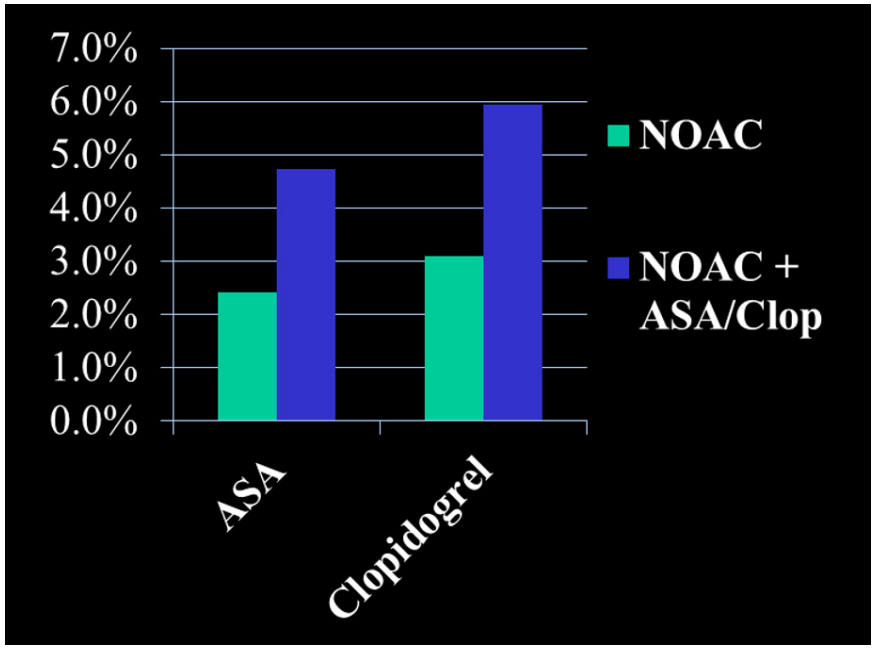
NOACs are Excellent Medications

But Not for Everyone…



RELY: Major Bleeding



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FDA Slide Deck. *Dabigatran FDA Review from Panel Meeting* 2010

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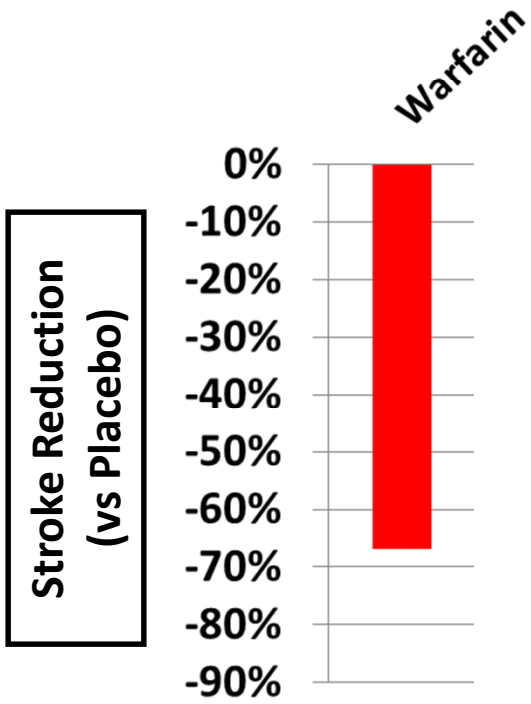
Preventing Stroke in Non-Valvular AF

Imputed Benefit of Different Strategies (*vs* Control)



* Reached statistical superiority relative to warfarin.

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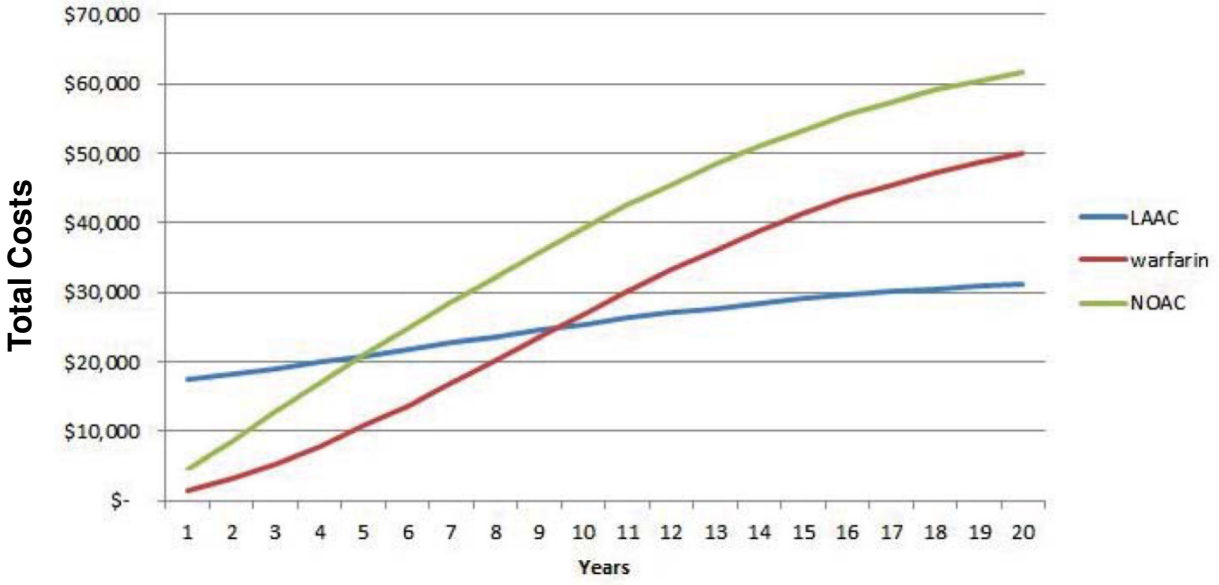
Economic Analysis: Cost Effectiveness

Watchman *vs* NOACs *vs* Warfarin

- Patient level Markov micro-simulation decision analytic model
- Assess Time-to-Cost Effectiveness (not just Lifetime horizon – 20 yrs)
- Economic costs from the U.S. perspective, and costs in 2015 US$
  - For LAAC procedure, we used the new DRG 273/274 (US average: $16,109)
- Latest PROTECT AF data (4 yrs f/u)
- NOAC meta-analysis of all 4 NOACs (Ruff et al, *Lancet* 383:955, 2014)
- Incorporated costs based on the level of disability resulting from strokes



VY.Reddy, RL.Akehurst, SO.Armstrong, SL.Amarosi, SM.Beard, DL.Holmes (*in press*)

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	Time to Cost Effectiveness (Cost/QALY)	Time to Dominance (More Effective, Less Costly)
LAAC *vs* warfarin	Year 7 ($42,994/QALY)	Year 10
NOACs *vs* warfarin	Year 16 ($48,446/QALY)	N/A
LAAC *vs* NOACs	Year 5 (Dominant)	Year 5

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VY.Reddy, RL.Akehurst, SO.Armstrong, SL.Amarosi, SM.Beard, DL.Holmes (*in press*)

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The Watchman Device

FDA Approval in March 2015

- **Watchman is indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who are:**
  1. **At increased risk for stroke and systemic embolism based on CHADS2 or CHA2DS2-VASc scores**
  2. **Are suitable for warfarin**
  3. **And have an appropriate rationale to seek a non-pharmacologic alternative to warfarin, taking into account the safety and effectiveness of the device compared to warfarin.**

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In whom should LAAC be employed?
Criteria that We Consider in the U.S.

1. **Patients with a history of bleeding (though not prohibitive bleeding: intra-cranial/ocular bleeding)**
2. **Patients at high risk for bleeding (eg, CAD patients taking anti-platelet agents)**
3. **Elderly patients**
4. **Patients with embolic events while on therapeutic OAC**
5. **Patients with renal dysfunction (especially dialysis pts)**
   - **WatchAFIB**
6. **Important lifestyle issues**
7. ***Patient preference***

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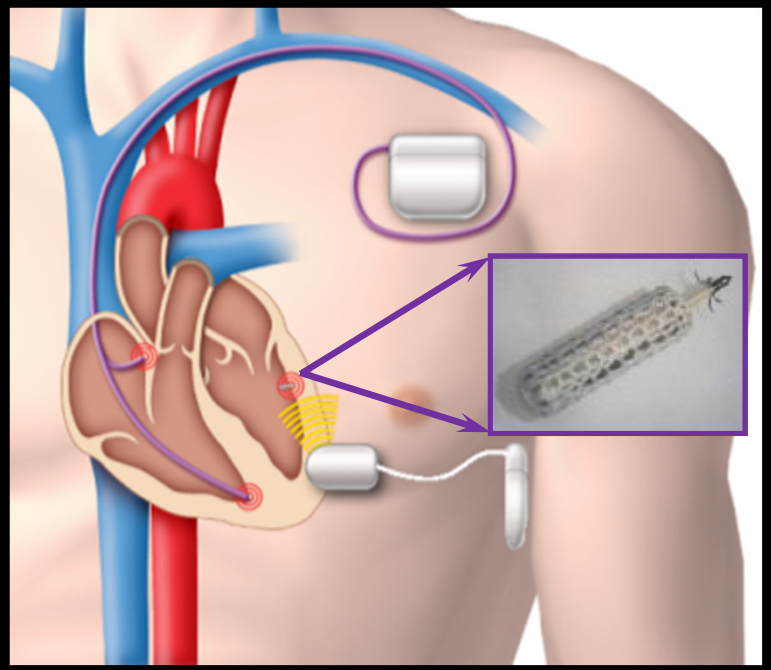
Final Thoughts

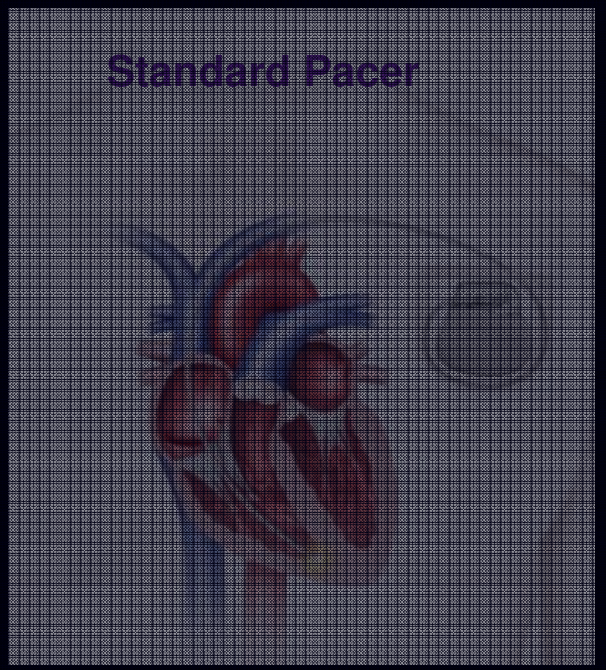
LA Appendage Closure & Stroke Prevention

- ~40% of patients are not protected against stroke w/ OACs
  - Especially elderly individuals
- "Local" therapy with LAA closure is comparable to Warfarin
  - LAAC less effective in preventing Ischemic Strokes, but balanced by fewer Hemorrhagic Strokes
  - Over 50% reduction in Disabling Strokes
  - Over 50% reduction in Cardiovascular Mortality
- Safety improves with Operator Experience
  - Tamponade Rate: 5% [PROTECT AF] → 1-2% [CAP/PREVAIL/CAP-2] → 0.2% [EWOLUTION]
- US Clinical Experience – (pending)

Leadless Pacing
Two Paradigms

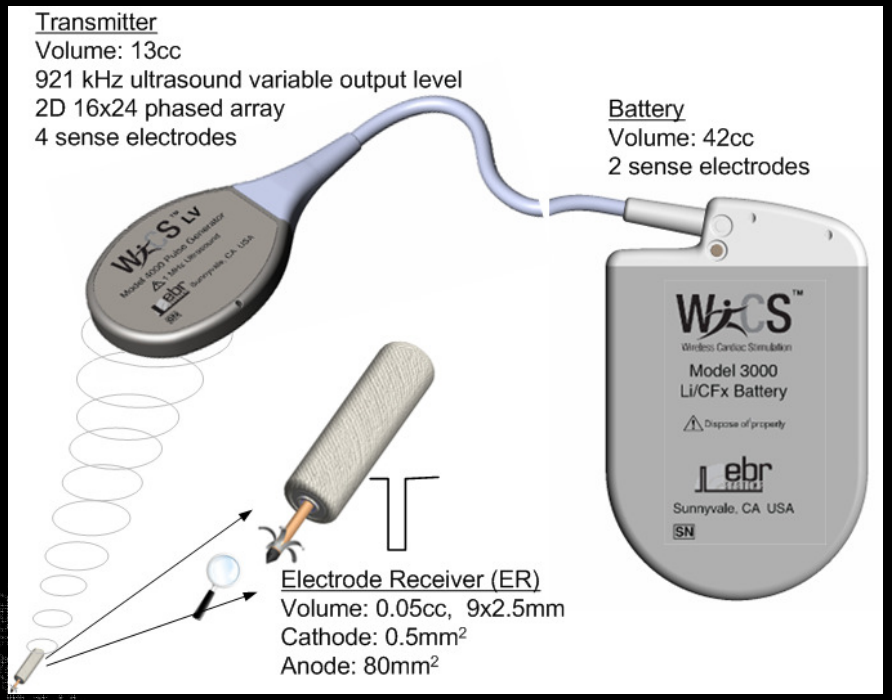
- **LV leadless pacing with subcutaneous generator**
  - **Subcutaneous generator: Transmits USN energy to LV**
  - **LV "pellet": Transduces USN energy to pacing output**
- **Leadless Pacemakers**
  - **Self-contained system to replace RV pacing**

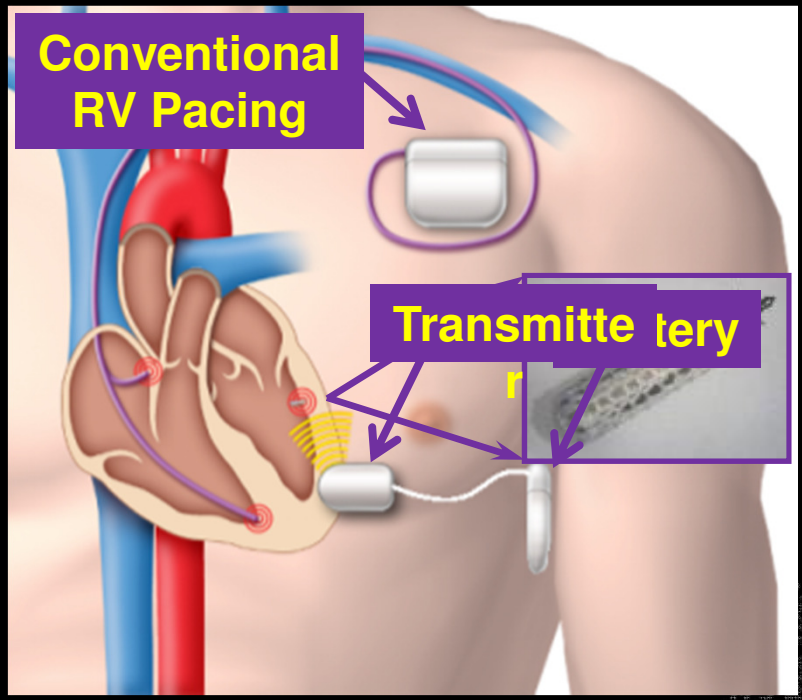




WiSE-LV Pacing System
Introduction

- LV leadless pacing with subcutaneous generator
  - Subcutaneous generator: Transmits USN energy to LV
  - LV "pellet": Transduces USN energy to pacing output





WiSE-LV Pacing System

Pacing Electrode Implantation Procedure

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Reddy VY / Neuzil P *HRS Scientific Sessions* (2014)

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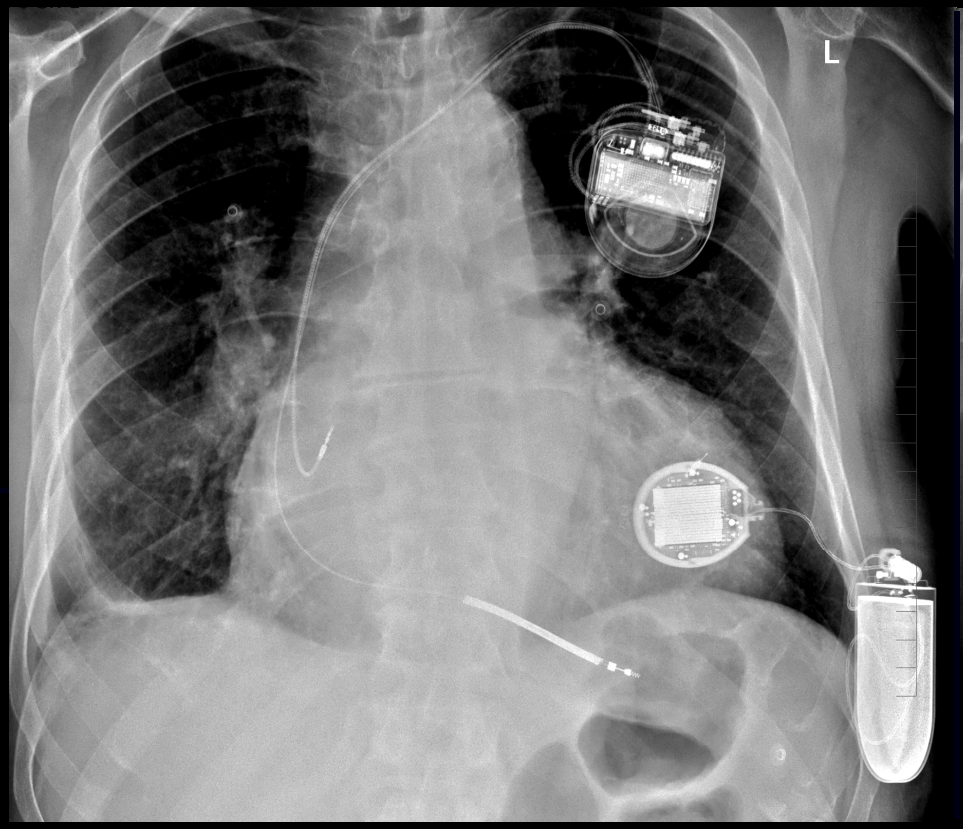
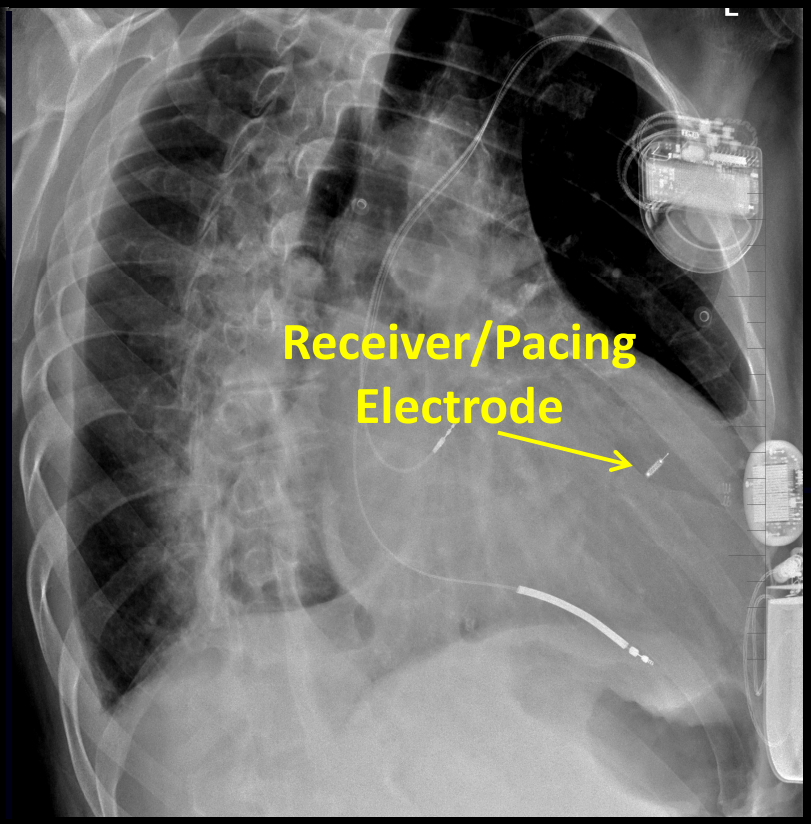
WiCS-LV System

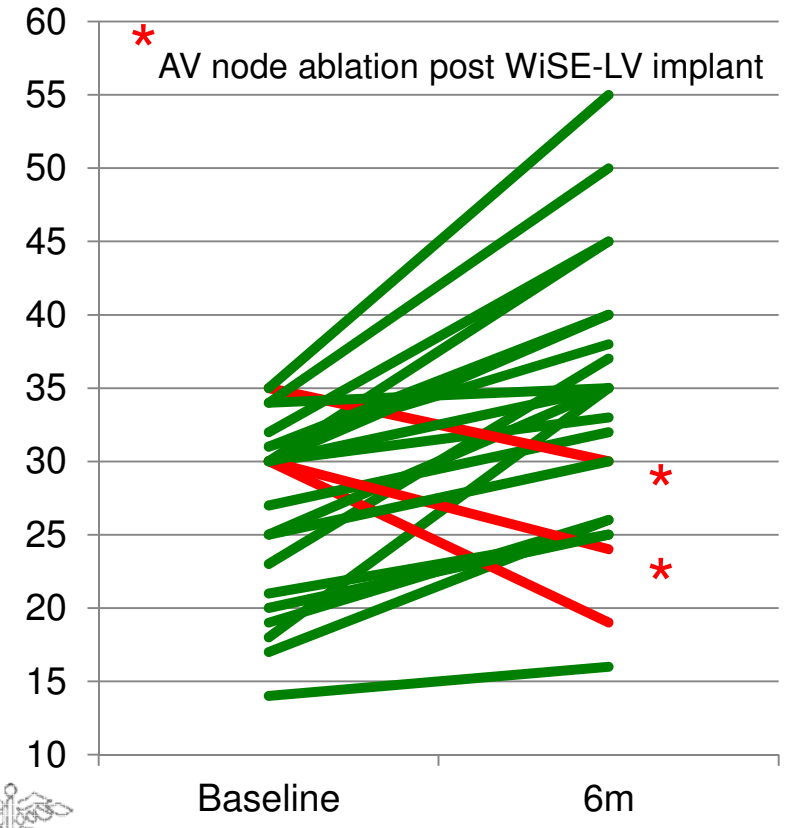




SELECT-LV Study

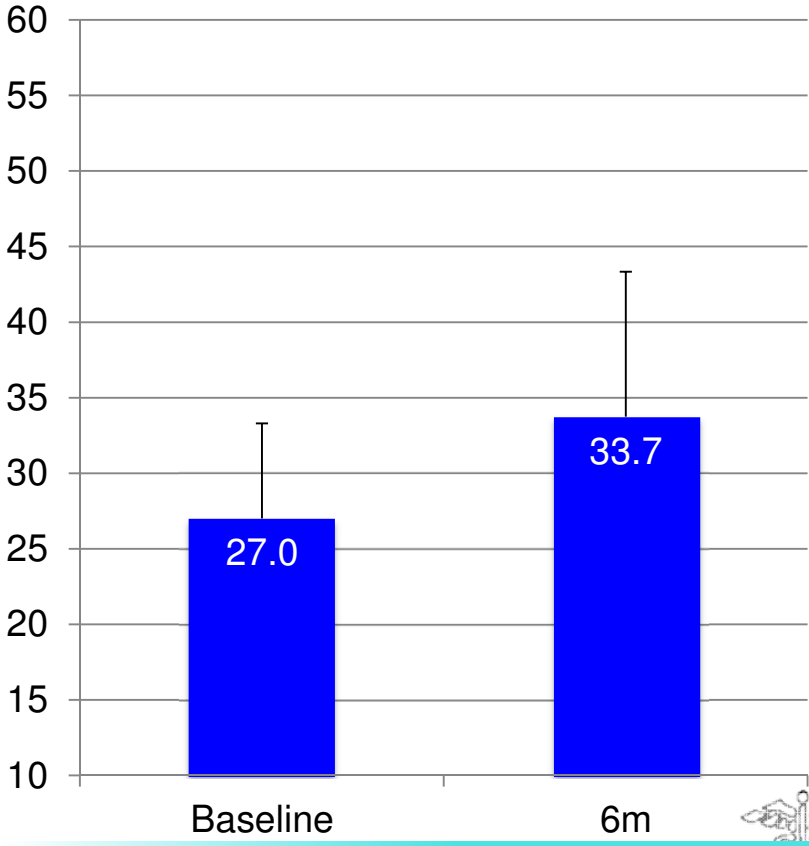
Preliminary efficacy - Ejection fraction

EF% by pt, baseline and 6m



69.5% pts ≥5% increase

EF%, baseline and 6m



Mean ± SD difference at 6m = 6.7 ± 7.6
Excl. AV node ablations = 7.9 ± 6.8

Reddy VY et al, *HRS Scientific Sessions,* LBCT (May 2015)

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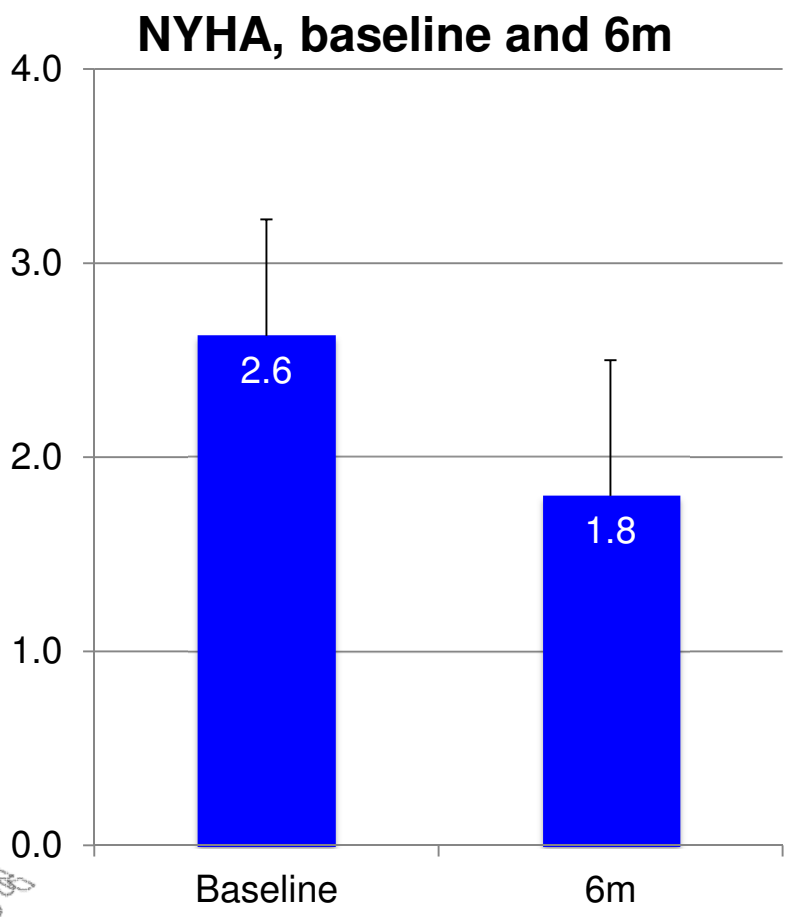
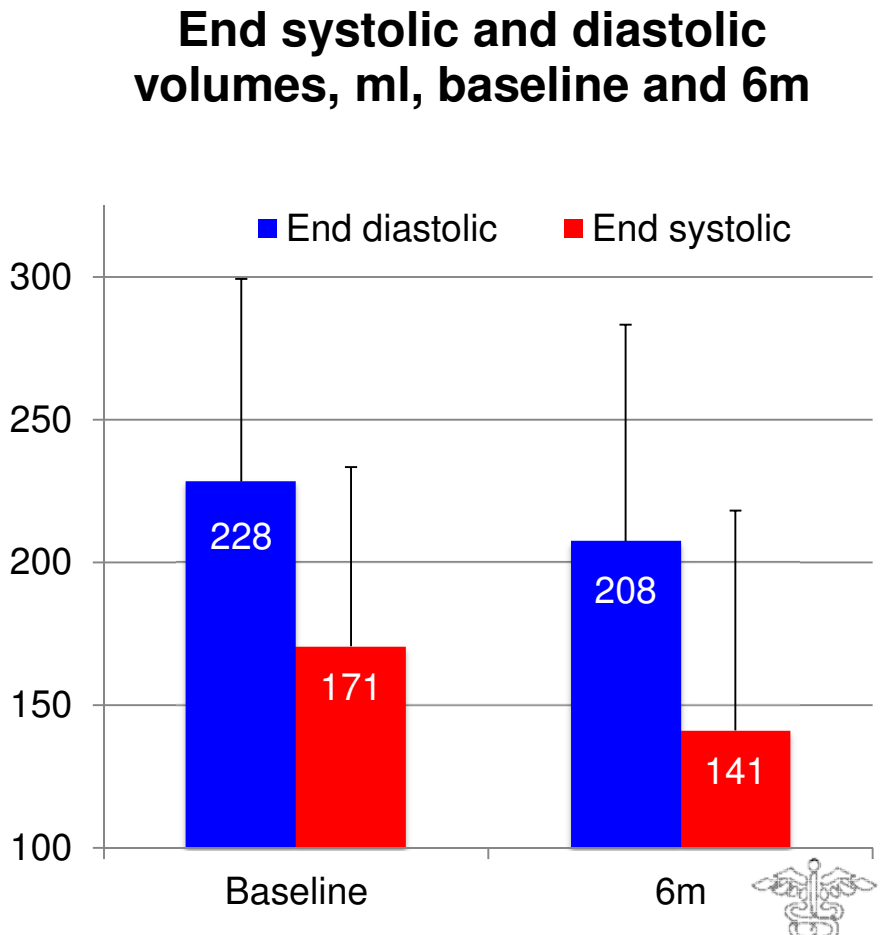
SELECT-LV Study

Efficacy – NYHA Class and LV Dimensions



61.5% pts ≥1 class improvement



64.7% pts ≥ 15% improvement in LVESV

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Reddy VY et al, *HRS Scientific Sessions,* LBCT (May 2015)

Leadless Pacing
Two Approaches

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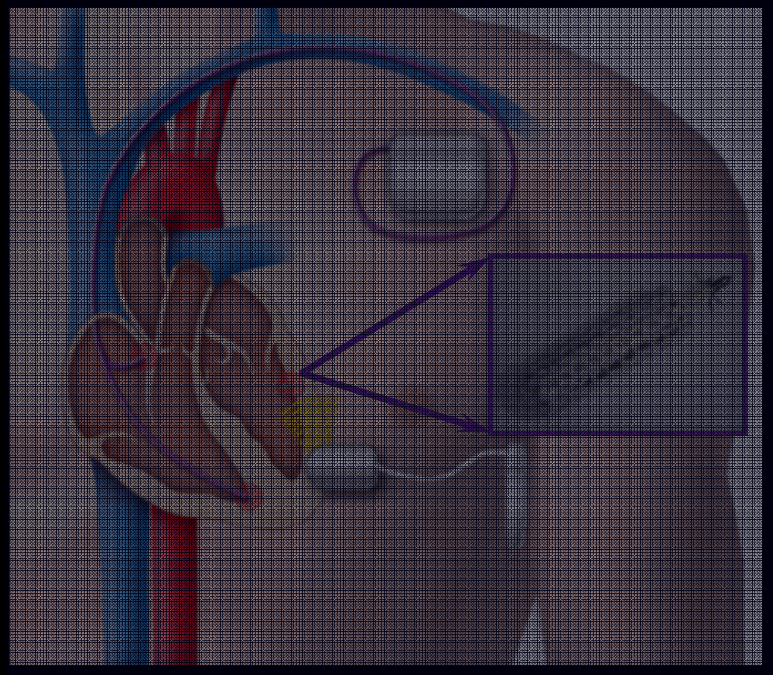

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Leadless Ventricular Pacemakers

Device Options

Nanostim

Micra

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Reddy VY, Exner DV, Cantillon DJ et al, *N Engl J Med* *373*:1125-1135 (2015)
Reynolds D, Duray GZ, Omar R et al, *N Engl J Med* doi:10.1056/NEJMoa1511643 (2015)

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Leadless Ventricular Pacemakers

Nanostim & Micra

TABLE 1 Characteristics of the LCP and TCP

Parameter	Nanostim	Micra
Polarity	Bipolar	Bipolar
Pacing modes	VVI (R)	VVI (R)
Rate modulation mechanism	Blood temperature	3-axis accelerometer
Battery technology	Lithium carbon monofluoride	Lithium silver vanadium oxide / carbon monofluoride
Programmer	St. Jude Medical, model 3650	Medtronic, model 2090
Energy capacity (mAh)	248	120
Estimated longevity		
ISO standard, yrs*	9.8 yrs	4.7 yrs
Alternative setting, yrs†	14.7 yrs	9.6 yrs
Size (h × w), maximum thickness, mm	42 mm × 5.99 mm	25.9 mm × 6.7 mm
Volume (cc)	1.0	0.8
Fixation mechanism	Helix (screw-in)	Tines

*Longevity based on fixed programming at the ISO International Organization for Standardization (ISO 14708) standard guidelines for reporting pacemaker battery duration longevity: 2.5 V, 0.4 ms, 600 Ω, 60 beats/min, and 100% pacing. †Longevity based on nominal settings (for the TCP): 1.5 V, 0.24 ms, 60 beats/min (with an impedance load of 500 ohms and 100% pacing).

LCP = leadless cardiac pacemaker; TCP = transcatheter pacing system.

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Miller MA / Reddy VY, *J Am Coll Cardiol* 66:1179 (2015)

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Leadless Pacemaker System: Nanostim

Implantation Procedure

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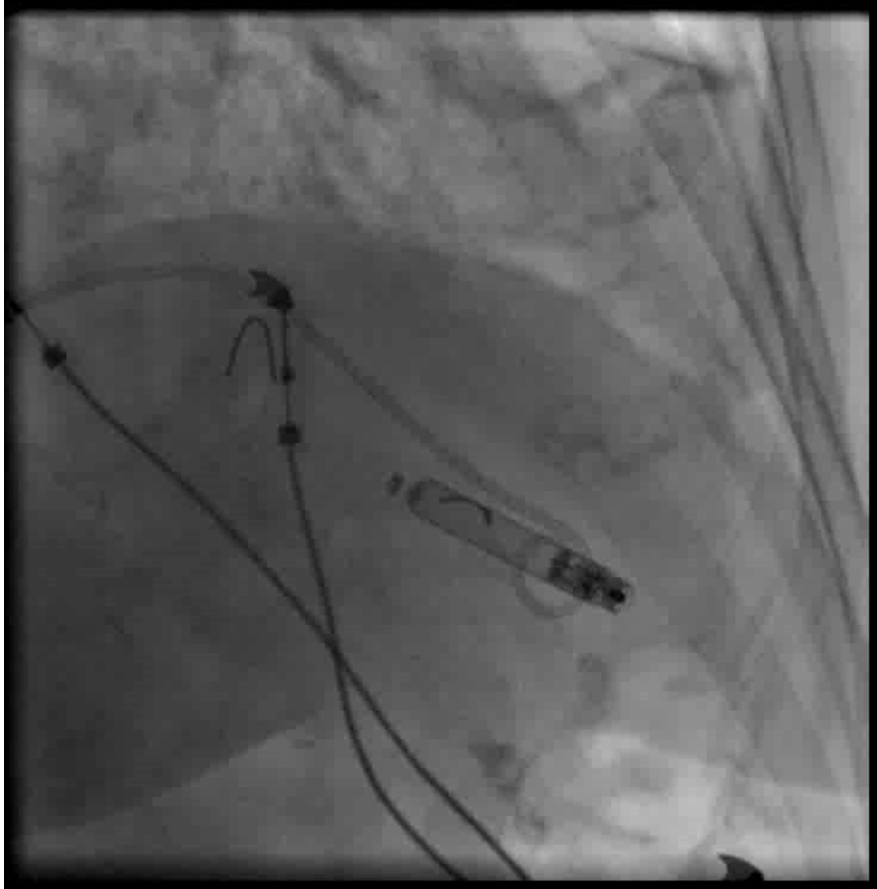
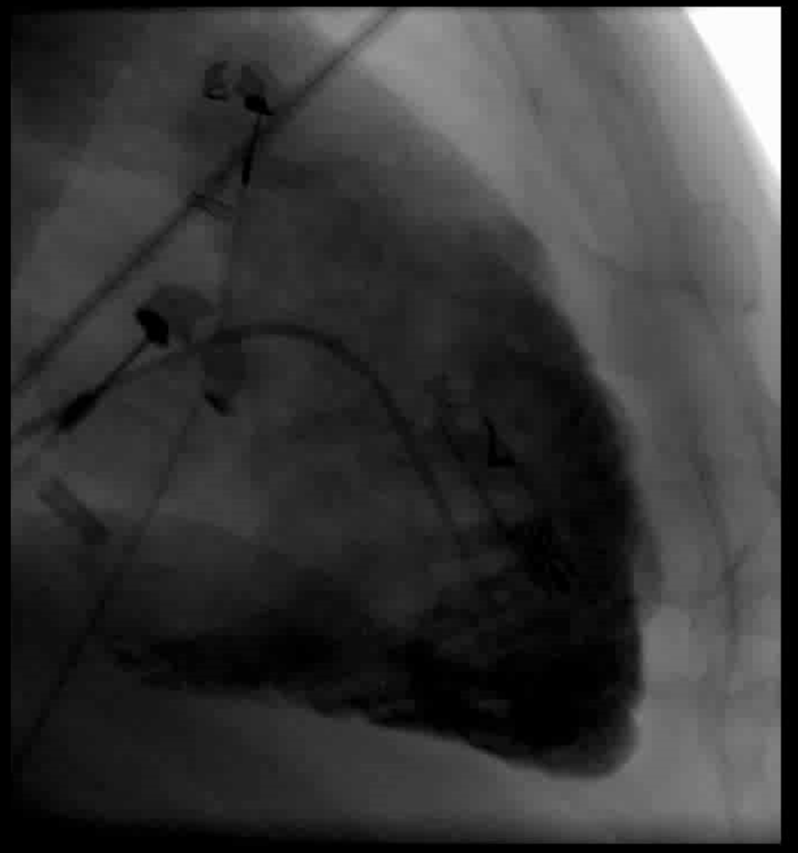
Leadless Pacemaker Case

Device Implanted





First-in-Man Study of Leadless Pacing

LEADLESS: A 3-Center, 33-Patient Study

Original Article

Permanent Leadless Cardiac Pacing
Results of the LEADLESS Trial

Vivek Y. Reddy, MD; Reinoud E. Knops, MD; Johannes Sperzel, MD; Marc A. Miller, MD; Jan Petru, MD; Jaroslav Simon, MD; Lucie Sediva, MD; Joris R. de Groot, MD, PhD; Fleur V.Y. Tjong, MD; Peter Jacobson, BS; Alan Ostrosff, MS; Srinivas R. Dukkipati, MD; Jacob S. Koruth, MD; Arthur A.M. Wilde, MD, PhD; Josef Kautzner, MD, PhD; Petr Neuzil, MD, PhD

Early performance of a miniaturized leadless cardiac pacemaker: the Micra Transcatheter Pacing Study

Philippe Ritter[1]*, Gabor Z. Duray[2], Clemens Steinwender[3], Kyoko Soejima[4], Razali Omar[5], Lluís Mont[6], Lucas VA Boersma[7], Reinoud E. Knops[8], Larry Chinitz[9], Shu Zhang[10], Calambur Narasimhan[11], John Hummel[12], Michael Lloyd[13], Timothy Alexander Simmers[14], Andrew Voigt[15], Verla Laager[16], Kurt Stromberg[16], Matthew D. Bonner[16], Todd J. Sheldon[16], and Dwight Reynolds[17], Micra Transcatheter Pacing Study Group

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Reddy VY / Knops R / Neuzil P *Circulation* 129:1466 (2014
Ritter P, *Eur Heart J* doi:10.1093/eurheartj/ehv214

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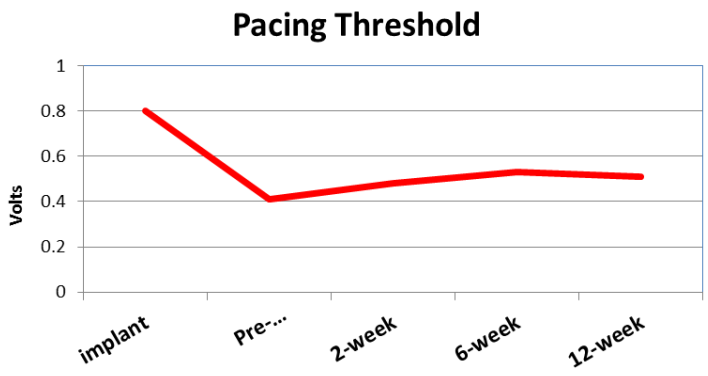
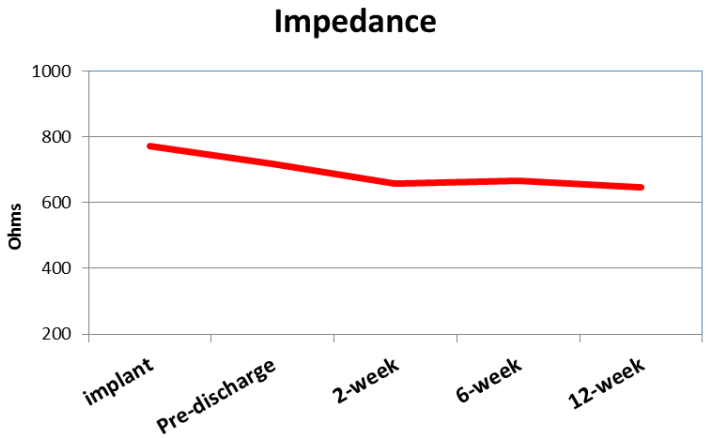
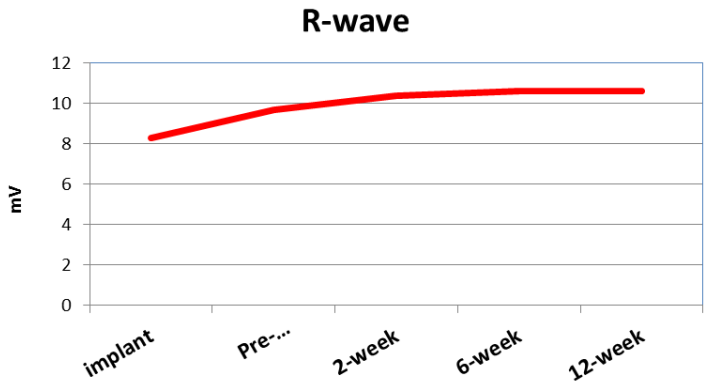
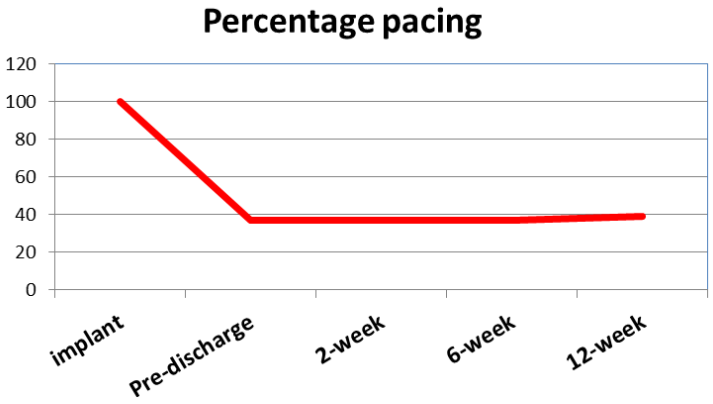
First-in-Man Study of Leadless Pacing

LEADLESS: A 3-Center, 33-Patient Study









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Reddy VY / Knops R / Neuzil P *Circulation* 129:1466 (2014)

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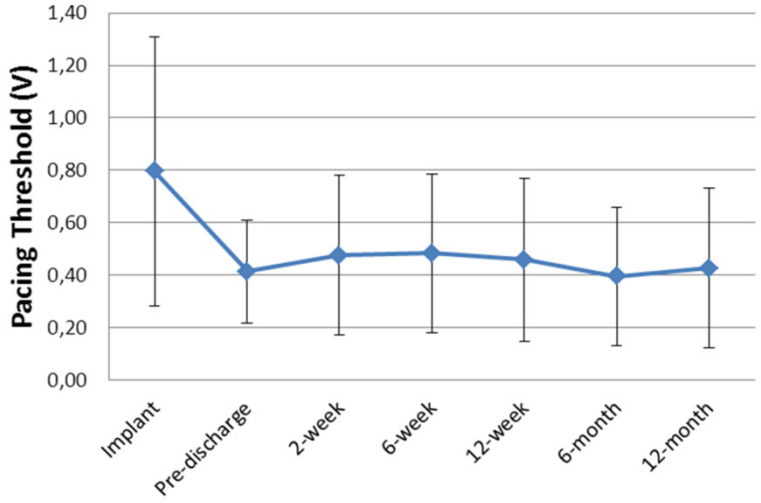
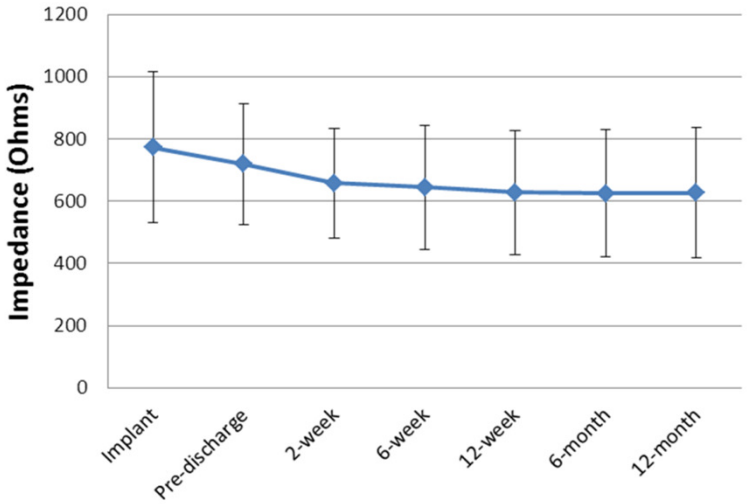
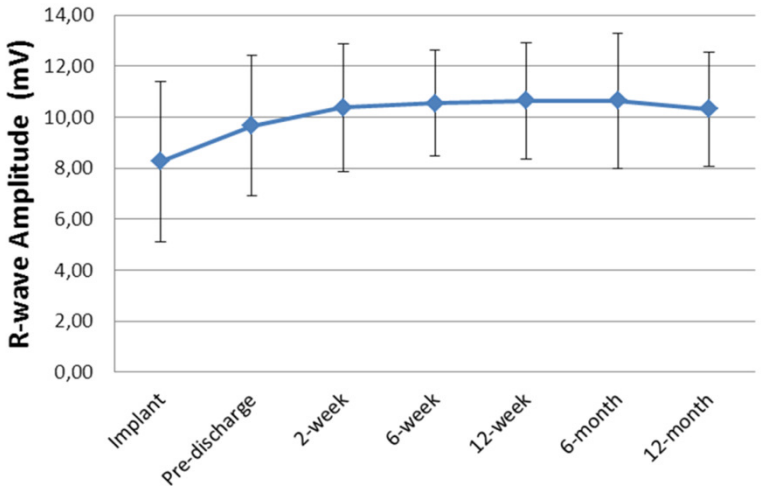
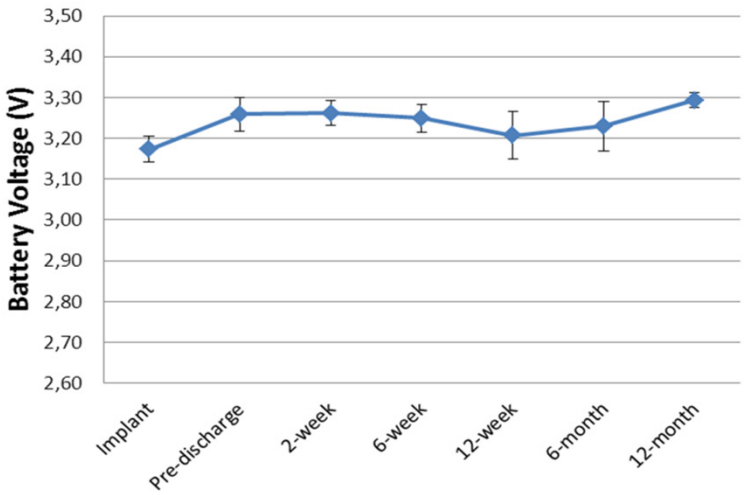
LEADLESS Study

One-Year Device Performance









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Reddy VY / Knops R / Neuzil P *HRS LBCT* 2014

Leadless II IDE Clinical Trial

Procedural Characteristics

Characteristic	Primary Cohort (N = 300)	Total Cohort (N = 526)
Procedural characteristics§		
Successful Implantation	96.3%	95.8%
Duration of implantation — min		
Total: sheath insertion to removal	50.0±27.3	46.5±25.3
Procedure: insertion of delivery catheter to removal	30.4±18.2	28.6±17.8
Duration of fluoroscopy — min	14.9±9.4	13.9±9.1
Device repositioning — no. of patients/total no. (%)		
None	199/289 (68.9)	354/504 (70.2)
1	53/289 (18.3)	89/504 (17.7)
2	24/289 (8.3)	39/504 (7.7)
>2	13/289 (4.5)	22/504 (4.4)
Final device position in right ventricle — no. of patients/ total no. (%)		
Apex	140/289 (48.4)	192/504 (38.1)
Apical septum	5/289 (1.7)	96/504 (19.0)
Outflow, septum, or other	144/289 (49.8)	215/504 (42.7)
Missing data	0/289	1/504 (0.2)

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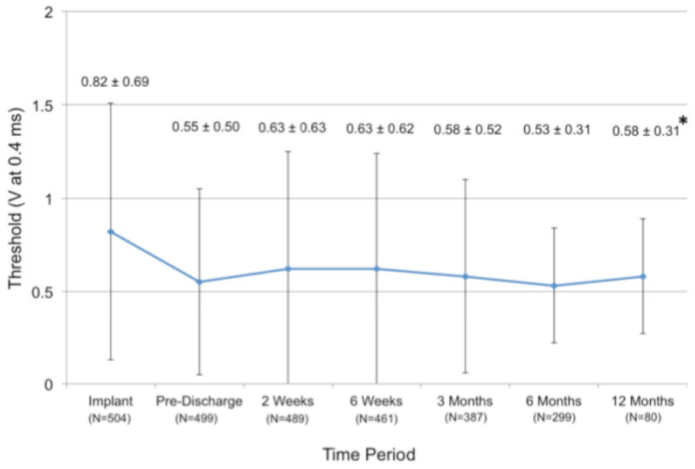
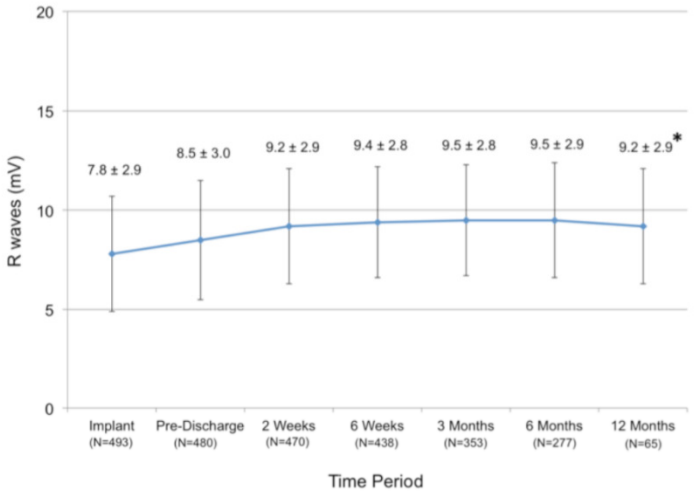
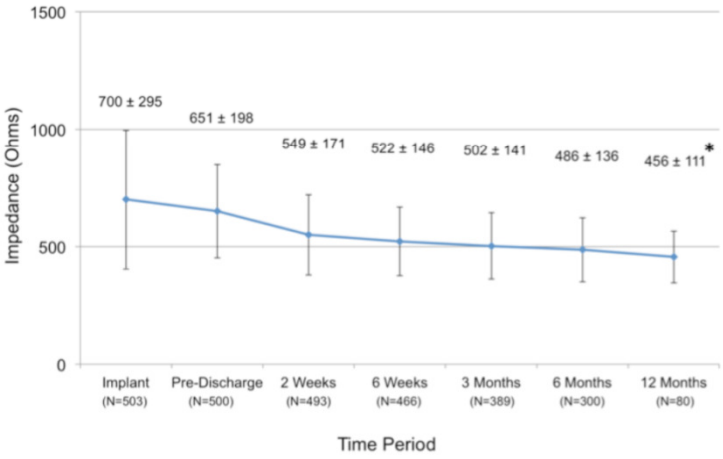
Reddy VY, Exner DV, Cantillon DJ et al, *N Engl J Med 373*:1125-1135 (2015)

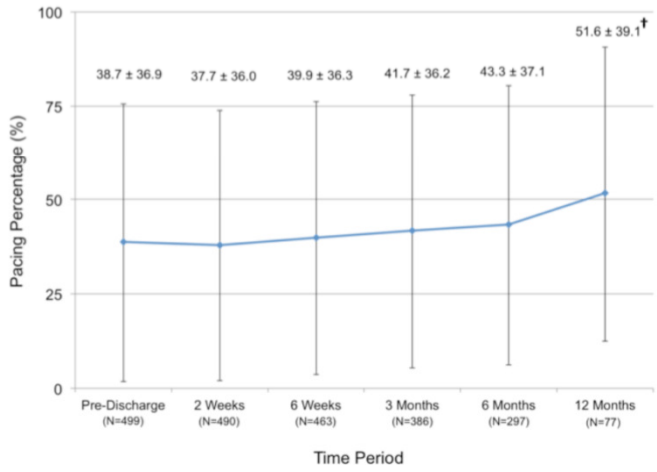
Leadless II IDE Clinical Trial

Device Electrical Measurements









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Reddy VY, Exner DV, Cantillon DJ et al, *N Engl J Med 373*:1125-1135 (2015)

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Leadless II IDE Clinical Trial

Device-Related SAEs

Event	Primary Cohort (N=300)			Total Cohort (N=526)		
	No. of Events	No. of Patients	Event Rate %	No. of Events	No. of Patients	Event Rate %
Total	22	20	6.7	40	34	6.5
Cardiac perforation	4	4	1.3	8	8	1.5
Cardiac tamponade with intervention	1	1	0.3	5	5	1.0
Cardiac perforation requiring intervention	1	1	0.3	1	1	0.2
Pericardial effusion with no intervention	2	2	0.7	2	2	0.4
Vascular complication	4	4	1.3	6	6	1.1
Arrhythmia during device implantation	2	2	0.6	3	3	0.6
Cardiopulmonary arrest during implantation procedure	0	0	0	1	1	0.2
Device dislodgement	5	5	1.7	6	6	1.1
Device migration during implantation owing to inadequate fixation	0	0	0	2	2	0.4
Pacing threshold elevation with retrieval and implantation of new device	4	4	1.3	4	4	0.8
Other						

* Includes: ischemic stroke, angina pectoris, pericarditis, acute confusion & expressive aphasia, dysarthria & lethargy post implant, contrast induced nephropathy, orthostatic hypotension with weakness, left leg weakness during implant, probable pulmonary embolism, ischemic stroke

Reddy VY, Exner DV, Cantillon DJ et al, *N Engl J Med* *373*:1125-1135 (2015)

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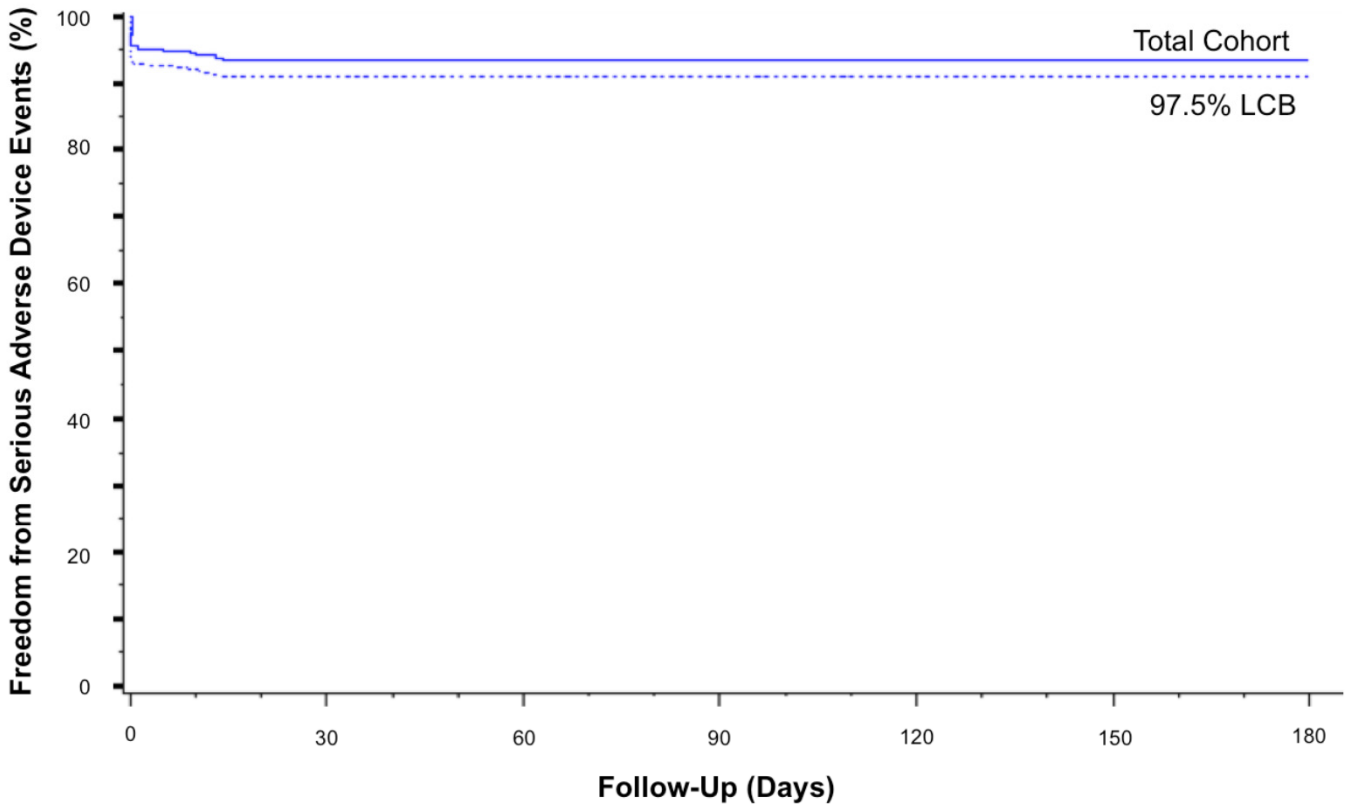
Freedom from SADEs

Total Cohort (n=526)



No. at Risk	526	479	430	381	334	308	279
Events	23	34	34	34	34	34	34
Censors	0	15	66	114	158	185	214
Success	95.6%	93.5%	93.5%	93.5%	93.5%	93.5%	93.5%
97.5% LCB	93.5%	91.1%	91.1%	91.1%	91.1%	91.1%	91.1%

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Leadless II IDE Clinical Trial

Battery Longevity: Projected *vs* "Observed"

Percent Pacing (%)	Battery Longevity (Years)*	
	500 Ohm Load	600 Ohm Load
100	8.8	9.8
75	10.6	11.7
50	13.3	14.5
25	17.9	18.9

* Assuming VVIR at 60 bpm, and output 2.5 V at 0.4 ms

Based on electrical parameters in the Primary Cohort, the battery longevity is estimated at 15.0 ± 6.7 yrs (95% CI, 14.2 to 15.8 yrs).

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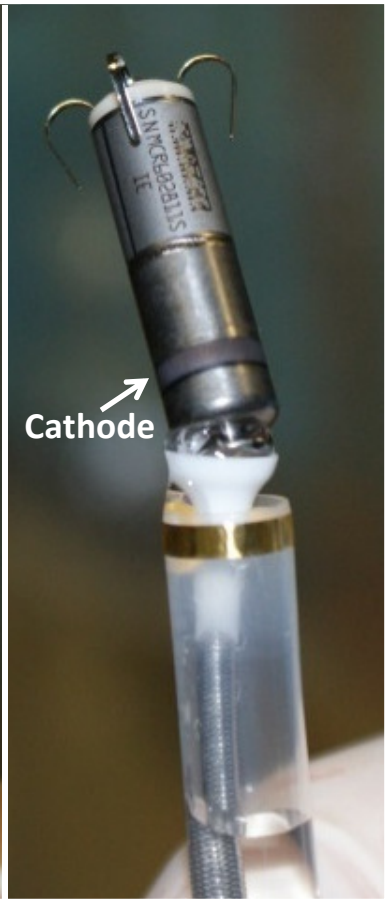
Reddy VY, Exner DV, Cantillon DJ et al, *N Engl J Med* *373*:1125-1135 (2015)

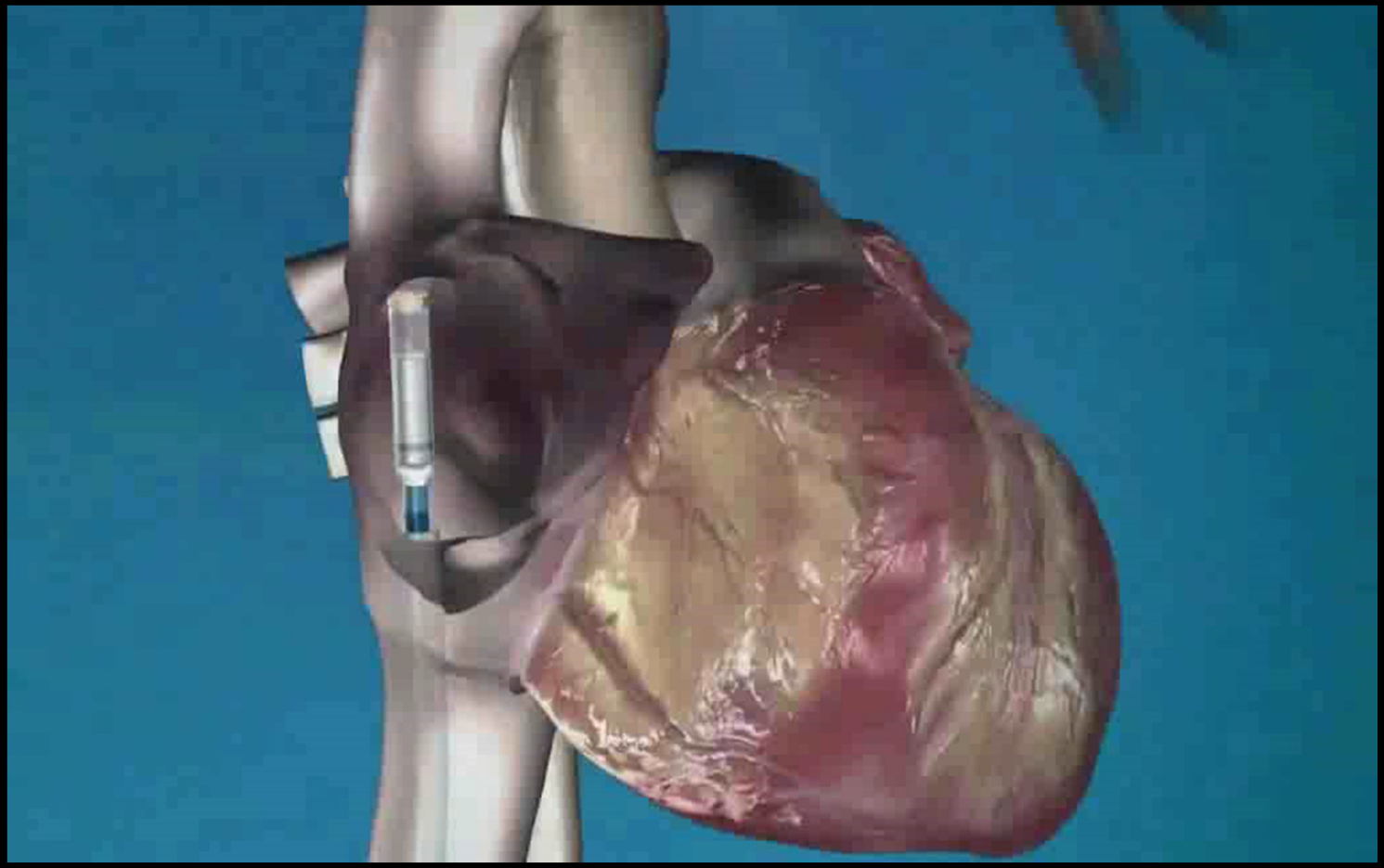
Leadless Cardiac Pacemaker: Micra

Device Deployment

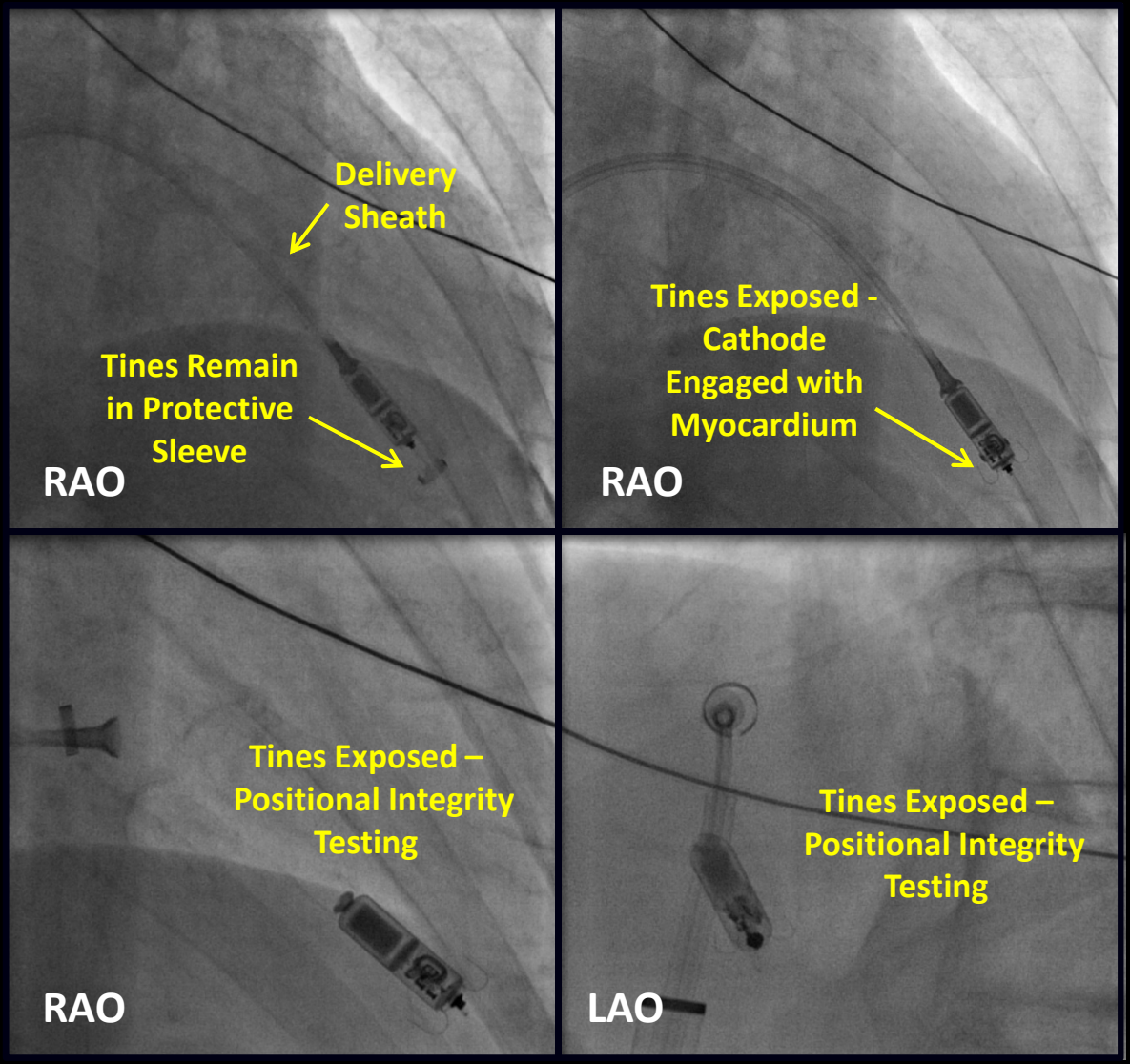
Protective Sleeve Being Withdrawn – Tines Extending	Tines Completely Retroflexed – Micra Still In Sheath	Protective Sleeve Further Withdrawn – Micra Further Exposed	Micra Remains Tethered at Delivery Tool Interface
			

Leadless Cardiac Pacemaker: Micra

Device Deployment

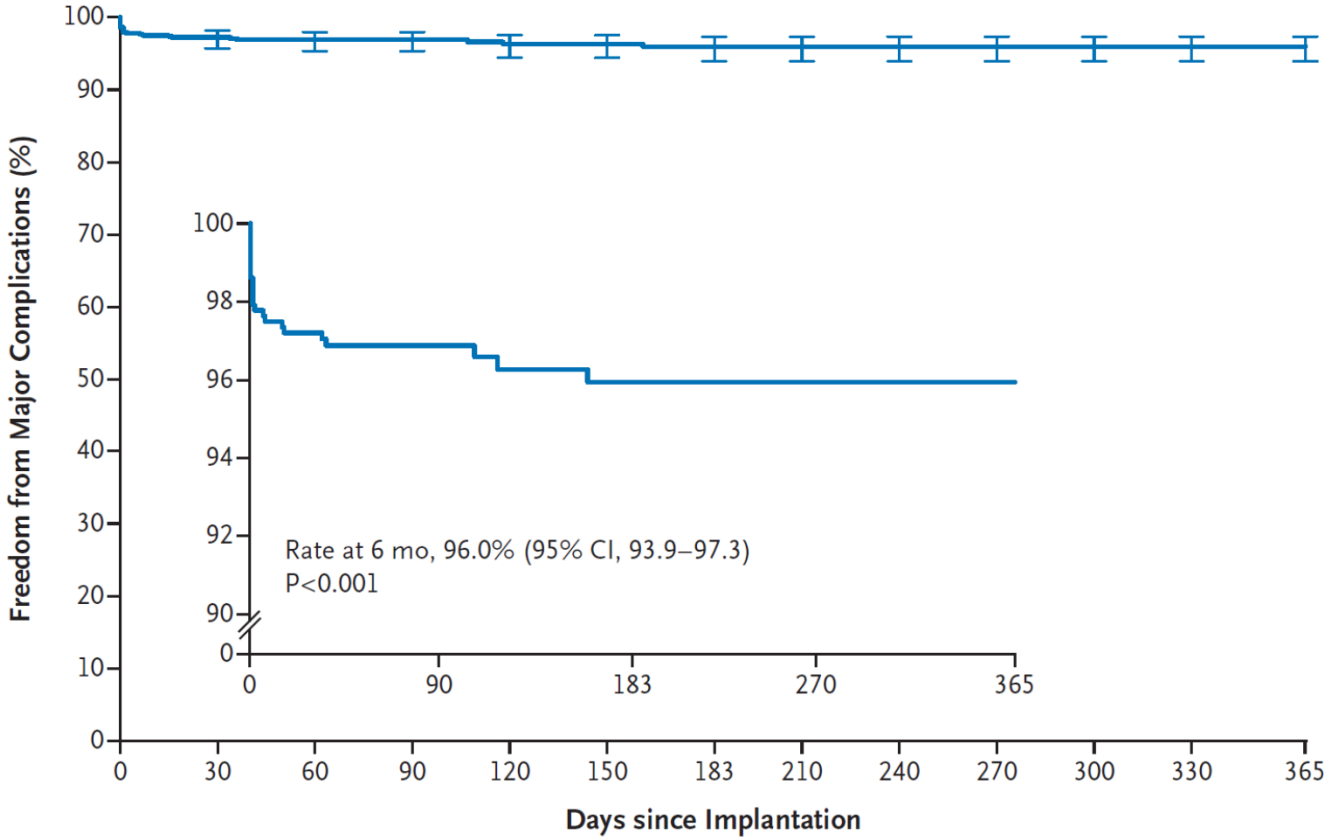


Micra Deployment
Clinical Case Example



Micra IDE Clinical Trial

Freedom From Major Complications (n=725)



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Reynolds D, Duray GZ, Omar R et al, *N Engl J Med* doi:10.1056/NEJMoa1511643 (2015)

Micra IDE Clinical Trial

Device-Related Complications

Adverse Event	No. of Events Associated with Major Complication Criterion*						No. of Patients (%)†
	Death	Loss of Device Function	Hospitalization	Prolonged Hospitalization‡	System Revision	Total Events	
Embolism and thrombosis	0	0	1	1	0	2	2 (0.3)
Deep vein thrombosis	0	0	0	1	0	1	1 (0.1)
Pulmonary thromboembolism	0	0	1	0	0	1	1 (0.1)
Events at groin puncture site: atrioventricular fistula or pseudoaneurysm	0	0	2	3	0	5	5 (0.7)
Traumatic cardiac injury: cardiac perforation or effusion	0	0	3	9	0	11	11 (1.6)
Pacing issues: elevated thresholds	0	1	2	1	2	2	2 (0.3)
Other events	1	0	5	4	1	8	8 (1.7)
Acute myocardial infarction	0	0	0	1	0	1	1 (0.1)
Cardiac failure	0	0	3	2	0	3	3 (0.9)
Metabolic acidosis	1	0	0	0	0	1	1 (0.1)
Pacemaker syndrome	0	0	1	0	1	1	1 (0.2)
Presyncope	0	0	0	1	0	1	1 (0.1)
Syncope	0	0	1	0	0	1	1 (0.1)
Total	1	1	13	18	3	28	25 (4.0)

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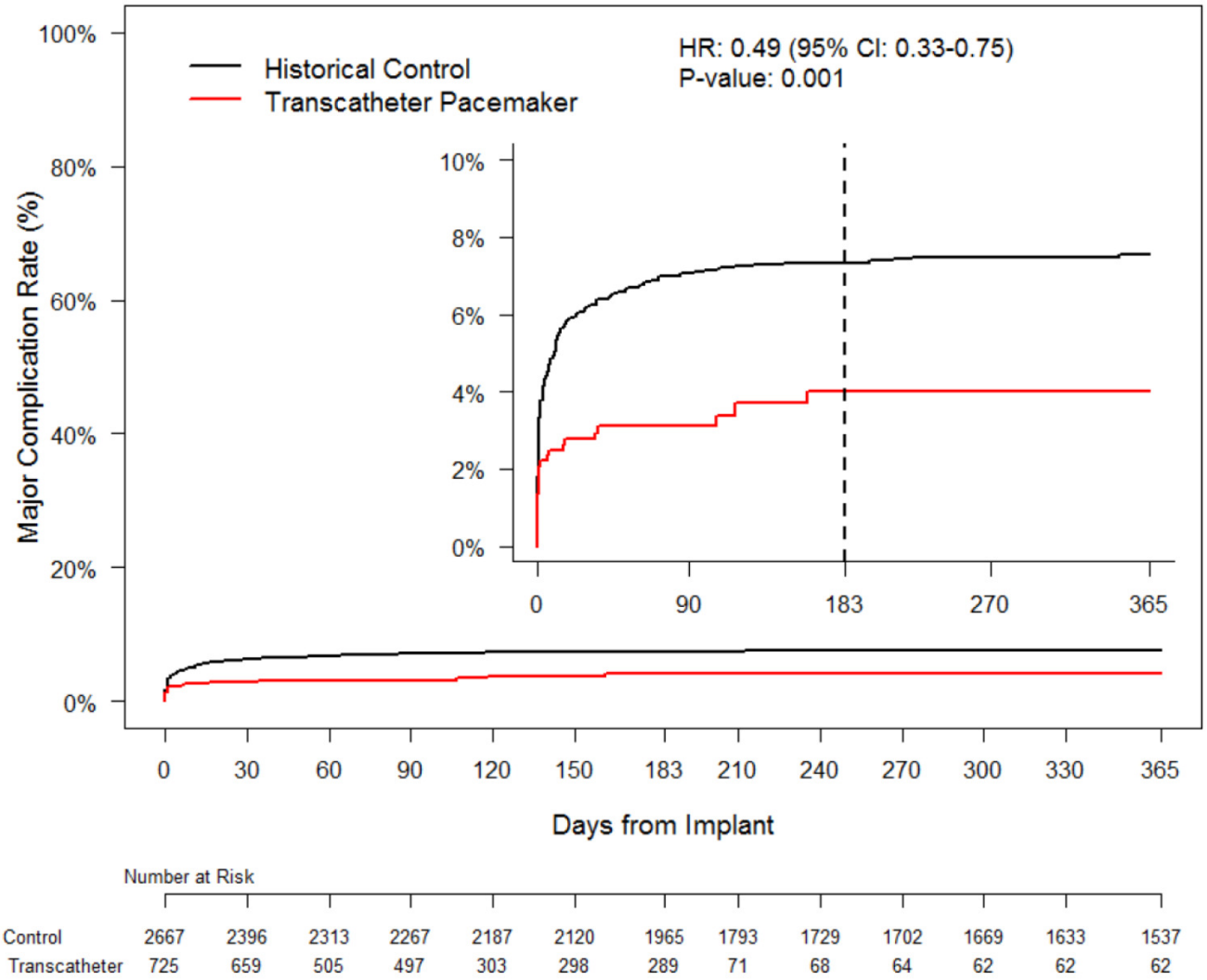
Micra IDE Complications

Comparison to Matched Historical Control



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Reddy VY, Exner DV, Cantillon DJ et al, *N Engl J Med 373*:1125-1135 (2015)

Leadless Pacemakers

Limitations

- Both observational studies (not Randomized)
- Mean Follow-Up only ~6 months
- How to manage device after battery depletion?
  - Possible to retrieve after ~1 year, but what about 5, 10, 15 yrs?
  - Retrieval ***vs*** Abandonment
- Limited device diagnostics (eg, no electrogram data)
- Large venous sheath (18Fr-21Fr)
  - Now increasingly common used for cardiology procedures
  - Low observed rate of hematomas
- Single-chamber (RV) pacing only
  - Device-to-device communication is in development …

Leadless II IDE Clinical Trial

Retrieveability of Chronically-Implanted Devices

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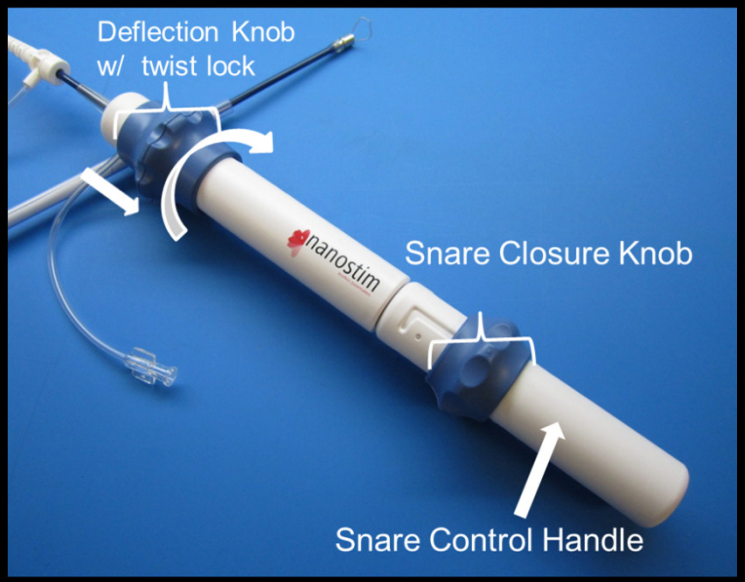
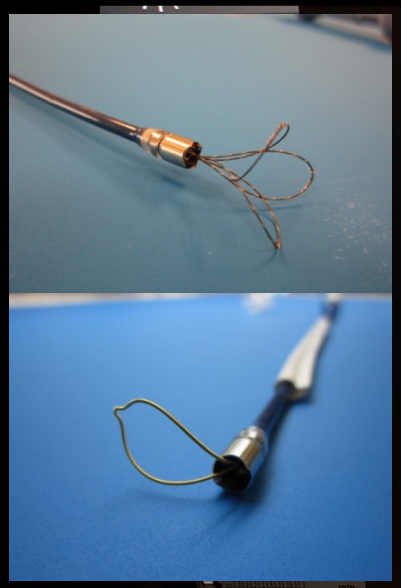
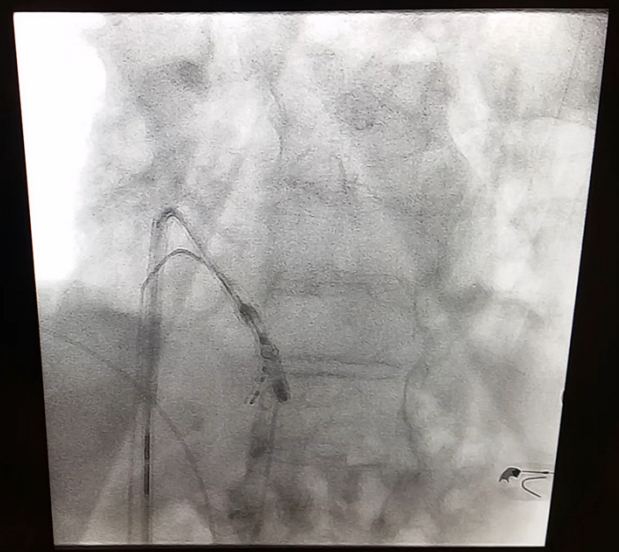
Leadless II IDE Clinical Trial

Retrieveability of Chronically-Implanted Devices







- Retrieval of 7 implanted devices → 100% success without complications
- Time from implant: 160 ± 180 days (Range = 1 to 413 days)
- Reasons for retrieval
  - Elevated Pacing Thresholds = 4 pts
  - Worsening CHF = 2 pts
  - Elective Explantation = 1 pt
- Retrieval is an important capability in the intermediate timeframe

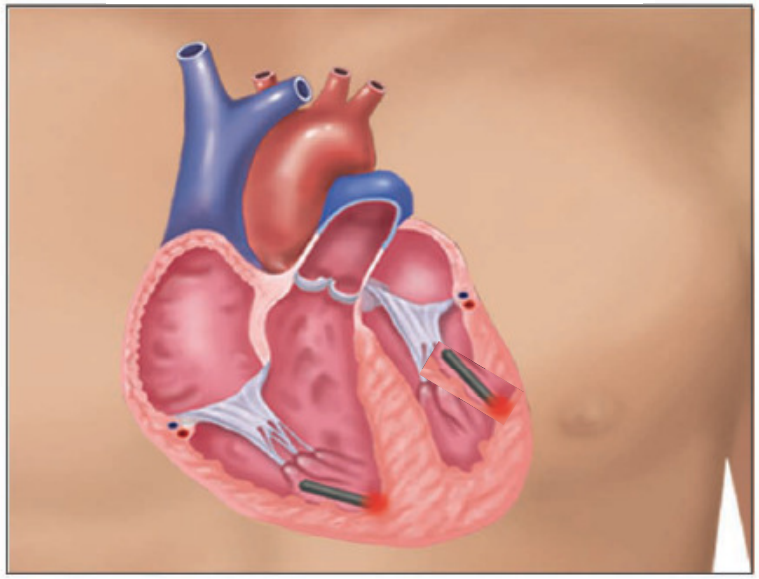
Reddy VY, Exner DV, Cantillon DJ et al, *N Engl J Med* *373*:1125-1135 (2015)

LV Pacing: Leadless Pacemakers?

Potentiated by Device-to-Device Communication

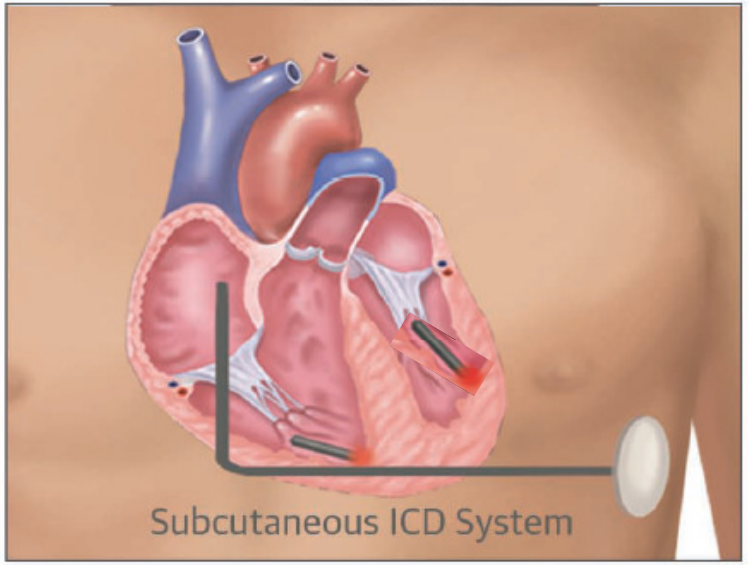
Bradycardia

Cardiac Resynchronization



Sudden Cardiac Death

CRT-D



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Miller MA / Neuzil P / Dukkipati SR / Reddy VY *J Am Coll Cardiol* 66:1180 (2015)


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