

Advances in Cardiac Devices to Reduce Long-Term Complications

Auroa Badin, MD FACC

Cardiac Electrophysiology

OhioHealth

Riverside Methodist Hospital

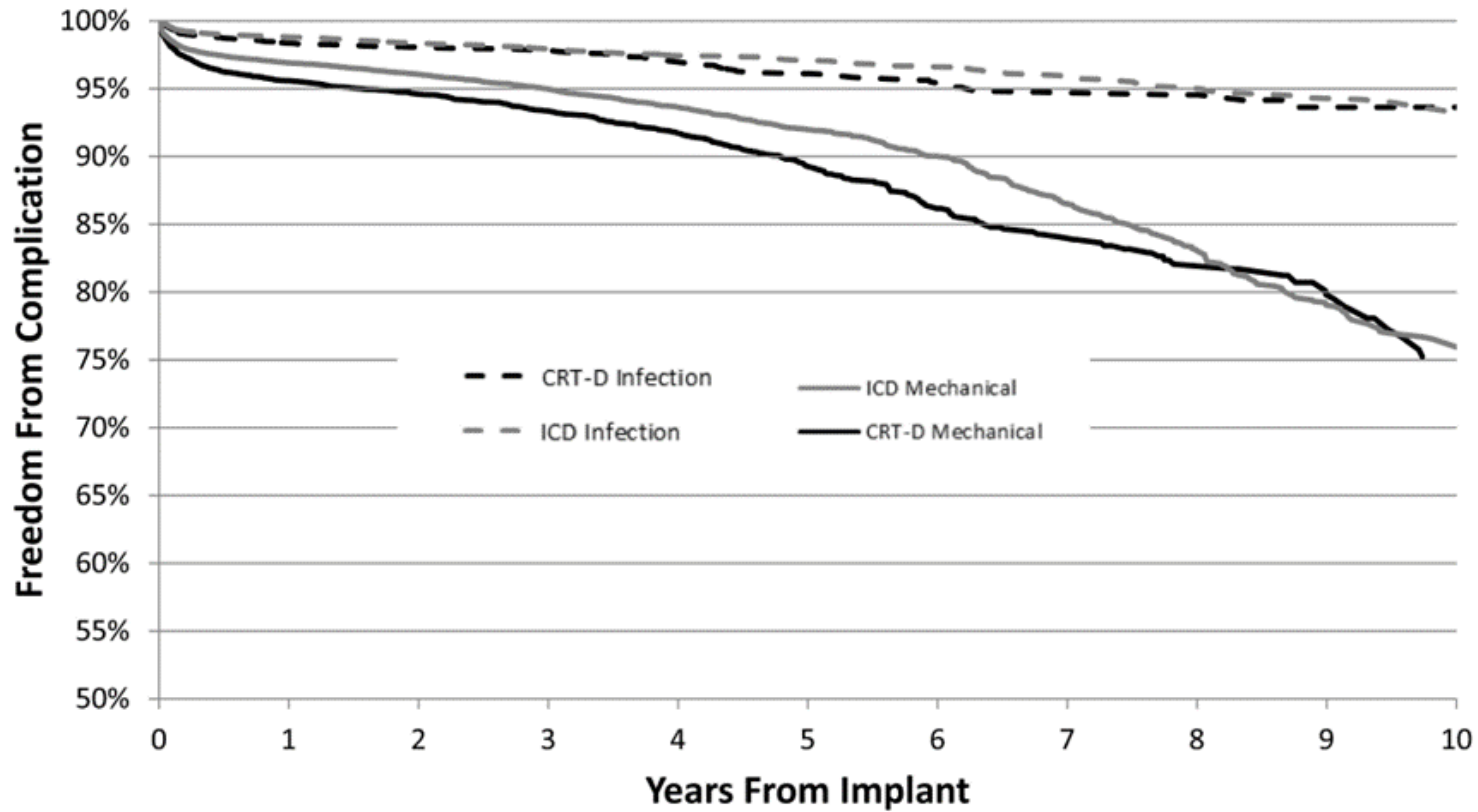
Columbus, Ohio



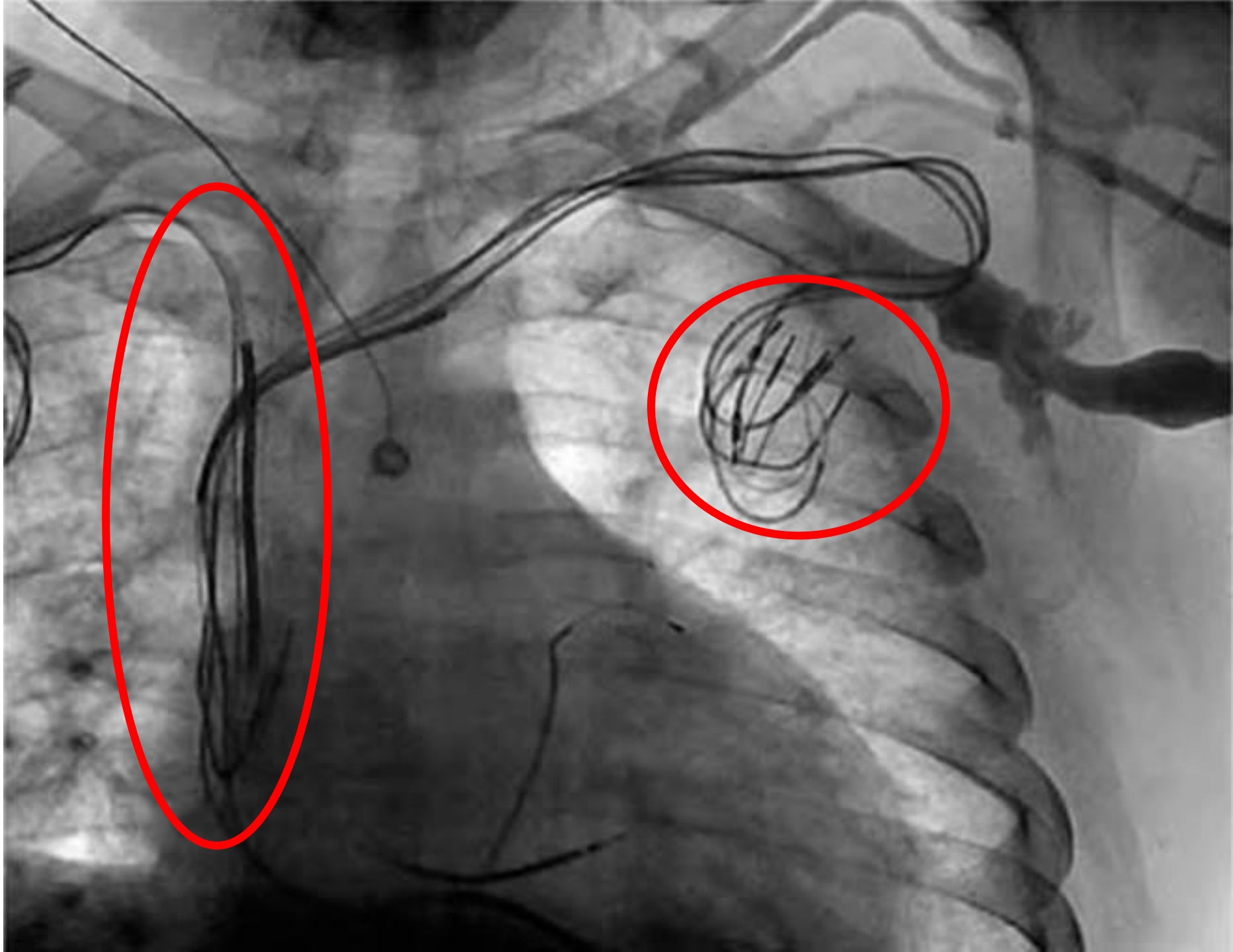
No relevant disclosure

1. Complications associated with transvenous devices
2. Pacing alternatives
3. Defibrillation alternatives
4. Unanswered questions and final thoughts

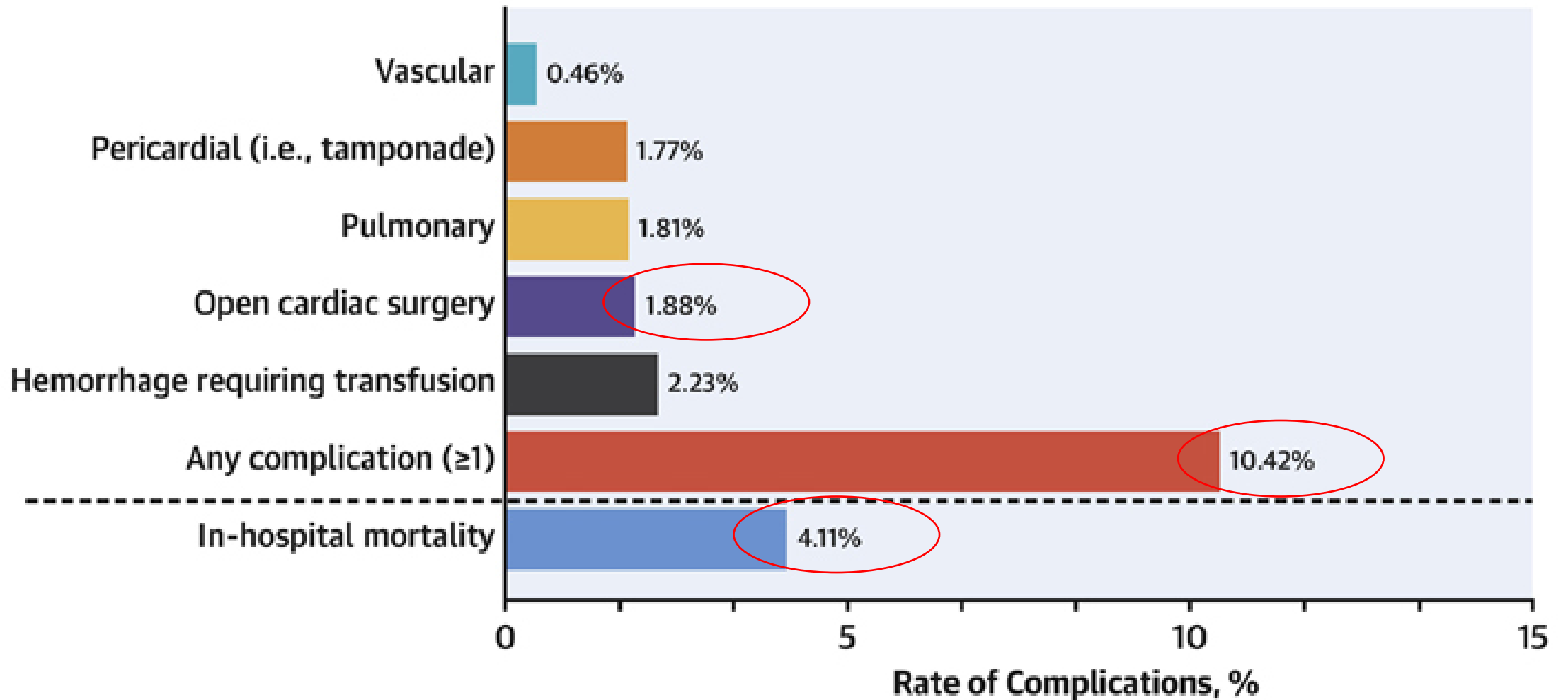
Complications Associated with Transvenous ICD Leads (10 years)

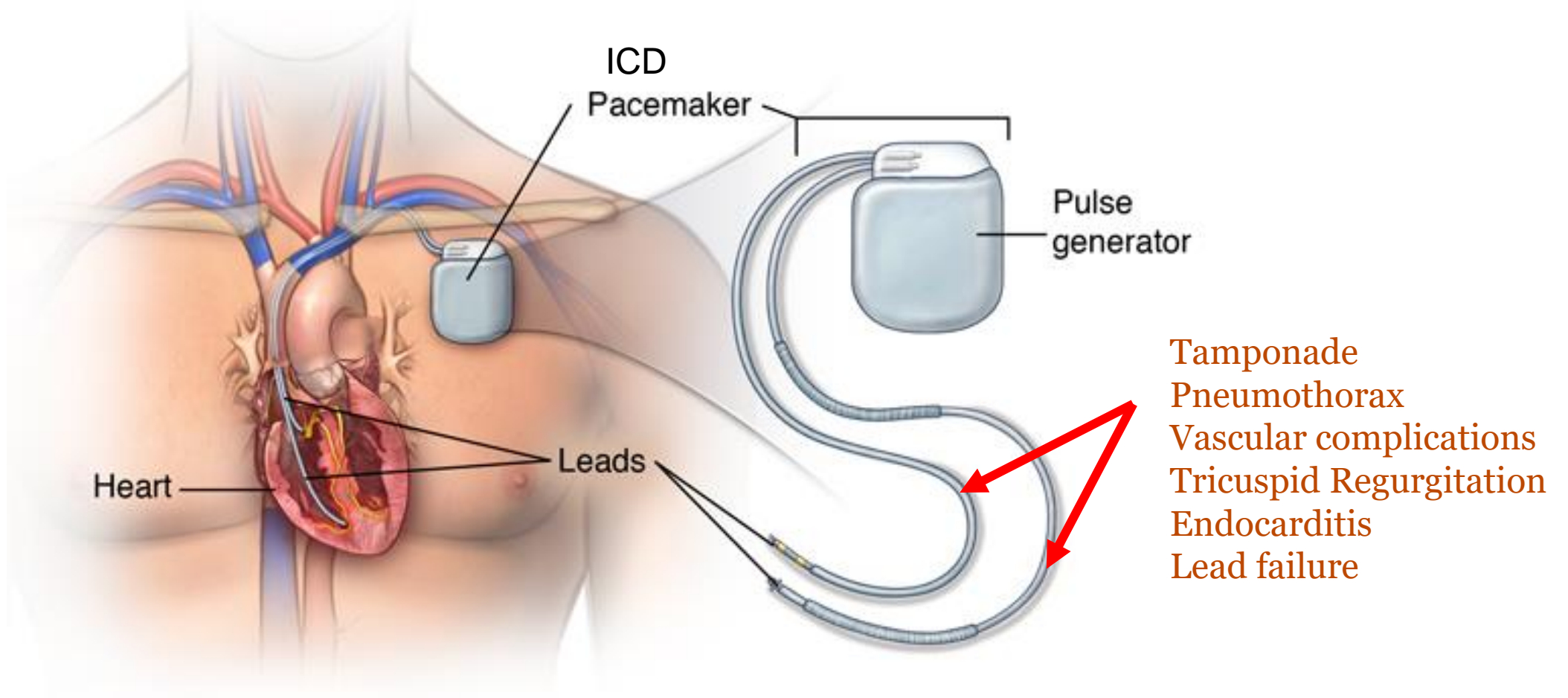


Infection	ICD	28,505	18,080 98.8%	11,968 98.4%	7,853 97.9%	5,382 97.4%	3,699 97.1%	2,387 96.6%	1,489 95.9%	1,035 95.1%	532 94.3%	275 93.2%
	CRT-D	12,285	7,619 98.4%	4,948 98.1%	3,077 97.8%	1,960 97.0%	1,300 96.1%	778 95.4%	683 94.8%	319 94.5%	179 93.6%	179 93.6%
Mechanical	ICD	28,505	17,784 96.9%	11,624 96.1%	7,643 95.0%	5,137 93.6%	3,374 92.0%	2,242 90.0%	1,352 86.5%	769 83.1%	432 79.1%	247 76.1%
	CRT-D	12,285	7,402 95.6%	4,626 94.6%	2,929 93.4%	1,865 91.7%	1,166 89.3%	705 86.2%	419 84.1%	279 82.1%	134 79.5%	75 75.2%



Peri-Procedural in-Hospital Complications of Transvenous lead extractions





Pacing solutions: LEADLESS pacemakers

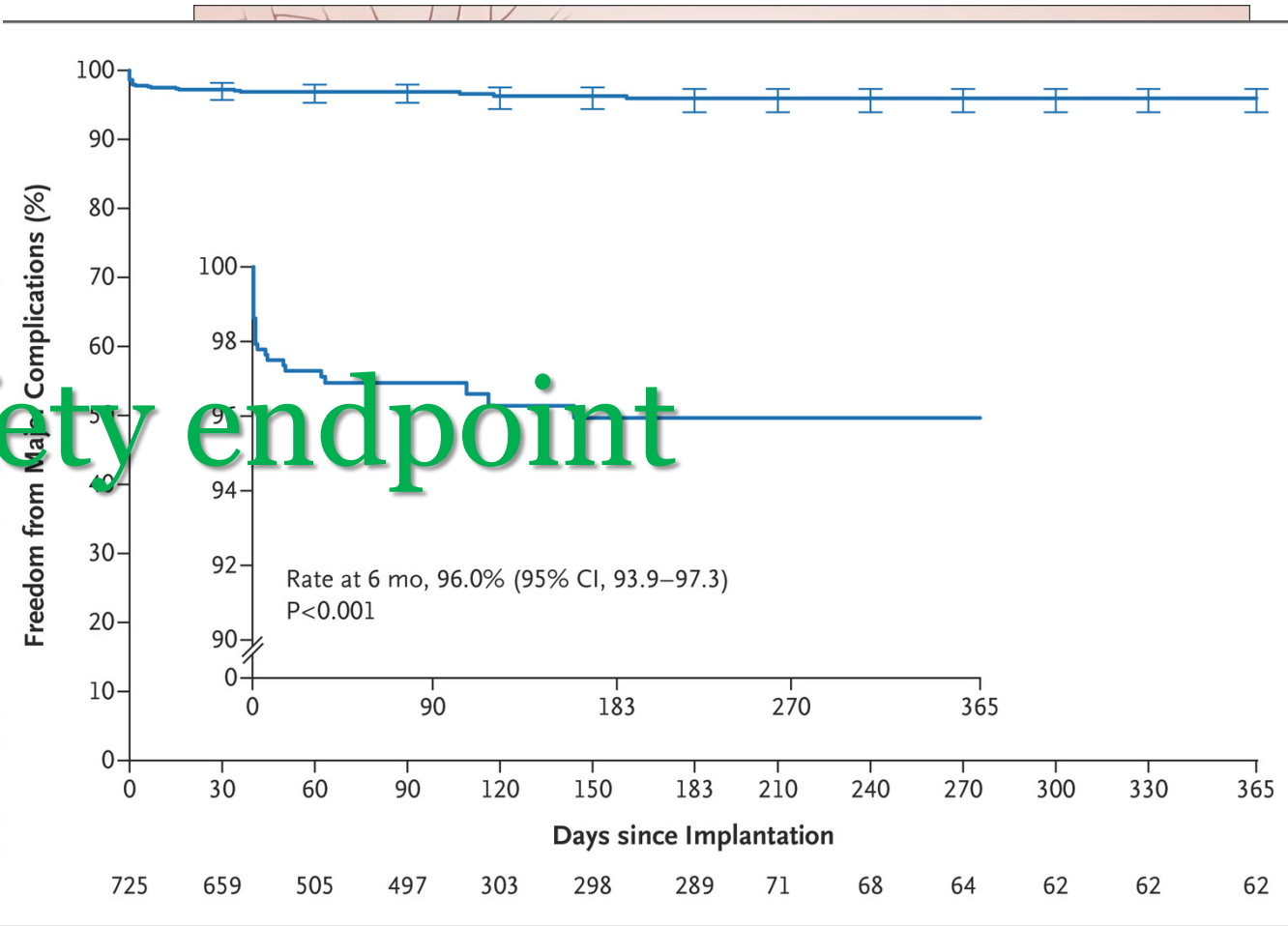


Aveir (Abbott)

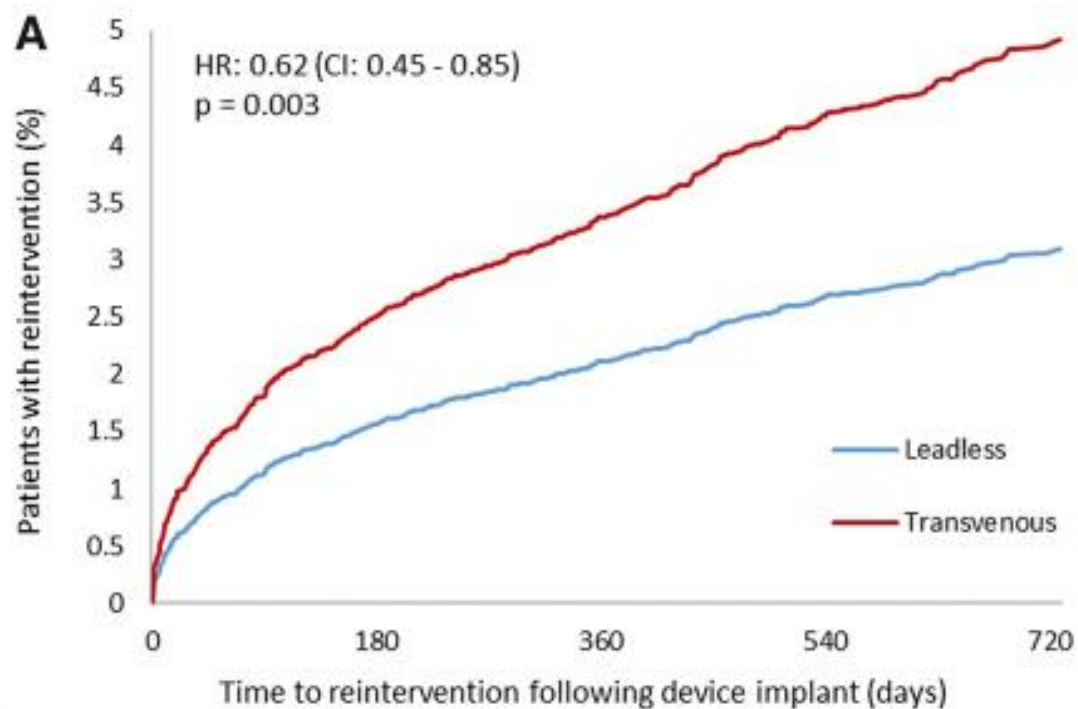
Event	Phase 1 Primary Cohort (n = 300)			Phase 2 Primary Cohort (n = 200)		
	No. of Events	No. of Patients	Event Rate, %	No. of Events	No. of Patients	Event Rate, %
Total	22	20¹	6.7%	9	8¹	4.0%
Cardiac perforation/tamponade/pericardial effusion	4	4	1.3%	3	3	1.5% ²
Premature deployment with device migration	0	0	0.0%	2	2	1.0% ³
Premature deployment without device migration	0	0	0.0%	1	1	0.5% ⁴
Access site bleeding event	2	2	0.7%	1	1	0.5%
Pulmonary embolism	1	1	0.3%	1	1	0.5%
Deep vein thrombosis	0	0	0.0%	1	1	0.5%
Device dislodgement	5	5	1.7%	0	0	0.0%
Threshold elevation resulting in LP retrieval	4	4	1.3%	0	0	0.0%
Arteriovenous fistula	1	1	0.3%	0	0	0.0%
Pseudoaneurysm	1	1	0.3%	0 </td <td>0</td> <td>0.0%</td>	0	0.0%
Asystole during implant procedure	1	1	0.3%	0	0	0.0%
Ventricular tachycardia or ventricular fibrillation during implant procedure	1	1	0.3%	0	0	0.0%
Pericarditis	1	1	0.3%	0	0	0.0%
Orthostatic hypotension with weakness	1	1	0.3%	0	0	0.0%

96% safety endpoint

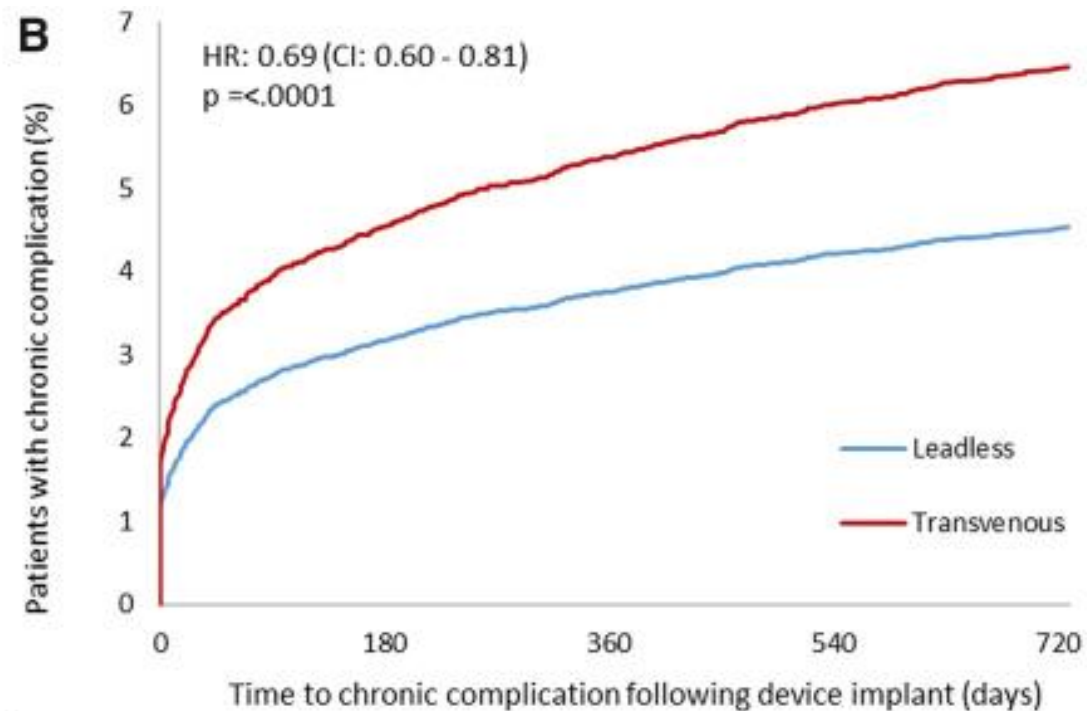
Micra (Medtronic)



Leadless Pacemaker vs transvenous VVI pacing



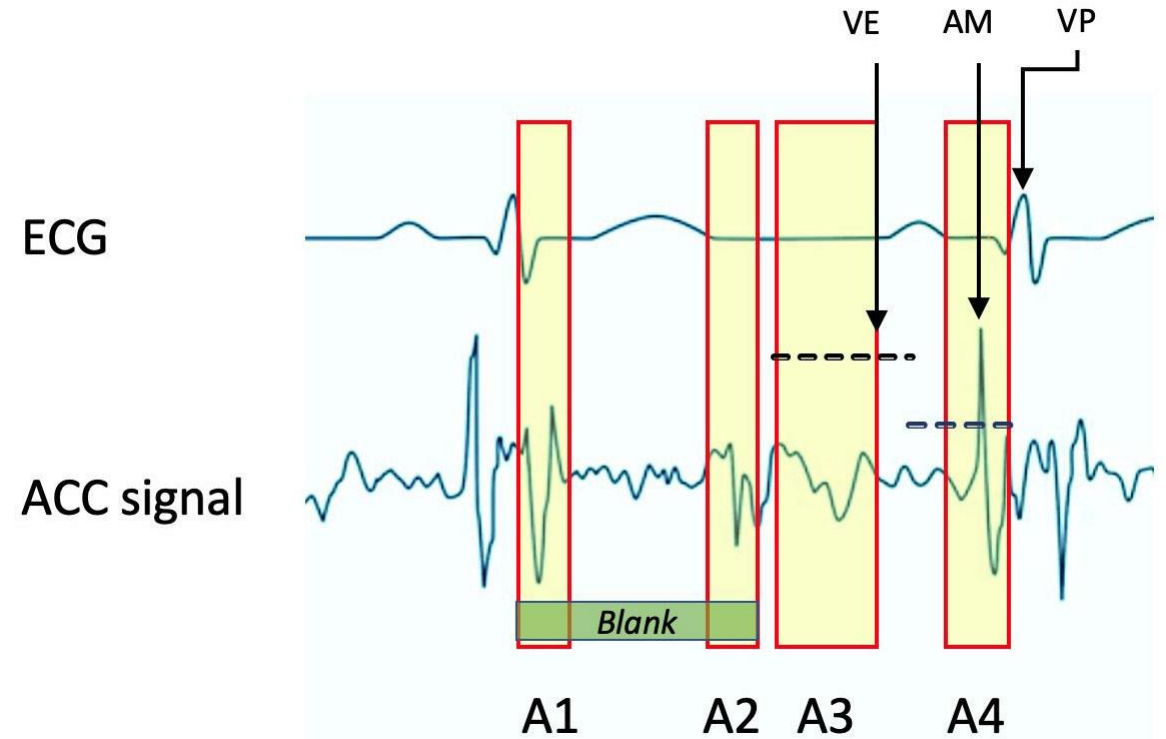
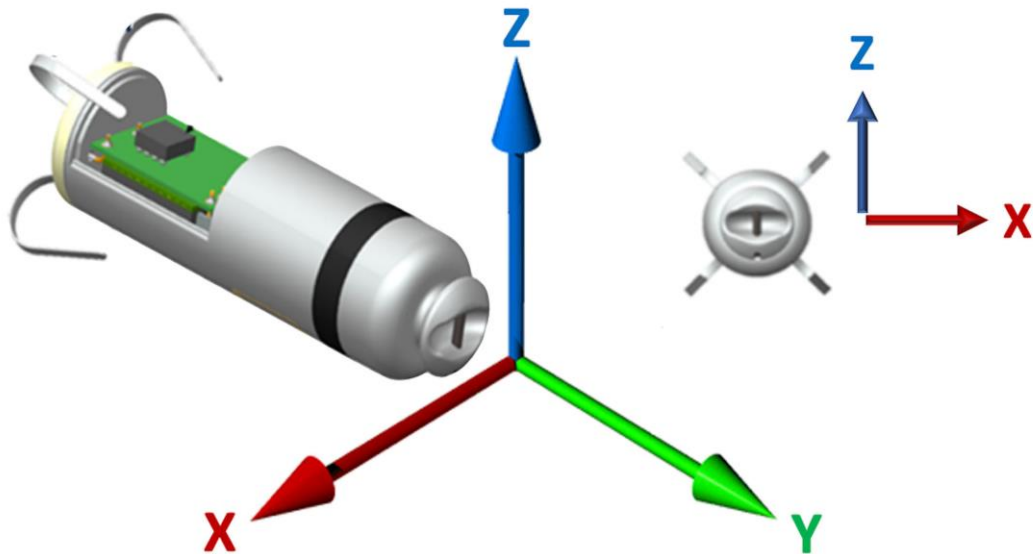
N at risk	0	180	360	540	720
Leadless	6219	5236	4742	2665	1194
Transvenous	10212	8671	7899	5353	2914



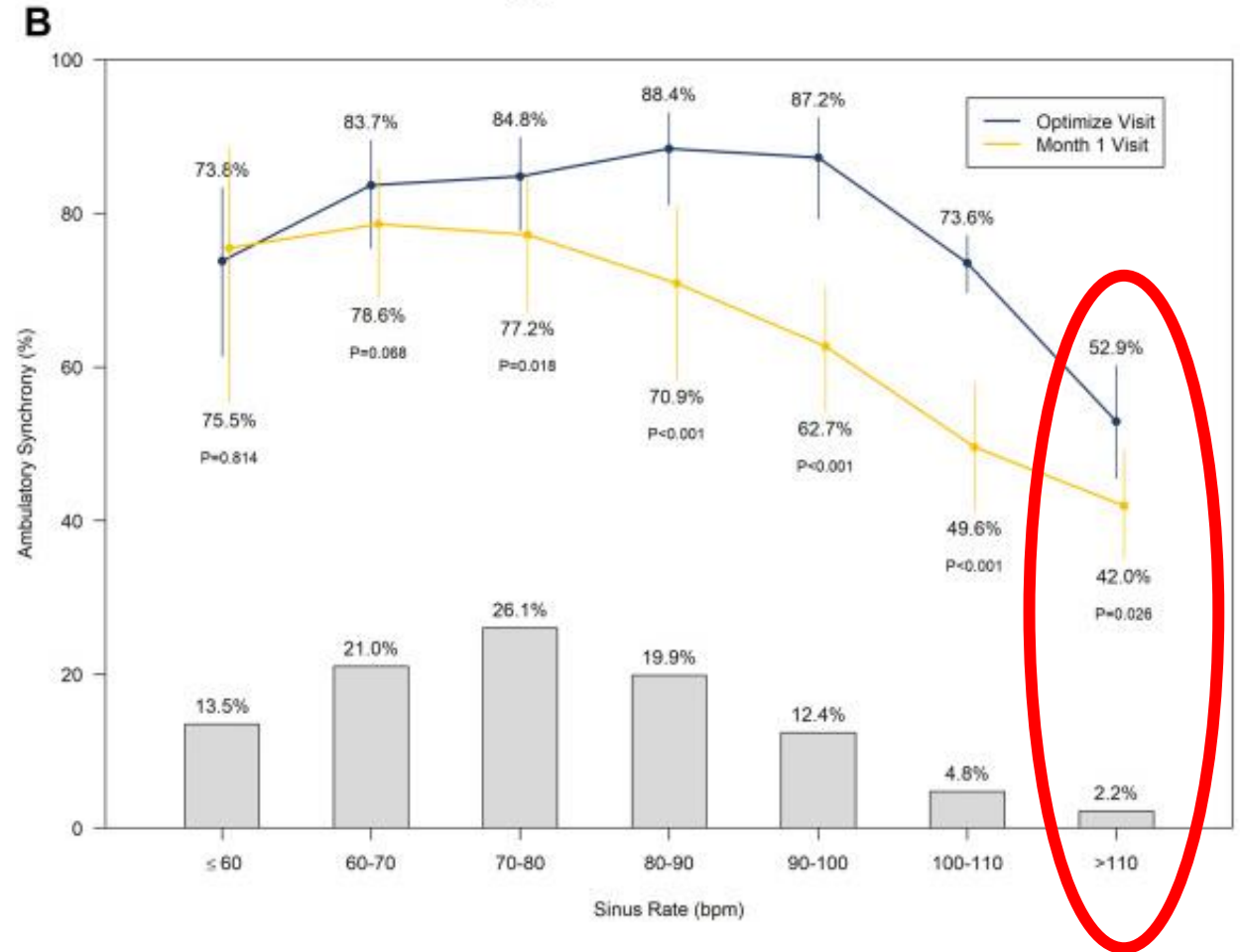
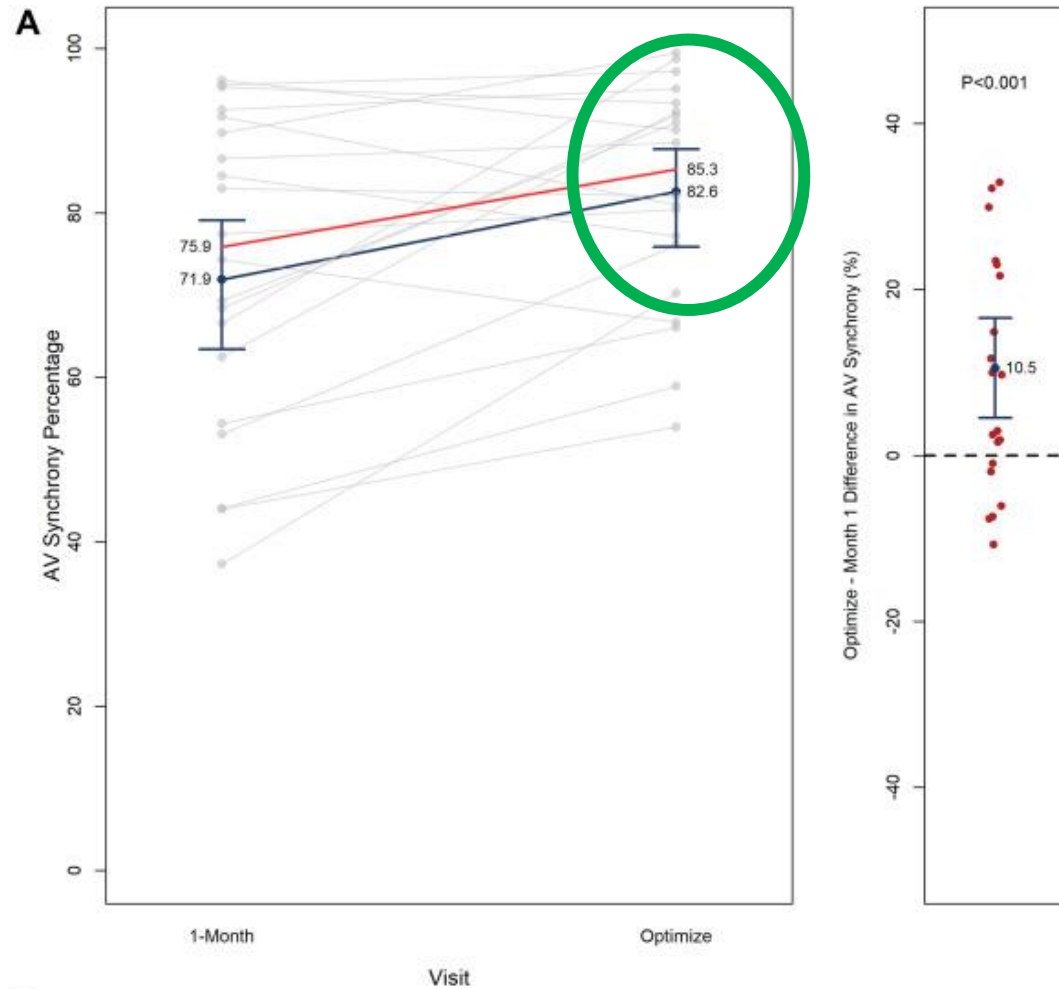
N at risk	0	180	360	540	720
Leadless	6219	5142	4659	2631	1183
Transvenous	10212	8556	7807	5300	2863

What about the synchronous pacing (tracking)?

Micra AV MC1AVR1
3 AXIS ACCELEROMETER - SENSING VECTORS



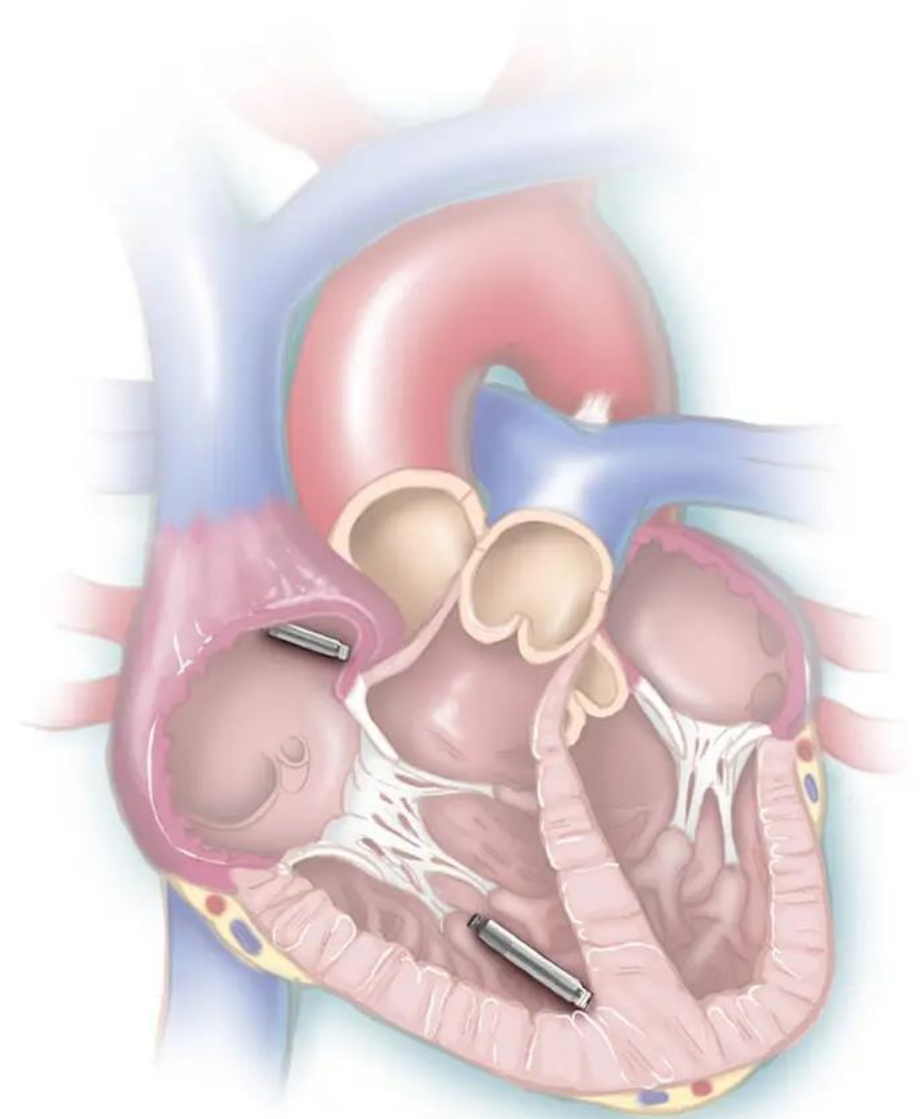
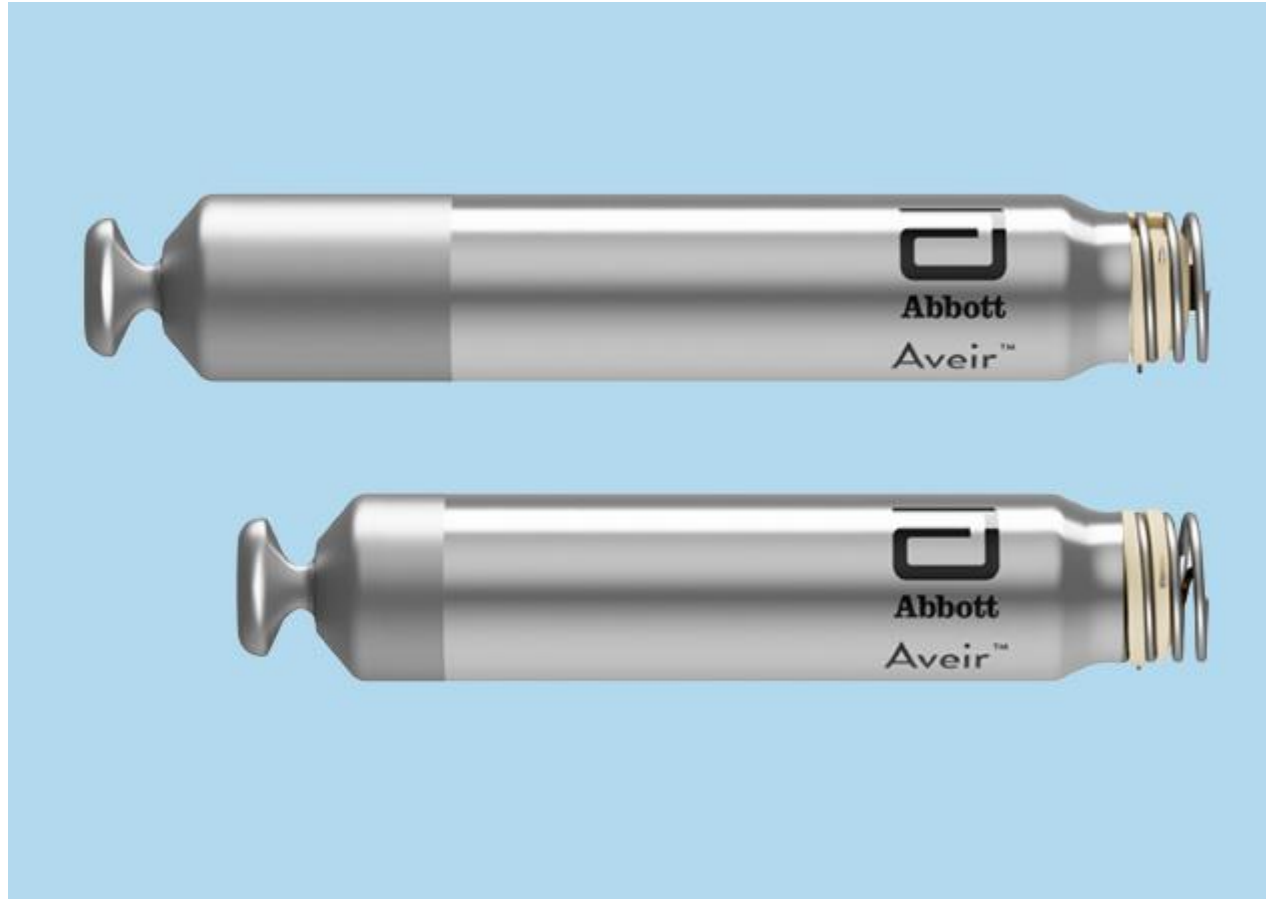
AV synchronous pacing using leadless pacemaker performance



Chintz et al. Heart Rhythm, 20, No 1, January 2023

How about atrial pacing?

Dual-Chamber Leadless Pacemaker

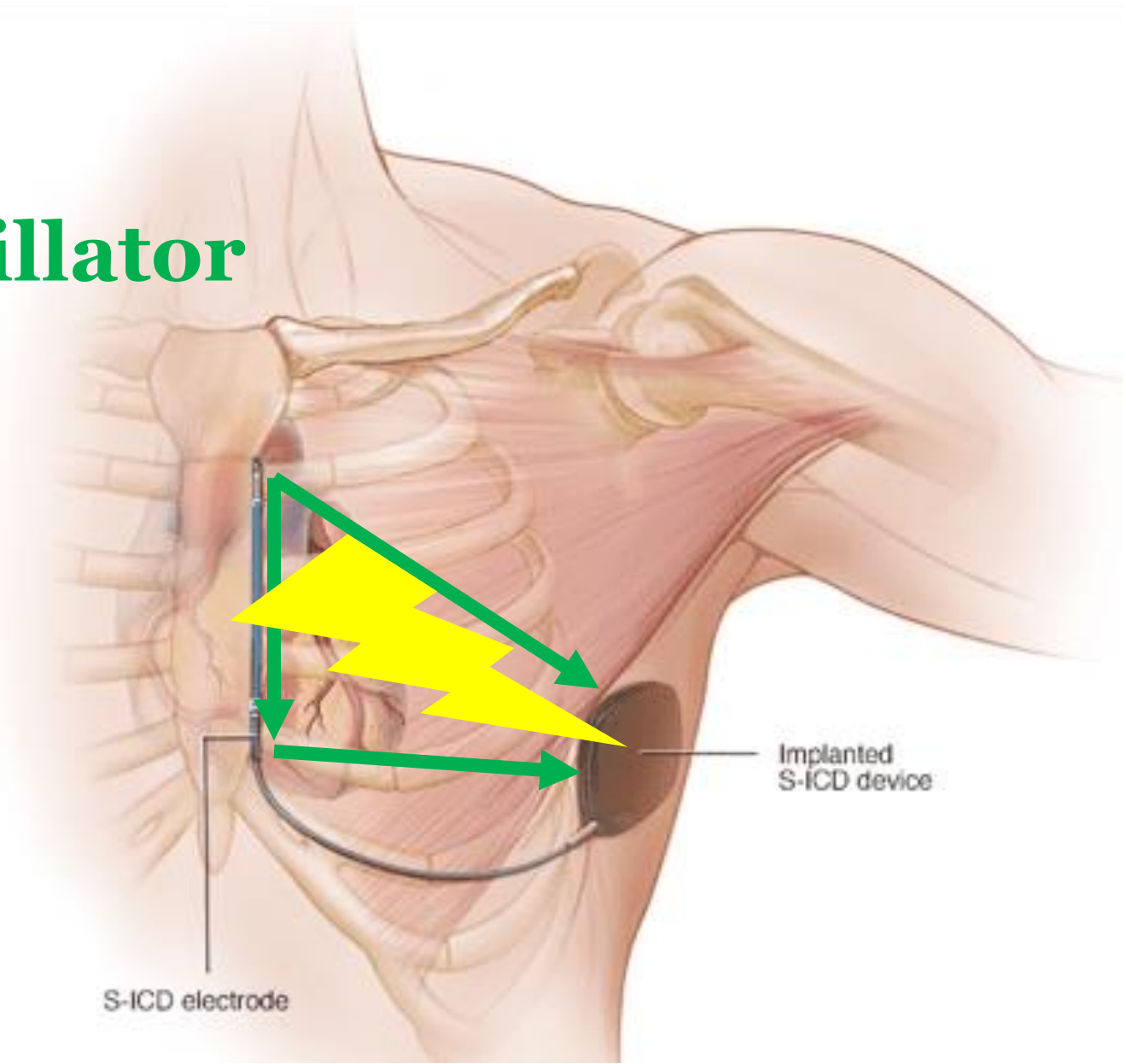


Aveir DR i2i Study

How about defibrillation?

Subcutaneous Defibrillator

(Boston Scientific)

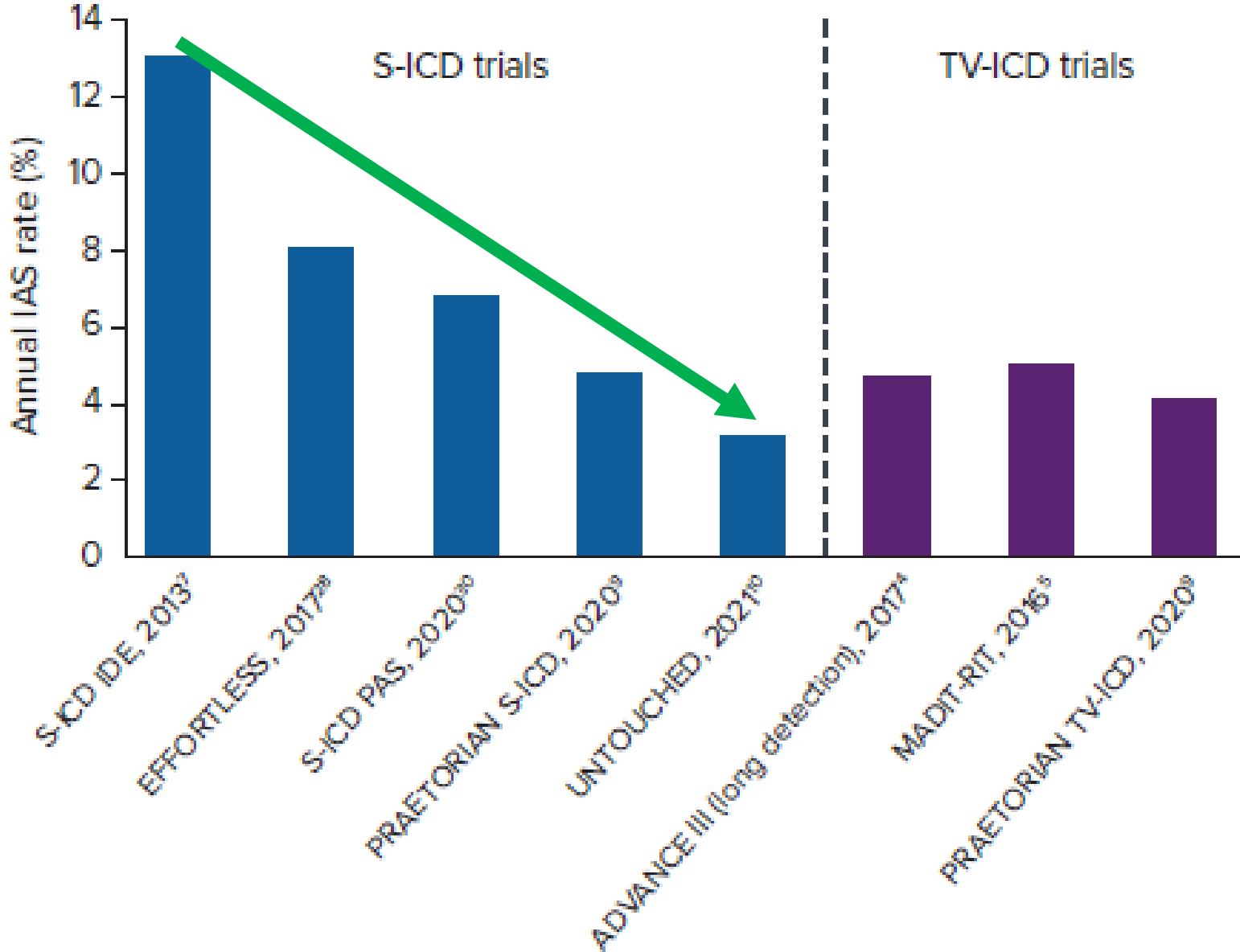


Subcutaneous or Transvenous Defibrillator Therapy

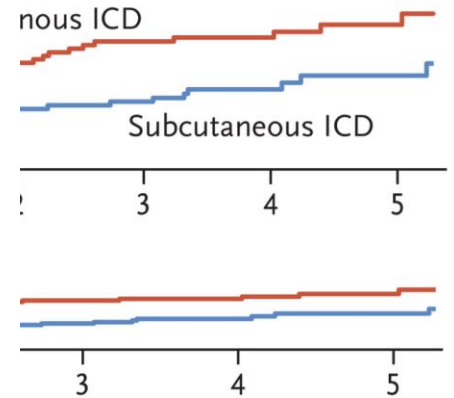
A Primary Composite I

Cumulative Incidence of Event (%)

No. at Risk
 Transvenous ICD 423
 Subcutaneous ICD 426



69 (95% CI, 0.44–1.09)



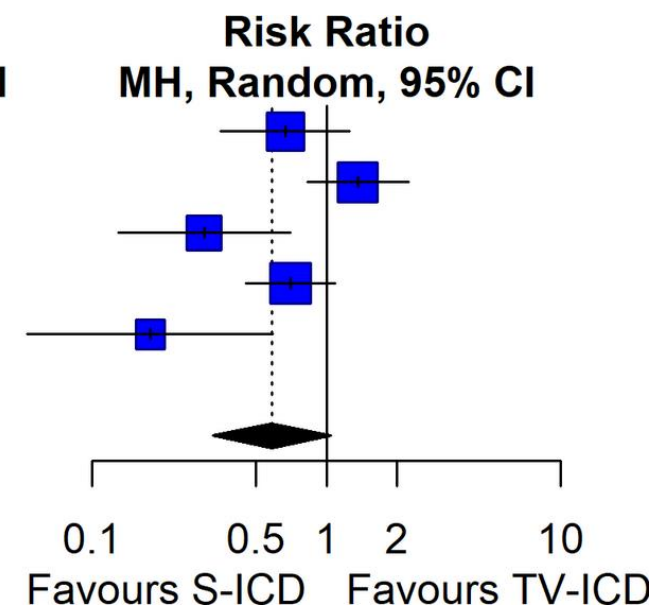
Follow-up

331	210	112
341	199	121

Device related complications (S-ICD vs TV-ICD)

Study	S-ICD		TV-ICD		Weight	Risk Ratio MH, Random, 95% CI
	Events	Total	Events	Total		
Brouwer 2016 ²⁷	14	140	21	140	21.3%	0.67 [0.35; 1.26]
Brouwer 2018 ³⁰	34	391	25	391	23.6%	1.36 [0.83; 2.24]
Honarbakshsh 2017 ²⁸	6	69	20	69	17.7%	0.30 [0.13; 0.70]
Knops 2020 ¹²	31	426	44	423	24.6%	0.70 [0.45; 1.09]
Palmisano 2021 ²⁹	3	169	17	169	12.7%	0.18 [0.05; 0.59]
Random effects model	1195		1192		100.0%	0.59 [0.33; 1.04]

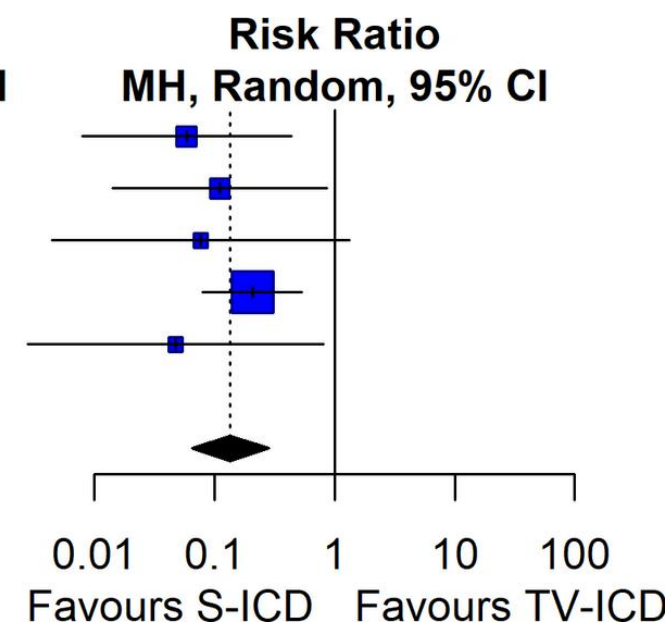
Heterogeneity: Tau² = 0.3051; Chi² = 15.75, df = 4 (P < 0.01); I² = 75%



Lead related complications (S-ICD vs TV-ICD)

Study	S-ICD		TV-ICD		Weight	Risk Ratio MH, Random, 95% CI
	Events	Total	Events	Total		
Brouwer 2016 ²⁷	1	140	17	140	13.6%	0.06 [0.01; 0.44]
Brouwer 2018 ³⁰	1	391	9	391	12.9%	0.11 [0.01; 0.87]
Honarbakshsh 2017 ²⁸	0	69	6	69	6.7%	0.08 [0.00; 1.34]
Knops 2020 ¹²	5	426	24	423	60.0%	0.21 [0.08; 0.54]
Palmisano 2021 ²⁹	0	169	10	169	6.8%	0.05 [0.00; 0.81]
Random effects model	1195		1192		100.0%	0.14 [0.07; 0.29]

Heterogeneity: Tau² = 0; Chi² = 2.26, df = 4 (P = 0.69); I² = 0%

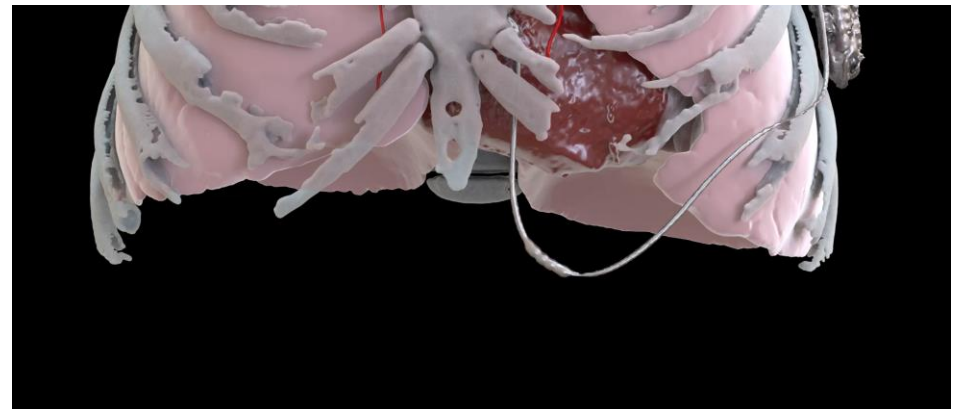


First-in-Human Chronic Implant Experience of the Substernal Extravascular (Medtronic) (5/2019)

Efficacy and Safety of an Extravascular Implantable Cardioverter–Defibrillator

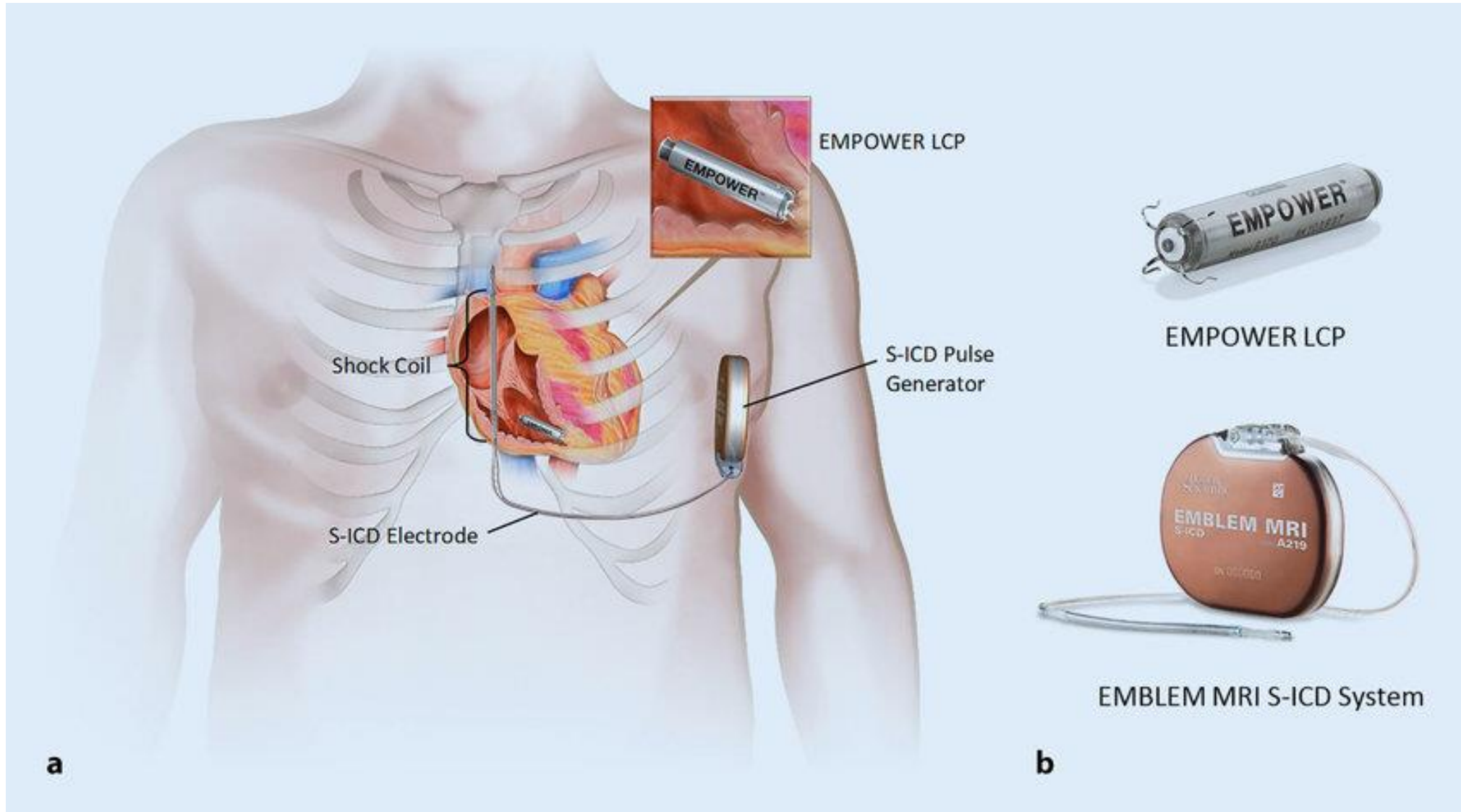
Paul Friedman, M.D., Francis Murgatroyd, F.R.C.P., Lucas V.A. Boersma, M.D., Ph.D., Jaimie Manlucu, M.D., David O'Donnell, M.B., B.S., Bradley P. Knight, M.D., Nicolas Clémenty, M.D., Ph.D., Christophe Leclercq, M.D., Ph.D., Anish Amin, M.D., Béla P. Merkely, M.D., Ph.D., D.Sc., Ulrika M. Birgersdotter-Green, M.D., Joseph Y.S. Chan, M.B., B.S., et al., for the Extravascular ICD Pivotal Study Investigators*

N Engl J Med 2022; 387:1292-1302



Haqqani, et al. Heart Rhythm. Late Breaking. May 2019

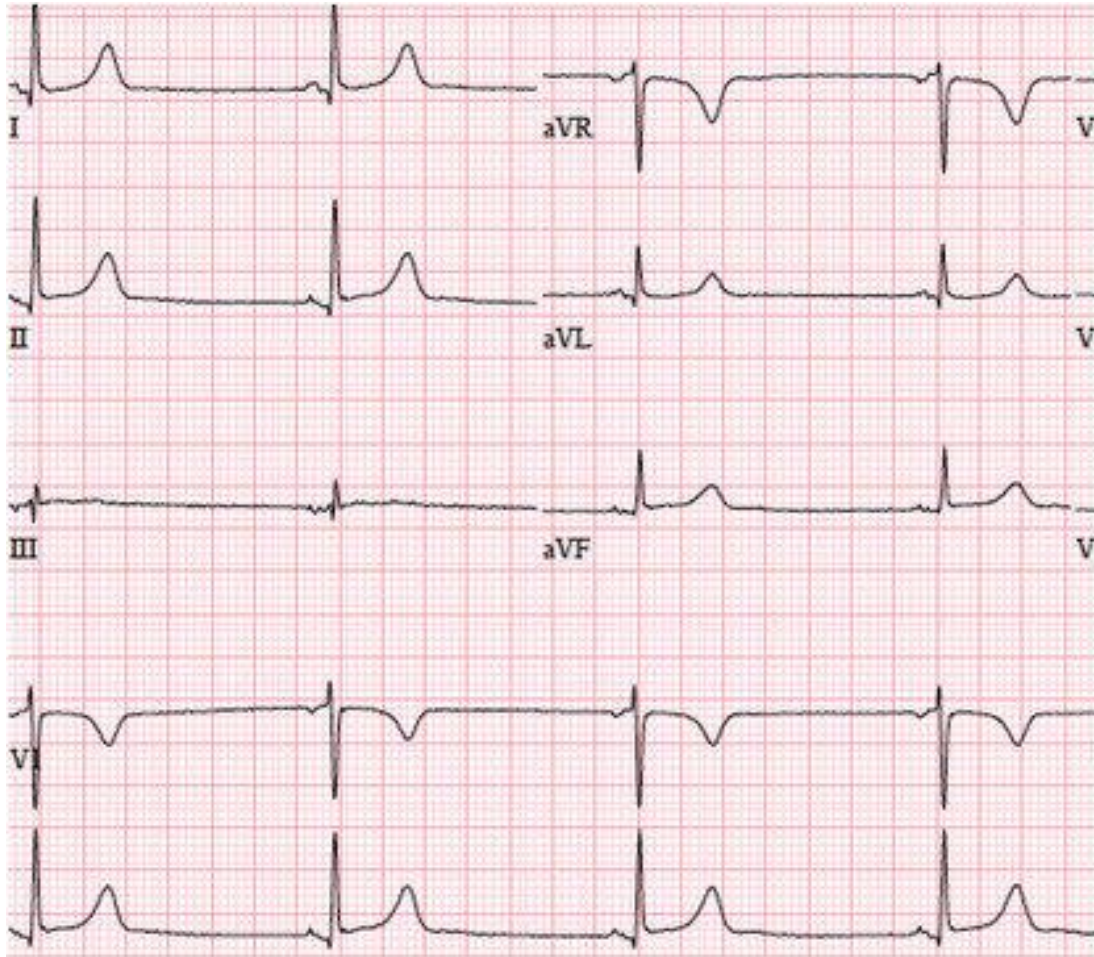
What if I needed to pace and defibrillate?



Unanswered questions:

1. Physiologic pacing
2. Need for CRT upgrade
3. Battery depletion (leadless-Pacer)

Final thoughts:



Conclusion

- Transvenous cardiac devices have significant short and long term complication rates.
- Extra-vascular defibrillators (EV-ICD and Subcutaneous-ICD) are good alternatives to avoid lead related complications.
- Leadless pacemakers are evolving and proven to be safer than transvenous pacemakers.
- Avoiding implantation of endocardial leads should be always sought when possible.

Thank you

Auroa.badin@Ohiohealth.com

[@BadinMD](#)