

Leadless Cardiac Devices: Unchain my Heart

Martin C. Burke, DO
CorVita Science Foundation



15th Annual Heart Rhythm Symposium
Rhythms of the Heartland



COI DISCLOSURES

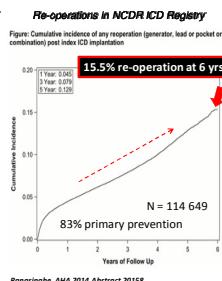
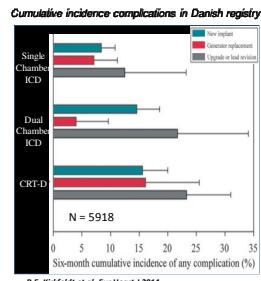
I have received lecture and proctoring honoraria from Spectranetics.

I have been funded by and NIH/SBIR grant to AJ Medical Devices, Inc. (AJMD) and research grants from Boston Scientific, Medtronic, St. Jude Medical, Guidant, Inc. and Cameron Health, Inc.

I am or have been a consultant to AJMD, Boston Scientific and Cameron Health.

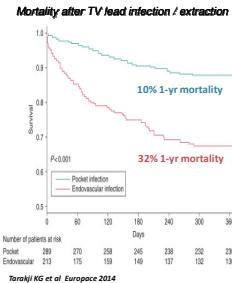
I have an equity stake in AtaCor Medical, Inc. and am Chief Medical Officer.

ICD therapy is well established and successful, but still associated with complications



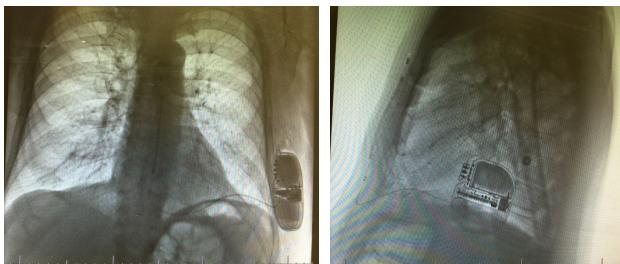
R.E. Kirfeldt et al. Eur Heart J 2014

Transvenous lead related complications associated with significant morbidity and mortality

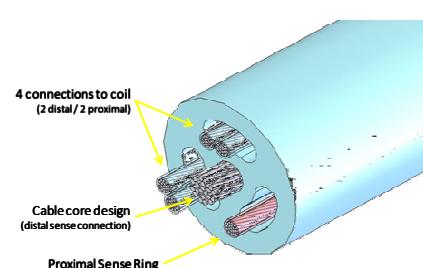


Torokji KG et al. Euro pace 2014

Entirely Subcutaneous ICD



S-ICD System Components: Q-TRAK™ Electrode

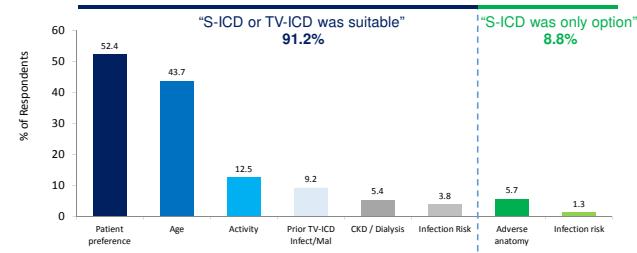


Real World Experience with the Subcutaneous ICD in the United States: The S-ICD Post-Market Approval Study

Michael R Gold MD, PhD, Johan D. Aasbo, DO, FHRS, Mikhael F. El-Chami, MD, FHRS, Mark Niebauer, MD, PhD, FHRS, John Herre, MD, Jordan M. Prutkin, MD, FHRS, Bradley P. Knight, MD, FHRS, Steven Kutalek, MD, FHRS, Kevin Hsu, MD, FHRS, Raul Weiss, MD, FHRS, Eric Bass, Michael Husby, MS, MPH, Timothy M. Stivland, MBA, **Martin C. Burke, DO**
and all PAS investigators

Heart Rhythm. 2017 May 11. pii: S1547-5271(17)30594-5. doi: 10.1016/j.hrthm.2017.05.016

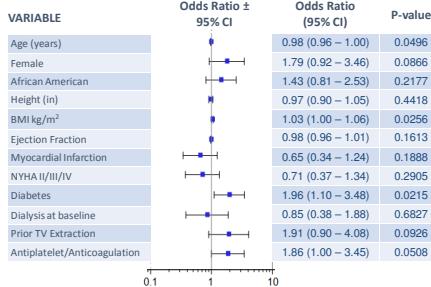
Reasons for S-ICD Device Choice (N=1637, multiple reasons could be chosen)



Heart Rhythm. 2017 May 11. pii: S1547-5271(17)30594-5. doi: 10.1016/j.hrthm.2017.05.016

30-Day Complications

Complication-Free Rate = 96.2%



Heart Rhythm. 2017 May 11. pii: S1547-5271(17)30594-5. doi: 10.1016/j.hrthm.2017.05.016

Performance of the subcutaneous implantable cardioverter defibrillator in primary prevention patients

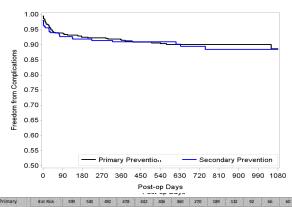
Lucas V. A. Boersma, MD, PhD, Craig S. Barr, MD, Martin Burke, DO, Angel R. Leon, MD, Dominic A. Theuns, PhD, John M. Herre, MD, Raul Weiss, MD, Mayer Rashtian, MD, FACS, Mark S. Kremers, MD, Petr Neuzil, MD, PhD, Michael P. Husby, MS, Nathan Carter, MS, Tim Stivland and Michael R. Gold, MD, PhD.

St. Antonius Ziekenhuis, Nieuwegein, Netherlands, Russells Hall Hospital, Dudley, United Kingdom, University of Chicago Hospitals, Chicago, IL, Emory University Hospital, Atlanta, GA, Mayo Clinic, Rochester, MN, Netherlands, Cardiovascular Consultants, Louisville, KY, Ohio State University Medical Center – Div. of Cardiovascular Medicine, Columbus, OH, Foothill Cardiology, Pasadena, CA, Novant Heart and Vascular Institute, Charlotte, NC, Na Homice Hospital, Prague 5, Czech Republic, Boston Scientific, St Paul, MN, Medical University of South Carolina, Charleston, SC

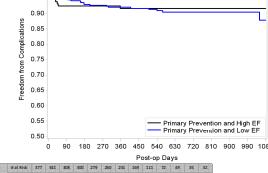
Heart Rhythm Journal <http://dx.doi.org/10.1016/j.hrthm.2016.11.025>

Complications

PP vs SP



PPrEF vs PPPeEF

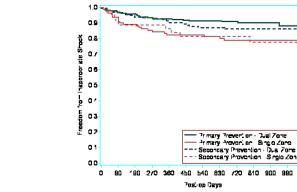


- Complications occur early, during and after implant
- Rates are low and consistent across groups

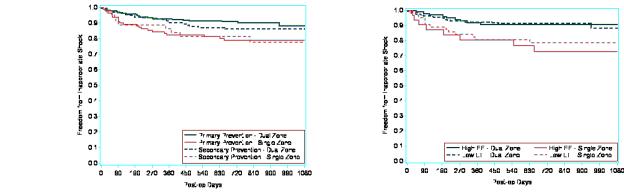
Heart Rhythm Journal
<http://dx.doi.org/10.1016/j.hrthm.2016.11.025>

Inappropriate Shocks

PP vs SP

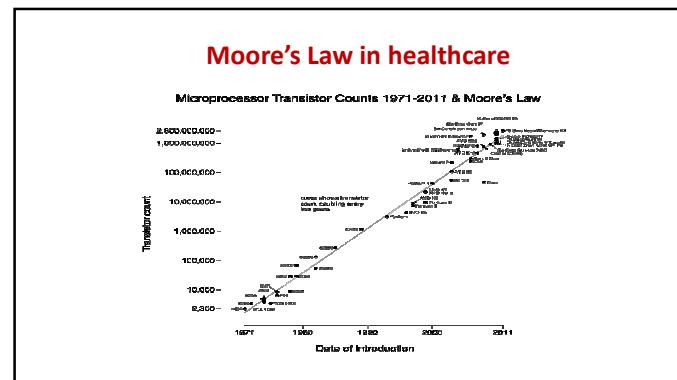
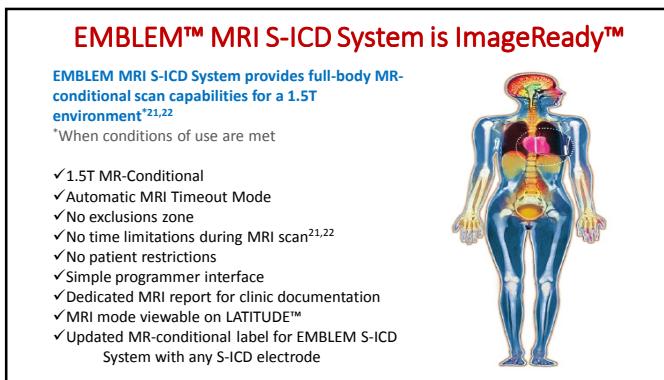
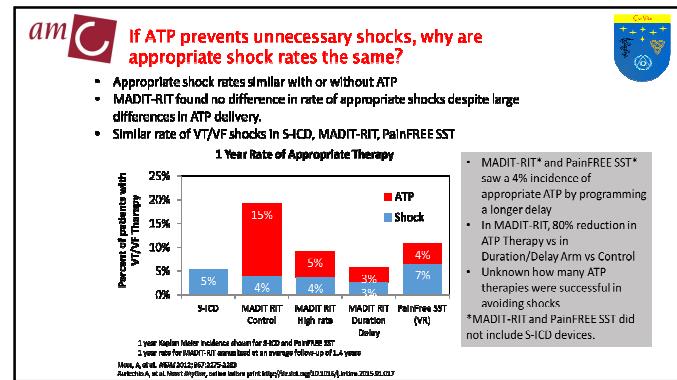
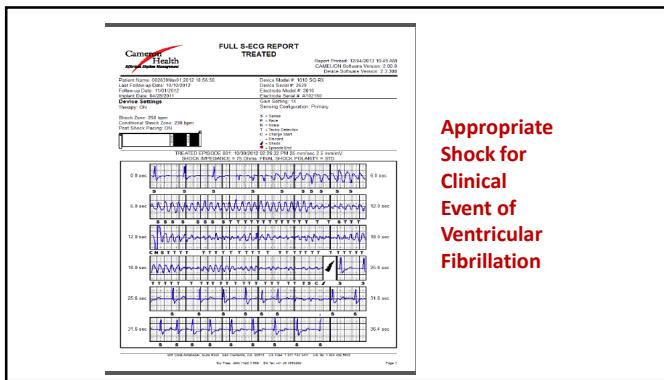
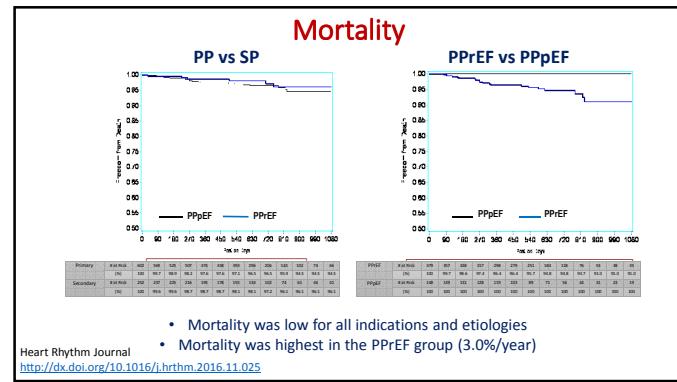
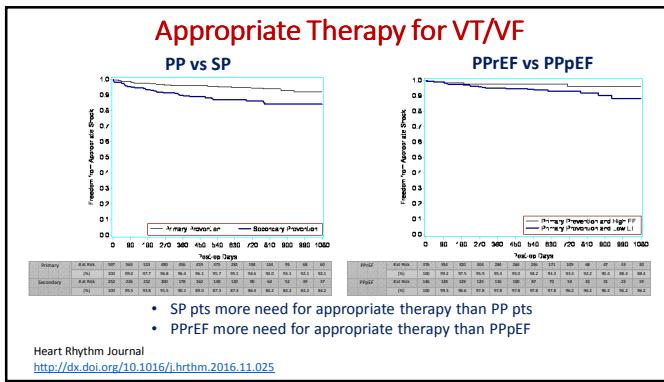


PPrEF vs PPPeEF

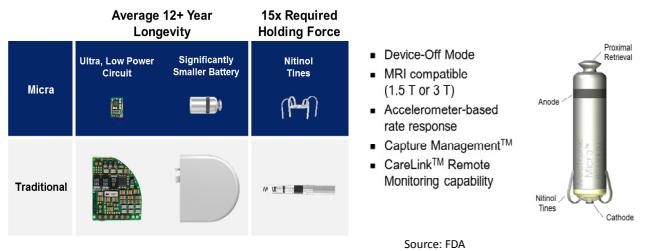


- Independent of PP or SP indication or etiology
- Inappropriate shock lower by dual zone programming

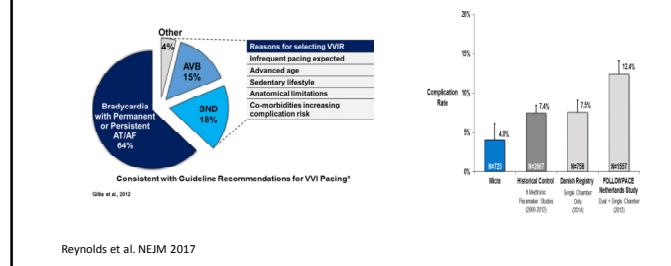
Heart Rhythm Journal
<http://dx.doi.org/10.1016/j.hrthm.2016.11.025>



Leadless Pacing: Technology Advances



Indications and Complications



Implant Technique

LCP implant steps:

- 1) RV angio
- 2) 2IF introducer
- 3) Delivery catheter + LCP
 - Telescope
- 4) Deployment
- 5) Tug test
- 6) Release

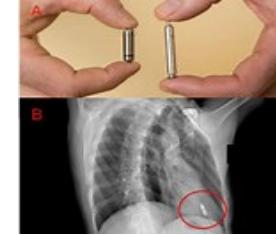
Tjong et al. JACC 2017



Worldwide Leadless Pacemaker Options

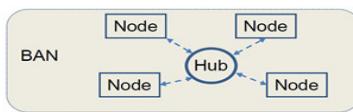
- Nanostim (Abbott) remains unapproved in US.
 - Premature battery depletion
 - Proximal cap dislodgements
- Micra (Medtronic) available in limited US rollout (expanding)
- Lacks AV synchronous pacing at this time.
- Still Chained to Heart

Reynolds et al. NEJM 2017
Lakkireddy et al. Heart Rhythm 2017



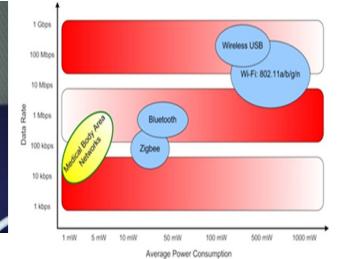
How does an MBAN system operate?

- A typical MBAN consists of:
 - a master programmer/control transmitter ("hub device"),
 - one or more client transmitters ("body sensors"), which are worn on the body and only transmit while maintaining communication with the hub that controls the transmissions.
 - The hub conveys data messages to the body-worn sensors to specify, for example, the transmit frequency that should be used. The hub and sensor devices will transmit in the 2360-2400 MHz band.

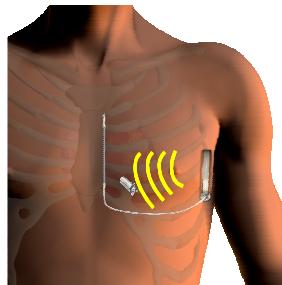


IEEE, 2008

Need More Power: Battery Technology



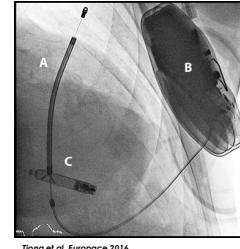
Combined implant of Communicating ATP-enabled Leadless Pacemaker and S-ICD



Burke, Tjong, Knops et al.
Europace HRC 2016

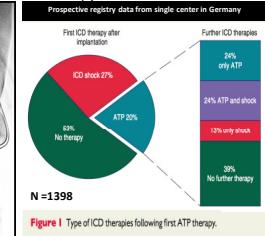
Application of S-ICD is limited due to lack of pacing capability

Bradypacing:
Limited evidence of S-ICD with LCP & TV-Pacers



Tjong et al. Europace 2016

Anti-tachy pacing: No solution
Substantial ICD subgroup benefits from ATP therapy



EBR Pacing System (Hybrid)

- CRT hybrid
- Pilot studies suggest improved CRT response in non-responders
- Inductive energy transfer
- Miniaturization



Reddy VY et al. JACC 2017

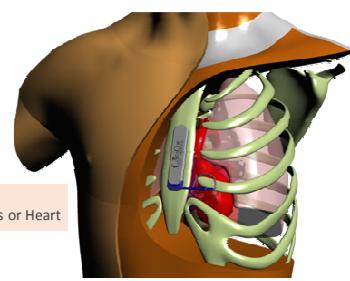
Not FDA Approved for Human Use – Seeking IDE

The AtaCor Pacing System...

PROVEN PACING THERAPY...
Without Touching the Heart

REMOVAL...
Without Risking Trauma to the Vessels or Heart

Not approved for human use

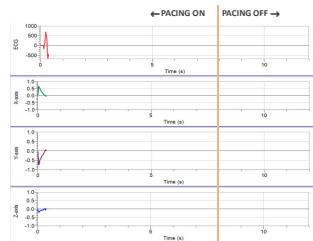


Human Studies: Method 2 Transcutaneous Pacing Leads to Skeletal Muscle Stimulation



Human Studies: Method 2

Intracostal Pacing Without Skeletal Muscle Stimulation

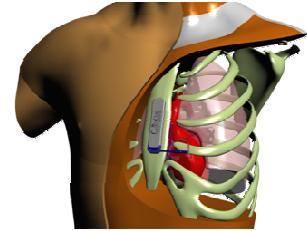


Intracostal Pacing: 2.7V @ 2.0ms
(capture threshold)

Intracostal Pacing Works

- 32
- Intracostal pacing can reliably pace the heart...
 - With reasonable pacing energies
 - Without leads in or on the heart
 - Without skeletal muscle stimulation

[Knops, Burke et al. Heart Rhythm 2017 \(abstract\)](#)



Individual Intelligence

The CardioMEMS™ HF System



Courtesy of St Jude Medical

